I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ranbaxy Laboratories Ltd. submitted in 2005 an application for Lamivudine and Zidovudine Tablets 150 + 300mg* (HA 286) to be assessed with the aim for acceptance of Lamivudine and Zidovudine Tablets 150 + 300mg to the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

Lamivudine and Zidovudine Tablets 150 + 300 mg 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. The countries of origin for the assessors involved with Lamivudine and Zidovudine Tablets 150mg + 300mg are Canada, Estonia, Ethiopia, Germany, Hungary, Portugal, Spain and Zimbabwe.

Licensing status:
Lamivudine and Zidovudine Tablets 150 + 300 mg has been licensed / registered in the following countries:

S. No.	Country	Registration Number
1	Benin	5835/06
2	Cameroon	D23-495/L/MSP/SG/DPM/SDM/SHPV
3	Congo	J15.30.02/5-186-VC
4	Ethiopia	RAN/IND/002
5	Ivory Coast	0027/MSHP/DGS/DPM/OHC
6	Kenya	14479
7	Malawi	PMPB/PL67/48
8	Nigeria	04-2891.
9	Togo	SP.TG 2133
10	Uganda	4293/06/03
11	Zambia	112/059
12	Zimbabwe	2003/7.13/4130
13	Myanmar	R1204 A 5261
14	Cambodia	583/06
15	Colombia	2005M-0004166
16	Ecuador	26.696-11-05
17	Guatemala	PF-38037-2006
18	Peru	EG 4939
19	Trinidad & Tobago	57580206T
20	Venezuela	EF 32.752
21	Ukraine	UA/8675/01/01
22	Kazakhstan	PK-JIC-No.008784
23	South Africa	A40/20.2.8.254
24	Burkina Faso	C18 04 10/08

* Trade names are not prequalified. Throughout this WHOPAR the proprietary name is given as an example only.

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	Lamivudine and Zidovudine Tablets 150 + 300 mg was accepted for 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:

Ranbaxy Laboratories Limited
Paonta Sahib
District Sirmour
Himachal Pradesh 173025
India

Commitments for prequalification

The Applicant committed to continue long-term testing of the APIs, lamivudine and zidovudine, for a period of time sufficient to cover the whole proposed retest date (NLT 24 months) and to report any out-of-specification results immediately to WHO;

The Applicant committed to long-term testing of the FPP, Lamivudine and Zidovudine Tablets 150+300 mg, for a period of time sufficient to cover the whole proposed shelf life period (NLT 24 months) and to report any out-of-specification results immediately to WHO.

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:
http://www.who.int/prequal