Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd., China submitted in 2014 an application for [HA622 trade name][*](HA622) to be assessed with the aim of including [HA622 trade name] in the list of prequalified medicinal products for the treatment of ceftriaxone-susceptible bacterial infections in people with severe or advanced HIV/AIDS disease.

[HA622 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

2. Steps taken in the evaluation of the product

July 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2014	The company's response letter was received.
July 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2015	The company's response letter was received.
September 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
December 2015	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The company's response letter was received.
May 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2016	Product dossier accepted (quality assurance)
15 August 2016	[HA622 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd.

No. 16, Lanqing Yilu, Hi-Tech Zone

Guanlan, Longhua New District

Shenzhen

China

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

API supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

Not inspected for GCP/GLP. No bioequivalence study was required due to the nature of the pharmaceutical formulation.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products