Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Emcure Pharmaceuticals Limited submitted in 2018 an application for [HA726 trade name]* (HA726) to be assessed with the aim of including [HA726 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA726 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 manufacturers of one API were inspected for compliance with WHO requirements for GMP.
September 2017 and February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 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	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.
August 2019	The applicant's response letter was received.
October 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 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.
April 2020	The applicant's response letter was received.
April 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2020	Product dossier accepted (quality assurance).

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

21 April 2020	[HA726 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

Emcure Pharmaceuticals Limited
Plot No. P-1 & P-2, ITBT Park
Phase II, MIDC, Hinjwadi, Pune
Maharashtra
411057
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

A desk review for evaluation of GMP compliance of one of the API manufacturers met WHO requirements.

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/