WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Truxima[1]

International Nonproprietary Name (INN):
Rituximab 100mg concentrate for solution for infusion

Abstract

Truxima 100mg concentrate for solution for infusion manufactured at Celltrion, Inc., Plant II (CLT 2) Yeonsu-gu, Incheon, 22014, Republic of Korea was submitted to be considered for prequalification in 2019 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 the 25 May 2020.

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.

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[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://www.who.int/medicines/regulation/biotherapeutic_products/en/

[3] https://www.who.int/medicines/regulation/03_Pilot_PQ_anticancer_AbridgedPathway_Feb2020.pdf?ua=1

[4] https://www.who.int/immunization_standards/vaccine_quality/vaccines_packaging_guidelines2019/en/

Furthermore, in accordance with the relevant guideline[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.

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/documents/overview/truxima-epar-medicine-overview_en.pdf
Part 3	Patient information Leaflet	https://www.ema.europa.eu/en/documents/product-information/truxima-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/truxima-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/truxima-epar-product-information_en.pdf
Part 6a	EPAR-Scientific Discussion	https://www.ema.europa.eu/en/documents/assessment-report/truxima-epar-public-assessment-report_en.pdf
Part 8	Steps taken after the Authorization	https://www.ema.europa.eu/en/documents/procedural-steps-after/truxima-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

Parts 2, 6b and 7 of the WHOPAR for Truxima 100mg concentrate for solution for infusion are included here.

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

Summary of Prequalification Status for:
Rituximab 100mg concentrate for solution for infusion:

	Initial acceptance	
	Date	Outcome
Status on PQ list	25 May 2020	listed
Dossier evaluation		
Verification	15 October 2019	MR
Quality	1 May 2020	MR
Pharmacovigilance	1 May 2020	MR
Inspection Status		
GMP (re-)inspection		
Drug Substance		*NA*
Drug Product		*NA*
GCP(re-)inspections		*NA*

MR: meets requirements
N/A: Not Applicable, not available

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