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COMMUNICATION STRATEGY WITHIN RWANDA FDA IN REGARDS TO SF MEDICAL PRODUCTS

1.0 INTRODUCTION

The magnitude of the substandard and falsified (SF) medical problem has recently gained significant public attention due to a number of high profile incidents and greater media focus. The presence of substandard and falsified medical products (medicines and medical devices) on the market constitutes a very big concern to the public health and socio-economic aspects. Actually, estimates put falsified medicines at around 1% of sales in developed countries, at more than 10% of the global medicines market, and around 25% to 50% in developing countries where drug regulation, controls and enforcement are weak. Thus far, as falsification methods become more sophisticated, counterfeits are increasingly present in all regions of the world

In line to combat the SF medical products in Rwanda, Rwanda Food and Drugs Authority, a national medicine regulatory Authority, was established by Law Nº 003/2018 of 09/02/2018 determining its organization and functioning especially in its Article 8 paragraph 9. The Authority is mandated to conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated under the Law. Rwanda FDA has put in place different strategies to prevent and management of SF products.

STRATEGIES TO COMBAT SF MEDICAL PRODUCTS IN RWANDA

Rwanda FDA has put in place measures to combat falsified and substandard medicines on Rwandan market that include:

- ✓ Registration of all medicines
- ✓ Good manufacturing inspection (GMP) at Pharmaceutical Industries.
- ✓ Physical inspection at port of entry
- ✓ Receive spontaneous reports on suspected poor quality products
- ✓ Post-marketing surveillance activities which consist of regular sampling of medicines
- ✓ Laboratory quality control analysis of sampled medicines
- ✓ Conduct customer complaint survey
- ✓ Regional harmonization process e.g East African Community Medicine regulatory harmonization
- ✓ Information sharing with other regional and international regulatory body

Rationale of the Communication strategies

All technical Divisions and departments of Rwanda FDA play key role in prevention of SF medical products. Starting with Assessment and Registration department that assess the common technical documents submitted by marketing Authorization to ensure the medical products are manufactured in accordance to norms and standards.

During the step of assessment, some major loop-hole in the system or procedure can be found and queries are formulated for corrective actions. Among the key requirements for product registration there is Good manufacturing practices report which is developed after physical inspection at the manufacturing site by the division in charge of inspection and compliance.

Via Import and Export Unit, to import a medical product in Rwanda requires importers to get Import permit which involves submission of documents including certificate of analysis and GMP or ISO certificate, which are screened to verify whether products comply with quality standards. At point of entry products are checked physically to verify compliance to Rwanda FDA quality standards by inspectors .

The Division for Pharmacovigilance and safety monitoring conducts Post marketing surveillance activities regularly to ensure products on the market are of good quality. The division receives complaints on poor quality from stakeholders including consumers, healthcare providers, supply

chain managers. The division investigates, take samples and submit sampled products for the analysis by Laboratory quality control division.

Once quality defects are confirmed, the Division for Pharmacovigilance and safety monitoring develop a recall which is reviewed by the Head of department for inspection and safety monitoring and approved by the Director General of Rwanda FDA.

As well detailed above, each division across departments of Rwanda FDA play important role in prevention of SF medical products. Strong communication strategy needs to be in place to exchange information on identified SF products and guide appropriate Regulatory decision.

2.0 Objectives

The main objective of this communication strategy is to exchange information on substandard and falsified medical products within Rwanda FDA departments towards prevention and proper management of SF products

2.1 Specific objectives

a) To establish communication channels between department and division in regards to SF medical products
b) To communicate the regulatory decision taken within department for the identified SF products
c) To exchange recommendation for further investigation when SF medical products is identified

INTERDEPARTMENTAL COLLABORATION TOWARDS PREVENTION AND DETECTION OF SF

DIVISIONS INITIATER	DIVISION RECEIVING INFORMATION	Information to be shared	Communication channels/Forum	Timeliness
PV-SM	QCL	-Samples for suspected SF medical product	Sample submission form	24 hours
	Inspection and Compliance (DIC)	-Recommended Inspection for premises identified with SF products -Recalls and call for quarantine issued - Recommendation given to the manufacturers on CAPA in case of quality complaint	- Notification - Recall and call for quarantine issued - CAPA report	Immediately Immediately 2 days after approval of the report
	Import and Export Unit	- Recalled batches and call for quarantine - List of Banned products due to safety or quality issues - List of suspended products due to safety or quality issues - Products under investigation	- Notification	Immediately
	FDAR	-Proposed regulatory decision on SF products -Signal on SF products -Medical products under Investigation -New safety information and recommendation to MAH	Notification Inter-department Meeting	Immediately Monthly

	Administration and communication Unit	- Recall or call for quarantine to be published - List of banned products due to quality issues	Approved Recall or call for quarantine Notification	Immediately after approval
QCL	PV-SM	-Certificate of Analysis for Out of specification on submitted suspected SF products -Recommendation to deep Investigation or analysis for SF medical products	- Notification -Submission of CoA	Immediately after analysis
DIC	PV-SM	- Information on suspected SF products found during the inspection	-Notification	24 hours
Import/Export Unit	PV-SM	- Suspected SF products detected at Port of Entry - Quarantined suspected SF products	-Notification	24 hours

COMMUNICATION PLATFORMS

Platform	**DIVISIONS/UNITS**	**Issues to be discussed on SF products**	**Action on SF products**
Peer-Review Meeting for registration of medical products	-DIC, FDAR, QCL, PV-SM	-PV-SM communicate the list of SF products identified and regulatory actions taken (Recalls, call for quarantine medicines) -PV-SM provides update on registered products identified as SF products in PMS activity	- Not issuing the registration certificate -Withdraw the registration certificate
Inter-department Meeting	-FDISM, FDAR, QCL division	PV-SM communicate the list of SF products identified and regulatory actions taken (Recalls, call for quarantine medicines) - Discuss on regulatory action to be taken for repetitive SF products from the same manufacturers - Premises that require for cause GMP inspection due to SF products - Premises that were found with major inefficiencies	- Plan a GMP inspection - Sampling plan for the suspected SF products - Temporally stop the importation of the products

Committee for Licensing of pharmaceutical licensing	DIC and PV	-Premises that will not be granted renewal of operational licenses because of intentionally manufacture, distribution and sell of SF products	-Refusal of premises licenses due to SF products -Refusal for the renewal of premise license

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