



## Palforzia

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/09/2022		PL	
PSUSA/10902 /202201	Periodic Safety Update EU Single assessment - defatted powder of arachis hypogaea l., semen (peanuts)	01/09/2022	n/a		PRAC Recommendation - maintenance

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



IB/0009	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	18/08/2022		SmPC	
IB/0010	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	03/08/2022	n/a		
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/05/2022	08/07/2022	Labelling and PL	
PSUSA/10902 /202107	Periodic Safety Update EU Single assessment - defatted powder of arachis hypogaea l., semen (peanuts)	10/03/2022	n/a		PRAC Recommendation - maintenance
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/10/2021	08/07/2022	PL	
II/0004/G	This was an application for a group of variations.  B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	02/09/2021	n/a		

	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
PSUSA/10902 /202101	Periodic Safety Update EU Single assessment - defatted powder of arachis hypogaea l., semen (peanuts)	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0003/G	This was an application for a group of variations.  C.z - Safety, Efficacy, Pharmacovigilance changes - Other variation A.6 - Administrative change - Change in ATC Code/ATC Vet Code	06/07/2021	08/07/2022	SmPC, Labelling and PL	
IB/0001	B.II.e.z - Change in container closure system of the Finished Product - Other variation	26/03/2021	n/a		