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.eu](mailto: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 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta (COM(2021) 997 final) (17 page(s), in English) |
| **6.** | **Description of content:** To ensure legal certainty and predictability the notified draft measure provides for permanent derogations from EU pharmaceutical law to ensure the continued long-term supply of and access to medicines from Great Britain to Northern Ireland ("NI"). In addition, it provides for three-year derogations to address outstanding supply concerns for Cyprus ("CY"), Malta ("MT") and Ireland ("IE"). Upon fulfilment of certain conditions as applicable, amendments to Directives 2001/20 and 2001/83 would allow imports of medicines without EU manufacturing and import authorisation from parts of the United Kingdom other than Northern Ireland. In addition,  amendments to Directive 2001/83 would allow the following:   * For NI + CY/MT/IE   + localisation of regulatory functions in parts of the United Kingdom other than Northern Ireland;   + exports of medicines to parts of the United Kingdom other than Northern Ireland and subsequently into NI/CY/MT/IE without the need to repeat batch testing if already carried out in the EU;   + quality control testing carried out in parts of the United Kingdom other than Northern Ireland; * for CY/MT   + the placing on the CY/MT market of a medicinal product based on an authorisation by a competent authority in parts of the United Kingdom other than Northern Ireland. * For NI   + the supply to patients in NI of innovative medicines at the same time as any other patients in other parts of the United Kingdom other than Northern Ireland;   + the marketing authorisation applicant to choose between the mutual recognition/decentralised procedures and the national authorisation procedure in respect of NI. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the measure are to ensure the protection of human health and in particular, to prevent shortages of medicines and ensure an adequate level of public health protection in Northern Ireland, Cyprus, Ireland and Malta.; Protection of human health or safety |
| **8.** | **Relevant documents:**   * Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20210526> * Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0020-20090807> |
| **9.** | **Proposed date of adoption:** 1st quarter 2022  **Proposed date of entry into force:** 1st or 2nd quarter 2022 with retroactive application from 1 January 2022 |
| **10.** | **Final date for comments:** 30 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](mailto:grow-eu-tbt@ec.europa.eu)  The text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/>  EUR-Lex - 52021PC0997 - EN - EUR-Lex (europa.eu)  <https://members.wto.org/crnattachments/2022/TBT/EEC/22_1848_00_e.pdf> |