I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd submitted in 2014 an application for Ritonavir 25 mg Tablets [*] (HA621) to be assessed with the aim of including Ritonavir 25 mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Ritonavir 25 mg 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 for the assessors involved with Ritonavir 25 mg Tablets were Germany, Netherlands, Nigeria, Rwanda, South Africa, Spain, Switzerland, Tanzania and Uganda.

Licensing status:
Ritonavir 25 mg Tablets has been licensed / registered in the following countries:
None

2. Steps taken for the assessment of the product

May 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept. 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan2015	The company's response letter was received.
Jan 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2015	The company's response letters were received.
May 2015	T During the meeting of the assessment team the additional quality data were reviewed an further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2015	The company's response letter was received.
Sept 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2015	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Dec 2015	Product dossier accepted (quality assurance)
16 Dec 2015	Ritonavir 25 mg Tablets 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. 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
F-4 & F-12, Malegaon MIDC, Sinnar
Nashik-422 113
Maharashtra State, India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The applicant was inspected and found to be in compliance with WHO requirements for GMP**.**
Not inspected for GCP and GLP. Previous site inspections by WHO showed acceptable outcome.

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