

REGULATION AND PREQUALIFICATION DEPARTMENT

NOTICE OF DELISTING

Centre Humanitaire des Métiers de la Pharmacie (CHMP)
4 voie militaire des Gravanches
Clermont-Ferrand 63100
France

Notice of Delisting (NOD) issued in terms of WHA57.14 read together with RPQ procedure on Change of prequalification status: suspension and delisting.

Your attention is invited to the World Health Assembly Resolution WHA57.14 *"Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS"* of 22 May 2004, which among other actions, requests WHO:

"3. (4) to ensure that the prequalification review process and the results of inspection and assessment reports of the listed products, aside from proprietary and confidential information, are made publicly available;"

Following the said resolution, the WHO Prequalification Unit (PQT), under the Regulation and Prequalification Department (RPQ) implemented in June 2008 a notification procedure that is applied when concerns are identified about a site's compliance with specified standards such as those relating to Good Manufacturing Practices (GMP), Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) or Good Clinical Practices (GCP). This can lead WHO to suspend or withdraw a prequalified quality control laboratory (QCL) from the list of prequalified QCLs when there is evidence of non-compliance with WHO-recommended quality standards for such laboratories and/or the related prequalification procedure. Such decisions are made in accordance with the principles outlined in the document *Prequalification of Quality Control Laboratories: Procedure for Assessing the Acceptability, in Principle, of Quality Control Laboratories for Use by United Nations Agencies* (WHO TRS 1003, Annex 3).

Based on these directives, the WHO Regulation and Prequalification Department hereby issues a Notice of Delisting relating to the status of GPPQCL standards at Centre Humanitaire des Métiers de la Pharmacie (CHMP), 4 voie militaire des Gravanches, Clermont-Ferrand 63100, France and the concerns on the site's implementation of GPPQCL.

The decision to delist the laboratory relates to a negative outcome of a reinspection conducted as part of WHO's ongoing monitoring of continued compliance with WHO-recommended quality standards for Quality Control Laboratories (QCLs). This includes non-compliance with GPPQCL. The inspection, held at CHMP from 18 to 20 June 2024, was followed by the laboratory's submission of evidence and Corrective and Preventive Action Plans (CAPA), but ultimately concluded with a finding of non-compliance on 13 September 2024, further confirmed by an independent ad-hoc committee on 2 January 2025 after an appeal submitted by CHMP.

On this basis, Centre Humanitaire des Métiers de la Pharmacie (CHMP) has been delisted from WHO Prequalified Pharmaceutical Quality Control Laboratories as of 13 January 2025.

For further information please visit the WHO Regulation and Prequalification Department website at <https://extranet.who.int/prequal/medicines/medicines-quality-control-laboratories> or contact RPQ Regulation and Safety - Laboratory Network and Services (LNS) directly at prequalabs@who.int.

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Web: [Monitoring of QCL Performance](https://extranet.who.int/prequal/medicines/monitoring-qcl-performance)
<https://extranet.who.int/prequal/medicines/monitoring-qcl-performance>