

QA Information Notice

IN N° 2019-07 Version: 25/07/2019	Recall of Batches of Co-Trimoxazole 120mg Dispersible tablets and Temporary suspension of procurement of Co-Trimoxazole 120mg Dispersible tablets, manufactured by Chi Pharmaceuticals Limited, Nigeria
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Addressees

- Any person involved in the procurement of medicine to treat HIV related conditions
- Any person having products in stock, in transit or under custom clearance
- Any procurers, buyers with a pending order

Purpose

The GF QA is issuing this information notice to provide information regarding the product recall of Co-trimoxazole 120mg dispersible tablet and **temporary suspension of the procurement of Co-Trimoxazole 120mg Dispersible tablets manufactured by Chi Pharmaceuticals Limited.**

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer involved and location	Chi Pharmaceuticals Limited, Plot#14, Chivita Avenue, Ajao Estate, Oshodi, Lagos
INN Name	Sulfamethoxazole/Trimethoprim
Name(s) of product(s) affected	Chitrim 120 dispersible Tablets® (Co-trimoxazole 120 mg)
Pharmaceutical form	Dispersible tablet
Strength	100mg/20mg
Expiry Date	Multiple

Background

GF QA received information from Procurement agent in middle august 2018 of quality complaint from the PR for a batch (418E) of Chitrim 120 dispersible Tablets® (Co-trimoxazole 120 mg)

manufactured by Chi Pharmaceuticals Limited. The description of the complaint has been classified as “Discoloration”. However, the tablets are white showing dark spots. By then, the PR had already discontinued usage of the affected batch and kept the product under quarantine. It was subsequently recalled to the central warehouse in Lagos and then by the vendor. At that time, results of investigations were not conclusive and in particular that was possibly due to exposure of the product to high temperature and moisture as a result of poor storage conditions during transportation and/or at the facilities.

As risk mitigation measure, the procurement agent conducted independent sampling and testing for the next order of this product and requesting blister integrity tests in addition to other routine tests. Following these tests, three batches of Chitrim 120 dispersible Tablets® (Co-trimoxazole 120 mg) failed to meet the expected quality criteria depending on the batch number, for appearance, hardness, friability test testing Additionally, one batch showed failure in blister integrity test.

Nature of defect(s)

Details of defect or problem.	Out of specification (OOS) for Appearance, hardness, friability test for Chitrim 120 dispersible Tablets® (Co-trimoxazole 120 mg) Failure in blister integrity
Is there any evidence or suspicion of a risk to public health?	Potential decrease in efficacy
Extent of the problem (eg. no batches).	The OOS were reported for 4 batches manufactured in March and November 2017 namely 418E, 1669E 1686E, 1687E, so-called “impacted batches”. While waiting for outcomes of the investigations, the present notice is applying to all Co-Trimoxazole 120mg Dispersible tablets manufactured by Chi Pharmaceuticals Limited
Extent of distribution of the product / batch (es).	For the impacted batches the following countries are identified: Nigeria. Worldwide distribution cannot be excluded
Number of patients potentially impacted	No impacted patients known/reported

Action/Investigations taken

Following the notification from Procurement Agent, the GF QA has requested the manufacturer to initiate and to share the result of the Out Of Specification investigations.

Preliminary results of the investigation are mentioning initial deviation in the manufacturing process. With reference to the updated investigation reports and addendum submitted for

CC/04/2018 and CC/05/2018 – shared with the GF QA on March 27, the final root cause analysis, needs to be confirmed.

While waiting for the confirmations of the investigations, the GF QA decided to take the following protective measures in consultation with the procurement agent to inform the PR:

- discontinue use of all batches of CTX 120mg DT and keep them in quarantine
- stop further distribution of the impacted batches within the supply chain.
- quarantine the remaining stock of the impacted batches at regional and central level
- Replacement stock of CTX 120mg DT

On the 10th of May 2019, the manufacturer initiated a recall (see Annex) for following defectives batch numbers: **1669E, 1686E, 1687E**.

As a precautionary measure, the recall was extended to batch numbers 1673E and 1766E that were supplied in the same order.

Next Steps

A re-audit of the manufacturing site is planned by the procurement agent to verify CAPA implementation.

Based on the information available to date and until further notice, the following actions as agreed in collaboration with the procurement agent are recommended by GF QA:

- To report to the manufacturer/procurers the available stock that was quarantined, referencing the GF QA Notice for further replacement
- **To suspend procurement of Co-Trimoxazole 120mg Dispersible tablets from this manufacturer**


Contacts

This IN does require specific written response from PR. PRs should copy GF QA Team of any correspondence regarding the matter for follow-up purpose.

Please direct the respective answers and any questions about this matter to the technical contact listed below

Organisation	Name / Function	E-mail address
Global Fund	Alain Prat, QA Specialist	Alain.Prat@theglobalfund.org
Global Fund	Amelie Darmon, QA Associate Specialist	Amelie.Darmon@theglobalfund.org

Annex: Manufacturer Product recall letter


Member of TGI Group of Companies

CHI PHARMACEUTICALS LTD.
RC. 350, 891

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Web site: <http://www.chipltd.com>

DIRECTOR:
MRS. F. O. ODUBOGUN (MBA)

May 10, 2019

The Director,
Drug Evaluation & Research
NAFDAC
Oshodi-Apapa Expressway
Isolo,
Lagos

Dear Sir,

RECALL OF CHI PHARMA BRAND OF COTRIMOXAZOLE 120MG DISPERSIBLE TABS

We received a report of quality incidence of spotting and friability and hardness issues from our customer, [REDACTED] on the following batches of our CHI Pharma brand of Cotrimoxazole 120mg Dispersible Tablets 100 x 10 pack size:

1669E, 1673E, 1686E, 1687E, 1766E

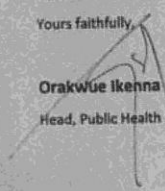
Following the report, and consequent quality investigation by both parties, we have activated the process of recall of these batches from quarantine in all the locations they were distributed (list of locations attached) back to our facility in Lagos. A total of 503 packs of 100 x 10 pack size that were identified will be retrieved.

The said products are not available for sale in the trade sector.

We will duly revert to your office as soon as all the product identified and quarantined are retrieved for the next steps leading to its destruction and disposal.

Thanks.

Yours faithfully,


Orakwue Ikenna
Head, Public Health & Institutions

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)
OFFICE OF THE DIRECTOR
RECEIVED
SIGN: [Signature] DATE: 13/5/19