Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2013 an application for [HA568 trade name]* (nevirapine 50 mg tablets) to be assessed with the aim of including [HA568 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA568 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 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the quality data and the additional efficacy data were reviewed and further information was requested.
June 2013	The company's response letter was received.
July 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The company's response letter was received.
Jan 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
Jan 2013	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Feb 2014	Product dossier accepted (quality assurance)
19 Feb 2014	[HA568 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 (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Micro Labs Limited
Plot No: S-155 to S-159 & N1, Phase III & IV
Verna Industrial Estate, Verna, Salcette, Goa - 403722
India

Commitments for Prequalification

None which has an impact on the benefit–risk profile of the medicinal product.

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