

Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sanofi-Aventis Deutschland GmbH submitted in 2022 an application for **Insulin Glargine Impact** 100 IU/ml solution for injection in a cartridge, to be assessed with the aim of including Lantus in the list of prequalified medicinal products for the treatment of diabetes mellitus.

Insulin Glargine Impact was assessed according to the “WHO Pilot Procedure for Prequalification of BTPs: human insulin”¹ 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 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 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 Insulin Glargine Impact be included in the list of prequalified medicinal products. Insulin Glargine Impact was listed on 05 May 2023.

Licensing status:

Lantus has been licensed / registered in the European Union.

2. Steps taken in the evaluation of the product

Nov-2022	The applicant submitted the dossier
Dec-2022	The assessment team reviewed the submitted data and accepted the dossier for assessment

¹ https://extranet.who.int/pqweb/sites/default/files/documents/01_Pilot_PQ_procedure_insulin_Feb2020.pdf

²

https://extranet.who.int/pqweb/sites/default/files/documents/03_GLs_Submission_SBP_Pilot_AbridgedPathway_insulinFeb2020.pdf

³ https://apps.who.int/iris/bitstream/handle/10665/69368/WHO_IVB_05.23_eng.pdf?sequence=1

Dec 2022	The assessment team reviewed the submitted document and further data was requested on quality and pharmacovigilance. Verification was found to be in compliance with WHO requirements
Apr 2023	The applicant's response letter was received.
Apr 2023	Data on quality and pharmacovigilance were found to be in compliance with WHO requirements
May 2023	Insulin Glargine Impact 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 manufacturers of the biological active substance

Sanofi-Aventis Deutschland GmbH

(LOC-100000869)

Brüningstraße 50

Höchst

65926 Frankfurt am Main

Germany

Name and address of the manufacturers responsible for batch release

Sanofi-Aventis Deutschland GmbH

(LOC-100000869)

Brüningstraße 50

Höchst

65926 Frankfurt am Main

Germany

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.