WHO Pre-Qualification Project
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA060 trade name]*

Lamivudine/Zidovudine 150 mg/300 mg film-coated tablets

[HA060 trade name], manufactured at Cipla Ltd, Vikhroli, Mumbai, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 5 May 2003. Due to the outcome of a WHO inspection the product was removed from the list of Prequalified medicines on 27 May 2004. Following submission of new bioequivalence data and re-inspection, [HA060 trade name] was re-listed on 30 November 2004.

[HA060 trade name] is indicated for the treatment of HIV infection in combination with at least one other antiretroviral drug. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of [HA060 trade name] are the nucleoside reverse transcriptase inhibitors (NRTI) lamivudine and zidovudine. Both APIs are marketed either alone or as components of fixed-dose combinations. Each is well established and documented for the treatment of HIV/AIDS in combination with other products.

The efficacy and safety of the combination of lamivudine is well established based on extensive clinical experience in the treatment of HIV infection.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of combination therapy with lamivudine and zidovudine in HIV infection, the team of assessors advised that [HA060 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA060 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of the Prequalification Status for [HA060 trade name]:
The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

	Initial Acceptance		**De-listed**		**Re-listed**	
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	5 May 03	listed	27 May 04	de-listed	30 Nov 04	re-listed
Dossier Evaluation						
Pharmaceutical quality	31 Jan 03	MR				
Bioequivalence	24 Jan 02	MR			23 Nov 04	MR
Safety, Efficacy						
GMP (re-)inspection						
API						
FPP	8 Oct 01	MR				
GCP (re-)inspection			19 May 04	Critical	29 Nov 04	MR
Batch Analysis						

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)

The table represents the status of relevant completed activities only.

Requalification	18 Apr 19	MR

MR: meets requirements