Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Anhui Biochem Bio-Pharmaceutical Co., Ltd submitted in 2015 an application for [HA656 trade name]* (HA656) to be assessed with the aim of including [HA656 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA656 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 for the assessment of the product

July 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July and Sept 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Nov 2015 and Jan 2016	The company's response letters were received.
Jan 2016	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
March 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
May and July 2016	The company's response letters were received.
July 2016	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
Aug 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Aug 2016	The company's response letter was received.
Sept 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2016	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.
Jan 2017	The company's response letter was received.
Jan 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2017	The company's response letter was received.
March 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2017	The company's response letter was received.
Nov 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2017	The company's response letter was received.
July 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Aug 2018	The company's response letter was received.

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

Aug 2018	The additional quality data were reviewed and further information was requested.
Oct 2018	The company's response letter was received.
Nov 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2018	The company's response letter was received.
Nov 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2018	Product dossier accepted (quality assurance)
18 Dec 2018	[HA656 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:
Anhui Biochem Bio-Pharmaceutical Co., Ltd
OSD workshop, 2nd floor of the Building 2,
No. 30 Hongfeng Road, Hi-Tech Development Zone, Hefei City,
Anhui Province, 230088
People's Republic of China

Inspection status
The sites inspected were found to be compliant with WHO requirements for GMP, GCP and GLP.

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