I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2014 an application for Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets [1] (HA632) to be assessed with the aim of including Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets me in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Atazanavir (as sulfate)/Ritonavir 300 mg/100 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 of the assessors involved with Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets were Canada, Ethiopia, Germany, Kenya, Nigeria, the Philippines, South Africa, Spain, Switzerland, Tanzania and Uganda.

Licensing status:
Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg Tablets has been licensed/registered in the following countries: None

2. Steps taken in the evaluation of the product

May 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2014	During the meeting of the assessment team the safety and efficacy data and the quality data was reviewed and further information was requested.
Nov 2014	The company's response letter was received.
Nov 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2015	The company's response letter was received.
July 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2016	The company's response letter was received.
Nov 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2017	The company's response letter was received.
March 2017	Product dossier accepted (quality assurance)

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

21 April 2017	Atazanavir (as sulfate)/Ritonavir 300 mg/100 mg 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:
Cipla Limited
Unit –II, A-42, MIDC
Patalganga: 410220
District: Raigad, Maharashtra
India

Commitments for Prequalification:
None which has an impact on the benefit–risk profile of the medicinal product.

Inspection status:
The sites inspected were found to be in compliance with WHO requirements for GMP, GLP/GCP.

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/