QA Information Notice for Health Products

IN Nº 2025-01 **Version - April 14, 2025**	**Precautionary measures in procuring non-WHO prequalified pharmaceutical products that are manufactured and/or controlled and/or released at Mylan Indore-Pithampur India facility.**

IN Nº 2025-01 dated April 14, 2025 supersedes IN Nº 2025-01 published on January 27, 2025

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 notice also considers the outcomes of the onsite for-cause inspection performed by WHO Prequalification Inspection Services at the facility in March 2025.

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 non-WHO prequalified products manufactured and/or controlled and/or released at the concerned facility[1]
Formulation	All non-WHO prequalified products manufactured and/or controlled and/or released at the concerned facility[1]
Batch(es)	All batches of non-WHO prequalified products released after the issuance of the warning letter (December 19, 2024)
Manufacturing Date	All batches of non-WHO prequalified products 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.

Consequently, The Global Fund published a QA notice (ref. IN No 2025-01) on January 27, 2025 to provide guidance on precautionary measures in procuring all pharmaceutical products manufactured and/or controlled and/or released at Mylan Indore-Pithampur India facility and delisting of Mylan Indore-Pithampur India facility.

WHO Prequalification Inspection Services performed an onsite for-cause inspection on Mylan’s Pithampur manufacturing site from March 3 to 7, 2025 and published an information note on March 31, 2025, available at the following link https://extranet.who.int/prequal/news/information-mylan-indore-31march2025 .

This inspection aimed to assess the potential impact of the USFDA findings on the WHO prequalified products and take any appropriate actions if necessary.

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

Based on the on-site for-cause inspection at the Mylan Indore site, the PQ inspection team observed that a significant remediation action plan is being implemented to holistically address the issues related to data integrity, testing on packaging materials, backlog of stability samples and other issues. All lots of the finished pharmaceutical products are subjected to enhanced quality checks and verifications including (1) additional supervision and oversight by Viatris Global Quality of the packaging material testing laboratory, (2) detailed review and clearance by Viatris Global Quality prior to release from the site, and (3) engaging third-party experts to review all investigations for any out of specification (OOS) and/or out of trend (OOT/atypical) results covering all products within expiry in the market. **As per WHO PQ conclusion it is determined that there is no direct impact on the quality, safety and efficacy on all finished pharmaceutical products manufactured on site.**

The inspection covered batches of WHO prequalified products released after the implementation of the enhanced quality oversight by the Global Quality Assurance, Viatris starting from August 12, 2024.

However, the information note, based on the inspection, applies only to WHO prequalified products. Other products were not covered during the inspection and as such the precautionary measures are maintained for non-WHO prequalified products manufactured and/or controlled and/or released at the concerned facility.

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].

[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.

Extent of the problem (e.g. No. of batches)	All batches of all non-WHO prequalified 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.

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 non-WHO prequalified 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 non-WHO prequalified 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**

Halt any new and open orders or procurements of non-WHO prequalified products released from Mylan Pithampur-Indore site.

Consider alternative procurement:

a) Of eligible product from other Mylan's approved sites, OR
b) Eligible product from an alternative supplier.

Halt any new and open orders or procurements of WHO prequalified products released from the Mylan Pithampur-Indore site before August 12, 2024.

- **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.

Any ongoing procurement (on hold for pick up or in transit) can proceed as planned, except for batches of non-WHO prequalified products released after the issuance of the warning letter (as per the date indicated on the certificate of analysis).

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 the non-WHO prequalified products manufactured and/or controlled and/or released at Mylan Pithampur-Indore India site. WHO prequalified pharmaceutical products manufactured and/or controlled and/or released at Mylan Pithampur-Indore India site, and pharmaceutical products manufactured, controlled and released at other eligible Mylan manufacturing sites are not affected by this QA Information Notice)

Antiretroviral Pharmaceutical Products

- Abacavir/Dolutegravir/Lamivudine 60mg /5mg /30mg dispersible tablets
  ANDA 218193
- Abacavir/Lamivudine 120mg/60mg dispersible tablets
  ANDA 204915
- Dolutegravir/Lamivudine/Tenofovir Alafenamide 50mg/300mg/25mg tablets
  ANDA 210865
- Lopinavir/Ritonavir 200mg/50mg tablets
  ANDA 079074
- Abacavir 300mg tablets
  ANDA 078742