



RWANDA FDA
Rwanda Food and Drugs Authority

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Kigali, 18 / 01 /2021

Ref. No: DAR/CRC/ 086 / FDA/2021

Re: Circular on registration of Antiseptic (Hand sanitizer) products

Reference is made to the circular Ref No: DAR/CRC/ 012 / Rwanda FDA/2020 dated 24/07/2020, Requesting all product on the market to comply with Law and Regulation on medicinal products registration,

Recalling the previous circular that, due to the substantial contribution of antiseptics and disinfectants in protecting and prevention of COVID-19 pandemic and the increasing need of these products by the general public and the need to protect public health from accessing counterfeits and substandard antiseptic and disinfectant products on the market, all antiseptic and disinfectants on the market were required to be registered by the Authority.

It is in this regard that, the Authority has issued the approved list of hand sanitizers which is accessed on the following link: <https://rwandafda.gov.rw/web/index.php?id=106>.

Subsequently, the Authority wishes to inform and remind the manufacturers and importers the following:

1. All antiseptic and disinfectant products on Rwandan market have to be registered. The application for registration shall be prepared and submitted to the Rwanda FDA according to the [Rwanda FDA Guidelines on submission of documentation for registration of antiseptic and disinfectant products](#) available on Rwanda FDA website.
2. All applications shall be submitted along with two (2) samples with the minimum volume of 500 ml to facilitate the testing and a proof of payment of non-refundable registration fee prescribed in the technical regulation [No CDB/TRG/004 Rev 1 related to regulatory service tariff and fees](#) available on Rwanda FDA website.
3. For local manufacturers, the Authority wishes to remind, that the operation license issued by Rwanda FDA following inspection of the premises does not guarantee the total quality,

safety, efficacy of the marketed products, therefore every local manufacturer should apply for registration of their products before there are placed on the Rwanda market.

The Authority would like to bring to the attention of all local and foreign stakeholders including manufacturers, importers/distributors, and local technical representatives whose products are not displayed on the approved list or wish to submit their hand sanitizers' product dossiers for registration, that the period has been extended to 31st March 2021.

After the issued deadline, all non-compliant products will not be permitted to be imported, sold or distributed on Rwandan market.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General



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