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Brendan Griffin, T.D.
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20th November 2024

PQ: 44435/24

To ask the Minister for Health further to Parliamentary Question No. 752 of 22 October 2024, when the HSE will meet the manufacturer to reconsider the possible approval of the reimbursement of palforzia for the treatment of peanut allergy; and if he will make a statement on the matter. -Brendan Griffin

Dear Deputy Griffin,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 44435/24), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(1) The health needs of the public,
(2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,

(3) The availability and suitability of items for supply or reimbursement,
(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and
(9) The resources available to the HSE

In terms of the specific details of the application for pricing and reimbursement of Defatted powder of Arachis hypogaea L., semen (peanuts) (Palforzia®) 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):

The HSE received a complete application for pricing / reimbursement on the 30th March 2022 from Aimmune Therapeutics (the applicant) for Defatted powder of Arachis hypogaea L., semen (peanuts) (Palforzia®) 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).

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 1st April 2022.

- The NCPE Rapid Review assessment report was received by the HSE on the 5th May 2022. The NCPE advised the HSE that a full HTA was recommended to assess the clinical effectiveness and cost effectiveness of Defatted powder of Arachis hypogaea L., semen (peanuts) (Palforzia®) compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment on the 26th May 2022 as per agreed processes.

- The NCPE Health Technology Assessment Report was received by the HSE on the 29th November 2023. The NCPE recommended that Defatted powder of Arachis hypogaea L., semen (peanuts) (Palforzia®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments. (https://www.ncpe.ie/defatted-powder-of-arachis-hypogaea-l-semen-peanuts-palforzia-hta-id-22019/)

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. CPU met with the applicant to discuss their application for Arachis hypogaea L., semen (peanuts) (Palforzia®).

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. The HSE Drugs Group consider all of the evidence and make a recommendation to the HSE Senior Leadership Team. The totality of clinical and economic

evidence for Defatted powder of Arachis hypogaea L., semen (peanuts) (Palforzia®) for the treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy was comprehensively and extensively reviewed by the Drugs Group at the September 2024 meeting. The HSE Drugs Group recommended in favour of reimbursement of Arachis hypogaea L., semen (peanuts) (Palforzia®) subject to an improved commercial offering.

- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

The application remains under consideration. The HSE CPU proposed a meeting with the applicant to discuss the HSE Drugs Group recommendation. The applicant communicated to the HSE CPU in October 2024 that they wished for the application for Palforzia® to be paused until the end of 2025. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie