WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA726 trade name]*

Emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg tablets

[HA726 trade name], manufactured at Emcure Pharmaceuticals Limited, Pune, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 April 2020.

[HA726 trade name] is currently indicated for treatment and prophylaxis of human immunodeficiency virus (HIV) and treatment of chronic hepatitis B. 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 of [HA726 trade name] are emtricitabine and tenofovir disoproxil fumarate.

The efficacy and safety of emtricitabine and tenofovir disoproxil fumarate. are well established based on extensive clinical experience in the treatment and prophylaxis of HIV and treatment of chronic hepatitis B.

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 emtricitabine and tenofovir disoproxil fumarate, the team of assessors advised that [HA726 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA726 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA726 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 April 2020	Listed
Pharmaceutical quality	08 April 2020	MR
Bioequivalence	09 April 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 September 2019	MR
API	01 October 2019	MR
FPP	15 February 2019	MR
GCP/GLP (re-)inspection	29 September 2017 23 February 2018	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review

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

GLP: good laboratory practice [quality standard]	(based on recent inspection reports) NA: not applicable, not available PQ: prequalification