Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-Pharmaceutical Co., Ltd. submitted in 2015 an application for [HA658 trade name][1] (HA658) to be assessed with the aim of including [HA658 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA658 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

Jan 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sep 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sep and Nov 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Mar 2016	The company's response letters were received.
Mar 2016	During the meeting of the assessment team the additional quality and additional efficacy data were reviewed and further information was requested.
Apr 2016	The company's response letters were received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jun 2016	The company's response letter was received.
Jul 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jul 2016	The company's response letter was received.
Sep 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sep 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Nov 2017	The company's response letter was received.
Nov 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2017	Product dossier accepted (quality assurance)
12 Dec 2017	[HA658 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Shanghai Desano Bio-Pharmaceutical Co., Ltd.

1479 Zhangheng Road

China (Shanghai) Pilot Free Trade Zone

Shanghai 201203

P.R. China

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