



RWANDA FDA

Rwanda Food and Drugs Authority

P.O. Box 84 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

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CIRCULAR ON IMPORTATION, STORAGE AND MANAGEMENT OF OXYTOCIN IN RWANDA

The role of the Rwanda FDA is to protect the public health by disseminating information to health professionals and to other concerned organs on quality and safety of products regulated under the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA.

In this regard, reference made to WHO/UNICEF/UNFPA joint statement on “**Appropriate Storage and Management of Oxytocin – a Key Commodity for Maternal Health**” Oxytocin is indicated for prevention and treatment of postpartum haemorrhage, is a lifesaving medicine. Recent and past surveys undertaken by WHO and others have revealed that a significant number of samples of oxytocin injection collected from the market contain unacceptable levels of the active ingredient and related substances. These non-compliant products, usually found in high ambient temperature countries, are of particular concern given the high risk of treatment failure.

According to WHO, Oxytocin has been shown to be a heat-sensitive product that requires refrigeration during transport, distribution, and storage at all points in the supply chain. While short excursions beyond 2-8 °C (35-46 °F) may not compromise the quality of the product, longer-term storage and distribution at a wide variety of ambient temperatures (e.g. warehouses without temperature control) are likely to result in product degradation and ineffective treatment. Countries with tropical climates are at particular risk for oxytocin failures if it is not maintained in an appropriate cold chain. One study showed that oxytocin can tolerate freeze-thaw cycles, however,

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data on long-term exposure to freezing temperatures were not found and freezing oxytocin should therefore be avoided.

Reference made also to different studies on quality of Oxytocin, WHO pre-qualification criteria, Rwanda FDA has formulated the following recommendations:

To: Importers/Distributors/Central medical stores

- Procure oxytocin with specifications clearly reference appropriate quality standards and requirements, including appropriate labeling for storage at 2-8 °C (35-46 °F) from recognized sources such as WHO prequalified or manufacturers approved by a recognized regulatory authority
- Ensure that oxytocin is managed in a cold chain of 2-8 °C (35-46 °F) for distribution and storage

To Supply Chain Managers and end users

- Supply chains managers should ensure that oxytocin is maintained at 2-8 °C (35-46 °F)

Note that Rwanda FDA will not approve the license and VISA for importation of Oxytocin to be stored at ambient temperature

Thanking for our continued collaboration



Dr. Charles KARANCWA
Ag. Director General of Rwanda FDA

CC:

- **Hon. Minister of Health**
- **Hon. Minister of state in Charge of Primary Health care**
- **Permanent Secretary/MOH**
- **DG/ Rwanda Biomedical Center**

References

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