Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Celltrion Inc. submitted in 2019 an application for [HA752 trade name]* (HA752) to be assessed with the aim of including [HA752 trade name] in the list of prequalified medicinal products for treatment of HIV/AIDS.

[HA752 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

January 2019	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
January 2020	During the meeting of the assessment team the safety and efficacy 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 safety and efficacy data were reviewed and further information was requested.
January and March 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
May 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2020	The applicant's response letter was received.
September and October 2020	The additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
November and December 2020	The additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2021	The applicant's response letter was received.
June 2021	The additional quality data were reviewed and further information was requested.
July 2021	The applicant's response letter was received.
August 2021	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.

October 2021	The additional quality data were reviewed and further information was requested.
February 2022	The applicant's response letter was received.
March 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
April 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional quality data were reviewed 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.
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.
December 2022	The applicant's response letter was received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
April 2023	The additional quality data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
June 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
June2023	Product dossier accepted (quality assurance)
27 June 2023	[HA752 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

Celltrion Pharm Inc.
82, 2 Sandan-ro, Ochang-eup
Cheongwon-gu, Cheongju-si
Chungcheongbuk-do, 28117
Republic of Korea

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products