Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceutical Limited submitted in 2011 an application for [HA514 trade name][*] (HA514) to be assessed with the aim of including [HA514 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA514 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 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2011	The applicant's response letters were received.
September 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2011	The applicant's response letters were received.
January 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2012	The applicant's response letters were received.
April 2012	In between the meetings of the assessment team the applicant's response letter was received *(when date of receipt is unknown*). The additional quality data were reviewed and further information was requested.
May 2012	The applicant's response letters were received.
June 2012	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
August 2012	The applicant's response letters were received.
September 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2012	The applicant's response letters were received.
November 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2012	The applicant's response letters were received.

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

January 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2013	The sites relevant for the bioequivalence study were inspected for compliance with
May 2013	The manufacturer of one of the APIs was inspected for compliance with WHO
September 2013	The applicant's response letters were received.
September 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2013	The applicant's response letters were received.
November 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2013	The applicant's response letters were received.
January 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2014	The applicant's response letters were received.
February 2014	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The applicant's response letters were received.
March 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2014	Product dossier accepted (quality assurance)
10 April 2014	[HA514 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

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 and 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