NOTIFICATION

The following notification is given in accordance with article 10.6.

1.	**Member notifying:** COSTA RICA **If applicable, name of the local government concerned (articles 3.2 and 7.2):**
2.	**Responsible organization:** Ministry of Health Directorate of Legal Affairs Telephone (506) 2233-0464 Fax: (506) 2291-2015 **Name and address (including telephone and fax numbers, as well as email addresses and Web sites, where applicable) of the agency or authority responsible for processing comments on the notification, in the case of a different body or authority:** Information on Technical Barriers to Trade Ministry of Economy, Industry and Commerce- MEIC Postal mail. 10216-1000 Phone: + (506) 2549-1479 Telefax: + (506) 2291 2015 Email: crotc@meic.go.cr Website: http://www.reglatec.go.cr
3.	**Notification made under article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], or by virtue of:**
Four.	**Products covered (HS or CCCN when appropriate, otherwise the national tariff heading), where appropriate, the ICS heading number may also be indicated:** 11,120.10
5.	**Title, number of pages and language (s) of the notified document:** Procedure for verification of compliance with good manufacturing practices for medicines for human use. (25 page (s), in Spanish)
6	**Description of the content:** This regulation establishes the rules related to the process of verification of compliance with Good Manufacturing Practices for Medicines in order to guarantee the quality of medicines, as one of the factors to reduce the risks associated with manufacturing. Likewise, it applies to manufacturing plants belonging to national or foreign laboratories that manufacture or market pharmaceutical products in the national territory, in order to guarantee the quality of the medicines.
7	**Objective and rationale, including, where appropriate, the nature of urgent problems:** Protection of human health
8	**Relevant documents:** • Executive Decree N ° 38732-S-COMEX-MEIC of July 2, 2014, which publishes Resolution No. 339-2014 (COMIECO-LXVII) of April 25, 2014 and its Annexes: Central American Technical Regulation RTCA 11.03.42: 07 Pharmaceutical products. Medicines For Human Use. Good Manufacturing Practices for the Pharmaceutical Industry. • Executive Decree N ° 38414-COMEX-MEIC-S of February 28, 2014, that Public Resolution No. 333-2013 (COMIECO-LXVI) dated December 12, 2013 • Central American Technical Regulation RTCA 11.03.59: 11 Pharmaceutical Products. Medicines for human use. Sanitary registration requirements.

9.	**Proposed date of adoption:** As of its publication in the Official Gazette, La Gaceta **Proposed date of entry into force:** 6 months after publication in the Official Gazette
10	**Deadline for submitting comments:** 60 days from the notification
eleven.	**Texts available in: National information service [X], or address, telephone and fax numbers and e-mail addresses and Web sites, as the case may be, from another institution:** Center of Technical Barriers to Trade Website: http://www.reglatec.go.cr Point of Contact OMC: crotc@meic.go.cr San Jose Costa Rica PO Box 10216-1000 Telephone + (506) 2549-1479 Fax: + (506) 2291-2015 Full text of the document: http://www.reglatec.go.cr/reglatec/principal.jsp https://members.wto.org/crnattachments/2017/TBT/CRI/17_5423_00_s.PDF