Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is given in accordance with article 10.6.

1.	**Member notifying:** PANAMA **If applicable, name of the local government concerned (articles 3.2 and 7.2):**
2.	**Responsible organization:** General Directorate of Standards and Industrial Technology Ministry of Commerce and Industries. Ricardo J. Alfaro Avenue, and El Paical Street , Plaza Edison Building, 3rd Floor, Panama. Telephone (507) 560-0716, Ext. 5968/5964/5786 Emails: dgnti@mici.gob.pa ; uperez@minsa.gob.pa ; edcastillo@minsa.gob.pa Website: www.mici.gob.pa **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:**
3.	**Notification made under article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 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 :** 11,120.01
5.	**Title, number of pages and language (s) of the notified document:** Central American Technical Regulation (RTCA) 11.03.59: 18, 1st Revision - Pharmaceutical Products, Drugs for Human Use. Sanitary Registration Requirements (31 page (s), in Spanish)
6	**Description of the content:** This Central American Technical Regulation (RTCA) establishes the conditions and requirements under which the sanitary registration of medicines for human use will be granted. Applies to medicines for human use that are manufactured or imported by natural or legal persons for commercialization in the territory of the States Parties.
7	**Objective and rationale, including, where appropriate, the nature of urgent problems:** Protection of health and human life and avoid practices that may mislead or deceive the consumer.
8	**Relevant documents:** • RTCA Pharmaceutical Products. Regulation of Validation of Analytical Methods for the Evaluation of the Quality of Drugs in its Current Version. • RTCA Pharmaceutical Products. Labeling of Pharmaceutical Products for Human Use in its Current Version. • RTCA Pharmaceutical Products. Stability Studies of Drugs for Human Use in its Current Version. • RTCA Pharmaceutical Products. Medicines For Human Use. Verification of Quality in its Current Version. • RTCA Pharmaceutical Products. Medicines For Human Use. Good Manufacturing Practices for the Pharmaceutical Industry in its Current Version.

9.	**Proposed date of adoption:** Six months (6) from its publication in the Official Gazette **Proposed date of entry into force:** Determined
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:** General Directorate of Standards and Industrial Technology Ministry of Commerce and Industries. Ricardo J. Alfaro Avenue, and El Paical Street , Plaza Edison Building, 3rd Floor, Panama. Telephone (507) 560-0716, Ext. 5968/5964/5786 Emails: dgnti@mici.gob.pa ; uperez@minsa.gob.pa ; edcastillo@minsa.gob.pa Website : www.mici.gob.pa Full text of the document: https://www.mici.gob.pa/documentos/dgnti/DGNTI-RTCA-11035918.pdf https://members.wto.org/crnattachments/2018/TBT/PAN/18_4358_00_s.pdf