STEPS BEFORE PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Arcolab Limited submitted in 2005 an application for Lamivudine/Zidovudine 150 mg/300 mg Tablets[1] (HA291) to be assessed with the aim including Lamivudine/Zidovudine 150 mg/300 mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Lamivudine/Zidovudine 150 mg/300 mg Tablets 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.

Licensing status:
Lamivudine/Zidovudine 150 mg/300 mg Tablets had not been registered in any country at the time of prequalification

2. Steps taken in the evaluation of the product

18 May 2004	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2005	During the meeting of the assessment team, the safety and efficacy data and quality data were reviewed and further information was requested.
April 2005	During the meeting of the assessment team the efficacy data were reviewed and further information was requested.
May 2005	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2005	The company's response letter was received.
May 2005	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
26 May 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2005	The company's response letter was received.
July 2005	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June/August 2005	The company's response letter was received.
September 2005	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2005	The company's response letter was received.
October 2005	During the meeting of the assessment team, the additional efficacy and safety data and quality data were reviewed and further information was requested.

[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.

January 2006	The company's response letter was received.
February 2006	During the meeting of the assessment team, the additional efficacy data were reviewedand further information was requested.
February 2006	The company's response letter was received.
March 2006	The additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
May 2006	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
27 May 2006	The sites relevant for the CRO were inspected for compliance with WHO Requirements for GCP.
30 June 2006	Lamivudine 150mg & Zidovudine 300 mg tablets was accepted to the list of prequalified medicines

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Strides Shasun Limited
36/7, Suragajakknahalli
Indlavadi Cross, Anekal Taluk
Bangalore-562 106
India

Commitments for Prequalification

The Applicant committed to continue long-term stability testing of the batches of the APIs (zidovudine and lamivudine) currently under evaluation for a period of time sufficient to cover the full retest period of 24 months and to report any out-of-specifications results as well as any significant changes immediately to WHO.

The Applicant committed to conduct long-term testing on three production scale batches for a period of time sufficient to cover the full proposed shelf life (NLT 24 months) and to report any out-of-specification results as well as any significant changes immediately to WHO.

Inspection status
The sites inspected were found to be in compliance with WHO requirements for GMP and GLP /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/