WORLD TRADE ORGANIZATION

G/TBT/N/GBR/86

26 April 2024

(24-3424)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** UNITED KINGDOM **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Department for Health and Social Care **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** UK TBT Enquiry Point Trade Policy, Implementation and Negotiations Department for Business and Trade Old Admiralty Building London SW1A 2DY tbtenquiriesuk@businessandtrade.gov.uk
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Human Medicinal Products
5.	**Title, number of pages and language(s) of the notified document:** The Human Medicines (Amendments Relating to the Windsor Framework) Regulations 2024
6.	**Description of content:** The Regulations provide that a "UK marketing authorisation" comprises the following different types of authorisation: UKMA(UK)(Category 1) and UKMA(Category 2), which permit marketing of a medicinal product in all the territories of the UK; UKMA(GB) which does not permit marketing of a medicinal product in Northern Ireland; and UKMA(NI) which does not permit marketing of a medicinal product in Great Britain. These Regulations make amendments to the 2012 Regulations ensure that the correct type of authorisation is referred to. The Regulations make provision to transition existing marketing authorisations with an authorisation with a territorial limit of Great Britain to be converted to authorisations valid across the UK. The Regulations also make provision for a new requirement, for each of the above categories of authorisation, for products to be labelled "UK only"; and provision to disapply the product identification and anti-tampering device rules contained in Commission Delegated Regulation (EU) 2016/161. The changes made by the Regulations mean that the same products, in the same packs with the same labels, will be available across the whole of the UK

7.	**Objective and rationale, including the nature of urgent problems where applicable:** These amendments will facilitate a UK wide system of licensing and regulation of human medicines, helping to secure the long-term supply of human medicinal products in Northern Ireland. Ensuring the proper functioning of the UK internal market; Consumer information, labelling
8.	**Relevant documents:** Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK (www.gov.uk) UK-wide licensing for human medicines - GOV.UK (www.gov.uk)
9.	**Proposed date of adoption:** 1 July 2024 **Proposed date of entry into force:** 1 January 2025
10.	**Final date for comments:** 60 days from notification
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** UK TBT Enquiry Point Trade Policy, Implementation and Negotiations Department for Business and Trade Old Admiralty Building London SW1A 2DY tbtenquiriesuk@businessandtrade.gov.uk