I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Glaxo Wellcome Operations, Middlesex, United Kingdom, submitted in 2001 an application for Retrovir 100 mg/10 ml oral solution[1] (HA114) to be assessed with the aim of including Retrovir in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Retrovir 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 Retrovir is included in the list of prequalified medicinal products. Retrovir was listed on 20 March 2002.

Retrovir'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 "ViiV Healthcare UK Limited" in 2011.

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

December 2015	WHO letter of request for requalification was sent to the applicant.
June 2016	The application letter was received.
December 2016	The assessment team reviewed the submitted data and further information was requested.
December 2017	The applicant's response letter was received.
July 2018	The assessment team reviewed the submitted data and further information was requested
August 2018	The applicant's response letter was received.
October 2018	The assessment team reviewed the submitted data and further information was requested
December 2018	The applicant's response letter was received.
January 2019	The submitted data were reviewed and found to comply with the relevant WHO requirements.
05 March 2019	Requirements of requalification were met. Retrovir 100 mg/10 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.