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@eecommission.org](mailto:dept_techregulation@eecommission.org)  Web-site: [www.eurasiancommission.org](http://www.eurasiancommission.org), <https://docs.eaeunion.org/ru-ru>  The Ministry of Health of the Republic of Belarus  Fax: (017) 222-46-27  e-mail: [mzrb@belcmt.by](mailto:mzrb@belcmt.by)  The Ministry of Health of the Russian Federation Tel: +7 (495) 628-44-53 E-mail: [info@rosminzdrav.ru](mailto:info@rosminzdrav.ru)  **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:** |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale (HS 3003); Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale (HS 3004) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft amendments to Requirements for stability testing of drugs and pharmaceutical substances. (2 page(s), in Russian) |
| **6.** | **Description of content:** The draft amendments to the Requirements for stability testing of drugs and pharmaceutical substances applies to put into circulation on the territory of the Eurasian economic Union drugs and calls for the unified approach to the definition of "production date of the series" in order to exclude the possibility of automatic updates of the shelf life of the pharmaceutical substance by a simple repackaging, and the calculation of the shelf life of finished drugs, issued in circulation in the customs territory of the Eurasian economic Union for the purpose of elimination of the possibility of automatic renewal of the shelf life of the pharmaceutical substance by its simple repackaging, as well as the use in the production of substances with an expiration date not corresponding to the shelf life of finished drugs, which may lead to inconsistencies of expert reports and recognition.  The draft guide has been prepared in order to:  - protection of life and health of the patient (as the final consumer of medicines);  - protection of the interests of the health care system as a whole (as the primary consumer of medicines)  - protection of the interests of the authorized bodies (expert organizations) that perform the procedure of evaluation of the registration dossier of the drug from the position of proof of its compliance with the specified quality standard. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  Draft amendments to Requirements for stability testing of drugs and pharmaceutical substances  [<https://docs.eaeunion.org/ria/ru-ru/0103838/ria_23122019>](https://docs.eaeunion.org/ria/ru-ru/0103838/ria_23122019)  Decision No.69 of the Board of the Eurasian economic Commission of 10 May 2018  <http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/drug_products.aspx> |
| **9.** | **Proposed date of adoption:** to be determined  **Proposed date of entry into force:** to be determined |
| **10.** | **Final date for comments:** 25 January 2020 |
| **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@eecommission.org](mailto:dept_techregulation@eecommission.org)  Web-site: [www.eurasiancommission.org](http://www.eurasiancommission.org), <https://docs.eaeunion.org/ru-ru>  <https://docs.eaeunion.org/ria/ru-ru/0103838/ria_23122019> <http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/drug_products.aspx> |