Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Celltrion Inc. submitted in 2017 an application for [TB351 trade name][*] (TB351) to be assessed with the aim of including [TB351 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB351 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

Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2017	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
Aug 2017	The applicant's response letter was received.
Sept 2017	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
July 2017 and Oct 2017	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
Dec 2017	The applicant's response letters were received.
Jan 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2018	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
March 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
May 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
July 2018	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Sept 2018	The applicant's response letter was received.
Sept 2018 and Jan 2019	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
Jan 2019	The applicant's response letters were received.
Jan 2019	The quality data were reviewed and found to comply with the relevant WHO requirements
Jan 2019	Product dossier accepted (quality assurance).
6 Feb 2019	[TB351 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture 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

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

Not inspected for GCP/GLP since a biowaiver applies.

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