Kapruvia

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
PSUSA/10995 /202308	Periodic Safety Update EU Single assessment - difelikefalin	07/03/2024	n/a		PRAC Recommendation - maintenance
IA/0006	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or	27/02/2024	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).

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
PSUSA/10995 /202302	Periodic Safety Update EU Single assessment - difelikefalin	28/09/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10995 /202208	Periodic Safety Update EU Single assessment - difelikefalin	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/09/2022	n/a		
IB/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/07/2022	17/07/2023	SmPC, Annex II, Labelling and PL	To implement editorial changes in sections 4.8, 5.1 and 5.2 of the SmPC, annex II and section 3 of the PL.