Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2020-02 **Version: 05/02/2020**	Recall of Batches of Sofosbuvir 400mg tablets and Temporary suspension of procurement Sofosbuvir 400mg tablets, manufactured by European Egyptian Pharmaceutical Industry, Egypt.

Addressees

- Any person having products in stock (pharmacies, retailer), in transit, at customs
- Any procurers, buyers with a pending order
- All PRs

Purpose

The GF QA is issuing this information notice to provide information regarding the product recall of Batches of Sofosbuvir 400mg tablets and Temporary suspension of procurement Sofosbuvir 400mg tablets, manufactured by European Egyptian Pharmaceutical Industry, El Amriya, Cairo Desert Road km 25 P.O. Box 111, El Manshia Alexandria Egypt.

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	European Egyptian Pharmaceutical Industry
INN Name	Sofosbuvir
Commercial Name(s)	Grateziano Sofosbuvir 400mg film coated tablets
Pharmaceutical form	tablet
Strength	400 mg
Packaging & Pack size	Bottle,HDPE Sofosbuvir 400 mg tablets 28x1
Batch(es)	7105002, 7105004, 7105005, 8105003, 8105004, 8105005
Expiry Date	09/2019, 12/2019, 7/2020, 2/2020
GF QA Standards	ERP authorized (from 20/06/2017 until 19/06/2018), at the time of delivery

Background

GF QA received information from his partner MSF, of the manufacture of Sofosbuvir 400 mg tablets using an unauthorized API source, not complying with the approved ERP submission. According to the Manufacturer European Egyptian Pharmaceutical Industry, 6 batches of sofosbuvir 400mg manufactured using the ERP authorized Specification and supplied during the ERP validity period, have been manufactured using the non-authorized API source.

Nature of defect(s)

Details of defect or problem.	**Usage of unapproved API in the manufacture of the Finish Pharmaceutical product (FPP)**
Is there any evidence or suspicion of a risk to public health?	**No concrete evidence of risk for patient. No assurance on the quality of the API. Potential decrease in efficacy**
Extent of the problem (eg. how many batches).	**6 batches–limited to the product manufactured and exported during ERP validity: 20th June 2017 until 19th June 2018**
Extent of distribution of the product / batch (es).	**No Global Fund distribution. Procurement by partners using ERP mechanism is anticipated**
Number of patients potentially impacted	**No impacted patients known**

Action/Investigations taken

- GF investigated and could confirmed that no procurement occurred for this product within the ERP validity period for GF supported programs.
- GF requested the manufacturer to proceed with the recall of the impacted batches manufactured and supplied during the ERP validity period.
- the manufacturer requested to proceed with the recall of 6 batches; recall letter is attached.

Based on the information available to date and until further notice, the following actions are recommended by GF QA.

Next Steps:

- no recall at user level;
- To put immediately in quarantine conditions the impacted batches at pharmacy and retail level of the supply chain and send it back to wholesaler/regional or central distributors;
- To stop immediately any shipment and further distribution of the impacted batches within the supply chain (wholesaler/regional or central distributors);
- To report or confirm to the supplier/procurer the stock put in quarantine conditions;
- To suspend the procurement of sofosbuvir 400mg tablets European Egyptian Pharmaceutical Industry from date of publishing of this notice until further notice.

Contacts

This IN does not require specific written response from PR.

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

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

Annex 1: manufacturer's recall letter

EUROPEAN PHARMACEUTICALS
a pharco company

Date: 3-2-2020

Recall Request

EEPI has decided to recall the following batches of Grateziano 400 mg Tablet Which were delivered to MSF

Batch number	Quantity(Box)	Mfg./Exp.	Destination
7105002	4465	9/2017 9/2019	France
7105004	100	12/2017 12/2019	France
7105005	100	12/2017 12/2019	France
8105003	3012	7/2018 7/2020	France
8105004	2899	2/2018 2/2020	France
8105005	4446	2/2018 2/2020	France

This voluntary recall is being conducted due to, upon our retrospective review which was done after WHO PQ Audit; we found that some batches were manufactured using unapproved API source (Pharco B Int.) instead of PQed Source (CAD).

This violation has no risk on the health of patients, as this API source is registered and used in our local market, with no harm or any side effects on all patients who were taken this product in Egypt, and there have been no product complaints received since that .

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Actions Required:

1- Check your inventory and immediate quarantine any Grateziano 400 mg tablet from these lots, referenced above.

2- Check the quantity distributed, and withdraw any remaining quantities in healthcare centers.

3- Destruct all quantities found from these lots, and send us a detailed report about quantity destructed.

This recall is conducted with the knowledge of WHO PQ team. At the present time, there are no available lots of Grateziano 400 mg tablet in the supply chain to replace the affected lots.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action,

Sincerely

Quality Unit Director

Dr./ Ayten Saleh

Ayten Saleh

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