Information note

31 March 2025

Information on the GMP status of Mylan Laboratories Ltd (Viatris, Inc.) manufacturing facility situated at Indore, Pithampur (Madhya Pradesh, India)[1]

Warning Letter MARCS-CMS 690897 — 19 December 2024, Reference No. 320-25-28[1], was issued by the U.S. Food and Drug Administration (FDA) further to an inspection of the finished pharmaceutical product manufacturing facility of Mylan Laboratories Limited, Inc., "a Viatris company," FEI 3010453141, located at Plot No. 11, 12 & 13, Indore SEZ Pharma Zone, Phase-II, Sector-III, Pithampur, Dhar, Madhya Pradesh, India, from 14 to 16 June 2024. Mylan notified PQT: Inspections on 10 October 2024, of the FDA483 that had been issued to the site, prior to the Warning Letter and of its ongoing corrective and preventive actions and of potential temporary supply disruptions for certain products manufactured at the Indore site.

WHO action and advice:
WHO Prequalification Inspection Services performed an on-site for-cause inspection on Mylan's Pithampur manufacturing site from 3 to 7 March 2025. This inspection aimed to assess the potential impact of the US FDA findings on the WHO Prequalified products and take any appropriate actions if necessary. The inspection team has noted that remedial actions initiated by Mylan are being implemented under the supervision and oversight of the Global Quality Assurance team, Viatris. The retention samples are being tested for the packaging materials as well as the finished pharmaceutical products.

WHO has prequalified several medicinal products, the manufacture of which is undertaken at the Mylan Laboratories Ltd. Indore, Pithampur facility. The prequalification status of the products manufactured at the mentioned site remains current. However, 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.

Based on the for-cause on-site 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. In addition, the PQ inspection team has found deficiencies related to no timely notification of the out-of-specification (OOS) for the ongoing stability batch of the FPP and inadequate comprehensive investigation of the confirmed OOS. The PQ inspection services are currently working with the manufacturer to ensure timely action on the affected batch of the FPP. Based on the for-cause on-site inspection, it is determined that there are no direct impact on the quality, safety and efficacy on the FPPs manufactured on-site.

Procurement agencies, distributors and regulatory authorities of Member States are welcome to contact the WHO Inspections Team for further information and updates.

Further information:
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[1] The full Warning Letter is available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/viatris-inc-690897-12192024