



19 May 2017

(17-2729)

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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: <u>PERU</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: <i>Ministerio de Salud</i> (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: <i>Ministerio de Comercio Exterior y Turismo</i> (Ministry of Foreign Trade and Tourism)
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: <i>Proyecto de Reglamento que regula los estudios de estabilidad de las especialidades farmacéuticas</i> (Draft Regulation governing stability studies for pharmaceutical specialties) (25 pages, in Spanish)
6. Description of content: The purpose of the notified Regulation is to establish: - the rules governing stability studies on pharmaceutical specialties; and - the information to be included in the document required for the evaluation of stability studies when registering or re-registering pharmaceutical specialties or when making changes to the pharmaceutical specialties sanitary register.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: <ol style="list-style-type: none"><i>Ley N° 29459 - Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios</i> (Law No. 29459 - Law on pharmaceutical products, medical devices and sanitary products)<i>Decreto Supremo N° 016-2011-SA, Reglamento para el Registro, Control y Vigilancia Sanitaria de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios</i> (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: 18 months after publication in the Official Journal <i>El Peruano</i> . Proposed date of entry into force: 18 months after publication in the Official Journal <i>El Peruano</i> .
10.	Final date for comments: 16 August 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 N° 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_2239_00_s.pdf