STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2011 an application for [HA521 trade name][1] (HA521) to be assessed with the aim of including [HA521 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA521 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

Jan 2011	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Sept 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Oct 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
July 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.
Jan 2013	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2013	The company's response letter was received.
April 2013	In between the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2013	The company's response letter was received.
June 2013	The quality data were reviewed and found to comply with the relevant WHO requirements
June 2013	Product dossier accepted (quality assurance)
14 June 2013	[HA521 trade name] was included in the list of prequalified medicinal products.

[1] 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:

Hetero Labs Limited
Unit III, Block B, # 22-110, I.D.A., Jeedimetla
Qutubullapur Municipality
Hyderabad, Zip Code: 500 055
Andhra Pradesh
INDIA

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP. Not inspected for GCP/GLP due to biowaiver being granted.

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/