RWANDA FDA
Rwanda Food and Drugs Authority

Kigali on 31 / 08 / 2022

Ref. Nº: DFAR/HMDAR/ 3440 ***/FDA/2022***

CIRCULAR

Subject: Reminder to comply with Registration Requirements of Human Medicinal and Biological Products

Reference is made to the **Law Nº003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority (Rwanda FDA), and determining its mission, organization, and functioning, specifically in its articles 3&9;

Reference is also made to the **Regulations Nº CBD/TRG/010**, governing registration of medicinal products, specifically in article 5 regarding application for registration of medicinal products; Article 13 regarding Good Manufacturing Practices (GMP) and Good Clinical Practices, and article 14 b regarding the manufacturing site of the medicinal product to comply with the Good Manufacturing Practices.

The Authority would like to remind all stakeholders including manufacturers, wholesalers, importers, local technical representatives, Non-Governmental Organizations, Clinical Research organizations & other researchers, and Marketing Authorization Holders **to comply with registration requirements on products manufactured, used, or imported into Rwanda.**

Registration is mandatory to market any human medicinal products in Rwanda. **Good Manufacturing Practices are also a requirement for the registration of any human medicinal product in Rwanda.** Therefore, the Authority wishes to inform and remind all applicants to comply with the above and particularly the application of GMP as part of registration requirements during the application for registration. A new checklist (**attached**) will always be requested during the submission of the application for registration, and **No application will be accepted if one of the requirements in the checklist is missing.**

This circular is effective from **1st September 2022.**

Sincerely,

Digitally signed by Rwanda FDA(Director General)
Date: 2022.08.30 19:59:10 +02'00'

Dr. Emile BIENVENU
Director General

CC:

- **Deputy Director General/Rwanda FDA**
- **Head of FDISM Department/Rwanda FDA**
- **Division Manager of FDIC Division/Rwanda FDA**

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Checklist for Human medicinal and biological product application

Product name, Strength and Dosage Form	Name of the FPP Manufacturer and Country	Name of the MAH and Country	Pack size and Number of samples submitted

You will find enclosed the submission dossier as specified hereafter:

☐ CTD format, 2 soft copies documents format that contains summaries in word format and body data in PDF format

☐ The relevant fees for this application have been paid.

☐ GMP application (Dossier and relevant GMP fees) or a valid GMP certificate issued by Rwanda FDA

☐ Two commercial Samples

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