Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Science Limited, Bangalore, Karnataka, India submitted in 2019 an application for [HA729 trade name][*] to be assessed with the aim of including [HA729 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA729 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

September 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
October 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2019	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
March 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.
March and May 2019	During the meetings of the assessment team the quality data were reviewed and further information was requested. The additional efficacy data were reviewed and further information was requested.
June 2019	The applicant's response letter was received.
July 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2019	The applicant's response letter was received.
October 2019	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2019	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2020	The applicant's response letter was received.
April 2020	The additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.

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

May 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2020	Product dossier accepted (quality assurance)
12 June 2020	[HA729 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

Strides Pharma Science Limited,
KRS Gardens Tablet Block,
36/7, Suragajakkanahalli, Indlavadi cross
Anekal Taluk, Bangalore
Karnataka-562 106,
India

Inspection status

API manufacturing sites were found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP met WHO requirements.

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