Kigali, 07 DEC 2018
Ref N°079/Rwanda FDA/2018

RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 84 Kigali
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www.rwandafda.gov.rw

Dear Health Care Professional

Title: Alert on suspected substandard misoprostol and oxytocin products on the market

Background

The University of Rwanda in collaboration with Tűbingen University is conducting an investigation on the quality of misoprostol and oxytocin on Rwandan market. Both products are used for prevention and treatment of post- partum hemorrhage, the most common cause of maternal mortality. Misoprostol is also used as an agent for labor induction.

The investigation has shown in its preliminary results that there are batches of these products that are extremely substandard in the case of Misoprostol and Oxytocin contain undeclared excipient. The table below summarizes the batches and the products found with quality issues

Brand name	Manufacturer	Country of Origin	Batches	Sample source
Cynomax® MAXTAR (Misoprostol)	BIO-GENICS	India	MTYX-1604 (exp. 7/2018) M8TAB1801 (exp. 4/2020)	District Hospitals
C-STOL® CORONA (Misoprostol)	Remedies Pvt Ltd	India	ERW-005	District hospitals, government & faith-based health centers, health centers
Oxytocin Jiangxi	Jiangxi Xierkangtai Pharmaceutical Co., Ltd	China	1604521 1606573	District hospitals, government & faith-based health centers

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Action Being taken by Rwanda FDA

The role of the Rwanda FDA is to protect the public health by disseminating information on quality and safety of products regulated under the LAW N° 003/2018 OF 09/02/2018 to health professionals and to other concerned organs. The organization will take into consideration every serious information from partners including the public and initiate its own investigation to verify the information.

While this quality signal is being evaluated, the Rwanda Food and Drugs Authority is requesting all the suppliers and retailers that have these products in their custody to stop their distribution and put them in quarantine. All public & private hospitals, health centers, clinics and retail pharmacies are instructed to stop the dispensing of the suspected products on patients until the investigations on quality issues to be conducted by Rwanda FDA is completed. The instruction applies not only on the batches found with the quality issues by the investigation, but also all the batches of the implicated brands.

You are urged to stop using the suspected products and spread this alert in your catchment area to protect the public health.

Sincerely,

Dr. Charles KARANGWA
Ag. Director General of Rwanda FDA

Cc:

- **Minister of Health**
- **State Minister for Primary Health care, Ministry of Health**
- **Permanent Secretary, Ministry of Health**
- **DG, Rwanda Biomedical Center**

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