Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2008 an application for [HA424 trade name][*] (HA424) to be assessed with the aim of including [HA424 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA424 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

October 2006	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2008	During the meeting of the assessment team, the quality data of the dossier were reviewed, and further information was requested.
June 2008	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2008	The company's response was received.
September 2008	During the meeting of the assessment team, the quality data were reviewed, and further information was requested.
November 2008	The company's response was received
January 2009	During the meeting of the assessment team, the additional quality data were reviewed, and further information was requested.
March 2009	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2009	During the meeting of the assessment team, the safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
June 2010	The company's response was received.
July 2010	During the meeting of the assessment team, the additional safety and efficacy data were reviewed, and further information was requested.
July 2010	The company's response was received.
February 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2010	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements
14 December 2010	[HA424 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
Sr. No. 366, Premier Industrial Estate
Kachigam
Daman (U.T.) 396 210
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
Not inspected for GCP/GLP since a biowaiver applies.

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