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***Case No COMP/M.6278 -
TAKEDA / NYCOMED***

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERGER PROCEDURE**

Article 6(1)(b) NON-OPPOSITION
Date: 29/07/2011

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EUROPEAN COMMISSION

Brussels, 29.7.2011

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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
ARTICLE 6(1)(b) DECISION

To the notifying party

Dear Sir/Madam,

**Subject: Case No COMP/M. 6278 - TAKEDA/NYCOMED
Notification of 27 June 2011 pursuant to Article 4 of Council Regulation
No 139/2004¹
Publication in the Official Journal of the European Union No C 196,
05.07.2011, p. 14.**

1. On 27/06/2011, the European Commission received the notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which Takeda Pharmaceutical Company Limited ("Takeda", Japan) acquires, within the meaning of Article 3(1)(b) of the Merger Regulation, control of the whole of Nycomed A/S ("Nycomed", Switzerland) by way of purchase of shares.

I. THE PARTIES

2. Takeda is the parent company of a global group of companies whose activities are divided into three business segments: ethical drug, consumer healthcare and other businesses (including the manufacture and marketing of reagents, clinical diagnostics and chemical products).
3. Nycomed offers a diversified product range focused on branded prescription medicines, consumer healthcare products and a contract manufacturing business.

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.

II. THE OPERATION AND THE CONCENTRATION

4. On 19 May 2011, Takeda and Nycomed's current owner, Nycomed Sweden Holding 2 AB, signed a Sale and Purchase Agreement pursuant to which Takeda will acquire the entire issued share capital of Nycomed².
5. The proposed transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the EU Merger Regulation.

III. EU DIMENSION

6. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million³ (Takeda: EUR 10 366 million, Nycomed: EUR 2 835 million). Each of them has an EU-wide turnover in excess of EUR 250 million (Takeda: EUR [...] million, Nycomed: EUR [...] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension.

IV. ASSESSMENT

7. The transaction concerns prescription-bound human pharmaceuticals.

PRODUCT AND GEOGRAPHIC MARKET DEFINITION

Pharmaceuticals

8. The notifying party notes that in the past the Commission has taken as a starting point for product market definition purposes the Anatomical Classification Guidelines (ATC), maintained by the European Pharmaceutical Marketing Research Association (“EphMRA”) and used by Intercontinental Medical Statistics (“IMS”).
9. This is a hierarchical classification into 16 categories (A, B, C, D, etc.) that each have up to four levels, from the most general (ATC 1), to the most detailed (ATC 4). The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. ATC 3 is generally used by the Commission⁴ as a starting point for market definition. Products classified in one and the same ATC 3 class generally have the same therapeutic indication and, subject to exceptions, cannot be substituted by products belonging to other ATC 3 classes. The Commission has previously departed from the ATC 3 class in cases where the market investigation indicated that another market definition was more appropriate, such as the ATC 4 class, the active pharmaceutical ingredient (“API”) or galenic form (dosage, pharmaceutical form and route of administration)⁵. The notifying party has provided an analysis both at ATC 3 and at ATC 4 level, and has confirmed that there are no horizontal overlaps between the parties at molecule (API) level.

² Takeda will not be acquiring the Nycomed US dermatological business (Nycomed US Inc.), which, following an internal restructuring at Nycomed, will be retained by Nycomed Sweden Holding 2 AB and does not form part of the notified transaction.

³ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p. 1).

⁴ See, for example, Case No COMP/M.5778, *Novartis/Alcon*, decision of 9 August 2010.

⁵ See, for example, Case No COMP/M.5295, *Teva/Barr*, decision of 19 December 2008.

10. In the past the Commission has taken the view that, in cases involving the pharmaceutical industry, a full assessment of the competitive position of the parties involved also requires an analysis of products which are not yet on the market but are at an advanced stage of development. The Commission has thus considered that products in research and development (“R&D”) are relevant for an assessment of the competitive situation on existing product markets as well as on possible future markets⁶.
11. Once research and pre-clinical tests (in laboratory and on animals) for a new compound have been completed, an application is filed with any relevant national authority in Europe to begin clinical trials to test the drug in people. This involves three different stages⁷.
12. In the past the Commission has limited its analysis to projects which are at Phase III. This gives a more accurate estimation of new compounds entering the market in the near future than earlier phases. The notifying party concurs with this view, since an analysis of projects at an earlier stage of development cannot give a reliable indication of products likely to enter the market within the time relevant for a merger control assessment.
13. Therefore, in addition to actual overlaps between existing products, (a) any potential overlaps between existing products, on the one hand, and Nycomed’s and/or Takeda’s R&D projects in Phase III, on the other hand (affected market-to-pipeline), and (b) any potential overlaps between Nycomed’s and Takeda’s R&D projects in Phase III (pipeline-to-pipeline) have been identified on the basis of information determining the ATC 3 category in which the relevant pipeline product (if ever commercially developed) would most likely fall.
14. The Commission has previously defined separate markets for non-prescription-bound pharmaceuticals and prescription-bound pharmaceuticals because the medical indications, legal framework, marketing and distribution differ between these categories, even if the active ingredients may be the same. The notifying party agrees with the Commission in this regard.
15. The notifying party also notes that in the past the Commission has consistently considered the geographic market for pharmaceutical⁸ products to be national in scope.

⁶ See, for example, Case No COMP/M.5778, *Novartis/Alcon*, decision of 9 August 2010; Case No COMP/M.5865, *Teva/Ratiopharm*, decision of 3 August 2010.

⁷ Phase I - These tests involve about 20 to 100 healthy volunteers (except in the case of cancer and HIV, for which first trials are often first carried out on patients). The tests study a drug’s safety profile, including the safe dosage range. These studies also determine how a drug is absorbed, distributed, metabolised and excreted as well as any measures of drug activity on physiological or biochemical pathways. The objective here is to identify a narrow range of dose levels, and a dose interval, or frequency, that will be used in Phase II.

Phase II - In this phase, controlled trials of approximately 100 to 500 volunteer patients (people with the disease) assess a drug’s effectiveness. Safety, toleration and pharmacokinetic data are also obtained in Phase II.

Phase III - This phase usually involves 1,000 to 5,000 patients in clinics and hospitals, and the objective is to confirm the efficacy and safety of the test compound versus placebo and/or the standard of care for a given disease. Physicians monitor patients closely to confirm efficacy and identify adverse events. The larger Phase III clinical trials usually involve multiple sites in different countries.

⁸ See, for example, Case No COMP/M.5865, *Teva/Ratiopharm*, decision of 3 August 2010.

There are no specific circumstances in this case that would indicate a need to alter this approach.

Active pharmaceutical ingredients

16. Active pharmaceutical ingredients ("APIs") are the molecules, either under patent or in generic form, used to manufacture finished pharmaceuticals. Pharmaceutical companies use APIs for in-house production of finished products, but also provide them both to their licensees (under a specific licence contract, to be used in the final product covered by the licence) and to third parties.
17. In previous decisions the Commission has considered that APIs form separate product markets which are upstream of the markets of the finished pharmaceutical products. The Commission has examined each individual API as potentially constituting a relevant product market by itself, whilst noting that it cannot be excluded that certain APIs may be substitutable with each other for all or for a range of applications⁹.
18. In the present case, the product market definition can be left open as no concerns arise even on the narrowest possible market definition, i.e. on the basis of considering each individual API as the relevant product market.
19. The Commission has previously considered that the geographic markets for the provision of APIs are wider than the geographic markets for finished dose pharmaceuticals and possibly worldwide¹⁰. However, the exact scope of the geographic market can be left open as no serious doubts arise on the basis of either an EEA-wide market or a worldwide market.

Contract manufacturing

20. The Commission has considered in previous cases that contract manufacturing of finished dose pharmaceuticals consists in the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products, which may or may not include final packaging. This third party then goes on to market the finished products under its own label or brands. This definition excludes the manufacturing of APIs, since such ingredients are not typically manufactured on the basis of contract manufacturing agreements and typically may be procured from a wide variety of sources¹¹.
21. In previous decisions the Commission has left open the product market definition for contract manufacturing. The Commission, however, has found that, whilst certain core technologies in contract manufacturing are widely available and correspond to the most common pharmaceutical forms, certain other technologies are more specialized and cannot be substituted with the former from either the demand or supply side. The Commission has also found that a majority of the core technologies are offered by most undertakings which are active in contract manufacturing either as their main business or as an adjunct to their captive production activities, and that a number of contract manufacturing markets could thus be defined in function of the pharmaceutical form and

⁹ See, for example, Case No COMP/M.5865, *Teva/Ratiopharm*, decision of 3 August 2010.

¹⁰ See, for example, Case No COMP/M.5865, *Teva/Ratiopharm*, decision of 3 August 2010.

¹¹ See, for example, Case No COMP/M.5865, *Teva/Ratiopharm*, decision of 3 August 2010.

in some cases of the conditions of manufacture (types of active ingredients involved, toxicity, sterile environment, etc.).¹²

22. In this case, the precise product market definition of contract manufacturing can be left open as, regardless of the definition considered, the transaction does not give rise to serious doubts.
23. The Commission has previously considered that markets for the provision of contract manufacturing are at least EEA-wide¹³. Since competition concerns do not arise on the basis of either an EEA-wide market or a worldwide market, the exact scope of the geographic market can be left open.

COMPETITION ASSESSMENT

Introductory remarks on licensing agreements

24. Both Takeda and Nycomed have concluded licensing agreements with third parties.
25. A licensing relationship is established when, under the terms set out in a contract (the licensing agreement), a pharmaceutical company (an originator) grants to a third party, the licensee, the right to manufacture and commercialize, under the name of the third party, one or more of the pharmaceutical products it has developed. Under the licensing agreement, the API is normally provided by the licensor, for a price, to the licensee, in order to ensure the quality of the pharmaceutical product being produced under licence.
26. These licensing agreements raise the question how to treat sales of finished pharmaceutical products by the parties' licensees, that is, whether such sales should be attributed to the licensor or to the licensee. In such instances, the Commission assesses whether or not licensees can be considered autonomous players on the relevant market in order to establish the parties' market shares for the analysis of horizontal overlaps.
27. Licensing agreements also require an analysis of possible vertical links between the parties in order to assess possible foreclosure effects stemming from the notified concentration.
28. In previous cases, the Commission noted that a number of considerations might be relevant for the assessment of the autonomy of a licensee, such as the degree of exclusivity of the relationship, the risk and cost of any leakage of sensitive information to competitors, change of control provisions and the effective possibility to change provider, the period in which such a change could be effected, and the degree of lock-in contained in the contracts¹⁴. In the past, the Commission has indicated that under certain conditions licensees may be considered as independent from their respective licensors

¹² See, for example, Case No COMP/M.5253 *Sanofi-Aventis/Zentiva*, decision of 4 February 2009; Case No COMP/M.5555 *Novartis/EBEWE*, decision of 22 September 2009; Case No COMP/M.5778 *Novartis/Alcon*, **decision of 9 August 2010**.

¹³ See, for example, Case No COMP/M.5253, *Sanofi-Aventis/Zentiva*, decision of 4 February 2009.

¹⁴ See, for example, for example, Case No COMP/M. 5865, *Teva/Ratiopharm* and decision of 3 August 2010 and Case No COMP/M.5253, *Sanofi-Aventis/Zentiva*, decision of 4 February 2009.

and, therefore, that the market shares of licensees and licensors should not be added up for the purposes of the horizontal competitive assessment¹⁵.

29. In the present case, the notifying party has provided evidence showing that the terms for the licensing agreements of both Takeda and Nycomed are such that the licensees can be considered as genuine third parties carrying out an independent business and not mere agent distributors. Licensees usually determine their own pricing, distribution system and marketing strategy for the products that they produce under licence from the originator (for example, many of the licence agreements concluded by Takeda contain an express provision that the licensee is free to set the price of the final product). In view of this, for the purpose of this case it is considered that the parties' licensees are autonomous and that their sales should therefore be attributed to them and not to Takeda or Nycomed.
30. With regard to the assessment of possible vertical foreclosure effects in this case, it must be noted that the parties supply APIs practically only to their licensees and not in the open market (except for APIs supplied by Nycomed to third parties for an amount of EUR [<5] million). In addition, neither the licensee nor the licensor can easily switch API supplier or customer respectively as such a switch would entail costly and time consuming regulatory procedures. A marketing authorisation for a pharmaceutical product is specific to the source of the active ingredient and the product manufacturing process for which it has been requested. Therefore, the switch to a different API supplier cannot generally be implemented by a marketing authorisation holder of an existing authorised pharmaceutical product but requires a new application and supporting data, even if the new API supplier is an EU-approved supplier. Finally, the licensing agreements concluded by the parties are long term (mostly 10 years or longer), so they cannot be quickly or easily terminated by the licensor.

Horizontal overlaps

31. In previous cases¹⁶, the Commission has distinguished three categories of affected human pharmaceuticals markets. 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 does not exceed 1%;

Group 3: the Parties' joint market share is between 15% and 35%.

32. For the purpose of determining horizontal overlaps, the notifying party has verified, on a Member State by Member State basis and for each product that Takeda sells, whether Nycomed sells a prescription drug within the same ATC 3 class or, where appropriate according to the Commission practice,¹⁷ ATC 4 class or a combination of classes. As

¹⁵ See, for example, Case No COMP/M. 5865, *Teva/Ratiopharm*, decision of 3 August 2010.

¹⁶ See, for example, Case No COMP/M.5476 Pfizer/ Wyeth, decision of 17 July 2009; Case No COMP/M.5778 *Novartis / Alcon*, decision of 9 August 2010; and Case No COMP/M. 5865, *Teva/Ratiopharm*, decision of 3 August 2010.

¹⁷ See, for example, Case No COMP/M.5295, *Teva/Barr*, decision of 19 December 2008.

indicated, the notifying party has confirmed that there are no horizontal overlaps between the parties at molecule (API) level.

33. For the purposes of calculating market shares, the notifying party used IMS data. The IMS' MIDAS database classifies medicines in categories based on the ATC Guidelines. This database includes prescription-bound and non-prescription-bound registered medicines and covers the pharmacy channel and hospital sales. While the category share has been determined by taking into account only prescription-bound products¹⁸, the notifying party also reviewed whether additional overlaps would be created if it were assumed that prescription-bound and non-prescription-bound products were in the same market¹⁹.
34. As part of the assessment of overlaps at ATC 3 and/or ATC 4 levels all product markets in which the combined market shares of Takeda and Nycomed exceed 15% have been identified, thereby obtaining the affected markets. The methodology used in presenting this analysis follows the market segmentation approach used in previous Commission decisions²⁰.
35. Overlaps above 15% between the overall product portfolios of Takeda and Nycomed were identified in Austria, Germany and Italy at ATC 4 level, class A2B2, for acid or proton pump inhibitors ("PPIs"), which are antiulcerants, a type of drugs used to treat a range of common disorders considered to be related to acid secretion by the stomach.
36. In the present case, in line with previous Commission practice, the detailed market investigation focused on affected markets falling into category 1 ("Group 1" markets).

Affected markets

37. The proposed transaction results in only one "Group 1" affected market and two "Group 3" affected markets. In this case there are no "Group 2" affected markets.

(i) Antiulcerants (A2B2) in Austria

38. The "Group 1" affected market covers products classified under ATC 4 class A2B2 in Austria, where the parties have a combined market share of [30-40]% (Takeda [0-5]%, Nycomed [30-40]%).
39. The notifying party argues that the combined market share of Takeda and Nycomed in this product market in Austria overstates their actual market strength because (i) the forceful entry of generics over the last 5 years makes that the market shares of originators such as Takeda and Nycomed are declining, (ii) there is strong competition in the market from large competitors, both originators and generics, (iii) the Austrian regulatory framework for setting prices for prescription medicines and determining their

¹⁸ All products sold by Takeda in the EEA are prescription-bound. Nycomed sells OTC products in addition to its prescription-bound/semi-ethical drugs. As a result, the only overlaps between the parties are for the supply of prescription medicines for a limited number of therapeutic applications.

¹⁹ For this purpose, it was verified whether there are instances where Takeda sells a prescription-bound product and Nycomed a non-prescription bound product within the relevant ATC category.

²⁰ See Case No COMP/M.3751, *Novartis/Hexal*, decision of 27 May 2005 and more recently Case No COMP/M.5778, *Novartis/Alcon*, decision of 9 August 2010.

reimbursement maintains prices at a low level and (iv) because of generics, barriers to entry/expansion in the market are low.

40. All of these points were confirmed by the market investigation. In particular, there will remain post-merger a number of credible competitors able to impose a competitive constraint on the parties (AstraZeneca: 23.7%, Novartis (Sandoz): 13.5%, Teva: 8%, Janssen-Cilag: 7%).
41. In the light of the above elements and the parties' combined market share (below 40%), it can be concluded that the notified transaction does not raise serious doubts as to its compatibility with the internal market with regard to the Austrian market for PPIs classified under ATC 4 class A2B2.

(ii) Antiulcerants (A2B2) in Germany and Italy

42. "Group 3" markets exist in Germany and Italy also for antiulcerants classified under ATC 4 class A2B2. The parties' combined market shares on these markets are [20-30]% in Germany (Takeda [0-5]%, Nycomed [20-30]%) and [10-20]% in Italy (Takeda [5-10]%, Nycomed [10-20]%).
43. In Germany, the parties' combined market share is moderate (below 25%) and the increment brought about by the proposed transaction is marginal (0.4%). In addition, there will remain post-merger a number of credible competitors able to impose a competitive constraint on the parties (Novartis (Sandoz): 25.1%, Teva: 13.8%, AstraZeneca: 9%, Stada: 7.4%).
44. In Italy, the parties' combined market share is also moderate (below 20%) and a number of credible competitors will likewise remain post-merger (AstraZeneca: 16.5%, Menarini: 15.9%, Bracco 8.8%, Janssen-Cilag: 6.8%).
45. In view of the foregoing, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to the German and Italian markets for PPIs classified under ATC 4 class A2B2.

Vertical links

46. Both parties supply APIs to their licensees. Nycomed also supplies APIs to third parties albeit in a very limited amount (sales of EUR [<5] million, less than [<1]% of its EEA turnover). However, there are no horizontal overlaps between the parties in APIs.
47. With regard to vertical links, the only instance where the combined market share of Takeda and Nycomed is above 25% downstream (under all market definitions) and either one or both of the parties supplies a licensee and/or a third party with an API for the production of PPIs classified under ATC 4 class A2B2 is the Belgian PPI market. On this market, Takeda supplies the required API to a licensee (Sanofi), and Nycomed has a PPI market share of [30-40]% but does not supply APIs to either licensees or third parties.
48. Given the duration of the licensing agreements concluded by Takeda and Nycomed with their licensees and the existence of costly and lengthy regulatory obstacles, neither the licensee nor the licensor can easily switch their API supplier or customer respectively.

For the same reasons, **it would be difficult for the parties to source APIs from each other** for the manufacture of a pharmaceutical product.

49. In any event, even if the parties had the ability and incentive to terminate post-merger Takeda's current licensing agreement in Belgium, given Nycomed's low market share on the EEA market for APIs (and therefore the existence of a significant number of alternative suppliers of APIs in the EEA), it is considered unlikely that the proposed transaction would lead to input foreclosure on the Belgian PPI market.
50. Concerning contract manufacturing, the notifying party submits that only Nycomed provides these services to a limited extent (EUR [50-100] million, with an EEA market share of around [<1]%). There is therefore no horizontal overlap between the Parties as regards contract manufacturing. With regard to vertical links, the notifying party states that Nycomed does not contract manufacture any pharmaceutical products which compete downstream with Takeda's pharmaceutical products.
51. In view of the foregoing, it can be concluded that the notified transaction does not raise serious doubts as to its compatibility with the internal market with regard to vertical links in relation to APIs and contract manufacturing.

V. CONCLUSION

52. For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation.

For the European Commission,

(Signed)

*Maria DAMANAKI
Member of the Commission*