WORLD TRADE ORGANIZATION

G/TBT/N/EU/1008

14 September 2023

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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:** EUROPEAN UNION **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** European Commission **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:** European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
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):** Medicinal products for human use and investigational medicinal products for human use
5.	**Title, number of pages and language(s) of the notified document:** Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)193 final); (182 page(s), in English), (37 page(s), in English)
6.	**Description of content:** This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts. It revises and replaces Regulation (EC) 726/2004 (general), Regulation (EC) 141/2000 (rare disease medicines) and Regulation (EC) 1901/2006 (paediatric medicines). The Regulation contains both technical regulations and conformity assessment procedures. 1. Technical regulations: The Regulation establishes certain conditions for the marketing authorisation of medicinal products for human use at central (EU) level. The Regulation also establishes rules at Union and at Member State level relating to the security of supply

	of medicinal products including the monitoring and management of shortages and critical shortages. 2. Conformity assessment procedures: The Regulation establishes the procedures for the authorisation of medicinal products for human use at central (EU) level. It also establishes procedures at Union and at Member State level relating to the security of supply of medicinal products including the monitoring and management of shortages and critical shortages.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 EUR-Lex - 32007R1394 - EN - EUR-Lex (europa.eu) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC EUR-Lex - 32014R0536 - EN - EUR-Lex (europa.eu)
9.	**Proposed date of adoption:** 31 December 2024 **Proposed date of entry into force:** 18 months days from publication in the Official Journal of the EU
10.	**Final date for comments:** 90 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:** European Commission, EU-TBT Enquiry Point, Fax: + (32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu The text is available on the EU-TBT Website : http://ec.europa.eu/growth/tools-databases/tbt/en/ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193 https://members.wto.org/crnattachments/2023/TBT/EEC/23_12355_00_e.pdf https://members.wto.org/crnattachments/2023/TBT/EEC/23_12355_01_e.pdf