I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Shasun Ltd submitted in 2012 an application for [HA552 trade name][1] (HA552) to be assessed with the aim of including Emtricitabine/Tenofovir disoproxil fumarate 200mg/300mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA552 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.

July 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Sept 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements
October 2012	The quality data were reviewed and further information was requested
Jan 2013	The manufacturer of one of the APIs was inspected for compliance with WHO requirement for GMP.
Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP.
Feb 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.
Oct 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2014	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP
Aug 2014	The manufacturer of two of the APIs was inspected for compliance with WHO requirements for GMP
Sept 2014	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP
Oct 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	The quality data were reviewed and found to comply with the relevant WHO requirements
Feb 2015	Product dossier accepted (quality assurance)
18 Feb 2015	[HA552 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. 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

Strides Pharma Science Limited
KRS Gardens, Tablet Block
36/7, Suragajakkanahalli
Indlavadi Cross
Anekal Taluk
Bangalore – 562 106
India
Tel: 91-80-67840600

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, GLP and GCP.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:
http://www.who.int/prequal