Kigali, 23/09/2021

Ref N° : DAR/3152**/FDA/2021**

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
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Re: Transitioning from Authorized List of Human Medicinal Products to the register

Reference is made to the Law No 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 8 Para 4 and article 9 paragraph 1 & 2.

Reference is made to the Regulation No CBD/TRG/010, governing registration of medicinal products, where it requires that all medicinal products shall be registered with Rwanda FDA before they are placed on Rwandan market.

Reference is also made to the Authorized List of Human Medicinal Products published on Rwanda FDA website in June 2021 as an interim measure to facilitate medical products availability in the Country and transition onto the Register; Rwanda FDA has put in place a transitional strategy to fully transit from the authorized list of medicinal products to the Medicinal products Register.

Rwanda FDA would like to inform all stakeholders including manufacturers, wholesalers/importers, Local Technical Representatives, Non-Governmental Organizations, Clinical Research Organizations, Researchers, and Market Authorization Holders, **that no medicinal product will be added onto the Authorized List from the date of issuance of this circular**.

Only correction of information on the authorized list will be permitted following the same procedure issued in the circular N° DAR/CRC/706/FDA/2021 of 12/03/2021 published on Rwanda FDA website.

Rwanda FDA informs all stakeholders that products whose applicants did not respect their application commitments will also be removed from the Authorized list of medicinal products.

Rwanda FDA would also like to remind all applicants to apply for product registration by referring to Rwanda FDA guideline on registration of human medicinal products published on Rwanda FDA website www.rwandafda.gov.rw.

Sincerely,

Dr. Emile BIENVENU
Director General