

**Quality Assurance (QA) for Health Products****QA Information Notice**

<b>IN N° 2020-06</b> <b>Version:09/10/2020</b>	<b>VOLUNTARY RECALL of 8 Batches of Isoniazid Tablets BP 100mg, supplied by Lupin Ltd India.</b>
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## Addressees

- Any person having products in stock (pharmacies, retailer) in transit or under custom clearance
- Any procurers, buyers with a pending order
- All PRs

## Purpose

The GF QA is issuing this information notice regarding the voluntary recall (level II Class) which was initiated for the below mentioned product by the manufacturer, Lupin on 29 August 2020.

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	<b>Lupin</b>
INN Name	<b>Isoniazid</b>
Commercial Name(s)	<b>Isoniazid Tablets BP 100mg</b>
Pharmaceutical form	<b>Tablet</b>
Strength	<b>100 mg</b>
Packaging & Pack size	<b>Blister Alu/PVC/PVdC: 10x10</b>
Batch(es)	<b>Several (see annex 1)</b>
Expiry Date	<b>Several (see annex 1)</b>

## Background

On the 03<sup>rd</sup> of September 2020, GF QA received information from the manufacturer Lupin Ltd India, of a voluntary recall that they have initiated (see annex 1). This recall is initiated based on an impact assessment of Out of Specification (OOS) results observed for the dissolution test at 48 months, 30°C/75%RH condition in the annual stability batch for the year-2016. Based on the product trend the likelihood of failure of batches that are currently on the market for more than 36 months can't be predicted. Hence, the manufacturer, Lupin decided to initiate a Class II level recall for batches manufactured in 2017 with 60 months shelf life.

#### Nature of defect(s)

Details of defect or problem.	<b>OOS results observed in dissolution test in annual stability batch.</b>
Is there any evidence or suspicion of a risk to public health?	<b>No concrete evidence of risk for patient. Potential decrease in efficacy.</b>
Extent of the problem (eg. how many batches).	<b>8 Batches (see annex 1)</b>
Extent of distribution of the product / batch (es).	<b>Several (see annex 1)</b>
Number of patients potentially impacted	<b>No impacted patients known</b>

#### Action/Investigations taken

- Manufacturer identified the countries which were impacted by the OOS and provided the list to GF QA;
- The procurement service agent in charge for TB medicines has supported the recall in sending out the information to the involved recipients.

#### Next Steps

Because the recall has already been initiated by the supplier and supported by Procurement Service Agent there is most probably no product remaining in the supply chain. However, the following actions are recommended by GF QA as full traceability of the stated products is completely ensured :

- Not to recall at user level;
- To put in quarantine conditions the impacted products at pharmacy and retail level of the supply chain and send it back to wholesaler/regional or central distributors;
- To stop any shipment and further distribution of the impacted product within the supply chain (wholesaler/regional or central distributors);
- To report or confirm to the supplier/procurer the stock put in quarantine;

#### Contacts

This IN requires a specific written response from the PR.

PRs should copy GF QA Team on any correspondence regarding this product recall.

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

<b>Organisation</b>	<b>Name / Function</b>	<b>E-mail address</b>
Global Fund	Amelie Darmon, Associate QA Specialist	<a href="mailto:Amelie.Darmon@theglobalfund.org">Amelie.Darmon@theglobalfund.org</a>
Global Drug Facility	Nigorsulton Muzafarova, Lead Product Quality Officer	<a href="mailto:nigorsultonm@stoptb.org">nigorsultonm@stoptb.org</a>

## Annex 1: Manufacturer's recall letter & Distribution List

### LUPIN LIMITED

A-28/1, MIDC, Chikalthana,  
Aurangabad - 431 210 - Maharashtra  
Tel : 91 - 240 - 2485871-72, 91 - 240 - 6612444  
Fax : 91 - 240 - 2484121



Date: 29<sup>th</sup> August 2020

To,  
Dr. Matthias Stahl,  
Head of Assessments,  
Prequalification of Medicines Programme,  
Quality Assurance and Safety: Medicines,  
World Health Organisation,  
Geneva, Switzerland.

**Subject:** Intimation of recall of product- TB 196 - Isoniazid Tablets BP 100 mg.

Dear Dr. Stahl,

We wish to inform you that, Recall is initiated against impact assessment of OOS Reference No. OOS/C/20/AUR/SS/003. Based on the product trend the likelihood of failure of the batches in market more than 36M age can not be predicted hence recall for batches manufactured in year 2017 with 60M shelf life is initiated.

Details of recalled batches from market are as mentioned below:

Sr. No.	Product Details (Name/ Strength/ Dosage Pack)	Batch / Lot No.	Mfg. Date / Expiry		Quantity released for Sale (Box)	Market
		FG Batch No.	Mfg. Date	Exp. Date		
1	ISONIAZID 100MG 10X10T GDF	A701161	Feb-17	Jan-22	6,137	North Korea
					5,353	Mozambique
2	ISONIAZID 100MG 10X10T GDF	A701163	Feb-17	Jan-22	11,748	Mozambique
3	ISONIAZID 100MG 10X10T GDF	A701164	Feb-17	Jan-22	11,511	Mozambique
4	ISONIAZID 100MG 10X10T GDF	A701165	Feb-17	Jan-22	343	Burkina Faso
					230	India
					797	India
					48	India
					755	India
					3,764	Mozambique
					2,311	Ivory Coast
					346	Congo
					705	North Korea
					1,146	Sri Lanka
					250	Ghana
					250	Ghana

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**Registered Office :** Kalpataru Inspire, 3rd Floor, Off. Western Express Highway, Santacruz (East),  
Mumbai - 400 055, India. Tel. : (91-22) 66402323. [www.lupin.com](http://www.lupin.com)  
**Corporate Identity Number :** L24100MH1983PLC029442

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Sr. No.	Product Details (Name/ Strength/ Dosage Pack)	Batch / Lot No.	Mfg. Date / Expiry		Quantity released for Sale (Box)	Market
		FG Batch No.	Mfg. Date	Exp. Date		
5	ISONIAZID 100MG 10X10T GDF	A702918	May-17	Apr-22	8,495	Tanzania
6	ISONIAZID 100MG 10X10T GDF	A703191	May-17	Apr-22	11,874	Tanzania
7	ISONIAZID 100MG 10X10T GDF	A703192	May-17	Apr-22	11,711	Tanzania
8	ISONIAZID 100MG 10X10T GDF	A705644	Oct-17	Sep-22	11,545	Uganda

This is for your information please.

Sincerely,

**For Lupin Limited**



**Sonika Gujarathi.**

**Manager – Quality Assurance.**