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 50 mg film-coated tablets in the list of prequalified medicinal products for the treatment and management of HIV/AIDS.

Tivicay 50 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.

Based on the data submitted the team of assessors advised that Tivicay 50 mg film-coated tablets is included in the list of prequalified medicinal products. Tivicay 50 mg film-coated tablets was listed on 14 October 2014.

Tivicay 50 mg film-coated tablets conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

2. Steps taken in the re-evaluation of the product

January 2024	WHO letter of request for requalification was sent to the applicant.
April 2024	The application letter was received.
June 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
04 July 2024	Requirements of requalification were met. Tivicay 50 mg film-coated tablets remained on the list of prequalified medicinal products.

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