I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company ViiV Healthcare UK Limited submitted in 2014 an application for Tivicay 50mg film-coated tablets [1] (HA634) to be assessed with the aim of including Tivicay 50mg film-coated tablets in the list of prequalified medicinal products for the treatment and management of HIV/AIDS.

Tivicay 50mg 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.

The marketing authorisation holder changed to Viiv Healthcare BV, The Netherlands in 2018.

2. Steps taken in the evaluation of the product

October 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
14 October 2014	Tivicay 50mg film-coated tablets was included in the list of prequalified medicinal products.

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

* Formerly ViiV Healthcare UK Limited