STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ranbaxy Laboratories Ltd. submitted in 2005 an application for [HA286 trade name]* (HA 286) to be assessed with the aim for acceptance of [HA286 trade name] to the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

[HA286 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 for the assessment of the product

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/May 2005	The company's response letters were received.
May 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2005	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
June 2005	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2005	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
June 2005	The company's response letters were received.
July 2005	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
July 2005	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
11 Aug 2005	[HA286 trade name] was accepted for the list of prequalified medicines

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Ranbaxy Laboratories Limited
Paonta Sahib
District Sirmour
Himachal Pradesh 173025
India

† Formerly Ranbaxy Laboratories Ltd.
* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Inspection status

The applicant was inspected and 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/