Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Limited submitted in 2008 an application for [HA444 trade name]* (HA444) to be assessed with the aim of including [HA444 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA444 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

September 2008	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
November 2008	During the meeting of the assessment team, the additional safety and efficacy data as well as the quality data were reviewed and further information was requested.
December 2008	The company's response letters were received.
January 2009	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
May 2009	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
July 2009	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
August 2009	The manufacture of the FPP was inspected for compliance with WHO requirements for GMP.
June 2010	The company's response letters were received.
July 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
August 2010	The company's response letters were received.
September 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
September 2010	The company's response letters were received.
October 2010	The additional safety and efficacy data as well as the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
25 October 2010	[HA444 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

Matrix Laboratories Limited
F-4, F-12, Malegaon M.I.D.C,
Sinnar, Nashik – 422113,
Maharashtra state, India
Tel.: +91 40 2348 0042

Inspection status

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

One of the API manufacturers was not inspected for GMP due to previous inspections (by a stringent regulatory authority) with acceptable outcome**.**

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