STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Arcolab Ltd submitted in 2011 an application for [HA524 trade name] [*] to be assessed with the aim of including [HA524 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA524 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

August 2011	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
August 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2011	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
December 2011	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
January 2012	The company's response letter was received.
January 2012	During the meeting of the assessment team, the quality data and the additional safety and efficacy data were reviewed and further information was requested.
March 2012	The company's response letter was received.
March 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2012	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
May 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
August 2012	The company's response letter was received.
Septemebr 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2012	The company's response letter was received.
January 2013	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
January 2013	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
February 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP.
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.
November 2013	The company's response letter was received.
November 2013	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility

December 2013	The company's response letter was received.
February 2014	The additional quality data were reviewed and further information was requested.
February 2014	The company's response letters were received.
March 2014	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.
April 2014	The additional quality data were reviewed and further information was requested.
April 2014	The company's response letter was received.
April 2014	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
May 2014	The additional quality data were reviewed and further information was requested.
May 2014	The company's response letter was received.
May 2014	The quality data were reviewed and found to comply with the relevant WHO requirements
May 2014	Product dossier accepted (quality assurance)
13 June 2014	Lamivudine/Nevirapine/Zidovudine Tablets, Film Coated, 150mg/200mg/300mg was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release: Strides Arcolab Limited
36/7,
Suragajakkanahalli
Indlavadi cross
Anekal Taluk
Bangalore –
562 106 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, 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/prequal/