WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Ituxredi[1]

Rituximab 500 mg/50 mL concentrate for solution for infusion

Abstract

Ituxredi manufactured at Dr. Reddy's Laboratories Ltd, Telangana, India, was submitted to be considered for prequalification in 2025 when the product was licensed / registered in the European Union, and subsequently accepted for inclusion in the WHO list of prequalified products for the WHO-recommended indications: treatment of diffuse large B-cell lymphoma, chronic lymphocytic leukaemia and follicular lymphoma, on 09 September 2025.

The "WHO Pilot Procedure for Prequalification of Biotherapeutic Products: rituximab and trastuzumab"[2] defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme is based on the approval by the European Medicines Agency (EMA: http://www.ema.europa.eu/ema/) in line with the "WHO Guidelines on submission of documentation for the pilot procedure for prequalification of rituximab or trastuzumab approved by stringent regulatory authorities"[3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Team: Medicines (PQTm). However, according to the above-mentioned guideline WHO requested additional data for the safe use of the product in regions relevant for prequalified products and this information is included in part 6b of this WHOPAR. In order to safeguard product quality throughout its entire intended shelf-life, WHO assessed the evidences to verify the adherence to the principles outlined in the most recent version of the WHO guidelines on the international packaging and shipping of vaccines[4], also partially applicable to other biotherapeutic products, to demonstrate suitability of the packaging to regions outside of climatic zone II. WHO assessed the packaging procedures for international shipments, the validation protocols and reports of the shipping boxes used for supply of the prequalified product.

In addition, the adequacy of the procedures for handling quality complaints and recalls with the inclusion of restrictions on distribution or recalls of the product in regions relevant for prequalified products was evaluated by the assessment team.

Furthermore, in accordance with the relevant guidelines[3], a WHO prequalification-specific addendum to the Risk Management Plan (RMP) was submitted and assessed by the team of assessors. With this addendum the Applicant outlined their approach how to identify the risks of the product and which measures will be applied to monitor and minimize such risks, taking into consideration potential differences in the health care setting that may change the benefit/risk profile defined within the SRA settings.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility.

[2] https://extranet.who.int/prequal/sites/default/files/document_files/01_Pilot_PQ_anticancer_procedure_feb2020.pdf
[3] https://extranet.who.int/prequal/sites/default/files/document_files/03_Pilot_PQ_anticancer_AbridgedPathway_Feb2020.pdf
[4] https://extranet.who.int/prequal/sites/default/files/document_files/WHO_IVB_05.23_eng.pdf

Country-specific adaptation and implementation of the RMP as detailed within the PQ-specific addendum to the RMP should be put in place by the Applicant.

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification.

WHOPAR part		**Reference**[5]
Part 1	Summary for the Public	https://www.ema.europa.eu/en/medicines/human/EPAR/ituxredi#overview
Part 3	Patient information Leaflet	https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/ituxredi-epar-product-information_en.pdf
Part 6b	EPAR-Scientific Discussion	https://www.ema.europa.eu/en/documents/assessment-report/ituxredi-epar-public-assessment-report_en.pdf
Part 8	Steps taken after the Authorization	https://www.ema.europa.eu/en/documents/procedural-steps-after/ituxredi-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

Parts 2, 6b and 7 of the WHOPAR for Ituxredi are included here.

[5] https://www.ema.europa.eu/en/medicines/human/EPAR/ituxredi

Summary of prequalification status for Ituxredi:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	09 September 2025	listed
Dossier evaluation		
Verification	28 April 2025	MR
Quality	21 July 2025	MR
Pharmacovigilance	03 September 2025	MR
Inspection Status		
GMP (re-)inspection drug substance		NA
GMP (re-)inspection drug product		NA
GCP/GLP (re-)inspection		NA

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

If you require any additional information, please send the request to WHO PQ Team Lead Medicines Assessment