

Kigali on A.J.../23.../2023 Ref. No: DFAR/VMDAR/ M 61 /FDA/2023

Stakeholders in Veterinary Products (All)

Re: Circular on Public consultation and call for comments on Veterinary Products' regulatory **Documents**

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 3 paragraphs 1, 2 & 7, Article 8 paragraph 4, and article 9 paragraphs 1 & 2. Rwanda FDA has the mandate to protect public health through the regulation of veterinary products.

The Authority has drafted various regulatory documents related to the registration of veterinary products in order to achieve its mission while adhering to international quality standards for conducting the assessment and registration of veterinary products.

Rwanda FDA would like to inform all veterinary medicines stakeholders and the general public that the drafts of veterinary regulatory documents listed below are being circulated for Public consultation and comments.

- 1. Draft Guidelines on Submission of Documentation for Registration of Veterinary Medical Devices and In-Vitro Diagnostics Devices- DFAR/VMDAR/GDL/006.
- Registered Veterinary Medicinal 2. Draft Guidelines on Variations to Products-DFAR/VMDAR/GDL/007.
- 3. Draft Guidelines for conditional approval of veterinary products- DAR/VMDAR/GDL/074.

The above-mentioned regulatory documents have been uploaded on the Rwanda FDA website www.rwandafda.gov.rw under "about FDA on Stakeholders" and will be available for comments/inputs for thirty (30) days. Thereafter, there will be a stakeholders' portal meeting /workshop to validate the comments/inputs.

Rwanda FDA would like to invite all veterinary products stakeholders, Local technical representatives (LTR), Applicants, Manufacturers, Importers, and other interested parties to provide written comments/inputs using the comments form number ODG/QMS/FMT/023 attached to this circular and send the completed form to email: info@rwandafda.gov.rw not later than 17th April 2023.

Sincerely,

5 (00 m) 12023 Dr. Emile BIENVENU

Director General

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