I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd, India, submitted in 2017 an application for ANCOTIL 500 mg tablet[1] (HA693) to be assessed with the aim of including ANCOTIL 500 mg tablet in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

ANCOTIL 500 mg tablet 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 marketing application holder changed to VIATRIS MEDICAL in 2024

2. Steps taken in the evaluation of the product

August 2017	The quality data were reviewed and further information was requested.
November 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The company's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.
March 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
14 March 2018	ANCOTIL 500 mg tablet was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products

[1] 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