I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Glaxo Wellcome Operations submitted in 2001 an application for Combivir 150mg/300mg film-coated tablets[1] (HA110) to be assessed with the aim of including Combivir in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Combivir 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 Combivir is included in the list of prequalified medicinal products. Combivir was listed on 18 March 2002.

Combivir 150 mg/300 mg film-coated tablets'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 2012 and to "ViiV Healthcare B.V"in 2019.

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.
December 2016	The submitted data were reviewed and further information was requested.
May 2017	The application letter was received.
November 2017	The submitted data were reviewed and found to comply with the relevant WHO requirements.
27 November 2017	Requirements of requalification were met. Combivir 150 mg/300 mg film-coated tablets remained on the list of prequalified medicinal products.

*Formerly ViiV Healthcare UK Ltd, UK

[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.