I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited India 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.

Licensing status:
SYMFI LO has been licensed / registered in the United States of Amerika.

2. Steps taken in the evaluation of the product

Oct 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
31 Oct 2018	SYMFI LO was included in 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