I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2018 an application for SYMFI LO[1] (HA721) to be assessed with the aim of including SYMFI LO in the list of prequalified medicinal products for the treatment of HIV/AIDS.

SYMFI LO 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 SYMFI LO is included in the list of prequalified medicinal products. SYMFI LO was listed on 31 October 2018.

SYMFI LO '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.
November 2024	The application letter was received.
January 2025	The assessment team reviewed the submitted data and further information was requested
April 2025	The applicant's response letter was received.
June 2025	The assessment team reviewed the submitted data and further information was requested
July 2025	The applicant's response letter was received.
July 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
29 July 2025	Requirements of requalification were met. SYMFI LO 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

[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.