Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Limited submitted in 2007 an application for [HA410 trade name]* (HA410) to be assessed with the aim of including [HA410 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS and hepatitis B.

[HA410 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 2007	During the meeting of the assessment team, the safety, efficacy and quality data were reviewed and further information was requested.
August 2007	The company's response letter were received.
September 2007	During the meeting of the assessment team the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
January 2008	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
June 2008	The company's response letter was received.
June 2008	The manufacturer of the API was inspected for compliance with WHO requirements for GMP
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.
February 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
April 2009	The company's response letter was received.
May 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
June 2009	The company's response letter was received.
July 2009	During the meeting of the assessment team the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements
August 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP
27 October 2009	[HA410 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
India

Inspection status

The sites inspected were 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