Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company, Emcure Pharmaceuticals Ltd submitted in 2022 an application for [CV010 trade name]* (CV010) to be assessed with the aim of including [CV010 trade name] in the list of prequalified medicinal products for treating mild or moderate COVID-19 in adults who do not require supplemental oxygen but who are at risk of their disease becoming severe.

[CV010 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

February 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2020	A desk review for evaluation of compliance of one manufacturer of the API for GMP was conducted and it met WHO requirements.
March 2022	A desk review for evaluation of compliance of one manufacturer of the API for GMP was conducted and it met WHO requirements.
April 2022	The assessment team reviewed the quality data and further information was requested.
May 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2022	The applicant's response letter was received.
May 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2022	The applicant's response letter was received.
June 2022	The assessment team reviewed the additional quality data and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
October 2022	The assessment team reviewed the additional quality data and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

November 2022	Product dossier accepted (quality assurance)
December 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
26 December 2022	[CV010 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 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/medicines/prequalified/finished-pharmaceutical-products