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Seán Crowe, T.D.  
Dáil Éireann,  
Leinster House,  
Kildare Street,  
Dublin 2.

5<sup>th</sup> March 2025

PQ: 6471/25

**To ask the Minister for Health if the drug vamorolone is currently being considered for approved use by the HSE. -Seán Crowe**

Dear Deputy Crowe,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 6471/25), which you submitted to the Minister for Health for response.

There is a National Application, Assessment & Decision Process for new medicines which is underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE must comply with the relevant legislation when considering investment decisions around new medicines. 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

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 any commercial negotiations with applicants, 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.

Pharmaceutical companies are required to submit formal applications to the HSE if they wish for their medicines to be added to the list of reimbursable items / funded via hospitals. The decision of pharmaceutical companies to market licensed medicines i.e. whether or not to submit a formal application, is outside the control of the HSE.

**In terms of the specific details of an application for pricing and reimbursement of vamorolone (Agamree®):**

As of the 5<sup>th</sup> March 2025, no pricing and reimbursement application has been received by the HSE for vamorolone (Agamree®).

As outlined above, the national assessment and decision process cannot commence in the absence of a pricing and reimbursement application submission.

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](mailto:Oireachtas.pcrs@hse.ie)