Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2011 an application for [HA516 trade name]* (HA516) to be assessed with the aim of including [HA516 trade name] in the list of prequalified medicinal products for HIV/AIDS and hepatitis B.

[HA516 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 company's response letter was received.
September 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. The additional quality data were reviewed and further information was requested
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2012	The company's response letter was received.
September 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2012	The company's response letter was received.
November 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
May 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2013	Product dossier accepted (quality assurance)
23 May 2013	[HA516 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. 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, 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