15 October 2020
EMA/CHMP/498161/2020
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Palforzia

defatted powder of *Arachis hypogaea L., semen* (peanuts).

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Palforzia, intended for desensitising children and adolescents to peanut allergy.

The applicant for this medicinal product is Aimmune Therapeutics Ireland Limited.

Palforzia will be available as an oral powder in capsules for opening (0.5, 1, 10, 20 and 100 mg) and oral powder in sachet (300 mg). The active substance of Palforzia is defatted powder of *Arachis hypogaea* L., semen (peanuts), an allergen that is given in increasing amounts to patients with peanut allergy to teach the immune system to tolerate small amount of peanuts. The powder is taken orally after mixing with an age-appropriate soft food.

The benefit of Palforzia is its ability to achieve desensitisation, meaning that a single dose of a least 1 gram of peanut protein would cause no more than mild allergy symptoms. The most common side effects are abdominal pain, throat irritation, pruritus, nausea, vomiting, urticaria, oral pruritus and upper abdominal discomfort.

The full indication is:

> Palforzia is indicated for the treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. Palforzia may be continued in patients 18 years of age and older.
>
> Palforzia should be used in conjunction with a peanut-avoidant diet.

This medicine should be administered under the supervision of a healthcare professional qualified in the diagnosis and treatment of allergic diseases.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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