STEPS TAKEN BEFORE PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Getz Pharma (Pvt) Limited submitted in 2015 an application for [TB311 trade name] * (TB311) to be assessed with the aim of including [TB311 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.
[TB311 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

May 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2015	The applicant's response letter was received.
July 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
May and August 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Aug 2015	The applicant's response letter was received.
Sept and October 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2015	The applicant's response letter was received.
January 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The applicant's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The applicant's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2017	The applicant's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2017	The applicant's response letter was received.
August 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The applicant's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The applicant's response letter was received.
May and June 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2018	The applicant's response letters were received.
July 2018	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.

December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
February 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2019	Product dossier accepted (quality assurance)
22 February 2019	[TB311 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Getz Pharma (Pvt) Limited
29-30/27, Korangi Industrial Area
Karachi-74900
Pakistan

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP.

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