Padcev

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
PSUR / EMA/PSUR/0000257872	- -	24/07/2025	17/09/2025	SmPC and PL	Variation

[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).

	In view of available data on pneumonia from clinical trials and from spontaneous reports including in some cases a close temporal relationship and a positive de-challenge the PRAC considers a causal relationship between enfortumab vedotin and pneumonia is at least a reasonable possibility. The PRAC concluded that the product information of products containing enfortumab vedotin should be amended accordingly. In view of available data on thrombocytopenia from clinical trials and from spontaneous reports including in some cases a close temporal relationship and a positive de-challenge the PRAC considers a causal relationship between enfortumab vedotin and thrombocytopenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing enfortumab vedotin should be amended accordingly.				
Variation type IB / EMA/VR/0000256819	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.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z - To update NI-PASS (7465-PV-0002) category 3 study milestone from 'Q4	05/06/2025	N/A		

	2024' to 'Q3 2025' after receipt of the CHMP conclusion for protocol amendment EMEA/H/C/005392/MEA/003.2. Furthermore, some minor editorial corrections are included.				
Variation type IB / EMA/VR/0000265102	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation - Accepted	13/05/2025	N/A		
Variation type IB / EMA/VR/0000248972	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted	03/03/2025	N/A		