WORLD TRADE ORGANIZATION

G/TBT/N/PER/96

30 June 2017

(17-3533)

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Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	**Notifying Member:** PERU **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** *Ministerio de Salud* (Ministry of Health) **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):** Pharmaceutical products, classified under Chapter 30 of the Harmonized System or Customs Tariff.
5.	**Title, number of pages and language(s) of the notified document:** *Proyecto de Reglamento que regula las condiciones para la presentación de los resultados de control de calidad del primer lote y subsiguientes lotes de productos farmacéuticos* (Draft Regulation laying down requirements for the submission of quality control results for the first and subsequent batches of pharmaceutical products) (8 pages, in Spanish)
6.	**Description of content:** The purpose of the notified Regulation is to establish the requirements for the quality control of the first and subsequent batches of pharmaceutical products, and the requirements for the submission of the results of such quality control, prior to marketing or distribution on the Peruvian market.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health.
8.	**Relevant documents:** • *Ley N° 29459 - Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios* (Law No. 29459 - Law on pharmaceutical products, medical devices and sanitary products) • *Decreto Supremo N° 016-2011-SA, Reglamento para el Registro, Control y Vigilancia Sanitaria de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios* (Supreme Decree No. 016-2011-SA, Regulations on the registration, control and sanitary surveillance of pharmaceutical products, medical devices and sanitary products)
9.	**Proposed date of adoption:** 180 days after publication in the Official Journal *El Peruano.* **Proposed date of entry into force:** 180 days after publication in the Official Journal *El Peruano.*

10.	**Final date for comments:** 25 September 2017
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** http://extranet.comunidadandina.org/sirt/public/index.aspx http://www.mincetur.gob.pe/reglamentostecnicos http://www.digemid.minsa.gob.pe/ Ministerio de Comercio Exterior y Turismo - MINCETUR Calle Uno Oeste Nº 50 - Urb. Corpac - Lima 27 - Perú Tel.: (+51-1) 513-6100, Ext. 1223 and 1239 Email: otc@mincetur.gob.pe https://members.wto.org/crnattachments/2017/TBT/PER/17_2969_00_s.pdf