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 [HA722 trade name][*] (HA722) to be assessed with the aim of including [HA722 trade name] in the list of prequalified medicinal products for treatment of HIV/AIDS.

[HA722 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 two APIs were inspected for compliance with WHO requirements for GMP.
November 2018	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.
March 2019	The applicant's response letter was received.
March + April 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
June 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	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met 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	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.
February 2020	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.

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 additional quality data were reviewed and further information was requested.
July 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
January 2021	The applicant's response letters were received.
January 2021	Due to concerns regarding GCP compliance a new bioequivalence study was submitted. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
February 2021	The additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
February 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2021	Product dossier accepted (quality assurance)
22 February 2021	[HA722 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. P1 & P2, I.T.B.T. Park Phase II,
MIDC, Hinjawadi, Pune,
Maharashtra – 411057
India

Inspection status

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