Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Ltd submitted in 2007 an application for [HA417 trade name]* (HA417) to be assessed with the aim of including [HA417 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA417 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

Sept 2007	During the meeting of the assessment team, the safety, efficacy and quality data were reviewed and further information was requested.
Nov 2007	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
Feb 2008	The company's response letter was received.
March 2008	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
July 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
July 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Aug 2008	The company's response letter was received.
Sept 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Oct 2008	The company's response letter was received.
Nov 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Jan 2009	The company's response letter was received.
Jan 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
May 2009	The manufacturer of one of the APIs was inspected for compliance with WHO requirement for GMP.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
† Formerly Matrix Laboratories Limited.

May 2009	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
Aug 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Oct 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
July 2010	During the meeting of the assessment team the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
Aug 2010	During the meeting of the assessment team the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
20 Aug 2010	[HA417 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

Matrix Laboratories Limited

F-4, F-12, Malegaon M.I.D.C

Sinnar

Nashik 422113

Maharashtra

India

Inspection status

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

One of the API manufacturers not inspected for GMP by WHO. Previous site inspections (by stringent regulatory authority) showed 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/