Time to Reimbursement in Ireland; Utilising Regression Analysis to Assess Factors Contributing to Overall Timelines

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01. Introduction

Improving access to new medicines has become a crucial issue for healthcare payers globally. This is particularly relevant in the current environment of increasing complexity of new technologies, rising costs of new medicines and the significant budgetary constraints faced by health systems.

Reimbursement timelines have also become a significant concern, with Ireland behind many European countries in terms of speed of access to new medicines, when considering time to reimbursement from initial submission to the assessor.

In Ireland, the National Centre for Pharmacoeconomics (NCPE), an independent body that is commissioned by the Irish Health Service Executive (HSE), conducts assessments on the clinical and cost-effectiveness of all new medicines seeking reimbursement. In 2009, the NCPE introduced a two-step assessment process to help facilitate a more efficient assessment of medicines that were considered efficacious and low-cost in comparison to Irish standard of care, and thus in turn do not pose considerable budgetary pressure.

This full process is detailed in Figure 1, with step one involving a rapid review (RR) submission.

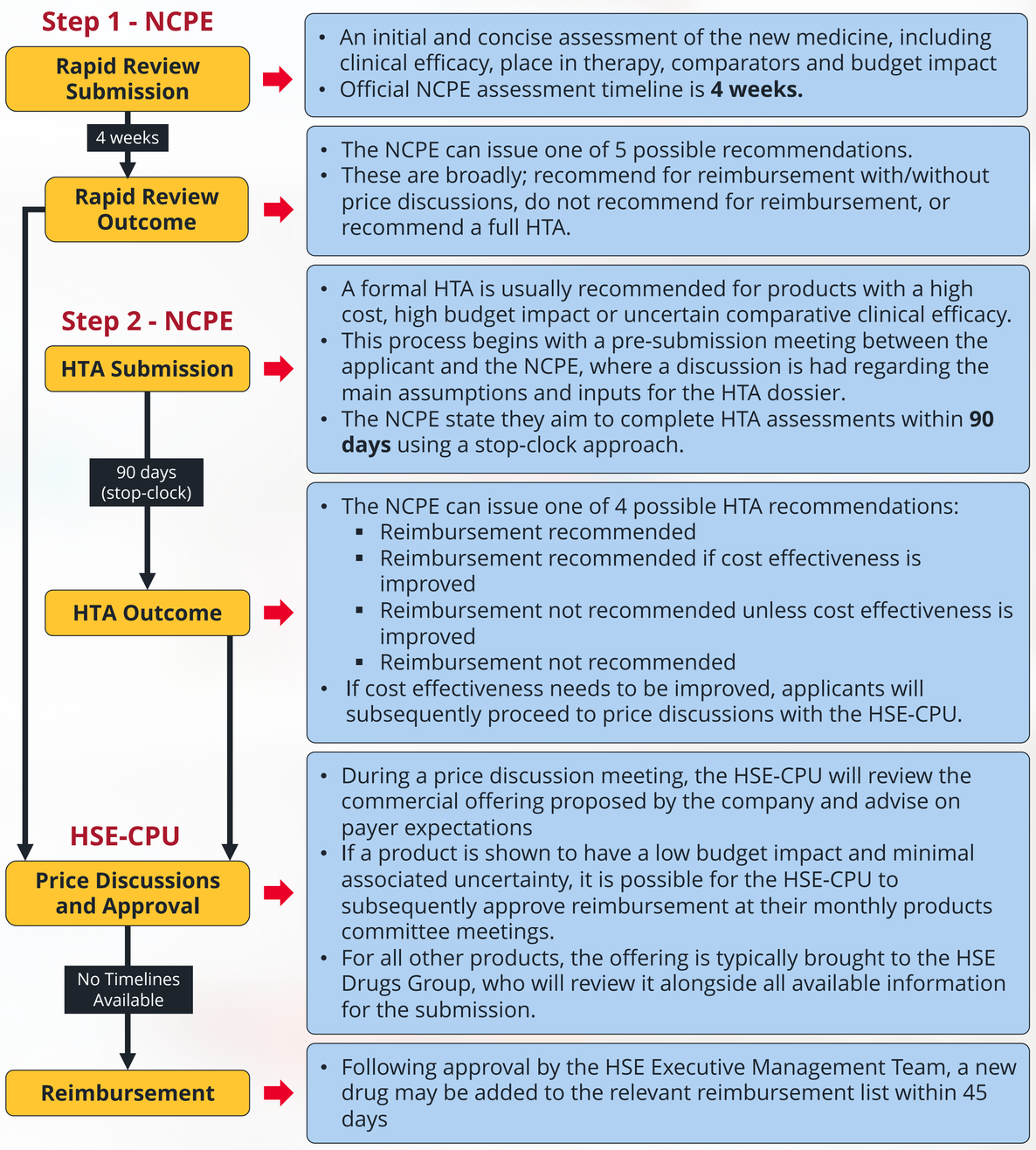
All new medicines in Ireland undergo a RR, after which medicines either require a full Health Technology Assessment (HTA) or can proceed straight to price discussions with the HSE's Corporate Pharmaceutical Unit (HSE-CPU). The NCPE have published research which shows that approximately 57% of the RR applications made from 2018 to 2024 did not require a full HTA submission.[1] AXIS Consulting has presented our analyses of timelines to reimbursement (TTR) over the past number of years with the starting point determined by the date the applicant company submits a RR to the NCPE and not by the date a company achieves a marketing authorisation. This is an important differentiator to other research published in TTR which takes a starting point of marketing authorisation, as time from RR submission to reimbursement is a more accurate reflection of timelines.

This research aims to;

1. Assess the number of medicines reimbursed over an eight-year period (June 2016 - June 2024);
2. Analyse over this timeframe, the overall TTR comparing medicines reimbursed at the RR stage versus those reimbursed following an HTA;
3. Analyse the factors which influence the TTR for recently reimbursed medicines, utilising regression analysis from a subsample of medicines reimbursed between 2021 and 2024.

02. Reimbursement Process Ireland

Figure 1: Overview of reimbursement pathway in Ireland



NCPE - National Centre for Pharmacoeconomics; HSE-CPU - Health Service Executive Corporate Pharmaceutical Unit

03. Methods

A centralised database is maintained at AXIS detailing submissions reported on the NCPE website between June 2016 and June 2024. The Primary Care Eligibility and Reimbursement Service (PCERS) list was utilised to identify reimbursement dates where information was not available on the NCPE website, and the minutes of the HSE Drugs Group were also utilised to identify reimbursement decisions at the monthly Drugs Group meetings. The specific data points extracted from each source are detailed in Table 1.

Table 1: Overview of sources and extracted data

Source	NCPE Website	PCERS List of Reimbursable Items	HSE Drugs Group Minutes
Extracted data points	Date of RR submission Date of RR outcome Date of NCPE pre-submission meeting Date of HTA submission Date of issue of NCPE preliminary questions Date of HTA outcome Date of confirmed reimbursement	Date of reimbursement (Addition to PCERS list)	Date of Drugs Group meeting Deliberations Outcome

Analysis Plan

The data extracted from the various sources above were consolidated in *Microsoft Excel*. The PCERS list of reimbursable items was only utilised if reimbursement dates were not reported on the NCPE website. Given that only the month of reimbursement is publicly provided, it was conservatively assumed that reimbursement falls on the 1st of each month for the purpose of timeline calculations.

For each appraisal, the following timelines were calculated:

- The time from RR submission to RR outcome
- The time from HTA submission to HTA outcome
- The time from RR submission to reimbursement decision (i.e., TTR)

A subset of the following data from 2021 to 2024 was utilised for regression analysis to assess factors which may influence TTR of recently reimbursed medicines:

- Total time to reimbursement
- HTA decision
- HTA decision at submitted price
- Drug classification (Oncology / Orphan / Neither)

04. Results

Of the 298 drugs with identified reimbursement dates between June 2016 and June 2024, **52.01%** (N=155) avoided an HTA and proceeded to price discussions and subsequent approval for reimbursement by the HSE, while **47.99%** (N=143) submitted an HTA to the NCPE**.**

The average time applications spent at each stage of the process is detailed in Table 2, with the RR process taking on average **27.07 working days** (5.41 calendar weeks) and the HTA process taking **168.42 working days** (33.68 calendar weeks).

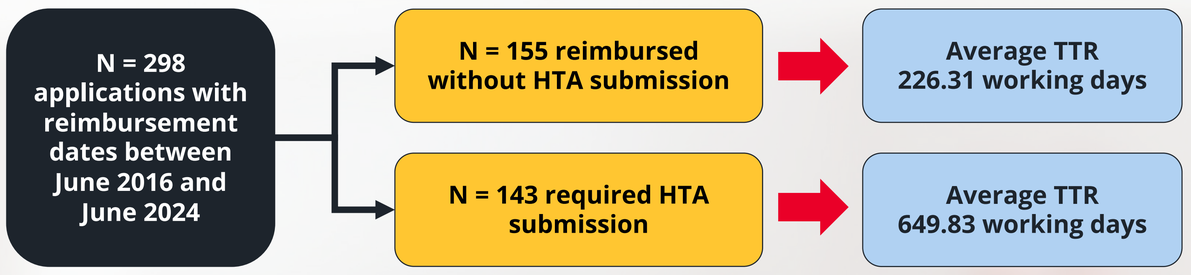
It is important to note that these timelines include time where the assessment sits with the applicant company and thus is not being assessed by the NCPE. The total average TTR, including the post-NCPE phase was **543.73 working days** (106.95 calendar weeks; 2.05 calendar years).

Table 2: Average process timeline for new medicines (January 2016 and June 2024)

RR Process (N=155)	HTA Process (N=143)	TTR (N=298)
37.90 calendar days 27.07 working days (5.41 calendar weeks)	235.79 calendar days 168.42 working days (33.68 calendar weeks)	748.61 calendar days 543.73 working days (106.95 calendar weeks; 2.05 calendar years)

As expected, the average TTR was significantly longer for applications requiring a full HTA assessment, **649.83 working days (2.49 calendar years)**, versus **226.31 working days (0.87 calendar years)** for applications not requiring a full HTA.

Figure 2: Total time to reimbursement with and without an HTA



Regression Analysis

Of the subset of 184 medicines which had a reimbursement date between 2021 and 2024, the average TTR was 456.30 working days. Of the medicines reimbursed in this period, 41.3% were oncology drugs and 26.63% were orphan drugs.

The multiple regression analysis showed that the RR outcome, and drug classification (oncology / orphan / neither) explain some of the variance in TTR (Adjusted $R^2 = 0.41$, $p = 8.53E\text{-}21$).

Orphan drugs and HTA decision at RR were positively correlated with the TTR, and Oncology drugs and HTA decisions at the submitted price were negatively correlated with TTR.

Table 3: Output of regression analysis	Coefficients
Intercept	328.04
Oncology Yes/No	-55.76
Orphan Drug Yes/No	73.3
Rapid review decision: HTA Yes/No	609.97
Rapid review decision HTA: at price Yes/No	-476.00

05. Conclusions and Recommendations

Completing a RR as well as a full HTA significantly increases the overall TTR. On average, reimbursed medicines that required a RR as well as a full HTA between June 2016 and June 2024 required an additional 197.89 NCPE appraisal days (28.27 weeks) in comparison to medicines that do not require a full HTA, before proceeding to the post-NCPE phase. Furthermore, based on the regression analysis, it could be concluded that Orphan drugs may generally have a greater TTR, whereas Oncology drugs have a shorter TTR.

Although the aTTR is significantly shorter for medicines which do not require a HTA, the imminent introduction of Joint Clinical Assessment (JCA) may leave the future of the RR in Ireland, uncertain. It is possible that the removal of the NCPE RR could negatively impact the aTTR for medicines in Ireland. As the JCA for oncology medicines come into effect in January 2025, it will be of particular interest to understand the impact this will have on future oncology submissions in Ireland.

The majority of time in the overall reimbursement process consists of post RR/HTA assessment, accounting for 93.28% of TTR for drugs that did not require an HTA, and 45.71% TTR for drugs that did require an HTA. There is no specified timeline for the decision making on reimbursement post RR/HTA assessment, where engagement with the HSE occurs.

Thus, if significant improvements are to be made regarding access to new medicines in Ireland, the key focus should be on the HSE engagement phase. In line with guidance from MAZARS, the HSE process should have public guidance timelines to increase transparency for the stakeholders.[2]

References: 1. NCPE Assessments: Rapid Reviews. PMI Market Access Masterclass. 26th September 2024; 2. Department of Health. MAZARS - Review of the Governance Arrangements and the Resources currently in place to support the HSE reimbursement and pricing decision-making process. 2020.

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