I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Abbott Laboratories Ltd. submitted in 2001 an application for Kaletra (80 mg + 20 mg) / ml oral solution [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 (80 mg + 20 mg) / ml oral solution was listed on 20 March 2002.

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

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

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

August 2024	WHO letter of request for requalification was sent to the applicant.
October 2024	The application letter was received.
November 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
12 November 2024	Requirements of requalification were met. Kaletra (80 mg + 20 mg) / ml oral solution remained on the list of prequalified medicinal 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.