Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2020-07 **Version: 28/09/2020**	**To remind of the importance of manufacturer's environmental conditions during storage, transportation and distribution for Clofazimine 100mg soft capsules manufactured by Sandoz Private Limited, Kalwe MIDC, Plot No.8-A/2, 8-B T.T.C, IND. AREA Village Dighe,Navi Mumbai, 400, India**

Addressees

- Any person having this product in stock (pharmacies, retailer) in transit or under custom clearance
- Any person involved in the procurement of this medicine for the treatment of drug resistant forms of tuberculosis
- Any procurers, buyers with a pending order
- Principal recipient and Partners agency for information

Purpose

The GF QA is issuing this information notice to remind of that the transport and storage conditions of the pharmaceutical's product complies with the specified condition as stated on the labelling when procuring Clofazimine 100mg soft capsules manufactured by Sandoz a Novartis Division, India.

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

Background:

The decision to issue this Notice has been made following recurrent complaints received from GF supported programs highlighting that capsules of the product were found to be agglomerated in the primary packaging.

As per WHO guidelines on Good Storage and distribution, storage conditions for pharmaceutical products should be implemented in compliance with the approved packaging and labelling, which is based on the results of stability testing approved by the regulatory mechanism.

As stated on this product labelling (see Annex 1), the recommended storage condition for Clofazimine is to store the product below 25 °C. This is of high importance because the product is produced in soft gelatine capsule having inherent property to take up moisture during storage at higher temperature and humidity. By consequence, the capsule shell hardness may get decreased with elevated temperature which further induces stickiness.

After consultation, the manufacturer didn't provide any additional measures that needs to be put in place to better manage such behaviour.

Identification of the product(s) and manufacturer

Name of Manufacturer	**Sandoz a Novartis Division**
INN Name	**Clofazimine**
Commercial Name(s)	**Lamprene®**
Pharmaceutical form	**Capsules(soft)**
Strength	**100 mg**
Packaging & Pack size	**Bottle HDPE: 100x1**
Batch(es)	**n/a**
Expiry Date	**n/a**

Nature of defect(s)

Details of defect or problem.	**OOS results observed appearance: agglomerated and or melted capsules found in the primary packaging**
Is there any evidence or suspicion of a risk to public health?	**No concrete evidence of risk for patient.**
Extent of the problem (eg. how many batches).	**n/a**
Extent of distribution of the product / batch (es).	**Worldwide**
Number of patients potentially impacted	**n/a**

Action/Investigations taken

- The procurement service agent in charge for TB will share the information to the involved recipients.

Recommendations and Next Steps

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

- To rigorously adhere to the storage conditions for the transport and storage of the product as stated on the labelling such as 25°C.
- To closely monitor the temperature and humidity conditions during the storage and transportation of the product and to maintain available data that conform compliance with these conditions have been implemented and monitored i.e. in using temperature logger.

Contacts

This IN is for action but does not require a specific written response from the PR.

PRs should copy GF QA Team on any correspondence regarding the matter for follow-up purposes.

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
Global Drug Facility	Nigorsulton Muzafarova, Lead Product Quality Officer	nigorsultonm@stoptb.org

Annex 1: Product Label