Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Richard Bruton, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

28th February 2022

PQ: 6836/22

To ask the Minister for Health the size of the budget for medicines; and the plans to manage it more effectively. -Richard Bruton

Dear Deputy Bruton,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 6836/22), 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 medicine 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).

In 2021, a total of 52 new medicines were approved by the HSE (29 new medicines, 21 new uses of existing medicines, and expanded reimbursement of a further 2 medicines). Despite a 5 year investment exceeding €477m by the HSE for these 52 medicines, approximately €400m in additional costs over the next 5 years will be avoided on these new medicines following price reductions as a result of assessments (carried out by the National Centre for Pharmacoeconomics), commercial negotiations (led by the Corporate Pharmaceutical Unit of the Primary Care Reimbursement Service) and the deliberative processes followed by the Drugs Group and the HSE Executive Management Team.

Budget 2022 allocated €30m for new medicines. The €30m 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. The HSE expects that the entire €30m budget will be spent in 2022 on new medicines.

A suite of measures are available to the HSE for the management of current and future medicines expenditure. This includes two new framework agreements between the State and the pharmaceutical industry. Additional cost saving measures include reference pricing and the implementation of value improvement measures such as best-value medicine initiatives.

New Framework Agreements between the State and the Pharmaceutical Industry
The State has agreed two new multiannual agreements with the Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI):

- Framework Agreement on the Supply and Pricing of Medicines (i.e., the 2021 IPHA Agreement)

- Framework Agreement on the Supply and Pricing of Generic, Biosimilar, and Hybrid medicines (i.e., the 2021 MFI Agreement)

These new framework agreements on the supply and pricing of medicines will contribute to the sustainable funding of new and existing medicines and are estimated to deliver additional savings to the State exceeding €600m than would otherwise have been realised. These savings will be achieved via a number of measures outlined in these agreements including enhanced price reductions for off-patent medicines and increased rebate contributions for on-patent medicines.

Reference Pricing

In accordance with the statutory legislation that underpins the pricing and reimbursement of medicines in Ireland, the HSE is mandated to deliver the maximum savings possible and optimise the use of the limited resources available to it commensurate with maintaining supplies in the market place to meet patient needs. The Health (Pricing and Supply of Medical Goods) Act 2013 introduced a system of generic substitution and reference pricing in Ireland, which allows patients to opt for lower cost interchangeable (i.e. generic) medicines. When medicines are off patent and designated as interchangeable by the Health Products Regulatory Authority, the HSE may set a reference price for such medicines utilising the powers set out in the Act. In doing so, the HSE is required to consider the following criteria as set out in Section 24 of the Act:

(*a*) the ability of suppliers of the relevant listed items to meet patient demand for the relevant listed items,
(*b*) the value for money afforded by the relevant listed items,
(*c*) the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed,
(*d*) the relevant prices of therapeutically similar listed items,
(*e*) the resources available to the Executive, and
(*f*) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medical or surgical appliances where the agreement relates, whether directly or indirectly, to the price of one or more of those items.

The prices set for each medicine will vary based on the assessment of the criteria outlined in the Health Act 2013. The aim in setting reference prices is to achieve the lowest price possible commensurate with continuity of supply and avoidance of co-payments for patients. If the HSE sets a price too low, suppliers may exit the market or alternatively may refuse to match the reference prices. Decisions in relation to reference pricing have been made with potential supply challenges in mind, such as Brexit. Prices of reference priced products are generally of the order of 70% - 90% lower than the prices paid when medicines were on patent. The first reference prices were set on 1st November 2013 and to date, the HSE has set reference prices for hundreds of interchangeable groups. Significant price reductions have been achieved for generic medicines resulting in savings of hundreds of millions to the State.

Best-Value Medicine Initiatives

Best-value medicines initiatives are an additional cost saving measure utilised by the HSE. Best-value medicines are often provided to the HSE at a much lower cost than the originator brands of medicines. This provides the HSE with an opportunity to reduce the cost of providing such medicines to patients.

From 1 February 2020, it is HSE policy that all adult patients who are commencing treatment with Adalimumab or Etanercept (biologic treatments for autoimmune conditions) should be

prescribed a best-value biological (BVB) medicine. The HSE Medicines Management Programme is responsible for determining the BVB. Of note, by the end of 2020, over 11,600 patients had been prescribed one of the identified BVB medicines for Adalimumab or Etanercept.

Prescribing of best-value medicines is leading to significant savings for the HSE and additional best-value medicine initiatives are planned to further contribute to the sustainable funding of new and existing medicines. Further information in relation to potential best-value medicine (BVM) initiatives for 2022 are available at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/best-value-medicines/mmp-bvb-and-bvm-processes-2022.pdf

In summary, the Budget 2022 allocated €30m for new medicines and the HSE expects that the entire €30m budget will be spent in 2022 on new medicines. HSE policies and initiatives targeting efficiencies in current and future medicines expenditure are under continuous evaluation and will contribute to the sustainable funding of new and existing medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service