Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2008 an application for [HA459 trade name]* (HA459) to be assessed with the aim of including [HA459 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA459 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

May 2009	During the meeting of the assessment team the quality data were reviewed and further information was requested
November 2009	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2010	The company's response was received
January 2010	The safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements
February 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
June 2010	The company's response was received
September 2010	During the meeting of the assessment team the quality data were reviewed and further information was requested
January 2011	A manufacturer of the APIs was inspected for compliance with WHO requirements for GMP
March 2011	Additional manufacturer of the APIs was inspected for compliance with WHO requirements for GMP
May 2011	The company's response was received
June 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested
August 2011	The company's response was received
August 2011	Additional manufacturer of the APIs was inspected for compliance with WHO requirements for GMP
September 2011	The quality data were reviewed and found to be in compliance with the relevant WHO requirements
18 October 2011	[HA459 trade name] was included in the list of prequalified medicinal products

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturers and Inspection status

Manufacturers of the finished product and responsible for batch release

Macleods Pharmaceuticals Limited
Plot No. 25–27 Survey No. 366,
Premier Industrial Estate Kachigam,
Daman 396 320
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP. Not inspected for GCP/GLP due to previously demonstrated compliance.

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