EUROPEAN COMMISSION

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PUBLIC VERSION

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Subject: **State Aid SA.43092 (2016/FC) – United Kingdom**
Complaint of Nurse Prescribers Ltd against the UK department of health

Sir,

1. PROCEDURE

(1) On 15 September 2015, the Commission received a complaint concerning the reimbursement of medical appliances and chemical reagents listed in part IX of the National Health Service Drug Tariff for England and Wales.

(2) On 7 October 2015, the Commission sent to the complainant a preliminary assessment of the complaint, finding that the measure at stake did not constitute State aid in the meaning of Article 107(1) TFEU. The complainant replied on 14 October 2015, contesting the Commission's preliminary assessment and inviting the Commission to reconsider its position.

(3) By letter of 13 November 2015, the Commission confirmed its preliminary assessment of the complaint finding that the measure at stake did not constitute State aid in the meaning of Article 107(1) TFEU. The complainant replied on 2 December 2015, contesting the Commission's preliminary assessment and inviting the Commission to reconsider its position.

The Rt Hon Boris JOHNSON
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King Charles Street
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(4) By letter of 10 May 2016, the Commission forwarded the non-confidential version of the complaint to the United Kingdom authorities. The United Kingdom authorities replied by letter of 8 June 2016.

2. DESCRIPTION OF THE MEASURE

(5) The Drug Tariff is a monthly publication issued by the prescription services of the National Health Service ("NHS") England and Wales. It outlines the rules for the prescription of medicines, medical appliances and chemical reagents and for the reimbursement of pharmacy contractors for the provision of these products to persons insured under the NHS.

(6) Part IX of the Drug Tariff concerns the reimbursement of medical appliances and chemical reagents by the NHS. It contains a list of the medical appliances and chemical reagents that can be prescribed and reimbursed under the NHS, as well as the price that will be paid to pharmacy contractors for the provision of these products.

(7) Manufacturers wishing to supply medical appliances and chemical reagents under the NHS system must seek approval from NHS prescription services for inclusion of their product into part IX of the Drug Tariff.

(8) For inclusion of a medical appliance or a chemical reagent in part IX of the Drug Tariff, the application must show that the product meets the three following criteria: i) it is safe and of good quality; ii) it is appropriate for prescription by general practitioners and, if relevant, for non-medical prescribing, and iii) it is cost effective. These criteria apply to all products for which inclusion into part IX of the Drug Tariff is sought.

(9) Products which bear the CE marking pursuant to Directive 93/42/EEC[1] and Directive 98/79/EC[2] will be considered by NHS prescription services as safe and of an acceptable quality. The majority of medical appliances listed in part IX of the Drug Tariff fall under the scope of these Directives. For the products that fall outside the scope of these Directives, i.e. custom devices and deodorants, the NHS prescription services will assess the quality and safety of these products themselves based on the data provided by the manufacturer.

(10) As regards the criterion of appropriateness for prescribing, the NHS prescription services will generally consider that it is met, if similar products are already listed in part IX of the Drug Tariff. If, on the other hand, a similar product is not yet listed, the NHS services will assess whether the product is appropriate for the treatment of a medical condition. The product should also be appropriate for self-administration by the patient and should not require enhanced training for its use.

(11) To determine cost effectiveness, the NHS prescription services will look at whether similar products are already listed. If so, the NHS prescription services will generally aim to ensure that the price of the new product is in line with those already listed. If similar products are not yet listed in the Drug Tariff, the NHS

[1] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1.

[2] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1.

prescription services will compare the cost and effectiveness of the new product with that of alternative treatments intended to treat the same condition.

(12) Once a product is included in the list, it can be prescribed under the NHS system by general practitioners, nurses or other health care providers entitled to prescribe medical appliances and chemical reagents. The prescription rules provide that prescribers may prescribe the products at stake either by brand name or using the generic name of the product. However, there is no system of recommended international non-proprietary names or British approved names that applies to medical appliances, as opposed to medicines. The United Kingdom authorities therefore consider that, in order to ensure that medical appliances are prescribed under the NHS in an accurate and safe way, it is necessary for the medical appliances listed in Part IX of the Drug Tariff to be described by reference to brand/manufacturer name. This means that, with a few exceptions, Part IX of the Drug Tariff does not describe the products listed in generic terms but uses the brand/manufacturer name of the product. This applies equally to branded products and to generic ones.

(13) Patients who have been prescribed a product listed in part IX of the Drug Tariff may get this product from a pharmacy contracting with the NHS. The pharmacist will be paid for the provision of the product at stake by the NHS, not by the patient, who will therefore get the product for free.

3. THE COMPLAINT BY NURSE PRESCRIBERS LTD

(14) On 15 September 2015, Nurse Prescribers Ltd. submitted a complaint to the Commission concerning part IX of the Drug Tariff. According to the complainant, part IX of the Drug Tariff would constitute State aid in the meaning of Article 107(1) TFEU because it would confer to the manufacturers of "well-known" and "well-advertised" branded products an advantage over the manufacturers of generic products.

(15) This advantage would stem in particular from the fact that, first, prescription rules do not impose on prescribers to prescribe medical appliances and chemical reagents by their generic names but allow them to prescribe products by brand name. Second, some of the generic descriptors to be used for generic prescription would be too cumbersome to be effectively used by prescribers. As a result, prescribers would continue to prescribe branded products instead of similar products without brand image, even though the latter are cheaper than the former.

(16) As pharmacists are obliged to provide patients with the product prescribed by the prescriber, the fact that well-known and well-advertised products are more easily prescribed by prescribers means that these products are purchased in a greater quantity under the NHS system. According the complainant, this situation would be unjustified, as these products are often more expensive than similar generic products and one of the purposes of the NHS system is cost containment of health care services.

4. ASSESSMENT OF THE MEASURE

(17) According to Article 107(1) TFEU, "*any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain*

goods shall, in so far as it affects trade between Member States, be incompatible with the internal market".

(18) It follows that, in order for a measure to be qualified as State aid within the meaning of Article 107(1) TFEU, the following cumulative conditions have to be met: i) the measure is imputable to the Member State and granted out of State resources, ii) it confers an economic advantage to undertakings, iii) it is selective, and iv) it distorts or threatens to distort competition and affects trade between Member States.

4.1 Selectivity

(19) To fall within the scope of Article 107(1) TFEU, a State measure must favour 'certain undertakings or the production of certain goods'. Hence, not all measures which favour economic operators fall under the notion of aid, but only those which grant an advantage in a selective way to certain undertakings or categories of undertakings or to certain economic sectors.

(20) Measures of purely general application which do not favour certain undertakings only or the production of certain goods only do not fall within the scope of Article 107(1) TFEU. According to the case law of the Court of Justice[3], a national measure will be considered as selective only if it discriminates between operators who are, in light of the objective pursued by that measure, in a comparable legal and factual situation.

(21) In the present instance, the Commission considers that part IX of the Drug Tariff is not a selective measure as it applies in the same way to all manufacturers of medical appliances and chemical reagents.

(22) As regards first the rules for the inclusion of medical appliances and chemical reagents in part IX of the Drug Tariff, they do not contain any exception in favour of "well advertised" and "well known" branded products nor create any distinction between these products and generic products. Any manufacturer of medical appliances or chemical reagents may apply for the inclusion of its product in part IX of the Drug Tariff. When deciding whether a product should be put on the list, the competent UK authorities will then assess the application according to the criteria listed in recitals (8) to (11) above, which are the same for all applications.

(23) Second, as regards the rules for prescription of medical appliances and chemical reagents, they provide that prescribers may prescribe any product in the list and to do so either by brand name or generically, if there is a generic descriptor. These rules apply in the same way to all medical appliances and chemical reagents. If a medical appliance or a chemical reagent is prescribed in a greater quantity than other similar products, it is the result of a preference of prescribers for this product. This preference may be due to different factors. For example, it may be due to the fact that prescribers are more familiar with the product at stake or to the fact that they think that this product is the best for their patients.

[3] Judgment of the Court of Justice of 14 January 2015, *Eventech Ltd*, C-518/13, EU:C:2015:9, paragraph 55.

(24) Based on the above, the Commission considers that part IX of the Drug Tariff is not a selective measure in the meaning of Article 107(1) TFEU, as it applies in the same way to all manufacturers of products falling under its scope.

4.2 Advantage

(25) As explained in recitals (6) and (13) above, the Drug Tariff sets out the rules for the reimbursement of the medical appliances to pharmacy contractors. There is therefore no direct transfer of State resources from the State to the manufacturers of the branded products listed in part IX of the Drug Tariff, who would, according to the complainant, be the beneficiaries of the alleged State aid.

(26) In that regard, the Commission recalls that an advantage can be conferred on undertakings other than those to which State resources are directly transferred (indirect advantage).[4] A measure can also constitute both a direct advantage to the recipient undertaking and an indirect advantage to other undertakings, for instance, undertakings operating at subsequent levels of activity.[5]

(27) However, such indirect advantages should be distinguished from mere secondary economic effects that are inherent in almost all State aid measures (for example through an increase of output). For this purpose, the foreseeable effects of the measure should be examined from an *ex ante* point of view. An indirect advantage is present if the measure is designed in such a way as to channel its secondary effects towards identifiable undertakings or groups of undertakings. This is the case, for example, if the direct aid is, *de facto* or *de jure*, made conditional on the purchase of goods or services produced by certain undertakings only (for example only undertakings established in certain areas).[6]

(28) In the present case, the Commission notes that prescribers are free to prescribe any medical appliances or chemical reagents included in part IX of the Drug Tariff and to do so either by brand name or generically, if a generic descriptor exists. It is their choice to prescribe the products which they think are the best for the patients. As noted in recital (23) above, it is because the prescribers may have a preference for certain medical appliances and chemical reagents that these products are provided in a greater quantity under the NHS system than other similar products. Reimbursement by the NHS of products listed in part IX of the Drug Tariff is however not in any way made, *de facto* or *de jure*, conditional on the purchase of particular branded products included in the list.

(29) Contrary to what has been argued by the complainant, the fact that some more expensive branded products are prescribed under part IX of the Drug tariff in a greater quantity than other similar but less expensive products, does not indicate

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[4] Judgment of the Court of Justice of 19 September 2000, *Germany* v *Commission*, C-156/98, EU:C:2000:467, paragraphs 26 and 27; Judgment of the Court of Justice of 28 July 2011, *Mediaset SpA* v *Commission*, C-403/10 P, EU:C:2011:533, paragraphs 73 to 77; Judgment of the Court of Justice of 13 June 2002, *Netherlands* v *Commission*, C-382/99, EU:C:2002:363, paragraphs 60 to 66; Judgment of the General Court of 4 March 2009, *Italy* v *Commission*, T-424/05, EU:T:2009:49, paragraphs 136 to 147. See also Article 107(2)(a) TFEU.

[5] In case an intermediary undertaking is a mere vehicle for transferring the advantage to the beneficiary and it does not retain any advantage, it should not normally be considered as a recipient of State aid.

[6] By contrast, a mere secondary economic effect in the form of increased output (which does not amount to indirect aid) can be found where the aid is simply channelled through an undertaking (for example a financial intermediary) which passes it on in full to the aid beneficiary.

that the measure is designed in such a way as to channel its secondary effects towards the manufacturers of the branded products. Indeed, in any system where the consumer of a product does not bear the cost of these products, its choice will not be influenced by the price of the product but by other factors such as the product's image or quality. All manufacturers of products listed in part IX of the Drug Tariff may take into account that reality and adapt their commercial strategy accordingly.

(30) Based on the above, the Commission considers that part IX of the Drug Tariff does not grant to manufacturers of branded products an advantage in the meaning of Article 107(1) TFEU.

5. CONCLUSION

(31) The Commission has accordingly decided that the measure does not constitute State aid in the meaning of Article 107(1) TFEU.

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Your request should be sent electronically to the following address:

European Commission,
Directorate-General Competition
State Aid Greffe
B-1049 Brussels
Stateaidgreffe@ec.europa.eu

Yours faithfully
For the Commission

Margrethe VESTAGER
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
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