Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited, India, submitted in 2013 an application for [HA598 trade name] [1] (HA598) to be assessed with the aim of including [HA598 trade name] in the list of prequalified medicinal products for the treatment and prevention of infections in Human Immunodeficiency Virus (HIV)/AIDS patients.

[HA598 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

Sept 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2014	The company's response letter was received.
Oct 2014	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2014	The company's response letter was received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2015	The company's response letter was received.
Jan 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2015	The manufacturer of the APIs were inspected for compliance with WHO requirements for GMP.
May 2015	The company's response letters were received.
May 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2015	Product dossier accepted (quality assurance)
23 May 2016	[HA598 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 (NMRA) responsibility.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Micro Labs Limited
Manufacturing unit: ML-08
15/A, II Phase, Kumbalgodu Industrial Area
Bangalore - 560074
Karnataka
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. Previous inspections by WHO showed acceptable outcome.

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/