Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2009 an application for [HA486 trade name][*] (HA486) to be assessed with the aim of acceptance of [HA486 trade name] for the list of prequalified medicinal products for the treatment and prophylaxis of HIV/AIDS.

[HA486 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 for the assessment of the product

August 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2009	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2010	During the meeting of the assessment team the quality data were reviewed and further information was requested.
August 2010	The company's response letter was received.
September 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2011	The company's response letter was received.
April 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2011	The company's response letter was received.
August 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2011	The company's response letter was received.
September 2011	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2011	Product dossier accepted (quality assurance)
3 November 2011	[HA486 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, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Hetero Labs Limited

Unit – III,# 22 – 110, IDA
Jeedimetla
Hyderabad 500 055
Telangana
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/medicines/prequalified/finished-pharmaceutical-products