I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd submitted in 2008 an application for Ritonavir Tablets 100 mg* (HA467) to be assessed with the aim of including Ritonavir Tablets 100 mg for the list of prequalified medicinal products for the treatment of HIV/AIDS.

Ritonavir Tablets 100 mg 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 for the assessors involved with Ritonavir Tablets 100 mg were Canada, China, Ghana, Saudi Arabia and Zambia.

Licensing status:

Ritonavir Tablets 100 mg has been licensed / registered in the following countries:

Country Name	Registration Number
MALAWI	PMPB/PL354/24 (Approved)
UGANDA	7413/30/11(Approved)
ZIMBABWE	2011/7.13/4674 (Approved)
PANAMA	78931 (Approved)

2. Steps taken for the assessment of the product

January 2008	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
June 2008	The API manufacturer was inspected for compliance with WHO requirements for GMP.
April 2009	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
August 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2009	CRO site inspected and found to be in compliance with WHO requirements for GCP and GLP
August 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2010	The data concerning quality aspects were reviewed and found to be in compliance with the relevant WHO requirements.
December 2010	During the meeting of the assessment team data concerning bioequivalence were reviewed and found to be in compliance with WHO requirements.
14 Dec 2010	Ritonavir Tablets 100 mg was added to the list of prequalified medicines.

* 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.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Mylan Laboratories Limited
R&D Centre, Plot No. 34-A,
Anrich Industrial Estate
Bollaram, Jinnaram Mandal,
Medak District - 502325
Andhra Pradesh, India

Commitments for Prequalification

None.

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:

www.who.int/prequal/