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 [HA561 trade name]* (HA561) to be assessed with the aim of including [HA561 trade name] in the list of prequalified medicinal products for the prophylaxis/treatment of HIV/AIDS.

[HA561 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

June 2012	The manufacturer of one the APIs was inspected for compliance with WHO requirements for GMP.
June 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP.
March 2013	The company's response letter was received.
March and May 2013	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2013	The company's response letter was received.

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

Jan 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2013	The manufacturer of one the APIs was inspected for compliance with WHO requirements for GMP.
March 2014	Product dossier accepted (quality assurance)
08 April 2014	[HA561 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 and 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 and GCP/GLP.

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