I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Abbott submitted in 2010 an application for Norvir (Ritonavir 100mg tablets)[1] (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 was listed on 01 June 2010.

Norvir's conformance to the requirements of the current SRA guideline[2] was re-evaluated 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.

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

Licensing status:
Norvir has been licensed / registered in the European Union.

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

Dec 2015	WHO letter of request for requalification was sent to the applicant.
Feb 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.
Dec 2016	The submitted data were reviewed and found to comply with the relevant WHO requirements.
05 Dec 2016	Requirements of requalification were met. Norvir remained on the list of prequalified medicinal products.

[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.

[2] "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"