



Kigali on 31/12 /2025

Ref. No: DD/PIL/5565/FDA/2025

Manufacturers of medical products (All)
Distributors of medical products (All)
Wholesalers of medical products (All)
Retailers of medical products (All)

Re: Circular on Public consultation and call for comments on regulatory documents

Reference made to the provisions of Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA), especially in its article 8. The Authority is mandated to regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use of products regulated under this Law. Rwanda FDA has reviewed and updated various regulatory documents related to licensing of public and private premises involved in the manufacture, storage, distribution, retail of human medicines and medical devices to achieve its mission.

Rwanda FDA would like to inform all stakeholders and the general public that the draft of updated regulatory documents listed below is being circulated for public consultation and comments starting from 19/12/2025.

1. Rev 6 -Regulations governing the licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products;
2. Rev 5 - Guidelines for licensing of public and private manufacturers, distributors, wholesalers and retailers of human medicines;

The aforementioned documents with the comment form No ODG/QMS/FMT/023 have been uploaded to the Rwanda FDA website www.rwandafda.gov.rw under About FDA/stakeholders portal and will be available for comments for 30 calendar days. Thereafter, there will be a stakeholder meeting to validate the inputs/comments.

The Authority would like to invite individuals, manufacturers, Local Technical Representatives, distributors, wholesalers, retailers and other interested parties to provide written input/comments using the attached comment Form No ODG/QMS/FMT/023 and send it to info@rwandafda.gov.rw not later than 19/01/2025.

Sincerely,

By Authority Delegation

Dr. Vedaste HABYALIMANA
Head of Drugs Department

for  

Cc:

- Director General of Rwanda FDA
- Deputy Director General of Rwanda FDA