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 [HA698 trade name][1] (HA698) to be assessed with the aim of including [HA698 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA698 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

Feb 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Oct 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
May 2018	The applicant's response letter was received.
May 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Oct 2018	The applicant's response letter was received.
Nov 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2019	The applicant's response letter was received.
Jan 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Feb 2019	The applicant's response letter was received.
March and May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
May 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2019	Product dossier accepted (quality assurance).
11 June 2019	[HA698 trade name] was included in the list of prequalified medicinal products.

[1] 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

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products