Tivicay

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type II /	This was an application for a variation	16/10/2025		SmPC and PL	Section 4.8 of the SmPC was updated to reflect

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000249653	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.8 of the SmPC in order to add 'sideroblastic anaemia' to the list of adverse drug reactions (ADRs) with frequency 'very rare', based on post-marketing data. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to include information about placental transfer for Triumeq and Dovato following the outcome of procedure EMEA/H/C/WS2620, to introduce minor editorial and formatting changes to the PI, and to update the list of local representatives in the Package Leaflet.				"sideroblastic anemia" with frequency "unknown" of dolutegravir (Tivicay) and its combinations (Triumeq, Juluca, Dovato). Additionally, a footnote was added to table 4.8, informing about cases of sideroblastic anemia with dolutegravir containing regimens. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000278110	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing	04/09/2025	N/A		To update the RMP with the latest available post-authorisation exposure data and to include the 2024 Antiretroviral Pregnancy Registry data. To update the submission date for the final CSR for category 3 PASS study DOLOMITE-NEAT ID (208759)from 30 September 2025 to 30 September 2026 for Tivicay,

	authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted To update the RMP with the latest available post-authorisation exposure data and to include the 2024 Antiretroviral Pregnancy Registry data. To update the submission date for the final CSR for category 3 PASS study DOLOMITE-NEAT ID (208759)from 30 September 2025 to 30 September 2026 for Tivicay, Triumeq and Juluca.				Triumeq and Juluca.
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