Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2025-01 **Version : 27-Jan-2025**	**Precautionary measures in procuring pharmaceutical products manufactured and/or controlled and/or released at Mylan Indore-Pithampur India facility**

Addressees

- Through Health Product Management (HPM) Specialists, all Principal Recipients (PR) reporting procurement of the affected product financed by the Global Fund.
- All procurers, buyers reporting procurement of the affected product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Information Notice to provide precautionary measures following the issuance of a warning letter and an import alert by the US Food and Drug Administration (USFDA) for the Mylan Indore-Pithampur India manufacturing site (the exact address is provided below).

This QA Information 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 & Address of the Manufacturer	Mylan Laboratories Limited, Inc., “a Viatris company”, located at Plot No. 11, 12 & 13, Indore SEZ Pharma Zone, Phase-II, Sector-III, District Dhar Pithampur, Madhya Pradesh, India
Commercial / Brand Name(s)	All pharmaceutical products manufactured and/or controlled and/or released at the concerned facility[1]
Formulation	All pharmaceutical products manufactured and/or controlled and/or released at the concerned facility[1]
Batch(es)	All batches released after the issuance of the warning letter (December 19, 2024)
Manufacturing Date	All batches released after the issuance of the warning letter (December 19, 2024)

Background

On December 19, 2024, the USFDA issued a warning letter and an import alert following a Good Manufacturing Practice (GMP) inspection of the Mylan Indore-Pithampur India site conducted in June 2024. The inspection revealed significant GMP violations, including failure to ensure reliability and integrity of quality control data during component release testing at the facility, as well as lack of adequate scientific rationale to support root cause determinations in the facility’s investigations into discrepancies and out-of-specification results.

WHO Prequalification Team is currently investigating the impact of the deficiencies being raised in the USFDA’s Warning Letter.

[1] A non-exhaustive list of affected pharmaceutical products can be found in Annex 1.

Nature of defect(s)

Details of the defect or problem	Significant GMP violations identified during a USFDA GMP inspection conducted in June 2024 (see Warning Letter 320-25-28 for further details Viatris, Inc. - 690897 - 12/19/2024 | FDA)
Is there any evidence or suspicion of a risk to users/others	According to USFDA warning letter the quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs manufactured by the company. USFDA placed products offered for import into the United States from Mylan Indore-Pithampur India facility on Import Alert 66-40 on December 19, 2024 Import Alert 66-40 (fda.gov).This alert indicates that the affected pharmaceutical products are subject to refusal of admission into the US market. However, certain products from Mylan Indore-Pithampur India facility have been excluded from the import alert[2].
Extent of the problem (e.g. No. of batches)	All batches of all pharmaceutical products manufactured and/or controlled and/or released at the concerned facility are affected.
Extent of distribution of the product / batch(es)	Affected batches of pharmaceutical products were distributed to various extent. Additionally, the procurement and distribution of any other eligible products manufactured and/or controlled and/or released at the concerned facility may have been organized directly through Principal Recipients, outside the pooled procurement mechanism and the Global Drug Facility.
Number of users/others affected	At the time of writing, no recall has been requested by the USFDA or initiated by the manufacturer. Actions such as customer communications, additional testing, additional stability studies, complaint monitoring and potential recalls are to be considered as part of the site risk assessment interim actions according to the USFDA warning letter.

[2] The products exempted from the import alert are Levothyroxine Sodium Tablets, Fingolimod Capsules, Atorvastatin Calcium Tablets, Metformin Hydrochloride Tablets. Please contact the Global Fund Quality Assurance Specialist if you are procuring these products from Mylan Indore-Pithampur India manufacturing site.

Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance & Compliance team as precautionary measures.

- **Eligibility**

QA Eligibility of all the pharmaceutical products manufactured and/or controlled and/or released at Mylan Pithampur-Indore India site is temporary suspended. Pharmaceutical products manufactured, controlled and released at other eligible Mylan manufacturing sites are not affected until further notice.

PR, procurers and buyers are expected to check that pharmaceutical products purchased from Mylan are not manufactured and/or controlled and/or released from the Mylan Indore-Pithampur India site.

- **New and open orders**

1. Halt any new and open orders or procurements of pharmaceutical products released from Mylan Pithampur-Indore site from the issuance date of the warning letter.
2. Consider alternative procurement:
    a) Of eligible product from other Mylan's approved sites, OR
    b) eligible product from an alternative supplier.

- **Already procured products (delivered or in transit or on hold for pick up)**

At the time of writing, no recall has been requested by the USFDA or initiated by the manufacturer. No action is required for already delivered products procured from the concerned site, and any ongoing procurement (on hold for pick up or in transit) can proceed as planned as long as the concerned batches have been released (as per the date indicated on the certificate of analysis) before the issuance of the warning letter.

In case of programmatic concerns, requests for case-by-case assessment can be addressed to the respective Country Team/HPM Specialist.

Users/Others

Users who have experienced any adverse reactions or quality problems with the use of the affected product may report this to the relevant Regulatory Authorities, manufacturer and the Global Fund Country Team/HPM Specialist.

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the affected products have been transferred.

Please maintain awareness of this QA Information Notice and resulting action for an appropriate period to ensure effectiveness of the action.

Contacts

This QA Information Notice does not require specific written responses from PR and procurers to the Global Fund.

PRs and procurers should copy the Global Fund's Country Team/HPM Specialist on correspondence regarding the matter for follow-up.

Please direct any questions about this matter to the technical contact listed below.

Organization	Name / Function	E-mail address
Global Fund	Respective Country Team/HPM Specialist for the portfolio	
Global Fund	Cathal Meere, Manager, Global Sourcing Pharmaceuticals • Strategic Sourcing	cathal.meere@theglobalfund.org
Global Fund	Sandrine Cloëz, Specialist, Pharmaceuticals Quality Assurance • Quality Assurance & Compliance	sandrine.cloez@theglobalfund.org
Global Drug Facility	Nigorsulton Muzafarova, Lead Product Quality Officer (for TB)	nigorsultonm@stoptb.org

Annex 1: Non-exhaustive list of affected pharmaceutical products

(The affected pharmaceutical products are those manufactured, controlled, or released at the Mylan Pithampur-Indore site in India. Pharmaceutical products manufactured, controlled, and released at other eligible Mylan manufacturing sites are not affected until further notice.)

Malaria Pharmaceutical Products

Artemether/Lumefantrine 20mg/120mg Tablet

Artemether/Lumefantrine 40mg/240mg Tablet

Antiretroviral Pharmaceutical Products

Abacavir 300 mg Tablet

Abacavir/Dolutegravir/Lamivudine 60mg /5mg/30mg Dispersible tablet

Abacavir/Lamivudine 120mg/60mg Tablets for Oral Suspension

Abacavir/Lamivudine 600mg/300mg Tablet

Dolutegravir (as sodium salt) 10mg Tablet for Oral Suspension

Dolutegravir (as sodium salt) 50mg Tablet

Dolutegravir/Emtricitabine/Tenofovir Alafenamide 50mg/200mg/25mg Tablet

Dolutegravir/Lamivudine/Tenofovir Alafenamide 50mg/300mg/25mg Tablet

Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate 50mg/300mg/300 mg Tablet

Efavirenz (EFV) 600mg Tablet

Efavirenz/Lamivudine/Tenofovir (Disoproxil Fumarate) 400mg/300mg/300mg Tablet

Emtricitabine/Tenofovir Disoproxil Fumarate 200mg/300mg Tablet

Emtricitabine/Tenofovir Alafenamide 200mg/25mg Tablet

Lamivudine/Tenofovir disoproxil fumarate 300mg/300mg Tablet

Lamivudine/Zidovudine 30mg/60mg Dispersible Tablet

Lamivudine/Zidovudine 150mg/300mg Tablet

Lopinavir/Ritonavir 40mg/10mg Oral Granules

Lopinavir/Ritonavir 100mg/25mg Tablet

Lopinavir/Ritonavir 200mg/50mg Tablet

Tuberculosis Pharmaceutical Products

Isoniazid/Pyridoxine/Sulfamethoxazole/Trimethoprim 300mg/25mg/800mg/160mg Tablet

Linezolid 600mg Tablet