



22 February 2023

(23-1274)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>RWANDA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Rwanda Food and Drugs Authority (Rwanda FDA) 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: Rwanda Food and Drugs Authority (Rwanda FDA) info@rwandafda.gov.rw Nyarutarama Plaza, KG 9 Avenue Toll Free:9707
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 (HS code(s): 30)
5. Title, number of pages and language(s) of the notified document: Regulations Governing Registration of Medicinal Products; (17 page(s), in English)
6. Description of content: The purpose of these Regulations is to put in place a legal framework to ensure effective and efficient registration of medicinal products, and to provide an open, transparent and nondiscriminatory process for the registration of all medicinal products regulated by Rwanda Food and Drugs authority. These regulations cover human and veterinary medicinal products, vaccines and biological products for human and animal use, herbal medicinal products, disinfectant and antiseptics excluding cosmetics as well as laboratory and household chemicals. The regulations apply to all medicinal products to be registered in Rwanda.
7. Objective and rationale, including the nature of urgent problems where applicable: Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety; Protection of animal or plant life or health; Quality requirements; Harmonization; Reducing trade barriers and facilitating trade; Cost saving and productivity enhancement
8. Relevant documents: LAW No 47/2012 OF 14/01/2013 RELATING TO THE REGULATION AND INSPECTION OF FOOD AND PHARMACEUTICAL PRODUCTS

9.	Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10.	Final date for comments: 60 days from notification
11.	<p>Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Mr. Johnny Uwimana Hassan WTO/TBT Enquiry point Rwanda Standards Board KK 15 Rd, 49 Kigali Tel: Hotline: 3250; +(250) 788636510 Fax: +(250)788303492 Email: info@rsb.gov.rw; johnny.uwimana@rsb.gov.rw Website: http://www.rsb.gov.rw</p> <p>Mr. James D. TAYEBWA WTO Notification Officer Ministry of Trade and Industry Department of Trade and Investment Kigali Tel: +(250) 788 636 406 Email: jtayebwa@minicom.gov.rw; dyebwa@gmail.com Website: http://www.minicom.gov.rw</p> <p>Ms. Beatrice UWUMUKIZA Ministry of Agriculture and Animal Resources WTO/Plant Health Enquiry Point Tel: +(250) 788 84 84 10 Email: infoinspection@minagri.gov.rw; buwumukiza@minagri.gov.rw</p> <p>Dr. Isidore Gafarasi Mapendo Director of Veterinary and Laboratory Services Rwanda Agriculture Board (RAB) Animal Health Enquiry Point Tel: +(250) 788503589 Email: info@rab.gov.rw; igafarasi@gmail.com</p> <p>Ms. MUKAMUNANA Alphonsine Ministry of Health Department of Environmental Health Desk Tel: +(250) 788673500</p> <p>https://members.wto.org/crnattachments/2023/TBT/RWA/23_1284_00_e.pdf https://members.wto.org/crnattachments/2023/TBT/RWA/23_1284_01_e.pdf</p>