Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Shasun Limited submitted in 2012 an application for [HA535 trade name]* (HA535) to be assessed with the aim of including [HA535 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS and hepatitis B.

[HA535 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

Dec 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2012	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. The quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Nov 2012 Jan 2013	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
March 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2013	The company's response letter was received.
Sept 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2013	Product dossier accepted (quality assurance)
21 Oct 2013	[HA535 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.
† Formerly Strides Shasun Limited.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Strides Shasun Limited
Oral solid dosage forms division
Tablet Block
36/7, Suragajakkanahalli,
Indlavadi Cross,
Anekal Taluk,
Bangalore - 560 106, INDIA.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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