Barriers to Reimbursement: Characteristics of Unfunded Medicines in Ireland (2006–2021)

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BACKGROUND

Ireland has a well-established and structured process for the reimbursement of new medicines, designed to ensure that treatments funded by the public health system offer both clinical benefit and value for money. This process involves two key stages managed by the National Centre for Pharmacoeconomics (NCPE) and the Health Service Executive (HSE) Drugs Group[1].

When a pharmaceutical company submits a medicine for reimbursement, the NCPE first carries out a Rapid Review. This assessment evaluates the medicine's clinical efficacy, cost, and expected budget impact. The outcome determines whether a more detailed Health Technology Assessment (HTA) is required and falls into one of five categories:

1. HTA recommended
2. HTA recommended at the submitted price
3. HTA not recommended
4. HTA not recommended at the submitted price
5. Reimbursement not recommended

Following NCPE recommendations of "HTA recommended at the submitted price" and "HTA not recommended at the submitted price", price negotiations are conducted by the HSE Drugs Group and a HTA may be avoided. The goal is to reach a price that aligns with the medicine's therapeutic value and the constraints of the public health budget.

Despite this process, some medicines remain unfunded due to cost-effectiveness concerns, pricing disagreements, or limited budget capacity. Examining the characteristics and trends among these unfunded medicines helps to highlight ongoing challenges in balancing timely access to innovation with affordability and sustainability in Ireland's healthcare system.

OBJECTIVE

The objective of this study is to investigate the characteristics of medicines that were not reimbursed between 2006 and 2021, focusing on reasons for non-reimbursement.

METHODS

We compiled a dataset of all new medicines that were evaluated by the NCPE from 2006 to 2021, allowing time for the reimbursement process to conclude (average 920 days)[2]. Data collected included indication, oncology/orphan status, reimbursement scheme and reimbursement recommendation from the NCPE website[2]. Data from the HSE Drugs Group meetings were added to the database, including date of first HSE and last Drugs Group meeting, number of meetings required and date of reimbursement recommendation[3]. Reimbursement status and date was also added to the database from multiple sources including the NCPE[2], the National Cancer Control Programme (NCCP)[4], and the Primary Care Reimbursement Service (PCRS) websites[5] . Descriptive statistics were then applied to the data.

RESULTS

Of 574 medicine evaluations conducted over the 2006-2021 period, 96 (17%) were not reimbursed. Figure 1 shows that the number and proportion of unfunded drugs in Ireland have varied over time but show a clear upward trend in recent years. After fluctuating through the early 2010s, both measures increased steadily from 2016 onward, reaching their highest levels in 2021. This suggests that a growing share of new medicines assessed by the NCPE are not progressing to reimbursement, reflecting increasing cost and affordability pressures within the system.

Neoplasms accounted for the largest proportion of both funded and unfunded medicines, with a slightly higher share being funded, suggesting prioritisation of oncology treatments (see Figure 2). Orphan and "other" categories showed a greater proportion of unfunded medicines, suggesting that rarer or more diverse therapeutic areas face additional reimbursement challenges. Endocrine and nervous system drugs displayed similar proportions between funded and unfunded groups.

Of the unfunded group, 78% did not complete an HTA. Among this group (unfunded medicines and did not complete an HTA), the largest share (39%) were recommended for a HTA, indicating that further evaluation was advised but not completed. Around one-fifth were not recommended for HTA (21%) or not recommended at the submitted price (20%), while smaller proportions were recommended at the submitted price (9%) or had reimbursement not recommended (11%). These results suggest that a substantial number of unfunded medicines stall before full economic evaluation (see Figure 3).

Among unfunded medicines that underwent HTA, the majority (70%) received a definitive decision of non-recommendation, while 30% were not recommended pending improvements in cost-effectiveness (see Figure 4).

Overall, only 23% of unreimbursed medicines were explicitly rejected following formal evaluation. The remaining 77% were not reimbursed due to HTA non-submission or unsuccessful price negotiations.

Figure 1: Number and Percentage of Unfunded Medicines in Ireland (2006-2021)

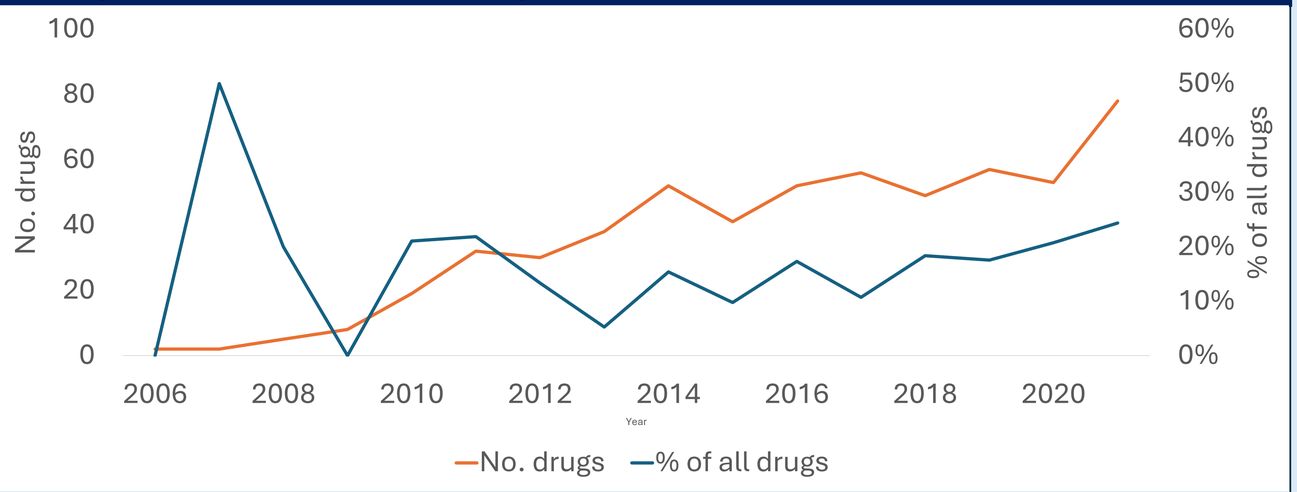


Figure 2: Disease Area and Orphan Status of Unfunded vs Funded Medicines

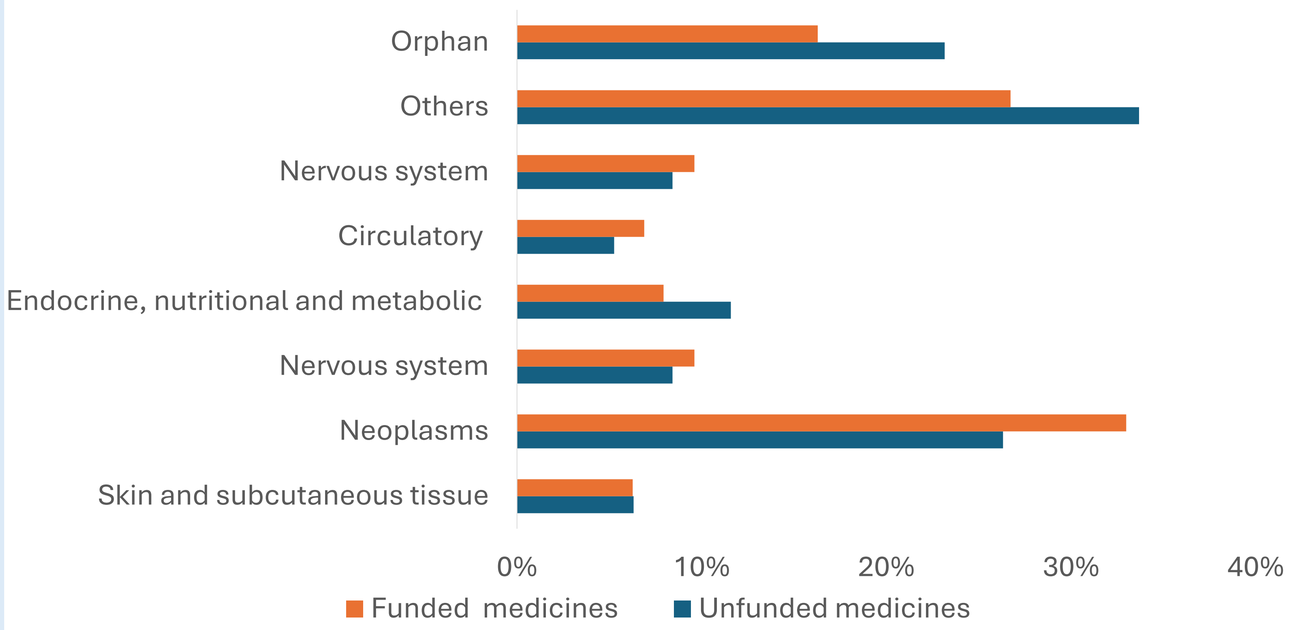
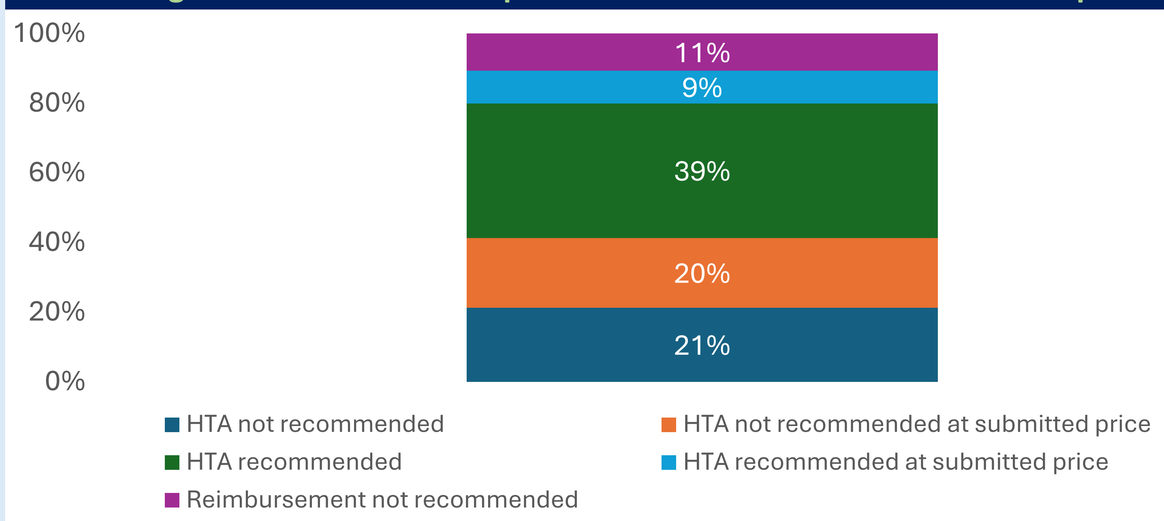
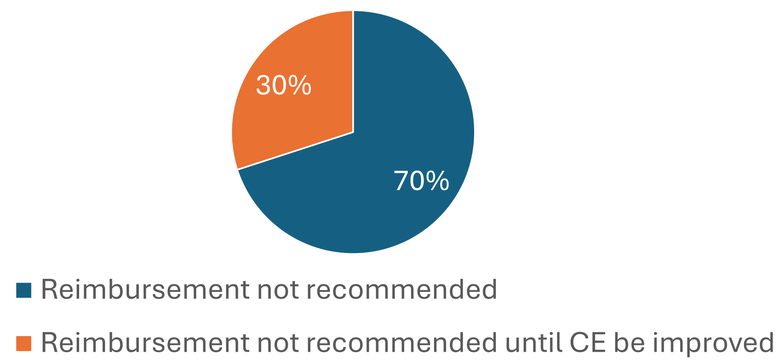


Figure 3: Outcomes of Rapid Reviews Where HTAs Were Not Completed



HTA: health technology assessments

Figure 4: Outcomes of HTA Where HTA Were Completed



CE: cost-effectiveness; HTA: health technology assessments

CONCLUSION

While most medicines in Ireland ultimately gain reimbursement (83%), those that do not are predominantly excluded due to failure to submit a full HTA or reach agreement on price, rather than negative clinical or economic assessments. 70% of unfunded medicines that underwent HTA were still not reimbursed, often due to unfavourable cost-effectiveness outcomes or budget impact considerations. High-cost therapeutic areas such as rare diseases were particularly affected, highlighting the financial pressures these treatments place on the system. Addressing these barriers—through improved manufacturer engagement, flexible pricing arrangements, and managed access agreements—may enhance access to innovative therapies while maintaining sustainability within Ireland's healthcare system.

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