



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Genvoya

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 group of	15/01/2026	N/A		

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/0000308403	variations. C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted				
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	A grouped application consisting of three Type II variations, as follows: C.I.11 for RMP: Submission of an updated RMP version 6.1 in order to propose the removal of the Important Identified Risk of 'Suicidal ideation/suicide attempt in patients with a preexisting history of depression or psychiatric illness' C.I.11 for RMP: Submission of an updated RMP version 6.1 in order to propose the removal of the Important Identified Risk of 'Concurrent use of drugs whose coadministration with Genvoya is contraindicated'. C.I.11 for RMP: Submission of an updated RMP version 6.1 in order to propose the removal of the following Missing Information: 'Safety in patients with cardiac conduction disorders'.				
Variation type IA / EMA/VR/0000284417	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A.5 Change in the name and/or address of a	02/09/2025	N/A		

	manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
PSUR / EMA/PSUR/0000248490	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing cobicistat / elvitegravir / emtricitabine / tenofovir alafenamide remains unchanged and therefore recommends the maintenance of the marketing authorisation.