I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Abbott Laboratories Ltd. submitted in 2006 an application for Kaletra[1] (Lopinavir/Ritonavir 200mg/50mg tablets), (HA381) to be assessed with the aim of including Kaletra in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Kaletra 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. Based on the data submitted the team of assessors advised that Kaletra is included in the list of prequalified medicinal products. Kaletra was listed on 30 Oct 2006.

Kaletra's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

The name of the supplier was changed to "AbbVie Ltd" in 2012, to AbbVie Deutschland GmbH Co. KG in 2018.

2. Steps taken in the re-evaluation of the product

December 2015	WHO letter of request for requalification was sent to the applicant.
February 2016	The application letter was received.
April 2016	The submitted data were reviewed and further information was requested.
June 2016	The company's response letter was received.
December 2016	The submitted data were reviewed and further information was requested.
March 2018	The company's response letter was received.
April 2018	The submitted data were reviewed and found to comply with the relevant WHO requirements.
04 April 2018	Requirements of requalification were met. Kaletra remained on the list of prequalified medicinal products.

* Formerly: AbbVie Ltd, UK

[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.