RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
Document Type:**Standard Operating Procedure**		Doc. Number	:DIS/SOP/00
RWANDA FDA Rwanda Food and Drugs Authority	Title: **RECEIVING AND RECORDING PROMOTION AND ADVERTISEMENT OF MEDICAL PRODUCTS**	Revision Number	:0
		Revision Date:	:24/05/2021
		Effective Date	:01/06/2021
		Review Due Date	:01/06/2024

1.0 Purpose

1.1 This standard operating procedures(SOPs) is to provide guidance for receiving, reviewing, recording of applications for promotion and advertisement of medicinal products

2.0 Scope

This SOP applies to all applications for promotion and advertisement 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 medicines, medical devices and cosmetics products.

4.0 Definitions and Abbreviations

"Advertisement" means a form of communication through media about medicinal products by an identified sponsor which is used to encourage, persuade or manipulate an audience to continue with or take some new actions

"Drug promotion" means any activity undertaken by any person or with its authority, which promotes the prescription, supply, sale or administration of its products.

"Promotional material" means any representation concerning the attributes of a product conveyed by any means whatever for encouraging the usage of a product.

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 reviewing and providing regulatory guidance to the decision taken by Pharmacovigilance and Safety monitoring division Manager.

5.3 Division Manager in charge of Pharmacovigilance and Safety monitoring is responsible for reviewing all requirements submitted by the applicant and the decision taken by the staff in charge

5.4 The drug Products information, advertisement and promotion specialist is responsible for receiving and recording the application for promotion of medicinal products and suggest a decision to be approved by supervisors.

5.5 Quality Assurance Analyst is responsible for ensuring that this SOP is regularly updated.

6.0 Distribution

6.1 Director General
6.2 Head food and drugs inspection and safety monitoring
6.3 Division manager of Pharmacovigilance and food safety monitoring
6.4 Drug 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 materials.
9.2 Application form for medicinal products promotional meeting.

10.0 PROCEDURES

10.1 Head of food and drugs inspection and safety monitoring cascades the application for promotion of medicinal products to Division Manager of Pharmacovigilance and food safety monitoring,

10.2 Division Manager of Pharmacovigilance and food safety monitoring assigns medicinal products information, promotion and advertisement specialist to vet the application,

10.3 Drugs products information, promotion and advertisement Specialist shall;

10.3.1 Receive application file on promotion and advertisement of medicinal products.

10.3.2 Check for completeness of the application by ensuring the presence of:

a) A duly signed cover letter addressed to Director General of the Authority,

b) A duly filled application form including Applicant details, Product particulars, products category, product name, registration number, type of advertisement, and channel of advertisement.

c) A copy of Certificate of premise licensing and product registration issued by Rwanda FDA.

d) A sample of the product in its approved final package. The sample will be returned to the applicant after vetting the application.

e) Samples of all Promotional materials in their final version.

f) Tangible or recognized scientific proof/facts to back up claims made by the applicant.

g) Proof of payment of non-refundable application fee as prescribed in the Authority Regulations nº CBD/TRG/004 related to regulatory service tariff/fees and fines.

h) Copy of recognized degree of qualified personnel who approved the message used for promotion of medicinal products at company level.

10.3.3 If the application is not complete, communicate with the applicant for additional information. Record it in database as incomplete application.

10.3.4 If the application is complete, record it in the database.

11.0 Document Revision History

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