Kigali on 25/05/2021
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RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
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RMS Ltd (All Branches)
Referral Hospitals (All)
District Hospitals (All)
Pharmaceutical Wholesalers (All)
Importers (All)
Retail Pharmacies (All)
Public and private Health facilities (All)

Title: Recall for batches of the below mentioned medical products due to Quality issues (Atropine Injection BP 1mg/ml, Phytomenadione injection 10mg/ml, Hyoscine butylbromide20mg/ml, Furosemide Injection BP 20mg/2ml)

Reference is made to the **Law Nº 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority especially in its article 8 paragraph 2 and 13.

Further reference is made to the deep investigation and Laboratory quality control tests performed by Rwanda FDA on reported suspected poor quality products which confirmed that the reported medicines are of poor quality;

It is with this background that Rwanda FDA recalls from the Rwandan market the following batches of different products:

No	DESCRIPTIONS	Batch Number	Expiry Date	Manufacturer	Quality Issue
1	Atropine Injection BP 1mg/ml	No: 16222001	Apr-23	Pharmax India Pvt Ltd, India	Presence of visible particulates in tested Vials

2	Phytomenadione injection 10mg/ml,	SA20C008E	Feb-22	INFUGEN PHARMA PVT LTD, India	Presence of visible particulates in tested Vials
3	Hyoscine butylbromide20mg/ml	3H20001	Jun-22	CENTURIO N Healthcare private Ltd, India	Presence of visible particulates in tested Vials
4	Hyoscine butylbromide20mg/ml	CH-1981	Nov-21	CENTURIO N Healthcare private Ltd, India	Presence of visible particulates in tested Vials
5	Hyoscine butylbromide20mg/ml	3H20002	Jul-22	CENTURIO N Healthcare private Ltd, India	Presence of visible particulates in tested Vials
6	Furosemide Injection BP 20mg/2ml	JFDIE-001	Oct-22	Laborate Pharmaceuti cals India Ltd, India	Presence of visible particulates in tested Vials

Action to be taken

- Rwanda Food and Drug Authority instructs all importers, central medical stores, Wholesalers, RMS Ltd branches, retailers, Public and Private Health Facilities to stop the distribution and dispensing of the above incriminated batches of the above mentioned products and return them to their supplier for proper disposal.

- The importers and Suppliers of the above incriminated batches of the above mentioned products are requested to report to Rwanda FDA within 10 working days the quantities imported, quantities distributed, quantities returned and final stock at hand.

- The importation of the above mentioned products manufactured by above mentioned manufacturers is suspended until they comply with Rwanda FDA products registration requirements.

- **Note:** For more information or to report any suspected poor quality products please call **0789193529** or **9707** or send email to: pv_sm@rwandafda.gov.rw

The Authority takes into consideration every information from stakeholders to ensure safe and quality medical products are available for the Rwandan population.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General