WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Tivicay 5 mg dispersible tablets [1]

Dolutegravir (as sodium) 5 mg dispersible tablets

Tivicay 5 mg dispersible tablets was submitted in 2021 by ViiV Healthcare BV to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 01 July 2021.
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/ha768

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: http://www.ema.europa.eu/ema/), 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 Applicant[4].

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. Store the tablets in the original package to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.

- The shelf-life at this storage condition is 36 months.

[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 5 mg dispersible 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	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/002753/WC500160681.pdf
Part 3	Package Leaflets	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002753/WC500160680.pdf
Part 4	Summaries Product Characteristics	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002753/WC500160680.pdf
Part 5	Labelling	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002753/WC500160680.pdf
Part 6	Discussion	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002753/WC500160683.pdf
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/002753/WC500171906.pdf

Parts 2 and 7 of Tivicay 5 mg dispersible 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 5 mg dispersible tablets:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 July 2021	listed
Dossier Evaluation	June 2021	MR
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