Kigali, 06/10/2021
Ref N°: DAR/3251/FDA/2021

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

**Re: Circular on application for retention and variation of Registered Human Medicinal Products.**

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA), and determining its mission, organization, and functioning, specifically in its article 3 para 1, 2 & 7,article 8 para 1,4 & 12 and article 9 para 1 & 2;

Reference is also made to the Regulations N° CBD/TRG/010, governing registration of medicinal products, specifically in its article 19 a, b and c, regarding the application for variation of registered medicinal products and article 20 a, b and c, regarding the retention of registered medicinal products on the register;

Further reference is made to the list of Rwanda FDA Registered Human Medicinal Products published on Rwanda FDA website in September 2021;

The Authority would like to bring to the attention of all Marketing Authorization Holders and Local Technical Representatives, whose medicinal products are registered by Rwanda FDA that:

1. Application for retention of registered medicinal product on the register should be submitted annually. All Marketing Authorization Holders whose products are registered for a period exceeding 10 months are reminded to apply for retention of their registered medicinal products on the register as per the Guidance DAR/GDL/001J for procedural aspects for application for Marketing Authorization of Human Medicines clause 6.3. and pay the prescribed fee as per the regulation N° CBD/TRG/004 Rev_2, related to regulatory service tariff/fees and fines.

The application requirements for a registered medicinal product retention include:

a) Application cover letter
b) Proof of payment of prescribed fees, and
c) Medicinal product annual safety reports (periodic post-marketing surveillance reports)

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2. Any post approval change must be communicated to the Authority as per the Guidelines N° DHT/GDL/012 for variation of Registered Human Medicinal Product. All Marketing Authorization Holders whose registered products have undergone any form of variations are reminded to apply for variation on the registered product as per the aforementioned guidelines.

The application requirements for registered medicinal product variation include:

a) Application cover letter
b) Application form for variation
c) Proof of payment for prescribed fees
d) Supporting documents as per the variation types

The Authority would like to bring to the attention of all Marketing Authorization Holders and Local Technical representatives whose products are registered by Rwanda FDA that, failure to apply for variation to a registered human medicinal product and for product retention on the register for any eligible registered human medicinal product will lead to suspension of the marketing authorization as per the Regulations N° CBD/TRG/010, governing registration of medicinal products, in its articles 21, 22, 24 b, d, e, and f.

All applications should be submitted to info@rwandafda.gov.rw. Applications for retention of registered medicinal products exceeding 10 months on the register should be submitted not later than November 30th, 2021 for further action.

Sincerely,

Digitally signed by Rwanda FDA (Director General)
Date: 2021.10.06 12:22:56 +02'00'

**Dr. Emile BIENVENU**
**Director General**