Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2018 an application for [HA713 trade name]* (HA713) to be assessed with the aim of including [HA713 trade name] in the list of prequalified medicinal products for HIV/AIDS

[HA713 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

July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June and September 2018	The quality data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
April 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2019	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional 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	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
January and February 2020	The additional quality data were reviewed and further information was requested.

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

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.
April 2020	The applicant's response letter was received.
April 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2020	Product dossier accepted (quality assurance)
21 May 2020	[HA713 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 No. 2
Village Theda
Post Office Lodhimajra
Tehsil Baddi
District Solan
Himachal Pradesh – 174101
India

Inspection status

The FPP site was inspected and found to be in compliance with WHO requirements for GMP.

The BE site was inspected and found to be incompliance with WHO requirements for GCP/GLP.

API manufacturers not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products