



David Cullinane, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

10th March, 2021

PQ: 9415/21

To ask the Minister for Health the drugs under consideration for approval on pricing and reimbursement of medicines under the community drugs scheme by the HSE in tabular form; the stage in the approval process and current and pending decision of each; and if he will make a statement on the matter. -David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 9415/21), which you submitted to the Minister for Health for response.

There is a national decision process for new medicines and new uses of existing medicines which is underpinned by primary legislation (Health (Pricing and Supply of Medical Goods) Act 2013). The HSE must comply with the relevant legislation when considering investment decisions around new medicines. HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

The HSE Drugs Group is a national committee and it is tasked with providing a recommendation to the HSE Executive Management Team (EMT) in relation to the pricing and reimbursement of new medicines and it considers all the criteria in the Health (Pricing and Reimbursement of Medical Goods) Act 2013.

- The Drugs Group considers the health technology assessment (HTA), the outputs from commercial negotiation, as well as a range of other information in advance of providing its advice to the EMT. Minutes from meetings up until January 2021 are now publically available <https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/>
- Legally, the EMT are required to consider all the criteria under the Health Act 2013 which are
 - a. *The health needs of the public,*

- b. *The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,*
- c. *The availability and suitability of items for supply or reimbursement,*
- d. *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,*
- e. *The potential or actual budget impact of the item or listed item,*
- f. *The clinical need for the item or listed item,*
- g. *The appropriate level of clinical supervision required in relation to the item to ensure patient safety,*
- h. *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*
- i. *The resources available to the HSE*

Final decision making is reserved to the HSE EMT. All positive recommendations from the February 2021 Drugs Group meeting have been progressed by the HSE Executive Management Team (EMT) to a final decision. There are no outstanding applications with the HSE EMT for a decision as of the 10th March 2021.

Information on reimbursement for medicines included under the community drug schemes is available from the PCRS website. An update on the reimbursement list is published towards the end of each month and will include relevant changes including new additions for reimbursement under the schemes. For a new addition (i.e. approval) to be included on this update the applicant must have liaised with the Data Admin unit of the PCRS to confirm the launch of the product which must be in line with the effective reimbursement date. This is a positive reimbursement list. The update is accessible on the PCRS website:

<https://www.hse.ie/eng/staff/pcrs/online-services/>
<https://www.sspcrs.ie/libr/html/monthlyproductupdate.pdf>

The HSE has approved 21 applications for funding from the 2021 NSP (National Service Plan) allocation of €50m for new drugs or new indications of existing drugs as of the 10th of March 2021.

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & 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