Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2020 an application for [HA765 trade name]* (HA765) to be assessed with the aim of including [HA765 trade name] in the list of prequalified medicinal products for treatment of HIV/AIDS.

[HA765 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' 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.

2. Steps taken in the evaluation of the product

October 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2020	The quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
July and October 2021	The additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2021	Product dossier accepted (quality assurance)
14 December 2021	[HA765 trade name] was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Macleods Pharmaceuticals Limited
Block N2, Village Theda
P.O. Lodhimajra
Tehsil Baddi, Dist. Solan
Himachal Pradesh, 174101
India

Macleods Pharmaceuticals Limited
Phase II, Unit II, Plot No. 25 – 27,
Survey No. 366,
Premier Industrial Estate,
Kachigam, Daman – 396210,
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:
https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products