I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Gilead Sciences Ireland UC submitted in 2018 an application for Epclusa [1] (HP024) to be assessed with the aim of including Epclusa in the list of prequalified medicinal products for the treatment of chronic hepatitis C infection.

Epclusa 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.

2. Steps taken in the evaluation of the product

November 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
December 2018	The company's response letter was received.
January 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
06 February 2019	Epclusa was included in 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

https://www.ema.europa.eu/en/medicines/human/EPAR/epclusa
EMEA/H/C/004210

[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