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 Combivir 150 mg/300 mg 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 150 mg/300 mg film-coated tablets was listed on 20 March 2002

Transfer of Marketing Authorisation took place in 2010.
The name of the supplier changed from "ViiV Healthcare UK Limited" and to ViiV Healthcare BV in 2021.

Combivir's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

August 2024	WHO letter of request for requalification was sent to the applicant.
September 2024	The application letter was received.
November 2024	The assessment team reviewed the submitted data and further information was requested.
January 2025	The applicant's response letter was received.
February 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
24 February 2025	Requirements of requalification were met. Combivir 150 mg/300 mg film-coated tablets remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products

https://www.ema.europa.eu/en/medicines/human/EPAR/combivir
EMEA/H/C/000190

[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.