Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novo Nordisk A/S submitted in 2022 an application for Insulatard Penfill 100 IU/ml suspension for injection (cartridge), to be assessed with the aim of including Insulatard Penfill in the list of prequalified medicinal products for the treatment of diabetes mellitus.

Insulatard Penfill 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 guidelines[2].

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 products[3], 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 Insulatard Penfill be included in the list of prequalified medicinal products. Insulatard Penfill was listed on 27 September 2022.

Licensing status:
Insulatard Penfill has been licensed / registered in the European Union.

2. Steps taken in the evaluation of the product

Jul-2022	The applicant submitted the dossier
Jul-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

Aug 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
Sep 2022	The applicant's response letter was received.
Sep 2022	Data on quality and pharmacovigilance were found to be in compliance with WHO requirements
Sep 2022	Insulatard Penfill 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

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

Novo Nordisk A/S

Hallas Allé

DK-4400 Kalundborg

Denmark

Name and address of the manufacturers responsible for batch release

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

Novo Nordisk Production SAS

45, Avenue d'Orléans

F-28000 Chartres

France

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.