Health Technology Assessment of Drugs in Ireland: An Analysis of Timelines (2021-2022)

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INTRODUCTION

The National Centre for Pharmacoeconomics (NCPE) conducts the health technology assessment (HTA) for all drugs seeking state reimbursement in Ireland. All new drugs are subjected to a rapid review (RR). Following this, drugs which are high cost or predicted to have a significant budget impact are then subjected to undertake a full HTA. The objective of this paper is to quantify each stage of the timeline from marketing authorisation (MA) to completion of HTA and explore the association between features of submissions (including orphan and cancer status) and the time to complete RRs and HTAs.

METHODS

All RRs and HTAs submitted to the NCPE (RR commissioned 2021 to 2022 inclusive) were included in the dataset. A number of dates and features (cancer medicine and orphan status) of each submission were also listed for the purpose of analysis.

The timeline from MA to completion of HTA appraisal was divided into five stages for analysis, as shown in Figure 1. Descriptive statistics (median, interquartile range) were calculated for overall timeline and each stage in the process. Timelines were compared for cancer, orphan, and other medicines with Kruskal-Wallis rank sum tests used to assess differences. Post-hoc analyses were carried out using Conover-Iman tests.

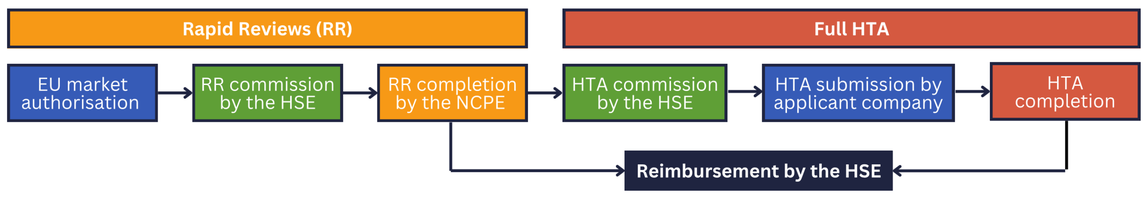

Figure 1: Five HTA timeline stages divided for analysis (from market authorisation to RR commission, from RR commission to completion, from RR recommendation to HTA commission, from HTA commission to HTA submission, from HTA submission to completion)

EU: European Union, RR: Rapid Reviews, HSE: Health Service Executive, NCPE: National Centre for Pharmacoeconomics, HTA: Health Technology Assessment

RESULTS

From January 2021 to December 2022 inclusive, 145 RRs were commissioned and completed by the NCPE. Of these 55 were submitted for full HTA. As of June 2024, 46 HTAs have been completed, with 9 ongoing. The full movement of all submissions are shown in Figure 2 below.

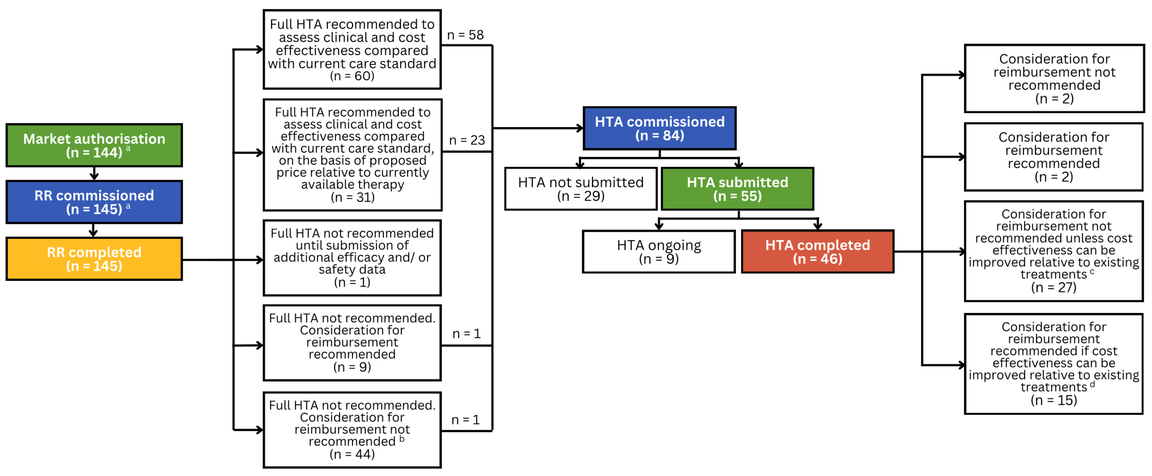

Figure 2: Full movement of all RR submissions to the NCPE in 2021 and 2022.

RR: Rapid Review, HTA: Health Technology Assessment

[a] Note: The Applicant company withdrew its application for marketing authorisation for one drug for COVID-19 after RR. RR can occur from CHMP opinion

[b] We recommend that the HSE consider not providing this medicine unless the HSE can agree a suitable price reduction with the pharmaceutical company. The price of the medicine is higher than other ways to manage this condition, and we believe that the medicine is not value for money. We believe enough information was provided in the Rapid Review.

[c] We recommend that the HSE consider not providing this medicine unless the HSE can agree a suitable price reduction with the pharmaceutical company. This is because we believe the medicine may work as well or better than other ways to manage this condition. However, the price of the medicine too high compared with other ways to manage this condition, and we believe that the medicine is very poor value for money. OR We believe it is not clear that the medicine works as well or better than other ways to manage this condition. The price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is very poor value for money.

[d] We recommend that the HSE consider providing this medicine if the HSE can agree a suitable price reduction with the pharmaceutical company. We believe the medicine may work as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is not value for money.

29% (42/145) of RRs were submitted within 30 days of MA being granted. Just under half of the submissions (41%) were recommended for HTA following RR. 58% (84/145) of drugs proceeded to be commissioned for a HTA by the HSE, with 66% (55/84) of these being submitted for a HTA by the Applicant company.

Description	Days (median (Q1-Q3))
MA to RR commission (n = 144)	95 (17-333)
RR commission to completion (n = 145)	30 (24-37)
RR completion to HTA commission (n = 84)	21 (16-28)
HTA commission to submission (n = 55)	212 (175-291.5)
HTA appraisal (n = 46) [a]	274 (227-301)

Figure 3: Median and interquartile range for each stage in the HTA process for RRs submitted in 2021 and 2022

Q1: quartile 1, Q3: quartile 3, MA: market authorisation, RR: rapid review, HTA: health technology assessment

[a] Note: The time from submission to completion of the HTA is not representative of the time taken for HTA appraisal. It includes time spent with the company due to the stop/clock process. It also includes time while the appraisal is waiting to start due to capacity constraint.

Timeline comparison of drug categories

Submissions were divided into three drug categories: Cancer, Non-cancer orphan (Orphan), and Non-cancer, non-orphan (Others).

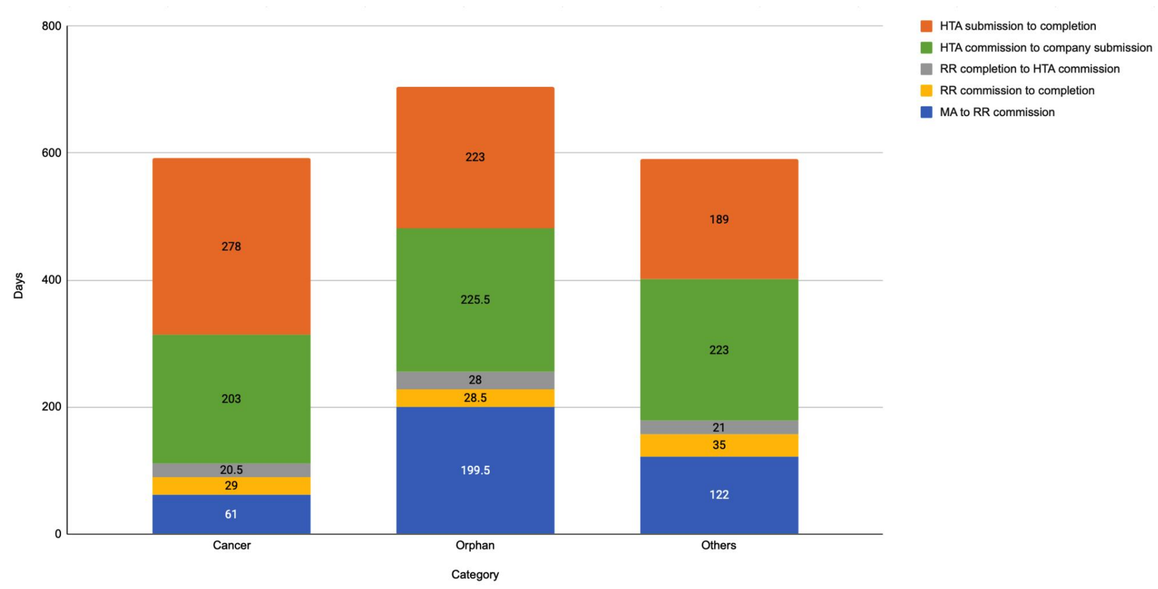

Figure 4: Stacked column chart of the HTA timeline of Cancer, Orphan, and Others drugs, using the median to represent each stage of the process

MA: market authorisation, RR: rapid review, HTA: health technology assessment

Category	MA to RR commission	RR commission to completion	RR to HTA commission	HTA commission to submission	HTA commission to completion
Cancer	61 (12-180) (n = 59)	29 (24-35) (n = 59)	20.5 (13.5-27) (n = 46)	203 (177-297) (n = 34)	278 (254-323) (n = 29)
Orphan	199.5 (59-824) (n = 22)	28.5 (23-35) (n = 22)	28 (18.5-36.5) (n = 15)	225.5 (198-276) (n = 10)	223 (198-274) (n = 9)
Others	122 (19-433.5) (n = 63)	35 (26-43) (n = 64)	21 (16.5-23) (n = 23)	223 (142.5-320) (n = 11)	189 (122-288) (n = 8)

Figure 5: Median and interquartile range for stages in the HTA process for each drug category

IQR: interquartile range, MA: market authorisation, RR: rapid review, HTA: health technology assessment

Overall, Kruskal-Wallis indicated there was sufficient evidence to conclude a difference between drug categories for the number of days from MA to RR commission (p = 0.022), RR commission to completion (p = 0.021), and HTA commission to completion (p = 0.026). Post-hoc analyses using Conover-Iman tests indicated a statistically significant difference between:

- Cancer and Orphan drugs for the number of days between MA and RR commission (p = 0.009), and the number of days to complete HTA (p = 0.025).
- Cancer and Others drugs for the number of days to complete RR and HTA (p = 0.035).
- Orphan and Others drugs for the number of days to complete RR (p = 0.0497).

CONCLUSION

This analysis quantifies individual stages of the HTA process and how they contribute to the overall timeline of the assessment process. It identifies which stages of the process make a substantial contribution to the HTA timeline and highlights that timelines are influenced by multiple stakeholders in the process. The efficiency of the two-step process is highlighted, as it is successful at preventing unnecessary HTAs being carried out when a RR is sufficient to make a reimbursement recommendation.