



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

20th July 2022

PQ: 35333/22

To ask the Minister for Health the number of new medicines added to the reimbursement scheme from 2016 to 2021 and to date in 2022 broken down by year and the cost for each new medicine; 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 35333/22), 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.

Information on reimbursement of medicines included under the Community Drug Schemes and under High Tech Drug Arrangements is published each month on the Primary Care Reimbursement Service (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 PCRS to confirm the launch of the product. The update and reimbursement list, along with the Reimbursement Price of each listed item is maintained on the PCRS website:

<https://www.hse.ie/eng/staff/pcrs/online-services/>

<https://www.sspcrs.ie/libr/html/monthlyproductupdate.pdf>

In addition to the above published sources, the HSE has collated additional information specifically in relation to years 2019, 2020, 2021 and 2022 YTD and that information (55 pages) is provided by attachment. As this information was only collated from 2019 onwards in this format a further Excel with high level information that details applications for new medicines or new uses of medicines approved over 2016-18 has also been attached.

Due to conditions of commercial confidentiality placed on the HSE by pharmaceutical companies (when negotiating improved commercial terms) the HSE cannot provide details at individual medicine level of the net additional cost of the addition of medicines to the reimbursement lists. The HSE cannot provide details on the costs associated with the extension in use of certain drugs to new indications (new uses) as the HSE does not collate diagnostic information on its reimbursement systems.

The HSE does provide the gross amounts reimbursed in relation to the top 100 medicines reimbursed under the community drug scheme and hospital reimbursement arrangements. The HSE historically published this information in its annual reports. The HSE maintains this information on the open data section of the PCRS website.

<https://www.sspcrs.ie/analytics/saw.dll?PortalPages>

The HSE PCRS is currently double checking and proof reading its Annual Report for 2021. The 2021 report will be published in the coming weeks.

<https://www.sspcrs.ie/portal/annual-reporting/report/annual>

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service