I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Matrix Laboratories Ltd submitted in 2007 an application for Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets* (HA414) to be assessed with the aim of including Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets 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. The countries of origin of the assessors involved with Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets were Canada, Ethiopia, France, Germany, Netherlands, South Africa, Uganda, Ukraine, United Kingdom and Zambia.

Licensing status:
Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets has been licensed / registered in the following countries:

Sl. No.	Country	Registration No.
1	USA	#22-141 (Tentatively Approved)
2	Zambia	014/002 (Approved)
3	Malawi	PMPB/PL354/13 (Approved)
4	Uganda	6030/06/07 (Approved)
5	Tanzania	TAN 08, 010 J05A MAT (Approved)
6	Kenya	19112 (Approved)
7	Nigeria	A4-3126 (Approved)
8	Namibia	10/20.2.8/0038 (Approved)
9	Ethiopia	MAT/IND/015 (Approved)
10	Burkina Faso	G 08 02 11/07 (Approved)
11	Ghana	FDB/GD.083-6022 (Approved)
12	Mali	09-1392/MS-SG (Approved)
13	Senegal	5218 (Approved)
14	Botswana	BOT 0901522 (Approved)
15	Trinidad & Tobago	65820608T (Approved)
16	Honduras	M-16918 (Approved)
17	Guatemala	PF-43942 (Approved)

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

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.
September 2007	During the meeting of the assessment team, the additional efficacy and 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.
April 2008	The company's response letter was received.
May 2008	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
June 2008	The company's response letter was received.
July 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Nov 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.
April 2009	The company's response letter was received.
May 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
May 2009	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2009	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
Aug 2009	The company's response letter was received.
Aug 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sept 2009	During the meeting of the assessment team the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
Oct 2009	The company's response letter was received.
Nov 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Jan 2010	The company's response letter was received.
Jan 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
March 2010	The company's response letter was received.
May 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.
30 June 2010	Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300mg Tablets was included in the list of prequalified medicinal products.

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 continue long-term stability testing on the current three production batches for a period of time sufficient to cover the shelf life (24 months); any out-of-specification results should immediately be reported to WHO.

The Applicant committed that the first three production scale batches larger than the currently approved production scale will be placed on stability as per the approved stability protocol in addition to other requirements of a scale-up variation.

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/

[†] Mylan Laboratories Limited is the new name where Matrix formerly the manufacturer name at time of prequalification