WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Tivicay 50 mg film-coated tablets [1]

Dolutegravir (as sodium) 50 mg film-coated tablets

Tivicay 50 mg film-coated tablets was submitted in 2014 by ViiV Healthcare UK Limited to be considered for prequalification and subsequently accepted for the WHO list of prequalified medicinal products for the treatment and management of HIV/AIDS on 14 October 2014.
Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/ha634

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm) is based on the approval by the European Medicines Agency (EMA: https://www.ema.europa.eu/en/medicines), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Team: Medicines (PQTm).

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant4.
Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Do not store above 30°C.
- The shelf-life at this storage condition is 36 months.

***** Formerly ViiV Healthcare UK Limited

[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] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

Based on the above, the WHOPAR for Tivicay 50 mg film-coated tablets refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference**[5]
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/assessment-report/tivicay-epar-public-assessm eport_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/en/documents/product-information/tivicay-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/tivicay-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/tivicay-epar-product-nformation_en.pdf
Part 6	Discussion	Tivicay-H-2753-AR-en (europa.eu)
Part 8	Steps taken following Authorization	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/002753500171906.pdf

Parts 2 and 7 of Tivicay 50 mg film-coated tablets are included here.

Tivicay contains dolutegravir (as sodium). Its WHO recommended use is for the treatment and management of HIV/AIDS.

Summary of Prequalification Status for Tivicay 50 mg film-coated tablets:

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	14 October 2014	listed	04 July 2024	listed
Dossier Evaluation	October 2014	MR	June 2024	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.

[5] https://www.ema.europa.eu/en/medicines/human/EPAR/tivicay EMEA/H/C/002753