STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in June 2001 an application for [HA060 trade name]* (HA060) to be assessed with the aim for acceptance, in principle, of [HA060 trade name] on the List of Prequalified pharmaceutical products for the treatment of HIV/AIDS.

[HA060 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

June 2001	Quality aspects of the dossier were reviewed and the company was invited to submit further documentation including information related to the synthesis of the APIs and for the FPP specifications of excipients, description of validation procedures. Bioequivalence data was reviewed and further bio-analytical validation data were requested.
September 2001	It was observed that data requested before was in part still outstanding and referred to the upcoming inspection.
October 2001	A GMP inspection took place and the manufacturing unit was found to be in compliance with WHO requirements for GMP for finished pharmaceutical products.
January 2002	Additional documentation was received, however description of the synthesis of the API's was considered incomplete and additional information requested. As to the bioequivalence study additional data on a new study were presented and both the clinical part as well as the bio-analytical method were considered acceptable as were the validation data presented. It was concluded that [HA060 trade name] has demonstrated to be bioequivalent to Combivir®.
April 2002	Additional information received was reviewed. Information on zidovudine was considered satisfactory. For lamivudine further specifications on the synthesis were requested; also results on stability were requested as soon as available.
July 2002	The information received from the sponsor was reviewed and follow up questions raised on the synthesis process of lamivudine; timing of availability of further stability data was also requested.
September 2002	Additional information on in-process control was reviewed and considered acceptable. Results of ongoing stability studies are expected.
January 2003	The received three months stability data was reviewed and a tentative retest period of 2 years could be allocated to lamivudine raw material. The application was accepted with the stipulation that for the FPP when available real time 24 months stability data must be submitted for confirmation of the retest period
5 May 2003	[HA060 trade name] was accepted to the list for prequalified medicines.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Cipla Ltd.,
LBS Marg
Vikhroli, Mumbai 400083
India
Tel : 91 22 25781791
Fax : 91 22 25781140

Inspection status.

The manufacturer was inspected and found to be in compliance with WHO requirements for GMP.

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/