Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd, submitted in 2011 an application for [HA523 trade name][*] (HA523) to be assessed with the aim of including [HA523 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA523 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

Feb 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Aug 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Nov 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Feb 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 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.
Aug 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2012	The company's response letter was received
Jan 2013	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Feb 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2013	Product dossier accepted (quality assurance)
05 Feb 2013	[HA523 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
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P. O. Lodhi Majra
Tehsil Baddi, Dist. Solan
Himachal Pradesh, India
Tel: +91-01795 661400
Fax: +91-01795 661452

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
Not inspected for GCP. No bioequivalence study was required due to the pharmaceutical formulation.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products