Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Gilead Sciences Ireland Unlimited Company submitted in 2025 an application for Lenacapavir Gilead 300 mg film-coated tablets[1] (HA810) to be assessed with the aim of including Lenacapavir Gilead in the list of prequalified medicinal products for the management of HIV/AIDS.

Lenacapavir Gilead 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

August 2025	The assessment team reviewed the submitted data and further information was requested.
September 2025	The company's response letter was received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The company's response letter was received.
September 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
06 October 2025	Lenacapavir Gilead 300 mg film-coated tablets 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/opinion-medicine-use-outside-EU/human/lenacapavir-gilead EMEA/H/W/006659

[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