Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2014 an application for [HA627 trade name][1] (HA627) to be assessed with the aim of including [HA627 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA627 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 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jul 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Jul and Sep 2014	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Oct 2014	The company's response letter was received.
Nov 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Mar 2015	The company's response letter was received.
May 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jul 2015	The company's response letter was received.
Jul 2015	During the meeting of the assessment team the additional 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 quality data were reviewed and further information was requested.
Feb 2016	The company's response letter was received.
Mar 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Mar 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
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.
Sep 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.
Nov 2016	The company's response letter was received.

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

Nov 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2016	Product dossier accepted (quality assurance)
21 Dec 2016	[HA627 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

Cipla Limited
Unit –II, A-42, MIDC
Patalganga: 410220
District: Raigad, Maharashtra,
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP/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