NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** RWANDA  **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](mailto: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 licensing of public and private manufacturers,  distributors, wholesalers and retailers of medical Products; (13 page(s), in English) |
| **6.** | **Description of content:** These Regulations enforce the legal framework for application, inspection, storage, distribution, and licensing of public and private manufacturers, distributors, wholesalers and retailers of Medical Products.  These Regulations apply to public, and private manufacturers, distributors, wholesalers and retailers of medical products involved in the manufacture, storage, sale, distribution, and dispensing of medical products. |
| **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.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  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](mailto:info@rsb.gov.rw); [johnny.uwimana@rsb.gov.rw](mailto:johnny.uwimana@rsb.gov.rw)  Website: http://www.rsb.gov.rw  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](mailto:jtayebwa@minicom.gov.rw); [dyebwa@gmail.com](mailto:dyebwa@gmail.com)  Website: <http://www.minicom.gov.rw>  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](mailto:infoinspection@minagri.gov.rw); [buwumukiza@minagri.gov.rw](mailto:buwumukiza@minagri.gov.rw)  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](mailto:info@rab.gov.rw); [igafarasi@gmail.com](mailto:igafarasi@gmail.com)  Ms. MUKAMUNANA Alphonsine  Ministry of Health  Department of Environmental Health Desk  Tel: +(250) 788673500  We notified both the Regulations and Guidelines because the Guidelines have all the necessary details for the Regulations>  <https://members.wto.org/crnattachments/2023/TBT/RWA/23_1283_00_e.pdf>  <https://members.wto.org/crnattachments/2023/TBT/RWA/23_1283_01_e.pdf> |