Palforzia

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
II/0014/G	This was an application for a group of variations. C.I.6.a (Extension of indication): Extension of indication to include treatment of patients 1 to 3 years old for PALFORZIA, based on final results from study ARC005; this is a Phase 3 randomised, double-blind, placebo-controlled Peanut Oral Immunotherapy Study of Early Intervention for	14/11/2024	19/12/2024	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Palforzia-H-C-004917-II-0014-G'.

[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).

	Desensitisation (POSEIDON) to evaluate the safety and efficacy of peanut powder in terms of superiority of placebo in children of 1 year to less than 4 years of age with peanut allergy. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.7, 4.8, 5.1, 6.5 and 8 of the SmPC are updated. The Package Leaflet and Labelling were updated accordingly. Version 1.2 of the RMP has also been updated. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes to the SmPC and to update the list of local representatives in the Package Leaflet. As part of the application the MAH is requesting a 1-year extension of the market protection. B.II.e.5.a: Introduction of a new pack-size of 16 capsules of 1 mg (Level 0) in blisters for PALFORZIA, 1 mg, oral powder in capsules for opening. Due to the lack of a suitable pack-size for the up-dosing phase for patients 1 to 3 years old, a new pack size Level 0 for the up-dosing phase will be introduced. Consequently modules 3.2.P.1 and 3.2.P.7 were updated. Labeling was updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update module 3.2.P.3.1 to take out the EU importation site (editorial change). The group of variations leads to amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) -				

	Addition of a new therapeutic indication or modification of an approved one B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
T/0017	Transfer of Marketing Authorisation	29/07/2024	06/09/2024	SmPC, Labelling and PL	
PSUSA/10902 /202401	Periodic Safety Update EU Single assessment - defatted powder of arachis hypogaea l., semen (peanuts)	05/09/2024	n/a		PRAC Recommendation - maintenance
IB/0016/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	28/08/2024	n/a		
PSUSA/10902 /202301	Periodic Safety Update EU Single assessment - defatted powder of arachis hypogaea l., semen (peanuts)	31/08/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10902 /202207	Periodic Safety Update EU Single assessment - defatted powder of arachis hypogaea l., semen	16/03/2023	n/a		PRAC Recommendation - maintenance

	(peanuts)				
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/09/2022	03/08/2023	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
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	03/08/2023	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	02/09/2021	n/a		

	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 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		