WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA714 trade name]*

Efavirenz/lamivudine/tenofovir disoproxil fumarate 400mg/300mg/300mg tablets

[HA714 trade name], manufactured at Macleods Pharmaceuticals Limited, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for HIV.

[HA714 trade name] is indicated for treatment of HIV. 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 [HA714 trade name] are efavirenz, lamivudine and tenofovir disoproxil fumarate.

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

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 efavirenz, lamivudine and tenofovir disoproxil fumarate in HIV, the team of assessors advised that [HA714 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA714 trade name] in the list of prequalified medicinal products.

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

Summary of prequalification status for [HA714 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	30 August 2019	listed
Quality	22 July 2019	MR
Bioequivalence	31 July 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	12 August 2016	MR
API	07 September 2017	MR
API	18 January 2019	MR
FPP	31 August 2018	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 NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.