Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Desano Pharmaceuticals Private Ltd. submitted in 2019 an application for [HA746 trade name][*] (HA746) to be assessed with the aim of including [HA746 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA746 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 APIs was inspected for compliance with WHO requirements for GMP.
September 2019	During the meeting of the assessment team the safety and efficacy 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 safety and efficacy data were reviewed and further information was requested.
September 2019 and January 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
February and March 2020	The applicant's response letters were received.
March 2020	During the meeting of the assessment team the additional safety and efficacy and the additional quality data were reviewed and further information was requested.
April 2020	The applicant's response letters were received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	The applicant's response letter was received.
September 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January and April 2021	The additional quality data were reviewed and further information was requested.

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

May 2021	The applicant's response letter was received.
May and June 2021	The additional quality data were reviewed and further information was requested.
July 2021	The applicant's response letter was received.
July and August 2021	The additional quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
March 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January and June 2022	The additional quality data were reviewed and further information was requested.
August 2022	The applicant's response letter was received.
	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2022	The applicant's response letters were received.
August 2022	Product dossier accepted (quality assurance)
02 September 2022	[HA746 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

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Inspection status

The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

The sites inspected 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