Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Science Limited submitted in 2019 an application for [HA731 trade name][*] (HA731) to be assessed with the aim of including [HA731 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA731 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

January 2019	The manufacturer of the API 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
March and April 2019	The quality data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.
May 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2019	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
October 2019	The applicant's response letter was received.
November 2019 and January 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2020	The applicant's response letter was received.
August 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2021	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The additional data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September and November 2021	During the meetings of the assessment team additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.

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

November 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2022	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
April 2022	The additional quality data were reviewed and further information was requested.
May 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2022	The applicant's response letter was received.
August 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2022	Product dossier accepted (quality assurance)
23 August 2022	[HA731 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
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Karnataka, 562 106
India
Tel: +91-80-67840600

Inspection status

The API manufacturing site was inspected and found to be in compliance with WHO requirements for GMP.
A desk review for evaluation of compliance of the manufacturer of FPP for GMP was conducted and it met WHO requirements.

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