RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 26/12/2020
Ref N°: DAR/CRC/3237/FDA/2020

Re: Circular on Human Medicinal Products Registration

Reference is made to the circular Ref N°: DAR/CRC/011/Rwanda FDA/2020 dated 30/06/2020 relating to compliance to the registration process and marketing authorization requirements
Further reference is also made to the Authority's resolutions in a meeting held on 21st December 2020, considering extending the deadline for submission of dossier for registration of human medicinal products.

The Authority would like to inform all stakeholders including manufacturers, wholesalers, importers, local technical representatives, Non-Governmental Organization, clinical research organizations & other researchers and Marketing Authorization Holders who have or wish to submit their human medicinal product dossiers for registration that the period has been extended from **31st December, 2020 to 31st January, 2021**.

From the first circular requesting all product on the market to comply with Laws and Regulations on registration of human medicinal products; Rwanda FDA has received many applications and among them they are those which are on Authorized medicines list published in May 2020.

It is in this regard that, the Authority has compiled a new products list including those that are registered, submitted application for registration and those with commitment from applicants. The revised list is shared on the following link: https://rwandafda.gov.rw/web/index.php?id=52 for your consideration and information and for every stakeholder to verify if no product has been missed out for the considered categories. All applicants/LTR are required to provide the list of products that are not on Rwanda FDA list on the above link and the deadline for submitting the list is 15th January 2021.

The status of application for registration should be provided in the format available in the above-mentioned link and be sent to areports@rwandafda.gov.rw for the Authority's consideration. The provided status of registration will be accompanied by supporting documents such as application letter for new applicants.

The Authority also wants to highlight that every foreign manufacturer is required to have a Local Technical Representative (LTR) in Rwanda; and only the LTR will be allowed to import the product

they represent in Rwanda. Manufacturer may need to have more than one distributor on Rwandan market, Manufacturer should notify the Authority through LTR for the additional distributor/s.

Subsequently, the Authority wishes to remind the following:

1. All applications for registration of human medicinal products on Rwandan market shall be prepared and submitted to Rwanda FDA according to the Rwanda FDA Guidelines on submission of documentation for registration of human medicinal products in line with the Common Technical Document (CTD) format and prescribed fees shall be paid.
2. All applications for product registration submitted before the introduction of the CTD format in January 2015 are required to submit a new dossier and pay the prescribed registration fees **not later than 15th January 2021** for consideration.
3. All products that have been granted pre-registration certificates before January 2015 using old requirements are requested to submit a new application in CTD format and pay the prescribed registration fees **not later than 15th January 2021** for consideration.
4. All applications previously submitted according to the CTD format and which have not been paid for, are requested to comply with the new regulations **not later than 15th January 2021.**
5. The Good Manufacturing Practices (GMP) inspection is part of registration process and all applications are required to fulfil the requirements for GMP applications and pay the prescribed GMP inspection fees before the product is registered.
6. The registration certificate is valid for five (5) years and the application for renewal shall be made three (3) months before expiration of the previous registration certificates.
7. A product that has been granted a registration certificate shall be required to apply for annual retention on the register and pay retention fees as per Rwanda FDA regulation No CBD/TRG/004 related to the regulatory service tariff/ fees and fines available on Rwanda FDA website.
8. Any variation on the registered product will be required to submit application as prescribed in the Rwanda FDA Guidelines on variation of registered human medicinal products and approved by the Authority upon compliance to the prescribed requirements.

The revised authorized medicinal product list will be published on **1st February 2021** on Rwanda FDA website and it shall then take effect.

This circular is effective from 26th December, 2020

Digitally signed by Rwanda FDA (HoD FDISM)
Date: 2020.12.26 22:09:37 +02'00'

For:
Dr. Charles KARANGWA
Ag. Director General