



18 December 2023

(23-8653)

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Committee on Market Access

Original: English

**NOTIFICATION PURSUANT TO THE DECISION ON NOTIFICATION PROCEDURES
FOR QUANTITATIVE RESTRICTIONS ([G/L/59/REV.1](#))**

UNITED KINGDOM

Addendum

The following communication, dated 15 November 2023, is being circulated at the request of the delegation of the United Kingdom.

A. Notifying Member: United Kingdom
B. Date of notification: 15 November 2023
C. First time notification: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No, last notification was made in (doc. symbol): G/MA/QR/N/GBR/2/Add.2
D. Type of notification: <input type="checkbox"/> 1. Complete (i.e. notification of all quantitative restrictions in force) <input checked="" type="checkbox"/> 2. Changes to a notification previously made in G/MA/QR/N/GBR/2 which are of the following nature: <input type="checkbox"/> 2.1 Introduction of new restrictions, as listed in Section 1. <input type="checkbox"/> 2.2 Elimination of restrictions, as described in G below. <input checked="" type="checkbox"/> 2.3 Modification of a previously notified restriction, as described in Section 1. <input type="checkbox"/> 3. Reverse notification of restrictions maintained by (Member):
E. The notification provides information for the following biennial period (e.g. 2012-2014): <u>2022-2024</u> and relates to restrictions in force as of <u>9 October 2023</u>
F. This notification contains information* relating to: <input checked="" type="checkbox"/> Section 1: List of quantitative restrictions that are currently in force. <input type="checkbox"/> Section 2: Cross-reference to other WTO notifications with information on quantitative restrictions that are currently in force and additional information.

* In English only.

G. Comments of a general nature, including a description of the elimination of restrictions notified under D.2.2 and the date they ceased to be in force.

1. The UK is notifying the addition of 20 medicines to the list in critical short supply, in lieu of other shortage mitigations taking effect.
2. **Molnupiravir** and **Nirmatrelvir** (3004.90.00) are antivirals used to treat patients who remain at risk of Covid following the vaccination programme. The UK is further protecting existing supply by placing limits on the amount of each drug that can be ordered from any community pharmacy.
3. **Semaglutide, Dulaglutide, Exenatide, Liraglutide** and **Insulin/GLP-1 combination** (3004.39.00) are critical medicines used in the treatment of Type 2 diabetes. A global supply problem with these medicines is expected until mid-2024. There are alternative classes of medicines available to treat Type 2 diabetes; however, switching to an alternative medicine can cause complications for patients.
4. **Glucagon powder for injection and pre-filled syringe** (3004.39.00) is a critical medicine used in the treatment of severe hypoglycaemia and beta blocker overdose. There is an intermittent supply problem and licensed alternatives are also in short supply; however, the UK is regularly engaging with the manufacturers to monitor stock levels.
5. **Progesterone 100mg capsules** (3004.39.00) is used in hormone replacement therapy for post-menopausal women. There is no licensed alternative available, however the UK has issued a Serious Shortage Protocol (SSP) to limit the amount that a pharmacist can dispense to a maximum of two months' supply.
6. **Permethrin 5% Cream** (3004.90.00) is a medicine used to treat scabies. The disruption has been caused by an uptick in demand. There is no direct alternative medicine available, but the UK has engaged manufacturers to take steps to increase supply.
7. **Ketamine** (3004.90.00) is an anaesthetic used in short procedures not involving intense pain. Although a limited supply of an alternative has been diverted to the UK by the supplier, this is not sufficient to meet demand.
8. **Bupivacaine with Fentanyl** and **Levobupivacaine** (3004.90.00) are used for pain management and the induction of anaesthesia, particularly for epidural procedures. Supply has been restricted for use in epidural procedures as no other alternative medicines are available.
9. **Human corticotrophin releasing hormone** (3004.32.00) is used to diagnose Cushing's syndrome, a hormonal disorder. There is no direct alternative available and the UK has prioritised the use of existing supply for specific specialist centres.
10. **Hyoscine hydrobromide** (3004.90.00) is used to treat travel sickness symptoms. Supply has decreased due to the closure of the manufacturing site, however transfer to a new manufacturing site has been scheduled.
11. **Bumetanide** (3004.90.00) is a critical medicine used to treat oedema. The disruption has been caused by issues with the supply of the active pharmaceutical ingredient used to produce the medicine. Although there are alternative medicines available, some patients may be intolerant to these.
12. **Methylphenidate hydrochloride, Atomoxetine, Dexamfetamine sulfate** and **Guanfacine** (3004.90.00) are critical medicines used to Attention Deficit Hyperactivity Disorder (ADHD). Advice has been given to healthcare professionals to manage existing supply as global demand for ADHD products increases.
13. The UK is also notifying minor technical changes to existing medicines on the restricted list.
14. Two duplicated listings of steroids used to treat a wide range of health conditions, Dexamethasone (tablets and capsules) and Dexamethasone (oral solution) (3004.32.00), are being combined into one listing, Dexamethasone (All) (3004.32.00).

15. The pharmaceutical form for Diamorphine (tablets) (3004.49.00) is being amended to Diamorphine (solution for injection).

16. These are temporary measures, in place to relieve critical shortages of medicines necessary for the protection of human health. Measures are reviewed regularly and only applied where the critical need cannot be met by alternative measures. On 24 June 2022, 30 (net) medicines were removed from the list. On 3 January 2023 1 (net) medicine was removed from the list. We expect the next review to take place in five months' time (April 2024).

The UK's notification [G/MA/QR/N/GBR/2](#) included details relating to the Windsor Framework (previously the Northern Ireland Protocol). This notification does not amend those details which continue to apply.

Section 1: List of quantitative restrictions that are currently in force

QR No.	General description of the restriction	Type of restriction	Tariff line code(s) affected, based on HS (2017)	Detailed Product Description	WTO Justification and Grounds for Restriction, e.g. Other International Commitments	National legal basis and entry into force	Administration, modification of previously notified measures, and other comments
	1	2	3	4	5	6	7
1	Measures to regulate exports of certain medicaments.	CP-X	Medicines fall under the following commodity codes: 3004.10.00 3004.20.00 3004.32.00 3004.39.00 3004.49.00 3004.90.00	1. <u>Heading 3004 - Classification</u> Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale. Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives. Other, containing antibiotics. Containing corticosteroid hormones, their derivatives or structural analogues. Other, containing hormones or other products of heading 2937 > Other. Other, containing alkaloids or derivatives thereof > Other. Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up	Article XX(b) GATT Protection of human, animal or plant life or health.	Regulation 43(2) of the Human Medicines Regulations 2012 requiring wholesale dealers to ensure continued supply of medicinal products so that the needs of patients in the UK are met. Further details can be found through: https://www.legislation.gov.uk/ukxi/2012/1916/contents/made . The date restrictions came into effect varies by medicine; this is specified for each medicine on the list, updated on 9 October 2023 and available on gov.uk at: https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk . Medicines on this list which have been produced to fulfil contracts overseas are not subject to restriction. As such, restrictions only apply to wholesaler dealer license holders that are not the market authorisation holder for a medicine intended for export. The measures are designed to	The list of medicines is maintained by the Department of Health and Social Care. These measures are reviewed regularly. A full change log of previous measures, from October 2019, can be found here: https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk . Medicines included on this list meet the following conditions: - The medicine is required to meet the needs of UK patients; - The medicine is currently in shortage or risk of being in shortage; - The export of the medicine would contribute to or exacerbate a shortage, or risk of shortage, of that medicine in the UK.

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				<p>in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale > Other.</p> <p>Further detail of these medicines can be found at: https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk.</p> <p>These restrictions apply in certain circumstances to exports of specified medicines which are placed on the UK market for UK patients and needed to protect human health, including to treat COVID-19, <i>inter alia</i>.</p>			<p>ensure wholesalers fulfil their legal obligations to maintain supply to UK patients.</p> <p>These restrictions are only applied and maintained where alternative measures are not considered sufficient on their own to ensure that UK supply meets demand.</p> <p>A number of exemptions apply to medicines in scope of these restrictions. For example, exports destined for international humanitarian organisations are not covered. A full list of exemptions can be found at: https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk.</p> <p>Requests for exemptions are considered on a case-by-case basis. These can be submitted by a foreign government or government agency, or a wholesaler on their behalf at: restrictedmedicines@dhsc.gov.uk.</p> <p>Further information on these measures is available here: https://www.gov.uk/guidance/parallel-export-and-hoarding-of-restricted-medicines.</p>