Rwanda Food and Drugs Authority

Rue. KN 3rd Boulevard de L'Union Africaine
P.O. Box 84, Kigali, Rwanda.
email: info@rwandafda.gov.rw; website:
www.rwandafda.gov.rw

VALIDATION WORKSHOP OF REGULATORY DOCUMENTS

Dates of Workshop February 17th -21st, 2020 Venue of the workshop: Kigali at ONOMO HOTEL

1. Introduction

Rwanda FDA is established by the Law Nº 003/2018 of 9/2/2018, establishing Rwanda Food and Drugs Authority, determining its mission, organization and functioning which was officially gazetted on "***Official Gazette nº Special of 27/02/2018***". The establishment of a fully Rwanda FDA is considered as one of the top priority area in promoting and protecting public health by ensuring that food and drugs in Rwanda are safe, efficacious and of good quality.

Rwanda FDA is implementing key regulatory functions such as drug registration, GMP inspections and quality control testing of pharmaceutical products, and would like to start registration of Medicated Cosmetics, Antiseptics and Disinfectants, Veterinary drugs and Medical devices. For that Rwanda FDA had to develop appropriate regulatory tools such as technical regulations and guidelines and standard operating procedures that would clearly define procedures and processes to support good regulatory practice, efficiency and transparency.

The drafts of these documents has already been developed, however, the existing drafts needed to be validated by the stakeholders as the Rwanda FDA staff had already revised the documents.

It is on that background that Rwanda FDA in collaboration with PSM organized a Workshop for validation of the regulations and guidelines to ensure effective implementation of Rwanda FDA operations regarding pharmaceutical product registration.

2. Purpose and Objectives of validation workshop

The purpose of validation workshop of different regulations and guidelines is to have a common format aligned with international regulatory documents and to have them approved by Rwanda FDA in order to be used as guidance by stakeholders and the authority.

The validated regulations and guidelines will assist Rwanda and Stakeholders the following:

- Preparation of documentation for pharmaceutical products by providing clear guidance on the format
- Provide guidance on the technical and other general data requirements.
- Reduce the time lines to compile applications for registration of medicines, cosmetics and pesticides
- Give more details on the requirements for active pharmaceutical ingredients (API) as well as finished pharmaceutical product (FPP).
- Promote effective and efficient processes for the development of these applications and the subsequent assessment processes by Rwanda FDA

3. Methodology used

Before the workshop the draft documents of Regulations and Guidelines have been shared to the participants/ stakeholders one week before the workshop, then during the workshop the review was done into different days. During this exercise the participants checked the quality of the document in their entirety and provide comment and inputs where necessary to have a reviewed and validated regulations and Guidelines.

4. Workshop Venue and Participants

The workshop for Validation of regulatory documents took place at ONOMO Hotel from 17st to 21th February 2020 and was attended by 10 Rwanda FDA staff and 40 people from stakeholders. List of participants is here to be attached as **Annex 1**.

5. Conduction of the workshop

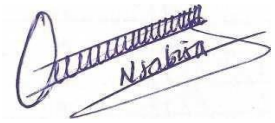
During the workshop, the participants deeply discussed on different key requirements of the regulations and guidelines for consensus and with reference to the other international regulatory documents such as ICH, WHO and EAC. During the workshop, different questions from stakeholders were asked and answered.

6. Outcome and recommendations of the workshop

During the validation workshop, the listed regulations and guidelines were validated in different days and will be prepared for approval and then posted on Rwanda FDA website for public use.

a. Regulation governing the registration of medicinal products
b. Guidelines for registration of human medicinal products
c. Guidelines for variation of a registered human medicinal product
d. Guidelines of abridged procedures for pharmaceutical product assessment
e. Guidelines for registration of Veterinary medicinal product
f. Guidelines for Registration of Similar Biotherapeutic Products
g. Regulation governing the registration of pesticides, chemicals and poisons substances
h. Regulation governing the control of cosmetics
i. Guidelines for registration of medicated cosmetics
j. Regulation governing the registration of Antiseptics and Disinfectants
k. Validation of authorized Veterinary medicines list
l. Validation of authorized medicated cosmetics list
m. Validation of authorized Human medicinal product list

Prepared by:



Isaïe NSABIMANA
Vaccines and Biologicals assessment and registration officer

Verified and Approved by:

Clarisse IRASABWA
D&HTA Division Manager