WORLD TRADE ORGANIZATION

G/TBT/N/GBR/64

26 July 2023

(23-5094)

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 of Health and Social Care: Medicines and Healthcare Products Regulatory Agency **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 Group Department for International Trade Old Admiralty Building London SW1A 2DY TBTEnquiriesUK@trade.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):** General Medical Devices, Active Implantable Medical Devices and *in vitro* Diagnostic Medical Devices, which are defined under regulation 2 of The Medical Devices Regulations 2002.
5.	**Title, number of pages and language(s) of the notified document:** The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2023; (14 page(s), in English)
6.	**Description of content:** This measure will amend the Medical Devices Regulations 2002 as applicable in Great Britain. The amendments seek to introduce clearer, risk proportionate Post-market Surveillance (PMS) requirements. This will help to improve the ability of both the manufacturer and the MHRA to identify issues with Medical Devices placed onto the Great Britain market and where necessary, take appropriate action to safeguard public health. Some of the key changes include: a. Increased scope of devices that must comply with the new PMS requirements, this includes CE marked devices. b. Detail of what must be included as part of a PMS system, including the methods for collecting PMS data to support improved capturing of PMS data and harmonisation across manufacturers.

	c. Enhanced serious incident reporting obligations for manufacturers to support the detection of safety issues sooner. d. More stringent requirements for manufacturers to conduct periodic reviews of their PMS data including for implantable medical devices. This aims to support manufacturers in earlier detection of trends/signals that may have an impact on the safety of a Medical Device. Improved coordination and collaboration between manufacturers, UK Approved Bodies and the MHRA to support regulatory oversight.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The objective of this measure is to introduce clearer PMS requirements that are risk proportionate, with improved regulatory oversight. This is to ensure protection of human health and safety. Currently, under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) once a medical device has been placed on the market, the manufacturer must continually monitor the performance of the medical device. However, there are limited regulatory provisions surrounding Post Market Surveillance (PMS), which are high-level. Manufacturers are required to maintain a PMS system however, the detail surrounding how they conduct their PMS and vigilance obligations are not covered by the current legislation but instead, are covered in guidance. Due to the lack of PMS requirements within the Medical Devices Regulations 2002, this has created inconsistencies in the way manufacturers placing devices on the GB market, perform their PMS activities. This also impacts the quality of adverse incident data reported to the MHRA. Protection of human health or safety
8.	**Relevant documents:** The Medical Devices Regulations 2002 (legislation.gov.uk) A consultation on the future regulation of Medical Devices in the United Kingdom was held between September and November 2021. The Government Response to that Consultation on the future regulation of medical devices in the United Kingdom is found here: Chapter 8 - Post-market Surveillance, Vigilance, Market Surveillance - GOV.UK (www.gov.uk) The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2023 (draft)
9.	**Proposed date of adoption:** December 2023 **Proposed date of entry into force:** June 2024
10.	**Final date for comments:** 60 days from notification
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** UK TBT Enquiry Point Trade Policy Group Department for International Trade Old Admiralty Building London SW1A 2DY TBTEnquiriesUK@trade.gov.uk https://members.wto.org/crnattachments/2023/TBT/GBR/23_11298_00_e.pdf