NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Russian Federation  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Eurasian Economic Commission Department for technical regulation and accreditation  Tel: +7(495)669-24-00  Fax: +7(495)669-24-15  E-mail: [dept\_techregulation@eecommission.org](mailto:dept_techregulation@eecommission.org)  Web-site: www.eurasiancommission.org  **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:**  Russian Scientific and Technical Centre for Information on Standardization, Metrology and Conformity Assessment  (Standartinform, National enquiry point for the TBT Agreement) Tel: +7(495) 531-26-59  Fax: +7(495) 531-27-05  E-mail: [enpoint@gostinfo.ru](mailto:enpoint@gostinfo.ru)  Website: [www.gostinfo.ru](http://www.gostinfo.ru) |
| **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):** Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3003); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3004) |
| **5.** | **Title, number of pages and language(s) of the notified document:** The Draft amendments to the Rules of the Good Manufacturing Practice in the Eurasian Economic Union (30 page(s), in Russian) |
| **6.** | **Description of content:** The Draft amendments to the Rules of the Good Manufacturing Practice in the Eurasian Economic Union applies to medicinal products put into circulation on the territory of the Eurasian Economic Union and envisages the need to establish a unified approach to the procedures for qualification and validation of medicinal products, in order to prove that the parameters of critical processes (equipment) meet the specified requirements, as well as in case of significant changes in premises, equipment and processes that may affect the quality of finished products, which makes it possible to ensure stable output of products with a given level of quality at pharmaceutical enterprises. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection; Protection of human health or safety; Quality requirements |
| **8.** | **Relevant documents:**   * Draft amendments to Rules good manufacturing practice the Eurasian Economic Union:   <https://docs.eaeunion.org/ria/ru-ru/0104038/ria_16062020>   * Decision No.77 of the Council of the Eurasian Economic Commission of 3 November 2016:   http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LSl/Pages/drug\_products.aspx |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **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:**  Eurasian Economic Commission Department for Technical Regulation and Accreditation Tel: + 7(495)669-24-00 Fax: + 7(495)669-24-15 Website: www.eurasiancommission.org E-mail: [dept\_techregulation@eecommission.org](mailto:dept_techregulation@eecommission.org)  http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LSl/Pages/drug\_products.aspx  <https://docs.eaeunion.org/ria/ru-ru/0104038/ria_16062020> |