DRUGS CONTROL ADMINISTRATION
Government of Telangana

Circular.Rc.No.2076/JD/Misc/2023 Dated: 14 .07.2023

Sub: DCA – Implementation of Regulation of Pre-Shipment document verification, Physical Inspection, Quality Control Testing and Issuance of clean report of inspection and analysis for pharmaceuticals for the Gambia – Regarding.

Ref: Letter dt: 20.06.2023 in F.No.ED/Misc/194/2023 of Drugs Controller General (India) & Central Licensing Authority, CDSCO, New Delhi

-x-x-x-

It is to inform that copy of reference cited together with its enclosures is enclosed for your information and necessary action.

14/7/23

JOINT DIRECTOR (I/C)
LICENSING AUTHORITY

To
All the Drug Manufacturers in Telangana

GOVERNMENT OF TELANGANA * DRUGS CONTROL ADMINISTRATION *
2076
HYDERABAD
23/06/23

F.No.ED/Misc/194/2023
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi-110002

Date: 20th June, 2023

To,
All State Drugs Controller/ UTs
All CDSCO-Zonal/ Sub-Zonal/ Port Offices
Manufacturing Associations-OPPI/IPA/IDMA/FOPE
Pharmexcil

Subject: - Implementation of Pre-shipment inspection under testing-reg.

Ref:-Medicines Control Agency, Gambia vide letter No. MCA/AD/23/MJK(149) dated 15.06.2023 (copy enclosed).

Sir,

With reference to the above subject, please find attached herewith the communication received from Medicines Control Agency, Gambia vide letter No. MCA/AD/23/MJK(149) dated 15.06.2023 mentioning that from 01.07.2023 onwards MCA introduce the regulation of pre-shipment document verification, physical inspection, quality control testing and issuance of Clean Report of Inspection and Analysis (CRIA) for Pharmaceuticals to address issues related to substandard and falsified (counterfiet) medicines entering the country. The regulation requires all imported pharmaceutical products to be inspected and sampled for testing to ensure conformity to quality standards prior to shipment from India.

In view of above, you are requested to disseminate the above information to all stakeholders.

This is for your information and immediate action.

23/6
Putup circular to IDMA, TS.
22/6

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing Authority

Copy to:
CDSCO Website

MEDICINES CONTROL AGENCY

54 Kairaba Avenue, Pipeline, P.O. BOX 3162, The Gambia. Tel. no. +220 4380632, Website: www.mca.gm.

Ref: MCA/AD/23/MJK(149)

Date: 15th June 2023

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General of India
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India.

Dear Sir,

Subject: (Implementation of Regulation of Pre-shipment Document Verification, Physical Inspection, Quality Control Testing and Issuance of Clean Report of Inspection and Analysis for Pharmaceuticals for The Gambia) – Communicated – Reg.

Greetings from the Medicines Control Agency of The Gambia.

We would like to announce that the Medicines Control Agency (MCA), The Gambia has introduced the regulation of pre-shipment document verification, physical inspection, quality control testing and issuance of Clean Report of Inspection and Analysis (CRIA) for Pharmaceuticals to address issues related to substandard and falsified (counterfeit) medicines entering the country. This regulation requires all imported pharmaceutical products to be inspected and sampled for testing to ensure conformity to quality standards prior to shipment from India.

The MCA has appointed Quntrol Laboratories Private Limited, an independent verification, inspection and testing company, to carry out the process and issue CRIA for all shipments. An importer shall require a CRIA issued by Quntrol to clear their goods at the Ports of Entry in The Gambia.

The regulation will be implemented from 1st July 2023. All shipments arriving into The Gambia with bill of lading dated on or after 1st July 2023 will be required to provide the CRIA for customs clearance at the Ports of Entry in The Gambia.

We wish to kindly request your office to disseminate the information to all Stakeholders in India including the State authorities, IDMA, Pharmexcil and Pharmaceutical Formulation Exporters.

Find attached herewith the Guidance document for pre-shipment inspection and testing of pharmaceutical products exported from India to The Gambia.

Please accept the assurances of our highest consideration.

Yours sincerely,

MEDICINES CONTROL AGENCY M C A THE GAMBIA

Markieu Janneh Kaira
Executive Director
Medicines Control Agency

CC: High Commissioner of The Gambia in India

Chief of Staff, Office of The President

Secretary General, Head of the Civil Service

Permanent Secretary, Ministry of Foreign Affairs

Permanent Secretary, Ministry of Health

File