Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2012 an application for [HA562 trade name]* (HA562) to be assessed with the aim of including [HA562 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA562 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

November 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January 2013	The company's response letter was received.
January 2013	During the meeting of the assessment team the 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.
February 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP.
April 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
September 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.
December 2013	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.
January 2014	The company's response letter was received.
March 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP

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

May 2014	Product dossier accepted (quality assurance)
August 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP
17 November 2014	[HA562 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
Phase II & Phase III, 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