

13 June 2024

(24-4411)

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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, MINSA (Ministry of Health)</i> Av. Salaverry 801 Jesús María - Lima, Lima Peru Tel.: (+51 1) 315 6600 Email: webmaster@minsa.gob.pe 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, MINCETUR (Ministry of Foreign Trade and Tourism)</i> Calle Uno Oeste N° 50 - Urb. Corpac - Lima 27 - Peru Tel.: (+51 1) 513 6100, Ext. 1223 or 1239 Email: otc@mincetur.gob.pe
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): 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 Decreto Supremo que regula lo dispuesto en el artículo 9 de la Ley N° 29698, Ley que declara de interés nacional y preferente atención el tratamiento de personas que padecen enfermedades raras o huérfanas, modificada por la Ley N° 31738</i> (Draft Supreme Decree regulating Article 9 of Law No. 29698, which declares the treatment of persons suffering from rare or orphan diseases to be of national interest and preferential consideration, as amended by Law No. 31738) (12 pages, in Spanish)
6.	Description of content: The purpose of the notified Supreme Decree is to establish provisions relating to the sanitary registration of pharmaceutical products for the diagnosis and/or treatment of rare or orphan diseases, and the sanitary registration of pharmaceutical products for the treatment of cancer, under Article 9 of Law No. 29698, which declares the treatment of persons suffering from rare or orphan diseases to be of national interest and preferential consideration, as incorporated by Law No. 31738.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety

8. Relevant documents:

1. *Ley N° 29698, Ley que declara de interés nacional y preferente atención al tratamiento de personas que padecen enfermedades raras o huérfanas.*
2. *Ley N° 31738, Ley que modifica la Ley 29698, Ley que declara de interés nacional y preferente atención el tratamiento de personas que padecen enfermedades raras o huérfanas.*
3. *Ley N° 29459, Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios.*
4. *Decreto Supremo N° 016-2011-SA, Reglamento para el Registro, Control y Vigilancia Sanitaria de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios.*
5. *Decreto Supremo N° 014-2011-SA, Reglamento de Establecimientos Farmacéuticos.*
6. *Decreto Supremo N° 016-2018-SA, Reglamento que regula la expedición del certificado de liberación de lote de productos biológicos: vacunas o derivados de plasma humano.*

9. Proposed date of adoption: To be determined

Proposed date of entry into force: Six months after publication in the Official Journal, *El Peruano*

10. Final date for comments: 60 days from notification**11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

Ministerio de Comercio Exterior y Turismo, MINCETUR (Ministry of Foreign Trade and Tourism)

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<https://www.gob.pe/institucion/minsa/normas-legales/5617998-373-2024-minsa>

<http://extranet.comunidadandina.org/sirt/public/buscapalavra.aspx>

<http://consultasenlinea.mincetur.gob.pe/notificaciones/Publico/FrmBuscador.aspx>

https://members.wto.org/crnattachments/2024/TBT/PER/24_03741_00_s.pdf