STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Limited submitted in 2008 an application for [HA433 trade name][*] to be assessed with the aim of including [HA433 trade name] for the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA433 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.[HA433 trade name]

2. Steps taken for the assessment of the product

May 2005	Two API manufacturers were inspected for compliance with WHO requirements for GMP.
October 2006	One API manufacturer was inspected for compliance with WHO requirements for GMP.
June 2008	One API manufacturer was inspected for compliance with WHO requirements for GMP.
July 2008	During the meeting of the assessment team, safety, efficacy and quality aspects of the dossier were reviewed and further information was requested.
June 2008	The company's response letter on the safety/efficacy issues was received.
July 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2008	During the meeting of the assessment team, the safety and efficacy aspects of the dossier were reviewed and found to be in compliance with the relevant WHO requirements.
November 2008	The company's response letter on the quality issues was received.
January 2009	During the meeting of the assessment team, quality aspects of the dossier were reviewed and further information was requested.
March 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team, quality aspects of the dossier 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 data concerning quality aspects were reviewed and found to be in compliance with the relevant WHO requirements.
July 2009	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
26 October 2009	[HA433 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.

[1] Formerly Matrix Laboratories Ltd

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments 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

Commitments for Prequalification

The manufacturer committed to continue long-term testing for a period of time sufficient to cover the full provisional shelf life of 24 months and to report any out-of-specification results or significant changes immediately to WHO.

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:

www.who.int/prequal/