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Matt Shanahan, T.D.
Dáil Éireann,
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PQ: 39906/20

To ask the Minister for Health the downstream and overall cost-benefit analysis conducted by the corporate pharmaceutical unit when assessing reimbursement applications for novel and generic drug applications; his views on whether the full system savings are being considered in such applications; if evidence of same in action can be demonstrated; and if he will make a statement on the matter. - Matt Shanahan

Dear Deputy Shanahan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 39906/20), which you submitted to the Minister for Health for response.

There is a national application, assessment & 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) put in place by the Oireachtas. 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.

A pharmaceutical company can apply to the HSE for reimbursement for a specific indication (use) of a specific licensed medicine. Medicines can have more than one licensed (market authorised) indication and each indication represents a separate application.

The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to pricing and reimbursement applications for medicines. 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. The role of the CPU is to manage the process around pricing and

reimbursement applications for medicines received by the HSE from industry and to lead on pricing negotiations with individual companies around specific medicines.

- **New medicines assessment process**:

  - In the event that an application for reimbursement is submitted to the HSE-CPU the National Centre for Pharmacoecomincs (NCPE) plays a pivotal role in assisting the HSE with the assessment of all new medicines.
  - Since September 2009, in collaboration with the HSE-CPU, the cost-effectiveness of all new medicines are considered prior to a decision being made by the HSE.
  - There is a two stage evaluation process. The first stage of the evaluation process commences once the applicant company submits a rapid review dossier, which can be anytime from when there is a positive opinion in relation to marketing authorisation (MA) from the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP). A principal purpose of the first assessment stage is to triage applications that require a more in-depth pharmacoeconomic evaluation, through a Health Technology Assessment (HTA), in order to determine the comparative clinical and cost-effectiveness and potential budget impact of the medicine.
  - The NCPE makes a recommendation in relation to reimbursement at the price submitted by the company in its rapid review or HTA dossier / application. The NCPE may recommend in favour of or may recommend against reimbursement.
  - In the event of a negative recommendation or a qualified recommendation, the HSE will enter negotiations in relation to the pricing and other commercial terms. These negotiations are led by the CPU.
  - 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 advices to the EMT. The EMT are the decision makers in relation to pricing and reimbursement of new medicines (with budget impacts).
  - 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*

- **Generic and biosimilar pricing frameworks and policies**

  - Reimbursement of generic and biosimilar medicines are automatically approved, provided the pricing is in line with the generic or biosimilar pricing frameworks.
  - The pricing of such medicines is linked to the price of the originator or patented medicine and the HSE typically does not engage in further commercial negotiations in order for reimbursement approval to be given
  - 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
  - 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

- **PCERS reports related to HSE-CPU processes:**

  - The HSE has approved 10 new medicines and 12 new uses of existing medicines in 2020. Commercial negotiations in relation to these medicines will deliver in excess of €80million in avoided additional costs over the next five years.
  - The NSP 2019 and 2020 reduced the funding to PCERS by €63.5m in lieu of biosimilar savings to be delivered. As of September 2020, at least €42.5m of biosimilar savings are expected to be delivered in 2020 (based on switches to date). That will align to a full year impact of €50m in 2021.
  - In 2010, the generic penetration rate of generic medicines was less than 40% in the off-patent market. Figures up to year end 2019, show that the current generic penetration rate is 73% of volume in the off-patent market

- **Evidence for savings reported in literature:**
  - Connors J. Future Sustainability of Pharmaceutical Expenditure. Department of Public Expenditure and Reform and IGEES. 2017. Available from: https://igees.gov.ie/wp-content/uploads/2015/02/Future-Sustainability-of-Pharmaceutical-Expenditure.pdf

- McCullagh LM, Tilson L, Adams R, Barry M. HTA Informed Price Negotiations: Cost Savings to the Health Payer in Ireland. *Value in Health*. 2014; 17(7):A420. Available from:doi: 10.1016/j.jval.2014.08.1030
- Smith A, Barry M. Combining health technology assessment and health technology management to deliver cost-effective prescribing. *Expert Review of Pharmacoeconomics & Outcomes Research* 2020; 20(5):431-436. Available from: doi:10.1080/14737167.2020.1822739

In summary, the HSE has robust assessment and commercial negotiation processes in place for the pricing and reimbursement of medicines to ensure 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. These processes challenge inappropriate costings from applicant companies and deliver improved value for money. The assessment process (carried out by the NCPE), the commercial negotiations (led by the CPU), and the deliberative processes followed by the Drugs Group and the HSE EMT have achieved multi-million euro savings (in avoided costs) for new medicines funded and reimbursed by the HSE over the last number of years.

HSE policies and initiatives targeting efficiencies while maintaining continuity of supply are under continuous evaluation. The HSE must take into account the wider context and address challenges faced by the health service.

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