Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company The Government Pharmaceutical Organization submitted in 2016 an application for [HA681 trade name]* (HA681) to be assessed with the aim of including [HA681 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA681 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

July 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
December 2016	The company's response letter was received.
November 2016 and January 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2017	The company's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	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.
June 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
December 2017	The company's response letter was received.
January + June 2018	The additional quality data were reviewed and further information was requested.
July 2018	The company's response letter was received.
July 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2018	Product dossier accepted (quality assurance)
15 August 2018	[HA681 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. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant 1
138 Moo 4, Rangsit-Nakhonnayok Road
Bueng Sanan
Thanyaburi
Pathumthani 12110
Thailand

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