Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Arcolab Limited submitted in 2010 an application for [HA494 trade name]* (HA494) to be assessed with the aim of including [HA494 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA494 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

September 2010	During the meeting of the assessment team, safety and efficacy data as well as the quality data of the dossier were reviewed and further information was requested.
October 2010	The company's response letter was received.
November 2010	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
January 2011	The company's response letter was received.
January 2011	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
February 2011	The company's response letter was received.
March 2011	During the meeting of the assessment team, the additional safety, efficacy and quality data were reviewed and further information was requested.
May 2011	The company's response letter was received.
May 2011	During the meeting of the assessment team, the additional safety, efficacy and quality data were reviewed and further information was requested.
June 2011	The additional safety and efficacy data were reviewed and found to comply with the relevant WHO requirements
July 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team, the additional quality data were reviewed and found to comply with the relevant WHO requirements.
November 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
December 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
22 December 2011	[HA494 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.
[1] Formerly strides Arcolab Limited

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Strides Pharma Science Limited
36/7, Suragajakkanahalli
Indlavadi Cross, Anekal Taluk
Bangalore -562106, India
Tel.: 91-80-67840600
Fax: 91-80-67840606

Inspection status

The applicant was inspected and found to be in compliance with WHO requirements for GMP. Not inspected for GLP/GCP. Previous site 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products