I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Gilead Sciences Ireland UC submitted in 2022 an application for Veklury [1] (CV011) to be assessed with the aim of acceptance of Veklury for the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19).

WHO's recommended use (as per the WHO Therapeutics and COVID-19 living guideline[2]) is for patients with non-severe COVID-19 at highest risk of hospitalization. Patients at highest risk of hospitalization would be e.g., older people, or those with immunodeficiencies and/or chronic diseases, further enhanced by lacking vaccination.

Veklury 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 for the assessment of the product

April 2022	The submitted data were reviewed and found to comply with the relevant WHO requirements.
25 April 2022	Veklury was included in the list for prequalified medicines.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:
https://www.ema.europa.eu/en/medicines/human/EPAR/veklury

[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.

[2] Therapeutics and COVID-19: Living guideline, 10 November 2023