Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Dr. Reddy's Laboratories Ltd submitted in 2025 an application for Ituxredi (BT-ON018)[*] to be assessed with the aim of including Ituxredi in the list of prequalified medicinal products for treatment of certain cancers.

Ituxredi was assessed according to "WHO Pilot Procedure for Prequalification of Biotherapeutic Products: rituximab and trastuzumab"[†] by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

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 guidelines, WHO verified that the product, and in particular, composition/formulation, strength, manufacturing, specifications, packaging, product information will, at the time of submission and after prequalification, in all respects, be the same as the product registered with the reference SRA ("verification"). Furthermore, WHO requested additional data for the safe use of the product in regions relevant for prequalified products and this information is included in the WHOPAR (part 6b). In order to safeguard product quality throughout its entire intended shelf-life, WHO assessed the evidence 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, also partially applicable to other biotherapeutic products[‡], to demonstrate suitability of the packaging to regions outside of climatic zone II. The WHO assessment included the packaging procedures for international shipments and the validation protocols and reports of the shipping boxes used for supply of the prequalified product.

Based on the data submitted, the team of assessors advised that Ituxredi be included in the list of prequalified medicinal products. Ituxredi was listed on 9 September 2025.

Licensing status:

Ituxredi has been licensed / registered in the European Union.

2. Steps taken in the evaluation of the product

February 2025	The applicant submitted the dossier.
April 2025	The assessment team reviewed the submitted data and accepted the dossier for assessment
May 2025	The assessment team reviewed the submitted documents and further data were requested on quality and pharmacovigilance.
June 2025	The applicant's response was received.
July 2025	The additional quality and pharmacovigilance data were reviewed. The quality data were found to comply with the relevant WHO requirements. Further pharmacovigilance information was requested.

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
[†] https://extranet.who.int/prequal/sites/default/files/document_files/01_Pilot_PQ_anticancer_procedure_feb2020.pdf
[‡] https://extranet.who.int/prequal/sites/default/files/document_files/WHO_IVB_05.23_eng.pdf

August 2025	The applicant's response was received.
September 2025	The pharmacovigilance data were reviewed and found to comply with the relevant WHO requirements.
9 September 2025	Ituxredi was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

Manufacturer, Commitments and Inspection Status

Manufacturer of the finished product and responsible for batch release

Name and address of the manufacturers of the biological active substances:

Dr. Reddy's Laboratories Ltd.

Biologics, Survey No. 47 & 44 (Part)

Bachupally Village

Bachupally Mandal, Medchal-Malkajgiri District, Pincode 500090

Telangana State, India

Name and address of the manufacturers responsible for batch release:

Dr. Reddy's Laboratories Ltd.

Biologics, Survey No. 47 & 44 (Part)

Bachupally Village

Bachupally Mandal, Medchal-Malkajgiri District, Pincode 500090

Telangana State, India

Commitments for Prequalification

The Applicant committed to submit to WHO, following each marketing authorization, a brief discussion on how the Applicant has addressed, after product prequalification, any potential differences in healthcare settings, compared to SRAs, that have required a revision of the adequacy of the safety concerns, pharmacovigilance activities, risk minimisation measures and/or traceability of the product.

Inspection status

Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority were acceptable.