NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **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.euWebsite: <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 Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)192 final); (184 page(s), in English), (103 page(s), in English) |
| **6.** | **Description of content:** This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use. It repeals and replaces Directive 2001/83/EC and Directive 2009/35/EC and it incorporates relevant parts of Regulation (EC) No 1901/2006;The Directive contains both technical regulations and conformity assessment procedures.1. Technical regulations: The Directive establishes standards of quality, safety and efficacy for the authorisation of medicinal products as it establishes the conditions for the marketing authorisation of medicinal products for human use at central (EU) and national (in different Member States) levels. The Directive also establishes the conditions for the manufacturing authorisation and wholesale distribution authorisation. It moreover establishes requirements on labelling and packaging.2. Conformity assessment procedures: The Directive establishes the procedures for the authorisation of medicinal products for human use at central (EU) and national (in different Member States. It also establishes procedures for the manufacturing authorisation and wholesale distribution authorisation. The Directive moreove establishes procedures for controls, supervision and inspections. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** Directive 2001/83/EC[EUR-Lex - 32001L0083 - EN - EUR-Lex (europa.eu)](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32001L0083)Directive 2009/35/EC[EUR-Lex - 32009L0035 - EN - EUR-Lex (europa.eu)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0035)Regulation (EC) No 1901/2006[EUR-Lex - 32006R1901 - EN - EUR-Lex (europa.eu)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1901) |
| **9.** | **Proposed date of adoption:** 31 December 2024**Proposed date of entry into force:** 18 months 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.euThe 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:52023PC0192><https://members.wto.org/crnattachments/2023/TBT/EEC/23_12354_00_e.pdf><https://members.wto.org/crnattachments/2023/TBT/EEC/23_12354_01_e.pdf> |