



Re: Response to Parliamentary Reply on Drug Reimbursement Process

Dear Minister,

I am writing on behalf of UCAN Ireland in response to your recent reply to a parliamentary question, raised on our behalf by Pdraig Rice TD, regarding the timeline for reviewing the drug reimbursement process, the involvement of patient advocacy in such a review, and your Department's broader plans for access to innovative medicines.

While we welcome the progress made in staffing and the recent launch of the Pricing & Reimbursement Application Tracker, we are concerned that your response does not address several specific commitments set out in the Programme for Government, in particular

- A commitment to review the drugs reimbursement process
- The investigation of early access schemes

The 2023 review referenced in your response was limited in scope and cannot be considered a substitute for a comprehensive, end-to-end review involving all key stakeholders. Such a review is essential to address the systemic inefficiencies and delays that continue to impact patients. It is important to note that this review actually took place in 2019.

In relation to funding, while it is noted that €128 million was allocated between 2021 and 2024 for new medicines, HSE data show that only €61.9 million of the €98 million earmarked between 2021 and 2023 was spent on new drugs, with over €36 million redirected to support existing treatments. The status of the €30m allocated in Budget 2024-2025 remains unclear. These discrepancies are deeply concerning given the urgent need for timely access to new treatments and have rightly been criticised by others, including MEP Billy Kelleher.

Regarding drug access numbers, your statement that 82 new cancer medicines were introduced between 2021 and 2024 does not align with publicly available data from the HSE Drugs Group minutes, which list the following:

- 2021 shows 15 approvals for new drugs or new indications for use.
- 2022 shows 9
- 2023 shows 14
- 2024 to May 2025 shows 23

This gives a total of 61 new treatments. We would welcome clarification on this discrepancy.



Finally, we draw attention to the EFPIA WAIT indicator, which shows Ireland's average time from EMA approval to patient access falls well short of our peers in Europe, taking 641 days on average in the period 2021-2024.

For people with life-threatening or seriously debilitating conditions, many European countries have implemented **Early Access Programmes (EAP)** that allow patients to access medicines shortly after regulatory approval. These programmes typically involve co-funding between industry and the public payer and are designed to reduce delays in treatment for patients with urgent clinical needs. A 2023 analysis found that 29 out of 35 European countries have such early access schemes in place. Countries without a scheme include only a small minority: Ireland, Albania, Belarus, Bosnia and Herzegovina, Lithuania, and Moldova. This places Ireland among a very limited group that has not acted to address the inequities in access caused by lengthy reimbursement timelines. For cancer patients, where time is often a critical factor, the lack of an EAP represents a serious systemic failure. This issue must be addressed without further delay as part of any meaningful reform to the drug reimbursement process.

UCAN Ireland calls again for the Government to fulfil its Programme for Government commitment to undertake a full, end-to-end review of the reimbursement process and Initiation of an EAP to ensure patient needs are met while the reimbursement process is underway. This review must include the HSE, NCPE, NCCP, expert clinicians, industry, and patient advocacy representatives. The goal must be a transparent, accountable, and time-bound system that ensures Irish patients receive timely access to innovative and life-saving treatments.

We would welcome the opportunity to meet with you to discuss these issues in more detail and to offer the perspective of patients who continue to be impacted by these systemic delays.

Yours sincerely,

Miriam Staunton, Chair UCAN

James Hastings, Co-chair UCAN

Martin Sweeney, Secretary UCAN

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