STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Ltd submitted in 2008 an application for [HA426 trade name][*] to be assessed with the aim of acceptance of [HA426 trade name] for the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

[HA426 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 for the assessment of the product

May 2005	One API manufacturer was inspected for compliance with WHO requirements for GMP.
March 2008	During the meeting of the assessment team, safety and efficacy aspects of the dossier were reviewed and further information was requested.
October 2006	One API manufacturer was inspected for compliance with WHO requirements for GMP.
April 2008	The company's response letter was received.
May 2008	During the meeting of the assessment team the additional data concerning safety and efficacy aspects was reviewed found to be in compliance with the relevant WHO requirements.
June 2008	One API manufacturer was inspected for compliance with WHO requirements for GMP.
July/Sept 2008	During the meeting of the assessment team, quality aspects of the dossier were reviewed and further information was requested.
July 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2008	The company's response letter was received.
November/January 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.
24 February 2009	[HA426 trade name] was accepted for the list of prequalified medicines.

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[*] 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
India

Commitments for Prequalification
The applicant committed to conduct long-term stability testing on production scale batches at the high end of the proposed production range, according to agreed protocols.

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP. Not inspected for GCP due to previously demonstrated compliance.

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/