RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
Document Type:**Standard Operating Procedure**		Doc. Number	:DIC/SOP/00
RWANDA FDA Rwanda Food and Drugs Authority	Title: **VETTING AND APPROVAL OF PROMOTIONAL MATERIAL OF MEDICINAL PRODDUCTS**	Revision Number	:0
		Revision Date:	:24/05/2021
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1.0 Purpose

These standard operating procedures (SOPs) is to:

1.1 Prescribe procedures for vetting applications for promotion of medicinal products in Rwanda FDA

1.2 Ensure effective control and monitoring of information used in promotion and advertisement of medical products which is disseminated to health professionals or general public as component to the rational use of medicated products

1.3 Ensure that all promotions and advertising materials of medicinal products are screened and approved by Rwanda FDA before it uses

2.0 Scope

This SOP applies to all promotional and advertising material of medicinal products

3.0 Policy

3.1 Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning

3.2 Rwanda FDA Regulations No.: CBD/TRG/017 governing promotion of regulated products.

3.3 Rwanda FDA Guidelines No.: …….. on control of promotion and advertisement of medicine, medical devices and cosmetics products.

4.0 Definitions

"Authority" means the Rwanda Food and Drugs Authority, Rwanda FDA
general public

"**Advertisement"** means a form of communication through the media about products, services or ideas by an identified sponsor that is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action

"Regulated product" means pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs, food supplements, food fortificants, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products.

"General public" means a person other than healthcare professionals

Promotional meetings include workshops, conferences, seminars and symposium that are organized or sponsored by any company or under its control targeting drug dealers or any other person for the purpose of promoting medicinal products or its launching.

5.0 Responsibility

5.1 Director General is responsible for the overall approval of the authorization to conduct promotion activities of registered medicinal products.

5.2 Head of Food and Drugs Inspection and Safety Monitoring Department is responsible for verifying the decision taken by Pharmacovigilance and Safety monitoring division manager and provide regulatory guidance

5.3 Division Manager in charge of Pharmacovigilance and Safety monitoring is responsible for reviewing the decision taken by the specialist in charge.

5.4 Drug Products information, advertisement and promotion specialist is responsible for receiving, recording and vetting the application for promotion materials and suggest a decision to be reviewed and approved by supervisors.

5.5 Quality Assurance analyst is ensuring that this SOP is regularly updated

6.0 Distribution

6.1 Director General
6.2 Head of food & Drug inspection and Safety monitoring Department
6.3 Division Manager of Pharmacovigilance and Food safety monitoring
6.4 Drug products information promotion and advertisement specialist
6.5 Quality Assurance Analyst

7.0 Reference

NA

8.0 Safety Precautions

NA

9.0 Materials and equipment

9.1 Application form for medicinal products promotional meeting

9.2 Application form for promotion and advertisement

10.0 Procedures

Drug products information, promotion and advertisement Specialist shall:

10.1.1 Analyze the application by going accurately through all required documents

10.1.2 Verify information submitted by the applicant in the cover letter and application form,

10.1.3 Check whether the provided premise licence and product registration certificates issued by Rwanda FDA are genuine and still valid,

10.1.4 Review and screen content of the message used in promotional materials

10.1.5 Refer to Regulations No.: CBD/TRG/017 governing promotion and advertisement of regulated products as well as Guidelines for control of promotion and advertisement of medicines, medical devices and cosmetics products to vet application.

10.1.6 Verify if medicinal information on the label of the submitted sample conforms to message used in promotion and ensure the message complies with all requirements.

10.1.7 Raise queries and inform applicant on the way forward; if the message is not complying with requirements.

10.1.8 draft the Authorization letter and send it, together with the application documents, to Division Manager of pharmacovigilance and food safety monitoring for review; if the application is complete and the message is complying with requirements.

10.2 The Division manager of pharmacovigilance and food safety monitoring shall;

10.2.1 Review the raised queries and provide comments if any,

10.2.2 Send the proposed Authorization or rejection letter to the Head of food and drugs inspection and safety monitoring for further review.

10.3 The Head of food and drugs inspection and safety monitoring shall;

10.3.1. Review the raised queries and provide comments if any,

10.3.2 Send the proposed authorization or rejection letter to the Director General for approval.

10.4 The Director General shall;

Approve authorisation letter for promotion or rejection letter.

11.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
		QMS Specialist	First issue