

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Abbott submitted in 2010 an application for Norvir 100 mg film-coated tablets¹ (HA491) to be assessed with the aim of including Norvir in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Norvir 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 Norvir is included in the list of prequalified medicinal products. Norvir 100 mg film-coated tablets was listed on 1 June 2010.

Norvir ‘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 and to “AbbVie Deutschland GmbH Co .KG“ in 2018.

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.
19 November 2024	Requirements of requalification were met. Norvir 100 mg film-coated tablets 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.