# Palforzia

## 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 |
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| Variation type IA_IN / EMA/VR/0000313034 | This was an application for a group of variations. | 19/11/2025 | 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).

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| | B.II.a.1 Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - B.II.a.1.a Changes in imprints, bossing or other markings - Accepted<br><br>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted<br><br>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted | | | | |
| Renewal - 5 year / EMA/R/0000264359 | - Renewal - | 18/09/2025 | 05/12/2025 | SmPC, Labelling and PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Palforzia in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| EMA/PSUR/0000268968 | Periodic Safety Update EU Single assessment Defatted powder of Arachis hypogaea L., semen (peanuts) | 04/09/2025 | N/A | | Maintenance |
| Variation type II / EMA/VR/0000256580 | C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet | 05/06/2025 | 05/12/2025 | SmPC | In clinical studies, 15 out of 1 319 subjects, aged 1 to 17 years, were diagnosed with biopsy-confirmed |

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| | 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.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted<br><br>Update of section 4.8 of the SmPC in order update the description of Eosinophilic esophagitis cases occurring in Palforzia clinical trials following CHMP request in EMEA/H/C/004917/P46/011 concerning report from study ARC008. The RMP version 1.3 has also been submitted. In addition, the MAH took the opportunity to bring minor updates to the SmPC following the PEI linguistic review. | | | | eosinophilic oesophagitis while receiving PALFORZIA compared with 0 of 409 subjects receiving placebo. After discontinuation of PALFORZIA, symptomatic improvement was reported in 11 of 15 subjects. In 7 subjects with available follow-up biopsy results, eosinophilic oesophagitis was resolved in 4 subjects and improved in 3 subjects. All events were diagnosed in subjects aged 4 – 17 years. For more information, please refer to the Summary of Product Characteristics. |
| Variation type IB / EMA/VR/0000248252 | This was an application for a group of variations.<br><br>B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted<br><br>B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of | 24/02/2025 | N/A | | |

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| | specification limits - Accepted | | | | |
| Variation type IA_IN / EMA/VR/0000244051 | B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted | 10/01/2025 | 05/12/2025 | Annex II and PL | |