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 [HA526 trade name]* (HA526) to be assessed with the aim of including [HA526 trade name] in the list of prequalified medicinal products for the treatment and prophylaxis of HIV/AIDS.

[HA526 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

February 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2012	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
October 2012	The company's response letter was received.
November 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2013	The company's response letter was received.
January 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.

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

April 2013	The company's response letter was received.
April 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2013	Product dossier accepted (quality assurance)
14 June 2013	[HA526 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

Block: N2, Village Theda

P. O. Lodhi Majra

Tehsil Nalagarh, District 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/GLP. 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/prequal/medicines/prequalified/finished-pharmaceutical-products