Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** RUSSIAN FEDERATION **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Eurasian Economic Commission **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**: 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 Website: www.eurasiancommission.org
3.	**Notified under Article 2.9.2 [ ], 2.10.1 [X], 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):** Pharmaceutical products
5.	**Title, number of pages and language(s) of the notified document:** Draft decision of The Board of the Eurasian Economic Union "On the establishment of the rules of bioequivalence testing of pharmaceutical products within the Eurasian Economic Union" (162 pages, in Russian).
6.	**Description of content:** Establishment of requirements for the development of bioequivalence testing design, for bioequivalence testing and for the analysis of results and for the grounds that enable to substitute in vivo tests by in vitro ones.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human health or Safety
8.	**Relevant documents:** Draft decision of The Board of the Eurasian Economic Union "On the establishment of the rules of bioequivalence testing of pharmaceutical products within the Eurasian Economic Union" https://docs.eaeunion.org/docs/ru-ru/0149273/clco_30122015_178 Agreement on common principles and rules of medicinal products circulation in the Eurasian Economic Union. http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/konsultComitet/Documents/1%20Sogl%20LS.pdf
9.	**Proposed date of adoption:** 5 July 2016 **Proposed date of entry into force:** 1 January 2017

10.	**Final date for comments:** 5 June 2016
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 Website: www.eurasiancommission.org