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 [HA699 trade name] [*] to be assessed with the aim of including [HA699 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA699 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.
March and April 2018	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July2018	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
August 2018	The applicant's response letters were received.
September 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 additional quality data were reviewed and further information was requested.
November 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 manufacturer of one API was inspected for compliance with WHO requirements for GMP.
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	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
March 2019	The applicant's response letter was received.
April 2019	The additional quality data were reviewed and further information was requested.
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.
August 2019	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
September 2019	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
October 2019	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP

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

	was conducted and it met WHO requirements.
October 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.
November 2019	The applicant's response letter was received.
December 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2019	Product dossier accepted (quality assurance).
17 December 2019	[HA699 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments 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

One active pharmaceutical ingredient manufacturing site and the finished pharmaceutical product manufacturing site were found to be in compliance with WHO requirements for GMP.

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

The sites relevant for the bioequivalence study were inspected for 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products