EN

Case No COMP/M.7276 - GLAXOSMITHKLINE/ NOVARTIS VACCINES BUSINESS (EXCL. INFLUENZA)/ NOVARTIS CONSUMER HEALTH BUSINESS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 28/01/2015

Office for Publications of the European Union
L-2985 Luxembourg

EUROPEAN COMMISSION

Brussels, 28.1.2015
C(2015) 539 final

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

To the Notifying Party:

Dear Madam(s) and/or Sir(s),

Subject: **Case M.7276 – GLAXOSMITHKLINE/ NOVARTIS VACCINES BUSINESS (EXCL. INFLUENZA)/ NOVARTIS CONSUMER HEALTH BUSINESS**
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1]

(1) On 28 November 2014, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which GlaxoSmithKline plc ("GSK") acquires the global human vaccines business (the "Novartis Vaccines business") of Novartis AG ("Novartis"), with the exception of Novartis' human flu vaccine business (the "Influenza business"), by way of purchase of assets. GSK and Novartis are also creating a new venture, under the sole control of GSK, combining their non-prescription (over the counter – "OTC" – or "consumer health") activities. GSK is hereinafter referred to as the "Notifying Party". GSK and Novartis are referred to as the "Parties". Novartis' contributed OTC activities are referred to as the "Novartis Consumer Health business", and the new venture is referred to as "the OTC JV". The Vaccines and OTC operations are together referred to as the "Transaction".[2]

1 OJ L 24, 29.1.2004, p. 1 ('the Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 Publication in the Official Journal of the European Union No C 248, 30.07.2014, p. 7.

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.

I. THE PARTIES

(2) **GSK** is a global pharmaceutical company headquartered in the UK. It is active in research, development, manufacturing and marketing in four general product areas: prescription pharmaceuticals and vaccines, consumer healthcare products, dermatological products (through its subsidiary Stiefel), and HIV/Aids pharmaceuticals (through the ViiV joint venture with Pfizer).

(3) **Novartis** is a global pharmaceutical company headquartered in Switzerland. It is active in research, development, manufacturing and marketing of pharmaceuticals, generic pharmaceuticals (via its subsidiary Sandoz), vaccines and consumer health products.

(4) The **Novartis Vaccines business** comprises vaccines that treat adult tickborne and Japanese encephalitis, rabies and meningococcal diseases. Novartis has also sales in monovalent and combination tetanus and diphtheria vaccines. In addition, Novartis currently has three pipeline products in the early stage of development, targeting five meningococcal serogroups (MenABCWY) for adolescents, group B streptococcus for adults and adolescents, and *Pseudomonas Aeruginosa*.

(5) The **Novartis Consumer Health business** includes branded products in several segments such as cold and flu, pain management, cold sore management and smoking cessation. In cold sore management, Novartis supplies antiviral creams containing the active substance *penciclovir* under the brands *Fenivir*, *Pencivir*, *Vectavir*, *Vectatone* and *Fenistil*. As regards smoking cessation, Novartis markets under the *Nicorette* brand a range of NRT products in the form of patches, gums, and lozenges in the majority of the EEA countries. Novartis also offers a range of different cold and flu treatments, with a particular focus on topical nasal preparations (*Otrivin*). Its product selection also includes multi-symptom cold and flu treatments (*Theraflu*), throat preparations (*Orofar*), cough treatments (*Sinecod*), and chest rubs (*Pulmex*). In pain management, Novartis supplies *Voltaren* across the EEA.

II. THE OPERATION AND CONCENTRATION

The Transaction

(6) On 22 April 2014, the Parties signed an agreement, further amended by several agreements on 29 May 2014, foreseeing a three steps transaction:

(a) GSK is acquiring Novartis' global human Vaccines business, excluding the Influenza business.[3]

(b) GSK and Novartis are combining in a new venture their global activities in Consumer Health (i.e. their non-prescription business, also called over the counter or OTC),[4] over which GSK will be the one exercising decisive influence; Novartis rights are limited to minority protection rights.

---

3 On 26 October 2014, Novartis announced divestiture of its influenza vaccines business to CSL. According to the Parties, the transaction is subject to regulatory approvals and is expected to close in the second half of 2015.

4 Prescription medicines will overall remain outside the scope of the OTC JV, as well as some OTC activities of GSK and Novartis. GSK will not transfer to the OTC JV its Indian business, Nigerian

(c) Novartis will acquire part of the GSK oncology business portfolio. This transaction is assessed separately by the Commission in Case M.7275 – Novartis / GlaxoSmithKline Oncology Business.

(7) The Vaccines and the OTC operations are notified together as GSK acquires control both of the Vaccines and of the Consumer Healthcare businesses and qualify for review as a single concentration under the Merger Regulation.

(8) According to the Notifying Party, the Transaction is intended to accelerate GSK's strategy to generate sustainable sales growth and improve GSK's long term earnings as it will strengthen two of its core business: Vaccines and OTC products. According to the Notifying Party, the Transaction will enable GSK and the OTC JV to compete more effectively on the concerned markets.

Sole control of the OTC JV

(9) GSK will acquire 63.5% of the OTC JV and Novartis will own a minority shareholding of 36.5%. GSK will be responsible for the day-to-day running and the overall direction, supervision, and management of the OTC JV. In addition, GSK will […]. GSK will appoint 7 out of 11 members of the OTC JV's Board of Directors. Novartis will appoint the remaining 4. […].[5]

(10) As the Transaction does not create a joint venture in which the parties share equally the voting rights, joint control could only arise in this case out of (i) veto rights with respect to decisions that are essential for the strategic commercial behaviour of a joint venture; or (ii) commonality of shareholders' interests.

(11) Veto rights that can be relevant for establishing control are those concerning budgets, appointment of management, business plans and investments, as well as other certain other rights such as the right to determine the OTC JV's pricing policy.

(12) Novartis' approval is required in matters such as […]. As such these matters are not decisive for the competitive strategy OTC JV. Moreover, Novartis […]. These powers conferred on Novartis are intended to protect the value of its minority interest in the OTC JV and will not grant control.

(13) Further, there is not a sufficiently high degree of mutual dependency among GSK and Novartis or any other factors that would lead to commonality of interests between GSK and Novartis in determining OTC JV's strategy, beyond the common interest inherent to any long-term commercial agreement.

Conclusion on the concentration

(14) The Commission therefore concludes that the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

---

businesses or pharmaceutical business. Novartis will not transfer to the OTC JV its animal health business, U.S. Nicotine Replacement Therapy business, pharmaceutical business, Alcon business or Sandoz generics business. A limited number of prescription products consolidated in Novartis' OTC business will be transferred. In this respect, the Parties submit that they have identified one overlap in relation to topical corticosteroid combinations in the UK, leading to no affected market.

5 […].

III. EU DIMENSION

(15) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (GSK: EUR 30 578 million; Novartis' Consumer Health Business: EUR [2 000-3 000] million; Novartis' Vaccines Business excluding the Influenza business: EUR [500-1 000] million).[6] Each of them has an EU-wide turnover in excess of EUR 250 million (GSK: EUR [5 000-10 000] million; Novartis' Consumer Health Business: EUR [500-1 000] million; Novartis' Vaccines Business excluding the Influenza business: EUR [0-500] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

(16) The Transaction therefore has an EU dimension within the meaning of Article 1(2) of the Merger Regulation.

IV. VACCINES

(17) Vaccines are biological medicinal products designed to improve immunity against one or several diseases. They stimulate the immune system by introducing weakened forms of the live organisms, its toxins or its surface proteins in the body. The immune system is then able to recognize the agent and destroy it more easily. Vaccines exist for both viral and bacterial diseases and can be based on activated or inactivated organisms as well as derived products. Following marketing authorisation, vaccines for specific diseases may be mandatory and included in national immunisation schedules.

(18) The global Vaccines industry was valued at USD 26 billion in 2013.[7]

(19) GSK has 30 different human vaccines against a large variety of bacterial and viral diseases such as hepatitis (A and B), diphtheria and tetanus, pertussis, measles, mumps, rubella, polio, typhoid, influenza and bacterial meningitis.

(20) Novartis' portfolio contains 13 vaccines for treatment against a variety of bacterial and viral diseases such as bacterial meningitis, rabies, as well as legacy sales of polio vaccines and sales of antigen for diphtheria and tetanus.

(21) The areas of horizontal overlap between the Parties' vaccines are:

(a) Meningococcal vaccines;

(b) Diphtheria and tetanus vaccines;

(c) Typhoid and hepatitis A vaccines.

(22) A vertical relationship also arises between the Parties regarding the bulk production of antigens used in vaccines manufacturing.

---

6 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p1).

7 GSK Circular to Shareholders, http://www.gsk.com/media/560424/gsk-novartis-circular.pdf.

IV.1. Relevant product markets

IV.1.1. Meningococcal vaccines

(23) Bacterial meningitis is the main disease targeted by meningococcal vaccines and is an infection of the meninges (protective membranes) around the brain and spinal cord. Meningococcus (*Neisseria meningitidis*) is one of the three bacteria causing bacterial meningitis. There are at least 13 meningococcal serogroups, five of which cause the majority of cases of meningococcal disease: A, B, C, W, and Y. Vaccines are currently available against all five of these most common serogroups. While vaccination against one serogroup does not create cross-immunity against any other serogroup, there exist polyvalent vaccines that provide immunisation against more than one serogroup.

(24) Meningococcal vaccines exist in two different forms: polysaccharide[8] vaccines ("PS" vaccines) induce a less enduring immune response than conjugate vaccines ("CJ" vaccines), which attach the polysaccharide antigen to a protein carrier (such as diphtheria or tetanus toxoids).

(25) The following types of meningococcal vaccines ("Men vaccines") are currently marketed in the EEA: MenC CJ, MenAC CJ, MenACWY PS, MenACWY CJ, MenB, and MenC-Hib[9] CJ. The letters after 'Men' indicate which serogroup(s) the vaccine targets.

(26) In the EEA, GSK markets MenACWY CJ, MenACWY PS and MenC-Hib vaccines, while Novartis markets MenACWY CJ, MenB and MenC CJ vaccines.

The Notifying Party's arguments

(27) The Notifying Party submits that MenC, MenACWY, MenB and MenC-Hib vaccines each constitute separate product markets, whereas MenACWY PS and MenACWY CJ vaccines are part of the same market.

(28) MenB vaccine provides protection for serogroup B while MenC, MenACWY and MenC-Hib cannot provide immunization against serogroup B. Therefore, the Notifying Party submits that MenB is a separate product market.

(29) MenC-Hib is designed for a specific requirement in the UK and is not sold anywhere else in the EEA but for minor sales in Poland. It is used as a booster for protection against both Hib and MenC.[10] The Notifying Party considers that monovalent MenC and Hib vaccines do not compete with MenC-Hib as boosters because of the desire to limit injections for infants and adolescents, and to some extent also for adults.

(30) The Notifying Party considers MenACWY and MenC vaccines as two different markets for the following reasons. First, the two vaccines have different age recommendations since MenC is approved for use after 2 months of life and MenACWY after 1 to 2 years. Second, MenC and MenACWY vaccines are priced differently, which results from the fact that only the former is included in most of the EEA coun-

8 The polysaccharides are long chains of sugar molecules that compose the cell wall of meningococcal bacteria.

9 Hib stands for *Haemophilus influenza* type B.

10 Minutes from a call with a customer dated 02 September 2014.

tries' national vaccine schedules. Last, and most importantly, each vaccine covers a different scope in terms of serogroups, which means that MenC vaccines cannot be used as a substitute for MenACWY in patients requiring immunisation against serogroups A, W and Y.

(31) Considering MenACWY PS and MenACWY CJ vaccines are protecting against the same serogroups, and considering MenACWY PS vaccine is being phased out by the more efficient MenACWY CJ vaccine, the Notifying Party further submits that they belong to the same product market.

Previous decisional practice

(32) The Commission has not yet had the opportunity to define product markets in the meningococcal vaccines area.

Commission's assessment

MenC and MenACWY

(33) Evidence from the market investigation confirms that MenACWY and MenC are used to protect against different serogroups of bacterial meningitis. While MenC vaccines protect against serogroup C only, MenACWY vaccines protect against serogroups A, C, W and Y. Customers indicated that MenACWY vaccines would be administered to "*people* [at risk of being] *exposed to a case of meningococcal infection (serogroup A, Y or W)*".[11] The substitutability between the two vaccines in these type of cases is limited, as MenACWY vaccines can be used against serogroup C, but MenC vaccines cannot be used against serogroups A, W and Y.

(34) Respondents in the market investigation highlighted that, with the exception of Greece[12] and Austria,[13] MenC vaccines are more appropriate than MenACWY vaccines for national vaccination schedules in the EEA: "*currently, in most EU countries only the MenC conjugate is included in the infant immunisation program*".[14] MenC vaccines are recommended in the vaccination schedules of 16 EEA countries, while only Greece and Austria added MenACWY vaccines to their national vaccinations schedules.

(35) In particular, a competitor provided the following four main reasons against the inclusion of MenACWY vaccines in national vaccination schedules:

---

11 Replies to question 8 of Questionnaire Q4 – Customers Meningitis Vaccines.

12 In Greece, the national vaccination schedule includes three mandatory MenC vaccinations at age 2 months, 4 months and from age 6 months to 6 years, and one mandatory MenACWY vaccination from age 11 years to 55 years. Regarding the three MenC vaccinations, the MenC vaccine is entirely reimbursed for the mandatory MenC vaccination and therefore is not expected to compete with MenACWY vaccines. Regarding the MenACWY vaccination from age 11 years to 55 years, MenC vaccines would not be suitable.

13 In Austria, the national vaccination schedule includes a mandatory MenC vaccination at age 12 months and a mandatory MenACWY vaccination at age 12 years. Regarding the MenC vaccination at age 12 months, MenC and MenACWY vaccines would therefore compete in Austria, although competition is expected to be limited as the overall pricing level for MenACWY is higher due to its broader scope of protection and its higher cost of production. Regarding the MenACWY vaccination at age 12 years, MenC vaccines would not be suitable.

14 Minutes of a call with a competitor dated 25 November 2014.

(a) "*there is no epidemiological data supporting the need for immunisation against Men A, W, and Y in Europe;*

(b) *the tetravalent vaccine is more expensive (not so much the case in Germany, but in most European countries);*

(c) *the licence of the tetravalent vaccine does not fully cover the age group for which vaccination is recommended;*

(d) *there is insufficient clinical data.*"[15]

(36) Once a specific vaccine (typically MenC) is included in the immunisation schedules, immunisation bodies only procure that specific type of vaccines, for example by restricting the specifications in the tender documentation.

(37) The great majority of vaccines customers confirmed that MenACWY is administered mainly to travellers, in particular in the context of the *"Hajj and Oumra [pilgrimages] to Saudi Arabia*"[16,17] or travels *"to the „Meningitis Belt" which is in sub-Saharan Africa*".[18] A competitor further confirmed that "*in Europe with the exception of Greece and Austria, the MenACWY vaccine is used for travellers*",[19] while a customer indicated that "*MenC is not relevant for travellers*".[20] Indeed, MenACWY is more appropriate since travellers usually need protection to additional serogroups on top of serogroup C: "*people requiring active immunisation against meningococcal meningitis caused by group A, C, W135 and Y meningococcal in adults/children who are visiting endemic/epidemic areas and Hajj/Umrah pilgrimage in Saudi Arabia*".[21]

(38) In light of the above, and in particular due to their protection against different serogroups and their targeting of different customers, the Commission takes the view that MenC and MenACWY vaccines constitute different product markets.

MenACWY PS and CJ

(39) Responses to the market investigation confirmed that MenACWY PS and CJ vaccines provide protection against the same serogroups (A, C, W and Y). MenACWY PS is generally viewed as a less efficacious alternative to MenACWY CJ.

(40) In light of the above, the Commission takes the view that MenACWY PS and CJ vaccines are part of the same product market.

MenB

(41) Responses to the market investigation confirmed that there is to date no multivalent vaccine providing protection against serogroup B, and that such a vaccine is unlikely to become available in the near future. Although Novartis is developing a (pipeline) MenABCWY vaccine, a competitor submitted that "*the idea of pentavalent vaccine*

15 Minutes of a call with a competitor dated 23 September 2014.

16 Replies to question 8 of Questionnaire Q4 - Customers Meningitis Vaccines.

17 MenACWY immunization is required above the age of 2 for the Hajj pilgrimage.

18 Replies to question 8 of Questionnaire Q4 - Customers Meningitis Vaccines.

19 Minutes of a call with a competitor dated 23 September 2014.

20 Minutes of a call with a customer dated 29 August 2014.

21 Replies to question 8 of Questionnaire Q4 - Customers Meningitis Vaccines.

must be regarded with scepticism […] The past has shown that putting antigens together is not easy and not always effective. It is possible that a combination of MenB and MenACWY vaccines would prove ineffective even if the two separate vaccines worked when injected at the same time".[22]

(42) In light of the above, and in particular due to their protection against different serogroups, the Commission takes the view that MenB vaccines constitute a separate product market. The question whether MenABCWY vaccines might have to be included in this market or in other meningococcal vaccines markets can be left open, as competitive concerns arise regarding MenACWY vaccines irrespective of the inclusion of MenABCWY vaccines.

MenC-Hib

(43) Responses to the market investigation confirmed that the UK national vaccination schedule requires a MenC-Hib booster at 12 months: "*The MenC-Hib vaccine, procured from GSK, is given as a booster vaccination [in the UK] at age 12 months*".[23] That product is specifically designed for the UK market,[24] and a UK customer suggested that the monovalent Hib vaccine is difficult to source in the UK as "*such products [monovalent Hib, D and T vaccines] are difficult to be found in the market and they are exception. Combination vaccines are more convenient and there is a general preference towards them*". [25]

(44) In light of the above, and in particular due to their protection against a very specific combination of infectious diseases and to their being designed to respond to a peculiar feature of the UK vaccination schedule, the Commission takes the view that MenC-Hib vaccines constitute a separate product market in the UK. The Commission does not need to conclude regarding the other EEA countries as the MenC-Hib vaccine is only marketed in the UK.

Conclusion on meningococcal vaccines

(45) The Commission takes the view that MenACWY vaccines (both PS and CJ), MenB vaccines, MenC vaccines and MenC-Hib vaccines each constitute separate product markets. The question whether MenABCWY vaccines, which are being developed but are not currently marketed, should be included in one or more of these markets can be left open.

IV.1.2. Diphtheria and tetanus vaccines

(46) Diphtheria is a respiratory illness caused by the *Corynebacterium Diphteriae* bacterium and characterized by sore throat, low fever and an adherent membrane on the

---

22 Minutes of a call with a competitor dated 23 September 2014.

23 Minutes of a call with a customer dated 2 September 2014.

24 The Parties indeed specify that "*Menitorix [GSK's MenC-Hib vaccine] has been designed specifically to meet a need in the UK vaccination schedule. Following a resurgence of Hib incidence in children of less than four years of age in the UK from 1999 onwards, a Hib booster dose in the second year of life was recommended in 2003, administered in combination with the scheduled MenC vaccination at around 12-13 months of age. It has been included in the UK immunisation schedule since 2005 […] GSK's Menitorix was specifically developed to address this situation [an excessive number of injections] in the UK and reduce the number of injections from four to three*".

25 Minutes of a call with a customer dated 2 September 2014.

tonsils, pharynx and/or nasal cavity. Tetanus is caused by the *Clostridium Tetani* bacterium and is often associated with rust. It is characterized by tightening of muscles and can lead to the locking of the jaw.

(47) Immunisation against diphtheria and tetanus is usually achieved through combination vaccines. Monovalent vaccines are available for both diseases, although they are not widely used. Lower dosage diphtheria vaccines ("d" vaccines) are used as a booster and concern adults and children from age 5 or 7 onwards, whereas higher dosage vaccines ("D" vaccines) are used for primary immunisation typically in infants under the age of 6 or 7. These vaccines can either be combination vaccines for diphtheria and tetanus only, or more commonly "broader combination vaccines" that also provide immunisation against other diseases such as pertussis,[26] poliomyelitis (IPV), hepatitis B (HepB), and Hib.

(48) The following types of diphtheria and tetanus vaccines are marketed in the EEA: monovalent diphtheria (D), monovalent tetanus (T), combination diphtheria and tetanus for infants (DT), combination diphtheria and tetanus for adults (dT), broader combination vaccines for infants (DTaP, DTaP-IPV, DTaP-Hib, DTaP-IPV-Hib, DTaP-IPV-Hib-HepB, DTwP, and DTwP-IPV) and broader combination vaccines for adults (dTaP, dTaP-IPV, and dT-IPV).

(49) In the EEA, Novartis markets D, T and dT vaccines, while GSK markets dT and DT vaccines, as well as broader combination paediatric and adult vaccines.

The Notifying Party's argument

(50) The Notifying Party considers that dT vaccines do not compete with D and DT vaccines, or with broader combination vaccines. Nonetheless, the Notifying Party considers dT vaccines compete to a limited extent with monovalent T vaccines for tetanus prophylaxis.[27]

(51) Given that low-dose and high-dose diphtheria vaccines do not target the same population, the Notifying Party considers dT vaccines do not compete with DT vaccines.

(52) According to the Notifying Party, in the EEA, national vaccination schedules for paediatrics are designed to minimise the number of injections and allow for the joint administration of several vaccines at a time, typically including diphtheria, tetanus, pertussis and poliomyelitis. Broader combination vaccines are therefore preferred, as they limit the number of injections required. Therefore, the Notifying Party submits that DT and dT vaccines do not generally compete with paediatric broader combination vaccines. The same argument would apply regarding adult broader combination vaccines.

(53) The Notifying Party submits that dT vaccines do not compete with monovalent D vaccines. Routine immunisation for diphtheria usually coincides with immunisation for tetanus. In this case, bivalent vaccines are typically preferred because they require only one injection.

Previous decisional practice

26 Regarding pertussis, the antigen can exist in two distinct forms: acellular pertussis ("aP") and whole-cell pertussis ("wP").

27 Preventive vaccination against tetanus in case of injuries and potential exposures to tetanus bacterium.

(54) The Commission has not yet had the opportunity to define product markets in the diphtheria and tetanus vaccines space.

Commission's assessment

(55) Even though the majority of respondents to the market investigation do not distinguish between dT and DT vaccines,[28] a number of customers' replies suggested a different usage: *"the difference between "d-" and "D-" vaccine is the diphtheria dosage. A capital D means a primary immunization dose of diphtheria for children's vaccination while small d implies booster strength of diphtheria which can be administrated to all ages"*,[29] *"the diphtheria compound in the adult vaccine is 10 times smaller than the one in the paediatric vaccine"*.[30]

(56) Respondents broadly confirmed that national immunisation schedules for diphtheria and tetanus usually coincide with schedules for other vaccines, including pertussis and poliomyelitis.[31] Therefore, broader combination vaccines would be preferred to dT/DT vaccines in order to limit the number of injections. Adult dT vaccines would not compete with broader combination vaccines since national vaccination schedules do not typically require boosters of other diseases for adults.

(57) Customers explained that in order to minimise the number of injections, multivalent or bivalent vaccines are usually preferred to monovalent D and T vaccine for boosters. Concerning in particular diphtheria booster, bivalent dT vaccines have relatively low prices and are widely available.[32]

(58) Nonetheless, both T and dT vaccines are used when emergency tetanus vaccination is needed: "*hospitals especially keep using T vaccine only or dT in the emergency rooms for tetanus prophylaxis since TdaP [dTaP] is more expensive*".[33]

(59) For all the above-mentioned reasons, the Commission takes the view that monovalent and bivalent diphtheria and tetanus vaccines (D, T, dT and DT vaccines) should be distinguished from broader combination vaccines for the purpose of market definition. D and DT vaccines should also be distinguished from dT and T vaccines. However, it is not necessary to conclude on the exact market definition(s) related to dT and T vaccines, as serious doubts as to the Transaction's compatibility with the internal market arise irrespective of the exact product market definition (in the affected markets, the same suppliers provide dT and T vaccines, see below in Section IV.3.3).

IV.1.3. Hepatitis and typhoid vaccines

(60) Vaccines against hepatitis A and typhoid are typical traveller vaccines. Protection either against hepatitis A, typhoid or both is provided in the EEA countries by the following oral and injectable vaccines: monovalent hepatitis A; monovalent typhoid; bivalent hepatitis A / hepatitis B; bivalent hepatitis A / typhoid.

---

28 Replies to question 11 of Questionnaire Q5 – Customers Vaccines Germany/Italy.

29 Minutes of a call with a customer dated 3 September 2014.

30 Replies to question 11 of Questionnaire Q5 – Customers Vaccines Germany/Italy.

31 Minutes of a call with a customer dated 04 September 2014.

32 Minutes of a call with a customer dated 20 August 2014.

33 Minutes of a call with a competitor dated 3 September 2014.

(61) GSK markets all four above-mentioned vaccines in the EEA. Novartis is not active in these areas, with the exception of Germany where Novartis distributes Crucell's monovalent vaccines against hepatitis A and typhoid.

The Notifying Party's argument

(62) The Notifying Party submits that monovalent hepatitis and monovalent typhoid vaccines are independent markets from the above-mentioned bivalent vaccines. Substitution with bivalent vaccines is limited to travellers planning to visit countries where protection against two or more type of diseases including hepatitis A, hepatitis B and typhoid is required.

Previous decisional practice

(63) The Commission has not yet had the opportunity to define product markets in the hepatitis and typhoid vaccines space.

Commission's assessment

(64) Responses to the market investigation suggest that hepatitis A and typhoid vaccines belong to the traveller segment: "*the hepatitis A vaccine belongs to the travellers segment*",[34] "*the typhoid vaccine is administrated to subjects who do travel from non-endemic areas to endemic areas*".[35] Therefore, the appropriate vaccine (monovalent or bivalent) is chosen in light of the country in which the subject is travelling.

(65) In any event, the market definition related to typhoid and hepatitis A vaccines can be left open as no competitive concerns arise irrespective of the exact product market definition.

IV.1.4. Bulk antigens

(66) Novartis is active in the upstream production of bulk diphtheria and tetanus antigens and also bulk diphtheria carrier proteins. Whilst the antigen provides immunity against the targeted disease (e.g., against tetanus in the case of a tetanus antigen) the carrier protein provides no such immunity; rather the carrier protein increases the immunogenic efficacy of a different antigen. The carrier protein is not immunogenic and cannot be used as an antigen.

(67) The carrier proteins area will not be considered further since neither GSK nor Novartis are active in this area (except for internal purposes). On the other hand, Novartis sells diphtheria and tetanus antigens to third parties, including GSK. GSK uses the antigens as an input for its downstream vaccines businesses.

The Notifying Party's argument

(68) The Notifying Party submits there is no need to delineate the market for bulk antigens since no competitive concerns arise irrespective of the exact product market definition.

34 Minutes of a call with a competitor dated 25 November 2015.

35 Replies to question 18 of Questionnaire Q5 – Customers Vaccines Germany/Italy.

Previous decisional practice

(69) The Commission has not yet had the opportunity to define product markets in the area of bulk antigen production.

Commission's assessment

(70) A respondent from the market investigation submitted that each vaccine relies on one or more specific antigen(s): "*development of a vaccine using alternative suppliers [of antigens] would require 5-7 years of development and clinical testing before it could come to the market*".[36] This suggests that each antigen is a separate product market since each vaccine is authorised with a specific antigen.

(72) In any event, the market definition related to bulk antigens can be left open as no competitive concerns arise irrespective of the exact product market definition.

IV.2. Relevant geographic markets

IV.2.1. Vaccines

(73) In line with past decisions, the vaccine markets are analysed at the national level. The Notifying Party does not contest such market definition.[37]

(74) Responses to the market investigation confirmed the national scope of the vaccine market, in particular in light of national regulatory frameworks, national vaccination schedules, prices and reimbursement. A competitor submitted in particular that vaccines "*prices and reimbursement levels are being established by the national authorities*".[38]

IV.2.2. Bulk antigens

(75) The Commission has previously considered the markets of active pharmaceutical ingredients (API) to be geographically larger than the markets for finished pharmaceutical products, with their scope likely to be at least EEA-wide in scope.[39] Regarding the markets for bulk antigens, such a market definition is in line with the Notifying Party's submission.[40]

IV.3. Competitive assessment

IV.3.1. Introduction

(76) In the vaccines space, the Transaction will lead to horizontal overlaps regarding (a) MenACWY vaccines in a number of EEA countries; (b) dT vaccines in Germany and Italy; (c) hepatitis and typhoid vaccines in Germany. It will also lead to a verti-

36 Replies to question 16 of Questionnaire Q6 – Vaccines competitors.

37 M.4049, *Novartis/Chiron* (2006) paragraph 32; Case IV/34.776, *Pasteur Mérieux-Merck* (1994), paragraph 55.

38 Minutes of a call with a competitor dated 23 September 2014.

39 M.1397, *Sanofi / Synthelabo* (1999), paragraph 49; M.4007, *Novartis/Hexal* (2005), paragraph 21; M.3394, *Johnson and Johnson/J&J MSD Europe* (2004), paragraph 18.

40 Indeed, GSK purchases from Novartis [location] bulk diphtheria and tetanus antigens that GSK uses in vaccines that it sells in more than 60 countries around the world. Similarly, Novartis exports the antigens to customers both in the EEA ([customer(s)]) and outside the EEA.

cal relationship between upstream markets for bulk diphtheria and tetanus antigens and downstream markets for vaccines.

IV.3.2. Horizontal overlaps – Meningococcal vaccines

(77) The only two suppliers of MenACWY vaccines marketed in the EEA are Novartis, with its *Menveo* CJ vaccine, and GSK, with its *Mencevax* PS and *Nimenrix* CJ vaccines.

The Notifying Party's arguments

(78) Novartis marketed the first MenACWY CJ vaccine in the EEA in 2010, followed by GSK in 2012. The Notifying Party acknowledges the concentration is a merger to monopoly in 13 EEA countries.[41] In Sweden, Norway and Finland, Novartis distributes *Menveo* through […]. In these countries, Novartis does not set or control prices; these are determined by […]. Therefore, the Notifying Party does not consider these three countries as part of the overlap.

(79) The Notifying Party claims that it has a strategy of [discussion on the Notifying Party's EEA strategy regarding MenACWY vaccines]. Since national bodies will assess the cost-benefit advantage of including MenACWY vaccines in their schedules, GSK will have no incentive to increase its prices post-merger. Furthermore, most EEA countries have price control mechanisms (such as caps on price increases, profit controls, price-setting by governmental bodies, or reference pricing systems) which would prevent a monopolist from raising prices.

(80) The Notifying Party submits that there are at least two competitors ready to enter the market, potentially strengthening competition in MenACWY vaccines: (1) Sanofi-Pasteur with its *Menactra* vaccine, currently marketed in the US, and (2) JN International with a phase III clinical trial MenACWY vaccine developed in the US and aimed for international markets.

(81) The Notifying Party therefore argues that the transaction would not impede effective competition in the EEA.

Commission's assessment

(82) Concerning MenACWY vaccines, the proposed concentration is a merger to monopoly in 13 EEA countries, with varying increments as indicated in the table below:

41 Austria, Cyprus, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Poland, Portugal, Spain, United Kingdom.

Table 1: Market size and market shares in value of the Parties in the EEA affected countries for MenACWY vaccines, 2011-2013[42]

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Austria	2013	[2,000-3,000]	[80-90]%	[10-20]%	**[90-100]%**
	2012	[2,000-3,000]	[20-30%	[70-80]%	**[90-100]%**
	2011	[0-1,000]	[20-30]%	[70-80]%	**[90-10]%**
Cyprus[43]	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[0-5]%	[0-5]%	**[0-5]%**
	2011	[0-1,000]	[0-5]%	[0-5]%	**[0-5]%**
Czech Republic	2013	[1,000-2,000]	[50-60]%	[40-50]%	**[90-100]%**
	2012	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[90-100]%	**[90-100]%**
France	2013	[5,000-6,000]	[30-40]%	[60-70]%	**[90-100]%**
	2012	[4,000-5,000]	[10-20]%	[80-90]%	**[90-100]%**
	2011	[3,000-4,000]	[20-30]%	[70-80]%	**[90-100]%**
Germany	2013	[4,000-5,000]	[60-70]%	[30-40]%	**[90-100]%**
	2012	[3,000-4,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[2,000-3,000]	[20-30]%	[70-80]%	**[90-100]%**
Greece	2013	[4,000-5,000]	[10-20]%	[80-90]%	**[90-100]%**
	2012	[1,000-2,000]	[30-40]%	[60-70]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[90-100]%	**[90-100]%**
Hungary	2013	[0-1,000]	[60-70]%	[40-50]%	**[90-100]%**
	2012	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[0-1,000]	[50-60]%	[40-50]%	**[90-100]%**
Ireland	2013	[0-1,000]	[70-80]%	[20-30]%	**[90-100]%**
	2012	[0-1,000]	[80-90]%	[10-20]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Italy	2013	[5,000-6,000]	[30-40]%	[70-80]%	**[90-100]%**
	2012	[1,000-2,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[1,000-2,000]	[20-30]%	[70-80]%	**[90-100]%**
Poland	2013	[1,000-2,000]	[70-80]%	[20-30]%	**[90-100]%**
	2012	[0-1,000]	[30-40]%	[60-70]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[90-100]%	**[90-100]%**
Portugal	2013	[0-1,000]	[10-20]%	[80-90]%	**[90-100]%**
	2012	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[0-1,000]	[5-10]%	[90-100]%	**[90-100]%**
Spain	2013	[1,000-2,000]	[60-70]%	[30-40]%	**[90-100]%**
	2012	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[1,000-2,000]	[20-30]%	[70-80]%	**[90-100]%**
United Kingdom	2013	[3,000-4,000]	[50-60]%	[40-50]%	**[90-100]%**
	2012	[2,000-3,000]	[50-60]%	[40-50]%	**[90-100]%**
	2011	[2,000-3,000]	[60-70]%	[30-40]%	**[90-100]%**

Source: GSK and Novartis

42 Throughout tables in this decision, the market shares of GSK, Novartis Business, and Combined are rounded to the digit, which can lead to seemingly inconsistent numbers.

43 GSK launched its *Nimenrix* MenACWY vaccine in Cyprus in 2013 only.

(83) There are also 13 markets in the EEA, in which the Transaction may have a significant impact (mostly where one of the Parties is the sole supplier of MenACWY vaccines):

Table 2: Market size and market shares in value of the Parties in the EEA countries in which the Transaction may further have a significant impact for MenACWY vaccines, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Belgium	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[60-70]%	[30-40]%	**[90-100]%**
Bulgaria	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[0-5]%	**[0-5]%**
Croatia	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Denmark	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[0-5]%	**[90-100]%**
Finland	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Iceland	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Luxembourg	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Malta	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Netherlands	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[90-100]%	**[90-100]%**
Norway	2013	[1,000-2,000]	[60-70]%	[0-5]%	**[60-70]%**
	2012	[1,000-2,000]	[70-80]%	[0-5]%	**[70-80]%**
	2011	[0-1,000]	[0-5]%	[0-5]%	**[0-5]%**
Slovakia	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[0-5]%	**[90-100]%**
Slovenia	2013	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2012	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
	2011	[0-1,000]	[90-100]%	[0-5]%	**[90-100]%**
Sweden	2013	[0-1,000]	[5-10]%	[0-5]%	**[5-10]%**
	2012	[0-1,000]	[0-5]%	[0-5]%	**[0-5]%**
	2011	[0-1,000]	[0-5]%	[0-5]%	**[0-5]%**

Source: GSK and Novartis

(84) In particular, Novartis has a distribution agreement with […] in the Scandinavian countries (Finland, Sweden, Norway) regarding MenACWY vaccines. The Notifying Party does not consider these countries as being affected markets on the basis that […] independently sets and controls prices in these countries. In any event, the Commission does not need to conclude on whether […]'s sales should be attributed to Novartis since the proposed commitments address competition concerns at EEA level.

(85) In the abovementioned countries (but Finland, Norway and Sweden where Crucell supplies Novartis' MenACWY vaccine), GSK is the only supplier and Novartis is the most likely entrant since it has a marketed MenACWY vaccine in the EEA. Therefore, the Transaction would remove a potential competitor in these markets.

(86) Regarding other potential competitors, Sanofi-Pasteur is marketing a MenACWY CJ vaccine (*Menactra*) in the USA, but the vaccine is currently in phase II trials in the EEA. As indicated by Sanofi-Pasteur, "*the development of this vaccine [Menactra] is still in phase II stage and it is premature, given the development risks, to foresee the expected launch date [in Europe]*".[44] Similarly, JN International's MenACWY CJ vaccine is still in phase III clinical trials in the EEA.

(87) In addition, respondents from the demand side confirmed that there is no alternative to the Parties for the supply of MenACWY vaccines. In particular, no customer in the EEA mentioned either Sanofi-Pasteur or JN International as potential suppliers of MenACWY vaccines.[45] Therefore, it is unlikely that new competitors would enter the MenACWY markets and grow into an effective competitive force in a timely manner.

(88) Regarding the impact of the Transaction on the price of MenACWY vaccines, replies from vaccines purchasers suggest that the entry of GSK in the MenACWY market in 2012 introduced competition and led to significantly lower prices compared to the previous Novartis monopoly: "*GSK launched its meningitis product Nimenrix at a significantly lower price (Menveo EUR 36 or more – Nimenrix: EUR 23, both prices without taxes). […] The move from a monopoly to two potential suppliers in the market allowed patients to pay less for an equally efficient product"*.[46] A substantial number of the meningitis vaccines customers believe that reverting to a monopoly would likely impede competition and lead to price increases.[47]

(89) In light of the above and of all available evidence, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market as regards MenACWY vaccines in at least 13 affected EEA countries[48] in which it would lead to the creation of a monopoly. The Transaction would also remove a potential competitor and strengthen the Parties' dominance in further 13 EEA countries.[49]

---

44 Replies to question 12.2 of Questionnaire Q6 – Vaccines Competitors.

45 Replies to question 7 of Questionnaire Q4 – Customers Meningitis Vaccines

46 Minutes of a call with a customer dated 29 August 2014.

47 Replies to question 11 of Questionnaire Q4 - Customers Meningitis Vaccines.

48 Austria, Cyprus, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Poland, Portugal, Spain, United Kingdom.

49 Belgium, Bulgaria, Croatia, Denmark, Finland, Iceland, Luxembourg, Malta, the Netherlands, Norway, Slovakia, Slovenia, Sweden.

IV.3.3. Horizontal overlaps – Diphtheria and tetanus vaccines

(90) A horizontal overlap arises regarding dT vaccines in Germany and Italy, where both Parties market bivalent dT vaccines, with Novartis further marketing monovalent T vaccines.

The Notifying Party's arguments

(91) The Notifying Party submits that the market for dT vaccines is small and declining in both volume and value. In practice, dT vaccines are mainly used in countries where national immunisation schedules provide for a dT-only booster (not recommending booster vaccination for other diseases at the same time).

(92) The Notifying Party also considers markets for dT and T vaccines to be commoditised. The Transaction would not affect prices in Germany and Italy since there has not been any shortage in the past, products of various competitors are fully substitutable and the market size is decreasing. Purchasers would not be dependent on GSK post-Transaction.

(93) Therefore, the Notifying Party does not consider that this concentration would significantly impede competition in Germany and Italy either in a dT or in a dT+T vaccines market.

Commission's assessment

(94) Concerning dT vaccines only, the Transaction would lead to two affected markets, Germany and Italy:

Table 3: Market size and market shares in value of the Parties in the affected EEA countries for dT vaccines, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Germany	2013	[4,000-5,000]	[5-10]%	[50-60]%	**[60-70]%**
	2012	[4,000-5,000]	[5-10]%	[60-70]%	**[70-80]%**
	2011	[4,000-5,000]	[5-10]%	[60-70]%	**[70-80]%**
Italy	2013	[1,000-2,000]	[5-10]%	[30-40]%	**[40-50]%**
	2012	[0-1,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[0-1,000]	[20-30]%	[60-70]%	**[80-90]%**

Source: GSK and Novartis

(95) In Germany, the combined market share is [60-70]% with a [5-10]% increment. This combined market share has decreased in the past 3 years. In Italy, the combined market share is [40-50]% with a [5-10]% increment. The combined market share has significantly decreased from [80-90]% in 2011, mainly due to the expansion of Sanofi-Pasteur's presence in the Italian dT market.

(96) Concerning dT and T vaccines together, the Transaction would also lead to two affected markets, Germany and Italy:

Table 4: Market size and market shares in value of the Parties in the affected EEA countries for dT and T vaccines, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Germany	2013	[6,000-7,000]	[5-10]%	[60-70]%	**[60-70]%**
	2012	[6,000-7,000]	[5-10]%	[60-70]%	**[60-70]%**
	2011	[7,000-8,000]	[5-10]%	[50-60]%	**[60-70]%**
Italy	2013	[4,000-5,000]	[0-5]%	[60-70]%	**[60-70]%**
	2012	[2,000-3,000]	[0-5]%	[40-50]%	**[50-60]%**
	2011	[3,000-4,000]	[0-5]%	[50-60]%	**[60-70]%**

Source: GSK and Novartis

(97) In Germany, the combined market share is [60-70]% with a [5-10]% increment. This combined market share has been stable for the past 3 years, although market value decreased. In Italy, the combined market share is [60-70]% with a [0-5]% increment. The combined market share has been stable for the past 3 years.

(98) In Italy, a large majority of purchasers mention Novartis, GSK or Sanofi as current or potential short term alternative suppliers of dT and T vaccines.[50] The Transaction would therefore be a "3-to-2" merger.

(99) In Germany, the great majority of purchasers mention Novartis, GSK, Baxter or Sanofi as current or potential short term alternative suppliers of dT and T vaccines.[51] The Transaction would therefore be a "4-to-3" merger.

(100) Regarding the impact of the Transaction on the price of dT vaccines, a number of German and Italian dT and T customers (around a third) expressed concerns on the potential impact of the concentration on prices of dT and T vaccines.[52]

(101) Furthermore, given the low value of this market and the challenges associated with vaccine certification at national level in the EEA, it is unlikely that any new company would be willing to enter this specific market. Therefore, no additional competitive pressure is expected.

(102) In light of the above and of all available evidence, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market as regards dT vaccines (possibly together with T vaccines) in Germany and Italy, as it would lead to a creation or strengthening of dominance.

IV.3.4. Horizontal overlaps – Hepatitis and typhoid vaccines

(103) In January 2005, Novartis and Crucell Switzerland AG ("Crucell") entered into a distribution agreement under which Novartis was selling two of Crucell's traveller vaccines, a hepatitis A vaccine under the brand name *HavPur* and a typhoid vaccine under the brand name *Typhoral L*.[53] The territorial scope of the agreement is limited to

50 Replies to question 13 of Questionnaire Q5 - Customers Vaccines Germany/Italy.

51 Replies to question 13 of Questionnaire Q5 - Customers Vaccines Germany/Italy.

52 Replies to question 21 of Questionnaire Q5 - Customers Vaccines Germany/Italy.

53 Marketed as *Vivotif* outside Germany.

Germany, since Novartis cannot sell *Havpur* or *Typhoral L* outside of Germany.[54] The Parties' activities overlap since GSK is active in both hepatitis A (with *Havrix*) and typhoid (with *Typhrix*) vaccines.

(104) Crucell sold its typhoid vaccines business to the U.S. vaccines manufacturer PaxVax in July 2014.[55] In the same transaction, PaxVax also acquired IP rights and clinical tests for Crucell's hepatitis A vaccine.[56]

The Notifying Party's arguments

(105) The Notifying Party submits there will be no competitions issues since production of Crucell's hepatitis A and typhoid vaccines distributed by Novartis stopped, and current stocks would be depleted by […].

Commission's assessment

(106) Based on market data,[57] this concentration constitutes a "3-to-2" merger in Germany regarding monovalent hepatitis and typhoid vaccines, with Novartis/Crucell and GSK's sole other competitor being Sanofi-Pasteur. Nevertheless, considering that at the end of 2013 (and therefore prior to the public announcement of the Transaction), Crucell announced that it would discontinue production of its hepatitis A and typhoid vaccines,[58] and that Novartis' sales are based on stocks that will be depleted by […], the current situation does not reflect the actual competitive environment.

(107) Regarding hepatitis A, Crucell's position was confirmed by Sanofi-Pasteur, which highlighted that: "*The main competitor of Sanofi-Pasteur in this field is GSK. Currently Crucell still plays a role with some doses that remained on the market; however this will be over soon since the company announced its plan to leave the market.*"[59]

(108) Regarding typhoid, the Commission understands that PaxVax has not yet decided who would distribute its typhoid vaccine in Germany. Nonetheless, PaxVax raised the following concern: "*Apart from the difficulty in finding an appropriate commercial partner, an additional element that may hinder PaxVax' commercial success in Germany is the lack of ownership of the brand name used so far by Novartis for the distribution of Crucell's typhoid vaccine. In fact, Vivotif has so far been distributed in Germany under Novartis' brand name Typhoral L.*"[60] Consequently, given that the *Typhoral L* brand under which Crucell's typhoid vaccine has been distributed in Germany belongs to Novartis and not to PaxVax, following the Transaction *Typhoral L* would belong to PaxVax' competitor, GSK. A competitor further raised the importance of the brand in the distribution of vaccines: *"Brand management is always an important element of a commercial strategy, and brands have a role also in*

54 For the sake of completeness, the Parties note that Novartis also distributes Crucell's *Dukoral* product (a drinkable vaccine protecting against diarrhoea caused by cholera), in Germany. However, there is no overlap as regards *Dukoral* as GSK does not market a competing diarrhoea or cholera vaccine.

55 http://www.PaxVax.com/about/news/PaxVax-acquires-the-fda-approved-typhoid-vaccinevivotif.

56 Minutes of a call with a competitor dated 11 December 2014.

57 GSK […] database and Novartis' actuals.
http://www.srf.ch/news/regional/bern-freiburgwallis/biotech-konzern-crucell-will-am-standort-bern-380-stellen-abbauen.

59 Minutes of a call with a competitor dated 25 November 2014.

60 Minutes of a call with a competitor dated 11 December 2014.

the vaccine segment. While the importance of brand recognition by consumers may be less evident than in other type of pharmaceutical products, evidence shows that doctors are, nonetheless, often reluctant to use new products".[61]

(109) The issue related to *Typhoral L* was resolved during the investigation as Novartis entered into a binding agreement whereby it assigned the *Typhoral L* brand to PaxVax.

(110) In light of the above and of all available evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as regards hepatitis A and typhoid vaccines in Germany.

IV.3.5. Vertical relationships – Bulk antigens / Vaccines

(111) The Transaction would result in a vertical integration of Novartis's bulk diphtheria and tetanus antigens production by GSK, of which GSK is currently the main purchaser.

(112) According to the Notifying Party, around [10-20]% of Novartis' diphtheria and tetanus antigen production is used in house. GSK accounts for around [90-100]% of the production sold to third parties, with the remainder ([5-10]%) being sold to Crucell, S.K Chemicals, Intervet Int., Sevapharma, WDT Serumwerk Memsen and Takeda.

Table 5: Novartis' supply and third party sales of products containing diphtheria and tetanus antigens, 2011-2013

Customer	2013 sales (k€)		2012 sales (k€)		2011 sales (k€)	
	Value	%	Value	%	Value	%
GSK	[160,000-170,000]	[90-100]%	[170,000-180,000]	[90-100]%	[170,000-180,000]	[90-100]%
[…]	[15,000-16,000]	[5-10]%	[16,000-17,000]	[5-10]%	[17,000-18,000]	[5-10]%
[…]	[0-1,000]	<[0-5]%	[1,000-2,000]	<[0-5]%	[1,000-2,000]	<[0-5]%
[…]	[0-1,000]	<[0-5]%	[0-1,000]	<[0-5]%	[0-1,000]	<[0-5]%
[…]	[0-1,000]	<[0-5]%	[0-1,000]	<[0-5]%	-	-
[…]	-	-	[0-1,000]	<[0-5]%	-	-
TOTAL	**[180,000-190,000]**	**100%**	**[190,000-200,000]**	**100%**	**[190,000-200,000]**	**100%**

Source: Novartis

The Notifying Party's arguments

(113) The Notifying Party claims that most vaccines manufacturers (and in particular its main competitors Sanofi-Pasteur and Statens Serum Institute) are already vertically integrated with regards to the production of antigens.

(114) Furthermore, the Notifying Party submits that among third parties purchasers of Novartis's diphtheria and tetanus antigens, only […] is marketing human vaccines based on these antigens in the EEA.[62]

61 Minutes of a call with a competitor dated 11 December 2014.

Commission's assessment

(115) Responses to the market investigation confirmed that, among Novartis' customers of bulk antigens, only [Novartis customer 1] is marketing human vaccines based on these antigens in the EEA. [Novartis customer 2] is also marketing *[...]*, for the developing world.

(116) Neither [Novartis customer 1] nor [Novartis customer 2] expressed concerns with regards to the supply of bulk diphtheria and tetanus antigens.

(117) In light of the above and of all available evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as regards the vertical relationship between the markets for bulk antigen production and the markets for vaccines production.

IV.3.6. Conclusion

(118) In the area of Vaccines, the Transaction raises serious doubts as to its compatibility with the internal market in relation to 2 areas: (i) MenACWY in 26 EEA countries, and (ii) dT vaccines in Germany and Italy.

V. CONSUMER HEALTH

V.1. INTRODUCTION

(119) The over-the-counter industry comprises pharmaceutical products which can be purchased without a prescription in pharmacies or in certain countries, in other type of stores such as supermarkets.[63] Internet sales are also expanding to some degree.[64] The Global OTC industry was valued at USD [100-150] billion in 2010, and projected to rise to more than USD [100-150] billion by 2015.[65]

(120) Brands play a significant role in the OTC industry. Brands are "[…]" and command "[…]".[66] Advertising is a key feature in the OTC industry. "*In general consumers become aware of brands and products through different channels: so called "above the line" (mass media, for example from TV), and visiting doctors and pharmacists*."[67] Whereas for most pharmaceuticals products pharma companies promote their products to doctors, in OTC "*the main target is the pharmacy and not the phy-*

---

62 More specifically, a monovalent T vaccine in Slovakia and the Czech Republic, while GSK does not market any monovalent T or bivalent dT vaccine in these two countries.

63 Minutes of a call with a customer dated the 30 September 2014; minutes of a call with a customer dated the 20 October 2014.

64 "*There has been a gradual removal of key pharmacy regulations in the last 20 years. There are four main types of regulation: (i) ownership restriction (i.e. pharmacies can only be owned by pharmacists); (ii) establishment restrictions (i.e. the pharmacies' licences have quotas on a geographical / population basis); (iii) OTC monopoly (i.e. OTC products can only be sold in pharmacies); and (iv) internet restriction.*" Minutes of a call with an industry association dated 18 September 2014.

65 Internal document of GSK, […].

66 Internal document of GSK, […].

67 Minutes of a call with a competitor dated 13 October 2014. See also Minutes of a call with a competitor dated 17 October 2014; minutes of a call with a distributor dated 20 October 2014; minutes of a call with a competitor dated 17 October 2014.

sician".[68] Consumers also rely on other factors such as therapeutic/labelled indication, active ingredients, format and price. Players estimate that in the OTC field 30 to 50% of the customers ask for pharmacist advice, and the others already know the product/brand they want.[69]

(121) Suppliers of OTC medicines in the EEA may be vertically integrated at various levels of the supply chain,[70] or can outsource to third parties. Contract manufacturers confirmed that "*Outsourcing is a common practice in the pharma industry. The trend is to go for out-sourcing, but some big pharma companies prefer manufacturing the products in-house*".[71] OTC suppliers are generally free to determine the prices at which they sell OTC products to customers. However, in some EEA countries OTC medicines are subject to price regulation.[72]

(122) OTC products can be sold to pharmacies via wholesalers, but large companies also sell directly to large customers. For instance, a wholesaler estimates that large pharma companies visit 6-7 000 out of about 20 000 pharmacies in Spain.[73] In countries of smaller size (for instance Latvia and Lithuania), companies such as the Parties frequently use distributors for the marketing of their OTC products.

(123) There are three principal types of regulatory authorisations required in order to bring a new product to market: manufacturing, distribution and marketing authorisation.

(124) When a marketing authorisation is granted, the competent authorities specifies the classification of the medicinal product into two categories: subject to medical prescription or not subject to medical prescription (OTC) depending of medical indications or specific precautions of use (for instance adverse reactions).

(125) The Commission has in the past defined separate product markets for OTC (non-prescription-bound) pharmaceuticals and prescription-bound pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distribution tend to differ between these categories. The Parties have followed this subdivision between OTC and prescribed medicines in their submissions.[74]

(126) The OTC JV would be the largest consumer healthcare business globally.[75]

(127) The areas of overlap between the Parties' products contributed to the OTC JV are:[76]

---

68 Minutes of a call with an industry association dated 18 September 2014. See also minutes of a call with a competitor dated 17 October 2014.

69 Minutes of a call with a competitor dated 17 October 2014; minutes of a call with a customer dated 17 October 2014; minutes of a call with a customer dated 03 October 2014.

70 Integration can take place at the level of manufacturing of the active pharmaceutical ingredients and/or finished dose OTC medicines.

71 Minutes of a call with a contract manufacturer dated 12 September 2014. See also minutes of a call with a contract manufacturer dated 11 September 2014; replies to question 4.1 of Questionnaire R1 – Market test of the Commitments – OTC.

72 Belgium, Greece, and Lithuania.

73 Minutes of a call with a wholesaler dated 10 September 2014. See also minutes of a call with a competitor dated 14 October 2014; minutes of a call with a competitor dated 17 October 2014; minutes of a call with a wholesaler dated 17 September 2014.

74 M.3394, *Johnson & Johnson/Johnson & Johnson MSD Europe* (2004), paragraphs 14-15.

75 GSK Circular to Shareholders, http://www.gsk.com/media/560424/gsk-novartis-circular.pdf.

(a) Smoking cessation;

(b) Cold sore management;

(c) Cold and flu treatments;

(d) Allergic rhinitis treatments;

(e) Pain management;

(f) Gastrointestinal treatments;

(g) Antifungals.

V.2. SMOKING CESSATION

(128) Smoking cessation products are aimed at reducing and ultimately eliminating the nicotine addiction that comes with smoking. There exist several pharmacological treatments for smoking cessation to deal with the physical withdrawal symptoms, such as cravings, irritability, inability to concentrate, and anxiety.

(129) Inhalation of nicotine through smoking increases the number of nicotine receptors in the brain. As a result, a smoker's brain requires a regular supply of nicotine to function normally. Most attempts to quit smoking are unsuccessful ("[…]"[77]). One player notes that "*sales of smoking cessation products are stable, with a slight impact of 'good resolutions' in September and January**".[78]

(130) The majority of smoking cessation aids are Nicotine Replacement Therapies ("NRT") products, which provide smokers with a slow release of nicotine in gradually smaller doses, thereby slowly reducing smokers' dependence on nicotine. There are, however, other types of smoking cessation products, such as the Nicotine De-Addiction Therapies ("NDT"). NDTs are prescription systemic products (for instance *Champix* in tablets) which aim at blocking the nicotine reward experience.

(131) The global OTC NRT category was estimated at GPB [1-2] billion in 2013, with J&J being the global leader.[79] In Europe, a competitor indicates that "*in smoking cessation, the UK, France, Germany and the Nordics account for most of the sales*".[80]

(132) The three main types of NRT products are (i) nicotine patches, (ii) nicotine gums and (iii) nicotine lozenges. Other formats include nicotine inhalators, sprays, orally dissolving strips and sublingual tablets.

---

76 During pre-notification, the Parties initially identified a further overlap in the antiseptics and disinfectants area. Nonetheless, the Parties later submitted that GSK discontinued its relevant products (*Zeasorb* in Ireland and the UK, *Daro Boor* in the Netherlands and *Drapolen* in Latvia), and that remaining stocks exhausted in 2013. As a result, GSK is no longer active and the Parties activities do not overlap in the antiseptics and disinfectants area. See email from GSK's external counsel to the case team dated 17 November 2014.

77 Internal document of GSK, […] undated.

78 Minutes of a call with a wholesaler dated 10 September 2014, courtesy translation from French to English.

79 Internal document of GSK, […].

80 Minutes of a call with a competitor dated 17 October 2014.

(133) GSK markets under the *NiQuitin* brand a range of NRT products in the form of patches, gums, lozenges and strips in the majority of EEA countries. The manufacturing of gums and strips is sourced from third parties contract manufacturers ([…]) whereas the lozenges and patches are produced by GSK in-house. Except for mini lozenges, the packaging is also contracted. GSK also supplies under the *Zyban* brand an NDT product, which will not be contributed to the Parties' proposed consumer health care joint venture.

(134) Novartis markets under the *Nicotinell* brand a range of NRT products in the form of patches, gums, and lozenges in the majority of EEA countries. It does not manufacture, nor packages the NRT formats, but sources them from [third party contract manufacturers]. Novartis also supplies NRT products to the UK retailers […] and […]. Novartis supplies NRT patches to the […] pharmaceutical company […]. Novartis does not supply any NDT products in the EEA, and […] in the EEA […]. Novartis' Sandoz division […].

V.2.1. Relevant product markets

The Notifying Party's arguments

(135) The Notifying Party distinguishes an upstream market for the manufacturing and direct sale of NRT products to pharmaceuticals firms and retailers (private labels), at which level only Novartis is active, and a downstream market for the supply of smoking cessation products.

(136) The Notifying Party considers that the product market definition for smoking cessation products should include not only all NRT products (all formats), but also NDTs and e-cigarettes. It also mentions non-medicated therapies, herbal remedies, and a pipeline vaccine by a competitor.

(137) First, the Notifying Party claims that prescription NDTs and NRTs have the same functionality and compete in a broader market for smoking reduction and cessation products. Notably, NDTs have gained increased visibility to smokers as an alternative to NRTs and can now be ordered online without visiting a doctor in some countries.

(138) Second, the Notifying Party takes the view that the competitive landscape for the supply of smoking reduction and cessation products has evolved significantly in the last years as regards e-cigarettes. The entry of e-cigarettes, launched in 2007 in the EEA, has had an impact on sales of other NRT and NDT products. Moreover, the Notifying Party submits that e-cigarettes are used as smoking cessation products, and are perceived as a threat to their offerings.

Previous decisional practice

(139) The Commission has previously identified an upstream market for the manufacturing and direct sale of nicotine patches, which is distinct from the manufacturing of other transdermal patches,[81] and a downstream market for the supply of OTC nicotine patches or a broader OTC market including other NRT products. Responses in the market investigation in 2006 clearly confirmed that other (non-NRT) smoking cessa-

81 M.4314, *Johnson & Johnson / Pfizer Consumer Healthcare* (2006), paragraph 55.

tion products were not substitutable to NRT products. It was inconclusive as to the various NRT formats. The exact dimension of the product market was left open.[82]

Commission's assessment

(140) The upstream market is not relevant in the present case as only Novartis is currently active, and to a limited extent.[83]

(141) As regards the downstream market, elements from the market investigation confirm that other (non-NRT) smoking cessation products are not part of the same market as NRT products. The majority of the customers who responded to the Commission's questionnaires state that NDTs are not substitutable to NRTs as they are only available on prescription.[84] This prescription status leads to differences in sales channels, price, and advertising. Prescription of NDTs is widely done by doctors, which imposes a cost[85] and implies a different customers' perception.[86] Prescription of NDTs is also often done by special smoking cessation centres, in particular in Italy and in the UK.[87] Meanwhile, NRTs are sold in a wider range of shops (supermarkets, petrol stations) than pharmacies only in several countries. The price difference is also due to regulation, for instance "*the price [of Champix, an NDT product] is fixed by the government**" in Spain.[88] A customer indicates that advertising is different for NDTs, as "*Champix cannot be displayed on the shelves inside the pharmacy […] whereas Nicorette / NiQuitin are found over-the-counter in pharmacies and advertised e.g. on television*".[89] In addition, the systemic format is seen as different from the NRT formats.[90]

(142) Competitors who replied to the Commission's questionnaire also take the same view that NDTs are not substitutable to NRTs.[91] For instance, one respondent stresses that there is a difference in consumer awareness due to the fact that the majority of customers do not know of the existence of prescription options to quit smoking. Furthermore, *"pharmacists are more likely to sell NRTs than to recommend to a potential client that he goes to the doctor."*[92] Moreover, NDTs are seen as a next step after failure with

---

82 M.4314, *Johnson & Johnson / Pfizer Consumer Healthcare* (2006), paragraphs 58-64.

83 Novartis is supplying […] in the UK, and supplies patches to […] for sales in France and Portugal. Novartis is stopping its supply to […] in the UK in 2015.

84 Replies to question 32.1 of Questionnaire Q1 – OTC Customers; replies to questions 4 and 4.1 of Questionnaire Q2 – OTC Customers. Minutes of a call with a competitor dated 17 October 2014.

85 Replies to question 32 of Questionnaire Q1 – OTC Customers; replies to question 4 of Questionnaire Q2–OTC Customers, Minutes of a call with a customer dated the 10 September 2014.

86 "*One limit to Champix expansion is that smokers do not see themselves as ill, but merely as having a bad habit.*" - Minutes of a call with a competitor dated 14 October 2014.

87 Minutes of a call with a pharmacists' association dated 30 September 2014; minutes of a call with a competitor dated 14 October 2014.

88 Minutes of a call with a wholesaler dated 10 September 2014, courtesy translation from French to English.

89 Minutes of a call with a customer dated 31 October 2014.

90 Replies to question 32 of Questionnaire Q1 – OTC Customers; replies to question 4 of Questionnaire Q2–OTC Customers.

91 Replies to questions 38 of Questionnaire Q3 – OTC Competitors.

92 Minutes of a call with a competitor dated 14 October 2014.

NRTs: "*Champix is usually prescribed by physicians after the consumers have tried several times to quit smoking with NRTs and failed*".[93]

(143) Additionally, elements from the market investigation indicate that e-cigarettes are not part of the same market as NRTs. There is a degree of uncertainty in relation to the status of e-cigarettes ("*The safety knowledge of e-cigarettes is very ambiguous*", "*The MHRA is still investigating how to qualify e-cigarettes*"[94]). E-cigarettes are accepted in some EEA countries, and banned in others. A large majority of customers (pharmacies, wholesalers, and supermarkets in some countries) having responded to the market investigation indicated that they do not sell e-cigarettes.[95] While a few respondents pointed to a decrease of NRT sales due to e-cigarettes, most customers explained that their clients actually view e-cigarettes as an alternative to cigarettes.[96] A customer in France for instance states that "*E-cigarettes are for smokers who want to keep gesture and 'smoke'*". The companies selling e-cigarettes and the sales channels ("*opening of specialized stores*" focusing only on e-cigarettes[97]) are also different from those for NRT products.

(144) Competitors emphasized that e-cigarettes mimic the behaviour of smoking closely, have flavours and do not have medicinal features.[98] Contrary to the Notifying Party's argument that e-cigarettes have taken business away from NRTs, a competitor states that NRT sales are not linked to e-cigarettes sales.[99] Another competitor states that "*There has been a fast adoption of e-cigarettes in the UK and France. But the consumers who adopted them were mostly incremental new users and different users than NRT users. E-cigarettes are rather a substitute for cigarettes*."[100] Another player sees e-cigarettes as having a "*pleasure*" use.[101]

(145) Non-medicated therapies and herbal remedies will not be considered in the analysis below, as it is clear that they are not comparable to NRTs under any sensible delineation (price, mechanism of action, sales channels, etc). Moreover, in relation to the pipeline vaccine mentioned by the Notifying Party as part of the Smoking cessation space, "*Pfizer also has an antismoking vaccine in its pipeline. It is only in phase 1 of development and approval is not expected within the next 3 years*".[102]

---

93 Minutes of a call with a competitor dated 14 October 2014.

94 Replies to questions 34-35 of Questionnaire Q1 – OTC Customers; replies to questions 6-7 of Questionnaire Q2 – OTC Customers; minutes of a call with a customer dated 17 October 2014.

95 Replies to questions 34-35 of Questionnaire Q1 – OTC Customers; replies to questions 6-7 of Questionnaire Q2 – OTC Customers; minutes of a call with a customer dated 30 September 2014.

96 Replies to questions 34-35 of Questionnaire Q1 – OTC Customers; replies to questions 6-7 of Questionnaire Q2 – OTC Customers; minutes of a call with a customer dated 17 September. 2014; minutes of a call with a competitor dated 17 October 2014; minutes of a call with a customer dated 30 September 2014.

97 Replies to questions 34-35 of Questionnaire Q1 – OTC Customers; replies to questions 6-7 of Questionnaire Q2 – OTC Customers. See also minutes of a call with a pharmacists' association dated 30 September 2014; minutes of a call with a wholesaler dated 17 September 2014.

98 Replies to question 40 of Questionnaire Q3 – OTC Competitors; Minutes of a call with a competitor dated 14 October 2014.

99 Replies to question 40 of Questionnaire Q3 – OTC Competitors.

100 Minutes of a call with a competitor dated 17 October 2014.

101 Minutes of a call with a competitor dated 17 December 2014.

102 Minutes of a call with a competitor dated 14 October 2014.

(146) In relation to the various formats of NRTs, the replies obtained in the phase I investigation were overall inconclusive. In particular, about half of the customers who responded to the Commission's questionnaires mentioned that the various formats are used interchangeably, the other stating the opposite.[103] Some respondents noted that patches and gums are sometimes used together.

(147) Some competitors stressed that the products are used interchangeably; another player that on the contrary customers tend to stick to one format.[104] Given that competition concerns arise in this area irrespective of a firm conclusion on the exact degree of substitutability between different NRT formats, and as the Notifying Party has submitted commitments, the exact product market definition with respect to NRT formats can be left open for the purpose of the present decision.

(148) To conclude, on the basis of the phase I investigation, the Commission considers that NRTs constitute a separate market from other products such as NDTs and e-cigarettes. Concerning the various NRT formats, the Commission will assess the impact of the Transaction on both an all-NRT markets and on all potential NRT format markets in section V.2.3.

V.2.2. Relevant geographic markets

(149) The Notifying Party does not contest the findings on the Commission's previous decisional practice[105] and take the view that the market for the supply of NRT products, as more widely for all OTC products, is national.

(150) Responses to the market investigation have confirmed that markets are national. Nearly all customers who responded to the Commission's questionnaires were active only in one country,[106] and a large majority of competitors stated that commercial relations take place at national level.[107] As stated by a competitor, "*In the OTC field the market overall is very fragmented at worldwide level. However one must look specifically at the situation in a given country as the competitive environment for OTC products varies on a country-by-country basis*".[108]

V.2.3. Competitive assessment

(151) The three main players active in national markets for NRT products in the EEA are J&J, GSK and Novartis. They each offer a range of products under the respective brands *Nicorette*, *NiQuitin*, and *Nicotinell*.

(152) In addition, depending on the country at stake, there are local/regional players as well.[109] For example, Sopharma is a competitor of in Bulgaria, Latvia, Lithuania and Poland. In Poland another competitor, USP Zdrowie, has been active on the market

---

103 Replies to question 33 of Questionnaire Q1 – OTC Customers; replies to question 5 of Questionnaire Q2 – OTC Customers.

104 Replies to question 33 of Questionnaire Q1 - OTC Customers.

105 M.4314, *Johnson & Johnson / Pfizer Consumer Healthcare* (2006), paragraph 66.

106 Replies to question 2 of Questionnaire Q1– OTC Customers; replies to question 2 of Questionnaire Q2 – OTC Customers.

107 Replies to question 4 of Questionnaire Q3 - OTC Competitors.

108 Minutes of a call with a competitor dated 13 October 2014.

109 Replies to question 42 of Questionnaire Q3 - OTC Competitors.

since 2014. Pierre Fabre sells in France the *Nicopatch* product (purchased from […]), as well as lozenges.

(153) The Transaction leads to 12 affected markets, of which 10 Group 1 markets (where the Parties' joint market share exceeds 35% and the increment exceeds 1%[110]) when looking at an all-NRT market. The Group 1 markets are: Belgium, France, Germany, Hungary, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK.

Table 6: Market size and market shares of the Parties in EEA affected countries based on an all-NRT market, 2011-2013[111]

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Belgium	2013	[10,000-11,000]	[40-50]%	[10-20]%	**[50-60]%**
	2012	[9,000-10,000]	[40-50]%	[10-20]%	**[50-60]%**
	2011	[9,000-10,000]	[30-40]%	[10-20]%	**[50-60]%**
France	2013	[50,000-60,000]	[10-20]%	[20-30]%	**[30-40]%**
	2012	[60,000-70,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[60,000-70,000]	[10-20]%	[20-30]%	**[30-40]%**
Germany	2013	[19,000-20,000]	[5-10]%	[30-40]%	**[30-40]%**
	2012	[16,000-17,000]	[0-5]%	[30-40]%	**[40-50]%**
	2011	[16,000-17,000]	[0-5]%	[30-40]%	**[40-50]%**
Hungary	2013	[1,000-2,000]	[40-50]%	[5-10]%	**[50-60]%**
	2012	[1,000-2,000]	[40-50]%	[10-20]%	**[50-60]%**
	2011	[1,000-2,000]	[40-50]%	[10-20]%	**[50-60]%**
Ireland	2013	[12,000-13,000]	[20-30]%	[5-10]%	**[30-40]%**
	2012	[13,000-14,000]	[20-30]%	[5-10]%	**[30-40]%**
	2011	[11,000-12,000]	[20-30]%	[5-10]%	**[30-40]%**
Italy	2013	[7,000-8,000]	[30-40]%	<[0-5]%	**[30-40]%**
	2012	[9,000-10,000]	[30-40]%	<[0-5]%	**[30-40]%**
	2011	[9,000-10,000]	[30-40]%	<[0-5]%	**[30-40]%**
Luxembourg	2013	[0-1,000]	[10-20]%	[30-40]%	**[50-60]%**
	2012	[0-1,000]	[10-20]%	[40-50]%	**[50-60]%**
	2011	[0-1,000]	[10-20]%	[40-50]%	**[50-60]%**
Netherlands	2013	[7,000-8,000]	[30-40]%	[50-60]%	**[80-90]%**
	2012	[8,000-9,000]	[30-40]%	[50-60]%	**[80-90]%**
	2011	[7,000-8,000]	[30-40]%	[40-50]%	**[80-90]%**
Portugal	2013	[2,000-3,000]	[40-50]%	[20-30]%	**[60-70]%**
	2012	[2,000-3,000]	[40-50]%	[20-30]%	**[60-70]%**

110 Given the often large number of affected markets in pharmaceutical cases, and in accordance with case practice, all affected pharmaceuticals markets are grouped in three categories. These groupings are: Group 1: The parties' joint market share exceeds 35% and the increment exceeds 1%; Group 2: The parties' joint market share exceeds 35% but the increment is less than 1%; Group 3: The parties' joint market share is between 15% and 35%. The Commission focuses mainly its assessment on Group 1 countries and on instances where one party is planning to enter a market. Group 1 are determined based on the data for the latest year available (2013 in the present decision).

111 IMS Global Analysis data is not available for some EEA countries: Cyprus, Malta, Liechtenstein and Iceland. The analysis is based on the available data. GSK had sales of NRT lozenges in Malta in 2013, and no NRT sales in Cyprus, Iceland, or Lichtenstein. Novartis doesn't have NRT sales in these four countries.

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
	2011	[2,000-3,000]	[10-20]%	[30-40]%	**[50-60]%**
Spain	2013	[13,000-14,000]	[10-20]%	[30-40]%	**[50-60]%**
	2012	[11,000-12,000]	<[0-5]%	[40-50]%	**[40-50]%**
	2011	[12,000-13,000]	<[0-5]%	[40-50]%	**[40-50]%**
Sweden	2013	[40,000-50,000]	[5-10]%	[30-40]%	**[40-50]%**
	2012	[40,000-50,000]	[5-10]%	[40-50]%	**[50-60]%**
	2011	[40,000-50,000]	[10-20]%	[40-50]%	**[50-60]%**
UK	2013	[90,000-100,000]	[30-40]%	[5-10]%	**[30-40]%**
	2012	[110,000-120,000]	[30-40]%	[5-10]%	**[30-40]%**
	2011	[100,000-110,000]	[30-40]%	[5-10]%	**[30-40]%**

Source: GSK, based on IMS Global Analysis data (Annex RFI 3 Q 3.1)

(154) By format, NRT products can be divided in: (i) patches, (ii) gums, (iii) lozenges, (iv) orally-dissolving strips and (v) sprays/inhalators. J&J, GSK and Novartis are strong players in different formats, as reflected in the market shares below.

(155) As for patches, GSK and Novartis have overlapping activities in several EEA countries. There are 14 affected markets (8 Group 1 markets), with a combined share of the Parties over 90% in several countries, as set out in the table below. The Group 1 markets are: Belgium, France, Germany, Luxembourg, the Netherlands, Portugal, Sweden, and the UK.

Table 7: Market size and market shares of the Parties in EEA affected countries for NRT patches, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Austria	2013	[0-1,000]	<[0-5]%	[20-30]%	**[20-30]%**
	2012	[0-1,000]	<[0-5]%	[20-30]%	**[20-30]%**
	2011	[0-1,000]	<[0-5]%	[30-40]%	**[30-40]%**
Belgium	2013	[3,000-4,000]	[80-90]%	[10-20]%	**[90-100]%**
	2012	[3,000-4,000]	[70-80]%	[10-20]%	**[90-100]%**
	2011	[2,000-3,000]	[70-80]%	[10-20]%	**[90-100]%**
France	2013	[20,000-30,000]	[10-20]%	[20-30]%	**[40-50]%**
	2012	[20,000-30,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[20,000-30,000]	[20-30]%	[20-30]%	**[40-50]%**
Germany	2013	[5,000-6,000]	[0-5]%	[70-80]%	**[80-90]%**
	2012	[4,000-5,000]	[0-5]%	[70-80]%	**[70-80]%**
	2011	[5,000-6,000]	[0-5]%	[60-70]%	**[70-80]%**
Hungary	2013	[0-1,000]	[70-80]%	[0-5]%	**[70-80]%**
	2012	[0-1,000]	[60-70]%	[0-5]%	**[60-70]%**
	2011	[0-1,000]	[60-70]%	[5-10]%	**[60-70]%**
Ireland	2013	[3,000-4,000]	[20-30]%	[5-10]%	**[30-40]%**
	2012	[4,000-5,000]	[20-30]%	[5-10]%	**[30-40]%**
	2011	[4,000-5,000]	[30-40]%	[5-10]%	**[30-40]%**
Italy	2013	[1,000-2,000]	[80-90]%	<[0-5]%	**[80-90]%**
	2012	[1,000-2,000]	[80-90]%	<[0-5]%	**[80-90]%**
	2011	[1,000-2,000]	[70-80]%	[0-5]%	**[80-90]%**
Lithuania	2013	[0-1,000]	[20-30]%	[10-20]%	**[30-40]%**
	2012	[0-1,000]	[30-40]%	[0-5]%	**[30-40]%**

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
	2011	[0-1,000]	[40-50]%	[0-5]%	**[40-50]%**
Luxembourg	2013	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
	2012	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[0-1,000]	[20-30]%	[70-80]%	**[90-100]%**
Netherlands	2013	[2,000-3,000]	[60-70]%	[30-40]%	**[90-100]%**
	2012	[2,000-3,000]	[60-70]%	[30-40]%	**[90-100]%**
	2011	[2,000-3,000]	[60-70]%	[30-40]%	**[90-100]%**
Portugal	2013	[0-1,000]	[40-50]%	[30-40]%	**[80-90]%**
	2012	[0-1,000]	[40-50]%	[30-40]%	**[80-90]%**
	2011	[0-1,000]	[40-50]%	[30-40]%	**[80-90]%**
Spain	2013	[2,000-3,000]	<[0-5]%	[80-90]%	**[80-90]%**
	2012	[2,000-3,000]	<[0-5]%	[80-90]%	**[80-90]%**
	2011	[3,000-4,000]	<[0-5]%	[80-90]%	**[80-90]%**
Sweden	2013	[3,000-4,000]	[60-70]%	[10-20]%	**[70-80]%**
	2012	[4,000-5,000]	[50-60]%	[20-30]%	**[70-80]%**
	2011	[3,000-4,000]	[50-60]%	[20-30]%	**[70-80]%**
UK	2013	[40,000-50,000]	[40-50]%	[5-10]%	**[50-60]%**
	2012	[50,000-60,000]	[40-50]%	[5-10]%	**[40-50]%**
	2011	[50,000-60,000]	[40-50]%	[5-10]%	**[40-50]%**

Source: GSK, based on IMS Global Analysis dat,(Annex RFI 3 Q 3.3)

(156) As for gums, the Parties both sell nicotine gums in 3 affected countries (no Group 1 market): France (with an increment <[0-5]%), Sweden (with an increment <[0-5]%) and the UK (combined market share of [20-30]% in 2013). GSK has a […]. It is planning […] in the EEA […], and a […]. Novartis is […].

Table 8: Market size and market shares of the Parties in EEA affected countries for NRT gums, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
France	2013	[17,000-18,000]	<[0-5]%	[20-30]%	**[20-30]%**
	2012	[17,000-18,000]	<[0-5]%	[20-30]%	**[20-30]%**
	2011	[17,000-18,000]	<[0-5]%	[20-30]%	**[20-30]%**
Sweden	2013	[20,000-30,000]	<[0-5]%	[40-50]%	**[40-50]%**
	2012	[20,000-30,000]	<[0-5]%	[40-50]%	**[40-50]%**
	2011	[20,000-30,000]	[0-5]%	[40-50]%	**[40-50]%**
UK	2013	[10,000-11,000]	[5-10]%	[10-20]%	**[20-30]%**
	2012	[12,000- 13,000]	[5-10]%	[10-20]%	**[10-20]%**
	2011	[11,000-12,000]	[0-5]%	[10-20]%	**[10-20]%**

Source: GSK, based on IMS Global Analysis data (Annex RFI 3 Q 3.3)

(157) As for lozenges, GSK and Novartis have overlapping activities in several EEA countries. There are 10 affected markets (9 Group 1 markets), with a combined share of the Parties over 90% in several countries, as set out in the table below. The Group 1 markets are: France, Germany, Hungary, Ireland, the Netherlands, Portugal, Spain, Sweden, and the UK.

(158) GSK's mini-lozenges format is notably popular with customers, and no other manufacturer offers this format.[112] GSK has a […]. Novartis is planning […].

(159) GSK has had issues with its lozenges manufacturing plant since the beginning of 2014, resulting in likely lower shares in 2014. It is expected to regain sales in 2015.

Table 9: Market size and market shares of the Parties in EEA affected countries for NRT lozenges, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
France	2013	[14,000-15,000]	[40-50]%	[10-20]%	**[50-60]%**
	2012	[13,000-14,000]	[40-50]%	[10-20]%	**[50-60]%**
	2011	[11,000-12,000]	[40-50]%	[5-10]%	**[50-60]%**
Germany	2013	[2,000-3,000]	[30-40]%	[40-50]%	**[70-80]%**
	2012	[1,000-2,000]	[40-50]%	[50-60]%	**[90-100]%**
	2011	[1,000-2,000]	[40-50]%	[50-60]%	**[90-100]%**
Hungary	2013	[0-1,000]	[80-90]%	[10-20]%	**[90-100]%**
	2012	[0-1,000]	[80-90]%	[10-20]%	**[90-100]%**
	2011	[0-1,000]	[60-70]%	[40-50]%	**[90-100]%**
Ireland	2013	[2,000-3,000]	[80-90]%	[10-20]%	**[90-100]%**
	2012	[2,000-3,000]	[70-80]%	[10-20]%	**[80-90]%**
	2011	[1,000-2,000]	[80-90]%	[10-20]%	**[90-100]%**
Italy	2013	[1,000-2,000]	[90-100]%	<[0-5]%	**[90-100]%**
	2012	[2,000-3,000]	[90-100]%	<[0-5]%	**[90-100]%**
	2011	[1,000-2,000]	[90-100]%	<[0-5]%	**[90-100]%**
Netherlands	2013	[2,000-3,000]	[50-60]%	[40-50]%	**[90-100]%**
	2012	[1,000-2,000]	[50-60]%	[40-50]%	**[90-100]%**
	2011	[1,000-2,000]	[60-70]%	[30-40]%	**[90-100]%**
Portugal	2013	[1,000-2,000]	[80-90]%	[5-10]%	**[90-100]%**
	2012	[1,000-2,000]	[80-90]%	[10-20]%	**[90-100]%**
	2011	[0-1,000]	[0-5]%	[70-80]%	**[70-80]%**
Spain	2013	[3,000-4,000]	[70-80]%	[20-30]%	**[90-100]%**
	2012	[1,000-2,000]	<[0-5]%	[90-100]%	**[90-100]%**
	2011	[1,000-2,000]	[0-5]%	[90-100]%	**[90-100]%**
Sweden	2013	[8,000-9,000]	[10-20]%	[60-70]%	**[80-90]%**
	2012	[7,000-8,000]	[20-30]%	[70-80]%	**[90-100]%**
	2011	[6,000-7,000]	[20-30]%	[70-80]%	**[90-100]%**
UK	2013	[11,000-12,000]	[80-90]%	[5-10]%	**[90-100]%**
	2012	[12,000-13,000]	[90-100]%	[5-10]%	**[90-100]%**
	2011	[10,000-11,000]	[90-100]%	[5-10]%	**[90-100]%**

Source: GSK, based on IMS Global Analysis data (Annex RFI 3 Q 3.4)

112 Minutes of a call with a competitor dated 17 October 2014.

(160) As for orally-dissolving strips, Novartis does not currently sell this format. GSK is selling this format in the Czech Republic, Hungary, Poland, Slovakia and the UK. GSK intends to […]. Novartis is […].

(161) As for sprays and inhalators, GSK and Novartis do no sell those formats of NRT in the EEA. J&J is the leader with its successful NRT spray.

The Notifying Party's arguments

(162) The Notifying Party considers that despite the significant market shares in certain Member States, the Transaction will not significantly impede effective competition in the EEA.

(163) The first line of arguments concerns a broader market with NDTs and e-cigarettes. These elements have been addressed in section V.2.1.

(164) Then, GSK firstly submits that sales share increment are limited in many countries.

(165) Second, GSK submits that several competitors exist. The Notifying Party submits that the combined entity will continue to face fierce and growing competition from global healthcare companies with strong portfolios such as J&J that has a significant presence in the affected markets. Moreover, local competitors, including Pierre Fabre, Orifarm, Medcor and Polyfarma have also obtained sizeable market share in a number of EEA countries. The Notifying Party also states that barriers to entry and expansion in this area are low.

(166) Third, the Notifying Party indicates that private label products and generics exert a competitive constraint on the pricing of the Parties' NRT products. In addition, the price of cigarettes is also likely to represent a constraint, as smokers may not attempt to quit if they perceive the NRT product to be significantly more expensive than cigarettes.

(167) Finally, the Notifying Party submits that the mass market retailers, wholesalers and pharmacy chains have significant buyer power.

Commission's assessment

(168) First, in terms of market shares, the Transaction would result in a large number of Group 1 and other affected markets, and increments are often high. As illustrated in Table 6, in some countries, the combined market share of the Parties would be particularly high based on an all-NRT market (for instance, [80-90]% in the Netherlands, [60-70]% in Portugal). By format, GSK and Novartis often reach an extremely high combined market share, including market shares of 100% in some EEA countries. Furthermore, in countries and formats where the Parties are currently not active, they are strong potential competitors, notably with GSK's planned launch of […].

(169) Second, looking at the competitive landscape, respondents to the market investigation identified a very limited number of players active in each country. J&J, GSK and Novartis are widely seen as the most significant players at EEA level.[113] Local

113 Minutes of a call with a customer dated 18 September 2014; minutes of a call with a customer dated 17 September 2014; minutes of a call with a customer dated 10 October 2014.

players may exert competitive pressure in some countries, but they have limited impact.[114]

(170) In line with the Notifying Party's argument, some respondents expressed that the presence of J&J on the market could ensure competition.[115] However, J&J is not a player in all formats, for instance in NRT lozenges. In this segment, "*when GSK lost its lozenges sales due to the supply issue, Novartis benefited and got GSK's sales*".[116] In any event, the fact that J&J is an effective competitor cannot be taken as excluding unilateral effects if the number of major competitors is reduced from three to two.

(171) Customers seem to expect that the Transaction will likely lead to price increase in several countries, such as the Netherlands, Portugal, Sweden, the UK and France.[117]

(172) Contrary to the Notifying Party's arguments, new entry has been limited in recent years in the EEA. The majority of respondents to the Commission's questionnaires pointed out that there were no entrants in the past 5 years.[118] For instance, in France, the generic company EG entered the NRT segment, but it has *"very small market shares for the moment"*. Clonmel Healthcare, part of Stada Group, entered the Irish market with a gum *"but (...), their impact on the overall NRT market has being negligible"*.[119]

(173) In terms of barriers to entry, competitors identified as the main barriers to entry into the NRT market: brand awareness/loyalty, pharmacists' recommendation, IP rights, formulations and clinical tests. *"There are clinical studies required to launch new products and new formats in the market, and so there is a cost hurdle that a new competitor would need to deal with in order to launch a new brand"*.[120] One of the respondents to the Commission's questionnaire indicated that *"NRTs have very strong, well-known brands, which make it difficult to compete as a new entry or brand. In addition, competing versus the constant development of new formulations by established brands would be a barrier"*.[121] Creating and maintaining a brand is costly. For instance, television advertising is seen as key element in this category, and "*costs in TV advertising and field force can represent a high percentage of turnover*".[122]

---

114 Minutes of a call with a customer dated 20 October 2014; minutes of a call with a customer dated 18 September 2014; minutes of a call with a customer dated 10 October 2014.

115 Replies to question 40 of Questionnaire Q1 - OTC Customers; replies to question 11 of Questionnaire Q2 - OTC Customers; minutes of a call with a customer dated 10 October 2014.

116 Minutes of a call with a customer dated 10 October 2014.

117 Replies to question 40 of Questionnaire Q1 - OTC Customers, replies to question 11 of Questionnaire Q2 - OTC Customers; minutes of a call with a customer dated 17 October 2014; minutes of a call with a customer dated 20 October 2014.

118 Replies to question 39 of Questionnaire Q1 - OTC Customers; replies to question 11 of Questionnaire Q2 - OTC Customers; replies to questions 43 and 43.1 of Questionnaire Q3 - OTC Competitors.

119 Replies to question 39 of Questionnaire Q1 - OTC Customers; replies to question 11 of Questionnaire Q2 - OTC Customers; replies to question 43 of Questionnaire Q3 - OTC Competitors.

120 Replies to question 41 of Questionnaire Q3 - OTC Competitors.

121 Replies to question 41 of Questionnaire Q3 - OTC Competitors.

122 Minutes of a call with a wholesaler dated 19 September 2014; minutes of a call with a competitor dated 13 October 2014.

(174) Third, generics and private labels do not appear to exert a competitive constraint in the Smoking cessation NRT area. Brand recognition is key, and manufacturing of the products is seen as complex.[123] As a result, J&J, GSK and Novartis are the three main players. For instance, an industry report on Belgium submitted by GSK summarizes the competitive situation as follows: "*The competitive environment is so concentrated, and brand equity is so strong in NRT smoking cessation aids, that there is no scope for the development of generics or private label products. Other than the three leading manufacturers, which continue to bank on their strong brand equity, there are no sufficiently experienced manufacturers which can work as subcontractors for the production of private label products or launch generic NRT products.*"[124] Similarly, in the Netherlands "*NRT smoking cessation aids is highly concentrated in the Netherlands with few brands such as Niquitin, Nicotinell and Nicorette being the references*."[125] In France, there is one local player (partially supplied by Novartis), and "*the competitive environment in NRT smoking cessation aids remains highly concentrated in 2013, with just four international manufacturers accounting for all value sales. Other than Laboratoires Pierre Fabre, local players are absent from NRT smoking cessation aids*."[126]

(175) Respondent customers to the Commission's questionnaires in majority find that generic companies do not play any role or play a *"very very small role*" in the area of Smoking cessation.[127] Similarly, a competitor notes "*None of these achieved dominance in their markets"*, another that *"Basically there are no generic products on most of the markets on which we operate"*.[128] The market investigation confirmed both from customers' and competitors' point of view that competition in this market takes place primarily at brand level.[129] One of the respondents pointed out that *"Generic products have therefore not been able to penetrate the market and do not play a vital role in this category. Generic products are quite new in this area and have a slow growth"*.[130] Nonetheless, a number of "branded generics" are sold in some markets and "*there are also some generic companies that are advertising (for instance, Sandoz in Poland and in Germany)*".[131] The existence of some branded generic players in some market does not however change the fact that generics overall do not exert a significant constraint to the Parties in the area of Smoking cessation NRT products.

(176) As for private label, few players are active due to limited success and difficulties in supplying products. For instance, in the UK Tesco has a small range of private label products. "*It has 2 gums and 2 lozenges. It used to have patches, but they did not sell*

123 Replies to questions 9 and 9.1 of Questionnaire R1 – Market test of the Commitments - OTC.

124 Document of Euromonitor International "NRT Smoking cessation aids in Belgium", submitted by Novartis, dated June 2014.

125 Document of Euromonitor International "NRT Smoking cessation aids in the Netherlands", submitted by Novartis, dated September 2013.

126 Document of Euromonitor International "NRT Smoking cessation aids in France", submitted by Novartis, dated June 2014.

127 Replies to questions 37-38 of Questionnaire Q1 - OTC Customers; replies to questions 9-10 of Questionnaire Q2 – OTC Customers.

128 Replies to questions 44-46 of Questionnaire Q3 - OTC Competitors.

129 Minutes of a call with a customer dated 31 October 2014; replies to questions 44-46 of Questionnaire Q3 - OTC Competitors; minutes of a call with an industry association dated 18 September 2014.

130 Replies to questions 44-46 of Questionnaire Q3 - OTC Competitors.

131 Minutes of a call with a competitor dated 17 October 2014.

well."[132] Another player "*had several attempts at entering the category, but it was difficult to find a manufacturer for private label products in this area*."[133] It notes that "*Out of the 3, J&J and GSK are not very willing to supply private labels. Novartis is open to supplying private labels to another large retailer in the UK.*" However, […]. Moreover, regulation does not always allow for private labels. For instance, a retailer notes that "*The Swedish legislation on OTC products does not allow private label products*."[134]

(177) Finally, buyer power appears limited. Wholesalers are mostly passing orders from pharmacies, with limited or no other considerations in particular in terms of price and volume.[135] They usually offer all NRT products. There is indeed in some EEA countries a degree of concentration of pharmacies, for instance in Scandinavia.[136] But because J&J, GSK and Novartis are strong players in different formats, theirs products are "must-have" under different formats. From a customer standpoint, it is important to sell the three brands "*due to the fact that each brand is strong in a different format*".[137] Smaller pharmacies sometimes sell only one brand, but typically do not exert significant buyer power.[138]

Conclusion

(178) In light of the above and of all available evidence, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market as regards the area of Smoking cessation NRT products, as it would lead to a creation or strengthening of dominance.

V.3. COLD SORE MANAGEMENT

(179) Cold sores (*herpes labialis*, also commonly known as herpes of the lips or fever blisters) are groups of small blisters on the lips and around the mouth, typically caused by a viral strain of the herpes simplex virus. During a cold sore outbreak, the skin on the lips and around the mouth becomes red, swollen, and sore, forming blisters. A typical outbreak from start to healing can last anywhere from several days to two weeks. Once an outbreak is fully healed, the virus travels back to the nerve cells where it remains dormant until it resurfaces as a new outbreak.

(180) Cold sores are incurable and outbreaks are generally managed with non-prescription topical products. Products aimed at cold sore management include notably topical antiviral (creams and gels), patches, lip balms, herbal remedies, analgesics and light/heat therapy devices.

---

132 Minutes of a call with a customer dated 10 October 2014.

133 Minutes of a call with a customer dated 17 October 2014.

134 Minutes of a call with a customer dated 20 October 2014.

135 "*Wholesalers have little influence on the pharmacist who is the one that can decide which products to buy*" - minutes of a call with a wholesaler dated 10 September 2014.

136 Minutes of a call with an industry association dated 18 September 2014; minutes of a call with a wholesaler dated 10 September 2014.

137 Minutes of a call with a customer dated 10 October 2014; minutes of a call with a customer dated 17 October 2014.

138 Minutes of a call with a pharmacists' association dated 30 September 2014; minutes of a call with a wholesaler dated 10 September 2014.

(181) Topical antivirals for the treatment of cold sore typically contain one of the following active ingredients: acyclovir, valaciclovir (a prodrug[139] of acyclovir), penciclovir, farmciclovir (a prodrug of penciclovir) and docosanol. Docosanol is the best-selling antiviral agent in the US, but has limited presence in the EEA.

(182) GSK and Novartis both market topical antiviral creams for the treatment of cold sore in the EEA.

(183) GSK sells the antiviral creams *Zovirax* and *Zovirax Duo* based on the active substance acyclovir. The patent for the acyclovir compound expired in the 1990s to early 2000s. *Zovirax* is available OTC in all countries in the EEA. *Zovirax Duo* is an antiviral and anti-inflammatory corticosteroid cream commercialised either OTC or on prescription, launched in the EEA in 2012. Finally, GSK also offers *ZoviProtect*, a cold sore patch that does not contain an antiviral. *Zoviprotect* was launched in the EEA in 2009 and is currently marketed only in Italy, Portugal and Spain.

(184) Novartis sells antiviral creams containing the active ingredient penciclovir under the brands *Fenivir, Pencivir, Vectavir, Vectatone* and *Fenistil*. Novartis' patent for the penciclovir compound expired between 2004 and 2009 in the EEA. The cream is either white or tinted. The cream is available OTC across the EEA, and on prescription in some EEA Member States.

V.3.1. Relevant product markets

The Notifying Party's arguments

(185) The Notifying Party submits that the relevant product market includes all topical cold sore treatments, including prescription and non-prescription products, since prescription topical cold sore treatments are functionally substitutable with topical non-prescription products, with the only difference being the unit size.

(186) The Notifying Party further submits that the market should also comprise other alternative treatments to antiviral creams such as cold sore patches, lip balm, heat and light therapy, due to the large substitutability between these products from the demand side. The Notifying Party stresses in particular the substitutability between cold sore patches and antiviral creams.

Previous decisional practice

(187) The Commission has previously considered that ATC3[140] class D6D "topical antivirals" (which includes both acyclovir and penciclovir) should be the starting point for

---

139 A prodrug is a medication that is administered in an inactive or less than fully active form, and is then converted to its active form through a metabolic process.

140 In previous decisions dealing with pharmaceutical products, the Commission has used the Anatomical Classification Guidelines (or "ATC" classification) devised by the WHO or the European Pharmaceutical Marketing Research Association ("EphMRA") as a reference for the definition of the relevant product markets. The ATC classification is hierarchical, and it includes 16 categories with each up to four levels. The Commission has relied in previous decisions on the third level of the ATC classification (ATC3) which allows medicines to be grouped in terms of their therapeutic indications, that is to say their intended use, as a starting point. However, in a number of cases, the Commission found that the ATC3 level classification did not yield the appropriate market definition within the meaning of the Commission Notice on the Definition of the Relevant Market. As a result, where appropriate, and

defining the relevant product market for the cold sore treatment.[141] The Commission has further distinguished between products within the ATC 3 class (D6D) based on the type of virus/underlying disease that they target. Consequently, the Commission considered that wart treatments should be part of a separate product market from herpes simplex (cold sore) treatment. However the product market definition was left open.[142] In addition, in its previous decisions, the Commission has considered that OTC and prescription products are not part of the same product market because the medical indication, the legal framework, the marketing and distribution tend to differ between the two categories of medicines, even when the active ingredients are identical.[143]

Commission's assessment

(188) Several elements from the market investigation point towards a marginal or lack of supply and demand side substitutability between topical antivirals and patches, lip balms and light or heat therapies.

(189) First, customers who responded to the Commission's questionnaires indicated a lack of substitutability from both supply and demand side between antiviral creams and light/heat therapies and between antiviral creams and lip balms.[144] Customers of the Parties generally offer antiviral creams. About half of the customers who replied to the Commission's questionnaires offer cold sore lip balms. Respondents who do not sell lip balms state that this is because they are not very successful and are less effective. A few respondents see lip balms as successful, and a retailer highlights that these products are "*seen as cheaper alternatives which a customer can use even if they aren't 100% sure that they have a cold sore yet*".

(190) The large majority of the respondents do not offer light and heat therapies for the treatment of cold sore.[145] Several customers pointed out a significant price difference between these devices and antiviral creams.[146] For instance, a respondent in the UK explains that: "*The Light Treatment product although very effective is deemed too expensive for most customers to consider*". Another UK player discontinued sales of light therapies "*as it did not resonate with customers*".[147]

---

based on the factual evidence collected during the market investigation, the Commission has defined the relevant product market at the ATC4 level or at a level of molecule or a group of molecules that are considered interchangeable so as to exercise competitive pressure on one another. The overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.

141 M.1846, *Glaxo Wellcome/SmithKline Beecham* (2000), paragraph 31; M.3751, *Novartis / Hexal* (2005), page 7.

142 M.5530, *GlaxoSmithKline/ Stiefel Laboratoires* (2009), paragraph 32.

143 M.5953, *Reckitt Benckiser/SSL* (2010), paragraph 13; M.3751, *Novartis / Hexal* (2005), page 3.

144 Replies to question 46 of Questionnaire Q1 – OTC Customers; replies to question 18 of Questionnaire Q2 – OTC Customers.

145 Replies to question 46 of Questionnaire Q1 – OTC Customers; replies to question 18 of Questionnaire Q2 – OTC Customers; minutes of a call with a pharmacists' association dated 30 September 2014.

146 Replies to question 46 of Questionnaire Q1 – OTC Customers; replies to question 18 of Questionnaire Q2 – OTC Customers; minutes of a call with a wholesaler dated 17 November 2014.

147 Minutes of a call with a customer dated 17 October 2014.

(191) As for competitors of the Parties, some consider that lip balms and light/heat therapies compete directly with topical antivirals, while other state the opposite, notably in view of differences in efficacy and ease of use.[148] Companies competing in the area of antiviral creams are overall not the same as those competing in the area of lip balms and light and heat devices.[149]

(192) Second, elements from the market investigation highlight a potential degree of substitutability in the use of antiviral creams and patches. Most customers who responded to the Commission's questionnaires sell both antivirals and patches. However they remain substantially different in terms of mechanism of action, way of administration and customer perception.

(193) A large number of respondents indicate that end customers typically use antiviral creams only or patches, but do not switch between them. To lesser extent customers use both antiviral creams and patches, favouring one or the other depending on the phase of the cold sore cycle.[150] A respondent to the market investigation stated that "*Antiviral creams are more effective than patches (not containing antiviral agent) and safe to use."*[151] In terms of shelf positioning, about half of the respondents position patches and antivirals next to one another on shelves, but in part because of complementarity and cross-selling. Broadly speaking, patches are medical devices and different regulations apply.[152] "*Compeed, patches which are displayed near the foot products on shelves. Creams are sold over the counter.*"[153] Similarly, a respondent in Latvia noted that "*Patches are non-medicines under normative regulations of the Republic of Latvia. Therefore they cannot be displayed next to the creams, which are medicines*". Several customers also flagged in the course of the market investigation that patches are rather "*cosmetic*" than OTC products.[154]

(194) Moreover, the economic evidence provided by the Notifying Party demonstrates that following the entry of cold sore patches in the mid-2000s, the total market for cold sore management product has increased in size, but there was no impact on the sale of antiviral creams. The following Graph 1 illustrates this point for Germany. Patches entered the market in 2006 and after a quick take off their sales volumes (indicated by the dashed line) dropped slightly and stabilized afterwards. No impact of this quick take-off of patches can be identified on the sales volumes of the standard antiviral drugs, suggesting that the entry of patches did not take sales away from antiviral creams.

---

148 Replies to questions 49 and 55 of Questionnaire Q3 – OTC Competitors.

149 Replies to question 49 of Questionnaire Q3 – OTC Competitors.

150 Replies to questions 42-46 of Questionnaire Q1 – OTC Customers; replies to questions 14-17 of Questionnaire Q2 – OTC Customers.

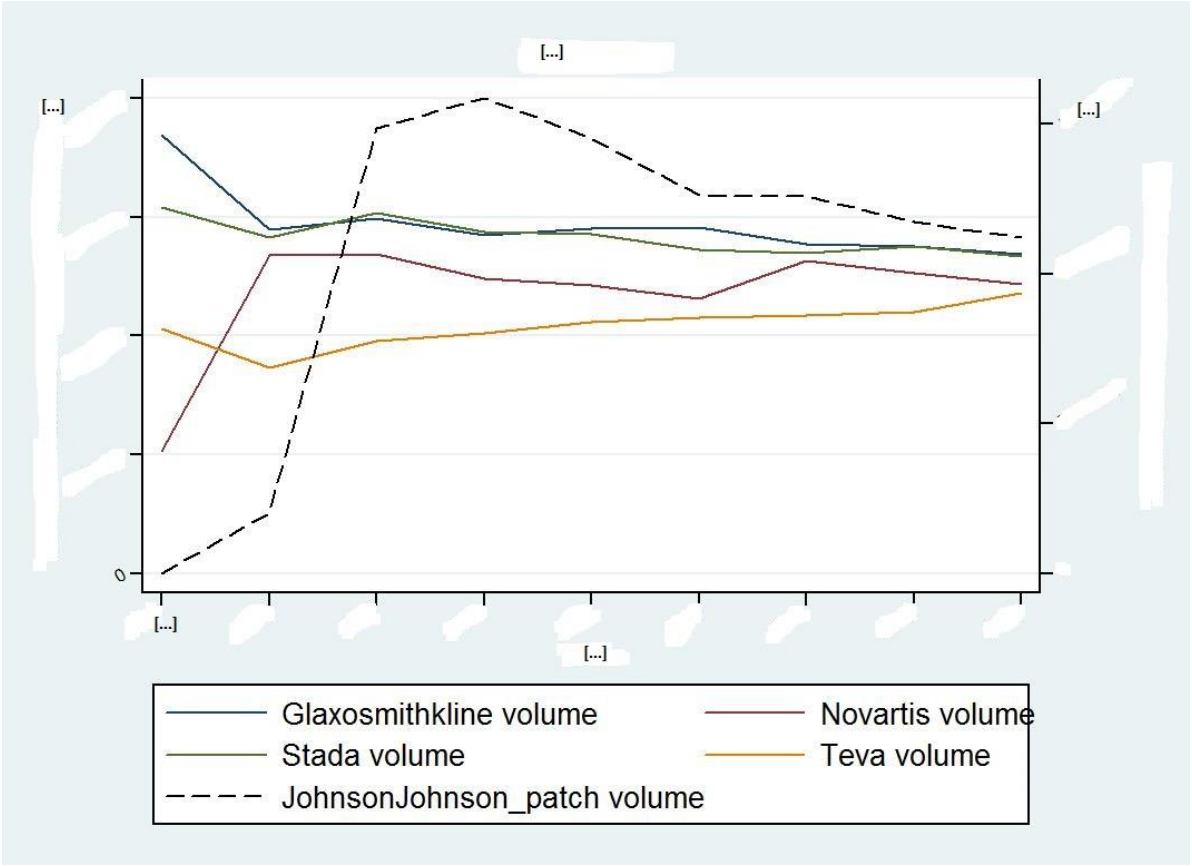
151 Replies to questions 18.3 of Questionnaire Q2 – OTC Customers.

152 In terms of the classification, patches/creams with antiviral agents fall under the pharmaceutical legislation, patches without antiviral fall under the medical device legislation and cream/lip balm without antiviral agents fall under the cosmetic legislation.

153 Minutes of a call with a competitor dated 17 October 2014.

154 Replies to question 45.1 of Questionnaire Q1 – OTC Customers; minutes of a call with a customer dated 17 October 2014; minutes of a call with a customer dated 30 September 2014; minutes of a call with a customer dated 17 September 2014.

Graph 1: Volume of antivirals and cold sore patches sold in Germany, […]



Source: Commission' analysis based on IMS data submitted by GSK

(195) This data analysis is in line with by the perception of companies active in the field, for instance in Spain "*Since the entry of Compeed, Compeed took a lot of the market, but the market for cold sore products has also expanded. The total cold sore market has increased by 30-40% since 2012.*"[155]

(196) In addition, internal documents of GSK also confirm that […].[156] […],[157] […][158], […].[159]

(197) In light of the above arguments, the Commission will analyse in section V.3.3 the market of topical antivirals used for the treatment of *herpes labialis.* Those products are classified under ATC3 class D6D and under the IMS OTC classification[160] as 06K1.[161]

---

155 Minutes of a call with a customer dated 19 September 2014.

156 Annex BP CSM 3, Internal document of GSK […], undated.

157 Annex BP CSM 9, Internal document of Novartis […], 2011.

158 Internal document of GSK […].

159 Annex BP CSM 21, Internal document of GSK […] undated.

160 The IMS OTC classes are based on the intended use/indications of the products. In most cases there is an ATC3 class that corresponds to an IMS OTC class, although in some cases there are more than one IMS OTC classes corresponding to an ATC3 class.

161 In line with previous decisions, wart treatments are not to be included in the relevant market.

V.3.2. Relevant geographic markets

(198) The Commission has previously defined the geographic market for pharmaceutical products, including for cold sore treatment, as national in scope.[162] The Notifying Party agrees that the geographic market should be regarded as national in scope. Elements from the market investigation widely confirmed this geographic market delineation.

V.3.3. Competitive assessment

(199) The Transaction will lead to 21 affected markets, of which 20 are Group 1 markets.[163] The Group 1 market are: Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Italy, Latvia, Luxembourg, the Netherlands, Norway, Portugal, the Slovak Republic, Spain, Sweden, the UK.

(200) […].

Table 10: Market size and market shares of the Parties in EEA affected countries in the market for topical antiviral for cold sore management, 2011-2013[164]

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Austria	2013	[1,000-2,000]	[10-20]%	[30-40]%	**[40-50]%**
	2012	[1,000-2,000]	[10-20]%	[30-40]%	**[40-50]%**
	2011	[1,000-2,000]	[10-20]%	[30-40]%	**[50-60]%**
Belgium	2013	[1,000-2,000]	[50-60]%	[0-5]%	**[50-60]%**
	2012	[1,000-2,000]	[50-60]%	[0-5]%	**[60-70]%**
	2011	[1,000-2,000]	[20-30]%	[5-10]%	**[30-40]%**
Bulgaria	2013	[500-1,000]	[10-20]%	[20-30]%	**[40-50]%**
	2012	[500-1,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[500-1,000]	[20-30]%	[10-20]%	**[30-40]%**
Czech Republic	2013	[1,000-2,000]	[20-30]%	[20-30]%	**[40-50]%**
	2012	[1,000-2,000]	[20-30]%	[20-30]%	**[40-50]%**
	2011	[1,000-2,000]	[20-30]%	[20-30]%	**[40-50]%**
Denmark	2013	[1,000-2,000]	[70-80]%	[0-5]%	**[70-80]%**
	2012	[1,000-2,000]	[70-80]%	[0-5]%	**[70-80]%**
	2011	[1,000-2,000]	[70-80]%	[0-5]%	**[70-80]%**
Estonia	2013	[0-500]	[20-30]%	[10-20]%	**[40-50]%**
	2012	[0-500]	[20-30]%	[10-20]%	**[40-50]%**
	2011	[0-500]	[30-40]%	[10-20]%	**[40-50]%**
Finland	2013	[1,000-2,000]	[70-80]%	[10-20]%	**[80-90]%**
	2012	[1,000-2,000]	[60-70]%	[10-20]%	**[80-90]%**
	2011	[1,000-2,000]	[60-70]%	[10-20]%	**[80-90]%**

162 M.1846 *Glaxo Wellcome/ Smithkline Beecham* (2000), paragraphs 73-74, and M. 5530 - *GlaxoSmithkline/Stiefel Laboratoires* (2009), paragraphs 40-42.

163 See footnote 110.

164 IMS Global Analysis data is not available for some EEA countries: Cyprus, Malta, Liechtenstein and Iceland. The analysis is based on the available data. Both Novartis and GSK market cold sore creams in Cyprus, Malta and Iceland. But in any event, it is noted that the commitments submitted by GSK cover the entire EEA (see section VI.5).

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Germany	2013	[17,000-18,000]	[30-40]%	[30-40]%	**[60-70]%**
	2012	[16,000-17,000]	[30-40]%	[30-40]%	**[60-70]%**
	2011	[17,000-18,000]	[30-40]%	[30-40]%	**[60-70]%**
Greece	2013	[1,000-2,000]	[60-70]%	[30-40]%	**[90-100]%**
	2012	[1,000-2,000]	[60-70]%	[30-40]%	**[90-100]%**
	2011	[1,000-2,000]	[40-50]%	[50-60]%	**[90-100]%**
Hungary	2013	[1,000-2,000]	[50-60]%	[0-5]%	**[50-60]%**
	2012	[1,000-2,000]	[50-60]%	[5-10]%	**[50-60]%**
	2011	[1,000-2,000]	[60-70]%	[5-10]%	**[70-80]%**
Italy	2013	[11,000-12,000]	[30-40]%	[20-30]%	**[60-70]%**
	2012	[11,000-12,000]	[30-40]%	[20-30]%	**[50-60]%**
	2011	[11,000-12,000]	[40-50]%	[20-30]%	**[60-70]%**
Latvia	2013	[0-500]	[20-30]%	[10-20]%	**[30-40]%**
	2012	[0-500]	[20-30]%	[10-20]%	**[30-40]%**
	2011	[0-500]	[20-30]%	[5-10]%	**[30-40]%**
Lithuania	2013	[500-1,000]	[10-20]%	[5-10]%	**[20-30]%**
	2012	[500-1,000]	[10-20]%	[10-20]%	**[20-30]%**
	2011	[0-500]	[10-20]%	[5-10]%	**[20-30]%**
Luxembourg	2013	[0-500]	[80-90]%	[10-20]%	**[90-100]%**
	2012	[0-500]	[80-90]%	[10-20]%	**[90-100]%**
	2011	[0-500]	[40-50]%	[20-30]%	**[60-70]%**
Netherlands	2013	[1,000-2,000]	[60-70]%	[20-30]%	**[80-90]%**
	2012	[1,000-2,000]	[60-70]%	[20-30]%	**[80-90]%**
	2011	[1,000-2,000]	[60-70]%	[10-20]%	**[80-90]%**
Norway	2013	[1,000-2,000]	[20-30]%	[10-20]%	**[30-40]%**
	2012	[1,000-2,000]	[10-20]%	[10-20]%	**[30-40]%**
	2011	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
Portugal	2013	[2,000-3,000]	[70-80]%	[10-20]%	**[90-100]%**
	2012	[2,000-3,000]	[80-90]%	[10-20]%	**[90-100]%**
	2011	[2,000-3,000]	[80-90]%	[10-20]%	**[90-100]%**
Slovak Republic	2013	[500-1,000]	[40-50]%	[10-20]%	**[50-60]%**
	2012	[500-1,000]	[30-40]%	[10-20]%	**[40-50]%**
	2011	[500-1,000]	[30-40]%	[10-20]%	**[40-50]%**
Spain	2013	[2,000-3,000]	[60-70]%	[10-20]%	**[80-90]%**
	2012	[2,000-3,000]	[60-70]%	[10-20]%	**[80-90]%**
	2011	[2,000-3,000]	[60-70]%	[10-20]%	**[80-90]%**
Sweden	2013	[3,000-4,000]	[10-20]%	[20-30]%	**[40-50]%**
	2012	[3,000-4,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[2,000-3,000]	[10-20]%	[20-30]%	**[30-40]%**
UK	2013	[3,000-4,000]	[60-70]%	[0-5]%	**[70-80]%**
	2012	[3,000-4,000]	[60-70]%	[0-5]%	**[60-70]%**
	2011	[3,000-4,000]	[60-70]%	[0-5]%	**[60-70]%**

Source: GSK, based on IMS Global Analysis data (Annex RFI 3 Q 4.1)

(201) Due to the presence of several generic players, including Novartis' Sandoz division, market shares in volume are lower, with nevertheless a large number of affected markets as can be seen in Table 11 below.

Table 11: Market shares in volume of the Parties in EEA affected countries in the market for topical antiviral for cold sore management, 2011-2013

Country	Year	GSK	Novartis business	Combined
Austria	2013	[10-20]%	[20-30]%	**[40-50]%**
	2012	[10-20]%	[20-30]%	**[40-50]%**
	2011	[10-20]%	[30-40]%	**[40-50]%**
Belgium	2013	[40-50]%	[0-5]%	**[50-60]%**
	2012	[40-50]%	[0-5]%	**[50-60]%**
	2011	[20-30]%	[5-10]%	**[20-30]%**
Bulgaria	2013	[5-10]%	[10-20]%	**[20-30]%**
	2012	[5-10]%	[10-20]%	**[10-20]%**
	2011	[5-10]%	[5-10]%	**[10-20]%**
Czech Republic	2013	[10-20]%	[10-20]%	**[20-30]%**
	2012	[10-20]%	[10-20]%	**[20-30]%**
	2011	[10-20]%	[10-20]%	**[20-30]%**
Denmark	2013	[60-70]%	[0-5]%	**[60-70]%**
	2012	[60-70]%	[0-5]%	**[60-70]%**
	2011	[60-70]%	[0-5]%	**[60-70]%**
Estonia	2013	[10-20]%	[10-20]%	**[20-30]%**
	2012	[10-20]%	[10-20]%	**[20-30]%**
	2011	[10-20]%	[10-20]%	**[30-40]%**
Finland	2013	[70-80]%	[10-20]%	**[80-90]%**
	2012	[60-70]%	[10-20]%	**[80-90]%**
	2011	[60-70]%	[10-20]%	**[70-80]%**
Germany	2013	[20-30]%	[20-30]%	**[40-50]%**
	2012	[20-30]%	[20-30]%	**[40-50]%**
	2011	[20-30]%	[20-30]%	**[40-50]%**
Greece	2013	[70-80]%	[20-30]%	**[90-100]%**
	2012	[70-80]%	[20-30]%	**[90-100]%**
	2011	[60-70]%	[30-40]%	**[90-100]%**
Hungary	2013	[40-50]%	[0-5]%	**[40-50]%**
	2012	[40-50]%	[5-10]%	**[50-60]%**
	2011	[50-60]%	[5-10]%	**[60-70]%**
Italy	2013	[30-40]%	[10-20]%	**[40-50]%**
	2012	[30-40]%	[10-20]%	**[40-50]%**
	2011	[30-40]%	[10-20]%	**[50-60]%**
Latvia	2013	[10-20]%	[5-10]%	**[10-20]%**
	2012	[10-20]%	[5-10]%	**[10-20]%**
	2011	[10-20]%	[0-5]%	**[10-20]%**
Lithuania	2013	[5-10]%	[0-5]%	**[10-20]%**
	2012	[5-10]%	[5-10]%	**[10-20]%**
	2011	[5-10]%	[0-5]%	**[10-20]%**

Country	Year	GSK	Novartis business	Combined
Luxembourg	2013	[80-90]%	[10-20]%	**[90-100]%**
	2012	[80-90]%	[10-20]%	**[90-100]%**
	2011	[30-40]%	[10-20]%	**[50-60]%**
Netherlands	2013	[50-60]%	[10-20]%	**[70-80]%**
	2012	[60-70]%	[10-20]%	**[70-80]%**
	2011	[50-60]%	[10-20]%	**[70-80]%**
Norway	2013	[20-30]%	[10-20]%	**[40-50]%**
	2012	[20-30]%	[10-20]%	**[30-40]%**
	2011	[10-20]%	[10-20]%	**[30-40]%**
Portugal	2013	[60-70]%	[5-10]%	**[70-80]%**
	2012	[70-80]%	[10-20]%	**[80-90]%**
	2011	[80-90]%	[10-20]%	**[90-100]%**
Slovak Republic	2013	[20-30]%	[5-10]%	**[30-40]%**
	2012	[10-20]%	[5-10]%	**[20-30]%**
	2011	[10-20]%	[10-20]%	**[20-30]%**
Spain	2013	[60-70]%	[10-20]%	**[70-80]%**
	2012	[60-70]%	[10-20]%	**[80-90]%**
	2011	[60-70]%	[10-20]%	**[80-90]%**
Sweden	2013	[10-20]%	[20-30]%	**[40-50]%**
	2012	[10-20]%	[20-30]%	**[40-50]%**
	2011	[10-20]%	[20-30]%	**[30-40]%**
UK	2013	[40-50]%	[0-5]%	**[40-50]%**
	2012	[30-40]%	[0-5]%	**[40-50]%**
	2011	[40-50]%	[0-5]%	**[40-50]%**

Source: GSK, based on IMS Global Analysis data (Annex RFI 3 Q 4.2)

(202) In terms of pipeline products, […].

The Notifying Party's arguments

(203) The Notifying Party considers that despite the significant market shares in certain Member States, the Transaction will not significantly impede effective competition in the EEA.

(204) The presence of generic acyclovir has grown significantly in recent years and the Parties submit that generic products are a serious and growing threat. The OTC JV would continue to face fierce and growing competition from generic manufacturers. Many of these are well-established generic manufacturers that could easily expand capacity in response to a price increase in the EEA among which Teva and Stada, Mylan, Meda, Servier, and Takeda. Private label products have also obtained sizable market share in a number of EEA countries over the past few years.

(205) Cold sore patches will continue to constrain the Parties, which see them as the greatest competitive threat and expect patch sales to continue growing in the future. The Parties further consider that light and heat therapy devices as well as lip balms and topical analgesics also present a competitive constraint.

(206) Then, the recent entry of docosanol based antiviral creams is seen as a significant competitive threat. Docosanol has obtained marketing authorisation in 13 EEA countries and is currently commercialised under the brand name of *Blistex Cold Sore Cream*, *Erazaban* and *Muxan.*

(207) The Parties further submit that they are not each other closest competitor since GSK's branded products compete closely with generic acyclovir. Customers, in particular wholesalers and pharmacies chains exercise significant buyer power in terms of negotiation, but also they are able to stock a range of competing products and can affect the volumes sold of a given product.

(208) Lastly, the Notifying Party submits that it would not have incentives to limit innovation. GSK will continue to have incentives to innovate in order to be able to compete with the growing cold sore patch treat. For example, GSK has launched its cold sore patch *ZoviProtect* in direct response to […].

Commission's assessment

(209) Considering market shares, most EEA markets are affected. In some of EEA countries, the combined share of the Parties is particularly high, above [80-90]% or [90-100]% (Greece).

(210) First, as has been submitted by the Notifying Party, generic players selling acyclovir products are indeed numerous. For example, "*In Spain there are 50-60 generics with acyclovir as the active ingredient*".[165] Generics have been mentioned in the phase I investigation by competitors as exerting competitive pressure on branded products.[166] However, other players state that "*The segmentation branded/generic cream is particularly important, although there is no difference between the two products.*"[167] Overall, in a significant number of Group 1 markets, generics have limited impact on sales, despite a lower price point. It is noted that one of the prominent generic player in the category is Novartis' Sandoz, with a market share above [10-20]% in Bulgaria, Estonia, Latvia, Lithuania, Poland and Ireland. Sandoz is also active (market share between [0-5] and [5-10]%) in Belgium, France, Germany and Italy. While the market perception is that Sandoz operates independently from Novartis[168], it remains a division of the company holding a significant minority shareholding in the OTC JV.

(211) As for private label, they have a very limited presence, with the exception of the UK, (market share below [20-30]%), and the Netherlands.

(212) Second, brands such as *Zovirax*, and to a lesser extent *Vectavir*, are considered as *« must have product »* by pharmacists.[169] A large number of respondents, both custom-

---

165 Minutes of a call with a wholesaler dated 19 September 2014. See also for Italy and more broadly for the EEA minutes of a call with a pharmacists' association dated 30 September 2014; minutes of a call with a wholesaler dated 17 September 2014; minutes of a call with an industry association dated 18 September 2014.

166 Replies to questions 51-53 of Questionnaire Q3 – OTC Competitors.

167 Minutes of a call with a wholesaler dated 17 November 2014.

168 Minutes of a call with a wholesaler dated 17 September 2014; minutes of a call with a competitor dated 13 October 2014.

169 Replies to questions 48-49 of Questionnaire Q1 – OTC Customers; replies to questions 20-21 of Questionnaire Q2 – OTC Customers.

ers and competitors state that the most relevant criterion for consumers choosing an antiviral cream is brand recognition.[170] According to respondents, competition in this market takes place primarily at brand level, followed by price and innovation.[171] "*As in most healthcare areas, brands provide the heritage and confidence for customers purchasing decisions.*"[172] For instance, TV commercials are highlighted as key, alongside with pharmacists' recommendation.[173] As the two most important branded players in the EEA for topical antivirals, the Parties are largely considered by their competitors to be each other's closest competitor.[174] Barriers to expansion are also considered high due to the importance of brands and habit of consumers ("*Consumers usually purchase the products which were used previously and proved effective.*").[175]

(213) Third, contrary to the Notifying Party's arguments, responses to the market investigation confirmed that the recent entry of docosanol has had a limited impact on the sales of acyclovir and penciclovir and this is likely to remain the case in the future.[176] A large majority of customers of the Parties do not sell docosanol-based antiviral creams. So far docosanol has had a very low market penetration, and "*very low sales*"[177] compared to other antiviral creams. One exception is Blistex, which is perceived as successful in Ireland and the UK.

(214) Fourth, data analysis suggests that patches are not an effective constraint for antiviral creams. In fact, in the years following their launch in the mid-2000s, patches gained a substantial share of the overall cold sore management space, but this was achieved mostly by expanding the space rather than gaining sales from antiviral creams. This suggests that, rather than taking market share from topical antivirals, patches created a 'new' market within the broader segment of cold sore management. As mentioned in section V.3.1, J&J's popular *Compeed* patch is perceived more as a "*cosmetic*" complement rather than as a substitute for the antiviral creams.[178] As patches currently on the market do not contain an active ingredient, competitors highlight "*efficacy gaps due to the lack of an antiviral ingredient*".[179]

---

170 Replies to questions 51-53 of Questionnaire Q3 – OTC Competitors.

171 Replies to question 49 of Questionnaire Q1 – OTC Customers; replies to questions 51 and 52 of Questionnaire Q3 – OTC Competitors. A Spanish player mentioned that the focus on Spain is mainly on brands, with nonetheless "*a change due to the economic crisis*". Minutes of a call with a wholesaler dated 19 September 2014.

172 Minutes of a call with a customer dated 10 October 2014.

173 Replies to question 48 of Questionnaire Q1 – OTC Customers; replies to questions 20 of Questionnaire Q2 – OTC Customers; minutes of a call with a pharmacists' association dated 30 September 2014.

174 Replies to questions 57 of Questionnaire Q3 – OTC Competitors.

175 Replies to questions 62 and 62.1 of Questionnaire Q3 – OTC Competitors; minutes of a call with a wholesaler dated 17 November 2014.

176 Replies to question 47 of Questionnaire Q1 – OTC Customers; replies to question 19 of Questionnaire Q2 – OTC Customers.

177 Replies to question 47 of Questionnaire Q1 – OTC Customers; replies to question 19 of Questionnaire Q2 – OTC Customers.

178 Minutes of a call with a customer dated 17 October 2014; minutes of a call with a customer dated 30 September 2014; minutes of a call with a customer dated 17 September 2014.

179 Replies to question 52 of Questionnaire Q3- OTC Competitors; minutes of a call with a competitor dated 17 October 2014.

(215) Fifth, wholesalers and pharmacies chains seem to have rather limited buyer power, since they base their decision making process on the need to be able to offer to customers the widest possible range of products. Wholesalers' purchasing pattern is essentially influenced by the delivery orders placed by pharmacies with limited or no other considerations in particular in terms of price and volume.[180] The Parties brands are also a "must-have" for many customers, therefore needed on shelves.

(216) Sixth, although there has recently been limited innovation in the topical antivirals market, responses to the market investigation confirmed that innovation can play an important role in this segment and it is an important criterion for consumers. Innovation focuses on offering improved versions of existing products able to cover a wider range of their needs (such as skin coloured creams, more convenient packaging). A competitor stresses the rewards of innovation due to current "*significant consumer dissatisfaction around existing cold sore solutions*".[181] The Transaction would have an impact on the innovation dynamics on the cold sore market as both Novartis and GSK were branded players active in innovation in the cold sore management area.

(217) Finally, based on replies to the market investigation, several customers and competitors expect price increases due to the Transaction, for instance in Germany, the Netherlands, Portugal, Greece, Italy, Sweden and France.[182]

Conclusion

(218) In light of the above and of all available evidence, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market as regards topical antivirals used in the treatment of cold sore, as it would lead to a creation or strengthening of dominance.

V.4. COLD AND FLU TREATMENTS

(219) Cold and flu OTC products treat the variety of symptoms generated by the common cold and *influenza*, commonly referred to as flu. Symptoms from cold and flu are multiple and can be treated by a number of different OTC products.

(220) Two broad categories of OTC products treating a cold and flu can be identified: (i) multi-symptoms products and (ii) single-symptoms products. Multi-symptoms products contain more than one active ingredient and treat multiple symptoms of the cold and flu. Single-symptoms products on the other hand contain a single active ingredient treating only a specific symptom. In contrast to prescription products or vaccines, OTC cold and flu treatments do not treat underlying infections (as antibiotics would), or build up immunity against viruses (as vaccines would), but rather target the symptoms of a cold or flu.

---

180 Minutes of a call with a customer dated 17 November 2014; minutes of a call with a customer dated 10 September 2014.

181 Replies to question 52 of Questionnaire Q3- OTC Competitors.

182 Replies to question 50 of Questionnaire Q1 – OTC Customers; replies to question 22 of Questionnaire Q2 – OTC Customers.

V.4.1. Relevant product markets

The Notifying Party's arguments

(221) The Notifying Party submits that the appropriate product market definition should be broader than each ATC3 classification and takes the view that a market including multi-symptoms cold and flu treatments (R5A), throat preparations (R2A), chest rubs and other inhalants (R4A), topical nasal preparations (R1A), systemic nasal preparations (R1B), expectorants (R5C) and antitussives (R5D) should be considered.

(222) The Notifying Party claims that products falling in ATC3 R2A, R5C and R5D classes are to be considered as substitutes for multi-symptoms cold and flu treatments. The Notifying Party substantiates this claim stating that consumers usually substitute combination of different mono-symptoms products with multi-symptoms products, depending on the stage of the cold and flu they are experiencing. According to the Notifying Party, in fact, consumer choices in this space are symptoms driven rather than category driven.

(223) The Notifying Party also claims that the product market should encompass all cold and flu products because single-ingredients products often cut across more than one symptom thus putting a single active ingredient across different ATC3 classes.

(224) In the Notifying Party's view the way cold and flu medicines are marketed in pharmacies also corroborates a wider market definition. In fact, pharmacies – including on line – generally group together all the cold and flu products in one single, broad category.

(225) From a supply side perspective, the Notifying Party claims that:

(a) all major players are active throughout the cold and flu space;

(b) switching production from one product to another is relatively easy and quick; and,

(c) companies can outsource production to contract manufacturers to be able to enter the market with new product ranges.

(226) In the Notifying Party's view this is a further confirmation that the relevant product market encompasses all cold and flu products.

(227) In order to support its view of the relevant market being broader than just multi-symptom products the Notifying Party submitted a price correlation study covering both single and multi-symptom products.[183] The study examined the correlation between the wholesale prices of multi-symptom products and individual single-symptom product groups (e.g. topical nasals, expectorants, etc.) in 6 Member States where the combined market share of the Parties exceeded 40% in the multi-symptom segment in 2013.

183 The study "Analysis of prices of multi-symptom and single-symptom products" was undertaken by Compass Lexecon and was submitted on the 24th of October 2014.

(228) The Notifying Party found in this study that price correlations (the extent to which prices move together over time) within multi-symptom and single-symptom products are not systematically higher than between multi- and single-symptom products and concluded that this evidence "*is consistent with prices of multi-symptom products and single-symptom products constraining each other at least to the same extent as price constraints within the multi-symptom segment*".[184] Based on this, the Notifying Party also concluded that the relevant product market could well be wider than the one defined at the ATC3 category level (including both multi-symptom and single-symptom products), which is consistent with the Commission's findings in previous cases.[185]

Previous decisional practice

(229) The Commission's starting point in defining the relevant product markets in the OTC cold and flu space has been the ATC3 classification. However, in some instances the Commission departed from the ATC3 classification and moved to the ATC4 classification or looked at group of ATC3 classes as plausible product markets.

(230) In case M.1846 *Glaxo Wellcome/Smithkline Beecham*, the market for topical nasal decongestant has been assessed at ATC4 level, as the ATC3 R1A (all topical nasal preparations) proved to be too wide. In that case, the ATC3 class R1A has been considered too wide as it encompasses a number of products for the topical application to the nose which cover different indications and offer different modes of action. [186]

(231) In case M.1878 *Pfizer/Warner Lambert*, the Commission analysed the cough remedies space. Following the ATC3 classification, it found that expectorants (R5C) and antitussives (R5D) are likely part of different product markets because of their substantially different way of action. In fact, expectorants loosen the mucus and, by producing cough, are meant to allow better coughing up of mucus. In contrast, antitussives suppress cough and are indicated in the cases of bothersome cough, especially during night-time. Therefore, a dry, hacking cough would require an antitussive while a productive cough would require an expectorant. The market definition was however ultimately left open.

(232) In case M.3354 *Sanofi – Synthélabo/Aventis*[187], the Commission made the analysis by reference to individual ATC3 classes, leaving however the market definition open.

(233) The Commission departed from a strict ATC3 approach in case M.4007 *Reckitt Benckiser/Boots Healthcare International*.[188] In that case the market investigation showed that ATC3 classification R5A "all products indicated for colds and influenza without infectives" did not properly reflect the market's structure. Hence a broader market including chest rubs and other inhalants (R4A), systemic nasal preparations

---

184 The Notifying Party's report also included results from specifications using seasonal dummies to control for common demand shocks across different product types. Moreover, it also examined price first differences to control for potential non-stationarity of price time series.

185 The study makes reference to Commission cases M.4007, *Reckitt Benckiser/Boots Healthcare International* (2006), paragraph 28; M.4402, *UCB/Schwartz Pharma* (2006), paragraph 27; M.6280, *Procter & Gamble/Teva OTC Business* (2011), paragraph 24.

186 M.1846, *Glaxo Wellcome/SmithKline Beecham* (2000), paragraphs 52-57.

187 M.3354, *Sanofi – Synthélabo/Aventis*(2004), paragraphs 14-17.

188 M.4007, *Reckitt Benckiser/Boots Healthcare International*, paragraph 12.

(R1B), nasal decongestants (R1A7) and other topical nasal decongestants (R1A9) was considered. Also in this case the exact market definition was ultimately left open.

(234) This broader approach to the market definition was adopted also in case M.4314 *Johnson & Johnson/Pfizer Consumer Healthcare.*[189] In that case the Commission considered the ATC3 R5A classification as appropriate to define the relevant product markets. However it also considered the possibility of further broadening the market by including also R4A (chest rubs and other inhalants), R1B (systemic nasal preparation), R1A7 and R1A9 (nasal decongestants without anti-infective and anti-allergic compound) in the relevant product market. Ultimately the market definition was left open.

(235) In case M.5953 *Reckitt Benckiser/ SSL* the Commission analysed OTC both the ATC3 and ATC4 levels as well as the molecule level. With reference to throat preparations the Commission considered a market definition, without closing it, based on ATC3 classification appropriate. The market investigation, in fact, was not conclusive on whether a further segmentation of the product market according to ATC4 classification would be meaningful in this space.

(236) In case M.6280 *Procter & Gamble/Teva OTC Business*[190], the Commission took the ATC3 level as an appropriate starting point on the basis of the therapeutic use of the products in question. In that case, however, the Commission also considered plausible markets defined at ATC4 level, without closing the market definition.

Commission's assessment

(i) Commission's assessment of the economic study

(237) The Commission identified three problems with the Notifying Party's price correlation analysis for product market definition purposes for the current case.

(238) First, there is very limited variation of these prices over time and the drivers of this variation in price are unclear. Moreover, prices are not necessarily the main drivers of the customer purchasing decisions in OTC pharmaceutical markets.[191] These factors question the appropriateness of price correlation analysis as a relevant market definition tool in the present case.

(239) Second, according to the Notifying Party's analysis there are a number of instances in which prices of individual multi-symptom products are more strongly correlated with prices of single-symptom products that with prices of other multi-symptom products. If the price correlation were to indicate substitutability between products in the present case, this would indicate that some single-symptom products are in fact closer substitutes to certain multi-symptom products than other multi-symptom products. This is implausible and casts further doubts on the relevance of the Notifying Party's correlation analysis.

---

189 M.4314, *Johnson & Johnson/Pfizer Consumer Healthcare*, paragraph 17-20.

190 M.6280, *Procter & Gamble/Teva OTC Business*, paragraphs 13-14.

191 Besides prices, customers also take into account, among others, therapeutic indications, active ingredients, brand reputation, recommendation from the pharmacist and previous experience.

(240) Third, the Commission considers that a price correlation analysis as a tool to quantify the degree of co-movement of prices over time, and indicating that the underlying products belong to the same relevant market, is best suited as a "separation" test (to conclude that products *are not* in the same market) rather than an "inclusion" test (to conclude that products *are* in the same market), as in general many factors other than substitution-based constraints can generate co-movements of prices of two candidate products, such as movements in common costs, similar demand trends.[192] This is the approach adopted by the Commission in a number of recent cases.[193]

(241) Based on the above, the Commission considers that the price correlation analysis submitted by the Notifying Party is not directly informative for the relevant product market definition.

(242) Furthermore, the Commission notes that the data underlying the Notifying Party's price correlation analysis was not limited to prices but also included sales volumes at the product level. In the Commission's view, an analysis of volume data (individually or in conjunction with prices) should allow a more direct evaluation of the substitutability relationship between various single and multi-symptom drugs that price correlations. Using this volume data, the Commission undertook a preliminary assessment of the impact of entry of *Menarini* (a single-symptom topical nasal drug producer) into the three Baltics countries and of Novartis in Romania and Slovakia on the volumes of topical nasal and multi-symptom drugs sold in those countries. The Commission also reviewed a similar analysis by the Notifying Party which the Commission had invited.[194] In the Commission's view, these analyses provided no clear evidence on the impact of these entries on the volumes of drugs sold from a different medicine group (e.g. there is no clear impact of the entry of a topical nasal drug on the sales of multi-symptom drugs). As a result, the preliminary analysis of volume data is not informative for the definition of the relevant product market.

(243) This, in turn, indicates that at this stage of the investigation the relevant product market needs to be defined based on the qualitative evidence collected from the market investigation.

(ii) Commission's assessment of the qualitative evidence

(244) In the case at hand, the result of the market investigation was not entirely conclusive as to the exact scope of the product market, while providing useful indications on possible delineations.

(245) First, elements from the market investigation indicate that a broad market encompassing all cold and flu products is unlikely. In fact, only a minority of customers

---

192 While the Notifying Party acknowledges these problems and took measures to control them, these measures are most often imperfect, leading to the price correlation coefficient overestimating the relationship between the two examined variables.

193 M.6850, *Marine Harvest/Morpol* (2013), M.6756, *Norsk Hydro/Orkla* (2013), M.6607, *AS Airways/American Airways* (2013), M.6541, *Glencore/Xstrata* (2014), and M.6360, *Nynas/Shell/ /Harbug Refinery* (2014).

194 The Notifying Party's analysis of sales volumes was developed in the subsequent study by Compass Lexecon, submitted on 12 December 2014.

view all single-symptoms products as interchangeable and that customers tend to treat the symptoms they have with the appropriate single-symptom product.[195]

(246) Some respondents indicated that customer may consider some group of single-symptom product as interchangeable; however there was no firm indication in this sense.[196]

(247) Second, as to the competitive constraint posed by multi-symptoms products on single-symptom products, the market investigation was unclear as to the appropriateness of regarding multi-symptom products as separate product market. In fact, albeit some customers have a preference for multi-symptoms products, which indicates that they could constitute a market on their own, others tend to use the appropriate single-symptoms product, or a combination thereof when experiencing more than one symptom.[197] Also, it emerged that some customers prefer to use both a multi-symptom product and the appropriate single product(s) when treating a cold and flu event. For instance "*When a consumer suffers from cold and flu, he will usually take a multi-symptom product as a basis, and then a single-symptom one depending on symptoms, both being perceived as complementary*".[198] This was also confirmed by another competitor stating that "*single symptoms products are not interchangeable with multi symptoms, but the may be used it concurrently*".[199]

(248) What emerges from the market investigation, therefore, is that multi-symptoms products pose a competitive constraint on single-symptom product; therefore product markets encompassing each individual single-symptom product and the multi-symptom products cannot be excluded.

(249) In any event, the precise scope can be left open since the Transaction raises serious doubts as to it compatibility with the internal market under alternative plausible market definitions described above, even if the precise scope of the product market definition is not defined.

V.4.2. Relevant geographic markets

(250) The Commission has previously defined the geographic market for pharmaceutical products, including for cold and flu treatment as national in scope.[200] Also, the Notifying Party submits that the geographic market should be regarded as national in scope.

---

195 Replies to question 7 of Questionnaire Q3 – OTC Competitors; replies to question 4 of Questionnaire Q1 – OTC Customers.

196 Minutes of a call with a competitor dated 19 November 2014; minutes of a call with a competitor dated 17 October 2014.

197 Minutes of a call with a competitor dated 19 November 2014; minutes of a call with a competitor dated 13 October 2014.

198 Minutes of a call with a competitor dated 17 October 2014.

199 Replies to question 8 of Questionnaire Q3 – OTC Competitors.

200 M.1846, *Glaxo Wellcome/ Smithkline Beecham* (2000), paragraphs 73-74.

V.4.3. Competitive assessment

(251) If the product market is defined as encompassing multi-symptom products only, the Transaction would lead to 7 affected markets, of which 6 Group 1 markets.[201]

Table 12: Market size and market shares of the Parties in EEA affected countries based on the market for Multi-Symptom Products for cold and flu, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Bulgaria	2013	[15,000-16,000]	[10-20]%	[10-20]%	**[20-30]%**
	2012	[14,000-15,000]	[10-20]%	[10-20]%	**[20-30]%**
	2011	[15,000-16,000]	[10-20]%	[10-20]%	**[20-30]%**
Estonia	2013	[1,000-2,000]	[40-50]%	[40-50]%	**[80-90]%**
	2012	[1,000-2,000]	[40-50]%	[30-40]%	**[80-90]%**
	2011	[1,000-2,000]	[40-50]%	[30-40]%	**[80-90]%**
Hungary	2013	[16,000-17,000]	[10-20]%	[30-40]%	**[50-60]%**
	2012	[15,000-16,000]	[20-30]%	[40-50]%	**[60-70]%**
	2011	[15,000-16,000]	[10-20]%	[40-50]%	**[60-70]%**
Latvia	2013	[3,000-4,000]	[10-20]%	[20-30]%	**[30-40]%**
	2012	[3,000-4,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[3,000-4,000]	[10-20]%	[20-30]%	**[40-50]%**
Lithuania	2013	[5,000-6,000]	[10-20]%	[20-30]%	**[40-50]%**
	2012	[5,000-6,000]	[10-20]%	[20-30]%	**[30-40]%**
	2011	[5,000-6,000]	[20-30]%	[20-30]%	**[40-50]%**
Romania	2013	[40,000-50,000]	[30-40]%	[10-20]%	**[40-50]%**
	2012	[40,000-50,000]	[30-40]%	[10-20]%	**[40-50]%**
	2011	[40,000-50,000]	[30-40]%	[5-10]%	**[40-50]%**
Slovak Republic	2013	[10,000-11,000]	[20-30]%	[20-30]%	**[40-50]%**
	2012	[9,000-10,000]	[20-30]%	[20-30]%	**[50-60]%**
	2011	[9,000-10,000]	[20-30]%	[20-30]%	**[50-60]%**

Source: GSK, based on IMS Global Analysis data (Annex CH CF 7.7)

(252) In most of Group 1 countries, the combined market shares exceed [40-50]% and the Parties appear to be very close competitors. In Estonia the combined market shares are particularly high ([80-90]%).

(253) If the relevant product markets were defined as encompassing a single-symptom product and the multi-symptoms product, on the plausible market encompassing multi-symptom and topical nasal products (ATC classes R5A+R1A7) the Transaction would lead to Group 1 markets in the following 8 Member States:

201 Estonia, Hungary, Latvia, Lithuania, Romania and the Slovak Republic.

Table 13: Market size and market shares of the Parties in EEA affected countries based on the market for Topical Nasal decongestants and Multi-Symptom Products for cold and flu, 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Bulgaria	2013	[20,000-30,000]	[10-20]%	[10-20]%	**[20-30]%**
	2012	[20,000-30,000]	[10-20]%	[10-20]%	**[20-30]%**
	2011	[20,000-30,000]	[10-20]%	[10-20]%	**[20-30]%**
Czech Republic	2013	[20,000-30,000]	[10-20]%	[5-10]%	**[20-30]%**
	2012	[20,000-30,000]	[10-20]%	[5-10]%	**[20-30]%**
	2011	[20,000-30,000]	[10-20]%	[5-10]%	**[20-30]%**
Estonia	2013	[3,000-4,000]	[20-30]%	[30-40]%	**[50-60]%**
	2012	[3,000-4,000]	[10-20]%	[30-40]%	**[50-60]%**
	2011	[2,000-3,000]	[20-30]%	[30-40]%	**[50-60]%**
Finland	2013	[8,000-9,000]	[10-20]%	[20-30]%	**[40-50]%**
	2012	[10,000-11,000]	[10-20]%	[20-30]%	**[30-40]%**
	2011	[8,000-9,000]	[10-20]%	[20-30]%	**[30-40]%**
Greece	2013	[14,000-15,000]	[20-30]%	[40-50]%	**[60-70]%**
	2012	[13,000-14,000]	[20-30]%	[40-50]%	**[70-80]%**
	2011	[12,000-13,000]	[10-20]%	[40-50]%	**[60-70]%**
Hungary	2013	[20,000-30,000]	[10-20]%	[20-30]%	**[30-40]%**
	2012	[20,000-30,000]	[10-20]%	[20-30]%	**[40-50]%**
	2011	[20,000-30,000]	[10-20]%	[30-40]%	**[40-50]%**
Latvia	2013	[5,000-6,000]	[5-10]%	[20-30]%	**[30-40]%**
	2012	[6,000-7,000]	[10-20]%	[20-30]%	**[30-40]%**
	2011	[5,000-6,000]	[10-20]%	[20-30]%	**[30-40]%**
Lithuania	2013	[9,000-10,000]	[10-20]%	[20-30]%	**[30-40]%**
	2012	[8,000-9,000]	[10-20]%	[20-30]%	**[30-40]%**
	2011	[8,000-9,000]	[10-20]%	[20-30]%	**[30-40]%**
Netherlands	2013	[14,000-15,000]	[5-10]%	[40-50]%	**[40-50]%**
	2012	[15,000-16,000]	[5-10]%	[40-50]%	**[40-50]%**
	2011	[15,000-16,000]	[5-10]%	[30-40]%	**[40-50]%**
Romania	2013	[50,000-60,000]	[20-30]%	[10-20]%	**[40-50]%**
	2012	[50,000-60,000]	[20-30]%	[10-20]%	**[40-50]%**
	2011	[50,000-60,000]	[20-30]%	[10-20]%	**[40-50]%**
Slovak Republic	2013	[20,000-30,000]	[10-20]%	[20-30]%	**[30-40]%**
	2012	[18,000-19,000]	[10-20]%	[20-30]%	**[30-40]%**
	2011	[18,000-19,000]	[10-20]%	[20-30]%	**[30-40]%**
Sweden	2013	[13,000-14,000]	[30-40]%	[50-60]%	**[80-90]%**
	2012	[13,000-14,000]	[30-40]%	[50-60]%	**[80-90]%**
	2011	[12,000-13,000]	[30-40]%	[40-50]%	**[80-90]%**
UK	2013	[30,000-40,000]	[40-50]%	[5-10]%	**[50-60]%**
	2012	[30,000-40,000]	[40-50]%	[5-10]%	**[50-60]%**
	2011	[30,000-40,000]	[40-50]%	[5-10]%	**[50-60]%**

Source: GSK, based on IMS Global Analysis data (Annex RFI 3 Q 5)

(254) In Sweden, the combined market share of the Parties would be particularly high ([80-90]%) and the OTC JV will be almost the only one supplier.

(255) If the market was to be defined as encompassing not only multi-symptom and topical nasal decongestant, but also ATC4 class R1A9 "other topical nasal preparations", the combined market shares of the Parties would significantly decrease in Greece ([30-40]% in 2013) and the UK ([50-60]% in 2013).

(256) In other Group 1 countries, the combined market shares exceed [40-50]% and the Parties appear to be very close competitors, in particular in Estonia, Hungary, Latvia, Lithuania and Romania.

The Notifying Party's arguments

(257) The Notifying Party considers that despite the significant market share accretions in certain Member States, the Transaction will not significantly impede effective competition in the EEA. It argues that (i) the combined entity will face strong competition post transaction, (ii) the Parties are not each other closest competitor, (iii) barriers to entry and expansion are limited, and (iv) customers (wholesalers, pharmacy chains/buying group as the case may be) exercise relevant buyer power.

(258) First, the combined entity will continue to face fierce and growing competition from global healthcare companies with strong portfolios such as J&J, Pfizer, Bayer, Reckitt Benckiser, PGT Healthcare (the joint-venture between Procter&Gamble and Teva), Boiron that have a significant presence in the affected markets. Local competitors, including Olvos Science in Greece, Biopharma in the Netherlands, the Polish company US Pharmacia in Lithuania and the Slovenian company KRKA in Latvia and Lithuania, have also obtained sizeable market shares. According to the Notifying Party, apart from brand, consumers may be interested in other factors such as label indication, active ingredients, price or the pharmacists' recommendation. Thus private label and generic products will exert a competitive constrain on the pricing of the OTC JV's products in the cold and flu area.

(259) Second, the Notifying Party indicates that the Parties are not each other's closest competitors. In fact, the Parties' product portfolios and presence are highly complementary: GSK focuses on multi-symptom cold and flu treatments whereas Novartis' focus is rather on topical nasal preparations.

(260) Third, the Notifying Party submits that the barriers to entry in the cold and flu segment are limited. Moreover, the probability of expansion, especially in response to a potential price increase is rather high as manufacturers can and do use contract manufacturers that are able to adapt their production facilities quickly and manufacture a variety of formulations and products. According to the Notifying Party, PGT has recently introduced a multi-symptom cold and flu under its Vicks brand in the EEA and Reckitt Benckiser has introduced a new cold and flu product in line with its *Nurofen* product.

(261) Finally, the Notifying Party submits that the combined entity will be constrained by large wholesalers and pharmacy chains that have negotiating power. Wholesalers can easily adapt their stock and inventory and favour suppliers that offer them the best conditions. Pharmacies can shift volume through shelf space policy, promotional support and recommendations to patients.

Commission's assessment

(262) Several elements from the market investigation indicate that a significant number of players are active in the cold and flu segment.[202] According to a competitor, *"the cold and flu market is a mature market with established players and stable prices"*.[203]

(263) Elements from the market investigation confirmed that generic products and private label product exert competitive constraint on branded products, however only to a limited extent.[204] In fact, the available evidence suggests that in the cold and flu space brand competition is a key factor.[205] "*For instance in the UK brands are still popular, although cheap alternatives exist.*"[206] For some plausible markets, the importance of brands seems to be lower. For a competitor, "*the role of generics in a given countries depends on the set up of distribution channels in the country*"[207] However, on the plausible product market encompassing multi-symptom products only, brand appears to be the key parameter of competition.[208]

(264) Also, the Parties have particularly strong brands, especially in the multi-symptoms products segment. This is also confirmed by the fact that a majority of respondents claim that they could not stop selling the Parties' products without incurring in significant loss of sales.[209]

(265) Brands are also a particularly important parameter of competition as, in the cold and flu space, the majority of end customer usually purchase the products without seeking advice of the pharmacist (so called "unassisted sales"). Also, in the course of the market investigation it emerged that, when approached by the end users for advice, pharmacist generally tend to suggest branded products[210] for a variety of reasons, including that customers tend to have trust in the effectiveness of branded products they are familiar with.[211]

(266) Second, contrary to the Notifying Party's arguments, elements from the market investigation confirmed that the Parties exert significant competitive constraints on each other. The majority of customers, in fact, perceive GSK and Novartis as amongst each other's closest competitor, if not the closest in some areas of the cold and flu space.[212] This is further confirmed by competitors who consistently classify GSK and Novartis among the top 5 competitors in various segments of the cold and flu space.[213]

---

202 Minutes of a call with a customer dated 31 October 2014.

203 Minutes of a call with a competitor dated 19 November 2014.

204 Minutes of a call with a competitor dated 17 October 2014.

205 Minutes of a call with a competitor dated 13 October 2014; replies to question 18.1 of Questionnaire Q 3 – OTC Competitors.

206 Minutes of a call with a competitor dated 13 October 2014.

207 Minutes of a call with a competitor dated 13 October 2014.

208 Replies to question 21 of Questionnaire Q3 – OTC Competitors.

209 Replies to question 21 of Questionnaire Q1 – OTC Customers.

210 Replies to question 18 of Questionnaire Q1 – OTC Customers.

211 Replies to question 18 of Questionnaire Q1 – OTC Customers.

212 Replies to question 15 of Questionnaire Q1 – OTC Customers.

213 Replies to question 18 of Questionnaire Q3 – OTC Competitors.

(267) Third, responses to the market investigation indicate that manufacturers of OTC products may encounter difficulties when they want to expand from one category to the other in the cold and flu segment. Contrary to the Notifying Party's representation, the majority of the respondents to the market investigation claim that expanding in segment of the cold and flu space where they are not yet active would require a high investment and a long time frame, in excess of two years.[214]

(268) Fourth, the available evidence does not support the Notifying Party's view with respect to the allegedly significant buyer power of wholesalers. In the course of the market investigation, in fact, it clearly emerged that wholesaler have little buyer power. In the vast majority of the cases, in fact, wholesalers tend to stock the full line of products from each player on the market, or at least from the strongest players on the market as the Parties are, without strongly negotiating on price. In fact, usually wholesalers pass on any price increase to the retail level.[215]

(269) In some Member States, such as the Netherlands and the UK, the Parties seem not to be particularly close competitors and the increment in market share is limited. In fact, on the plausible market for topical nasal decongestants and multi-symptom products, the increment derives from single-symptoms sales and multi-symptoms sale.

Conclusion

(270) In light of the above and of all available evidence, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market as regards multi-symptom products and topical nasal products in Estonia, Finland, Hungary, Latvia, Lithuania, Romania, Slovak Republic and Sweden, as it would lead to a creation or strengthening of dominance.

V.5. ALLERGIC RHINITIS TREATMENTS

(271) Allergic rhinitis ("AR") is the inflammation of the mucous membrane of the nasal passages caused by an allergic reaction. There is no known cure for allergic rhinitis; the treatment focuses largely on the alleviation of symptoms after exposure to an allergen. The traditional treatments consist of anti-histamines, nasal corticosteroids and systemic nasal preparations.

(272) Allergic rhinitis treatments can be broadly divided in preventive treatments and reactive treatments. Preventive treatments (nasal corticosteroids without anti-infectives ATC class R1A1, systemic antihistaminic ATC class R6A and nasal anti-allergic agents ATC class R1A6) are used before the occurrence of allergy symptoms to avoid their occurrence. Reactive treatments (systemic nasal preparations ATC class R1B and topical nasal decongestants ATC class R1A7) are used only to ease the symptoms.

(273) However, reactive treatments are the same products as in the cold and flu space and have no direct effect on the allergic process. They are just used to alleviate the symptoms (as for example a runny nose) which are similar to the ones of cold and flu.

---

214 Replies to questions 13 and 14 of Questionnaire Q3 – OTC Competitors.

215 Minutes of a call with a customer dated 17 November 2014; minutes of a call with a customer dated 10 September 2014.

(274) GSK sells *Flixonase*, a nasal spray that contains fluticasone propionate (R1A1), a synthetic corticosteroid (or steroid). The medicine is indicated for the prophylaxis and treatment of allergic rhinitis. In some EEA Member States it is a prescription product, whereas in others it is sold as OTC. GSK also supplies, only in Ireland and the UK, *Piriton* and *Piriteze*. *Piriton* contains the sedating antihistamine *chlorphenamine maleate* as active ingredient. *Piriteze* contains the antihistamine *cetirizine hydrochloride*. These products are systemic antihistamines (R6A) and can be used for symptomatic control of all allergic conditions responsive to antihistamines.

(275) Novartis sells *Fenistil* and *Tavegil*, systemic antihistamines (R6A) indicated to prevent symptoms such as runny nose, itchy watery eyes, and sneezing. Novartis also supplies *Vibrocil*, a nasal anti-allergic agent (R1A6), which is available as nasal drops, nasal spray, and gel. *Vibrocil* is indicated for acute and chronic rhinitis, allergic rhinitis, and sinusitis.

V.5.1. Relevant product markets

The Notifying Party's arguments

(276) The Notifying Party claims that a distinction should be drawn between preventive and reactive AR treatments. It is unlikely that patients will substitute preventive treatments for reactive treatments or vice versa, as there are significant differences in therapeutic use, mode and speed of action, and side effects. Hence, the Notifying Party submits that reactive nasal decongestants (R1A7) and systemic nasal preparations (R1B) should be distinguished from preventive dedicated allergy treatments. Preventive treatments often need to be taken continuously and should be used for a whole period whereas the reactive treatments are typically faster acting and should be used for a short period of time to address acute symptoms.

(277) Furthermore, within preventive AR treatments, the Notifying Party indicates that it is appropriate to consider the different types of preventive allergic rhinitis treatments (AR treatments for systemic antihistamines (R6A), nasal corticosteroids without anti-infectives (R1A1), and nasal anti-allergic agents (R1A6)) as part of a single relevant market. Nasal anti-allergic agents and systemic antihistamines prevent the effects of histamine release, while nasal corticosteroids block the allergy process at an earlier stage. However, despite the different mode of action, the Notifying Party points out that each of these types of products are preventive, dedicated allergy treatments.

Previous decisional practice

(278) In past decisions the Commission has analysed the relevant product market with reference to ATC3 or ATC4 classification given the significant differences between products at the ATC4 level.

(279) In several former cases the Commission considered separate markets at ATC3 level for systemic anti-histamines (R6A), topical nasal preparations (R1A), and systemic nasal preparations (R1B) but did not reach a conclusion on the market definition.[216] However, in M.1846 *Glaxo Wellcome/SmithKline Beecham* the Commission consid-

[216] M.5253, *Sanofi-Aventis/Zentiva* (2009), paragraph 171; M.5295 - *Teva/Barr* (2008), paragraph 172; M 3354, *Sanofi-Synthelabo/ Aventis* (2004), paragraph 23; M.5502, *Merck/Schering-Plough* (2010), paragraphs 40-48.

ered the ATC4 level as appropriate for defining the product market. In that case, the ATC3 class R1A has been considered too wide as it encompasses a number of products for the topical application to the nose which cover different indications and offer different modes of action. [217]

Commission's assessment

(280) Elements from the market investigation confirmed that the allergy products likely constitute a separate category from cold and flu. The majority of respondent to the market investigation, in fact, claimed that end customers do not purchase reactive (cold and flu) products to treat an AR, and when this happens is generally due to misdiagnosis of the symptoms they are experiencing. "*At the beginning or at the end of the season, allergic people may misdiagnose their symptoms of hay fever and believe that they suffer from cold and flu. Therefore, they will buy a cold and flu product. However, this behaviour is marginal*." [218]

(281) Also, as stated by one competitor "*the cold and flu and the allergy segments are distinct, both in terms of consumer perception and of size. The allergy category is smaller than the cough and cold in Europe. Prescriptions have a much more prominent role in allergy than in cough and cold, which shapes the way marketing activities are conducted. In cough and cold the target is the final consumer, while physicians are also a target in the allergy segment. European consumers typically show better ability to distinguish between allergy and cough and cold, both in terms of diagnosis and product choice. In other geographies, like for instance the emerging countries, misdiagnosis is more common than in Europe. The quality of the health systems and easy access to physicians in Europe partially explains these differences. Currently, in Europe the overlap between the allergy segment and the cough and cold segments is minimal."*[219]

(282) One respondent to the market investigation pointed out that "*Allergy is treated differently than cold and flu. The pattern of symptoms and the seasonality are sufficiently differentiated and it allows customers to be in general able to self-assess the cause, distinguishing between allergy and cold*".[220] Further, the respondent indicated that "*Across Europe, customers typically have good access to professional advice and are increasingly able of self-diagnose and treat of these types of conditions*." Besides, *"cold & flu products and allergy products are typically not available in the same shelf space, facilitating that customers make the right choice."*

(283) As to the appropriateness of further segmenting the product market, responses to the market investigation indicate that generally topical and systemic products are not regarded as interchangeable. However the market investigation was not conclusive on this point.

(284) As to a further segmentation of topical AR treatment by ATC4 classification, the available evidence does not allow for a definite conclusion. However, products falling in ATC4 R1A6 and products falling in ATC4 class R1A1 have different mode of

---

217 M.1846, *Glaxo Wellcome/SmithKline Beecham* (2000), paragraphs 52-57.

218 Minutes of a call with a customer dated 17 October 2014.

219 Minutes of a call with a competitor dated 21 November 2014; minutes of a call with a customer dated 30 September 2014; replies to question 12 of Questionnaire Q1- OTC Customers.

220 Minutes of a call with a competitor dated 19 November 2014.

action, generally treat allergies of different severities and greatly differ in prices. Therefore, it is plausible to consider nasal corticosteroids without anti-invectives (R1A1), and nasal anti-allergic agents (R1A6) to constitute separate product market.

(285) In any event, the exact market can be left open as the Transaction does not raise serious doubts under any plausible market definition set out above.

V.5.2. Relevant geographic markets

(286) The Notifying Party does not contest the considerations in Commission's previous decisional practice[221] and take the view that the market for the supply of AR products is national for the same reasons as other OTC pharmaceuticals. Elements from the market investigation have entirely confirmed the Notifying Party's view.[222]

V.5.3. Competitive assessment

(287) If ATC4 classes R1A6 and R1A1 and ATC3 class R1B were to be considered as separate product markets, the Transaction would not lead to any overlap.

(288) On the contrary, if the product market was defined as encompassing ATC4 classes R1A1 and R1A6, the Transaction would generate 1 Group country: Latvia, with a post transaction [90-100]% combined market share. This, however, does not fully reflect the dynamics of the market, as clarified below.

The Notifying Party's arguments

(289) The Notifying Party claims that in this space the Transaction does not lead to any competition concerns due to the following elements: (i) The combined entity will face strong competition post transaction; (ii) The Parties are not each other closest competitor; (iii) Barriers to entry and expansion are limited; and (iv) Customers (wholesalers, pharmacy chains/buying group as the case may be) exercise buyer power.

(290) First, the Notifying Party submits that the combined entity will continue to face fierce and growing competition from global healthcare companies with strong portfolios such as J&J, Omega, Merck, and Sanofi, which are active throughout the EEA. Local competitors, including Olainfarma in Latvia, Orion in Finland, Bracco in Italy and Almirall in Sweden will also exert a significant competitive pressure on the OTC JV. Private label products also play an increasingly important role in countries with well-established pharmacy chains. In the UK, in addition to Boots, all major pharmacy and retail chains have a range of private label products that compete with the Parties' products. According to the Notifying Party, generic products also exert significant competitive pressure.

(291) Second, the Notifying Party indicates that the Parties are not each other's closest competitor. In fact, the Parties' products portfolio and presence are highly complementary; GSK focuses on nasal corticosteroids without anti-infectives (R1A1), in which Novartis is active in one Member State without a geographic overlap whereas Novartis' focus is rather on products containing antihistamines.

---

221 M.5502, *Merck/Schering-Plough* (2010), paragraph 16.

222 See section V.2.2.

(292) Third, the Notifying Party further points out the limited barriers to entry in the market. Moreover, the probability of expansion, especially in response to a potential price increase is rather high as manufacturers can and do use contract manufacturers that are able to adapt their production facilities quickly and manufacture a variety of formulations and products. According to the Notifying Party, Actavis has recently introduced its *cetirizin* systemic antihistamine product to Latvia. Similarly, Omega Pharma entered the UK, and Ireland with the nasal anti-allergic *Prevalin* in 2011.

(293) Finally, the Notifying Party submits that the OTC JV will be constrained by large wholesalers and pharmacy chains that have negotiating power. Wholesalers can easily adapt their stock and inventory and favour suppliers that offer them the best conditions. Pharmacies can shift volume through shelf space policy, promotional support and recommendations to patients. For instance, the Notifying Party points out that Apoteket AB, Sweden's biggest pharmacy chain, is actively positioning its allergy brand *Apofri* against the competing products through shelf policy, promotions and recommendations.

Commission's assessment

(294) The AR is a competitive market where a number of players are active. In this space, generic products exert a significant competitive pressure on branded products.

(295) In the AR space, the main elements of competition appear to be price and innovation. Customers in this segment are usually more price sensitive and more prone to purchasing generic or private label products than for other OTC categories. Some respondent also pointed out that an innovative product could grant a competitive advantage, however this does not exclude the possibility of effectively compete with generic products based on expired IP rights.[223]

(296) It also emerged that the AR space is less mature compared to the Cold and Flu space and brand awareness and loyalty are less relevant than in the latter.

(297) Furthermore, if the product market was to be defined as encompassing ATC4 classes R1A1 and R1A6, the Parties would not be close competitors.

(298) First, the products from GSK and Novartis have different active ingredients and different mode of actions. GSK' product, *Flixonase*, is a topical nasal corticosteroid which contains corticosteroids as active ingredient. Corticosteroids intervene at a very early stage of the allergic process preventing the release of the inflammatory mediators, including histamines. Antihistamines, the active ingredient contained in Novartis' *Vibrocil*, on the contrary intervene at a subsequent stage of the allergic event. These categories of active ingredients do not prevent the release of histamines but rather counteract their effect on the body.

(299) Second, the Parties' products target different severity of allergies. Corticosteroids are recommended to treat severe allergies whereas antihistamines are best placed to treat mild allergies.

(300) Third, nasal corticosteroid and antihistamine do not offer the same level of effectiveness against the spectrum of allergy triggers. Corticosteroids, in fact, are effective against the full spectrum of allergy triggers (such as smoke, pollution, strong smells,

223 Replies to questions 22.8 and 22.9 of Questionnaire Q3 – OTC Competitors.

temperature changes, pollen, house dust mites, mold spores and animal dander) whereas anti-histamines are effective against a more limited number of allergy triggers (pollen, house dust mites, mold spores and animal dander).

(301) Fourth, the Parties' products are sensibly differently priced. Based on IMS data, in Latvia nasal corticosteroids (such as *Flixonase* from GSK) are on average almost [factor] as expensive as topical anti allergic agents (such as *Vibrocil* from Novartis). According to IMS data, on average the price of a nasal corticosteroid product is EUR [5-10] per pack and EUR [0.05-0.10] per dose whereas the price of a nasal anti-allergic agent is EUR [1-5] per pack and EUR [0.01-0.05] per dose. This ratio applies also to the respective products of the Parties.

(302) In addition, the majority of respondents to the market investigation in fact do not consider the Parties as each other close competitors.[224]

Conclusion

(303) In light of the above and of all available evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as regards Allergic Rhinitis products under any plausible market definition.

V.6. PAIN MANAGEMENT

V.6.1. Relevant product markets

(304) Humans experience pain in various forms, *i.e.* acute (*e.g.* toothaches, muscle sprains), episodic (*e.g.* headaches, menstrual pain, muscle strain) or chronic (*e.g.* arthritis) pain, and across different parts of the body, such as in the head, muscles, bones, joints, or mouth.

(305) OTC pain management products are designed to enable consumers to manage the symptoms of mild to moderate acute, episodic or chronic pain on their own. These can be systemic treatments (for oral intake), which target pain centrally, and topical pain treatments (applied to the skin), which treat pain symptoms locally and tend to have different active ingredients to systemic pain treatments.

(306) Most OTC pain management products are classified in ATC classes "N2 – Analgesics", "M – Musculo-Skeletal System" or "A – Alimentary Tract and Metabolism":

Table 14: Pain Management treatments, ATC classes

ATC Code	
Oral Intake (Systemic Products)	
N2B	Non-Narcotics and Anti-Pyretics
N2C	Anti-Migraine Preparations
M1A	Anti-Rheumatics, Non-Steroidal
M5X	All Other Musculoskeletal Products
G2X1	Gynaecological Antispasmodics
A3D	Antispasmodic/Analgesic Combinations
Applied to Skin (Topical Products)	
M2A	Topical Anti-Rheumatics and Analgesics

Source: Form CO

224 Replies to question 15 of Questionnaire Q1 – OTC Customers.

(307) GSK is mostly active in systemic pain management treatments, in particular with its core product line *Panadol*, a family of analgesic and anti-pyretic preparations with the active ingredient *paracetamol*. *Panadol* is recommended for the treatment of most painful and febrile conditions, including rheumatic and muscle pains or non-serious arthritis. Novartis is mostly active in topical pain management treatments, in particular with its key product *Voltaren*, a non-steroidal anti-inflammatory preparation that contains the active ingredient *diclofenac*. *Voltaren* gel is indicated for the local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises, localised forms of soft tissue rheumatism.

(308) The Parties' activities overlap in several Member States for the ATC3 classes N2B (to which systemic *Panadol* belong) and M2A (to which topical *Voltaren* belong).

The Notifying Party's arguments

(309) The Notifying Party submits that topical and systemic pain relief products belong to separate product markets, as systemic pain management products relieve pain generally (headache, backache, menstrual pain, mouth pain, etc.) and are taken centrally, irrespective of the location of pain, while topical products are designed for local relief of specific and targeted pain (*e.g.* musculoskeletal pain).

(310) The Notifying Party also claims that topical anti-rheumatics and analgesics (M2A) make up a separate market within topical pain relief products.

(311) With respect to systemic pain relief products, the Notifying Party considers that it would be more meaningful to consider a broad systemic pain management market including non-narcotics and anti-pyretics (N2B), anti-migraine preparations (N2C), non-steroidal anti-rheumatics (M1A), all other musculoskeletal products (M5X), antispasmodics (A3D) and gynaecological antispasmodics (G2X1). Indeed, these products typically contain the very same ingredients (*paracetamol*, non-steroidal anti-inflammatory drugs such as *aspirin* or *ibuprofen*, and supplemental ingredients like caffeine), and often even in the same doses. Consumers also consider general systemic pain relief products as substitutes for targeted systemic products such as anti-rheumatics.

(312) Finally, the Notifying Party does not consider that a further segmentation between paediatric and adult products would be appropriate. While, in some instances, there are dedicated paediatric treatments in the over-the-counter pain management space, which may come in a different galenic form (suspension and suppositories) from adult treatments, they are generally based on the same active ingredient, with different dosage or concentration levels and potentially with slightly different packaging. In practice, adult pain relievers often contain dosage instructions for children and adults and may thus be used for both adults and children. As a result the boundaries between paediatric and adult use are often blurred.

Previous decisional practice

(313) The Commission has distinguished between topical and systemic pain management products in its case precedents:

(a) Regarding systemic products, the Commission identified a separate product market consisting of ATC3 class N2B (non-narcotics and anti-pyretics).[225] Within this market, the Commission left open the distinction between adult and paediatric treatments.[226]

(b) Regarding topical products, the Commission identified a separate product market consisting of ATC3 class M2A (topical anti-rheumatics and analgesics).[227]

Commission's assessment

(314) While elements from the market investigation and internal documents from the Parties suggested alternative product markets,[228] the distinction between systemic and topical pain management products was broadly confirmed. One competitor mentioned that "*systemic pain management products are used for the treatment of different types of pain, while topical pain management products are typically used for body pain (for instance, back pain or sport injuries)*",[229] while another submitted that "*the systemic and topical pain management markets are separate*".[230]

(315) Furthermore, while respondents to the market investigation in this case suggested these markets may be broader in scope, on the basis of all available evidence the Commission cannot exclude the existence of a separate N2B market and a separate M2A market. In any event, the exact dimension of the product market definition can be left open for the purposes of the present decision. In particular, as to the ATC3 class N2B, the distinction between adult and paediatric treatments can be left open as serious doubts arise in this case regardless of the precise product market definition.

V.6.2. Relevant geographic markets

(316) In line with past decisions, the pain management markets are analysed at the national level.[231] The Notifying Party does not contest this.

V.6.3. Competitive assessment

(317) The Transaction would result in one affected market for non-narcotics and anti-pyretics (N2B), Sweden, and two affected markets for topical anti-rheumatics and analgesics, France and Poland.

---

225 M.5953, *Reckitt Benckiser / SSL* (2010), paragraph 17; M.4007, *Reckitt Benckiser / Boots Healthcare* (2006), paragraph 11; M.4314, *Johnson & Johnson / Pfizer Consumer Healthcare* (2007), paragraph 23; M.3544, *Bayer Healthcare / Roche* (2004), paragraphs 21-23; M.3354, *Sanofi-Synthelabo / Aventis* (2004), paragraph 99.

226 M.5953, *Reckitt Benckiser / SSL*, 2010, paragraph 18; M.4314, *Johnson & Johnson / Pfizer Consumer Healthcare* (2007), paragraphs 24-26; M.3544, *Bayer Healthcare / Roche (OTC Business)* (2004), paragraph 23.

227 M.6705, *Procter & Gamble / Teva Pharmaceuticals OTC II* (2012), paragraph 16; M.3751, *Novartis / Hexal* (2005), page 10.

228 In particular by distinguishing the various types of pain (musculoskeletal pain, headache/migraine, menstrual pain, etc.).

229 Minutes of a call with a competitor dated 19 November 2014.

230 Minutes of a call with a competitor dated 17 October 2014.

231 See footnotes 224-226.

(318) The Parties' market shares would not vary significantly based on a further segmentation between adult and paediatric treatments. The overlaps between the Parties in **adult** general pain relief are largely similar to the overlaps in general pain treatments (non-narcotics and antipyretics, N2B), and would also result in only one affected market, Sweden. There is no geographic overlap in **paediatric** general pain relief. This further segmentation will therefore not be discussed separately.

V.6.3.1. Horizontal overlaps – Systemic pain management products

Table 15: Market size and market shares of the Parties in EEA affected countries based on a market for non-narcotics and anti-pyretics (N2B), 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Sweden	2013	[40,000-50,000]	[40-50]%	[10-20]%	**[50-60]%**
	2012	[40,000-50,000]	[40-50]%	[10-20]%	**[50-60]%**
	2011	[40,000-50,000]	[40-50]%	[10-20]%	**[50-60]%**

Source: GSK, based on IMS data (Annex CH PM 7.3)

The Notifying Party's arguments

(319) The Notifying Party claims that their combined shares are moderate ([50-60]%) and that the merged entity will continue to face strong competition from international players Meda ([20-30]%), Takeda ([5-10]%) and J&J ([0-5]%), as well as from local players Apofri ([5-10]%) and Orifarm ([0-5]%), which only recently entered the Swedish market (in 2009 and 2010 respectively) and have already gained a notable market share.

(320) The Notifying Party believes that the Parties' products are not each other's closest substitutes. GSK offers the *paracetamol*-based Panodil and Alvedon general pain treatment tablets, mainly associated with general pain, fever and headache, while Novartis offers Voltaren tablets and soft capsules based on the non-steroidal anti-inflammatory drug *diclofenac*, mainly associated with more severe pain, inflammation and joint stiffness caused by arthritis and sport injuries. GSK views Meda's Treo (*aspirin*) and J&J's Ipren (*ibuprofen*) as closest and strongest competitors to Panodil and Alvedon in Sweden. In terms of product characteristics, GSK submits that a close substitute to Panodil and Alvedon is Takeda's branded generic *paracetamol*-based Pamol, launched in 2010. Apofri's private label Paracetamol Apofri and Orifarm's generic Paracetamol Orifarm also have the same active ingredient as Panodil and Alvedon.

(321) Finally, the Notifying Party submits that there is a high degree of buyer power in Sweden, where the market is consolidated at pharmacy level. Indeed, there are four to five large pharmacy chains in Sweden, accounting for around [80-90]% of total OTC retail sales. Two of these (Kronans Droghandel and Apoteket AB) are owned and controlled by two of the large wholesalers (Oriola and Apoteket AB).

Commission's assessment

(322) First, the Commission takes note that the majority of Swedish respondents from the demand-side expect that the price of pain management products will likely increase following the Transaction. One customer indicated that "*GSK and Novartis are two very strong suppliers of pain management products […] and have a powerful position with this merger to increase any prices in this segment with few competitors*",

while another highlighted that "*GSK and Novartis own two of the three largest brands in pain management in terms of sales value*".[232]

(323) Internal documents from the Parties show that […]. There is a high-degree of cross-usage for these brands. For instance an internal survey indicates that *[…]*.[233] Based on IMS data, in 2013, these five brands amounted to […] of the N2B market in Sweden, while the Parties' three brands amounted to […] of this market.[234] Furthermore, a strategy document from Novartis shows that […], and reads "[…]", clearly evidencing […].[235]

Conclusion

(324) In light of the above and of all available evidence, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market as regards non-narcotics and anti-pyretics (N2B) in Sweden, as it would lead to a creation or strengthening of dominance.

V.6.3.2. Horizontal overlaps – Topical pain management products

Table 16: Market size and market shares of the Parties in EEA affected countries based on a market for topical anti-rheumatics and analgesics (M2A), 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
France	2013	[80,000-90,000]	[10-20]%	[10-20]%	**[30-40]%**
	2012	[80,000-90,000]	[10-20]%	[10-20]%	**[30-40]%**
	2011	[80,000-90,000]	[10-20]%	[10-20]%	**[30-40]%**
Poland	2013	[50,000-60,000]	<[0-5]%	[20-30]%	**[20-30]%**
	2012	[40,000-50,000]	<[0-5]%	[10-20]%	**[10-20]%**
	2011	[50,000-60,000]	[0-5]%	[10-20]%	**[10-20]%**

Source: GSK, based on IMS data (Annex CH PM 7.2)

The Notifying Party's arguments

(325) In France, the Notifying Party claims that the combined entity will continue to face vigorous competition from a variety of international, generics, private label and local competitors, including Laboratoires Genevrier ([10-20]% market share), Merck ([5-10]%), Cooper France ([5-10]%), Pfizer ([5-10]%) and Sanofi ([5-10]%).

(326) In Poland, GSK claims that its topical product Ketoprom was discontinued in 2011, in connection with the product switching from OTC to prescription bound status. There were only minimal sales in 2013, and GSK […].

---

232 Replies to question 31 of Questionnaire Q1 – OTC Customers.

233 GSK's internal document, […], dated May 2014. Attachment of an email of […] to the case team, dated 23 December 2014.

234 2013 market shares for an N2B market (IMS data): *Alvedon*: [30-40]%; *Treo*: [20-30]%; *Voltaren*: [10-20]%; *Panodil*: [5-10]%; *Ipren*: [0-5]%.

235 Novartis' internal document, […], dated 23 September 2014. Annex 9 of an email of […] to the case team, dated 14 January 2015.

Commission's assessment

(327) In France, the Parties' combined market share is modest ([30-40]%), and there will remain a number of local and international competitors following the Transaction. In Poland, GSK will bring a very small increment resulting from sales of a product discontinued in 2011 (which generated almost no sales in 2012 and 2013).

Conclusion

(328) In light of the above and of all available evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as regards topical anti-rheumatics and analgesics (M2A).

V.7. GASTROINTESTINAL TREATMENTS

V.7.1. Relevant product markets

(329) Proton pump inhibitors ("PPIs"), H2 antagonists, alginates and antacids are considered to form part of a hierarchy of treatments for the diseases of the upper gastrointestinal area.

(330) Antacids, antiflatulents and carminatives belong to the ATC3 class A2A. These drugs are used for the treatment of mild digestive disorders, often for self-medication. This is therefore essentially an OTC market, although some products may also be reimbursable when bought on prescription.

Table 17: Acid-related gastrointestinal treatments, ATC classes

ATC Code	
A2A – Antacids, antiflatulents, carminatives	
A2A1	Plain antacids
A2A2	Plain antiflatulents
A2B – Antiulcerants	
A2B1	H2 antagonists
A2B2	Acid pump inhibitors

Source: Form CO

(331) GSK manufactures and markets mostly antacids, with products *ENO*, *Tums* and *Andrews*, and an H2 antagonist *Zantac* in a limited number of countries. It does not market PPIs. Novartis manufactures and markets *Pantoloc Control*, a PPI tablet, and also supplies to a limited extent *Bicarbonato Torrez Munoz*, an antacid that contains sodium bicarbonate and is sold only in Spain in the EEA.

The Notifying Party's arguments

(332) The Notifying Party takes the view that the market should be defined at the ATC4 level. The Notifying Party submits in particular that PPIs (A2B2) constitute a relevant product markets separate from antacids (A2A1). PPIs are used preventively to provide extensive relief of chronic heartburn and are much stronger whereas antacids are used reactively for immediate relief. The Notifying Party further submits that H2 antagonists (A2B1) should also be considered as forming a separate relevant product market from antacids, as they are normally used preventively and do not provide immediate relief.

Commission's assessment

(333) The Commission has previously considered that antacids, antiflatulants and carminatives may constitute a relevant product market.[236] However, there are also grounds to consider antacids separately from antiflatulants and carminatives, given that stomach acidity is a distinct condition from intestinal gas.[237]

(334) As regards proton pump inhibitors, the Commission concluded in the past that there were grounds to assess a product market definition comprising only PPIs.[238] In any event, the exact dimension of the product market definition can be left open for the purposes of the present decision, as the Transaction does not give rise to any competitive concerns under any potential market definition.

V.7.2. Relevant geographic markets

(335) In line with past decisions, the gastrointestinal markets are analysed at the national level.[239] The Notifying Party does not contest this.

V.7.3. Competitive assessment

(336) At ATC4 level, with antacids (A2A1), H2 antagonists (A2B1) and PPIs (A2B2) forming separate markets, the Parties' activities only overlap in Spain, which is not an affected market (combined share [10-20]%).

(337) In a broad market including all acid-related GI treatments (A2A+A2B), the Transaction would only result in five country-level overlaps[240] and would not result in any affected markets. Furthermore, the OTC JV will continue to face competition from global healthcare companies such as J&J, Bayer, Reckitt Benckiser and Sanofi.

(338) In light of the above and of all available evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as regards gastrointestinal treatments.

V.8. ANTIFUNGALS

(339) Antifungals are pharmaceuticals used to treat infections caused by a fungus or yeast. Fungus can grow anywhere on the body (for example, on the skin or nails) or inside the body (organs, mouth and throat). Dermatological antifungals are mainly used for the treatment of skin infections caused by fungus.

---

236 M.1878, *Pfizer/Warner-Lambert* (2000), paragraph 17.

237 M.5253, *Sanofi-Aventis/Zentiva* (2009), paragraph 35, M. 5953, *Reckitt Benckiser/SSL* (2004), paragraph 39.

238 M.4418, *Nycomed Group/Altana Pharma* (2006), paragraph 17.

239 *Opt. cit.*

240 Combined shares are as follows: Czech Republic ([0-5]%), Portugal ([5-10]%), Slovakia ([5-10]%), Spain ([10-20]%) and UK (<[0-5]%).

Table 18: Antifungals, ATC classes[241]

ATC Code	
D1A – Antifungals, dermatological	
D1A1	Topical dermatological antifungals
D1A3	Topical scalp antifungals

Source: Form CO

(340) GSK markets *Clotrimazole Glao*,[242] an antifungal cream that contains the active ingredient *clotrimazole* and is primarily indicated for the topical treatment of skin infections. GSK also supplies *Stieprox*,[243] a scalp antifungal treatment indicated for the treatment of seborrheic dermatitis. Novartis markets *Lamisil*, a topical antifungal preparation in various galenic forms (gel, spray or cream) with the active ingredient *terbinafine hydrochloride* which is primarily used to treat athlete's foot, ringworm and jock itch.

V.8.1. Relevant product markets

The Notifying Party's arguments

(341) The Notifying Party submits that the relevant product market should be defined at ATC4 level, as there is limited substitutability between topical, systemic and scalp antifungal products.

Commission's assessment

(342) In previous cases, the Commission has generally left the product market definition open while noting that topical dermatological antifungals (D1A1) may be viewed as forming a separate market from scalp antifungals (D1A3).[244]

(343) In any event, the exact product market definition can be left open for the purposes of the present decision, as the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any potential market definition set out above.

V.8.2. Relevant geographic markets

(344) In line with past decisions, the gastrointestinal markets are analysed at the national level.[245] The Notifying Party does not contest this.

V.8.3. Competitive assessment

(345) At ATC4 level (D1A1), the Transaction would lead to two affected markets in Latvia and in Poland:

---

241 ATC3 class D1A also includes systemic dermatological antifungals classified in ATC4 class D1A2, but this category only includes prescription products.

242 *Clotrimazole Glao* is sold OTC in Latvia and Poland.

243 *Stieprox* is sold OTC in Denmark, France, Latvia, Lithuania and Norway.

244 M.5253 *Sanofi-Aventis / Zentiva* (2009), paragraph 104.

245 *Opt. cit.*

Table 19: Market size and market shares of the Parties in EEA affected countries at ATC4 level (D1A1), 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Latvia	2013	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
	2012	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
	2011	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
Poland	2013	[9,000-10,000]	[10-20]%	[5-10]%	**[20-30]%**
	2012	[9,000-10,000]	[10-20]%	[10-20]%	**[30-40]%**
	2011	[10,000-11,000]	[10-20]%	[10-20]%	**[30-40]%**

Source: GSK, based on IMS data(Annexes CH AF 7.2)

(346) At ATC3 level (D1A1 + D1A3), the Transaction would result in six country-level overlaps in Denmark, France, Latvia, Lithuania, Norway and Poland:

Table 20: Market size and market shares of the Parties in EEA affected countries at ATC3 level (D1A1 + D1A3), 2011-2013

Country	Year	Market size (€ '000s)	GSK	Novartis business	Combined
Denmark	2013	[2,000-3,000]	<[0-5]%	[30-40]%	**[30-40]%**
	2012	[2,000-3,000]	<[0-5]%	[30-40]%	**[30-40]%**
	2011	[2,000-3,000]	<[0-5]%	[30-40]%	**[30-40]%**
France	2013	[30,000-40,000]	[20-30]%	[0-5]%	**[30-40]%**
	2012	[30,000-40,000]	[20-30]%	[0-5]%	**[30-40]%**
	2011	[30,000-40,000]	[20-30]%	[5-10]%	**[30-40]%**
Latvia	2013	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
	2012	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
	2011	[1,000-2,000]	[10-20]%	[10-20]%	**[20-30]%**
Lithuania	2013	[500-1,000]	[5-10]%	[20-30]%	**[30-40]%**
	2012	[500-1,000]	[5-10]%	[20-30]%	**[30-40]%**
	2011	[500-1,000]	[5-10]%	[30-40]%	**[30-40]%**
Norway	2013	[2,000-3,000]	<[0-5]%	[30-40]%	**[30-40]%**
	2012	[2,000-3,000]	<[0-5]%	[30-40]%	**[30-40]%**
	2011	[2,000-3,000]	<[0-5]%	[30-40]%	**[30-40]%**
Poland	2013	[9,000-10,000]	[10-20]%	[5-10]%	**[20-30]%**
	2012	[9,000-10,000]	[10-20]%	[10-20]%	**[30-40]%**
	2011	[10,000-11,000]	[10-20]%	[10-20]%	**[30-40]%**

Source: GSK, based on IMS data (Annex CH AF 7.3)

(347) The Transaction does not raise competitive concerns. First, there will be no Group 1 countries under all plausible market definitions. Second, the combined entity will continue to face vigorous competition from well-established international players such as J&J, Bayer, Teva, Myla, Merck, Omega Pharma and Sanofi. Local or regional competitors in the affected countries (such as Orifarm in Denmark, Pierre Fabre in France, Aflofarm in Poland), will also exert competitive pressure.

(348) In light of the above and of all available evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as regards antifungals.

V.9. CONCLUSION

(349) The Transaction raises serious doubts as to its compatibility with the internal market in relation to several OTC product areas: (i) Smoking cessation NRT products, (ii) Cold sore management topical antivirals, (iii) Cold and flu multi-symptom and nasal products, and (vi) Pain management products.

VI. COMMITMENTS

VI.1. Overview

(350) In order to address the serious doubts raised by the Transaction regarding several Vaccines and OTC areas, and render the concentration compatible with the internal market, GSK has modified the notified Transaction by entering into the following commitments, which are annexed to this decision and form an integral part thereof.

VI.1.1. Procedure

(351) On 7 January 2015, GSK submitted a package of commitments, containing the 8 elements as listed below. The commitments were amended and resubmitted on 9 January 2015 ("First Remedy Package").

Table 21: Vaccines – First Remedy Package of 9 January 2015

Area	#	Commitment	Countries
MenACWY	1	Divestiture of GSK's **Nimenrix** and **Mencevax** vaccines	Global
Diphteria and tetanus	2	Exclusive distribution agreement, […]-year supply agreement, and transfer of marketing authorizations for Novartis' **TD-Pur** and **Dif-Tet-All** dT vaccines[246]	Germany and Italy[247]

246 At the option of the purchaser, the remedy package includes a technology transfer for both vaccines.

247 At the option of the purchaser, the remedy package covers all EEA markets where TD-Pur and Dif-Tet-All are marketed.

Table 22: OTC– First Remedy Package of 9 January 2015

Area	#	Commitment	Countries
Cold and flu	1	Divestiture of GSK's **Coldrex** branded cold and flu products	EEA
	2	Divestiture of GSK's **Nezeril** and **Nasin** nasal sprays/drops products	Sweden
Smoking cessation	3	Divestiture of GSK's **NiQuitin** business	EEA (and Turkey)
Cold sore management	4	Divestiture of Novartis' **Fenivir, Penciclovir, Vectatone and Vectavir** products A temporary licence for **Fenistil**	EEA (and Turkey) UK and Netherlands
Allergy	5	Divestiture of Novartis' **[…]** topical nasal anti-allergic business	[…]
Pain management	6	Divestiture of GSK's **Panodil** OTC and prescription products	Sweden

(352) On 9 January 2015, the Commission launched a market test with the purpose of verifying whether the First Remedy Package was sufficient to clearly rule out the preliminary doubts identified by the Commission. In particular, the market test aimed at verifying whether the Commitments proposed in this case were overall suitable in that they contain all the necessary assets, provide for divestiture of a stand-alone business and are likely to lead to an emergence of a new player in the specific vaccine and OTC segments.

(353) In relation to Allergy, as detailed above in section V.5, the Commission concluded in its phase I investigation that the Transaction did not raise serious doubts as its compatibility with the internal market.

(354) Further to the market test, the First Remedy Package has been improved.

(355) On 21 January 2015, GSK submitted the final set of commitments ("Final Commitments"). The Final Commitments are annexed to this decision and form an integral part thereof.

Table 23: Vaccines – Final Commitments of 21 January 2015

Area	#	Commitment	Countries
Meningitis ACWY	1	Divestiture of GSK's **Nimenrix** and **Mencevax** vaccines	Global
Diphteria and tetanus	2	Exclusive distribution agreement, […]-year supply agreement, and transfer of marketing authorizations for Novartis' **TD-Pur** and **Dif-Tet-All** dT vaccines[248]	Germany and Italy[249]

248 At the option of the purchaser, the remedy package includes a technology transfer for both vaccines.

249 At the option of the purchaser, the remedy package covers all EEA markets where TD-Pur and Dif-Tet-All are marketed.

Table 24: OTC– Final Commitments of 21 January 2015

Area	#	Commitment	Countries
Cold and flu	1	Divestiture of GSK's **Coldrex** branded cold and flu products	EEA
	2	Divestiture of GSK's **Nezeril** and **Nasin** nasal sprays/drops products	Sweden
Smoking cessation	3	Divestiture of GSK's **NiQuitin** business	EEA (and Turkey)
Cold sore management	4	Divestiture of Novartis' **Fenivir, Penciclovir, Vectatone and Vectavir** products A temporary licence for **Fenistil**	EEA (and Turkey) UK and Netherlands
Pain management	5	Divestiture of GSK's **Panodil** OTC and prescription products	Sweden

VI.1.2. Framework for the Commission's assessment of the commitments

(356) Where a concentration raises serious doubts as to its compatibility with the internal market, the notifying parties may undertake to modify the concentration so as to remove the grounds for the serious doubts identified by the Commission with a view to having the transaction approved in phase I of the merger review procedure. In this respect, the Commission has the power to accept commitments provided that they are deemed capable of rendering the concentration compatible with the internal market.

(357) As set out in the Commission Notice on Remedies,[250] the commitments have to eliminate the competition concerns entirely and have to be comprehensive and effective from all points of view and must be capable of being implemented effectively within a short period of time as the conditions of competition on the market will not be maintained until the commitments have been fulfilled.[251]

(358) In assessing whether or not the remedies will restore effective competition, the Commission considers the type, scale and scope of the remedies by reference to the structure and the particular characteristics of the market in which the competition concerns arise.[252]

(359) The 7 elements of the Final Commitments are detailed and assessed below, in one section for each area, starting with Vaccines.

250 Commission Notice on remedies acceptable under Council Regulation (EEC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (OJ C 267, 22.10.2008, p. 1-27).

251 Commission Notice on remedies, paragraph 9.

252 Commission Notice on remedies, paragraph 12.

VI.2. COMMITMENTS – VACCINES – Men ACWY

VI.2.1. Commitments submitted by GSK

(360) With respect to MenACWY vaccines, in the Final Commitments, GSK committed to divest its entire MenACWY vaccine business, composed of its *Mencevax* PS vaccine and *Nimenrix* CJ vaccine, globally (the "MenACWY Divestment Business").

(361) GSK submitted that the MenACWY Divestment Business is currently integrated into GSK's vaccine business, which comprises some 30 human vaccines. Consequently, a carve-out of the MenACWY Divestment Business would have to be achieved prior to its transfer to the purchaser.

(362) More specifically, the MenACWY Divestment Business is composed in particular of:

(a) the master seed and working seed for *Neisseria Meningitidis* (antigen production) and the working seed for *Clostridium Tetani* (tetanus toxoid production for conjugation purposes);

(b) the trademarks and trade-dress for *Mencevax*;

(c) an exclusive, worldwide, royalty-free and perpetual trademark license with a right to sub-licence for the trademark *Nimenrix*, including the customary maintenance and renewal costs to be covered by GSK;

(d) the trade-dress for *Nimenrix*;

(e) worldwide licences to the relevant patent cases for the production of *Mencevax* and *Nimenrix*, on an exclusive basis when currently owned by GSK or Novartis, on a non-exclusive basis when owned by a third party;

(f) completed and on-going R&D studies including: […];[253]

(g) transfer of marketing authorisations for *Nimenrix* and *Mencevax* for all current marketing or pending marketing authorisations held by GSK;

(h) relevant customer, credit and other records;

(i) depending on the purchaser's needs, up to: (i) […] R&D/clinical personnel; (ii) […] manufacturing and quality personnel; (iii) […] commercial personnel for the EEA; and (iv) depending on the purchaser's needs, an additional […] commercial personnel for countries outside the EEA;[254]

(j) the following Key Personnel, depending on the purchaser's needs: Global Commercial Lead acting as General Manager; Medical Affairs Lead; Tender

---

253 For the completed studies, the purchaser will only need to take over the documentation of the studies and no further knowledge transfer is necessary. For the remaining ongoing studies, GSK offers, at the purchaser's preference, to either transfer those studies to the purchaser or to complete the studies.

254 GSK submits that, with the exception of […] Global Neisseria Marketing Director and […] Global Neisseria Sr. Marketing Managers for commercial, […] of the personnel is dedicated to the MenACWY Divestment Business.

Manager; Manufacturing Process Expert; Regulatory Affairs Lead; Clinical Development Lead;

(k) a technology transfer relating to the production process for the MenACWY Divestment Business to the purchaser over the course of a transitional period of up to […] years. The technology transfer will be of three stages: (i) transfer of the packaging process to the purchaser, (ii) transfer of secondary production processes (formulation, filling and lyophilisation) to the purchaser, combined with performing stability requirements and file preparation for the regulatory filings, and (iii) transfer of technology for primary production (production of bulk antigens, bulk carrier proteins, and conjugation) to the purchaser, combined with completion of stability work and file preparation for regulatory approval. Ring-fenced transitional services teams will support the technology transfer process. GSK will share in the cost for such technology transfer in line with the standards of the industry;

(l) a temporary supply agreement with *Nimenrix* and *Mencevax* and the relevant components thereof, mirroring the technology transfer timeline (finished vaccines until stage (i) is completed, then naked vials to be packaged until stage (ii) is completed, then bulk antigens and tetanus toxoid carrier proteins until stage (iii) is completed) at full manufacturing cost (to be determined), at current quality and quantity levels or quantities otherwise agreed between GSK and the purchaser that reflect changes in the customer demand.

(363) GSK further explains that, due to the integration into its other vaccines activities, which account for the large majority of the capacity usage, the MenACWY Divestment Business does not include the existing sites where *Nimenrix* and *Mencevax* are manufactured and R&D relating to these vaccines is undertaken.

VI.2.2. Assessment of the proposed remedies

The Notifying Party's arguments

(364) The Notifying Party considers that the Commitments completely remove the overlap between GSK and Novartis in MenACWY vaccines in the EEA. As a result of the implementation of these commitments, the potential anti-competitive effects resulting from the Transaction within this product area will be removed.

(365) The Notifying Party argues that the production of both *Nimenrix* and *Mencevax* takes place at three GSK facilities in Wavre, Belgium; Gödöllö, Hungary; and Rixensart, Belgium. None of those facilities is dedicated purely to the production of either *Nimenrix* or *Mencevax*: to the contrary, the Notifying Party submits that the production relating to *Nimenrix* and *Mencevax* accounts for only a […] fraction of the production activities at each of these facilities.

(366) The Notifying Party indicates that the Commitments do not provide for a full trademark divestiture for *Nimenrix* as the suffix *–rix* in Nimenrix is used for a variety of GSK vaccines. Due to the importance of the *–rix* suffix for GSK's vaccines business, the Nofiying Party expressed willingness to grant to the purchaser an exclusive and perpetual licence for *Nimenrix*.

Results of the market test and assessment of the commitments

(367) In general, no substantiated concerns were expressed as to the appropriateness of the commitments as a whole, although one competitor indicated that access to the relevant distribution channels is an important factor in a vaccines business: "*a large part of a continuing business is the access to the distribution channels, which there according to our understanding of the commitment is not made part of the divestment*".[255] Another competitor further noted that "*the acquirer would need to have significant resources and capabilities including but not limited to manufacturing, marketing, safety including surveillance monitoring, distribution, analytical testing capabilities and demonstrated capability in cold chain management*".[256]

(368) These concerns are addressed by the purchaser criteria, which constitute an important element of the Final Commitments, whereby the purchaser of the MenACWY Divestment Business shall in particular:

(a) be an established supplier of vaccines, which has existing R&D, manufacturing and distribution capabilities in the EEA;

(b) have an established presence in distribution channels typically used in the vaccines business in the EEA countries in which the MenACWY Divestment Business is active.

(369) The majority of respondents to the market test indicated that offering manufacturing assets is not necessary in order for a company already active in vaccines in Europe to become a viable and competitive player,[257] and that the technology transfer proposed by GSK is in line with the way technology transfers are typically conducted in the vaccine industry.[258] Given that the production relating to the MenACWY Divestment Business accounts for only a small fraction of the production activities at each of GSK's facilities, and that the purchaser criteria foresee that a suitable purchaser would have existing manufacturing capabilities in the EEA, the Commission takes the view that manufacturing assets are not necessary in the MenACWY Divestment Business.

(370) While the great majority of respondents did not foresee an impact of the *Nimenrix* licence (as opposed to a full trademark divestiture) on the viability or attractiveness of the MenACWY Divestment Business, a respondent indicated that "*acquisition of trademarked assets is generally preferred to a simple licensing, unless a licensor would agree to retain the trademark maintenance costs*".[259] This concern is addressed by the Final Commitments.

VI.2.3. Conclusion on the Commitments – Vaccines – Men ACWY

(371) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as regards MenACWY vaccines in the EEA.

---

255 Replies to question 1 of Questionnaire R2 - Market test of the Commitments – Vaccines.

256 Replies to question 1 of Questionnaire R2 - Market test of the Commitments – Vaccines.

257 Replies to question 2 of Questionnaire R2 - Market test of the Commitments – Vaccines.

258 Replies to question 3 of Questionnaire R2 - Market test of the Commitments – Vaccines.

259 Replies to question 4 of Questionnaire R2 – Market test of the Commitments – Vaccines.

VI.3. COMMITMENTS – VACCINES – Diphtheria tetanus

VI.3.1. Commitments submitted by GSK

(372) With respect to dT vaccines, GSK committed to conclude an exclusive distribution agreement of Novartis' *TD-Pur* and *Dif-Tet-All* bivalent dT vaccines business in Germany and Italy combined with a […] year supply agreement (the "dT Divestment Business"). At the purchaser's option, the provisions can be extended to the other EEA countries in which Novartis has a valid national marketing authorisation, namely Austria, Hungary, Poland, and Slovenia. Furthermore, primary production and formulation and secondary manufacturing for *TD-Pur* and *Dif-Tet-All* can be transferred at the purchaser's option.

(373) More specifically, the dT Divestment Business is composed of:

(a) the trademarks and trade dress for Novartis' *TD-Pur* and *Dif-Tet-All* in Germany and Italy and, dependent on the purchaser's choice as to the other countries in which Novartis has valid marketing authorisations in the EEA, the other trademarks at a Community level;

(b) transfer of the current national marketing authorisations for Novartis' *TD-Pur* and *Dif-Tet-All* in Germany and Italy, respectively, and, dependent on the purchaser's choice, the other countries for which Novartis holds a national marketing authorisation for bivalent dT vaccines in the EEA, namely Austria, Hungary, Poland and Slovenia;

(c) relevant customer, credit and other records;

(d) a […] year supply agreement of *TD-Pur* and *Dif-Tet-All* vaccines up to a volume per year that corresponds to Novartis' annual average 2011-2013 bivalent dT vaccines sales in the EEA +[30-40]% at full manufacturing cost (to be determined.

(e) at the option of the purchaser, the technology transfer relating to the secondary production processes, and additionally, the technology transfer and know-how for the primary production and formulation for *TD-Pur* and *Dif-Tet-All*.[260]

(374) GSK further explains that, due to the integration into Novartis' other vaccines activities, which account for the large majority of the capacity usage, the dT Divestment Business does not include the existing sites where *TD-Pur* and *Dif-Tet-All* are manufactured and R&D relating to these vaccines is undertaken.

VI.3.2. Assessment of the proposed remedies

The Notifying Party's arguments

(375) The Notifying Party considers that the Commitments completely remove the overlap between GSK and Novartis in dT vaccines (including together with T vaccines) in

---

260 In case the purchaser opts for the technology transfer, the dT Divestment Business would include personnel that the purchaser needs long-term (in addition to the temporary support offered for manufacturing of the dT products forming part of the dT Divestment Business).

Germany and Italy. As a result of the implementation of these commitments, the potential anti-competitive effects resulting from the Transaction within this product area will be removed.

(376) The Notifying Party also argues that only a minor part of the respective production capacity at all levels of production is used for in-house production of bivalent dT vaccines.

Results of the market test and assessment of the commitments

(377) In general, no substantiated concerns were expressed as to the appropriateness of the commitments as a whole.

(378) The majority of respondents to the market test indicated that offering manufacturing assets is not necessary in order for a company already active in vaccines in Europe to become a viable and competitive player,[261] and that the technology transfer proposed by GSK is in line with the way technology transfers are typically conducted in the vaccine industry.[262] Given that the production relating to dT Divestment Business accounts for only a minor part of GSK's respective production capacity at all levels of production, and that the purchaser criteria foresee that a suitable purchaser opting for the technology transfer would have existing manufacturing capabilities in the EEA, the Commission takes the view that manufacturing assets are not necessary in the MenACWY Divestment Business.

(379) The Commission considered whether the technology transfer should be mandatory in the dT Divestment Business in order to ensure a structural remedy. One respondent "*question[ed] whether a technology transfer for only the limited markets specified would be viable*",[263] while another submitted that "*markets are too small for the investment in technology transfer*".[264] In light of the above, and in particular of the complexity of technology transfers in the vaccines industry and the relative size of the affected markets compared to the investment required for the technology transfer, the Commission takes the view that the technology transfer should be left at the option of the purchaser.

VI.3.3. Conclusion on the Commitments – Vaccines – Diphtheria tetanus

(380) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as regards dT vaccines (including together with T vaccines) in Germany and Italy.

VI.4. COMMITMENTS – CONSUMER HEALTH - SMOKING CESSATION

VI.4.1. Commitments submitted by GSK

(381) In order to address the concerns in the Smoking cessation NRT area, GSK committed to divest the assets and rights comprising GSK's *NiQuitin*-branded products across the EEA (and Turkey).

---

261 Replies to question 13 of Questionnaire R2 - Market test of the Commitments – Vaccines.

262 Replies to question 14 of Questionnaire R2 - Market test of the Commitments – Vaccines.

263 Replies to question 12 of Questionnaire R2 - Market test of the Commitments – Vaccines.

264 Replies to question 16 of Questionnaire R2 - Market test of the Commitments – Vaccines.

(382) The Smoking cessation divestment business in the Final Commitments comprises the following:

(a) all tangible and intangible assets (including intellectual property rights), by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the divestment business, including notably the *NiQuitin* trademark in the EEA and Turkey;

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the divestment business;

(c) the technology necessary for the manufacture of *NiQuitin* patches and lozenges;

(d) contracts, leases, commitments and customer orders;

(e) contracts with suppliers, including contracts with contract manufacturers that produce *NiQuitin* orally-dissolving strips and gums;

(f) relevant customer, credit and other records;

(g) the Key Personnel, consisting of [...] employees with an option for […] more marketing employees; and

(h) at the option of the purchaser, arrangements for the supply of products and services by GSK or Affiliated Undertakings for a transitional period.

(383) In the light of the fact that GSK has no production facility dedicated exclusively to the EEA Smoking cessation divestment business, the commitment does not include any production facility.

VI.4.2. Assessment of the proposed remedies

The Notifying Party's arguments

(384) The Notifying Party considers that the commitments completely remove the overlap between GSK and Novartis in NRT products in the EEA. As a result of the implementation of these commitments, the potential anti-competitive effects resulting from the Transaction within this product area will be removed.

Results of the market test and assessment of the commitments

(385) In general, no substantiated concerns were expressed as to the appropriateness of the commitments as a whole.[265] A large number of respondents to the Commission's market test considered that the commitments were sufficiently attractive to attract suitable purchasers.[266]

(386) Remarks were made with respect to the duration of transitional supply agreements.[267] Some respondents stressed that a longer period was needed, for instance:

265 Replies to question 17 of Questionnaire R1 - Market test of the Commitments – OTC.

266 Replies to question 18 of Questionnaire R1 - Market test of the Commitments – OTC.

267 Replies to questions 5, 5.1 and 17 of Questionnaire R1 - Market test of the Commitments – OTC.

"a minimum transitional supply period of 3 years (ideally 5 years) as well as a reliable access to know-how, remanufacturing and the regulatory dossiers for the products in question are indispensable".[268]

(387) The market test indicated that the commitments ensure that, after the Transaction, a purchaser satisfying the purchaser criteria of the commitments can become an active competitive force against GSK in the market.[269] In this regard, one respondent to the market test pointed out that *"a strategic buyer with sufficient expertise in the OTC markets and tech transfer background should be able to compete".* The market test also indicated that *"selling the business to local players would probably not be sufficient to counteract the power of GSK/Novartis".*[270]

(388) Although some respondents pointed a potential need to transfer some manufacturing assets, notably "*as these manufacturing technologies are less commonly available*", a majority of respondents considered it was not necessary to include manufacturing assets in the package, provided a transition period was foreseen.[271]

(389) While for respondents, the Key personnel of […] people was deemed sufficient to ensure the viability and the competitiveness of the divestment business, it emerged from the market test that "*Sales & marketing personnel at least should be transferred with product to retain expertise and market knowledge*".[272]

(390) Further to the market test, the commitments were improved to ensure: (i) a sufficient transitional supply; and (ii) an option for the transfer of […] personnel.

(391) The Final Commitments provide at the option of the purchaser a transitional supply and/or transitional distribution agreement for *NiQuitin* gums and/or *NiQuitin* orally-dissolving strips until such time as the required changes to the marketing authorisations and artwork of these respective products have been completed.

(392) In addition, if the purchaser requires, the Notifying Party commits to transfer up to […] additional personnel with suitable skills and experience in […].

VI.4.3. Conclusion on the Commitments – OTC – Smoking cessation

(393) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as regards Smoking cessation NRT products.

VI.5. COMMITMENTS – CONSUMER HEALTH - COLD SORE MANAGEMENT

VI.5.1. Commitments submitted by GSK

(394) In order to address the concerns in the Cold sore management topical antivirals area, GSK committed to divest the assets and rights comprising Novartis' *Fenivir, Pencivir, Vectatone* and *Vectavir* branded products across the EEA (and Turkey), and to

---

268 Replies to question 5.1 of Questionnaire R1 - Market test of the Commitments – OTC.

269 Replies to question 19 of Questionnaire R1 - Market test of the Commitments – OTC.

270 Replies to question 19.1 of Questionnaire R1 - Market test of the Commitments – OTC.

271 Replies to questions 2.1 and 9 of Questionnaire R1 - Market test of the Commitments – OTC.

272 Replies to question 10 of Questionnaire R1 - Market test of the Commitments – OTC.

assign a temporary licence for *Fenistil* for use in the OTC Cold sore management topical antivirals area in the UK and the Netherlands.

(395) The Cold sore management divestment business in the Final Commitments comprises the following:

(a) all tangible and intangible assets (including intellectual property rights), by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the divestment business, including notably the trademarks *Fenivir, Pencivir, Vectatone* and *Vectavir* in the EEA;

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the divestment business;

(c) an exclusive license for the UK and the Netherlands of the Licensed Trademark *Fenistil* for use in the field of OTC Cold sore management topical antivirals for […], followed by a […] "black-out" period;

(d) contracts, leases, commitments and customer orders;

(e) relevant customer, credit and other records;

(f) the Hold Separate Manager, unless the purchaser does not require the Hold Separate Manager; and

(g) at the option of the purchaser, transitional agreements with the Parties or affiliated undertakings for the supply of products and services.

(396) In the light of the fact that GSK has no production facility dedicated exclusively to the Cold sore Divestment Business and that there are no employees dedicated exclusively to it, the commitments do not include any production facility or employee, save for the Hold Separate Manager.

VI.5.2. Assessment of the proposed remedies

The Notifying Party's arguments

(397) The Notifying Party considers that the Remedies completely remove the overlap between GSK and Novartis in Cold Sore products in the EEA. As a result of the implementation of these commitments, the potential anti-competitive effects resulting from the Transaction within this product area will be removed.

Results of the market test and assessment of the commitments

(398) In general, no substantiated concerns were expressed as to the appropriateness of the commitments as a whole.[273] Most respondents to the Commission's market test considered that the commitments were sufficiently attractive to attract suitable purchasers.[274] Respondents overall considered that the offering manufacturing assets and/or

273 Replies to question 17 of Questionnaire R1 - Market test of the Commitments – OTC.

274 Replies to question 18 of Questionnaire R1 - Market test of the Commitments – OTC.

personnel was not necessary in order for a company already active in consumer health in Europe to become a viable and competitive player.[275]

(399) However, several respondents raised concerns with respect to (i) the duration of the transitional supply agreement, (ii) the supply of penciclovir; (iii) the provisions related to the rebranding of *Fenistil* and the length of the non-compete clause.

(400) First, the First Remedy Package included transitional supply of the active ingredient by Novartis up to […], and transitional supply of finished topical antivirals for cold sore management up to […]. It emerged from the market test that a period of […] was needed to ensure a smooth transition.[276]

(401) Second, uncertainty in relation to sources of supply for the active ingredient penciclovir was mentioned as problematic.[277]

(402) Third, the large majority of respondents to the market test indicated that the proposed commitments ensure that, after the Transaction, the purchaser will be able to effectively compete with the combined entity.[278] One respondent, however, stressed that "*all brands and the associated products can be managed and returned to growth by a suitable buyer with innovation capability, the doubts pertaining to Fenistil [..] relate to the obligation to change visual identity and/or brand names immediately after acquisition. As the values of these business[es] primarily resides with the brand equity with loyal OTC shoppers and consumers, the risk depends on the specific obligations towards the seller with regards to the packaging changes*."[279]

(403) As regards the duration proposed to allow the suitable purchaser to re-brand the *Fenistil* brand, the large majority of the respondents indicated that a period of […] was not sufficient to ensure the viability and competitiveness of the business.[280] One of the respondents indicated that *"whilst it would be technically feasible to execute such a rebranding within the stipulated timeframe, this harbours significant risk for value erosion with consumers, shoppers and clients, given that it is a very old established OTC brand. […] would be reasonable to allow for appropriate diligence with consumers/shoppers and appropriate engagement with all associated stakeholders"; another that "This type of re-branding could take many years beyond the […]offered "*.[281]

(404) Finally, respondents indicated the need for a longer protection in order for the consumers to get used to the new brand, as "acquiring a brand for a short time would not allow the purchaser to effectively compete against the remaining brands".[282] "*The re-introduction of Fenistil after only […] could essentially restore GSK's original position in the market as if the divestiture did not take place*".

---

275 Replies to question 4 of Questionnaire R1 - Market test of the Commitments – OTC.

276 Replies to question 5.1 of Questionnaire R1 - Market test of the Commitments – OTC.

277 Replies to questions 5 and 17 of Questionnaire R1 - Market test of the Commitments – OTC.

278 Replies to question 2 of Questionnaire R1 - Market test of the Commitments – OTC.

279 Replies to question 2.1 of Questionnaire R1 - Market test of the Commitments – OTC.

280 Replies to question 11 of Questionnaire R1 - Market test of the Commitments – OTC.

281 Replies to question 11.1 of Questionnaire R1 - Market test of the Commitments – OTC.

282 Replies to question 11.1 of Questionnaire R1 - Market test of the Commitments – OTC.

(405) Further to the market test, the commitments were improved so as to ensure: (i) a sufficient transitional supply; (iii) provisions for the supply of penciclovir; and (ii) sufficient time for the rebranding of *Fenistil*.

(406) The Final Commitments extended the duration of the transitional supply agreement for both penciclovir and the finished products to cover a period of […] months as well as additional […] months if required by the purchaser.

(407) Then, the Final Commitments foresee an assignable and revocable supply agreement with a suitable third-party manufacturer for the supply of the active ingredient penciclovir.

(408) Furthermore, the Notifying Party committed to assign the exclusive licence for the UK and the Netherlands for […] followed by the […] black-out period. [283]

VI.5.3. Conclusion on the Commitments – OTC – Cold sore management

(409) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as regards Cold sore topical antivirals.

VI.6. COMMITMENTS – CONSUMER HEALTH - COLD AND FLU multi-symptoms treatments

VI.6.1. Commitments submitted by GSK

(410) In order to address the concerns in the Cold and Flu market, GSK committed to divest the assets and rights comprising GSK's Coldrex-branded cold and flu products which is marketed in Bulgaria, Croatia, Czech Republic, Estonia, Finland, Hungary, Latvia, Lithuania, The Netherlands, Poland, Romania, Slovak Republic and Slovenia.

(411) The Cold and Flu Divestment Business in the Final Commitments comprises the following:

(a) tangible assets, including all finished goods inventory, supplies, sales and promotional material;

(b) the *Coldrex* and *Coldrex Lary* trademarks in the EEA;

(c) all copyrights in the EEA related to the Cold and Flu Divestment Business, covering, *inter alia*, information booklets and website content;

(d) rights to any domain name related to the Cold and Flu Divested Business in the EEA;

(e) all know-how for the manufacturing of products by the Cold And Flu Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in the EEA;

---

283 In addition, the Notifying Party committed to refrain from launching any other *Fenistil*-branded OTC product in the United Kingdom […]. In the Netherlands, Novartis sells *Fenistil*-branded drops for allergic reaction that do not form part of the remedy.

(f) an irrevocable, assignable, sub-licensable and royalty-free license to all copyrights and patents and access to all know-how for exclusive use in and limited to the EEA relating to any existing pipeline product intended to be marketed in the EEA under the *Coldrex and Coldrex Lary* brands;

(g) a transfer or assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organization and held by the Notifying Party that are exclusively necessary to manufacture and/or sell the products belonging to the Cold and Flu Divestment Business;

(h) a transfer to a third party manufacturer or the purchaser itself, at the purchaser's election, of all manufacturing technology and know-how necessary to enable the third party manufacturer or the purchaser itself at the purchaser's election, to manufacture *Coldrex or Coldrex Lary* products for the purchaser for the Cold and Flu Divestment Business;

(i) a transitional contract manufacturing and packaging agreement with the Purchaser for the *Coldrex* products until […] or for […] months, with the possibility of a […] months extension at the option of the purchaser. The transitional contract manufacturing agreement would be concluded on a reasonable […], and in accordance with good industry practice;

(j) the transfer of the supply and packaging agreements in place with third party manufacturers relating to *Coldrex and Coldrex Lary* products or, at the choice of the purchaser, GSK will enable the purchaser to conclude a new supply and packaging agreement with the third party manufacturers in relation to *Coldrex and Coldrex Lary* products. In the event the third party manufacturers refuse the transfer of the contracts in place with GSK to the purchaser, the former will enter into a back-to-back supply agreement […] with the latter;

(k) the existing contracts with customers in the EEA relating to the Cold and Flu Divestment Business, to the extent the customers accept such a transfer;

(l) relevant customer list and customer credits;

(m) the Hold Separate Manager, unless the purchaser does not require the Hold Separate Manager.

(412) In the light of the fact that GSK has no production facility dedicated exclusively to the Cold and Flu Divestment Business and that there are no employees dedicated exclusively to it, the commitment does not include any production facility or employee, save for the Hold Separate Manager.

VI.6.2. Assessment of the proposed remedies

The Notifying Party's arguments

(413) The Notifying Party submits that the Commitment completely remove the overlap between GSK and Novartis in Estonia, Hungary, Latvia and Lithuania and would significantly reduce the overlap between GSK and Novartis in Romania and the Slovak Republic.

Results of the market test and assessment of the commitments

(414) In general, no substantiated concerns were expressed as to the appropriateness of the commitments as a whole. The vast majority of respondents to the market test consider the proposed remedy can address the concerns raised by the Commission and that the Cold and Flu Divestment Business, as structured in the commitments, is a viable business. [284]

(415) The large majority of respondents to the market test indicated that the proposed commitments ensure that, after the Transaction, a purchaser satisfying the purchaser criteria can become an active competitive force against GSK in the cold and flu segment.[285] However, the results of the market test indicated that the Divestment Package implies risks related to the duration of the transitional supply.[286]

(416) The large majority of the respondents also indicated that neither manufacturing assets nor personnel are considered as necessary for the viability of the Cold and Flu Divestment Business as *"the products […] are standard and readily available. A […] year commitment to continue supply by the seller should suffice to switch production to a new supplier, assuming that the regulatory files are in order, which can only be assessed in due diligence"*.[287] The transitional agreement as provided for by, i.e. until the relevant authorisations have been obtained by the purchaser or for a […] months period, with the possibility of further […] months extension, addresses this issue.

(417) As for the geographic scope of the commitment, while some respondents to the market test pointed out that full divestiture of the *Coldrex* brand across the EEA is not necessary, a significant number asserted the contrary. [288] According to one respondent, *"it is relevant for one company to own the brand in the whole of EEA. OTC brands are typically managed at the global or regional level, which provides efficiencies in manufacturing, maintaining regulatory dossiers, and developing new products/ technologies and marketing campaigns. The complexity of managing pharmaceuticals demands gaining efficiencies across many functions in order to ensure continued profitability and growth of the brand. A brand that is limited to only a few countries can become orphaned, thus limiting its ability to gain market shares."*[289]

(418) Finally, respondent to the market test do not foresee difficulties or risks in the implementation of the commitments.[290]

VI.6.3. Conclusion on the Commitments – OTC – Cold and flu multi-symptoms treatments

(419) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as re-

284 Replies to questions 1 and 2 of Questionnaire R1 - Market test of the Commitments – OTC.

285 Replies to question 19 of Questionnaire R1 - Market test of the Commitments – OTC.

286 Replies to question 17 of Questionnaire R1 - Market test of the Commitments – OTC.

287 Replies to questions 4 and 4.1 of Questionnaire R1 - Market test of the Commitments – OTC.

288 Replies to question 7 of Questionnaire R1 - Market test of the Commitments – OTC.

289 Replies to question 7.1 of Questionnaire R1 - Market test of the Commitments – OTC.

290 Replies to question 17 of Questionnaire R1 - Market test of the Commitments – OTC.

gards multi-symptom products and topical nasal products in Estonia, Finland, Hungary, Latvia, Lithuania, and Romania.

VI.7. COMMITMENTS – CONSUMER HEALTH - COLD AND FLU nasal products

VI.7.1. Commitments submitted by GSK

(420) In order to address the concerns in the Cold and Flu market in Sweden, GSK committed to divest the assets and rights comprising GSK's cold & flu products sold under the *Nasin* and *Nezeril* trademarks in Sweden (the "Swedish Divested Business").

(421) The Swedish Divestment Business comprises the following:

(a) tangible assets, including all finished goods inventory, supplies, sales and promotional material;

(b) the *Nasil* and *Nezeril* trademarks in Sweden;

(c) all copyrights in the EEA related to the Swedish Divestment Business, covering, *inter alia*, information booklets and website content;

(d) rights to any domain name related to the Swedish Divested Business in the EEA;

(e) all know-how for the manufacturing of products by the Swedish Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in Sweden;

(f) a transfer or assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organization and held by the Notifying Party that are exclusively necessary to manufacture and/or sell the products belonging to the Swedish Divestment Business;

(g) a transfer to the third party […] (or, at the purchaser's election, an alternative third-party supplier or the purchaser itself) of all manufacturing technology and know-how necessary to enable […] (or, at the purchaser's election, an alternative third-party supplier or the purchaser itself) to manufacture the divested products;[291]

(h) the relevant portions of all contracts with third-party suppliers of products or services to the Swedish Divestment Business, including contracts with third-party contract manufacturers. In the event that such arrangements cannot be made, the Notifying Party is prepared to conclude back-to-back supply agreements with the purchaser […];

(i) the existing contracts with customers in the EEA relating to the Cold and Flu Divestment Business, to the extent the customers accept such a transfer;

(j) customer list and customer records;

291 Currently the divested products are manufactured by a third party, […].

(k) the Hold Separate Manager, unless the purchaser does not require the Hold Separate Manager;

(l) transitional supply and/or transitional distribution agreements for the products to enable the continued sale of the products under the *Nezeril* and *Nasin* brands. The transitional agreement shall be in place until […] or for […] months, with the possibility of a […] months extension at the option of the purchaser. The transitional agreement(s) will be entered on a reasonable […], in accordance with good industry practice.

VI.7.2. Assessment of the proposed remedies

The Notifying Party's arguments

(422) The Notifying Party submits that the Commitment completely remove the overlap between GSK and Novartis as regards topical nasal decongestants in Sweden.

Results of the market test and assessment of the commitments

(423) In general, no substantiated concerns were expressed as to the appropriateness of the commitments as a whole. The vast majority of respondents to the market test consider the proposed remedy can address the concerns raised by the Commission and that the Cold and Flu Divestment Business, as structured in the commitments, is a viable business.[292] With respect to the duration of the supply agreements, one respondent to the market test stressed that *"a minimum transitional supply period of 3 years (ideally 5 years) as well as a reliable access to know-how, remanufacturing and the regulatory dossiers for the products in question are indispensable"*.[293]

(424) According to the results of the market test, the proposed commitments ensure that, after the Transaction, the purchaser will exert a significant competitive constrain on the combined entity.[294] Several respondents pointed out that the planned transfer of manufacturing technology to a third party provides sufficient guarantees to the purchaser. However, according to one respondent, *"a period of back-up sourcing should be provided upon transfer to a new site in order to avoid product disruption."*[295] This issue is addressed by the proposed transitional supply and/or distribution agreements proposed by the Notifying Party.

(425) The large majority of the respondents also indicated that neither manufacturing assets nor personnel are considered as necessary for the viability of the Swedish Divestment Business.[296]

(426) Finally the large majority of the respondents indicated that they do not foresee difficulties or risks in the implementation of the commitments.[297]

---

292 Replies to questions 17 and 19 of Questionnaire R1 - Market test of the Commitments – OTC.

293 Replies to question 5.1 of Questionnaire R1 - Market test of the Commitments – OTC.

294 Replies to questions 19 of Questionnaire R1 - Market test of the Commitments – OTC.

295 Replies to questions 8 and 8.1 of Questionnaire R1 - Market test of the Commitments – OTC.

296 Replies to question 4 of Questionnaire R1 - Market test of the Commitments – OTC.

297 Replies to questions 17 of Questionnaire R1 - Market test of the Commitments – OTC.

VI.7.3. Conclusion on the Commitments – OTC – Cold and flu nasal products

(427) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as regards topical nasal products in Sweden.

VI.8. COMMITMENTS – CONSUMER HEALTH – ALLERGIC RHINITIS LATVIA

(428) The Notifying Party also submitted in its First Remedy Package a commitment to solve the competition concerns preliminary identified as regards topical AR products in Latvia. The commitment consisted in the divestiture of the *[…]*.

(429) However, following the assessment of new evidences submitted by the Notifying Party, and included in the competitive assessment in section V.5.3, the Commission concluded that the Transaction does not raise serious doubts as to its compatibility with the internal market with regards to topical AR products in Latvia. The corresponding commitment proposed in the First Remedy Package is therefore not necessary.

VI.9. COMMITMENTS – CONSUMER HEALTH - PAIN MANAGEMENT

VI.9.1. Commitments submitted by GSK

(430) As regards the Pain management segment, GSK committed to divest assets and rights comprising GSK's *Panodil*-branded pain management products in Sweden, including both prescription and OTC products (the "Pain Management Divestment Business").

(431) The Pain Management Divestment Business includes in particular:

(a) the *Panodil* trademarks in Sweden;

(b) all know-how for the manufacturing of products, as well as know-how associated with obtaining manufacturing and marketing approvals for those products in Sweden;

(c) relevant customer, credit and other records, including existing contracts with customers in Sweden;

(d) all licences, permits, and authorisations issued by any governmental organisation and held by GSK that are exclusively necessary to manufacture and/or sell the products;

(e) the obligation for the purchaser to change the artwork and trade dress for the divested products within the period of […] months of closing (further improved to […] months in the Final Commitments).

(432) Neither personnel[298] nor manufacturing assets are included in the Pain Management Divestment Business.

---

298 With the exception of the Hold Separate manager (unless not required by the purchaser).

VI.9.2. Assessment of the proposed remedies

The Notifying Party's arguments

(433) The Notifying Party considers that the Commitments remove almost entirely the overlap between GSK and Novartis in an N2B market in Sweden. As a result of the implementation of these commitments, the potential anti-competitive effects resulting from the Transaction within this product area will be removed.

Results of the market test and assessment of the commitments

(434) In an N2B market, the 2013 market shares are as follows:

(a) GSK's *Alvedon*: [30-40]%;

(b) Novartis' *Voltaren*: [10-20]%;

(c) GSK's *Panodil*:[5-10]%.

(435) The Commission therefore takes the view that the divestment of GSK's *Panodil* as foreseen in the Commitments removes almost entirely Novartis' increment in an N2B market in Sweden.

(436) Overall, the market test indicated that the Commitments will remove the competition concerns raised by the Transaction, although one competitor mentioned that "*although the divestiture of a pain management brand would remove competition concerns in Sweden, the choice of Panodil may not be best suited as a viable competitor*".[299] Nonetheless, the Pain Management Divestment Business removes the overlap brought by the Novartis Consumer Health Business almost entirely.

(437) No substantiated concerns were expressed as to the appropriateness of the commitments as a whole. A number of respondents considered that the duration of […] months to change the artwork and trade dress is not sufficient. The most quoted minimum duration amongst these respondents was […] months.[300] Eventually, the Final Commitments addressed these concerns by increasing the duration to […] months.

(438) While a competitor submitted that "*the only way to make the divested business viable would be to extend the geographic scope of the divestiture; for instance by including other Nordic countries (e.g., Norway and Denmark)*",[301] a number of respondents to the market test confirmed that the geographic scope (Sweden) was sufficient.[302] Finally, a number of respondents confirmed that both OTC and prescription products should be divested to ensure the viability and competitiveness of the Divestment Business.[303]

299 Replies to questions 1 and 1.1 of Questionnaire R1 - Market test of the Commitments – OTC.

300 Replies to question 16 of Questionnaire R1 - Market test of the Commitments – OTC.

301 Replies to question 3 of Questionnaire R1 - Market test of the Commitments – OTC.

302 Replies to question 14 of Questionnaire R1 - Market test of the Commitments – OTC.

303 Replies to question 15 of Questionnaire R1 - Market test of the Commitments – OTC.

VI.9.3. Conclusion on the Commitments – OTC – Pain management

(439) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis as regards pain management products in Sweden.

VI.10. COMMITMENTS – Conclusion

(440) In light of the above, the Commission concludes that the Final Commitments are sufficient to eliminate all serious doubts identified in the competition analysis.

(441) The commitments in section B of the Final Commitments for MenACWY; section B of the Final Commitments for dT; section B of the Final Commitments for smoking cessation, section B of the Final Commitments for cold sore management; section B of the Final Commitments for cold and flu multi-symptoms treatments; section B of the Final Commitments for cold and flu nasal products; section B of the Final Commitments for pain management of the respective Annexes constitute conditions attached to this decision, as only through full compliance therewith can the structural changes in the relevant markets be achieved. The other commitments set out in the Annexes constitute obligations, as they concern the implementing steps which are necessary to achieve the modifications sought in a manner compatible with the internal market.

VII. CONDITIONS AND OBLIGATIONS

(442) Under the first sentence of the second subparagraph of Article 6(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the Commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the internal market.

(443) The achievement of the measure that gives rise to the change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's decision declaring the concentration compatible with the internal market no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(6)(b) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.

(444) In accordance with the basic distinction between conditions and obligations, the decision in this case is conditional on full compliance with the requirements set out in section B of the Final Commitments for MenACWY; section B of the Final Commitments for dT; section B of the Final Commitments for smoking cessation, section B of the Final Commitments for cold sore management; section B of the Final Commitments for cold and flu multi-symptoms treatments; section B of the Final Commitments for cold and flu nasal products; section B of the Final Commitments for pain management of the respective Annexes, whereas the remaining sections of the Final Commitments constitute obligations on the Parties.

VIII. CONCLUSION

(445) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the Final Commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in sections B of the Final Commitments for MenACWY; section B of the Final Commitments for dT; section B of the Final Commitments for smoking cessation, section B of the Final Commitments for cold sore management; section B of the Final Commitments for cold and flu multi-symptoms treatments; section B of the Final Commitments for cold and flu nasal products; section B of the Final Commitments for pain management annexed to the present decision and with the obligations contained in the other sections of said commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission
(Signed)
Margrethe VESTAGER
Member of the Commission

January 21, 2015

Case COMP/M.7276
GlaxoSmithKline/Novartis Vaccines Business (Excl. Influenza)

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "Merger Regulation"), GlaxoSmithKline plc. ("GSK") hereby enters into the following Commitments (the "Commitments") vis-à-vis the European Commission (the "Commission") with a view to rendering the proposed acquisition of Novartis AG's ("Novartis") global human vaccines business, excluding flu vaccine products (the "Novartis Vaccines Business") (the "Transaction") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(2) of the Merger Regulation to declare the Transaction compatible with the internal market and the functioning of the EEA Agreement (the "Decision"), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "Remedies Notice").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by GSK or Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "Consolidated Jurisdictional Notice").

Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 6 (a), (b) and (c) and described more in detail in the Schedule.

Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

Closing Period: the period of 3 month from the approval of the Purchaser and the terms of sale by the Commission.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divestment Business: the business or businesses as defined in Section B and in the Schedule which GSK commits to divest.

Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., the notifying party, incorporated in the UK, with registered offices at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Business, as listed in the Schedule, including the Hold Separate Manager.

Monitoring Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated in Switzerland, with registered offices at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Personnel: a number of full-time equivalents matching the number of full-time equivalents currently employed by the Divestment Business that will be transferred long-term to the Purchaser, except for a smaller number of employees active in R&D.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing more in detail the Divestment Business.

Technical Expert: one or more natural or legal person(s), appointed by and reporting to the Monitoring Trustee, who has/have industry expertise relevant to the Divestment Business. The Technical Expert will, if this is deemed necessary by the Monitoring Trustee,[1] assist and advice the Monitoring Trustee with regard to all technical aspects related to the Divestment Business. All information provided to the Monitoring Trus-

1 Subject to the Commission's view and final decision on the necessity of involving the Technical Expert.

tee may also be exchanged with the Technical Expert. The Technical Expert will be independent of GSK and will not have or be exposed to any conflict of interest. If the Monitoring Trustee has the necessary technical expertise, Monitoring Trustee and Technical Expert can be the same natural or legal person. GSK and Purchaser shall have the right to be heard with any reasoned objections against technical expert candidates, *e.g.*, lack of competence or conflict of interest. In cases of controversy between GSK and the Monitoring Trustee, and/or Purchaser and the Monitoring Trustee as to the suitability of the technical expert candidate, the Commission will decide on the matter.

Transitional Services: The services to be provided to the Purchaser by GSK in the period following Closing, including, but not limited to, R&D, Manufacturing, and Commercial services required for the supply of *Nimenrix* and *Mencevax* and their phased technology transfer to the Purchaser.

Transitional Services Team: GSK personnel providing the Transitional Services.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The commitment to divest and the Divestment Business

Commitment to divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. [*Not applicable*]

4. GSK shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 30; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

5. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of

exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and definition of the Divestment Business

6. The Divestment Business consists of GSK's *Nimenrix* and *Mencevax* meningococcal MenACWY vaccines businesses, as further defined in the Schedule. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets and staff that are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

   (a) all tangible and intangible assets (including intellectual property rights) that are necessary to ensure the viability and competitiveness of the Divestment Business under the control of the Purchaser;

   (b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;

   (c) all contracts, leases, commitments, and customer orders of the Divestment Business; all customer, credit, and other records of the Divestment Business; and

   (d) the Personnel.

7. The transfer of the Divestment Business will be accompanied by a phased technology transfer of the Divestment Business' production processes to the Purchaser of up to […] after Closing, with interim supply of *Mencevax*, *Nimenrix* and their component elements pending the completion of the technology transfer process at full manufacturing cost (to be determined), ex-works, at current quality and quantity levels or quantities otherwise agreed between GSK and the Purchaser that reflect changes in customer demand, all as overseen by the Monitoring Trustee. In the event of a dispute between GSK and the Purchaser regarding the full manufacturing cost or the quantities, the matter shall be referred to the Monitoring Trustee (together with the Technical Expert) for resolution. To support the technology transfer process, GSK will provide Transitional Services for R&D/clinical, manufacturing and commercial services. GSK also offers to support the initial commercialisation of the product and physically distribute *Mencevax* and *Nimenrix* at the Purchaser's direction for a transitional period of up to […] after Closing. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such service and supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside GSK's operations.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

8. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Busi-

ness, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular GSK undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, any resources required by the Purchaser for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business, and not to solicit or move any Personnel to GSK's remaining business. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Business, GSK shall provide a reasoned proposal to replace the person or persons concerned to the Purchaser, Commission, and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.

Hold-separate obligations

9. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the businesses it is retaining and to ensure that unless explicitly permitted under these Commitments, in particular in relation to the Transitional Services: (i) management and staff of the businesses retained by GSK have no involvement in the Divestment Business and (ii) the Key Personnel and Personnel of the Divestment Business have no involvement in any meningococcal vaccines business retained by GSK and do not report to any individual outside the Divestment Business.

10. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the businesses which GSK is retaining. Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager. The Hold Separate Manager, who shall be part of the Key Personnel, shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK (save with respect to the Transitional Services, see above). The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee, who, in case the Monitoring Trustee does not have the necessary industry expertise, is assisted by the Technical Expert. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 8(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

11. [*Not applicable*]

Ring-fencing

12. GSK shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business and that any such Confidential Information obtained by GSK before the Effective Date will be eliminated and not be used by GSK. In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law. In order to ensure the effectiveness of the ring-fencing measures, in light of the Transitional Services required, GSK commits to create effective ring-fencing mechanism.

Non-solicitation clause

13. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Business for a period of […] after Closing.

Due diligence

14. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

(a) provide to potential purchasers sufficient information as regards the Divestment Business;

(b) provide to potential purchasers sufficient information within the boundaries of applicable data privacy regulation relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

15. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

16. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

17. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

(a) The Purchaser shall be independent of and unconnected to GSK and its Affiliated Undertakings (this being assessed having regard to the situation following the divestiture).

(b) The Purchaser shall be an established supplier of vaccines, which has existing R&D, manufacturing and distribution capabilities in the EEA.

(c) In particular, the Purchaser shall have an established presence in distribution channels typically used in the vaccines business in the EEA countries in which the Divestment Business is active, namely Austria, Belgium, Croatia, Finland, France, Germany, Hungary, Iceland, Italy, Luxembourg, Malta, Norway Slovenia, and UK.

(d) The Purchaser shall have expertise and experience in working with authorities in the EEA in order to obtain necessary regulatory approvals (*e.g.*, marketing authorizations), and in having relevant interactions with relevant national bodies in the EEA that decide on recommendations and the vaccination schedules.

(e) The Purchaser shall have the financial resources, proven expertise, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with GSK and other competitors;

(f) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor does it give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

18. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets or parts of the Personnel, or by substituting one or more Assets or parts of the Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment procedure

19. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Transaction before the appointment of a Monitoring Trustee. The Monitoring Trustee shall be assisted by the Technical Expert with regard to all technical questions related to the Divestment Business. The Technical Expert shall be appointed by and report to the Monitoring Trustee (with GSK and Purchaser having the right to be heard as to the suitability of the technical expert candidates). In cases of controversy between GSK and the Monitoring Trustee, and/or Purchaser and the Monitoring Trustee as to the suitability of the technical expert candidate, the Commission will decide on the matter.

20. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

21. The Trustee shall:

(i) at the time of appointment, be independent of GSK and its Affiliated Undertakings;

(ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(iii) neither have nor become exposed to a Conflict of Interest.

22. The Trustee and the Technical Expert shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

23. No later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

24. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by GSK

25. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 22 of these Commitments.

Trustee nominated by the Commission

26. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

27. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GSK give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

28. The Monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(ii) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 10 of these Commitments;

(c) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business, save in order to carry out the required Transitional Services,

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK, save in order to carry out the required Transitional Services and

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary (beyond what is necessary for carrying out the required Transitional Services) to allow GSK to carry out the divestiture or as the disclosure is required by law;

(d) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and GSK or Affiliated Undertakings;

(iii) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(iv) be involved in the divestiture process by reviewing and assessing potential purchasers as well as the progress of the divestiture process and verifying that, dependent on the stage of the divestiture process:

(a) potential purchasers receive sufficient and correct information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(b) potential purchasers are granted reasonable access to the Personnel.

(v) Additionally, the Monitoring Trustee shall act as a contact point for any disagreements that might arise in negotiations between GSK and Purchaser. To that end, the Monitoring Trustee shall be assisted by the Technical Expert.

(vi) act as a contact point for any requests by third parties, in particular potential purchasers in relation to the Commitments;

(vii) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Personnel so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(viii) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(ix) within one week after receipt of the documented proposal referred to in paragraph 18 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser

(x) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

29. If the Monitoring and Divestiture Trustee are not the same (legal or natural) persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

30. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 17 and 18 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

31. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report

written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

IV. Duties and obligations of the Parties

32. GSK shall provide and shall cause its advisors to provide the Trustee and the Technical Expert with all such co-operation, assistance and information as the Trustee and the Technical Expert may reasonably require to perform its tasks. The Trustee and the Technical Expert shall have full and complete access to any of GSK's or the Divestment Business's books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments, and GSK and the Divestment Business shall provide the Trustee and the Technical Expert upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee and the Technical Expert two or more offices on their premises and shall be available for meetings in order to provide the Trustee and the Technical Expert with all information necessary for the performance of its tasks.

33. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

34. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

35. GSK shall indemnify the Trustee and its employees and agents as well as the Technical Expert (each an "Indemnified Party") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the performance of the Trustee's and Technical Expert's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, Technical Expert, its employees, agents or advisors.

36. At the expense of GSK, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the

Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 29 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

37. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

38. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties of the identity and the tasks of the Monitoring Trustee.

39. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

40. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

(a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

(b) GSK may, with the prior approval of the Commission, replace the Trustee.

41. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraph 19-26 of these Commitments.

42. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The review clause

43. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

44. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into force

45. The Commitments shall take effect upon the date of adoption of the Decision.

Brussels, January 21,2015

[…]
duly authorised for and on behalf of
GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business (comprising GSK's *Nimenrix* and *Mencevax* meningococcal MenACWY vaccines businesses) is currently integrated into GSK's vaccine business, which comprises some 30 human vaccines against a large variety of bacterial and viral diseases. It is not embodied in a specified legal entity. Consequently, a carve-out of the Divestment Business will have to be achieved prior to its transfer to the Purchaser. Dedicated assets and resources will be carved out by GSK prior to the sale to the Purchaser.

2. In accordance with paragraph 6 of these Commitments, the Divestment Business includes, but is not limited to:

(a) the following main tangible assets:

- the master seed and working seed for *Neisseria Meningitidis*, the bacteria strains from which the *Nimenrix* and *Mencevax* polysaccharides are developed and the working seed for *Clostridium Tetani* from which the tetanus toxoid used in the conjugation of *Nimenrix* is developed, as part of the technology transfer process.

- depending on the Purchaser's existing facilities and equipment[2], a site in […], that could be transformed into a vaccines production and R&D facility for the Divestment Business if Purchaser is interested.

(b) the following main intangible assets:

- the trademarks *ACWYVAX* and *Mencevax*, (as set out in Annex 1);

- and an exclusive, worldwide, royalty-free and perpetual trademark license with a right to sub-license for the trademark *Nimenrix* (as set out in Annex 1) without restrictions to its geographical use, the sale of the license, or any other restriction limiting the Purchaser's business practices in line with the standards of the industry, beyond the applicable laws and regulations in force in the respective territories, and including the customary maintenance and renewal costs associated with the *Nimenrix* trademark to be covered by GSK;

- the trade-dress (*i.e.*, total image or overall design or appearance of product or its packaging) for *Nimenrix* and *Mencevax*;

- the registered domain names for *Mencevax* (Acwyvax.co.uk, mencevax.com, MenCevax.de, and mencevax.eu) and *Nimenrix* (nimenrix.com, nimenrix.cz, nimenrix.co.uk and nimenrix.de);

---

2 Subject to review and assessment of the Monitoring Trustee and the Technical Expert.

- exclusive worldwide licenses with a right to sub-license for the following GSK-owned patent cases (as set out in Annex 2) covering: (i) a specific conjugation process used for MenA and MenC in *Nimenrix*; (ii) the immunogenic composition of a vaccine containing conjugated antigens with particular saccharide sizes; (iii) the immunogenic composition comprising conjugated antigens; conjugated by different methods such that some are directly conjugated and some are conjugated through linkers; (iv) the immunogenic composition comprising conjugated antigens with different ratios of saccharide protein; (v) Serum Bacterial Antibody ("SBA") assays for MenA and MenW; and (vi) co-administration with DTP based vaccines;

- exclusive worldwide licenses with a right to sub-license for patent cases (currently owned by Novartis and covering *Nimenrix*), which, as a result of the Transaction, will be held by GSK in the future (as set out in Annex 2);

- non-exclusive worldwide sub-license with a right to sub-license for a group of third party patents owned by the […] relating to the conjugation of polysaccharides to carrier proteins (as set out in Annex 2);

- non-exclusive worldwide sub-license with a right to sub-license for a group of third party patents to which GSK acquired a license as part of an agreement with […] covering quadrivalent conjugate vaccines, including *Nimenrix* (as set out in Annex 2);

- copyrights to the current and previous iterations of *Nimenrix* and *Mencevax* product packaging and other related get-up;

- know-how embodied in business records containing business information maintained exclusively for the Divestment Business including all document and other material whether human, computer or machine readable and, for know-how related to non-transfer technology (*i.e.*, know-how related to the technology for diluent, needles and empty vials for *Nimenrix* and *Mencevax*);

- know-how relating to the applicable quality control procedures; and

- completed and on-going R&D studies including: […][3], […].

(c) the following main licences, permits and authorisations:

- transfer of marketing authorisations for *Nimenrix* and *Mencevax* for all current marketing or pending marketing authorisations held by GSK (as set out in Annex 3), including all relevant dossiers relating to the current or pending marketing authorisation and where neces-

3 […].

sary, assisting the Purchaser as much as is reasonably possible in obtaining the necessary marketing authorisations.

(d) the following main contracts, agreements, leases, commitments, and understandings

- in relation to contracts with third parties providing services in support of on-going studies for the Divestment Business (*e.g.* contracts between GSK and suppliers of general supplies and logistics, clinical sample testing and epidemiological studies), GSK will support transfer of existing contracts, use its reasonable endeavours to secure the entry of third parties into new agreements with the Purchaser, assist the Purchaser to the extent required to fulfil existing contractual obligations and, where contracts cannot be transferred, pass-through relevant goods and services if required to complete an on-going study; and

- in relation to supply agreements for materials in instances where the Purchaser may be interested in entering into agreements with GSK's existing suppliers, GSK will assist the Purchaser in this process.

(e) the following customer, credit and other records:

- in relation to the transfer of on-going tender contracts, GSK will use reasonable endeavours to transfer such contracts, including the benefit of these contracts, to the Purchaser where possible;

- GSK's Transitional Services offers to assist Purchaser in respect of any call for new tenders relating to *Mencevax* and *Nimenrix* between closing and the transfer of marketing authorisation in the relevant country.

(f) the following personnel:

- personnel currently working for the Divestment Business, *i.e.*, having the relevant expertise relating to *Nimenrix* and *Mencevax*, including (i) R&D/clinical personnel, (ii) manufacturing and quality personnel, and (iii) commercial personnel; while, with the exception of one Global Neisseria Marketing Director and two Global Neisseria Sr. Marketing Managers for commercial none of the personnel is dedicated to the Divestment Business, depending on the Purchaser's needs[4] and based on GSK's current estimates, GSK commits to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to make available and transfer to Purchaser up to:

  (i) […] R&D/clinical personnel;

  (ii) […] manufacturing and quality personnel;

  (iii) […] commercial personnel for the EEA; and

4 Subject to review and assessment of the Monitoring Trustee and the Technical Expert.

(iv) depending on Purchaser's needs,[5] additional […] commercial personnel for countries outside the EEA.

(g) the following Key Personnel

- while this depends on the Purchasers' needs,[6] GSK has identified the following key roles for product expert specialists for which GSK commits to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to make available and transfer these specialists to Purchaser:

  (i) **Global Commercial Lead acting as General Manager**: The General Manager will manage the overall day-to-day operations of the Divestment Business and ensure compliance with ring-fencing obligations, and assist in carving-out the divestment assets. The Global Commercial Lead will take over this role in addition to having expert product knowledge of *Nimenrix* and *Mencevax*, and being responsible for product positioning in the EU and rest of the world markets.

  (ii) **Medical Affairs Lead**: The Medical Affairs Lead will provide the medical and scientific support to the vaccines and lead implementation success by offering medical advice and act as the medical reference contact for local country organizations.

  (iii) **Tender Manager**: The Tender Manager will have central oversight of the tender business and will be responsible for management of the local tender managers.

  (iv) **Manufacturing Process Expert**: The Manufacturing Process Expert will have technical process expertise specific for each step of the *Nimenrix* and *Mencevax* manufacturing processes.

  (v) **Regulatory Affairs Lead**: The Regulatory Affairs Lead will develop clinical and technical packages for regulatory submissions, handle questions from regulatory authorities, and give the regulatory inputs.

  (vi) **Clinical Development Lead**: The Clinical Development Lead will have overall responsibility and accountability of the clinical development.

- Given that there are no key employees dedicated to the Divestment Business and that the described key roles do not currently exist, there are at this stage no identified individuals for the proposed Key Personnel. GSK commits to work together with Purchaser[7] to identify

---

5 Subject to review and assessment of the Monitoring Trustee and the Technical Expert.

6 Subject to review and assessment of the Monitoring Trustee and the Technical Expert.

7 Subject to review and assessment of the Monitoring Trustee and the Technical Expert.

the Key Personnel needed by Purchaser who have the experience and expertise to fulfil the identified functions. GSK will take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage these Key Personnel to transfer to Purchaser.

(h) the arrangements for the supply with the following products and provision of the following services by GSK or Affiliated Undertakings for a transitional period of up to […] after Closing:

- GSK will provide technology transfer relating to the production process for the Divestment Business to the Purchaser over the course of a transitional period of up to […] at cost. GSK will share in the cost for the technology transfer in line with the standards of the industry. […]. The technology transfer will be of three stages: (i) transfer of the packaging process to Purchaser, (ii) transfer of secondary production processes (formulation, filling and lyophilisation) to Purchaser, combined with performing stability requirements and file preparation for the regulatory filings, and (iii) transfer of technology for primary production (production of bulk antigens, bulk carrier proteins, and conjugation) to Purchaser, combined with completion of stability work and file preparation for regulatory approval;

- GSK will, pending completion of the technology transfer of the vaccine production and receipt of the necessary regulatory approvals, supply the Purchaser under a temporary supply agreement with *Nimenrix* and *Mencevax* and the relevant components thereof, mirroring the technology transfer timeline at full manufacturing cost (to be determined), ex-works, at current quality and quantity levels or quantities otherwise agreed between GSK and the Purchaser that reflect changes in customer demand, all as overseen by the Monitoring Trustee:

  (i) GSK will supply, from in-market inventory, directly to the Purchaser's customers and, following, if necessary, the Purchaser's set-up of a central warehouse, supply to the Purchaser's central warehouse finished *Nimenrix* and *Mencevax* vaccines;

  (ii) GSK will supply, to Purchaser for packaging, naked vials to be packaged; and

  (iii) GSK will supply (1) for *Nimenrix* bulk polysaccharide antigens and bulk tetanus toxoid carrier proteins to Purchaser's site for conjugation and (2) for *Mencevax* bulk polysaccharide antigens direct to Purchaser for the secondary production stage;

  In the event of a dispute between GSK and the Purchaser regarding the full manufacturing cost or the quantities, the matter shall be referred to the Monitoring Trustee (together with the Technical Expert) for resolution.

- GSK offers to provide, to support the technology transfer process relating to the Divestment Business, ring-fenced Transitional Services Teams, as required:[8]

    (i) for R&D/clinical, a transitional service team in order to (a) finish on-going clinical studies, (b) transfer clinical studies, assays and technology, (c) provide assistance for pharmacovigilence and regulatory submissions, and (d) train Purchaser's designated medical personnel;

    (ii) for manufacturing, to support the preparation and equipping of the Purchaser's chosen manufacturing site(s);

    (iii) for commercial functions, a transitional service team to support the Purchaser to integrate the Divestment Business into its salesforce and its promotional, sales, and distribution strategy.

- GSK offers to provide, with respect to the physical distribution of the *Nimenrix* and *Mencevax* vaccines, distribution services for the Purchaser for up to […] after Closing.

3. The Divestment Business shall not include:

- Due to the integration into GSK's other vaccines activities, which account for the large majority of the capacity usage, the existing sites where *Nimenrix* and *Mencevax* are manufactured and R&D relating to these vaccines is undertaken.

- Due to the importance of the *–rix* suffix for GSK's vaccines business, any right of Purchaser to use the *–rix* suffix for any other product than *Nimenrix* or any improvements thereof, *i.e.*, any changes to the product falling within the scope of a variation to the marketing authorization, including products that could later be developed by Purchaser using the MenACWY antigens;

- books and records that are not used exclusively in, or do not arise exclusively out of, the Divestment Business or that GSK is required by law to retain or which contain information in which any member of GSK has legal privilege.

4. If there is any asset or personnel which is not covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Business and necessary for the continued viability and competitiveness of the Divestment Business, that asset or adequate substitute will be offered to potential purchasers.

---

8 Subject to review and assessment of the Monitoring Trustee and the Technical Expert.

ANNEX 1

Brands in GSK's MenACWY Business

[…]

ANNEX 2

Patents Relevant for the Divestment Business

[…]

ANNEX 3

Marketing Authorizations In GSK's MenACWY Vaccines Business

[…]

January 21, 2015

Case COMP/M.7276
GlaxoSmithKline/Novartis Vaccines Business (Excl. Influenza)

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "Merger Regulation"), GlaxoSmithKline plc. ("GSK") hereby enters into the following Commitments (the "Commitments") vis-à-vis the European Commission (the "Commission") with a view to rendering the proposed acquisition of Novartis AG's ("Novartis") global human vaccines business, excluding flu vaccine products (the "Novartis Vaccines Business") (the "Transaction") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(2) of the Merger Regulation to declare the Transaction compatible with the internal market and the functioning of the EEA Agreement (the "Decision"), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "Remedies Notice").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by GSK or Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "Consolidated Jurisdictional Notice").

   Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 6 (a), (b) and (c) and described more in detail in the Schedule.

   Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

   Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

   Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

   Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

   Divestment Business: the business or businesses as defined in Section B and in the Schedule which GSK commit to divest.

Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., the notifying party, incorporated in the UK, with registered offices at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Manufacturing Services: the primary and secondary manufacturing services (unless and until the latter (filling and packaging) is technology transferred to the Purchaser) of the dT vaccines, which comprise the Divestment Business, to be provided by a designated team within GSK's manufacturing organisation.

Monitoring Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated in Switzerland, with registered offices at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing more in detail the Divestment Business.

Technical Expert: one or more natural or legal person(s) appointed by and reporting the Monitoring Trustee, who has/have expertise relevant to the Divestment Business. The Technical Expert will, if this is deemed necessary by the Monitoring Trustee,[1] assist and advise the Monitoring Trustee with regard to all technical aspects related to the Divestment Business. All information provided to the Monitoring Trustee may also be exchanged with the Technical Expert. The Technical Expert will be independent of GSK and will not have or be exposed to any conflict of interest. If the Monitoring Trustee has the necessary technical expertise, Monitoring Trustee and Technical Expert can be the same natural or legal person. GSK and Purchaser shall have the right to be heard with any reasoned objections against technical expert candidates, *e.g.*, lack of competence or conflict of interest. In cases of controversy between GSK and the Monitoring Trustee,

1 Subject to the Commission's view and final decision on the necessity of involving the Technical Expert.

and/or Purchaser and the Monitoring Trustee as to the suitability of the technical expert candidate, the Commission will decide on the matter.

Technology Transfer: at the Purchaser's request, the technology transfer by GSK of the (1) secondary production of the relevant dT vaccines forming part of the Divestment Business (meaning filling and packaging activities) to the Purchaser or a CMO selected by the Purchaser and/or (2) primary production and formulation of the relevant dT vaccines forming part of the Divestment Business (meaning the manufacturing of the bulk antigens and formulation of the relevant vaccines). The Purchaser shall decide prior to Closing whether it opts for the technology transfer of secondary and/or primary production. The cost, in respect of the personnel required to carry out the technology transfer will be jointly borne by Purchaser and GSK in proportion to the overall value of the Divestment Business. If the Purchaser opts for either or both of these technology transfers:

(i) the transferred technology, assets and know-how may only be used for manufacturing the products included in the Divestment Business (i.e., Novartis' *TD-Pur* and *Dif-Tet-All* bivalent dT vaccines in the forms and formulations existing at the time purchased by Purchaser) in Germany and Italy (and, at Purchasers option, the other countries in which Novartis has a valid national marketing authorisation, namely Austria, Hungary, Poland, and Slovenia);

(ii) the transferred technology, assets and know-how shall not be used in any way whatsoever for the manufacturing, research or development of any single or multi-valent vaccines other than the *TD-Pur* and *Dif-Tet-All* bivalent dT vaccines in the forms and formulations existing at the time purchased by the Purchaser; and

(iii) the Purchaser shall install and maintain a strict firewall between any employees having access to such transferred technology, assets and know-how and any other employees involved in other diphtheria or tetanus manufacturing, research or development activities.

Transitional Services: The services to be provided to the Purchaser by GSK in the period following Closing, including, but not limited to, R&D and commercial services required for the supply of the dT vaccines, which comprise the Divestment Business, and the maintenance of their marketing authorisations.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The commitment to divest and the Divestment Business

Commitment to divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Di-

vestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. [*Not applicable*].

4. GSK shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 18; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

5. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and definition of the Divestment Business

6. The Divestment Business consists of an exclusive distribution agreement, combined with an overall […] supply agreement on a full manufacturing cost (ex-works) basis and the transfer of national marketing authorisations of Novartis' *TD-Pur* and *Dif-Tet-All* bivalent dT vaccines business in Germany and Italy, respectively, and, at Purchasers option, the other countries in which Novartis has a valid national marketing authorisation, namely Austria, Hungary, Poland, and Slovenia. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets and in case of Technology Transfer employees needed by the Purchaser to ensure the viability and competitiveness of the Divestment Business, in particular:

   (a) all tangible and intangible assets (including intellectual property rights);

   (b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;

   (c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business; and

(d) personnel if, at the request of the Purchaser, the Technology Transfer takes place, and to the extent that the Purchaser does not already have the necessary personnel.

7. Due to the nature of the Divestment Business, GSK will continue to be responsible for the primary and secondary manufacture of the relevant dT vaccines to be distributed by the Purchaser, unless the Purchaser opts for the Technology Transfer, in which case the relevant technical know-how and personnel, to the degree needed by Purchaser, will be transferred to the Purchaser by GSK. The finished vaccine packs will be supplied to the Purchaser for a total of […] at full manufacturing cost (to be determined), ex-works, as overseen by the Monitoring Trustee. In the event of a dispute between GSK and the Purchaser regarding the full manufacturing cost, the matter shall be referred to the Monitoring Trustee (together with the Technical Expert) for resolution. If the Purchaser opts for the Technology Transfer, GSK will supply the finished packs on the same basis until such time as the transfer of secondary or primary production has been completed (not to exceed a total of […] after Closing). To support the transfer of the national marketing authorisation for the relevant dT vaccines, GSK will provide such Transitional Services as may be required pending the transfer of the marketing authorisation. GSK also offers to support the initial commercialisation of the product and physically distribute the relevant dT vaccines at the Purchaser's direction for a transitional period after Closing. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from, such service and supply arrangements will only be shared within designated teams within GSK's operations and, in particular, not be shared with, or passed on to, GSK's commercial team.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

8. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular GSK undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) (only in case the Purchaser (i) opts for the Technology Transfer and requires the transfer of some personnel for this activity and (ii) in cooperation with GSK identifies the employees needed by the Purchaser depending on its specific needs) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage such personnel to transfer with the Divestment Business (in the event such personnel are required by the Purchaser), and not to

solicit or move any such personnel to GSK's remaining business. Where, nevertheless, individual members of the personnel identified by GSK and Purchaser exceptionally leave the Divestment Business, GSK shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.

Hold-separate obligations

9. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the businesses it is retaining (as far as practically possible in light of the fact that (i) primary and secondary production of the dT products forming part of the Divestment Business is only transferred if the Purchaser so requires and (ii) unless the Purchaser so requires, no employees will be transferred with the Divestment Business) to ensure that, unless explicitly permitted under these Commitments, in particular in relation to the Transitional and Manufacturing Services and the Technology Transfer, if any: (i) commercial staff of the competing dT businesses retained by GSK have no involvement in the Divestment Business; (ii) personnel of the Divestment Business, if the Purchaser requests a long-term transfer of personnel for production of the dT vaccines forming part of the Divestment Business, have no involvement in any dT vaccine business retained by GSK.

10. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that (as far as practically possible in light of the fact that (i) primary and secondary production of the dT products forming part of the Divestment Business is only transferred if the Purchaser so requires and (ii) unless the Purchaser so requires no employees will be transferred with the Divestment Business) the Divestment Business is managed as a distinct and saleable business separate from the businesses which GSK is retaining (save with respect to the required Transitional and Manufacturing Services and Technology Transfer if so requested by the Purchaser, see above). Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager who has no involvement with the dT activities GSK retains. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK (save with respect to the required Transitional and Manufacturing Services and Technology Transfer if so requested by the Purchaser, see above). At the Purchaser's option , the Hold Separate Manager will transfer with the Divestment Business, but, even if not transferred, is willing to stay available post-Closing of the Divestment Transaction in the context of Transitional Services rendered by GSK. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee, who, in case the Monitoring Trustee does not have any necessary industry expertise, is assisted by the Technical Expert, and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 8(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

11. [*Not applicable*].

Ring-fencing

12. GSK shall (as far as practically possible in light of the fact that (i) primary and secondary production of the dT products forming part of the Divestment Business is only transferred if the Purchaser so requires and (ii) unless the Purchaser so requires, no employees will be transferred with the Divestment Business) implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business and that any such Confidential Information obtained by GSK before the Effective Date will be eliminated and not be used by GSK, save in order to carry out the required Transitional and Manufacturing Services and Technology Transfer. In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law. In order to ensure that measures are effective, in light of the required Transitional and Manufacturing Services and Technology Transfer (if so requested by Purchaser), GSK commits to create additional reasonable mechanisms with regard to the personnel involved in the provision of such services to ensure that any Confidential Information is not shared with GSK's commercial teams.

Non-solicitation clause

13. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the personnel, if any, transferred with the Divestment Business for a period of […] after Closing.

Due diligence

14. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide to potential purchasers sufficient information as regards the Divestment Business;

    (b) provide to potential purchasers sufficient information relating to the personnel potentially to be transferred to them depending on each potential purchaser's specific needs if it opts for the Technology Transfer and allow them reasonable access to such personnel.

Reporting

15. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

16. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. <u>The Purchaser</u>

17. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

(a) The Purchaser shall be independent of and unconnected to GSK and its Affiliated Undertakings (this being assessed having regard to the situation following the divestiture).

(b) The Purchaser shall have an established presence in distribution channels typically used in the vaccines business in Germany and Italy, and, dependent on the Purchaser's choice, the other countries in which Novartis has a valid national marketing authorisation, namely Austria, Hungary, Poland, and Slovenia.

(c) The Purchaser shall, if it chooses Technology Transfer, be an established supplier of vaccines with existing R&D and manufacturing capabilities in the EEA.

(d) The Purchaser shall have expertise and experience in working with authorities in these countries in order to obtain necessary regulatory approvals (*e.g.*, marketing authorizations), and in having relevant interactions with relevant national bodies in these countries that decide on recommendations and the vaccination schedules.

(e) The Purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

(f) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

18. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets and personnel (if any), or by substituting one or more Assets or parts of and employees (if any) with one or more different assets

or employees, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment procedure

19. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Concentration before the appointment of a Monitoring Trustee. The Monitoring Trustee shall be assisted by the Technical Expert with regard to all technical questions related to the Divestment Business. The Technical Expert shall be appointed by and report to the Monitoring Trustee (with GSK and the Purchaser having the right to be heard as to their suitability). In cases of controversy between GSK and the Monitoring Trustee, and/or Purchaser and the Monitoring Trustee as to the suitability of the technical expert candidate, the Commission will decide on the matter.

20. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

21. The Trustee shall:

(i) at the time of appointment, be independent of GSK and its/their Affiliated Undertakings;

(ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(iii) neither have nor become exposed to a Conflict of Interest.

22. The Trustee and the Technical Expert shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

23. No later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

24. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by GSK

25. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 24 of these Commitments.

Trustee nominated by the Commission

26. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

27. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GSK, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

28. The Monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(ii) oversee, in close co-operation with the Technical Expert and Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of

the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 10 of these Commitments;

(c) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business, save in order to carry out the required Transitional and Manufacturing Services and Technology Transfer (if so requested by Purchaser),

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK, save in order to carry out the required Transitional and Manufacturing Services and Technology Transfer (if so requested by Purchaser), and

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary (beyond what is necessary for carrying out the required Transitional and Manufacturing Services and Technology Transfer (if so requested by Purchaser)) to allow GSK to carry out the divestiture or as the disclosure is required by law;

(d) monitor the splitting of assets and the allocation of personnel between the Divestment Business and GSK or Affiliated Undertakings (if such personnel allocation is required by the Purchaser);

(iii) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(iv) be involved in the divestiture process by reviewing and assessing potential purchasers as well as the progress of the divestiture process and verifying that, dependent on the stage of the divestiture process:

(a) potential purchasers receive sufficient and correct information relating to the Divestment Business in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(b) potential purchasers are granted reasonable access to the personnel (if any personnel are required by the Purchaser).

(v) Additionally, the Monitoring Trustee shall act as a contact point for any disagreements that might arise in negotiations between GSK and the Purchaser. To that end, the Monitoring Trustee shall be assisted by the Technical Expert.

(vi) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(vii) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of personnel (if any) so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(viii) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(ix) within one week after receipt of the documented proposal referred to in paragraph 18 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets or not all of the personnel (if any) affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser;

(x) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

29. If the Monitoring and Divestiture Trustee are not the same (legal or natural) persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

30. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 17 and 18 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legit-

imate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

31. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

III. Duties and obligations of the Parties

32. GSK shall provide and shall cause its advisors to provide the Trustee and the Technical Expert with all such co-operation, assistance and information as the Trustee and the Technical Expert may reasonably require to perform its tasks. The Trustee and the Technical Expert shall have full and complete access to any of GSK's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and GSK and the Divestment Business shall provide the Trustee and the Technical Expert upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee and the Technical Expert two or more offices on their premises and shall be available for meetings in order to provide the Trustee and the Technical Expert with all information necessary for the performance of its tasks.

33. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

34. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

35. GSK shall indemnify the Trustee and its employees and agents and the Technical Expert(each an "Indemnified Party") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the performance of the Trustee's and Technical Expert's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, Technical Expert, its employees, agents or advisors.

36. At the expense of GSK, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

37. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

38. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

39. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. <u>Replacement, discharge and reappointment of the Trustee</u>

40. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

    (a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

    (b) GSK may, with the prior approval of the Commission, replace the Trustee.

41. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.

42. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The review clause

43. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause**.** This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

44. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into force

45. The Commitments shall take effect upon the date of adoption of the Decision.

Brussels, January 21, 2015

[…]
duly authorised for and on behalf of
GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business, comprising an exclusive distribution agreement, combined with a […] supply agreement on a full manufacturing cost (ex-works) basis, and the transfer of national marketing authorisations of Novartis' *TD-Pur* and *Dif-Tet-All* bivalent dT vaccines business in Germany and Italy, respectively, and, at Purchasers option, the other countries in which Novartis has a valid national marketing authorisation, namely Austria, Hungary, Poland, and Slovenia. Novartis' *TD-Pur* and *Dif-Tet-All* vaccines business in these countries is currently fully integrated in Novartis's broader vaccine business. There are no dedicated production assets nor employees, and it is not embodied in a specified legal entity. Consequently, the legal and functional changes necessary to permit the operation of the Divestment Business will have to be achieved prior to its transfer to the Purchaser.

2. In accordance with paragraph 6 of these Commitments, the Divestment Business includes, but is not limited to:

(a) the following main tangible assets:

- all of the Divestment Business' records, commercial documentation, and promotional materials for Germany and Italy and, dependent on the Purchaser's choice, the other countries in which Novartis has valid national marketing authorisations in the EEA;

- in-market stocks of finished packs of the relevant dT vaccines, at full manufacturing cost (to be determined), ex-works, as overseen by the Monitoring Trustee. Such finished packs will be supplied by GSK to the Purchaser's customers as part of the transitional distribution services until such time as the Purchaser is able to undertake such distribution itself; and,

- if, at the Purchaser's option, there is a technology transfer of the primary production of the diphtheria and tetanus antigens, GSK will provide the required working seed (subject to the protections set out under 'Technology Transfer' in Section A of these Commitments).

(b) the following main intangible assets:

- the trademarks and trade dress (*i.e.*, total image or overall design or appearance of product or its packaging) for Novartis' *TD-Pur* and *Dif-Tet-All* in Germany and Italy and, dependent on the Purchaser's choice as to the other countries in which Novartis has valid marketing authorisations in the EEA, the other trademarks at a Community level.

(c) the following main licences, permits and authorisations:

- transfer of the current national marketing authorisations for Novartis' *TD-Pur* and *Dif-Tet-All* in Germany and Italy, respectively, and, dependent on the Purchaser's choice, the other countries for which Novartis holds a national marketing authorisation for bivalent dT vaccines in the EEA, namely Austria, Hungary, Poland and Slovenia, including all relevant dossiers relating to the current or pending marketing authorisation and where necessary, assisting the Purchaser as much as is reasonably possible in maintaining the marketing au-

thorisations (including any variations in the marketing authorisation such as those occasioned by changes in the manufacturing process or product information).

(d) [*Not Applicable*]

(e) the following customer, credit and other records:

- in relation to the transfer of on-going tender contracts, GSK will use reasonable endeavours to transfer such contracts, including the benefit of these contracts, to the Purchaser where possible; and,

- as part of Transitional Services GSK offers to assist the Purchaser in respect of any call for new tenders relating to the relevant dT vaccines between closing and the transfer of marketing authorisation in the relevant country.

(f) personnel that the Purchaser needs long-term (in addition to the temporary support offered by GSK for manufacturing of the dT products forming part of the Divestment Business) in case the Purchaser opts for the Technology Transfer.

- Due to the nature of the remedy proposed, no personnel (and in particular no key employees) are envisaged being transferred to the Purchaser. However, if the Purchaser opts for the Technology Transfer, GSK offers, in addition to transferring the relevant technical know-how to the Purchaser, to transfer such personnel as may be required for the primary and/or secondary production of the dT products forming part of the Divestment Business by the Purchaser (to the extent that the Purchaser does not already have the necessary personnel and expertise). GSK is willing to cooperate with the Purchaser to identify the personnel required by the Purchaser and to transfer such personnel within the applicable legal limitations.

(g) the arrangements for the supply with the following products or services by GSK or Affiliated Undertakings for a period of up to [...] after Closing:

- GSK will supply, for a maximum period of […] after Closing, the Purchaser with finished packs of *TD-Pur* and *Dif-Tet-All* , at full manufacturing cost (to be determined), ex-works, as overseen by the Monitoring Trustee. In the event of a dispute between GSK and the Purchaser regarding the full manufacturing cost, the matter shall be referred to the Monitoring Trustee (together with the Technical Expert) for resolution. GSK commits to provide the Purchaser with vaccines up to a volume per year that corresponds to Novartis' annual average 2011-2013 bivalent dT vaccines sales in the EEA +[30-40]%.

- If the Purchaser chooses to have the secondary production for *TD-Pur* and *Dif-Tet-All* transferred to it (or a chosen CMO), GSK will provide the technology transfer relating to such secondary production processes and transfer the relevant technical know-how. The technology transfer will be a staged process whose composition and duration will depend on the nature and facilities of the Purchaser.

    - Pending completion of the technology transfer relating to the secondary production steps, GSK offers to supply the Purchaser

under a temporary supply agreement with the finished packs until the transfer of secondary production is completed. Following completion of the technology transfer of secondary manufacturing, if so requested by the Purchaser, GSK will provide the Purchaser with formulated tetanus and diphtheria antigens for filling and packaging (again up to a volume per year that corresponds to Novartis' annual average 2011-2013 bivalent dT vaccines sales in the EEA +[30-40]%).

- If the Purchaser chooses, additionally, to have the technology and know-how for the primary production and formulation for *TD-Pur* and *Dif-Tet-All* transferred to it (or a chosen CMO), GSK will provide the technology transfer relating to such production processes and transfer the relevant technical know-how. In this scenario, the transferred technology and know-how may only be used for manufacturing bivalent dT vaccines and not for the development and/or manufacturing of any other (combination) vaccine (as further provided for under 'Technology Transfer' in Section A of these Commitments). Such transfer will relate to the existing production process, and GSK will not be obliged to develop (and then transfer) new know-how for a production process at a materially different scale and/or for materially different volumes. GSK will share in the cost for such technology transfer in proportion to the overall value of the Divestment Business and in line with the standards of the industry. […]. The know-how transferred to manufacture the dT antigens will be limited to use in the transferred vaccines (*TD-Pur* and *Dif-Tet-All*). The technology transfer will be a staged process whose composition and duration will depend on the nature and facilities of the Purchaser.

    - Pending completion of the technology transfer relating to the primary production and formulation steps, GSK offers to supply the Purchaser under a temporary supply agreement with the formulated diphtheria and tetanus antigens until the transfer of primary production and formulation is completed.

- GSK offers to support the process of transferring of national marketing authorisations.

- GSK offers to provide, with respect to the physical distribution of the relevant dT vaccine in Italy and Germany and, dependent on the Purchasers choice, the other countries in which Novartis has a national marketing authorisation in the EEA, namely Austria, Hungary, Poland and Slovenia, distribution services for the Purchaser temporarily after Closing.

3. The Divestment Business shall not include:

- Due the nature of the Divestment Business, it will not include any other assets, licenses, authorisations, other than those described above in this Schedule. In particular, no sites, production equipment, key employees or personnel will be transferred. No personnel will be transferred unless the Purchaser opts to have primary and/or secondary production transferred to it and requires personnel for the primary (bulk antigen manufacturing), formulation, or secondary stages of production (filling and packaging), to be transferred to it. In case the Purchaser needs certain employees, these are to be identified through discussion between GSK and the Purchaser and, depending on Purchaser's needs, these will be included as part of the Divestment Business.

- If the Purchaser chooses to have the technology and know-how for the primary production and formulation transferred to it, the diphtheria and tetanus antigens manufactured using such transferred technology and know-how may not be used for any other purpose other than the development and/or manufacturing of bivalent dT vaccines (as further provided for under 'Technology Transfer' in Section A of these Commitments).

4. If there is any asset which is not covered by paragraph 2 of this Schedule but which is both used in the Divestment Business and necessary for the continued viability and competitiveness of the Divestment Business, that asset or adequate substitute will be offered to potential purchasers.

Case COMP/M.7276 – GlaxoSmithKline / Novartis Consumer Health Business

COMMITMENTS TO THE EUROPEAN COMMISSION RELATING TO GSK'S NIQUITIN SMOKING CESSATION BUSINESS IN THE EEA AND TURKEY

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "***Merger Regulation***"), GlaxoSmithKline ("***GSK***") hereby enters into the following Commitments (the "***Commitments***") vis-à-vis the European Commission (the "***Commission***") with a view to rendering GSK's acquisition of sole control over a company named GSK Consumer Healthcare ("***GSKCH***") (the "***Concentration***"), comprising the consumer healthcare business of GSK[1] and the over-the-counter business of Novartis AG,[2] compatible with the internal market and the functioning of the EEA Agreement.

The Commitments shall take effect upon the date of adoption of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "***Decision***"). This text shall be interpreted in light of the Commission's Decision, in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "***Remedies Notice***").

SECTION A. DEFINITIONS

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by GSK, including GSKCH, or by Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

   Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 5 (382)(a), (b), (382)(b), (382)(g), (e) and (382)(h), and described in more detail in the Schedule.

   Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

   Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

---

1 Excluding GSK's consumer healthcare business in India and Nigeria, and products that are managed by, and reported for financial purposes within, GSK's Pharmaceutical Division.

2 Excluding Novartis' products that are managed by, and reported for financial purposes within, Novartis' Pharmaceutical Division, Alcon Division, and Sandoz Division.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divested Products: GSK's nicotine replacement therapy products sold by the Divestment Business under the *NiQuitin* trademark in the EEA and in Turkey.

Divestment Business: assets and rights comprising GSK's *NiQuitin* business in the EEA and in Turkey, as further defined in Section B and in the attached Schedule, which GSK commits to divest.

Divestiture Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., incorporated under the laws of England and Wales, with its registered office at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Business, as listed in the Schedule, including the Hold Separate Manager.

Monitoring Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated under the laws of Switzerland, with its registered office at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 19 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing in more detail the Divestment Business.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

SECTION B. THE COMMITMENT TO DIVEST AND THE DIVESTMENT BUSINESS

Commitment to Divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 20 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement (which will be subject to final approval by the Commission) for the sale of the Divestment Business within the First Divestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 32 in the Trustee Divestiture Period.

3. GSK shall be deemed to have complied with this commitment if:

(a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 20; and

(b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 46 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and Definition of the Divestment Business

5. The Divestment Business consists of GSK's nicotine replacement therapy ("NRT") business, marketed under the brand name *NiQuitin*, in the EEA and in Turkey. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

   (a) all tangible and intangible assets (including intellectual property rights and relevant internet domain names), by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the Divestment Business, as specified in the Schedule;

   (b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business, as specified in the Schedule;

   (c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business, as specified in the Schedule;

   (d) all contracts with suppliers, including contracts with contract manufacturers that produce the Divested Products, as specified in the Schedule;

   (e) the Key Personnel and, if required by the Purchaser, up to […] additional personnel, as specified in the Schedule; and

   (f) at the option of the Purchaser, transitional agreements with GSK or Affiliated Undertakings for the supply of products and/or technical assistance, as specified in the Schedule.

6. For the avoidance of doubt, the Divestment Business shall not include:

   (a) intellectual property rights which do not contribute to the current operation of the Divestment Business;

   (b) the GSK company name, mark, or logo in any form;

   (c) any GSK R&D facilities;

   (d) any GSK manufacturing facilities, or equipment held at such facilities, used to manufacture goods for the Divestment Business;

   *(e) any personnel other than the Key Personnel listed in **Annex 1** and, if required by the Purchaser, up to […] additional personnel, as specified in the Schedule;*

   (f) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request;

(g) *general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request; and*

(h) *GSK's* NiQuitin *business, and any rights relating exclusively thereto, outside the EEA and Turkey.*

SECTION C. RELATED COMMITMENTS

Preservation of Viability, Marketability and Competitiveness

7. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular GSK undertakes:

(a) *not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;*

(b) *to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;*

(c) *to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business, consistent with paragraph 8 of these Commitments. The Monitoring Trustee shall determine whether GSK has taken or procured all reasonable steps in this regard, in accordance with Section E of these Commitments. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Business prior to Closing, GSK shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission;*

(d) *to take all reasonable steps, or procure that all reasonable steps are being taken, to ensure that the Divestment Business continues to receive all the necessary support from GSKCH it needs to allow it to meet the Divestment Business' 2015 business plan. In particular, this shall mean that GSKCH will ensure that current resources available for the brand marketing, sales, regulato-*

*ry affairs and supply chain management for the Divested Products will continue during the Hold Separate Period to ensure that the Divestment Business' 2015 business plan is achieved. The incentive programmes for personnel involved in the Divestment Business shall continue throughout the Hold Separate Period to be dependent upon the success of the Divestment Business. In the event that such personnel become unable to perform their roles in the Divestment Business (*e.g.*, as a result of resignation), GSK shall replace such personnel with appropriate alternatives to ensure the delivery of the Divestment Business' 2015 business plan. GSKCH representatives and the Hold Separate Manager will hold regular meetings to discuss achievement of the Divestment Business' goals and the need for any adjustments in resource or personnel to ensure the goals are achieved. The Hold Separate Manager may request additional resources reasonably necessary to meet the Divestment Business' 2015 business plan. GSK shall make available such additional resources. To the extent GSK disagrees with the need for these additional resources, the Monitoring Trustee shall assess and have the final authority to determine whether the additional resources requested are reasonably necessary. Notwithstanding the above, consistent with GSK's ring-fencing obligations, sales and marketing personnel who work on the* NiQuitin *brand, during the Hold Separate Period, shall not work on brands of Novartis directly competing with the Divestment Business.*

8. Key Personnel (including, for the avoidance of doubt, the Hold Separate Manager) and up to […] additional personnel, as specified in the Schedule, will transfer to the Purchaser with the Divestment Business unless the Purchaser does not require it.[3] With respect to such Key Personnel and the up to […] additional personnel who receive an offer of employment from the Purchaser (conditional on or following the Closing), GSK shall do the following:

   (a) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Key Personnel or additional personnel from being employed by the Purchaser, and not offer any incentive to the Key Personnel or additional personnel to decline employment with the Purchaser; and

   (b) if the Key Personnel or additional personnel accept such offer of employment from the Purchaser, GSK shall cooperate with the Purchaser in effecting

3 Consistent with these commitments, GSK will proactively facilitate and endeavour to procure the transfer of a specific Hold Separate Manager and Key Personnel, and up to […] additional personnel as specified in the Schedule, to the Purchaser should the Purchaser so require. If that is not possible then GSK will source suitable alternative talent for the Purchaser.

transfer of the Key Personnel and additional personnel to the employ of the Purchaser.

Hold-Separate Obligations

9. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the business(es) it is retaining and to ensure that the Key Personnel have no involvement in any business retained by GSK and do not report to any individual outside the Divestment Business.

10. Until Closing, GSK commits to apply its existing incentive scheme governing the remuneration of its employees in respect of any activities relating to the Divestment Business. GSK further commits not to reduce the total amount of employee time currently dedicated to the Divestment Business, without prejudice to paragraph 12 below.

11. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable commercial entity separate from the business(es) which GSK is retaining. Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager. The Hold Separate Manager, who shall be part of the Key Personnel, shall manage the Divestment Business independently and in the best interest of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK.

12. Until Closing, consistent with the commitment in paragraph 7, GSK commits to make available to the Hold Separate Manager sufficient resources (including personnel) reasonably necessary to ensure the development of the Divestment Business on the basis and continuation of the existing business plans. The Monitoring Trustee shall assess the reasonableness of any requests for resources from the Hold Separate Manager and GSK's performance under this commitment, in accordance with Section E of these Commitments.

13. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 7(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

Ring-Fencing

14. GSK shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business, except as is necessary to ensure the viability of the Divestment Busi-

ness (including as is necessary for GSK to provide transitional services to the Divestment Business). In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law.

Non-Solicitation Clause

15. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel or the up to […] additional personnel transferred with the Divestment Business for a period of […] after Closing.

Due Diligence

16. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide to potential purchasers sufficient information as regards the Divestment Business; and

    (b) provide to potential purchasers sufficient information relating to the Key Personnel and up to […] additional personnel, as specified in the Schedule, and allow them reasonable access to the Key Personnel and such additional personnel. The Monitoring Trustee shall determine whether GSK has provided reasonable access to the personnel described in this paragraph 16(b), in accordance with Section E of these Commitments.

Reporting

17. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

18. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

SECTION D. THE PURCHASER

19. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

    (a) *the Purchaser shall be independent of and unconnected to GSK and Novartis and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);*

    (b) *the Purchaser shall have experience in the supply of consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);*

    (c) *the Purchaser shall have an established presence in and/or access to distribution channels typically used in the consumer healthcare business in each of the EEA countries in which the Divestment Business is active;*

    (d) *the Purchaser shall have experience in the marketing, promotion, sales and distribution of branded consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);*

    (e) *the Purchaser shall have experience in working with authorities in the EEA in obtaining necessary regulatory approvals (*e.g.*, marketing authorisations);*

    (f) *the Purchaser shall have the financial resources, proven experience, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in the EEA in competition with the Parties and other competitors; and*

    (g) *the acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission,* prima facie *competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.*

20. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. The sale and purchase agreement shall contain a purchase price that is finally determined at Closing and not be dependent on the Divestment Business' performance after Closing (*i.e.*, the purchase price should not be conditional on the performance of the Divestment Business after Closing or subject to royalties). For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets or parts of

the Key Personnel, or by substituting one or more Assets or parts of the Key Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

SECTION E. TRUSTEE

I. Appointment Procedure

21. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Concentration before the appointment of the Monitoring Trustee.

22. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

23. The Trustee shall:

(a) at the time of appointment, be independent of GSK and Novartis and their Affiliated Undertakings;

(b) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(c) neither have nor become exposed to a Conflict of Interest.

24. The Trustee shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

25. No later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 23 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or Rejection by the Commission

26. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New Proposal by GSK

27. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 21 and 25 of these Commitments.

Trustee Nominated by the Commission

28. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

29. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GSK, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

30. The Monitoring Trustee shall:

(a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(b) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued

economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 7 and 9 of these Commitments;

(ii) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 11 of these Commitments;

(iii) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK and

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary to allow GSK to carry out the divestiture or as the disclosure is required by law; and

(iv) monitor the splitting of assets and the allocation of Key Personnel between the Divestment Business and GSK or Affiliated Undertakings;

(c) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business consistent with Section C of these Commitments, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(d) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(i) potential purchasers receive sufficient and correct information relating to the Divestment Business and the Key Personnel, and up to […] additional personnel, as specified in the Schedule, in particular by

reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(ii) potential purchasers are granted reasonable (in the view of the Monitoring Trustee) access to the Key Personnel and up to […] additional personnel, as specified in the Schedule;

(e) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(f) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Key Personnel so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(g) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(h) within one week after receipt of the documented proposal referred to in paragraph 20 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets or not all of the Key Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser; and

(i) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

31. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and Obligations of the Divestiture Trustee

32. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 19 and 20 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and pur-

chase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

33. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

III. Duties and Obligations of the Parties

34. GSK shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of GSK's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and GSK and the Divestment Business shall provide the Trustee upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

35. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

36. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

37. GSK shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

38. At the expense of GSK, the Trustee may appoint advisors (including in respect of such matters as: corporate finance, legal advice, technical requirements, R&D, clinical/regulatory, manufacturing, and distribution), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 37 of these Commitments shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

39. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply mutatis mutandis.

40. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

41. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, Discharge and Reappointment of the Trustee

42. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

    (a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

    (b) GSK may, with the prior approval of the Commission, replace the Trustee.

43. If the Trustee is removed according to paragraph 42 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 21-28 of these Commitments.

44. Unless removed according to paragraph 42 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

SECTION F. THE REVIEW CLAUSE

45. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

46. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

47. If the approval of the GSK/Novartis Consumer Health Business transaction by another antitrust authority is made subject to requirements that:

    (a) are potentially inconsistent with these Commitments; or

    (b) would, when combined with the obligations in these Commitments, result in the divestiture of assets or businesses beyond that which is necessary to maintain or restore effective competition in the EEA,

GSK may request a review and adjustment of these Commitments in order to avoid such inconsistencies or obligations beyond those necessary to restore effective competition.

SECTION G. ENTRY INTO FORCE

48. The Commitments shall take effect upon the date of adoption of the Decision.

Brussels, January 21, 2015

[…]

duly authorised for and on behalf of

GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business is operated by GSK as part of GSK's Consumer Healthcare division.

2. In accordance with paragraph 5 of these Commitments, the Divestment Business will include:

*(a) a transfer (by way of sale) of the following main tangible assets: all finished goods inventory, supplies, sales and promotional material relating exclusively to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis, or GSKCH) held at the date of Closing;*

*(b) a transfer (by way of sale, assignment or licence, as appropriate) of the following main intangible assets insofar as they relate exclusively to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH):*

(i) the trademark *NiQuitin* in the EEA and in Turkey;

(ii) rights to any domain names within the EEA and Turkey that relate exclusively to the Divestment Business (the transfer to be effected by means of withdrawal and re-registration);

(iii) patents for the EEA and Turkey held by GSK in relation to the Divestment Business, which are listed in **Annex 2**;

(iv) all copyrights in the EEA and Turkey related to the Divestment Business, covering, *inter alia*, information booklets and website content;

(v) all know-how for the manufacturing of products by the Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in the EEA and in Turkey. The know-how is embodied in design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, and quality control standards; and

(vi) an irrevocable, assignable, sub-licensable and royalty-free licence to all copyrights and patents and access to all know-how, for exclusive use in and limited to the EEA and Turkey, relating to any existing pipeline product intended to be marketed in the EEA or Turkey under the *NiQuitin* brand. GSK will also provide, at the option of the Purchaser, technical assistance to the Purchaser in relation to the transfer of all pipeline projects in order to enable the Purchaser successfully to continue the development of such projects without delay.

*For the avoidance of doubt, GSK will retain ownership of intangible assets that do not relate exclusively to the Divestment Business (*i.e.*, intangible assets which also relate to the retained business of GSK) (*e.g.*, existing R&D relating to GSK smoking cessation products that are marketed outside the EEA/Turkey*

and/or are not marketed under the NiQuitin *brand). However, in respect of such shared intangible assets, GSK will provide the Purchaser with an irrevocable, assignable, sub-licensable and royalty-free licence to all copyrights and patents and access to all know-how, on a non-exclusive basis, for use in and limited to the EEA and Turkey. The Monitoring Trustee shall supervise GSK's performance in this regard, in accordance with Section E of the Commitments;*

*(c) a transfer or assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organisation and held by GSK that are exclusively necessary to manufacture and/or sell the products belonging to the Divestment Business (*i.e. *not necessary to manufacture and/or sell the products belonging to the retained business of GSK, Novartis or GSKCH), including any dossiers relating to current or pending authorisations available to GSK and, where necessary, assistance related to the transfer to the Purchaser of such licences, permits, and authorisations concerning the Divestment Business, and providing assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorisations. For the avoidance of doubt, licences that are held by, required for the continued operation of, and specific to any manufacturing site will be retained by that manufacturing site and will not be transferred to the Purchaser;*

(d) a transfer to […] (or, at the Purchaser's election, an alternative third party supplier or the Purchaser itself) of all manufacturing technology and know-how necessary to enable […] (or, at the Purchaser's election, an alternative third party supplier or the Purchaser itself) to manufacture NiQuitin *patches for the Divestment Business. GSK will use its reasonable best efforts to facilitate such a transfer. The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;*

(i) without limitation to the above, GSK commits to use its reasonable best efforts to assign or sub-license, or to procure that […] will license, to […] (or, at the Purchaser's election, to an alternative third party supplier or the Purchaser itself), on an exclusive basis, for use in and limited to the EEA and Turkey, technology that […] currently licenses to GSK for use in the manufacturing process for *NiQuitin* patches for the Divestment Business. The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;

(e) a transfer to […] (or, at the Purchaser's election, an alternative third party supplier or the Purchaser itself) of all manufacturing technology and know-how necessary to enable […] (or, at the Purchaser's election, an alternative third party supplier or the Purchaser itself) to manufacture NiQuitin *lozenges for the Divestment Business. GSK will use its reasonable best efforts to facilitate such a transfer. The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;*

*(f) a transfer or assignment of, as appropriate, the following additional contracts, agreements, leases, commitments and understandings to the extent exclusively related to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH):*

(i) GSK will use its reasonable best efforts to transfer to the Purchaser the supply agreement(s) with […] relating to orally-dissolving *NiQuitin* strips or to enable the Purchaser to conclude a new supply agreement with […] in relation to orally-dissolving *NiQuitin* strips for the Divestment Business. In the event that such arrangements cannot be made, GSK is prepared to conclude back-to-back supply agreements with the Purchaser on an […];

(ii) GSK will use its reasonable best efforts to transfer to the Purchaser the supply agreement(s) with […] relating to *NiQuitin* gums or to enable the Purchaser to conclude a new supply agreement with […] in relation to *NiQuitin* gums for the Divestment Business. In the event that such arrangements cannot be made, GSK is prepared to conclude back-to-back supply agreements with the Purchaser on an […]; and

(iii) GSK will use its reasonable best efforts to transfer GSK's existing distribution agreements and contracts with customers, or the part of such agreements or contracts, pertaining to the Divestment Business to the Purchaser.

The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;

*(g) the transfer of the following customer, credit and other records to the extent exclusively related to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH): GSK's customer lists and customer records;*

*(h) if required by the Purchaser, the Key Personnel listed in **Annex 1** and up to […] additional personnel with suitable skills and experience in […];*

(i) the arrangements for the supply of the following products or services by GSK or Affiliated Undertakings for a transitional period in order to maintain the economic viability and competitiveness of the Divestment Business:

(i) if required by the Purchaser, GSK is prepared to conclude a transitional contract manufacturing and packaging agreement with the Purchaser for *NiQuitin* patches, and to use its reasonable best efforts to procure that […] enters into a packaging agreement with the Purchaser for secondary packaging services in relation to *NiQuitin* patches, until the transfer of technology and know-how relating to the manufacture of *NiQuitin* patches is complete. In the event that such arrangements with […] cannot be made, GSK shall conclude back-to-back agreements with the Purchaser on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee.[1] GSK's transitional contract manufacturing and packaging agreement with the Purchaser shall be concluded on a reasonable […] in accordance with good industry practice under the supervision of the

[1] […].

Monitoring Trustee. The transitional contract manufacturing agreement may be extended at the request of the Purchaser and with the consent of GSK based on a report of the Monitoring Trustee;

(ii) if required by the Purchaser, GSK is prepared to conclude a transitional contract manufacturing agreement for *NiQuitin* mini and large lozenges, and a transitional vial packaging agreement for *NiQuitin* mini and large lozenges, and to use its reasonable best efforts to procure that […] enters into a packaging agreement with the Purchaser for blister packaging services for *NiQuitin* large lozenges, until the transfer of technology and know-how relating to the manufacture of *NiQuitin* mini and large lozenges is complete. In the event that such arrangements with […] cannot be made, GSK shall conclude back-to-back agreements with the Purchaser on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee. GSK's transitional contract manufacturing and packaging agreement with the Purchaser shall be concluded on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee. The transitional contract manufacturing may be extended at the request of the Purchaser and with the consent of GSK based on a report of the Monitoring Trustee; and

(iii) if required by the Purchaser, GSK is prepared to conclude a transitional supply and/or transitional distribution agreement for *NiQuitin* gums and/or *NiQuitin* orally-dissolving strips until such time as the required changes to the marketing authorisations and artwork of these respective products have been completed. Any such transitional supply and distribution agreement with the Purchaser would be concluded on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee.

(iv) if required by the Purchaser, GSK is prepared to collaborate with the Purchaser to identify any reasonable need for any additional transitional service agreements to be concluded between GSK and the Purchaser.

Following the expiry of the transitional supply agreements above, the Purchaser will either use its own manufacturing site and equipment or use a third-party contract manufacturer for manufacturing and packaging.

3. The Divestment Business shall not include:

(a) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(b) the GSK company name, mark, or logo in any form;

(c) any GSK R&D facilities;

(d) any GSK manufacturing facilities, or equipment held at such facilities, used to manufacture goods for the Divestment Business;

(e) *any personnel other than the Key Personnel listed in **Annex 1** and, if required by the Purchaser, up to […] additional personnel, as specified in paragraph 2(h) of this Schedule;*

(f) *books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request;*

(g) *general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request; and*

(h) *GSK's* NiQuitin *business, and any rights relating exclusively thereto, outside the EEA and Turkey.*

4. The Monitoring Trustee shall supervise GSK's implementation of this Schedule, in accordance with Section E of the Commitments.

5. GSK acknowledges that the Purchaser may elect to carry out itself all or some of the manufacturing and/or distribution activities that are currently carried out by third parties for the Divestment Business. Nothing in this Schedule or in the Commitments shall be construed as restricting the Purchaser's freedom in this regard.

Annex 1
Key Personnel

The Key Personnel are:

- [Names of employees]

Annex 2

Patents relating to the NiQuitin Business

[…]

Case COMP/M.7276 – GlaxoSmithKline / Novartis Consumer Health Business

COMMITMENTS TO THE EUROPEAN COMMISSION RELATING TO TOPICAL OVER-THE-COUNTER COLD SORE MANAGEMENT PRODUCTS IN THE EEA AND TURKEY

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "***Merger Regulation***"), GlaxoSmithKline ("***GSK***") hereby enters into the following Commitments (the "***Commitments***") vis-à-vis the European Commission (the "***Commission***") with a view to rendering GSK's acquisition of sole control over a company named GSK Consumer Healthcare ("***GSKCH***") (the "***Concentration***"), comprising the consumer healthcare business of GSK[1] and the over-the-counter business of Novartis AG,[2] compatible with the internal market and the functioning of the EEA Agreement.

The Commitments shall take effect upon the date of adoption of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "***Decision***"). This text shall be interpreted in light of the Commission's Decision, in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "***Remedies Notice***").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by GSK, including GSKCH, or by Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

   Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 5 (a), (b), (c), (d) and (e), and described in more detail in the Schedule.

   Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

---

1 Excluding GSK's consumer healthcare business in India and Nigeria, and products that are managed by, and reported for financial purposes within, GSK's Pharmaceutical Division.

2 Excluding Novartis' products that are managed by, and reported for financial purposes within, Novartis' Pharmaceutical Division, Alcon Division, and Sandoz Division.

Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divested Products: Novartis' topical over-the-counter Cold Sore Management ("***CSM***") products sold by the Divestment Business under the Divested Trademarks in the EEA and Turkey.

Divested Trademarks: all trademarks and tradenames relating to: (i) the products sold under Novartis' *Fenivir*, *Pencivir*, *Vectavir*, and *Vectatone* brands in all EEA jurisdictions, and (ii) the products sold under the *Vectavir* brand in Turkey.

Divestment Business: Novartis' topical over-the-counter Cold Sore Management ("***CSM***") business, comprising the Licensed Trademark and the Divested Products in the EEA and in Turkey, as further defined in Section B and in the attached Schedule, which GSK commits to divest.

Divestiture Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., incorporated under the laws of England and Wales, with its registered office at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Licensed Trademark: Novartis' *Fenistil* trademark for the marketing of topical over-the-counter CSM products in the United Kingdom and the Netherlands.

Monitoring Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated under the laws of Switzerland, with its registered office at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing in more detail the Divestment Business.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The Commitment to Divest and the Divestment Business

Commitment to Divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of, the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement (which will be subject to final approval by the Commission) for the sale of the Divestment Business within the First Divestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. GSK shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 18; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and Definition of the Divestment Business

5. The Divestment Business consists of Novartis' topical over-the counter topical Cold Sore Management ("CSM") business in the EEA and in Turkey, comprising the Divested Products, the Divested Trademarks, and the Licensed Trademark. The legal and

functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

(a) all tangible and intangible assets (including intellectual property rights and relevant internet domain names), by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the Divestment Business, including the Divested Trademarks and the Licensed Trademark, as specified in the Schedule;

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business, as specified in the Schedule;

(c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business, as specified in the Schedule;

(d) the Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager), as specified in the Schedule; and

(e) at the option of the Purchaser, transitional agreements with the Parties or Affiliated Undertakings for the supply of products and/or technical assistance, as specified in the Schedule.

6. GSK will ensure, or cause Novartis to ensure, that strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone other than Novartis and the Purchaser.

7. For the avoidance of doubt, the Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities used to manufacture the Divested Products;

(b) any ongoing R&D or pipeline products relating to *systemic* CSM products;

(c) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(d) the *Fenistil* brand or trademark outside the United Kingdom and outside the Netherlands and for any use other than for the Divested Product;

(e) the GSK or Novartis company names, marks, or logos in any form;

(f) any personnel other than the Hold Separate Manager;

(g) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that GSK will cause Novartis to provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request; and

(h) general books of account and books of original entry that comprise Novartis' or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will cause Novartis to provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request.

Section C. Related commitments

Preservation of Viability, Marketability and Competitiveness

8. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular, GSK undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage the Hold Separate Manager to remain with the Divestment Business, consistent with paragraph 9 of these Commitments. The Monitoring Trustee shall determine whether GSK has taken or procured all reasonable steps in this regard, in accordance with Section E of these Commitments. Where, nevertheless, the Hold Separate Manager leaves the Divestment Business, GSK shall provide, or shall cause Novartis to provide, a reasoned proposal to replace the Hold Separate Manager to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by the Hold Separate Manager. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission;

(d) to take all reasonable steps, or procure that all reasonable steps are being taken, to ensure that the Divestment Business continues to receive all the necessary support from GSKCH it needs to allow it to meet the Divestment Business' 2015 business plan. In particular, this shall mean that GSKCH will ensure that current resources available for the brand marketing, sales, regulatory affairs and supply chain management for the Divested Products will continue during the Hold Separate Period to ensure that the Divestment Business' 2015 business plan is achieved. The annual incentive programmes for personnel involved in the Divestment Business shall continue throughout the Hold Separate Period to be dependent upon the success of the Divestment Business. In the event that such personnel become unable to perform their roles in the Divestment Business (*e.g.*, as a result of resignation), GSK shall replace such personnel with appropriate alternatives to ensure the delivery of the Divestment Business' 2015 business plan is achieved. GSKCH rep-

resentatives and the Hold Separate Manager will hold regular meetings to discuss achievement of the Divestment Business' goals and the need for any adjustments in resource or personnel to ensure the goals are achieved. The Hold Separate Manager may request additional resources reasonably necessary to meet the Divestment Business' 2015 business plan. GSK shall make available such additional resources. To the extent GSK disagrees with the need for these additional resources, the Monitoring Trustee shall assess and have the final authority to determine whether the additional resources requested are reasonably necessary. Notwithstanding the above, consistent with GSK's ring-fencing obligations, sales and marketing personnel who work on the Divested Trademarks, during the Hold Separate Period, shall not work on brands of GSK directly competing with the Divestment Business.

9. The Hold Separate Manager will transfer to the Purchaser with the Divestment Business unless the Purchaser does not require such a transfer.[3] In case the Hold Separate Manager receives an offer of employment from the Purchaser (conditional on or following the Closing), GSK shall do the following:

   (a) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Hold Separate Manager from being employed by the Purchaser, and not offer any incentive to the Hold Separate Manager to decline employment with the Purchaser;

   (b) if the Hold Separate Manager accepts such offer of employment from the Purchaser, GSK shall cooperate with the Purchaser in effecting transfer of the Hold Separate Manager to the employ of the Purchaser.

Hold-Separate Obligations

10. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the business(es) it is retaining.

11. Until Closing, GSK commits to apply its existing incentive scheme governing the remuneration of its employees in respect of any activities relating to the Divestment Business. GSK further commits not to reduce the total amount of employee time currently dedicated to the Divestment Business, without prejudice to paragraph 13 below.

12. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable commercial entity separate from the business(es) which GSK is retaining. Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK.

---

3 Consistent with these Commitments, GSK will proactively facilitate and endeavor to procure the transfer of a specific Hold Separate Manager to the Purchaser should the Purchaser so require. If that is not possible then GSK will source suitable alternative talent for the Purchaser.

13. Until Closing, consistent with the commitment in paragraph 8, GSK commits to make available to the Hold Separate Manager sufficient resources (including personnel) reasonably necessary to ensure the development of the Divestment Business on the basis and continuation of the existing business plans. The Monitoring Trustee shall assess the reasonableness of any requests for resources from the Hold Separate Manager and GSK's performance under this commitment, in accordance with Section E of these Commitments.

14. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 8(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

Ring-Fencing

15. GSK shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business, except as is necessary to ensure the viability of the Divestment Business (including as is necessary for GSK to provide transitional services to the Divestment Business). In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law.

Non-Competition

16. GSK commits not to launch in the EEA or Turkey any topical or systemic OTC CSM product that contains the active ingredients *penciclovir* or *famciclovir* for a period of […] years after Closing.

17. GSK commits not to launch any Fenistil-branded OTC product in the United Kingdom during the time period it takes the Purchaser to re-brand the Fenistil product in the United Kingdom, but in any event for a period no longer than […] years.

Non-Solicitation Clause

18. GSK undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Hold Separate Manager transferred with the Divestment Business for a period of […] after Closing.

Due Diligence

19. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide to potential purchasers sufficient information as regards the Divestment Business;

(b) allow potential purchasers reasonable access to the Hold Separate Manager. The Monitoring Trustee shall determine whether GSK has provided reasonable access to the Hold Separate Manager, in accordance with Section E of these Commitments.

Reporting

20. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

21. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

22. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

(a) The Purchaser shall be independent of and unconnected to GSK and Novartis and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

(b) The Purchaser shall have experience in the supply of consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

(c) The Purchaser shall have an established presence in and/or access to distribution channels typically used in the consumer healthcare business in each of the EEA countries in which the Divestment Business is active;

(d) The Purchaser shall have experience in the marketing, promotion, sales and distribution of branded consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

(e) The Purchaser shall have experience in working with authorities in the EEA in obtaining necessary regulatory approvals (*e.g.*, marketing authorisations);

(f) The Purchaser shall have the financial resources, proven expertise, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in the EEA in competition with the Parties and other competitors; and

(g) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be ex-

pected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

23. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. The sale and purchase agreement shall contain a purchase price that is finally determined at Closing and not be dependent on the Divestment Business' performance after Closing (*i.e.*, the purchase price should not be conditional on the performance of the Divestment Business after Closing or subject to royalties). For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets, or by substituting one or more Assets with one or more different assets, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment Procedure

24. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Concentration before the appointment of the Monitoring Trustee.

25. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

26. The Trustee shall:

(a) at the time of appointment, be independent of GSK and Novartis and their Affiliated Undertakings;

(b) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(c) neither have nor become exposed to a Conflict of Interest.

27. The Trustee shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of

the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

28. No later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 26 and shall include:

    (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

    (b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

    (c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or Rejection by the Commission

29. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New Proposal by GSK

30. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 24 of these Commitments.

Trustee Nominated by the Commission

31. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. <u>Functions of the Trustee</u>

32. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the re-

quest of the Trustee or GSK, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

33. The Monitoring Trustee shall:

(a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(b) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(ii) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 12 of these Commitments; and

(iii) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK,

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary to allow GSK to carry out the divestiture or as the disclosure is required by law; and

(iv) monitor the splitting of assets between the Divestment Business and GSK or Affiliated Undertakings;

(c) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business consistent with Section C of these

Commitments, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(d) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(i) potential purchasers receive sufficient and correct information relating to the Divestment Business in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(ii) potential purchasers are granted reasonable (in the view of the Monitoring Trustee) access to the Hold Separate Manager;

(e) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(f) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(g) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(h) within one week after receipt of the documented proposal referred to in paragraph 18 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser; and

(i) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

34. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and Obligations of the Divestiture Trustee

35. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the Purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in

accordance with paragraphs 17 and 18 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

36. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

III. Duties and Obligations of the Parties

37. GSK shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of GSK's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and GSK and the Divestment Business shall provide the Trustee upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

38. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

39. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

40. GSK shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the

performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

41. At the expense of GSK, the Trustee may appoint advisors (including in respect of such matters as: corporate finance, legal advice, technical requirements, R&D, clinical/regulatory, manufacturing, and distribution), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 40 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

42. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17(1) and (2) of the Merger Regulation apply *mutatis mutandis*.

43. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

44. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, Discharge and Reappointment of the Trustee

45. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

    (a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

    (b) GSK may, with the prior approval of the Commission, replace the Trustee.

46. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.

47. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implement-

ed. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

48. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

49. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

50. If the approval of the GSK/Novartis Consumer Health Business transaction by another antitrust authority is made subject to requirements that:

    (a) are potentially inconsistent with these Commitments; or

    (b) would, when combined with the obligations in these Commitments, result in the divestiture of assets or businesses beyond that which is necessary to maintain or restore effective competition in the EEA,

    GSK may request a review and adjustment of these Commitments in order to avoid such inconsistencies or obligations beyond those necessary to restore effective competition.

Section G. Entry into Force

51. The Commitments shall take effect upon the date of adoption of the Decision.

Brussels, January 21, 2015

[…]
duly authorised for and on behalf of
GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business is operated by Novartis as part of Novartis' Consumer Healthcare division.

2. In accordance with paragraph 6 of these Commitments, the Divestment Business will include:

   (a) A transfer (by way of sale) of the following main tangible assets: all finished goods inventory, supplies, sales and promotional material relating exclusively to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH) held at the date of Closing.

   (b) A transfer (by way of sale, assignment or license, as appropriate) of the following main intangible assets insofar as they relate exclusively to the Divestment Business (*i.e.*, not related to the retained business of GSK, Novartis, or GSKCH):

      (i) the Divested Trademarks in the EEA and in Turkey;

      (ii) rights to any domain names within the EEA and Turkey that relate exclusively to the Divestment Business (the transfer to be effected by means of withdrawal and re-registration);

      (iii) patents for the EEA and Turkey held by Novartis in relation to the Divestment Business, which are listed in **Annex 1**;

      (iv) all copyrights in the EEA and Turkey related to the Divestment Business, covering, *inter alia*, information booklets and website content;

      (v) all know-how for the manufacturing of products by the Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in the EEA and in Turkey. The know-how is embodied in design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, and quality control standards; and

      (vi) an irrevocable, assignable, sub-licensable, royalty-free, license to all copyrights and patents and access to all know-how, for exclusive use in and limited to the EEA and Turkey, relating to any existing topical CSM pipeline product intended to be marketed in the EEA and Turkey under the Divested Trademarks. GSK will also provide, at the option of the Purchaser, technical assistance to the Purchaser in relation to the transfer of all pipeline projects in order to enable the Purchaser successfully to continue the development of such projects without delay.

   For the avoidance of doubt, GSK or Novartis, as applicable, will retain ownership of intangible assets that do not relate exclusively to the Divestment Business (*i.e.*, intangible assets which relate to the retained business of GSK or Novartis, as applicable), (*e.g.*, existing R&D relating to GSK, Novartis, or GSKCH topical CSM products that are marketed outside the EEA and Turkey,

and/or are not marketed under the Divested Trademarks). However, in respect of such shared assets GSK will, or will cause Novartis to, provide the Purchaser with an irrevocable, assignable, sub-licensable, royalty-free license to all copyrights and patents and access to all know-how on a non-exclusive basis, for use in and limited to the EEA and Turkey. The Monitoring Trustee shall supervise GSK's performance in this regard, in accordance with Section E of the Commitments.

(c) A transfer of, assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organization and held by Novartis that are exclusively necessary to manufacture and/or sell the products belonging to the Divestment Business (*i.e.*, not necessary to manufacture and/or sell the products belonging to the retained business of GSK, Novartis or GSKCH), including any dossiers relating to current or pending authorisations available to Novartis and, where necessary, assistance related to the transfer to the Purchaser of such licences, permits, and authorisations concerning the Divestment Business, and providing assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorisations;

(d) An assignment of an exclusive licence (containing usual and customary provisions related to quality control and the use, enforcement and maintenance of the Licensed Trademark and its associated goodwill) for the United Kingdom and the Netherlands for […] years to the Licensed Trademark for the marketing of topical over-the-counter cold sore management products, followed by a […]-year "black-out" period, during which GSK will abstain from using the Licensed Trademark in the cold sore management segment in the United Kingdom and the Netherlands, along with a commitment by GSK not to launch any *Fenistil*-branded OTC product in the United Kingdom during the time period it takes the Purchaser to re-brand the *Fenistil* product in the United Kingdom, but in any event for a period no longer than […] years;

(e) A transfer or assignment of, as appropriate, the following main contracts, agreements, leases, commitments and understandings to the extent exclusively related to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH):

(i) GSK will use its reasonable best efforts to transfer, or cause Novartis to transfer, or assign, as appropriate, all contracts with third-party suppliers of products or services to the Divestment Business, including current Novartis in-house supply arrangements for the API and finished products in place at Closing. In the event that such arrangements cannot be made, GSK is prepared to conclude back-to-back supply agreements with the Purchaser on an […];

(ii) GSK will use its reasonable best efforts to transfer, or cause Novartis to transfer, or assign, as appropriate, distribution agreements or the part of such agreements pertaining to the Divestment Business to the Purchaser; and

(iii) GSK will, or will cause Novartis to, use its reasonable best efforts to enter into a supply agreement with a suitable third-party manufacturer

for the supply of the active ingredient *penciclovir* to the Divestment Business, to be in place no later than 6 months after the Effective Date for supply to commence as of the expiry of the transitional *penciclovir* supply agreement referenced in Paragraph 2(h) below. This supply agreement shall be assigned to the Purchaser, and shall be revocable in the event the Purchaser prefers to source *penciclovir* from an alternate source (or produce it in-house). Alternatively, at the Purchaser's request, GSK will use its reasonable best efforts to support the Purchaser in concluding a new supply agreement with a third-party manufacturer for the supply of *penciclovir* to the Divestment Business.

The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;

(f) The transfer of the following customer, credit and other records to the extent exclusively related to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH): Novartis' customer lists and customer records;

(g) The Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager); and

(h) The arrangements for the supply of the following products or services by Novartis or Affiliated Undertakings for a transitional period in order to maintain the economic viability and competitiveness of the Divestment Business:

(i) If required by the Purchaser, GSK will, or will cause Novartis to, enter into an agreement, for a transitional period not extending beyond […], to supply the active ingredient *penciclovir* to the Divestment Business. Notwithstanding, in the event that the Purchaser has not been able to obtain an alternative source of *penciclovir* through the process set out in paragraph (e)(iii) above, GSK will, or will cause Novartis to, enter into an agreement to supply *penciclovir* to the Divestment Business at sufficient volumes to enable the production of finished topical CSM products to cover a transitional period of […] months from Closing as well as additional […] months if required by the Purchaser. GSK's or Novartis' transitional contract manufacturing agreement with the Purchaser would be concluded on a reasonable […][1] in accordance with good industry practice and under the supervision of the Monitoring Trustee; and

(ii) If required by the Purchaser, GSK will, or will cause Novartis, to enter into an agreement to supply finished topical CSM products to the Divestment Business for a transitional period not extending beyond […]. Notwithstanding, the agreement will provide for sufficient supply of finished products to cover a transitional period of […] months from

[1] […].

Closing as well as additional […] months if required by the Purchaser. GSK's or Novartis' transitional contract manufacturing and packaging agreement with the Purchaser would be concluded on a reasonable […] in accordance with good industry practice and under the supervision of the Monitoring Trustee.

(iii) If required by the Purchaser, GSK is prepared to collaborate with the Purchaser to identify any reasonable need for any transitional service agreements to be concluded between GSK and/or Novartis, as appropriate, and the Purchaser.

Following the expiry of the transitional supply agreement, the Purchaser will either use its own manufacturing site and equipment or use a third-party contract manufacturer for manufacturing and packaging. To enable the Purchaser, or a contract manufacturer on behalf of the Purchaser, to manufacture the Divested Products, GSK commits to transfer or license, or cause Novartis to transfer or license, any specific manufacturing technology to the Purchaser.

3. The Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities used to manufacture the Divested Products;

(b) any ongoing R&D or pipeline products relating to systemic CSM products;

(c) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(d) the *Fenistil* brand or trademark outside the United Kingdom and outside the Netherlands and for any use other than for the Divested Product;

(e) the GSK or Novartis company names, marks and logos in any form;

(f) any personnel other than the Hold Separate Manager;

(g) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that GSK will cause Novartis to provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request; and

(h) general books of account and books of original entry that comprise Novartis' or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will cause Novartis to provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser.

4. The Monitoring Trustee shall supervise GSK's implementation of this Schedule, in accordance with Section E of the Commitments.

5. GSK acknowledges that the Purchaser may elect to have all or some of the manufacturing carried out by third-parties for the Divestment Business. Nothing in this Schedule

or in the Commitments shall be construed as restricting the Purchaser's freedom in this regard.

Annex 1
PATENTS RELATING TO THE DIVESTMENT BUSINESS

[…]

Case COMP/M.7276 – GlaxoSmithKline / Novartis Consumer Health Business

COMMITMENTS TO THE EUROPEAN COMMISSION RELATING TO COLDREX COLD AND FLU PRODUCTS IN THE EEA

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "***Merger Regulation***"), GlaxoSmithKline ("***GSK***") hereby enters into the following Commitments (the "***Commitments***") vis-à-vis the European Commission (the "***Commission***") with a view to rendering GSK's acquisition of sole control over a company named GSK Consumer Healthcare ("***GSKCH***") (the "***Concentration***"), comprising the consumer healthcare business of GSK[321] and the over-the-counter business of Novartis AG,[322] compatible with the internal market and the functioning of the EEA Agreement.

The Commitments shall take effect upon the date of adoption of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "***Decision***"). This text shall be interpreted in light of the Commission's Decision, in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "***Remedies Notice***").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by GSK, including GSKCH, or Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

   Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 5 (a), (b), (c), (d), (e), and (f) and described in more detail in the Schedule.

   Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

   Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

---

321 Excluding GSK's consumer healthcare business in India and Nigeria, and products that are managed by, and reported for financial purposes within, GSK's Pharmaceutical Division.

322 Excluding Novartis' products that are managed by, and reported for financial purposes within, Novartis' Pharmaceutical Division, Alcon Division, and Sandoz Division.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divested Products: GSK's cold and flu products sold, or intended as of the date of the Commitments to be launched, by the Divestment Business under the *Coldrex* and *Coldrex Lary* trademarks (including multi- and single-symptom *Coldrex* products) in the EEA.

Divestment Business: assets and rights comprising GSK's *Coldrex*- and *Coldrex Lary*-branded cold and flu products (including multi- and single-symptom *Coldrex* products) in the EEA, as further defined in Section B and the attached Schedule, which GSK commits to divest.

Divested Trademarks: GSK's *Coldrex* and *Coldrex-Lary* trademarks in the EEA.

Divestiture Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., incorporated under the laws of England and Wales, with its registered office at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Monitoring Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated under the laws of Switzerland, with its registered office at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing in more detail the Divestment Business.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The Commitment to Divest and the Divestment Business

Commitment to Divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 20 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement (which will be subject to final approval by the Commission) for the sale of the Divestment Business within the First Divestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. GSK shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 20; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and Definition of the Divestment Business

5. The Divestment Business consists of GSK's *Coldrex* and *Coldrex Lary* cold and flu products (including multi- and single-symptom *Coldrex* products) in the EEA, comprising the Divested Products and the Divested Trademarks. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

   (a) all tangible and intangible assets (including intellectual property rights and relevant internet domain names) by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the Divestment Business, including the Divested Trademarks, as specified in the Schedule;

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business, as specified in the Schedule;

(c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business, as specified in the Schedule;

(d) all contracts with suppliers, including contracts with contract manufacturers that produce the Divested Products, as specified in the Schedule;

(e) the Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager), as specified in the Schedule; and

(f) at the option of the Purchaser, transitional agreements with GSK or Affiliated Undertakings for the supply of products and/or technical assistance, as specified in the Schedule.

6. For the avoidance of doubt, the Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities used to manufacture the Divested Products;

(b) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(c) the GSK company name, mark, or logo in any form;

(d) any personnel other than the Hold Separate Manager;

(e) books and records required to be retained by GSK or any of its Affiliated Undertakings pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser; and

(f) general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser.

Section C. Related Commitments

Preservation of Viability, Marketability and Competitiveness

7. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular GSK undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage the Hold Separate Manager to remain with the Divestment Business, consistent with paragraph 8 of these Commitments. The Monitoring Trustee shall determine whether GSK has taken or procured all reasonable steps in this regard, in accordance with Section E of these Commitments. Where, nevertheless, the Hold Separate Manager leaves the Divestment Business prior to Closing, GSK shall provide a reasoned proposal to replace the Hold Separate Manager to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by the Hold Separate Manager. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission;

(d) to take all reasonable steps, or procure that all reasonable steps are being taken, to ensure that the Divestment Business continues to receive all the necessary support from GSKCH it needs to allow it to meet the Divestment Business' 2015 business plan. In particular, this shall mean that GSKCH will ensure that current resources available for the brand marketing, sales, regulatory affairs and supply chain management for the Divested Products will continue during the Hold Separate Period to ensure that the Divestment Business' 2015 business plan is achieved. The annual incentive programmes for personnel involved in the Divestment Business shall continue throughout the Hold Separate Period to be dependent upon the success of the Divestment Business. In the event that such personnel become unable to perform their roles in the Divestment Business (*e.g.*, as a result of resignation), GSK shall replace such personnel with appropriate alternatives to ensure the delivery of the Divestment Business' 2015 business plan. GSKCH representatives and the Hold Separate Manager will hold regular meetings to discuss achievement of the Divestment Business' goals and the need for any adjustments in resource or personnel to ensure the goals are achieved. The Hold Separate Manager may request additional resources reasonably necessary to meet the Divestment Business' 2015 business plan. GSK shall make available such additional resources. To the extent GSK disagrees with the need for these additional resources, the Monitoring Trustee shall assess and have the final authority to determine whether the additional resources requested are reasonably necessary.

8. The Hold Separate Manager will transfer to the Purchaser with the Divestment Business unless the Purchaser does not require such a transfer.[323] In case the Hold Separate Manager receives an offer of employment from the Purchaser (conditional on or following the Closing), GSK shall do the following:

---

323 Consistent with these Commitments, GSK will proactively facilitate and endeavour to procure the transfer of a specific Hold Separate Manager to the Purchaser should the Purchaser so require. If that is not possible then GSK will source suitable alternative talent for the Purchaser.

(a) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Hold Separate Manager from being employed by the Purchaser, and not offer any incentive to the Hold Separate Manager to decline employment with the Purchaser; and

(b) if the Hold Separate Manager accepts such offer of employment from the Purchaser, GSK shall cooperate with the Purchaser in effecting transfer of the Hold Separate Manager to the employ of the Purchaser.

Hold-Separate Obligations

9. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the business(es) it is retaining.

10. Until Closing, GSK commits to apply its existing incentive scheme governing the remuneration of its employees in respect of any activities relating to the Divestment Business. GSK further commits not to reduce the total amount of employee time currently dedicated to the Divestment Business, without prejudice to paragraph 12 below.

11. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable commercial entity separate from the business(es) which GSK is retaining. Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK.

12. Until Closing, consistent with the commitment in paragraph 7, GSK commits to make available to the Hold Separate Manager sufficient resources (including personnel) reasonably necessary to ensure the development of the Divestment Business on the basis and continuation of the existing business plans. The Monitoring Trustee shall assess the reasonableness of any requests for resources from the Hold Separate Manager and GSK's performance under this commitment, in accordance with Section E of these Commitments.

13. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 7(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

Ring-Fencing

14. GSK shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business, except as is necessary to ensure the viability of the Divestment Business (including as is necessary for GSK to provide transitional services to the Divestment Business). In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law.

Non-Solicitation Clause

15. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Hold Separate Manager transferred with the Divestment Business for a period of […] after Closing.

Due Diligence

16. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide to potential purchasers sufficient information as regards the Divestment Business;

    (b) allow potential purchasers reasonable access to the Hold Separate Manager. The Monitoring Trustee shall determine whether GSK has provided reasonable access to the Hold Separate Manager, in accordance with Section E of these Commitments.

Reporting

17. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

18. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

19. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

    (a) The Purchaser shall be independent of and unconnected to GSK and Novartis and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

    (b) The Purchaser shall have experience in the supply of consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

    (c) The Purchaser shall have an established presence in and/or access to distribution channels typically used in the consumer healthcare business in each of the EEA countries in which the Divestment Business is active;

(d) The Purchaser shall have experience in the marketing, promotion, sales and distribution of branded consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

(e) The Purchaser shall have experience in working with authorities in the EEA in obtaining necessary regulatory approvals (*e.g.*, marketing authorisations); and

(f) The Purchaser shall have the financial resources, proven experience, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in the EEA in competition with the Parties and other competitors.

(g) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

20. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. The sale and purchase agreement shall contain a purchase price that is finally determined at Closing and not be dependent on the Divestment Business' performance after Closing (*i.e.*, the purchase price should not be conditional on the performance of the Divestment Business after Closing or subject to royalties). For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets, or by substituting one or more Assets with one or more different assets, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment Procedure

21. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Concentration before the appointment of a Monitoring Trustee.

22. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

23. The Trustee shall:

(a) at the time of appointment, be independent of GSK and Novartis and their Affiliated Undertakings;

(b) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(c) neither have nor become exposed to a Conflict of Interest.

24. The Trustee shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

25. Not later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or Rejection by the Commission

26. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New Proposal by GSK

27. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 25 of these Commitments.

Trustee Nominated by the Commission

28. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

29. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GSK, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

30. The Monitoring Trustee shall:

(a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(b) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(ii) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 11 of these Commitments; and

(iii) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK and

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary to allow GSK to carry out the divestiture or as the disclosure is required by law; and

(iv) monitor the splitting of assets between the Divestment Business and GSK or Affiliated Undertakings;

(c) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, consistent with Section C of these Commitments, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(d) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(i) potential purchasers receive sufficient and correct information relating to the Divestment Business in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(ii) potential purchasers are granted reasonable (in the view of the Monitoring Trustee) access to the Hold Separate Manager;

(e) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(f) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(g) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(h) within one week after receipt of the documented proposal referred to in paragraph 20 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser; and

(i) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

31. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and Obligations of the Divestiture Trustee

32. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 17 and 20 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

33. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

III. Duties and Obligations of the Parties

34. GSK shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of GSK's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and GSK and the Divestment Business shall provide the Trustee upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

35. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

36. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

37. GSK shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

38. At the expense of GSK, the Trustee may appoint advisors (including in respect of such matters as: corporate finance, legal advice, technical requirements, R&D, clinical/regulatory, manufacturing, and distribution), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

39. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17(1) and (2) of the Merger Regulation apply *mutatis mutandis*.

40. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

41. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, Discharge and Reappointment of the Trustee

42. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

    (a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

    (b) GSK may, with the prior approval of the Commission, replace the Trustee.

43. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.

44. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implement-

ed. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

45. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

46. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into Force

The Commitments shall take effect upon the date of adoption of the Decision.
Brussels, January 21, 2015

[…]
duly authorised for and on behalf of
GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business is operated by GSK as part of GSK's Consumer Healthcare division.

2. In accordance with paragraph 6 of these Commitments, the Divestment Business will include:

   (a) A transfer (by way of sale) of the following main tangible assets: all finished goods inventory, supplies, sales and promotional material relating exclusively to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH) held at the date of Closing.

   (b) A transfer (by way of assignment or licence, as appropriate) of the following main intangible assets insofar as they relate exclusively to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH):

      (i) the *Coldrex* and *Coldrex Lary* trademarks in the EEA;

      (ii) all copyrights in the EEA related to the Divestment Business, covering, *inter alia*, information booklets and website content to the extent necessary for the Divestment Business; and

      (iii) rights to any domain names within the EEA that relate exclusively to the Divestment Business (the transfer to be effected by means of withdrawal and re-registration); and

      (iv) all know-how for the manufacturing of products by the Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in the EEA. The know-how is embodied in design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, and quality control standards to the extent necessary for the Divestment Business; and

      (v) an irrevocable, assignable, sub-licensable and royalty-free licence to all copyrights and patents and access to all know-how for exclusive use in and limited to the EEA relating to any existing pipeline product intended to be marketed in the EEA under the *Coldrex and Coldrex Lary* brands. GSK will also provide, at the option of the Purchaser, technical assistance to the Purchaser in relation to the transfer of all pipeline projects in order to enable the Purchaser successfully to continue the development of such projects without delay.

   For the avoidance of doubt, GSK will retain ownership of intangible assets that do not relate exclusively to the Divestment Business (*i.e.* intangible assets which also relate to the retained business of GSK) (*e.g.*, existing R&D relating to GSK cold and flu products that are marketed outside of the EEA and/or are not marketed under the *Coldrex* or *Coldrex Lary* brands. However, in respect of such shared intangible assets, GSK will provide the Purchaser with an irrevocable, assignable, sub-licensable and royalty-free licence to all copyrights and patents and access to all know-how, on a non-exclusive basis

for use in and limited to the EEA. The Monitoring Trustee shall supervise GSK's performance in this regard, in accordance with Section E of the Commitments;

(c) A transfer or assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organisation and held by GSK that are exclusively necessary to manufacture and/or sell the products belonging to the Divestment Business (*i.e.* not necessary to manufacture and/or sell the products belonging to the retained business of GSK, Novartis or GSKCH), including any dossiers relating to current or pending authorisations available to GSK and, where necessary, assistance related to the transfer to the Purchaser of such licences, permits, and authorisations concerning the Divestment Business, and providing assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorisations. For the avoidance of doubt, licences that are held by, required for the continued operation of, and specific to, any manufacturing site will be retained by that manufacturing site and will not be transferred to the Purchaser;

(d) A transfer to a third party manufacturer or the Purchaser itself, at the Purchaser's election, of all manufacturing technology and know-how necessary to enable the third party manufacturer or the Purchaser itself at the Purchaser's election, to manufacture *Coldrex* or *Coldrex Lary* products for the Purchaser for the Divestment Business. GSK will use its reasonable best efforts to facilitate such a transfer. The Monitoring Trustee shall supervise GSK's efforts in this regards, in accordance with Section E of the Commitments;

(e) A transfer or assignment of, as appropriate, the following main contracts, agreements, leases, commitments and understandings to the extent exclusively related to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH):

(i) GSK will use its reasonable best efforts to transfer to the Purchaser the relevant portions of the supply and packaging agreement with […] relating to *Coldrex* and *Coldrex Lary* products or to enable the Purchaser to conclude a new supply and packaging agreement with […] in relation to *Coldrex* and *Coldrex Lary* products for the Divestment Business. In the event that such arrangements cannot be made, GSK is prepared to conclude back-to-back supply agreements with the Purchaser on an […];

(ii) GSK will use its reasonable best efforts to transfer GSK's existing contracts with customers in the EEA relating to the products belonging to the Divestment Business with the consent of the customers.

The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments.;

(f) The transfer of the following customer, credit and other records to the extent exclusively related to the Divestment Business (*i.e.* not relating to the retained business of GSK or GSKCH): GSK's customer list and customer records;

(g) The Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager); and

(h) The arrangements for the supply of the following products or services by GSK or Affiliated Undertakings for a transitional period in order to maintain the economic viability and competitiveness of the Divestment Business:

(i) If required by the Purchaser, GSK is prepared to conclude a transitional contract manufacturing and packaging agreement with the Purchaser for the Divested Products and use its reasonable best efforts to procure that […] enter into manufacturing and packaging agreements with the Purchaser with respect to the Divested Products they manufacture and package for GSK. GSK's transitional contract manufacturing agreement with the Purchaser would be concluded on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee. These transitional arrangements shall be in place until the later of receipt of the last of the specified set of approvals or […] months from Closing (with the possibility of a […] month extension at the option of the Purchaser). The transitional arrangements may also be further extended at the request of the Purchaser and with the consent of GSK based on a report of the Monitoring Trustee; and

(ii) If required by the Purchaser, GSK is prepared to collaborate with the Purchaser to identify any reasonable need for any additional transitional service agreements to be concluded between GSK and the Purchaser.

Following the expiry of the transitional supply agreement, the Purchaser will either use its own manufacturing site and equipment or use a third-party contract manufacturer for manufacturing and packaging. To enable the Purchaser, or a contract manufacturer on behalf of the Purchaser, to manufacture the Divested Products, GSK commits to transfer or licence or cause Novartis to transfer or licence any specific manufacturing technology to the Purchaser.

3. The Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities;

(b) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(c) the GSK company name, mark, or logo in any form;

(d) any personnel other than the Hold Separate Manager;

(e) books and records required to be retained by GSK or any of its Affiliated Undertakings pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser; and

(f) general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser.

4. The Monitoring Trustee shall supervise GSK's implementation of this Schedule, in accordance with Section E of the Commitments.

5. GSK acknowledges that the Purchaser may elect to carry out itself all or some of the manufacturing and/or distribution activities that are currently carried out by third parties for the Divestment Business. Nothing in this Schedule or in the Commitments shall be construed as restricting the Purchaser's freedom in this regard.

Case COMP/M.7276 – GlaxoSmithKline / Novartis Consumer Health Business

COMMITMENTS TO THE EUROPEAN COMMISSION RELATING TO COLD & FLU PRODUCTS IN SWEDEN

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "***Merger Regulation***"), GlaxoSmithKline ("***GSK***") hereby enters into the following Commitments (the "***Commitments***") vis-à-vis the European Commission (the "***Commission***") with a view to rendering GSK's acquisition of sole control over a company named GSK Consumer Healthcare ("***GSKCH***") (the "***Concentration***"), comprising the consumer healthcare business of GSK[324] and the over-the-counter business of Novartis AG,[325] compatible with the internal market and the functioning of the EEA Agreement.

The Commitments shall take effect upon the date of adoption of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "***Decision***"). This text shall be interpreted in light of the Commission's Decision, in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "***Remedies Notice***").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by GSK, including GSKCH, or Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

   Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 5 (a), (b), (c), (d), (e) and (f) and described in more detail in the Schedule.

   Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

   Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

---

324 Excluding GSK's consumer healthcare business in India and Nigeria, and products that are managed by, and reported for financial purposes within, GSK's Pharmaceutical Division.

325 Excluding Novartis' products that are managed by, and reported for financial purposes within, Novartis' Pharmaceutical Division, Alcon Division, and Sandoz Division.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divested Products: GSK's cold & flu products sold by the Divestment Business under the *Nasin* and *Nezeril* trademarks in Sweden.

Divested Trademarks: GSK's *Nasin* and *Nezeril* trademarks in Sweden.

Divestment Business: GSK's business comprising the Divested Products in Sweden, as further defined in Section B and in the attached Schedule, which GSK commits to divest.

Divestiture Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., incorporated under the laws of England and Wales, with its registered office at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Monitoring Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated under the laws of Switzerland, with its registered office at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing in more detail the Divestment Business.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The Commitment to Divest and the Divestment Business

Commitment to Divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement (which will be subject to final approval by the Commission) for the sale of the Divestment Business within the First Divestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. GSK shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 18; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and Definition of the Divestment Business

5. The Divestment Business consists of GSK's consumer healthcare cold & flu business in Sweden, comprising the Divested Products and the Divested Trademarks. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

   (a) all tangible and intangible assets (including intellectual property rights and relevant internet domain names) by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the Divestment Business, including the Divested Trademarks, as specified in the Schedule;

   (b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business, as specified in the Schedule;

(c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business, as specified in the Schedule;

(d) all contracts with suppliers, including contracts with contract manufacturers that produce the Divested Products, as specified in the Schedule;

(e) the Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager), as specified in the Schedule; and

(f) at the option of the Purchaser, transitional agreements with GSK or Affiliated Undertakings for the supply of products and/or technical assistance, as specified in the Schedule.

6. For the avoidance of doubt, the Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities;

(b) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(c) the GSK company name, mark, or logo in any form;

(d) any personnel other than the Hold Separate Manager;

(e) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request; and

(f) general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request.

Section C. Related Commitments

Preservation of Viability, Marketability and Competitiveness

7. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular GSK undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to en-

courage the Hold Separate Manager to remain with the Divestment Business, consistent with paragraph 8 of these Commitments. The Monitoring Trustee shall determine whether GSK has taken or procured all reasonable steps in this regard, in accordance with Section E of these Commitments. Where, nevertheless, the Hold Separate Manager leaves the Divestment Business, GSK shall provide a reasoned proposal to replace the Hold Separate Manager to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by the Hold Separate Manager. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission;

(d) to take all reasonable steps, or procure that all reasonable steps are being taken, to ensure that the Divestment Business continues to receive all the necessary support from GSKCH it needs to allow it to meet the Divestment Business' 2015 business plan. In particular, this shall mean that GSKCH will ensure that current resources available for the brand marketing, sales, regulatory affairs and supply chain management for the Divested Products will continue during the Hold Separate Period to ensure that the Divestment Business' 2015 business plan is achieved. The incentive programmes for personnel involved in the Divestment Business shall continue throughout the Hold Separate Period to be dependent upon the success of the Divestment Business. In the event that such personnel become unable to perform their roles in the Divestment Business (*e.g.*, as a result of resignation), GSK shall replace such personnel with appropriate alternatives to ensure the delivery of the Divestment Business' 2015 business plan. GSKCH representatives and the Hold Separate Manager will hold regular meetings to discuss achievement of the Divestment Business' goals and the need for any adjustments in resource or personnel to ensure the goals are achieved. The Hold Separate Manager may request additional resources reasonably necessary to meet the Divestment Business' 2015 business plan. GSK shall make available such additional resources. To the extent GSK disagrees with the need for these additional resources, the Monitoring Trustee shall assess and have the final authority to determine whether the additional resources requested are reasonably necessary. Notwithstanding the above, consistent with GSK's ring-fencing obligations, sales and marketing personnel who work on the Divested Trademarks, during the Hold Separate Period, shall not work on brands of Novartis directly competing with the Divestment Business.

8. The Hold Separate Manager will transfer to the Purchaser with the Divestment Business unless the Purchaser does not require such a transfer.[326] In case the Hold Separate Manager receives an offer of employment from the Purchaser (conditional on or following the Closing), GSK shall do the following:

(i) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Hold Separate Manager from being employed by the Purchaser, and not offer

326 Consistent with these commitments, GSK will proactively facilitate and endeavour to procure the transfer of a specific Hold Separate Manager to the Purchaser should the Purchaser so require. If that is not possible then GSK will source suitable alternative talent for the Purchaser.

any incentive to the Hold Separate Manager to decline employment with the Purchaser; and

(ii) if the Hold Separate Manager accepts such offer of employment from the Purchaser, GSK shall cooperate with the Purchaser in effecting transfer of the Hold Separate Manager to the employ of the Purchaser.

Hold-Separate Obligations

9. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the business(es) it is retaining.

10. Until Closing, GSK commits to apply its existing incentive scheme governing the remuneration of its employees in respect of any activities relating to the Divestment Business. GSK further commits not to reduce the total amount of employee time currently dedicated to the Divestment Business, without prejudice to paragraph 12 below.

11. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable commercial entity separate from the business(es) which GSK is retaining. Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK.

12. Until Closing, consistent with the commitment in paragraph 7, GSK commits to make available to the Hold Separate Manager sufficient resources (including personnel) reasonably necessary to ensure the development of the Divestment Business on the basis and continuation of the existing business plans. The Monitoring Trustee shall assess the reasonableness of any requests for resources from the Hold Separate Manager and GSK's performance under this commitment, in accordance with Section E of these Commitments.

13. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 7(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

Ring-Fencing

14. GSK shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business, except as is necessary to ensure the viability of the Divestment Business (including as is necessary for GSK to provide transitional services to the Divestment Business). In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law.

Non-Solicitation Clause

15. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Hold Separate Manager transferred with the Divestment Business for a period of […] after Closing.

Due Diligence

16. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide to potential purchasers sufficient information as regards the Divestment Business;

    (b) allow potential purchasers reasonable access to the Hold Separate Manager. The Monitoring Trustee shall determine whether GSK has provided reasonable access to the Hold Separate Manager, in accordance with Section E of these Commitments.

Reporting

17. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

18. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

19. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

    (a) The Purchaser shall be independent of and unconnected to GSK and Novartis and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

    (b) The Purchaser shall have experience in the supply of consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

    (c) The Purchaser shall have an established presence in and/or access to distribution channels typically used in the consumer healthcare business in each of the EEA countries in which the Divestment Business is active;

(d) The Purchaser shall have experience in the marketing, promotion, sales and distribution of branded consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

(e) The Purchaser shall have experience in working with authorities in the EEA in obtaining necessary regulatory approvals (*e.g.*, marketing authorisations);

(f) The Purchaser shall have the financial resources, proven experience, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in the EEA in competition with the Parties and other competitors; and

(g) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

20. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. The sale and purchase agreement shall contain a purchase price that is finally determined at Closing and not be dependent on the Divestment Business' performance after Closing (*i.e.*, the purchase price should not be conditional on the performance of the Divestment Business after Closing or subject to royalties). For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets, or by substituting one or more Assets with one or more different assets, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed Purchaser.

Section E. Trustee

I. Appointment Procedure

21. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Concentration before the appointment of a Monitoring Trustee.

22. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

23. The Trustee shall:

(a) at the time of appointment, be independent of GSK and Novartis and their Affiliated Undertakings;

(b) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(c) neither have nor become exposed to a Conflict of Interest.

24. The Trustee shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

25. No later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or Rejection by the Commission

26. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New Proposal by GSK

27. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 24 of these Commitments.

Trustee Nominated by the Commission

28. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

29. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GSK, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

30. The Monitoring Trustee shall:

(a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(b) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(ii) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 11 of these Commitments;

(iii) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK, and

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary to allow GSK to carry out the divestiture or as the disclosure is required by law; and

(iv) monitor the splitting of assets between the Divestment Business and GSK or Affiliated Undertakings;

(c) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, consistent with Section C of these Commitments, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(d) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(i) potential purchasers receive sufficient and correct information relating to the Divestment Business in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(ii) potential purchasers are granted reasonable (in the view of the Monitoring Trustee) access to the Hold Separate Manager;

(e) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(f) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(g) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(h) within one week after receipt of the documented proposal referred to in paragraph 18 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser; and

(i) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

31. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and Obligations of the Divestiture Trustee

32. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 17 and 18 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

33. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

III. Duties and Obligations of the Parties

34. GSK shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of GSK's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and GSK and the Divestment Business shall provide the Trustee upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

35. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

36. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

37. GSK shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

38. At the expense of GSK, the Trustee may appoint advisors (including in respect of such matters as: corporate finance, legal advice, technical requirements, R&D, clinical/regulatory, manufacturing, and distribution), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

39. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17(1) and (2) of the Merger Regulation apply *mutatis mutandis*.

40. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

41. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, Discharge and Reappointment of the Trustee

42. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

    (a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

    (b) GSK may, with the prior approval of the Commission, replace the Trustee.

43. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.

44. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implement-

ed. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

45. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

46. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into Force

47. The Commitments shall take effect upon the date of adoption of the Decision.

Brussels, January 21, 2015

[…]
duly authorised for and on behalf of
GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business is operated by GSK as part of GSK's Consumer Healthcare division.

2. In accordance with paragraph 6 of these Commitments, the Divestment Business will include:

   (a) A transfer (by way of sale) of the following main tangible assets: all finished goods inventory, supplies, and sales and promotional material, relating exclusively to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH) held at the date of Closing.

   (b) A transfer (by way of assignment or licence, as appropriate) of the following main intangible assets insofar as they relate exclusively to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH):

      (i) the Divested Trademarks; and

      (ii) all copyrights related to the Divestment Business, covering, *inter alia*, information booklets and website content; and

      (iii) rights to any domain names within Sweden that relate exclusively to the Divestment Business (the transfer to be effected by means of withdrawal and re-registration); and

      (iv) all know-how for the manufacturing of products by the Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in Sweden. The know-how is embodied in design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, and quality control standards.

   For the avoidance of doubt, GSK will retain ownership of existing and future intangible assets that do not relate exclusively to the Divestment Business (*i.e.*, intangible assets which also relate to the retained businesses of GSK) (*e.g.*, existing R&D relating to GSK cold and flu products that are marketed outside of Sweden and/or that are not marketed under the *Nasin* or *Nezeril* brands). However, in respect of such shared intangible assets, GSK will provide the Purchaser with an irrevocable, assignable, sub-licensable and royalty-free licence to all copyrights and patents and access to all know-how, on a non-exclusive basis for use in and limited to Sweden. The Monitoring Trustee shall supervise GSK's performance in this regard, in accordance with Section E of the Commitments.

   (c) A transfer or assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organization and held by GSK that are exclusively necessary to manufacture and/or sell the products belonging to the Divestment Business (*i.e.*, not necessary to manufacture and/or sell the products belonging to the retained business of GSK, Novartis or GSKCH), including any dossiers relating to current or pending authorisations available to GSK and, where necessary, assistance related to the transfer to the Purchaser

of such licences, permits, and authorisations concerning the Divestment Business, and providing assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorisations;

(d) A transfer to […] (or, at the Purchaser's election, an alternative third-party supplier or the Purchaser itself) of all manufacturing technology and know-how necessary to enable […] (or, at the Purchaser's election, an alternative third-party supplier or the Purchaser itself) to manufacture the Divested Products;

(e) A transfer or assignment of, as appropriate, the following main contracts, agreements, leases, commitments and understandings to the extent exclusively related to the Divestment Business (*i.e.*, not relating to the retained business of GSK, Novartis or GSKCH):

(i) GSK will use its reasonable best efforts to transfer to the Purchaser the relevant portions of all contracts with third-party suppliers of products or services to the Divestment Business, including contracts with third-party contract manufacturers in place at Closing. In the event that such arrangements cannot be made, GSK is prepared to conclude back-to-back supply agreements with the Purchaser on an […];

(ii) GSK will use its reasonable best efforts to transfer GSK's existing contracts with customers in Sweden relating to the products belonging to the Divestment Business with the consent of the customers.

The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;

(f) The transfer of the following customer, credit and other records to the extent exclusively related to the Divestment Business (*i.e.*, not relating to the retained businesses of GSK, Novartis or GSKCH): GSK's customer list and customer records;

(g) The Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager);

(h) The arrangements for the supply of the following products or services by GSK or Affiliated Undertakings for a transitional period in order to maintain the economic viability and competitiveness of the Divestment Business:

(i) If required by the Purchaser, GSK is prepared to conclude with the Purchaser transitional supply and/or transitional distribution agreements for the Divested Products to enable the continued sale of the products under the *Nezeril* and *Nasin* brands for the benefit of the Purchaser. These transitional agreements with the Purchaser would be concluded on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee. These transitional arrangements shall be in place until the later of receipt of the last of the specified set of approvals or […] months from Closing (with the possibility of a […] month extension at the option of the Purchaser). These transitional arrangements may also be further extended at the request of the Purchaser and with the consent of GSK based on a report of the Monitoring Trustee; and

(ii) If required by the Purchaser, GSK is prepared to collaborate with the Purchaser to identify any reasonable need for any additional transitional service agreements to be concluded between GSK and the Purchaser.

3. The Divestment Business shall not include:

   (a) any production or R&D facilities or equipment held at such facilities;

   (b) intellectual property rights which do not contribute to the current operation of the Divestment Business;

   (c) the GSK company name, mark, or logo in any form;

   (d) any personnel other than the Hold Separate Manager;

   (e) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request; and

   (f) general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon request.

4. The Monitoring Trustee shall supervise GSK's implementation of this Schedule, in accordance with Section E of the Commitments.

5. GSK acknowledges that the Purchaser may elect to carry out itself all or some of the manufacturing and/or distribution activities that are currently carried out by third parties for the Divestment Business. Nothing in this Schedule or in the Commitments shall be construed as restricting the Purchaser's freedom in this regard.

Case COMP/M.7276 – GlaxoSmithKline / Novartis Consumer Health Business

COMMITMENTS TO THE EUROPEAN COMMISSION RELATING TO PANODIL PAIN MANAGEMENT PRODUCTS IN SWEDEN

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "***Merger Regulation***"), GlaxoSmithKline ("***GSK***") hereby enters into the following Commitments (the "***Commitments***") vis-à-vis the European Commission (the "***Commission***") with a view to rendering GSK's acquisition of sole control over a company named GSK Consumer Healthcare ("***GSKCH***") (the "***Concentration***"), comprising the consumer healthcare business of GSK[327] and the over-the-counter business of Novartis AG,[328] compatible with the internal market and the functioning of the EEA Agreement.

The Commitments shall take effect upon the date of adoption of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "***Decision***"). This text shall be interpreted in light of the Commission's Decision, in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "***Remedies Notice***").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by GSK, including GSKCH, or by Novartis, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

   Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 6 (a), (b), (c), (d), (e) and (f) and described in more detail in the Schedule.

   Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

   Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

---

327 Excluding GSK's consumer healthcare business in India and Nigeria, and products that are managed by, and reported for financial purposes within, GSK's Pharmaceutical Division.

328 Excluding Novartis' products that are managed by, and reported for financial purposes within, Novartis' Pharmaceutical Division, Alcon Division, and Sandoz Division.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divested Products: GSK's pain management products sold by the Divestment Business under the *Panodil* trademark in Sweden.

Divestment Business: assets and rights comprising GSK's *Panodil*-branded pain management products in Sweden, as further defined in Section B and in the attached Schedule, which GSK commits to divest.

Divested Trademarks: *Panodil* trademarks in Sweden.

Divestiture Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK and who has/have received from GSK the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

GSK: GlaxoSmithKline plc., incorporated under the laws of England and Wales, with its registered office at 980 Great West Road, Brentford, TW8 9GS, United Kingdom.

Hold Separate Manager: the person appointed by GSK for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Monitoring Trustee: one or more natural or legal person(s), independent from GSK and Novartis, who is/are approved by the Commission and appointed by GSK, and who has/have the duty to monitor GSK's compliance with the conditions and obligations attached to the Decision.

Novartis: Novartis AG, incorporated under the laws of Switzerland, with its registered office at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

Parties: GSK and Novartis.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 20 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Purchaser Obligation: the obligation on the Purchaser to change the artwork and trade dress for the Divested Products within the period of […] months of Closing.

Schedule: the schedule to these Commitments describing in more detail the Divestment Business.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The Commitment to Divest and the Divestment Business

Commitment to Divest

2. In order to maintain effective competition, GSK commits to divest, or procure the divestiture of the Divestment Business, subject to the Purchaser Obligation, by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 21 of these Commitments. To carry out the divestiture, GSK commits to find a purchaser and to enter into a final binding sale and purchase agreement (which will be subject to final approval by the Commission) for the sale of the Divestment Business within the First Divestiture Period. If GSK has not entered into such an agreement at the end of the First Divestiture Period, GSK shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business, subject to the Purchaser Obligation, in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.

3. GSK shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, GSK or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 21; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, GSK shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from GSK showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

5. In order to further support the effect of the Commitments, GSK shall commit not to enter the over-the-counter and prescription pain management space in Sweden with the *Panadol* brand for a period of […] after closing.

Structure and Definition of the Divestment Business

6. The Divestment Business consists of GSK's *Panodil* pain management products in Sweden, comprising the Divested Products and the Divested Trademarks. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes all assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

(a) all tangible and intangible assets (including intellectual property rights and relevant internet domain names) by way of transfer, sale, assignment or licence, necessary to ensure the viability and competitiveness of the Divestment Business, including the Divested Trademarks, as specified in the Schedule;

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business, as specified in the Schedule;

(c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business, as specified in the Schedule;

(d) all contracts with suppliers, including contracts with contract manufacturers that produce the Divested Products, as specified in the Schedule;

(e) the Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager), as specified in the Schedule; and

(f) at the option of the Purchaser, transitional agreements with GSK or Affiliated Undertakings for the supply of products and/or technical assistance, as specified in the Schedule.

7. For the avoidance of doubt, the Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities used to manufacture the Divested Products;

(b) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(c) the GSK company name, mark, or logo in any form;

(d) any personnel other than the Hold Separate Manager;

(e) books and records required to be retained by GSK or any of its Affiliated Undertakings pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser; and

(f) general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser.

The sale of the Divestment Business will be subject to the Purchaser Obligation.

Section C. Related Commitments

Preservation of Viability, Marketability and Competitiveness

8. From the Effective Date until Closing, GSK shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible

any risk of loss of competitive potential of the Divestment Business. In particular GSK undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage the Hold Separate Manager to remain with the Divestment Business, consistent with paragraph 9 of these Commitments. The Monitoring Trustee shall determine whether GSK has taken or procured all reasonable steps in this regard, in accordance with Section E of these Commitments. Where, nevertheless, the Hold Separate Manager leaves the Divestment Business prior to Closing, GSK shall provide a reasoned proposal to replace the Hold Separate Manager to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by the Hold Separate Manager. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission;

(d) to take all reasonable steps, or procure that all reasonable steps are being taken, to ensure that the Divestment Business continues to receive all the necessary support from GSKCH it needs to allow it to meet the Divestment Business' 2015 business plan. In particular, this shall mean that GSKCH will ensure that current resources available for the brand marketing, sales, regulatory affairs and supply chain management for the Divested Products will continue during the Hold Separate Period to ensure that the Divestment Business' 2015 business plan is achieved. The incentive programmes for personnel involved in the Divestment Business shall continue throughout the Hold Separate Period to be dependent upon the success of the Divestment Business. In the event that such personnel become unable to perform their roles in the Divestment Business (*e.g.*, as a result of resignation), GSK shall replace such personnel with appropriate alternatives to ensure the delivery of the Divestment Business' 2015 business plan. GSKCH representatives and the Hold Separate Manager will hold regular meetings to discuss achievement of the Divestment Business' goals and the need for any adjustments in resource or personnel to ensure the goals are achieved. The Hold Separate Manager may request additional resources reasonably necessary to meet the Divestment Business' 2015 business plan. GSK shall make available such additional resources. To the extent GSK disagrees with the need for these additional resources, the Monitoring Trustee shall assess and have the final authority to determine whether the additional resources requested are reasonably necessary.

9. The Hold Separate Manager will transfer to the Purchaser with the Divestment Business unless the Purchaser does not require such a transfer.[329] In case the Hold Separate Manager receives an offer of employment from the Purchaser (conditional on or following the Closing), GSK shall do the following:

   (a) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Hold Separate Manager from being employed by the Purchaser, and not offer any incentive to the Hold Separate Manager to decline employment with the Purchaser; and

   (b) if the Hold Separate Manager accepts such offer of employment from the Purchaser, GSK shall cooperate with the Purchaser in effecting transfer of the Hold Separate Manager to the employ of the Purchaser.

Hold-Separate Obligations

10. GSK commits, from the Effective Date until Closing, to keep the Divestment Business separate from the business(es) it is retaining.

11. Until Closing, GSK commits to apply its existing incentive scheme governing the remuneration of its employees in respect of any activities relating to the Divestment Business. GSK further commits not to reduce the total amount of employee time currently dedicated to the Divestment Business, without prejudice to paragraph 13 below.

12. Until Closing, GSK shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable commercial entity separate from the business(es) which GSK is retaining. Immediately after the adoption of the Decision, GSK shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by GSK.

13. Until Closing, consistent with the commitment in paragraph 7, GSK commits to make available to the Hold Separate Manager sufficient resources (including personnel) reasonably necessary to ensure the development of the Divestment Business on the basis and continuation of the existing business plans. The Monitoring Trustee shall assess the reasonableness of any requests for resources from the Hold Separate Manager and GSK's performance under this commitment, in accordance with Section E of these Commitments.

14. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 7(c) of these Commitments. The Commission may, after having heard GSK, require GSK to replace the Hold Separate Manager.

---

[329] Consistent with these Commitments, GSK will proactively facilitate and endeavour to procure the transfer of a specific Hold Separate Manager to the Purchaser should the Purchaser so require. If that is not possible then GSK will source suitable alternative talent for the Purchaser.

Ring-Fencing

15. GSK shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business, except as is necessary to ensure the viability of the Divestment Business (including as is necessary for GSK to provide transitional services to the Divestment Business). In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. GSK may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to GSK is required by law.

Non-Solicitation Clause

16. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Hold Separate Manager transferred with the Divestment Business for a period of […] after Closing.

Due Diligence

17. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, GSK shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide to potential purchasers sufficient information as regards the Divestment Business;

    (b) allow potential purchasers reasonable access to the Hold Separate Manager. The Monitoring Trustee shall determine whether GSK has provided reasonable access to the Hold Separate Manager, in accordance with Section E of these Commitments.

Reporting

18. GSK shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). GSK shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

19. GSK shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

20. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

(a) The Purchaser shall be independent of and unconnected to GSK and Novartis and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

(b) The Purchaser shall have experience in the supply of consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

(c) The Purchaser shall have an established presence in and/or access to distribution channels typically used in the consumer healthcare business in each of the EEA countries in which the Divestment Business is active;

(d) The Purchaser shall have experience in the marketing, promotion, sales and distribution of branded consumer healthcare products in the EEA (not necessarily limited to pharmaceutical products);

(e) The Purchaser shall have experience in working with authorities in the EEA in obtaining necessary regulatory approvals (*e.g.*, marketing authorisations); and

(f) The Purchaser shall have the financial resources, proven experience, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in the EEA in competition with the Parties and other competitors.

(g) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

21. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When GSK has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. GSK must be able to demonstrate to the Commission that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. The sale and purchase agreement shall contain a purchase price that is finally determined at Closing and not be dependent on the Divestment Business' performance after Closing (*i.e.*, the purchase price should not be conditional on the performance of the Divestment Business after Closing or subject to royalties). For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets, or by substituting one or more Assets with one or more different assets, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed Purchaser.

Section E. Trustee

I. Appointment Procedure

22. GSK shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. GSK commits not to close the Concentration before the appointment of a Monitoring Trustee.

23. If GSK has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GSK at that time or thereafter, GSK shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

24. The Trustee shall:

(a) at the time of appointment, be independent of GSK and Novartis and their Affiliated Undertakings;

(b) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

(c) neither have nor become exposed to a Conflict of Interest.

25. The Trustee shall be remunerated by GSK in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by GSK

26. Not later than two weeks after the Effective Date, GSK shall submit the name or names of one or more natural or legal persons whom GSK proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, GSK shall submit a list of one or more persons whom GSK proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or Rejection by the Commission

27. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GSK shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GSK shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New Proposal by GSK

28. If all the proposed Trustees are rejected, GSK shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 24 of these Commitments.

Trustee Nominated by the Commission

29. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GSK shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

30. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GSK, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

31. The Monitoring Trustee shall:

(a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(b) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by GSK with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(ii) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 12 of these Commitments; and

(iii) with respect to Confidential Information:

– determine all necessary measures to ensure that GSK does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,

– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

– make sure that any Confidential Information relating to the Divestment Business obtained by GSK before the Effective Date is eliminated and will not be used by GSK and

– decide whether such information may be disclosed to or kept by GSK as the disclosure is reasonably necessary to allow GSK to carry out the divestiture or as the disclosure is required by law; and

(iv) monitor the splitting of assets between the Divestment Business and GSK or Affiliated Undertakings;

(c) propose to GSK such measures as the Monitoring Trustee considers necessary to ensure GSK's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, consistent with Section C of these Commitments, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(d) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(i) potential purchasers receive sufficient and correct information relating to the Divestment Business in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(ii) potential purchasers are granted reasonable (in the view of the Monitoring Trustee) access to the Hold Separate Manager;

(e) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(f) provide to the Commission, sending GSK a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(g) promptly report in writing to the Commission, sending GSK a non-confidential copy at the same time, if it concludes on reasonable grounds that GSK is failing to comply with these Commitments;

(h) within one week after receipt of the documented proposal referred to in paragraph 21 of these Commitments, submit to the Commission, sending GSK a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser; and

(i) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

32. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and Obligations of the Divestiture Trustee

33. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price and subject to the Purchaser Obligation, the Divestment Business to a Purchaser, provided that the Commission has approved both the Purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 20 and 21 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) the Purchaser Obligation and such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall further include in the sale and purchase agreement the obligation on GSK not to enter the over-the-counter pain management space in Sweden with the *Panadol* brand, consistent with Section B, Paragraph 5. The Divestiture Trustee shall protect the legitimate financial interests of GSK, subject to GSK's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

34. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to GSK.

III. <u>Duties and Obligations of the Parties</u>

35. GSK shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of GSK's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and GSK and the Divestment Business shall provide the Trustee upon request with copies of any document. GSK and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available

for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

36. GSK shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. GSK shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. GSK shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

37. GSK shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GSK shall cause the documents required for effecting the sale and the Closing to be duly executed.

38. GSK shall indemnify the Trustee and its employees and agents (each an "***Indemnified Party***") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to GSK for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

39. At the expense of GSK, the Trustee may appoint advisors (including in respect of such matters as: corporate finance, legal advice, technical requirements, R&D. clinical/regulatory, manufacturing, and distribution), subject to GSK's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should GSK refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard GSK. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served GSK during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

40. GSK agrees that the Commission may share Confidential Information proprietary to GSK with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17(1) and (2) of the Merger Regulation apply *mutatis mutandis*.

41. GSK agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

42. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, Discharge and Reappointment of the Trustee

43. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

(a) the Commission may, after hearing the Trustee and GSK, require GSK to replace the Trustee; or

(b) GSK may, with the prior approval of the Commission, replace the Trustee.

44. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.

45. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

46. The Commission may extend the time periods foreseen in the Commitments in response to a request from GSK or, in appropriate cases, on its own initiative. Where GSK requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. Only in exceptional circumstances shall GSK be entitled to request an extension within the last month of any period.

47. The Commission may further, in response to a reasoned request from GSK showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to GSK. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into Force

48. The Commitments shall take effect upon the date of adoption of the Decision.

Brussels, January 21, 2015

[…]

duly authorised for and on behalf of

GlaxoSmithKline plc.

SCHEDULE

1. The Divestment Business is operated by GSK as part of GSK's Consumer Healthcare division.

2. In accordance with paragraph 6 of these Commitments, the Divestment Business will include:

   (a) A transfer (by way of sale) of the following main tangible assets: all finished goods inventory, supplies, sales and promotional material relating exclusively to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH) held at the date of Closing;

   (b) A transfer (by way of assignment or licence, as appropriate) of the following main intangible assets insofar as they relate exclusively to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH):

      (i) the *Panodil* trademarks in Sweden;

      (ii) all copyrights in Sweden related to the Divestment Business, covering, *inter alia*, information booklets and website content to the extent necessary for the Divestment Business;

      (iii) rights to any domain names in Sweden that relate exclusively to the Divestment Business (the transfer to be effected by means of withdrawal and re-registration);

      (iv) all know-how for the manufacturing of products by the Divestment Business as well as know-how associated with obtaining manufacturing and marketing approvals for those products in Sweden. The know-how is embodied in design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, and quality control standards, to the extent necessary for the Divestment Business; and

      (v) an irrevocable, assignable, sub-licensable, royalty-free, licence to all copyrights and patents and access to all know-how, for exclusive use in and limited to Sweden, relating to any existing pipeline product intended to be marketed in Sweden under the *Panodil* brand. GSK will also provide, at the option of the Purchaser, technical assistance to the Purchaser in relation to the transfer of all pipeline projects in order to enable the Purchaser successfully to continue the development of such projects without delay.

   For the avoidance of doubt, GSK will retain ownership of intangible assets that do not relate exclusively to the Divestment Business (*i.e.* intangible assets which also relate to the retained business of GSK) (*e.g.*, existing R&D relating to GSK pain management products that are marketed outside of Sweden and/or are not marketed under the *Panodil* brand, such as […]. However, in respect of such shared intangible assets, GSK will provide the Purchaser with an irrevo-

cable, assignable, sub-licensable, royalty-free, licence to all copyrights and patents and access to all know-how, on a non-exclusive basis for use in and limited to Sweden. The Monitoring Trustee shall supervise GSK's performance in this regard, in accordance with Section E of the Commitments;

(c) A transfer of, assignment of, or access to, as appropriate, all licences, permits, and authorisations issued by any governmental organization and held by GSK that are exclusively necessary to manufacture and/or sell the products belonging to the Divestment Business (*i.e.* not necessary to manufacture and/or sell the products belonging to the retained business of GSK, Novartis or GSKCH), including any dossiers relating to current or pending authorisations available to GSK and, where necessary, assistance related to the transfer to the Purchaser of such licences, permits, and authorisations concerning the Divestment Business, and providing assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorisations. For the avoidance of doubt, licences that are held by, required for the continued operation of, and specific to, any manufacturing site will be retained by that manufacturing site and will not be transferred to the Purchaser;

(d) A transfer to a third party manufacturer or the Purchaser itself, at the Purchaser's election, of all manufacturing technology and know-how necessary to enable the third party manufacturer or the Purchaser itself at the Purchaser's election, to manufacture *[...]* for the Purchaser for the Divestment Business. GSK will use its reasonable best efforts to facilitate such a transfer. The Monitoring Trustee shall supervise GSK's efforts in this regards, in accordance with Section E of the Commitments;

(e) A transfer or assignment of, as appropriate, the following main contracts, agreements, leases, commitments and understandings to the extent exclusively related to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH):

(i) GSK will use its reasonable best efforts to transfer to the Purchaser the relevant portions of the supply and packaging agreement with […] relating to *[...]* and *[...]* or to enable the Purchaser to conclude a new supply and packaging agreement with […] in relation to *[...]* and *[...]* for the Divestment Business. In the event that such arrangements cannot be made, GSK is prepared to conclude back-to-back supply agreements with the Purchaser on an […];

(ii) GSK will use its reasonable best efforts to transfer GSK's existing contracts with customers in Sweden relating to the products belonging to the Divestment Business with the consent of the customers.

The Monitoring Trustee shall supervise GSK's efforts in this regard, in accordance with Section E of the Commitments;

(f) The transfer of the following customer, credit and other records to the extent exclusively related to the Divestment Business (*i.e.* not relating to the retained business of GSK, Novartis or GSKCH): GSK's customer list and customer records;

(g) The Hold Separate Manager (unless the Purchaser does not require the Hold Separate Manager); and

(h) The arrangements for the supply of the following products or services by GSK or Affiliated Undertakings for a transitional period in order to maintain the economic viability and competitiveness of the Divestment Business:

(i) If required by the Purchaser, GSK is prepared to conclude a transitional contract manufacturing and packaging agreement with the Purchaser for the Divested Products and use its reasonable best efforts to procure that […] enter into manufacturing and packaging agreements with the Purchaser with respect to the Divested Products they manufacture and package for GSK. GSK's transitional contract manufacturing agreement with the Purchaser shall be concluded on a reasonable […] in accordance with good industry practice under the supervision of the Monitoring Trustee. These transitional arrangements shall be in place until the later of receipt of the last of the specified set of approvals or […] months from Closing (with the possibility of a […] month extension at the option of the Purchaser). The transitional arrangements may also be further extended at the request of the Purchaser and with the consent of GSK based on a report of the Monitoring Trustee; and

(ii) If required by the Purchaser, GSK is prepared to collaborate with the Purchaser to identify any reasonable need for any additional transitional service agreements to be concluded between GSK and the Purchaser.

Following the expiry of the transitional supply agreement, the Purchaser will either use its own manufacturing site and equipment or use a third-party contract manufacturer for manufacturing and packaging. To enable the Purchaser, or a contract manufacturer on behalf of the Purchaser, to manufacture the Divested Products, GSK commits to transfer or licence or cause Novartis to transfer or licence any specific manufacturing technology to the Purchaser.

3. The Divestment Business shall not include:

(a) any production or R&D facilities or equipment held at such facilities;

(b) intellectual property rights which do not contribute to the current operation of the Divestment Business;

(c) the GSK company name, mark, or logo in any form;

(d) any personnel other than the Hold Separate Manager;

(e) books and records required to be retained by GSK or any of its Affiliated Undertakings pursuant to any statute, rule, regulation or ordinance, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser; and

(f) general books of account and books of original entry that comprise GSK's or any of its Affiliated Undertakings' permanent accounting or tax records, provided that GSK will provide copies of such documents necessary for the Divestment Business to the Purchaser, upon reasoned request from the Purchaser.

4. The sale of the Divestment Business will be subject to the Purchaser Obligation.

5. The Monitoring Trustee shall supervise GSK's implementation of this Schedule, in accordance with Section E of the Commitments.

6. GSK acknowledges that the Purchaser may elect to carry out itself all or some of the manufacturing and/or distribution activities that are currently carried out by third parties for the Divestment Business. Nothing in this Schedule or in the Commitments shall be construed as restricting the Purchaser's freedom in this regard.