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 10 mg/ml oral solution 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.

Epivir 10 mg/ml oral solution '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 and to ViiV Healthcare BV, 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.
March 2018	The application letter was received.
July 2018	The assessment team reviewed the submitted data and further information was requested
August 2018	The applicant's response letter was received.
October 2018	The assessment team reviewed the submitted data and further information was requested.
November 2018	The applicant's response letter was received.
December 2018	The submitted data were reviewed and found to comply with the relevant WHO requirements.
14 December 2018	Requirements of requalification were met. Epivir 10 mg/ml oral solution remained on the list of prequalified medicinal products.

Further information is available at:

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

Epivir | European Medicines Agency (europa.eu)

* 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