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.

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

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,

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

Guidance for Pre-shipment Inspection and Testing of Pharmaceutical Products Exported to The Gambia from India

Medicines Control Agency (MCA), Republic of The Gambia
Pre-shipment document verification, physical inspection, quality control testing and issuance of Clean Report of Inspection and Analysis for Pharmaceuticals

1. Introduction

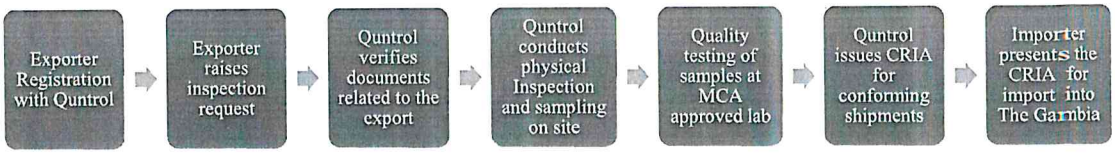
The Medicines Control Agency (MCA), The Gambia has introduced the regulation of pre-shipment document verification, physical inspection, quality control testing and issuance of Clean Report of Inspection and Analysis (CRIA) for Pharmaceuticals to address issues related to substandard and falsified (counterfeit) medicines entering the country. This regulation requires all imported pharmaceutical products from India to be inspected and tested for conformity of quality standards prior to shipment from India. This is a mandatory process to be followed for all consignments imported into The Gambia from India.

The MCA has appointed Quntrol Laboratories Private Limited, an independent verification, inspection and testing company, to carry out mandatory document verification, physical inspection, quality control testing and issuance of CRIA for all shipments. An importer shall in addition require a (CRIA) issued by Quntrol to clear their goods at the ports in The Gambia. Without this mandatory CRIA document, goods will not be accepted in the importation process.

Quntrol shall conduct document verification, physical inspection of the consignment and sampling, for laboratory testing for each shipment. If conformity is established at all levels, Quntrol shall issue the mandatory CRIA document. If conformity is not established with regards to quality of the product, the shipment will be quarantined or seized by the MCA and the necessary regulatory actions shall be taken.

The regulation will be implemented from 1st July 2023. All shipments arriving in 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.

Process flow to obtain the CRIA:



Please refer to Annexure 1 for Timelines related to the process.

2. Detailed Process

The following steps of the process shall be communicated by Quntrol to Exporters.

2.1. Process for exporter registration:

A pharmaceutical exporter in India who intends to ship pharmaceutical products from India to The Gambia shall carry out one-time registration with Quntrol. Registration shall be mandatory before inspection requests can be raised by the exporter.

a. Visit www.quntrol.com
b. Click on "Login" tab and "New Exporter Sign up"
c. Contact us on the email address (gambia@quntrol.com) provided on the web page so we can create an account for you.
d. A verification link will be sent to your registered email address. After clicking the verification link, you will be able to login to your account with your registered email address and password provided to you.
e. Login to your account to begin the Exporter Registration process.
f. Exporter Registration Form (ERF) can be accessed by clicking "Exporter Registration" tab. You are required to read the introduction and fill all sections including:
    i. Company Information – Company details, address, contact details, specify contact person details designated to liaise with Quntrol for pre-shipment inspection activities.
    ii. Site Information – Specify your preference for inspection to be carried out at your manufacturing/warehouse site or at the port warehouse. Enter details about your manufacturing site or warehouse where inspection shall be carried out. Upload valid Manufacturing License copy and WHO GMP Certificate copy for the manufacturing site(s).
    iii. Importer Information – Enter details of the company importing your shipments.
    iv. Product Information – Download the format given to fill details about your products exported to The Gambia. Details to be given include product details, specifications (specify the pharmacopoeia or in-house specs), product registration number, date of registration and expiry, and which market the product is intended to be sold in (private, tender, donor). Upload the completed file in this section of the Exporter Registration Form. This step is optional during registration, and product details can even be added at the time of raising an inspection request.
g. Submit the form after reading and accepting the terms and conditions document. Specify details about the authorized person who has completed the form.
h. Quntrol shall check the information and approve the registration. Thereafter, the exporter shall pay a one-time non-refundable registration fee of INR 20,000 plus applicable taxes.
i. This shall complete the registration process for the exporter. The exporter can now raise and manage inspection requests by logging into their account.

2.2. Process for Raising an Inspection Request:

A pharmaceutical exporter in India who intends to ship a consignment of pharmaceutical products from India to The Gambia shall raise a request for inspection by logging into their account on the Quntrol website www.quntrol.com.

a. Click on "Raise Inspection Request" tab to access the Inspection Request Form (IRF).
b. Select the site at which you would like Quntrol to conduct physical inspection and sampling
c. Select the Importer of the consignment
d. Submit required information and documents for the consignment. Failure to provide all necessary information and/or documentation may result in delays to the physical inspection.
    i. Final invoice of the goods for the shipment.
    ii. Final packing list for the goods in the shipment
    iii. Provide details about the products that will be shipped in the consignment. For each product, following information and documents must be uploaded:
        1. Batch numbers
        2. Certificate of Analysis for each batch for all products.
        3. Method of Analysis or Standard Testing Procedure in case in-house method has been used for analysis
        4. Copy of valid product permission as issued by the appropriate state FDA in India.
        5. Product registration certificate issued by MCA.
        6. Valid COPP of the products
    iv. The exporter shall confirm that they have read and understood the guidelines for pre-shipment inspection provided.
e. The specification and artwork of the products being shipped should be the same as what is approved in the dossier during product registration.
f. After the exporter has submitted the inspection request, Quntrol will verify and check the details and documents provided in the IRF. Quntrol shall raise its invoice to the exporter for the services.
g. After receiving the payment, Quntrol shall assign a mutually convenient date for physical inspection, usually within 24-48 hours or as requested by the exporter. The goods must be inspected at the time of loading the container. The date and time of inspection therefore must take into account the arrival of the container and the loading plans.
h. The exporter shall ensure that the consignment will be "Inspection ready" on the assigned date of inspection. Inspection ready consignment means that the goods are 100% manufactured, packed, released and the container is available for loading. In case the exporter would like to revise the date of inspection or cancel the inspection request on the assigned mutually agreed date or the day before, Quntrol has been authorized and reserves the right to retain a part of the sum paid.

2.3. Process to be followed for the physical inspection:

Before the inspector arrives at the site premises, the exporter shall ensure that:

a. The consignment is inspection ready. Quntrol shall only carry out inspection of the goods that are inspection ready. The inspector is authorized to wait for a maximum of one hour upon arrival at the inspection premises until the consignment is presented to him/her for inspection. In case the consignment is not 100% inspection ready and presented to the inspector within the one-hour waiting period, the inspection request will be cancelled. In this case, Quntrol has been authorized and reserves the right to retain the cost of inspection. The next inspection request for the same consignment shall be considered as a new request. In case the exporter requests the Quntrol inspector

to stay back at the site until the goods are ready for inspection, Quntrol shall use its discretion to accommodate such requests. If so, the costs related to accommodation, transport and food shall be borne by the exporter.

b. In case the exporter has selected the port warehouse for inspection, it is the exporter's responsibility to obtain the necessary permissions from the port authorities to allow inspection and sampling to be done by Quntrol at the time of container loading. The exporter shall assign its clearing agent to act and sign on behalf of the exporter and be responsible for all activities required of the exporter during the inspection as per these guidelines. The necessary authorization letter will have to be submitted to Quntrol.

Quntrol shall provide the details of the assigned Quntrol inspector to the exporter when the inspection has been scheduled. The inspector shall visit the selected manufacturing/ warehouse/port warehouse site on the assigned date and time and report to the exporter's assigned person.

The exporter is expected to present the goods in adequate condition and make arrangements at their own cost for handling and presentation of the goods so as to enable the inspector to perform the inspection. The container loading shall be done after the arrival of the inspector at the site.

The inspector will carry out physical inspection and sampling as follows:

a. Physical inspection of the consignment – The inspector shall verify the products, their batch numbers and quantity in the consignment as per the final packing list. The inspector shall also check the physical condition of the goods for damage.

b. Visual inspection of the label – The inspector will check the product label compliance and shelf life. Please refer to Annexure 2 for the labelling requirements. Note that goods below 60% remaining shelf life upon arrival at the ports shall not be allowed for customs clearance.

c. Sampling for analytical testing – Samples of each batch of all products in the shipment shall be withdrawn by the Quntrol inspector for the purpose of analytical testing to be carried out at the MCA approved laboratory.
Total quantity to be sampled will be equivalent to one set for analysis plus extra sample to be retained as control samples. You may refer to the Annexure 3 to check the quantity of sample that will be withdrawn by the inspector. The exporter shall replace this quantity, manufactured in the same batch, in the presence of the inspector such that the quantity of goods in the consignment is exactly as per the final packing list. In case the required replacement quantity is not available, then the exporter shall inform the same to the inspector. The exporter shall modify the packing list accordingly.

d. Sealing of the shipper boxes - Shippers from which samples were withdrawn for analytical testing shall be sealed by the inspector with the approved Quntrol tape.

e. Sealing the samples withdrawn – The inspector shall seal the samples withdrawn. The seal shall be signed by the inspector and the exporter's assigned person. The exporter shall provide outer boxes/cartons/cooling case needed for sending the samples by courier. The exporter shall send the samples to Quntrol's head office via courier.

f. Physical Inspection Report (PIR) - The inspector shall complete the PIR which shall be signed by the inspector and the exporter's assigned person. Copy of this report shall be made accessible to the exporter for their records on the portal. The PIR report refers only to the physical inspection of the goods and at this stage it is pending verification by Quntrol head office. In case of non-conformity at this stage, Quntrol will inform the exporter about the result. If the exporter is able to correct the non-conformity and

the evidence of such revision is confirmed by Quntrol through re-inspection if required, Quntrol shall carry on with the remaining part of the process.

g. Photographs – The inspector shall take photos of the container, products and container seal as per the standard operating procedure.

2.4. Process that will be followed for analytical testing of samples:

Quntrol shall send the samples to one of the analytical laboratories approved by MCA. The laboratory shall carry out complete analytical testing of the sample as per the pharmacopoeia method and specifications. In case the exporter or manufacturer has used in-house methods, the laboratory shall carry out the analysis as per their in-house method and specifications.

The exporter is required to provide the applicable reference standards and/or working standards and impurities to carry out the testing, if required by Quntrol.

After completion of the analysis of the samples, the COA will be generated. In case the COA establishes that a sample is out-of-specification, Quntrol will contact the exporter to inform them about the result. If the exporter is not satisfied with the results in the COA, the exporter shall have an option to request for repeat analysis using the control samples withdrawn by the inspector. If required, the repeat testing can be done in the presence of the exporter's representative in order to avoid any discrepancies. The exporter shall submit a request to Quntrol for the same. Quntrol shall charge the exporter for additional costs related to such repeat testing. If sample passes with repeat testing, Quntrol shall issue the CRIA to the exporter provided the physical inspection report shows compliance. If sample fails the repeat testing, Quntrol shall not issue the CRIA for the product to be cleared at the port of entry in The Gambia.

2.5. Clean Report of Inspection and Analysis (CRIA) issued by Quntrol:

Upon completion of the above activities, Quntrol shall issue the CRIA to the exporter if conformity is established in document verification, physical inspection and analysis. The CRIA should be sent to the exporter, who shall share it with the importer. The importer shall present the document to MCA for issuance of the import clearance permit.

The CRIA once issued shall be valid for a period of 90 (ninety) days from the date of issuance and therefore the shipment of the said consignment must be performed during this validity period. In case, the goods are not shipped within this period, the exporter will have to re-apply for the pre-shipment inspection and testing process.

The above-mentioned process may be revised from time to time and the same will be communicated to you as and when the changes are implemented.

3. Queries or Clarification

Quntrol can be contacted for any questions or clarifications required. For further details, please email gambia@quntrol.com or call +91-22-23610145/46 / +91 9930279149

Annexure 1:

Approximate Timelines for the Process

S. no.	Activity	Timeline
1	Response to Emails	Within 24 hours
2	Document verification	Within 24 hours
3	Scheduling inspection	Within 24-48 hours upon request
4	Analysis (after receipt of sample at the lab)	
	Tablets/Capsules	Single API – 6 days Multiple APIs – 8 days
	Oral liquids	8 - 9 days
	Injectables	15 days
	Sprays/inhalers	8 days
	Eye drops/Ear drops	8 days
	Topical ointments/ creams/ gels	8 days
5	Generating CRIA upon conformity	Within 1 day

Annexure 2:

Product labeling requirements

The primary or secondary container of every medicine shall bear a clearly and legible written label in English language and include:

- the generic name and where applicable the proprietary name of the medicine;
- dosage form and strength (if not included in the name);
- the approved name of each active ingredient and the quantity contained in a dosage unit, or per suitable mass or volume or unit;
- in the case of medicines produced using genetic engineering, the active substance and the name of the genetically modified micro-organism or cell line used in its manufacture;
- in the case of herbal medicinal products, the identification of the active ingredient(s) given by the Latin botanical name in addition to the common name;
- excipients that have a recognised action or effect as determined by the Agency and all excipients, if the medicine is injectable or a topical or eye preparation;
- the presentation and pack size expressed in the appropriate unit or volume;
- instructions for use prior to intake of the medicine where applicable;
- the method, and if necessary, route of administration by means of suitable words or abbreviations;
- the batch or lot number of the medicine;
- the manufacture and expiry date in a clear and visible font size;
- the name and address of the manufacturer and marketing authorisation holder;
- instructions for the storage with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;
- special or cautionary warnings as applicable;
- nutritional information in case of nutritional supplements;
- the words "for animal treatment only" and the species of animal for which the medicine is indicated, as applicable in case of veterinary medicines;
- the registration number of the medicine allocated by the Agency (where applicable);
- any specified warnings to be provided on the label as a condition of registration determined by the Agency.

Annexure 3:

Quantity of sample required for testing

Quantity Requirement for Analysis			
Dosage form	Dosage form	Pack Size	Quantity Required for Analysis (number of units)
Tablet/Capsule	Oral Solid	NA	80
Syrup/Suspension	Oral Liquid	10ml	20
Syrup/Suspension		30ml	20
Syrup/Suspension		50ml	20
Syrup/Suspension		100ml,	10
Syrup/Suspension		200ml	5
Dry Syrup	Dry Powder for suspension	60gm	15
Cream/Ointment/Gel/Lotion	Topical	15gm	15
Cream/Ointment/Gel/Lotion		30gm	10
Cream/Ointment/Gel/Lotion		60gm	10
Cream/Ointment/Gel/Lotion		100ml	10
Eye/Ear	Sterile Ointment	3-5 gm	50
Liquid Drop-Eye/Ear	Drops	1ml	80
Liquid Drop-Eye/Ear	Drops	2ml	80
Liquid Drop-Eye/Ear	Drops	5ml	80
Liquid Drop-Eye/Ear	Drops	10ml	60
Powder for injection	Dry Powder	100mg	80
Powder for injection	Dry Powder	500mg	70
Powder for injection	Dry Powder	1000mg	60
Liquid Injection	Small Volume Parenteral	1ml	80
Liquid Injection	Small Volume Parenteral	2ml	80
Liquid Injection	Small Volume Parenteral	5ml	80
Liquid Injection	Small Volume Parenteral	10ml	60
Intravenous Infusion	Large Volume Parenteral	50ml	45
Intravenous Infusion	Large Volume Parenteral	100ml	15
Intravenous Infusion	Large Volume Parenteral	250ml	10
Intravenous Infusion	Large Volume Parenteral	500ml	5
Intravenous Infusion	Large Volume Parenteral	1000ml	4
Spray/Inhaler	Inhaler	200 Actuation	20
Sachet	Oral Powder	20-27gm	15