I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company ViiV Healthcare Pty Ltd submitted in 2023 an application for APRETUDE prolonged-release suspension for injection.[1] (HA789) to be assessed with the aim of including APRETUDE in the list of prequalified medicinal products for the management of HIV/AIDS.

APRETUDE prolonged-release suspension for injection 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 and October 2023	The assessment team reviewed the quality data and further information was requested.
November 2023	The company's response letter was received.
November and December 2023	The additional quality data were reviewed and further information was requested.
December 2023	The company's response letter was received.
December 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
22 December 2023	APRETUDE prolonged-release suspension for injection.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