Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sun Pharmaceutical Industries Limited submitted in 2018 an application for [HA708 trade name][*] (HA708) to be assessed with the aim of including [HA708 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA708 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 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May and July 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
October 2018	The applicant's response letter was received.
November 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2019	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2019	The applicant's response letter was received.

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

July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2020	The applicant's response letters were received.
April 2020	The additional quality data were reviewed and further information was requested.
June and July 2020	The applicant's response letters were received.
August 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2020	Product dossier accepted (quality assurance)
18 August 2020	[HA708 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

Sun Pharmaceutical Industries Limited
Village Ganguwala
Paonta Sahib
District Sirmour
Himachal Pradesh
173 025
India

Inspection status

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