Rannán na nOspidéil Ghéarmhíochaine
Aonad 4A, Áras Dargan
An Ceantar Theas
An Bóthar Míleata
Cill Mhaighneann
Baile Átha Cliath 8

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28th July 2022

Deputy Cathal Crowe,
Dáil Eireann,
Leinster House
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Dublin 2

PQ 39085/22 "To ask the Minister for Health the engagement that he has had with his Department officials and HSE officials regarding the use of innovative payment models between industry and the State in respect of the drug reimbursement process for rare disease therapies; if he will provide innovative solutions to ensure greater access; and if he will make a statement on the matter".

Dear Deputy Crowe,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question, which you submitted for response. I have examined the matter and the following outlines the position.

'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.

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

I trust this answers your question to your satisfaction.

Yours sincerely,

Brian Dunne
General Manager, Acute Operations