Piasky

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 IB /	This was an application for a group of	17/10/2025		SmPC, Annex	

[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/0000296137	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.z Other RMP changes (e.g. agreed wording + template change) - 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.z Other obligations and conditions (e.g. agreed wording + QRD template) - Accepted C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Other variation - Accepted C.I.11.z To update the Annex II of Piasky 340mg/2ml solution for injection/infusion to remove the Controlled Access Program. This change has been requested (and the wording was agreed) by the PRAC in the PRAC recommendation for the PSUSA			II and PL	

	(PSUSA/00011071/202502) Piasky. The English wording was agreed by the PRAC but the translations were not reviewed. C.I.11.z To update the RMP of Piasky 340mg/2ml solution for injection/infusion to version 2.0 to remove the Controlled Access Program. The summary of changes have been agreed by the PRAC in the PRAC recommendation, for the PSUSA (PSUSA/00011071/202502). C.I.3.z To update Section 4.4 of the SmPC to include a statement on the educational materials (including annual reminders) addressed to healthcare professionals which clearly and succinctly explains the purpose and scope of the materials in order to comply with the EMA Guideline on the SmPC and Guideline on good pharmacovigilance practices (GVP) – Module XVI – Risk minimisation measures (Rev 3) (EMA/204715/2012 Rev 3 of 26 July 2024). Section 2 of the package leaflet is updated accordingly.				
Variation type IB / EMA/VR/0000262158	B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted	25/04/2025		SmPC, Labelling and PL	
PSUR / EMA/PSUR/0000268996	- -				Maintenance
