I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Abbott Laboratories Ltd. submitted in 2001 an application for Kaletra[1] (HA098) 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 20 March 2002.

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.

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 assessment team reviewed the submitted data and further information was requested
June 2016	The applicant's response letter was received.
December 2016	The submitted data were reviewed and found to comply with the relevant WHO requirements.
05 December 2016	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 (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.