NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** NICARAGUA**If applicable, name of local government involved (Articles 3.2 and 7.2):** |
| **2.** | **Agency responsible:***Ministerio de Salud* (Ministry of Health)*Dirección General de Regulación Sanitaria*, DGRS (Directorate-General of Health Regulation)*Direccion de Farmacia* (Pharmacy Directorate)Conchita Palacios, Costado Oeste Colonia Primero de mayo.Tel.: 2289-4700, Ext. 1005, 2289-4401Email: dgrs@minsa.gob.ni; farmaciadir@minsa.gob.ni**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:***Ministerio de Fomento, Industria y Comercio* (Ministry of Development, Industry and Trade)Address: Kilómetro 6 de Carrera a Masaya, frente a Camino de OrienteTel.: (+505) 2248 9300 Ext.: 1314, 1310Email: normalizacion@mific.gob.ni imartinez@mific.gob.niWebsite: <http://www.mific.gob.ni/es-ni/snc.aspx> |
| **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):** Pharmaceutics in general (ICS 11.120.01) |
| **5.** | **Title, number of pages and language(s) of the notified document:** *NTON 19 014 - 20 Productos Farmacéuticos. Medicamentos de uso Humano. Bioequivalencia e intercambiabilidad* (Nicaraguan Mandatory Technical Standard (NTON) No. 19 014 - 20 Pharmaceutical products. Medicines for human use. Bioequivalence and interchangeability) (44 pages, in Spanish) |
| **6.** | **Description of content:** The notified Technical Standard establishes the therapeutic equivalence guidelines to be met by multi-origin medicines in order to carry out the sanitary registration procedure.These guidelines supplement the requirements established in the version of Nicaraguan Mandatory Technical Standard (NTON)/Central American Technical Regulation (RTCA) Pharmaceutical products. Medicines for human use. Sanitary registration requirements, currently in force.They apply to all multi-origin pharmaceutical products that require proof of therapeutic equivalence according to a prioritized list based on sanitary risk criteria. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:*** *Reglamento Técnico Centroamericano RTCA 11.03.59:11 Requisitos de Registro Sanitario de Medicamentos para Uso Humano - Resolución 333-2013 (COMIECO - LXVI)*;
* Good Clinical Practices: Document of the Americas, Pan American Network on Drug Regulatory Harmonization (PANDRH) - Pan American Health Organization (PAHO);
* *Resolución No. 148-2005 (COMIECO XXXIII) que aprueba el Reglamento Técnico Centroamericano. Primera actualización Productos Farmacéuticos. Estudios de Estabilidad de Medicamentos para uso humano (NTON 19 002 - 10/ RTCA 11.01.04:10)*;
* *Resolución No. 340-2014 (COMIECO LXVII) que aprueba el Reglamento Técnico Centroamericano. Etiquetado de Productos Farmacéuticos para Uso Humano. (NTON 19 001 - 05/RTCA 11.01.02:04)*;
* *Resolución No. 339-2014 (COMIECO-LXVII) Reglamento Técnico Centroamericano RTCA 11.03.42:07 Buenas Prácticas de Manufactura para la Industria Farmacéutica de Medicamentos para Uso Humano*;
* *Resolución No. 188-2006 (COMIECO XL) Reglamento Técnico Centroamericano RTCA 11.03.39:06 Validación de Métodos Analíticos para la Evaluación de la Calidad de los Medicamentos para Uso Humano*;
* *Resolución No. 214-2007 (COMIECO XLVII) Reglamento Técnico Centroamericano RTCA 11.03.47:07 Verificación de la Calidad de Medicamentos para Uso Humano*;
* Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. In: WHO Expert Committee on Specifications for Pharmaceutical Products: fortieth report. World Health Organization: Geneva; 2006: Annex 7 (WHO Technical Report Series, No. 992);
* *Norma para la Regulación de Ensayos Clínicos de Medicamentos en Seres Humanos en Nicaragua*.
 |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 20 February 2021 |
| **11.** | **Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**Ministerio de Fomento, Industria y Comercio(+505) 2248 9300, Ext. 1314 or 1310notificacion@mific.gob.ni; normalizacion@mific.gob.ni; imartinez@mific.gob.ni<http://www.mific.gob.ni/en-us/snc.aspx> <https://members.wto.org/crnattachments/2021/TBT/NIC/21_0330_00_s.pdf> |