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](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](mailto:info@gostinfo.ru)  Web-site: [www.gostinfo.ru](http://www.gostinfo.ru) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****],** **5.6.2 [****X],** **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 amendment to the Guideline on Non-clinical Safety Studies for the Conduct of Clinical Trials and Marketing Authorization of Medicinal Products; (1 page(s), in Russian) |
| **6.** | **Description of content:** Granting the right to drug manufacturers to submit data from the full preclinical development program on individual components of a drug from a combination of 2 active substances at any stage of development, while limiting themselves to short-term studies of the combination itself. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** National security requirements; Consumer information, labelling; Prevention of deceptive practices and consumer protection; Reducing trade barriers and facilitating trade |
| **8.** | **Relevant documents:**  Draft amendment to the Guideline on Non-clinical Safety Studies for the Conduct of Clinical Trials and Marketing Authorization of Medicinal Products |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 17 June 2022 |
| **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](http://www.eurasiancommission.org)  <https://docs.eaeunion.org/ria/ru-ru/0105347/ria_13052022> |