Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2013 an application for [HA574 trade name][*] (HA574) to be assessed with the aim of including [HA574 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA574 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

March 2013	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
May 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2013	The company's response letter was received.
November 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2014	The company's response letter was received.
January 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
June 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2014	The company's response letter was received.
September 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
October 2014	The company's response letter was received.
November 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2014	The company's response letter was received.
January 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2015	The company's response letter was received.

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

May 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The company's response letter was received.
July 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2015	Product dossier accepted (quality assurance).
09 September 2015	[HA574 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
P.O. Lodhi Majra
Tehsil Baddi
Distric.: Solan
Himachal Pradesh, 174101
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP/GCP. 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/prequal/medicines/prequalified/finished-pharmaceutical-products