NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** Russian Federation **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Eurasian Economic CommissionDepartment for Technical Regulation and Accreditation Tel: +7(495)669-24-00 Fax: +7(495)669-24-15 E-mail: dept\_techregulation@eurasiancommission.org Website: [www.eurasiancommission.org](http://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 Website: 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):** Medicinal products |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft amendments to the Guidelines for the preparation of a regulatory document on the quality of a medicinal product (69 page(s), in Russian) |
| **6.** | **Description of content:** The following are clarified:* the procedure for the preparation of a regulatory document on quality, taking into account the specifications for a medicine, including specifications for the active pharmaceutical substances (active substances, APIs), intermediates and finished pharmaceutical products, as well as pharmacopoeial monographs;
* approaches to the identification and justification of the acceptance criteria (acceptable limits) and the identification of analytical methods used to evaluate these criteria.
 |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** Draft amendments to the Guidelines for the preparation of a regulatory document on the quality of a medicinal product <https://docs.eaeunion.org/ria/ru-ru/0104992/ria_29112021> |
| **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 Website: [www.eurasiancommission.org](http://www.eurasiancommission.org) <https://docs.eaeunion.org/ria/ru-ru/0104992/ria_29112021> |