Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Beximco Pharmaceuticals Limited submitted in 2016 an application for [HA668 trade name]* (HA668) to be assessed with the aim of including [HA668 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA668 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 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June and Aug 2016	The quality data were reviewed and further information was requested.
Jan and Feb 2017	The company's response letters were received.
Feb 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2017	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
April 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Sept and Oct 2017	The company's response letters were received.
Oct 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Nov 2017	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
Dec 2017	The company's response letter was received.
Jan 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan and July 2018	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
Sept 2018	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
Dec 2018	The company's response letter was received.
Dec 2018	The additional quality data were reviewed and further information was requested.
Dec 2018	The company's response letter was received.
Dec 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.

Jan 2019	Product dossier accepted (quality assurance)
21 Jan 2019	[HA668 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

Beximco Pharmaceuticals Limited
OSD Unit, Track II
126 Kathadia, Auchpara
Tongi 1711
Gazipur
Bangladesh

Inspection status

The finished product manufacturing site and the bioequivalence study site were found to be in compliance with WHO requirements for GMP, GLP and GCP.

Inspection of the API manufacturers waived based on risk assessment.

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