



Kigali on, 03/03/2023  
Ref N°:FDISM/FDIC/M 33/FDA/2023

Wholesale pharmacies (All)  
Retail pharmacies (All)

**Subject: Stakeholders Notice**

Reference is made to the law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning especially in its article 3 (12) which requires compliance with quality standards for storage, sale and use of products regulated by that Law;

Reference is also made to the Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products especially in its paragraphs 3&7&8 of article 32 which provides that no person shall open a pharmacy unless the pharmacy is under the supervision of a registered pharmacist, when a pharmacist resigns, is dismissed from his/her job or dies, the pharmacy shall remain closed until another pharmacist is recruited and no pharmaceutical product written on the medical prescription can be dispensed without the supervision of an authorized person;

Further reference is made to the Regulations N° FDISM/FDIC/TRG/001 Rev\_3 governing licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products;

It is in this regards that Rwanda FDA wants to remind all stakeholders involved in pharmacy business the following:

1. No pharmacy shall operate without a registered responsible pharmacist.
2. No pharmacy shall operate without a valid premise license issued by Rwanda FDA.
3. No pharmacy shall close when it is officially on duty.
4. No pharmacy shall dispense narcotics/ controlled drugs without medical prescription.
5. All pharmacies must keep distribution/dispensing records, temperature monitoring records, unfit products and recalled products records.

Stakeholders are reminded to comply with the above, failure to do so will result in regulatory actions.

Sincerely,

*E. Bienvenu*

Dr. Emile BIENVENU  
Director General



**CC:**

- Honourable Minister of Health
- Honourable Minister of State in the Ministry of Health
- Chairperson of National Pharmacy Council
- Chairperson of Rwanda Community Pharmacists Union