I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company ViiV Healthcare BV submitted in 2021 an application for Tivicay 5 mg dispersible tablets[1] (HA768) to be assessed with the aim of acceptance of Tivicay 5 mg dispersible tablets for the list of prequalified medicinal products for the treatment and management of HIV/AIDS.

Tivicay 5 mg dispersible 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 for the assessment of the product

May 2021	During the meeting of the assessment team the submitted data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
June 2021	The submitted data were reviewed and found to comply with the relevant WHO requirements.
01 July 2021	Tivicay 5 mg dispersible tablets 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/tivicay

[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.