Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company MSN Laboratories Private Limited submitted in 2018 an application for [HA723 trade name][*] (HA723) to be assessed with the aim of including [HA723 trade name] in the list of prequalified medicinal products for treatment of HIV

[HA723 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

November 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional safety and efficacy data and 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.
July 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 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.
November 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.
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.
March 2020	During the meeting of the assessment team 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 2020	Desk reviews for evaluation of compliance of the manufacturer of the API and the FPP for GMP were conducted and they met WHO requirements.
June 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.
September 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 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
September and December 2021	The additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
February 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2022	Product dossier accepted (quality assurance)
01 March 2022	[HA723 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

MSN Laboratories Private Limited
Formulations Division, Unit-II
Survey Nos. 1277, 1319 to 1324
Nandigama (Village & Mandal)
Rangareddy District, Telangana 509228, India

Inspection status

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

Not inspected for GCP/GLP since a biowaiver applies.

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