I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company GlaxoSmithKline Research & Development Limited, submitted in 2001 an application for Retrovir 10mg/ml concentrate for solution for infusion [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.
April 2016	The application letter was received.
June 2016	The assessment team reviewed the submitted data and further information was requested
February 2017	The applicant's response letter was received.
April 2017	The assessment team reviewed the submitted data and further information was requested
July 2017	The applicant's response letter was received.
November 2017	The assessment team reviewed the submitted data and further information was requested
November and December 2017	The applicant's response letters were received.
Jan 2018	The submitted data were reviewed and found to comply with the relevant WHO requirements.
19 Jan 2018	Requirements of requalification were met. Retrovir 10 mg/ml IV concentrate for solution for infusion 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.