



22 May 2024

(24-3928)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>RUSSIAN FEDERATION</u> 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 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 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: The Draft Amendments to the Decision of the Council of the Eurasian Economic Commission №. 83 of November 3, 2016 https://docs.eaeunion.org/ria/ru-ru/0106666/ria_14052024 ; (44 page(s), in Russian)
6. Description of content: The draft amendment to the Decision of the Council of the Eurasian Economic Commission №. 83 of November 3, 2016 envisages the establishment of uniform approaches to the procedures for conducting pharmaceutical inspections of research organizations (testing centers, testing laboratories) for compliance with the requirements of the Rules of Good Laboratory Practice of the Eurasian Economic Union in circulation of medicines.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of the interests of manufacturers of medicinal products; Protection of the interests of authorized bodies (expert organizations) performing inspections of testing centers for compliance with the requirements of the Rules of Laboratory Practice of testing centers (laboratories, sites) for compliance with the requirements of the Rules of Laboratory Practice.
8. Relevant documents: The Draft Amendments to the Decision of the Council of the Eurasian Economic Commission No. 83 of November 3, 2016 https://docs.eaeunion.org/ria/ru-ru/0106666/ria_14052024 Decision of the Board of the Eurasian Economic Commission No. 83 of November 3, 2016 https://docs.eaeunion.org/docs/ru-ru/01411936/cncd_21112016_83
9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10. Final date for comments: 16 June 2024
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