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 250 mg capsules, hard[1] (HA109) 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 29 May 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 2019	The application letter was received.
July 2019	The assessment team reviewed tFhe submitted data and further information was requested
August 2019	The applicant's response letter was received.
August 2020	The submitted data were reviewed and found to comply with the relevant WHO requirements.
26 August 2020	Requirements of requalification were met. Retrovir 250 mg capsules, hard 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.