WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA713 trade name]*

Dolutegravir (as sodium) /lamivudine/ tenofovir disoproxil fumarate 50 mg/ 300 mg/ 300 mg tablets

[HA713 trade name] manufactured at at Macleods Pharmaceuticals Limited, Mumbai, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 21 May 2020.

[HA713 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. 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 [HA713 trade name] are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety profile of [HA713 trade name] is well established based on extensive clinical experience in the treatment of HIV/AIDS.

On the basis of data submitted and public information on the use of [HA713 trade name] in tuberculosis, the team of assessors advised that HA713 name] is of acceptable quality, efficacy and safety to allow inclusion of [HA713 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA713 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 May 2020	listed
Quality	22 April 2020	MR
Bioequivalence	27 April 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	01 February 2019	MR*
FPP	23 October 2019	MR
GCP/GLP (re-)inspection	14 July 2017	MR
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

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