I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited. submitted in 2022 an application for Ritonavir Tablet USP, 100 mg[1] (HA778) to be assessed with the aim of including Ritonavir Tablet USP, 100 mg in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Ritonavir Tablet USP, 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.

2. Steps taken in the evaluation of the product

September 2022	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2022	The company's response letter was received.
September 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
04 October 2022	Ritonavir Tablet USP, 100 mg was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/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