WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA622 trade name]*

Ceftriaxone (sodium) 1g powder for solution for injection

[HA622 trade name], manufactured at Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd., China, was included in the WHO list of prequalified medicinal products for the treatment of ceftriaxone-susceptible bacterial infections in people with severe or advanced HIV/AIDS disease on 15 August 2016.

[HA622 trade name] is indicated for the treatment of bacterial infections. 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 [HA622 trade name] is the antibacterial agent ceftriaxone.

The efficacy and safety of ceftriaxone is well established based on extensive clinical experience in the treatment of bacterial infections.

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 ceftriaxone in bacterial infections, the team of assessors advised that [HA622 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA622 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA622 trade name]:

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

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 August 2016	Listed
Pharmaceutical quality	05 July 2016	MR
Bioequivalence	13 May 2016	MR
Safety, efficacy	NA	MR
GMP (re-)inspection		
API	NA	MR
FPP	16 October 2015	MR
GCP/GLP (re-)inspection	NA	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

Requalification	28 March 2022