# 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 150mg/300 mg film-coated tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Combivir 150 mg/300 mg film-coated tablets 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 150 mg/300 mg film-coated tablets is included in the list of prequalified medicinal products. Combivir 150 mg/300 mg film-coated tablets was listed on 18 March 2002.

Combivir 150 mg/300 mg film-coated tablets's conformance to the requirements of the current SRA guideline[2] was re-evaluated by the team of WHO assessors.

The name of the supplier was changed to "ViiV Healthcare UK Limited" in 2012.

**Licensing status:**
Combivir 150 mg/300 mg film-coated tablets has been licensed / registered in the European Union.

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

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| Dec 2015 | WHO letter of request for requalification was sent to the applicant. |
| April 2016 | The application letter was received. |
| Dec 2016 | The submitted data were reviewed and further information was requested. |
| May 2017 | The application letter was received. |
| Nov 2017 | The submitted data were reviewed and found to comply with the relevant WHO requirements. |
| 27 Nov 2017 | Requirements of requalification were met.<br>Combivir 150 mg/300 mg film-coated tablets remained on the list of prequalified medicinal products. |

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"