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 [IN020 trade name]* (IN020) to be assessed with the aim of including [IN020 trade name] in the list of prequalified medicinal products for the treatment of influenza.

[IN020 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

October 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
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.
December 2018 February 2019	The quality data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
March 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2019	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
September and November 2019	During the meetings 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	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
March and May 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

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

June 2020	The applicant's response letter was received.
June 2020	The additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2020	Product dossier accepted (quality assurance)
14 July 2020	[IN020 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

API manufacturer not inspected for GMP. Previous site inspections by WHO were acceptable.

The FPP manufacturer underwent desk review and was found to be in compliance with WHO requirements for GMP.

The CRO (contract research organisation) underwent desk review and was 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/prequal/