

Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sandoz GmbH submitted in 2018 an application for Rixathon¹ 100mg/10mL concentrate for solution for infusion, to be assessed with the aim of including Rixathon in the list of prequalified medicinal products for the treatment of diffuse large B-cell lymphoma, chronic lymphocytic leukaemia and follicular lymphoma.

Rixathon was assessed according to the WHO Pilot Procedure for Prequalification of Biotherapeutic Products: rituximab and trastuzumab² and relevant applicable guidelines 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.

The prequalification of this product by the WHO Prequalification of Medicines Programme is based on the approval by a stringent regulatory authority (SRA), namely the “European Medicines Agency” (EMA; <http://www.ema.europa.eu/ema/>) in line with the applicable guidelines².

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 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 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, also partially applicable to other biotherapeutic products³, 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 Rixathon is included in the list of prequalified medicinal products. Rixathon was listed on 17 September 2020².

Licensing status:

Rixathon has been licensed / registered in the European Union.

2. Steps taken in the evaluation of the product

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| Oct 2018 | The applicant submitted the dossier. |
| Jul 2019 | The assessment team reviewed the submitted data and accepted the dossier for assessment. |
| Sep 2019 | The assessment team reviewed the submitted document for the verification, quality and pharmacovigilance data and further information was requested. |

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/immunization_standards/vaccine_quality/vaccines_packaging_guidelines2019/en/

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| Oct 2019 | The applicant's response letter was received. |
| Dec 2019 | The assessment team reviewed the submitted data and further data was requested on quality and pharmacovigilance. The verification was found to be in compliance with WHO requirements |
| Feb 2020 | The applicant's response letter was received. |
| Apr 2020 | The assessment team reviewed the submitted data and further data was requested on pharmacovigilance. The quality was found to be in compliance with WHO requirements |
| Jul 2020 | The applicant's response letter was received. |
| Jul 2020 | The assessment team reviewed the submitted data and further data was requested on pharmacovigilance. |
| Aug 2020 | The applicant's response letter was received. |
| Sep 2020 | The assessment team reviewed the submitted data. Pharmacovigilance data were found to be in compliance with WHO requirements |
| Sep 2020 | Rixathon 100mg/10mL concentrate for solution for infusion was included in the list of prequalified medicinal products. |

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Name and address of the manufacturer(s) of the biological active substance(s)

Sandoz GmbH Schaftenau
Biochemiestr. 10
6336 Langkampfen
AUSTRIA

Novartis Manufacturing GmbH
Emil-von-Behring-Straße 76
35041 Marburg
Germany

Boehringer Ingelheim Pharma GmbH & Co. KG
Birkendorfer Straße 65
88397 Biberach an der Riss
Germany

Name and address of the manufacturer(s) responsible for batch release

Sandoz GmbH Schaftenau
Biochemiestr. 10
6336 Langkampfen
AUSTRIA

Lek Pharmaceuticals d.d. Ljubljana
Verovškova 57
1526 Ljubljana
Slovenia

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

The sites are inspected by a stringent regulatory authority.