WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA734 trade name]*

dexamethasone phosphate 4 mg/mL solution for injection

[HA734 trade name], manufactured at Farmak JSC, 74 Kyrylivska St., Kyiv, Ukraine, was included in the WHO list of prequalified medicinal products for the management of conditions responsive to parenteral treatment with a potent glucocorticoid on 5 November 2020.

[HA734 trade name] is indicated in a wide range of conditions for its anti-inflammatory and immunosuppressant effects. 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 ingredient of [HA734 trade name] is dexamethasone phosphate, a glucocorticoid.

The efficacy and safety of dexamethasone is well established based on extensive clinical experience in the treatment of a wide range of conditions. 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, the team of assessors advised that [HA734 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA734 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA734 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	5 November 2020	listed
Quality	31 October 2020	MR
Bioequivalence	2 November 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	24 January 2020	MR
GCP/GLP (re-)inspection	NA	NA

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.

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