



8 August 2023

(23-5402)

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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): Medical products
5. Title, number of pages and language(s) of the notified document: Draft amendments to the Pharmacopoeia of the Eurasian Economic Union http://docs.eaeunion.org/ria/ru-ru/0106113/ria_31072023 ; (303 page(s), in Russian)
6. Description of content: The draft amendments to the Pharmacopoeia of the Eurasian Economic Union provides for 46 general pharmacopoeia articles added, in terms of biological tests, biological medicinal products and radiopharmaceuticals.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of life and health of the patients (as the end users of medicinal products); Protection of healthcare institutions in general (as the primary user of medicinal products); Protection of the interests of medicinal products' manufacturers.

8. Relevant documents:

Draft amendments to the Pharmacopoeia of the Eurasian Economic Union G/TBT/N/ - 2 -
http://docs.eaeunion.org/ria/ru-ru/0106113/ria_31072023

Decision of the Board of the Eurasian Economic Commission No. 100 of August 11, 2020
http://docs.eaeunion.org/docs/ru-ru/01426917/err_13082020_100

9. Proposed date of adoption: The effective date of the draft amendments will be 180 calendar days after the date of official publication

Proposed date of entry into force: The effective date of the draft amendments will be 180 calendar days after the date of official publication

10. Final date for comments: 3 September 2023

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
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