I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company GlaxoSmithKline Research & Development Limited submitted in 2001 an application for Epivir 10 mg/ml oral solution [1] (HA128) to be assessed with the aim of including Epivir 10 mg/ml oral solution in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Epivir 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 Epivir is included in the list of prequalified medicinal products. Epivir 10 mg/ml oral solution was listed on 20 March 2002.

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

The Marketing Authorization was transferred in 2010 to "ViiV Healthcare UK Limited" and to ViiV Healthcare BV in 2018.

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
December 2024	The applicant's response letter was received.
Februaryl2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
25 February 2025	Requirements of requalification were met. Epivir 10 mg/ml oral solution 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

Epivir | European Medicines Agency (europa.eu)

[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