



RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali,
Ref. No

11.3 FEB 2019

0108/Rwandafda/2019

To: Health Facilities

Title: Recall of Misoprostol 200µg batches for quality issue

Dear Sir/Madam

Referring to the letter No. 079/Rwanda FDA/2018 dated 07th December 2018 alerting the public on the suspected substandard misoprostol and oxytocin products on the market where Rwanda FDA has requested all suppliers and retailers that had these products in their custody to stop their distribution and put them in quarantine also requesting public and private health facilities to stop their dispensing for further investigations;

Rwanda FDA has completed the investigations and Reference made to quality control reports from a WHO prequalified and accredited Laboratory; we regret to notify that the following batches were revealed to be substandard:

Brand name	Manufacturer	Country of origin	Batch Number/Exp.date
Cynomax® MAXTAR (Misoprostol 200µg)	BIO-GENICS	India	M8TAB1801 Mfg date: 05/2018 (exp date: 4/2020)
C-STOL® CORONA (Misoprostol 200µg)	CORONA Remedies Pvt Ltd	India	ERW-005 Mfg date: 03/2018 Exp. Date: 02/2021

Also Rwanda FDA would want to inform the public that Oxytocin 10UI/mL that was suspected to be substandard was revealed to be of good quality:

Brand name	Manufacturer	Country of origin	Batch Number
Oxytocin 10UI/mL Jiangxi	Jiangxi Xierkangtai Pharmaceutical Co., Ltd	China	Batch No:1604521 Mfg: 04/2016 Exp date: 04/2019

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Action to be taken

Rwanda FDA instructs all wholesalers, retailers, District Pharmacies, Public and Private Health facilities that above-mentioned substandard batches of Misoprostol 200µg should be returned to the supplier for suitable disposal.

Also Rwanda FDA wish to inform all wholesalers, retailers, District Pharmacies, Public and Private Health facilities that the above-mentioned suspected batch of Oxytocin 10UI/mL should be released from the quarantine for use.

You are urged to spread this information in your catchment area

Thank for your collaboration

Sincerely,



Dr. Charles KARANGWA
Ag. Director General of Rwanda FDA

CC:

- **Hon. Minister of Health**
- **Hon. Minister of State in Charge of Primary Health Care**
- **Permanent Secretary/MOH**
- **D.G Rwanda Biomedical Center**

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