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Paul Lawless, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

22nd July 2025

PQ: 37441/25
To ask the Minister for Health if she is aware of the drug "ryeqo" to treat endometriosis; if she will be willing to consider adding it to the list of reimbursable items for medical card holders; and if she will make a statement on the matter. -Paul Lawless

Dear Deputy Lawless,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 37441/25), 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 applications for pricing and reimbursement of relugolix / estradiol / norethisterone acetate (Ryeqo®):

Uterine fibroids:

The HSE received an application for pricing and reimbursement on the 12th November 2021 from Gedeon Richter (the applicant) for relugolix / estradiol / norethisterone acetate (Ryeqo®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

- 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 16th November 2021.
- The NCPE Rapid Review assessment report was received by the HSE on the 3rd February 2022. The NCPE advised the HSE that a full Health Technology Assessment (HTA) is not recommended. The NCPE recommends that relugolix CT not be considered for reimbursement at the submitted price. https://www.ncpe.ie/relugolix-with-estradiol-and-norethisterone-acetate-ryeqo-hta-id-21055/ .
- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. The CPU have met with the applicant to discuss their application.
- 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 considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team. The totality of clinical and economic evidence for relugolix / estradiol / norethisterone acetate (Ryeqo®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age was comprehensively and extensively reviewed by the Drugs Group at the November 2022 meeting. The Drugs Group unanimously did not recommend in favour of reimbursement of relugolix / estradiol / norethisterone acetate (Ryeqo®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age on the basis of the available clinical evidence and the price premium relative to alternative pharmacological treatment options. https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-november-2022.pdf .
- 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 HSE Senior Leadership Team supported the Drugs Group recommendation not to reimburse

relugolix / estradiol / norethisterone acetate (Ryeqo®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

The application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing assessment processes. In line with the Health (Pricing and Supply of Medical Goods) Act 2013, the next step in the process involves the HSE providing formal written notice of the HSE Senior Leadership Team's proposed decision, together with the reasons for the relevant decision to the applicant. The applicant will then be afforded the opportunity to make representations on the proposed decision. The HSE cannot comment on potential outcomes pending the notice of proposal and representation process.

Endometriosis:

The HSE received an application for pricing and reimbursement on the 24th May 2024 from Gedeon Richter (the applicant) for relugolix / estradiol / norethisterone acetate (Ryeqo®) indicated in adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.

- 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 28th May 2024.
- The NCPE Rapid Review assessment report was received by the HSE on the 15th July 2024. The NCPE advised the HSE that a full HTA is recommended to assess the clinical effectiveness and cost effectiveness of relugolix CT compared with the current standard of care.
- The HSE commissioned a full HTA on the 31st July 2024 as per agreed processes.

- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessments of relugolix / estradiol / norethisterone acetate (Ryeqo®) for endometriosis are available at: https://www.ncpe.ie/relugolix-with-estradiol-and-norethisterone-acetate-ryeqo-hta-id-24018/

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications.
- 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. Pharmacoeconomic reports are reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team.

- 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 with the HSE. 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