



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

7th December 2021

PQ: 57505/21

To ask the Minister for Health the way the €30 million announced in Budget 2022 for new drugs will be allocated; the sub-allocation to measures within this new measures grouping in tabular form; the amount remaining unallocated; the amount which relates to other new measures funding group commitments; if this is included as a whole or pro-rata; 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 57505/21), 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 Corporate Pharmaceutical Unit (CPU) is the unit within the HSE that is responsible for accepting and considering pricing and reimbursement applications from the pharmaceutical industry.

Pharmaceutical companies are required to submit formal applications if they wish their medicines to be added to the list of reimbursable items / funded via hospitals. This process first involves a company making an application and submitting a clinical and economic dossier to support its pricing and reimbursement application. That dossier is reviewed by experts at the National Centre for Pharmacoeconomics (NCPE). The NCPE then provides a report to the HSE in relation to the company dossier. The NCPE process also enables the provision of a Patient Interest Group Submission. The NCPE uses a decision framework to systematically assess whether a

drug is cost-effective as a health intervention. The NCPE makes recommendations on reimbursement to assist HSE decisions.

The HSE must then consider the report and the pricing & reimbursement application from the company. Frequently the HSE Corporate Pharmaceutical Unit will engage with companies to discuss and explore solutions to issues raised in NCPE reports.

The HSE has a national committee, the HSE Drugs Group, which is set up to provide advice to the HSE Executive Management Team (EMT) arising out of the information included in the NCPE report, the company response, patient interest group submission and any commercial discussions. The responsibility of the Drugs Group is to make a recommendation in relation to each individual application having considered the criteria set down by the Oireachtas in relation to pricing and reimbursement of new medicines.

The HSE must consider the following criteria prior to making any decision on funding / reimbursement:

- (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

Final Decision making is reserved to the HSE Executive Management Team (EMT).

The €30m in the budget 2022 for new medicines has initially been allocated to the Primary Care Reimbursement Service (PCRS) and it will be allocated during 2022 on the basis of each new medicine or new use of an existing medicine approved by the HSE Executive Management Team and the budget impact assessments (following commercial negotiations) which arise in relation to each medicine. Where a new medicine (when approved by the HSE EMT) is not reimbursed by the Primary Care Reimbursement Service the PCRS will reallocate the appropriate budget for that medicine to the HSE division responsible for providing the new medicine.

Sub-allocations detailing which new medicines will be funded and the amounts in relation to same will only become clear when reimbursement decisions in relation to each individual medicine is made. The HSE expects that the entire €30m budget will be spent in 2022 on new medicines. In making decisions on new medicines the HSE

considers the 5 year costs of such medicines and includes the expected costs of such medicines in the subsequent year in the relevant year pre-budget submission.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Suzanne Doyle', written in black ink.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service