Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Zhejiang Huahai Pharmaceutical Co., Limited submitted in 2022 an application for [CV016 trade name]* (CV016) to be assessed with the aim of including [CV016 trade name] in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19).

[CV016 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

October 2020	A desk review for evaluation of compliance of the manufacturer of one FPP for GMP was conducted and it met WHO requirements.
November 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
December 2022	The assessment team reviewed the quality data and further information was requested.
January 2023	The applicant's response letters were received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional 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.
March 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.

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

August 2023	The applicant's response letter was received.
August 2023	The additional quality data were reviewed and further information was requested.
August 2023	The applicant's response letter was received.
August 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2023	Product dossier accepted (quality assurance)
December 2023	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
December 2023	A desk review for evaluation of compliance of the manufacturer of one FPP for GMP was conducted and it met WHO requirements.
18 December 2023	[CV016 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Zhejiang Huahai Pharmaceutical Co., Ltd.
Xunqiao Linhai
Zhejiang 317 024
P.R.China

Inspection status

A desk review for evaluation of compliance of the manufacturer of APIs and FPPs for GMP was conducted and it met WHO requirements.

The sites inspected were found to be in compliance with WHO requirements for GLP and GCP.

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