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 CommissionEU-TBT Enquiry PointFax: +(32) 2 299 80 43E-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 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicinal products and medical devices; Medical equipment (ICS 11.040), Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020) 725) (53 page(s), in English) |
| **6.** | **Description of content:** This draft Regulation provides for, within the European Medicines Agency, a framework for and the means to:(a)        prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;(b)        monitor and report on shortages of medicinal products for human use and medical devices;(c)        provide advice on medicinal products for human use with the potential to address public health emergencies ('candidate medicines'); (d)        provide support for the medical device expert panels designated in accordance with Commission Implementing Decision (EU) 2019/1396. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The general objectives of the proposal are to: 1. ensure a high level of human health protection by strengthening the Union's ability to manage and respond to public health emergencies, which have an impact on medicinal products and medical devices; 2. contribute to ensuring the smooth functioning of the EU internal market for such products during public health emergencies. The specific objectives of the proposal are to: 1. monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health; 2. ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing a given public health emergency; 3. ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices. The rationale for the proposal is based on the experience of the COVID-19 pandemic and the clear need demonstrated for a strengthened framework for crisis preparedness and response to deal with future crises with an impact on medicinal products and medical devices.; Protection of human health or safety |
| **8.** | **Relevant documents:** The proposed Regulation will be a 'stand-alone' Regulation and will thus not revise or amend any current legislation on medicinal products, medical devices or the European Medicines Agency. It should be read in conjunction with Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2017/745, Regulation (EU) 2017/746, and Commission Implementing Decision (EU) 2019/1396: 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%3A32001L0083&qid=1606553610761>Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R0726&qid=1606553637213>Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745&qid=1606553663620>Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746&qid=1606553780760>Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019D1396&qid=1606553835020> |
| **9.** | **Proposed date of adoption:** 2021**Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU (with the exception of Article 28, the provisions shall apply on entry into force)  |
| **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:** European CommissionEU-TBT Enquiry PointFax: + (32) 2 299 80 43E-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://members.wto.org/crnattachments/2020/TBT/EEC/20_7638_00_e.pdf> |