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@eurasiancommission.org](mailto:dept_techregulation@eurasiancommission.org)  Website: 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 Center for Information on Standardization, Metrology and Conformity Assessment  (Standartinform, National enquiry point for the TBT Agreement)  Tel: +7(495) 531-26-59  E-mail: [info@gostinfo.ru](mailto:info@gostinfo.ru)  Website: www.gostinfo.ru |
| **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 |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft amendments to the Rules for marketing authorization and assessment of medicinal products for human use; (24 page(s), in Russian) |
| **6.** | **Description of content:** The draft amendments to the Rules for marketing authorization and assessment of medicinal products for human use provide for the updating of the Rules for marketing authorization and assessment of medicinal products for human use with account of the experience of law enforcement of these Rules on the procedure for marketing authorization of medicinal products and bringing the registration dossier in line with the requirements of the Eurasian Economic Union. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** <https://docs.eaeunion.org/ria/ru-ru/0105925/ria_14042023> |
| **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  E-mail: [dept\_techregulation@eurasiancommission.org](mailto:dept_techregulation@eurasiancommission.org)  Website: www.eurasiancommission.org |