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 [HA553 trade name]*, (HA553) to be assessed with the aim of including [HA553 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA553 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

February 2011	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
July 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2012	The applicant's response letter was received.
September 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2013	The applicant'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.
October 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
December 2013	The company's response letter was received.
January 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2014	The applicant's response letter was received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
August 2014	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
August 2014	The applicant's response letter was received.
August 2014	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
September 2014	The applicant's response letter was received.
September 2014	During the meeting of the assessment team the additional quality data were reviewed

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.

ǂ Formerly Strides Shasun Limited

	and further information was requested.
September 2014	The applicant's response letter was received.
November 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2014	Product dossier accepted (quality assurance)
12 December 2014	[HA553 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Strides Shasun Limited
KRS Gardens
Tablet Block
36/7, Suragajakkanahalli
Indlavadi Cross
Anekal Taluk
Bangalore – 562 106
India

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP.

Not inspected for GCP/GLP. 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