



29 February 2024

(24-1880)

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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

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| 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: Draft amendments to the Rules for Investigation of Biological Medicinal Products in the Eurasian Economic Union; (140 page(s), in Russian) |
| 6. Description of content: The draft amendments to the Rules for Investigation of Biological Medicinal Products in the Eurasian Economic Union provide for the elimination of differences in the requirements for pharmaceutical development, planning and conducting studies of the safety and quality of medicines based on human somatic cells and medicines containing genetically modified cells by establishing uniform, objective and transparent rules for research of these groups of medicines. |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of life and health of the end users of medicinal products; Protection of the interests of manufacturers of medicines based on human somatic cells and medicines containing genetically modified cells, authorized bodies (expert organizations) in the sphere of healthcare of the Member States of the Union |

8. Relevant documents:

Draft amendments on the Rules for Investigation of Biological Medicinal Products of the Eurasian Economic Union (140 pages in Russian)

https://docs.eaeunion.org/ria/ru-ru/0106437/ria_09022024

Decision № 89 of the Council of the Eurasian Economic Commission of November 3, 2016

https://docs.eaeunion.org/docs/ru-ru/01411954/chcd_21112016_89

9. Proposed date of adoption: To be determined

Proposed date of entry into force: To be determined

10. Final date for comments: 16 March 2024

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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