Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2019 an application for [HA735 trade name][*] (HA735) to be assessed with the aim of including [HA735 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

[HA735 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

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

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

28 January 2021	[HA735 trade name] was included in the list of prequalified medicinal products.

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, 174 101
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