WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA553 trade name]*

Efavirenz/emtricitabine/tenofovir disoproxil fumarate 600 mg/200 mg/300 mg tablets

[HA553 trade name] manufactured at Strides Pharma Science Limited, Bangalore, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 12 December 2014.

[HA553 trade name] is indicated for treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents weighing at least 35 kg.

Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SmPC), which is part of this WHOPAR.

The active pharmaceutical ingredients (APIs) of [HA553 trade name] are the non-nucleoside reverse transcriptase inhibitor efavirenz, the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.

The APIs efavirenz, emtricitabine and tenofovir disoproxil fumarate have been investigated in combination therapy in several clinical trials, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of efavirenz, emtricitabine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV infection.

On the basis of data submitted and public information on the use of efavirenz, emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA553 trade name] is of acceptable quality, efficacy and safety to allow the inclusion of [HA553 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA553 trade name]:

Initial Acceptance	**Date**	**Outcome**
Status on PQ list	**12 December 2014**	**listed**
Quality	28 November 2014	MR
Bioequivalence	08 December 2014	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	16 February 2011	MR
API	19 January 2014	MR
API	19 June 2014	MR
APIs	28 August 2014	MR
API	12 September 2014	MR
FPP	22 October 2013	MR
GLP (re-)inspection	**NA**	**NA**

API: active pharmaceutical ingredient	GMP: good manufacturing practice [quality standard]
FPP: finished pharmaceutical product	MR: meets requirements
GCP: good clinical practice [quality standard]	MR*: desk review (based on recent inspection reports)
GLP: good laboratory practice [quality standard]	NA: not applicable, not available
	PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	03 August 2021	MR