

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Pfizer Limited submitted in 2022 an application for Paxlovid 150 mg/100 mg film-coated tablets¹ (CV007) to be assessed with the aim of including Paxlovid 150 mg/100 mg film-coated tablets in the list of prequalified medicinal products for the treatment of Coronavirus disease 2019 (Covid-19)

Paxlovid 150 mg/100 mg film-coated tablets 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

February 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
22 April 2022	Paxlovid 150 mg/100 mg film-coated tablets was included in the list of prequalified medicinal products.

Further information is available at:

<https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products>

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