



REPUBLIC OF SOUTH SUDAN
DRUG AND FOOD CONTROL AUTHORITY
Office of the Secretary General



OFFICIAL NOTICE

12/11/2024

Subject: Introduction of Pre-shipment Verification, Inspection, and Quality Control Regulation for Pharmaceutical Imports into South Sudan

To:

The Central Drugs Standard Control Organization (CDSCO)
Indian Pharmaceutical Manufacturer Associations (Pharmexcil)

Dear Sir/Madam,

The Drugs and Food Control Authority of South Sudan hereby notifies the Central Drugs Standard Control Organization and Pharmexcil of the recent enactment of a regulatory framework aimed at enhancing the quality and safety of pharmaceutical products imported into South Sudan. This new regulation mandates rigorous pre-shipment verification, including document verification, physical inspection, quality control testing, and the issuance of a Clean Report of Inspection and Analysis (CRIA) for all pharmaceutical products entering South Sudan from India

This regulatory requirement has been implemented in response to concerns regarding the infiltration of substandard and falsified (SF) medical Products into South Sudan. All pharmaceutical products imported from

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India will now be required to undergo thorough inspection and quality testing to confirm their adherence to established quality standards prior to shipment. This is a mandatory process for all consignments imported into South Sudan. Complies with quality standards. Importers must present the CRIA from CTRS Group at South Sudanese ports to clear their goods. Without the CRIA, shipments will be prohibited from entering the country.

The CTRS Group will:

Verify all relevant documents,
Perform a physical inspection of each consignment,
Collect samples for laboratory testing, and
Issue the CRIA upon confirmation of compliance.

In cases where products do not meet quality standards, the shipment will be either, quarantined or seized by the Drugs & Food Control Authority, and appropriate regulatory measures will be enforced.

Implementation Date: This regulation will come into effect on December 15, 2024. All shipments with a bill of lading dated on or after this date will be required to provide a valid CRIA to secure customs clearance at South Sudanese ports of entry.

We appreciate your cooperation and adherence to this regulatory measure and encourage all stakeholders within the Indian pharmaceutical industry to take necessary actions to ensure compliance. For additional information or clarification, please contact the Drugs & Food Control Authority of South Sudan.

Thank you for your attention to this important regulatory requirement.



Sincerely,

Dr. Mawien Atem Mawien

Secretary General

Drugs and Food Control Authority

The Republic of South Sudan



To ensure the effectiveness and independence of the verification process, the Drugs & Food Control Authority has appointed the Centre for Testing and Research Services (CTRS Group), an independent entity specializing in verification, inspection, and quality testing. CTRS Group will conduct all necessary document verification, physical inspections, and laboratory testing, and will issue a CRIA for each shipment that co