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Colm Burke, T.D.
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PQ: 37830/22

To ask the Minister for Health his plans to improve the health data infrastructure of the State; the way that these plans can support innovative payment models in respect of the reimbursement of orphan medicinal products and advanced therapy medicinal products; and if he will make a statement on the matter. -Colm Burke

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 37830/22), which you submitted to the Minister for Health for response.

The following information has been provided to address the information sought in relation to reimbursement systems.

In 2021 the HSE, the Department of Health, the Department of Public Expenditure & Reform and the Irish Pharmaceutical Healthcare Association engaged in negotiations that led to a new Medicines Supply Agreement i.e. the 2021 IPHA Agreement. As part of the negotiation of the Agreement significant effort was spent considering a range of options to improve the efficiency of pricing and reimbursement application processes. The Irish Pharmaceutical Healthcare Association, the representative organisation for many multi-national pharmaceutical companies, in its press release welcoming the 2021 Agreement flagged that the Agreement *"will improve patients' access to the latest innovative medicines"* and that *"the Agreement provides for adequate, sustained investment in innovative new medicines, with allocations decided annually based on horizon scanning and the budgetary process"* and *"has the potential to improve the operating environment for the adoption of innovative new medicines in the health services"* https://www.ipha.ie/new-medicines-supply-agreement-to-improve-patients-access-to-innovative-new-treatments/

The HSE has statutory responsibility for decisions on pricing and reimbursement of medicines in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, using the resources available (provided) to it and the HSE considers a range of proposals from Industry when assessing pricing and reimbursement applications. The 2013 Act enables the HSE to consider the terms of any framework agreement in place when it is making decisions in relation to pricing. The HSE robustly assesses applications to ensure available resources can be stretched 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 and are in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE is required to 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

The HSE is required to consider the following criteria when it is making decisions in relation to pricing of Medicines:

(*a*) the equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,
(*b*) the relevant prices of therapeutically similar listed items,
(*c*) the potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,
(*d*) the potential budget impact of the item if it were to become a listed item,
(*e*) the ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,
(*f*) the resources available to the Executive, and
(*g*) 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 medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.

The HSE Drugs Management Programme has developed a strategy for the Procurement of Medicines in Acute and non-Acute Hospitals available at: https://www.hse.ie/eng/about/who/national-drugs-management-programme/procurement-of-medicines-strategy-document.pdf.

The strategy provides for the introduction of a National Dynamic Purchasing System (DPS) as the preferred model to facilitate compliant procurement of medicines by HSE and HSE-funded hospitals.

In addition to making payments in relation to medicines under the General Medical Services Scheme, the Drugs Payment Scheme and the Long Term Illness Scheme, the HSE Primary Care Reimbursement Service (PCRS) also makes payments to suppliers and manufacturers of High Tech drugs as part of the High Tech Arrangements. High Tech drugs are specialised medicines initiated in secondary care and are appropriate to be dispensed in the community setting. High Tech medicines include expensive and innovative pharmaceuticals. PCRS also facilitates direct payments to public hospitals involved in the provision of national treatment programmes such as the National Cancer Control Programme, the National Hepatitis C Treatment Programme and Multiple Sclerosis Services. This ensures that there is a single funding strategy for the use of such high cost medicines in public hospitals and that there is no variation in access to funding for these medicines across the country.

The HSE has negotiated a series of managed entry schemes or managed entry agreements (MEAs) for medicines it has approved in recent years, including medicines for rare diseases. These agreements include innovative financial or pricing measures including confidential rebates or discounts, budget caps and/or other outcomes based innovative measures such as clinical outcomes monitoring or aspects of payment by results. The preference of the HSE would be that such pricing arrangements would be clear and transparent, but suppliers and manufacturers of these medicines will generally only agree to such measures on the condition of commercial confidentiality. Notwithstanding the lack of transparency due to commercial confidentiality required by Industry these innovative measures do contribute significantly to reducing the cost of new therapies being reimbursed, thus improving both access and affordability of new medicines.

Increasingly the HSE is also agreeing disease-specific reimbursement, with specified eligibility criteria for reimbursement, for approval of medicines on a named patient basis. In such cases, the treating physican completes an online / paper-based application for reimbursement which is submitted to the PCRS and/or HSE Medicines Management Programme (MMP) for pre-authorisation. Examples of medicines for rare diseases that have robust reimbursement protocols in place include Eculizumab, Patisiran and Nusinersen.

The HSE continues to cooperate with colleagues in Austria, Belgium, Luxembourg and the Netherlands under the BeNeLuxA initiative to explore innovative solutions across a range of work programmes including:

- sharing of early insights on new pharmaceutical products and on new indications of existing products coming to the market (i.e. Horizon Scanning);
- exchanging expertise and by mutual recognition of Health Technology Assessments;
- sharing policy expertise and best practices
- seeking to improve transparency on pricing between the collaborating countries and exploring further options for joint negotiations, following on from the successful joint negotiation for the medicine Zolgensma® (for the management of the rare condition spinal muscular atrophy) in 2021.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service