WORLD TRADE ORGANIZATION

G/TBT/N/CRI/171

6 December 2017

(17-6709)

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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:** COSTA RICA **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** *Ministerio de Salud* (Ministry of Health) *Dirección de Asuntos Jurídicos* (Directorate of Legal Affairs) Tel.: (+506) 2233-0464 Fax: (+506) 2291-2015 **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:** *Información de Obstáculos Técnicos al Comercio* (TBT Enquiry Point) *Ministerio de Economía, Industria y Comercio*, MEIC (Ministry of the Economy, Industry and Trade) Apartado Postal 10216-1000 Tel.: +(506) 2549-1479 Fax: +(506) 2291-2015 Email: crotc@meic.go.cr Website: http://www.reglatec.go.cr
3.	**Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [X], 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):** 11.120.10
5.	**Title, number of pages and language(s) of the notified document:** *Procedimiento para la verificación del cumplimiento de las buenas prácticas de manufactura de medicamentos para uso humano* (Procedure for the verification of compliance with good manufacturing practices for medicines for human use) (25 pages, in Spanish)
6.	**Description of content:** The notified text establishes the regulations governing the process to verify compliance with good manufacturing practices for medicines, with the aim of ensuring the quality of medicines, as one of the factors for the reduction of risks associated with manufacturing. It applies to manufacturing plants belonging to national or foreign laboratories that manufacture or market pharmaceutical products in the national territory, to ensure the quality of medicines.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health.

8. **Relevant documents:**

- *Decreto Ejecutivo N° 38732-S-COMEX-MEIC del 02 de julio de 2014, que Publica Resolución N° 339-2014 (COMIECO-LXVII) del 25 de abril del 2014 y sus Anexos* (Executive Decree No. 38732-S-COMEX-MEIC of 2 July 2014 publishing Resolution No. 339-2014 (COMIECO-LXVII) of 25 April 2014 and the annexes thereto)
- *Reglamento Técnico Centroamericano RTCA 11.03.42:07 Productos Farmacéuticos. Medicamentos Para Uso Humano. Buenas Prácticas de Manufactura para la Industria Farmacéutica* (Central American Technical Regulation (RTCA) No. 11.03.42:07: Pharmaceutical products. Medicines for human use. Good manufacturing practices for the pharmaceutical industry)
- *Decreto Ejecutivo N° 38414-COMEX-MEIC-S del 28 de febrero de 2014, que Pública Resolución Nº 333-2013 (COMIECO- LXVI) de fecha 12 de diciembre del 2013* (Executive Decree No. 38414-COMEX-MEIC-S of 28 February 2014 publishing Resolution No. 333-2013 (COMIECO- LXVI) of 12 December 2013)
- *Reglamento Técnico Centroamericano RTCA 11.03.59:11 Productos Farmacéuticos. Medicamentos para uso humano. Requisitos de registro sanitario* (Central American Technical Regulation (RTCA) No. 11.03.59:11 Pharmaceutical products. Medicines for human use. Sanitary registration requirements)

9. **Proposed date of adoption:** Upon publication in Official Journal *La Gaceta.*

Proposed date of entry into force: Six months after publication in the Official Journal *La Gaceta*.

10. **Final date for comments:** 60 days from the date of notification.

11. **Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

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Full text available online at:
http://www.reglatec.go.cr/reglatec/principal.jsp

https://members.wto.org/crnattachments/2017/TBT/CRI/17_5423_00_s.PDF