Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Lab. Ltd submitted in 2006 an application for [HA392 trade name]* (HA392) to be assessed with the aim of acceptance of [HA392 trade name] for the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

[HA392 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

17 October 2006	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2007	During the meeting of the assessment team, safety and efficacy aspects of the dossier were reviewed and further information was requested.
April 2007	The company's response letter was received.
May 2007	During the meeting of the assessment team, safety and efficacy aspects of the dossier were reviewed and further information was requested.
26 July 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2007	During the meeting of the assessment team, safety and efficacy aspects of the dossier were reviewed and further information was requested. The quality aspects of the dossier were also reviewed and further information was requested.
July 2007	The company's response letter was received.
September 2007	During the meeting of the assessment team the additional data concerning safety and efficacy aspects was reviewed and found to be in compliance with the relevant WHO requirements.
December 2007	The company's response letter was received.
January 2008	During the meeting of the assessment team the additional data on the quality aspects of the dossier were reviewed and further information was requested.
January 2008	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
February 2008	The company's response letter was received.
March 2008	During the meeting of the assessment team the additional data concerning quality aspects was reviewed and found to be in compliance with the relevant WHO requirements.
23 April 2008	[HA392 trade name] was accepted for the list of prequalified medicines.

*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 – 422103,
Maharashtra state
India

Inspection status

The applicant was inspected and found to be in compliance with WHO requirements for GMP 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/prequal/medicines/prequalified/finished-pharmaceutical-products