# 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.

Based on the data submitted the team of assessors advised that Epclusa is included in the list of prequalified medicinal products.

Epclusa 400 mg/100 mg film-coated tablets was listed on 06 February 2019.

Epclusa '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

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| August 2024 | WHO letter of request for requalification was sent to the applicant. |
| November 2024 | The application letter was received. |
| November 2024 | The submitted data were reviewed and found to comply with the relevant WHO requirements. |
| 25 November 2024 | Requirements of requalification were met.<br>Epclusa 400 mg/100 mg film-coated tablets 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

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