STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd 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 the treatment of 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.

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.
Aug 2011	The company's response letters was received.
Sept 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 letters 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 letters was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2012	The company's response letters was received.
Sept 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 letters was received.
Nov 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 letters 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
Block A, Module-IV
Plot No. 2209, GIDC Industrial Estate
At & Post Sarigam
Umbergeon
Valsad 396 155
Gujarat, 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/