WORLD TRADE ORGANIZATION

G/TBT/N/KGZ/59

27 August 2025

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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:** KYRGYZ REPUBLIC **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Eurasian Economic Commission
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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Pharmaceutical products
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Draft amendments to the Rules for Conducting Bioequivalence Research in the Eurasian Economic Union (64 pages, in Russian); (64 page(s), in Russian) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2025/TBT/KGZ/25_05698_00_x.pdf https://regulation.eaeunion.org/orv/3162/ 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 httos://docs.eaeunion.org/ru-ru
6.	**Description of content:** - Updating the methodology of IN VITRO skin penetration (IVRT) research (taking into account the revision of the international acts of research, bioequivalence of multisource (generic) pharmaceutical product (acts of the Food and Drug Administration (FDA)), as well as the law enforcement practice of authorized bodies of the Member States of the Eurasian Economic Union; - Establishment of the possibility of conducting these studies using an alternative technique - an artificial membrane analog of human skin.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** - protection of the patient's life and health (as an end user of medicines); - protection of the interests of the healthcare system; - protection of the interests of manufacturers of multisource (generic) pharmaceutical product, - protection of the interests of research organizations conducting clinical (bioequivalent) research; - protection of the interests of authorized bodies (expert organizations) carried out the procedure for assessment of the registration dossier of a medicinal product from the standpoint of proving its safety and compliance with a given quality standard; Protection of human health or safety

8.	**Relevant documents:** Draft amendments to the Rules for Conducting Bioequivalence Research of Medicines in the Eurasian Economic Union https://regulation.eaeunion.org/orv/3162/ Decision of the Council of the Eurasian Economic Commission No. 85, November 3, 2016 https://docs.eaeunion.org/documents/306/2592/
9.	**Proposed date of adoption:** Not less than 30 calendar days from the date of official publication **Proposed date of entry into force:** Not less than 30 calendar days from the date of official publication
10.	**Provision of comments** **Final date for comments:** 27 September 2025 **[ ] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** 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 httos://docs.eaeunion.org/ru-ru