Time to Reimbursement of Novel Anticancer Drugs in Ireland Compared to Six European Countries and the UK

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BACKGROUND

An independent study was published recently by Post (2023) on the time to reimbursement (TTR) of novel anti-cancer drugs across six European countries: Belgium, Germany, France, the Netherlands, Norway, Switzerland, and the UK [1]. It found that the TTR between these countries differ, contributing to un-equal access and delays of new anti-cancer drugs, leading to a substantial loss of quality of life and life years for cancer patients [1]. With the exception of Germany, all of the countries listed were selected as they follow a similar national reimbursement process. This includes the submission of a clinical and cost effectiveness dossier, evaluation by an expert committee, followed by price negotiations [1].

In Ireland, The National Centre for Pharmacoeconomics (NCPE) assesses all new drugs approved by the European Medicines Agency (EMA). The Corporate Pharmaceutical Unit (CPU) of the Health Service Executive (HSE) notifies the pharmaceutical applicant to prepare a Rapid Review (RR) which is then submitted to the NCPE for assessment. Reimbursement is officially triggered by the submission of a RR. The purpose of a RR is to determine whether a Full Health Technology Assessment (HTA) is required or not and to support price negotiations in cases where a HTA can be avoided. TTR of novel anti-cancer drugs are extended if a HTA is required.

OBJECTIVE

The objective of this study was to give an appropriate representation of the TTR for novel oncology medicines in Ireland compared to six European countries and the UK.

METHODS

We abstracted the 35 novel anti-cancer medicines included in the Post (2023) analysis from our database which includes all drugs evaluated by the NCPE along with reimbursement timelines [1]. The start date was 1 January 2016 and database lock was 1 January 2021. The study design involved investigating TTR for novel anticancer medicines across 7 high income European countries and the UK. For these sample of countries, except for the Netherlands, the data on TTR were publicly available. For Ireland, two TTR measures were estimated: from EMA approval to reimbursement (TTR_e) consistent with the Post (2023) analysis and from RR submission to reimbursement (TTR_{rr}). The relevant Health Technology Assessment (HTA) and reimbursement websites for each country were used to identify decision information and dates. To evaluate TTR, the time interval was calculated in calendar days for both TTR_e and TTR_{rr} measures in each country for each drug. A median was obtained for each country to analyse the TTR.

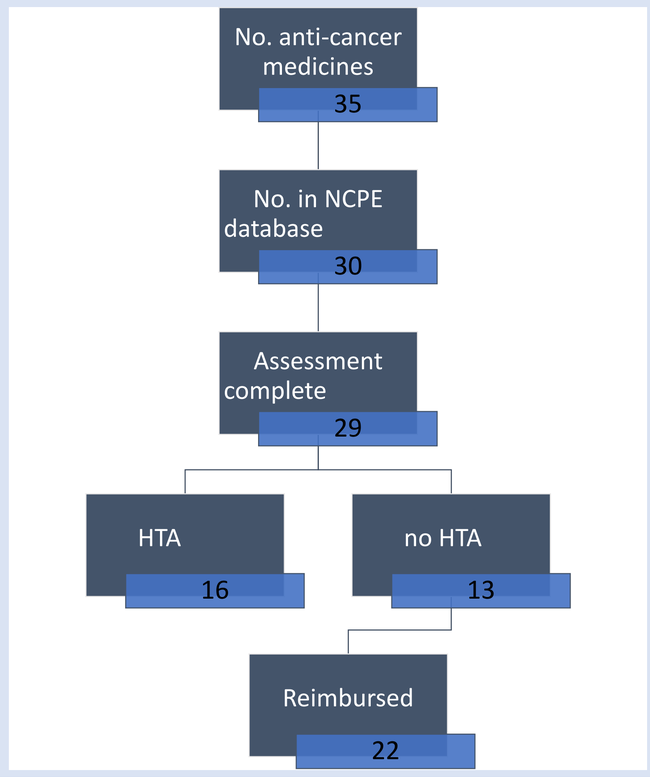
RESULTS

Figure 1 shows that 30 of the 35 anti-cancer medicines were assessed by the NCPE with 29 of the assessment completed by database lock. Of the 29 medicines, 56% were subject to a HTA and 44% were subject to price negotiations and therefore avoided a HTA. 22 of the 35 (63%) medicines were reimbursed in Ireland (Figure 1 and 2). This compares to a median reimbursement rate of 80% across the seven countries. Only Belgium had a lower reimbursement rate than Ireland at 60%. Median TTR_e in Ireland was 675 days which compares to a median TTR of 234 across the seven countries. Only Belgium had longer TTR than Ireland with a median TTR of 742 days (Figure 3). Median TTR_{rr} was 566 days in Ireland, placing Ireland ahead of Belgium, Switzerland and Norway. Figure 4 shows the proportion of total time attributed to the different stages of the reimbursement process in Ireland. One third of the total TTR is due to delays in submitting the RR and HTA. The other two thirds are attributed to NCPE review time and price negotiations.

CONCLUSION

The study confirms previous analysis showing Ireland lagging behind other European countries in terms of access to novel oncology medicines using TTR_E. However, Ireland's ranking improves when arguably the more accurate TTR_{rr} measure is used. These findings suggest delay in TTR among high-income countries is most likely caused by the process of HTA , price negotiations and in the case of Ireland, delays in submitting the RR and HTA submissions. Further work is required to uncover the true start date for other countries for a more accurate representation of TTR across Europe and where in the reimbursement process do the delays occur.

Figure 1: Flow diagram for Ireland



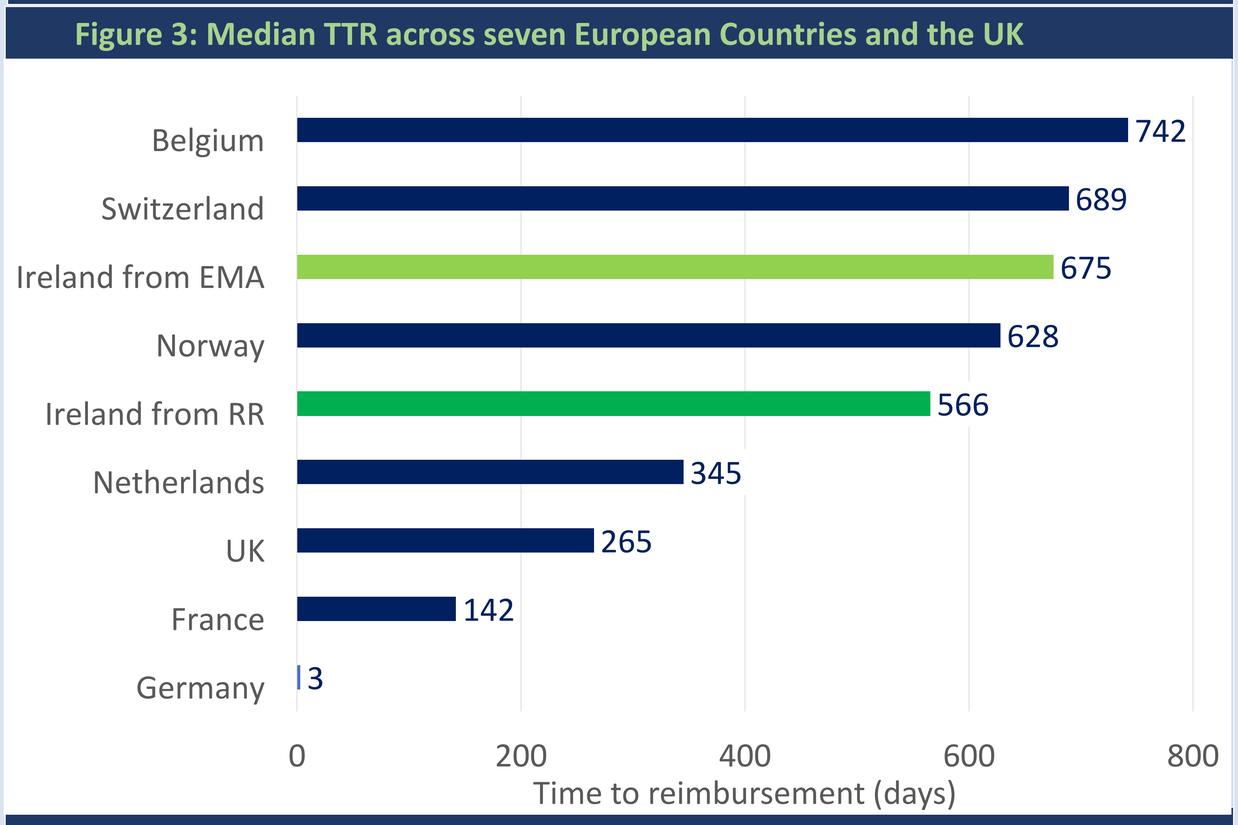
Source: Salutem Insights

Figure 2: Reimbursement rates across seven European countries and the UK

Country	No. censored	No. applied for reimbursement	Reimbursement rate
Germany	0	35	100%
France	6	29	83%
UK	5	30	86%
Netherlands	5	30	86%
Norway	9	26	74%
Switzerland	12	23	66%
Ireland	13	22	63%
Belgium	14	21	60%

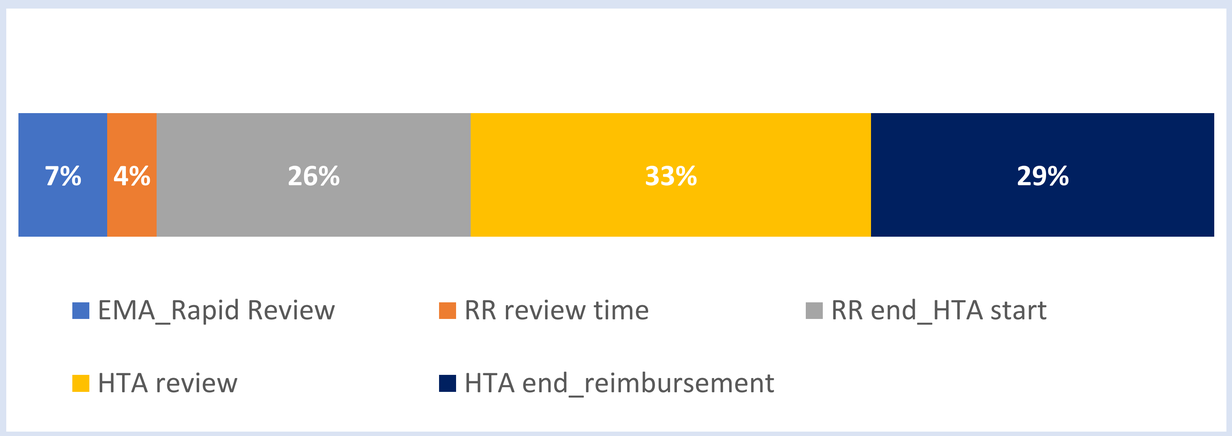
Source: Post et al (2023), Salutem Insights

Figure 3: Median TTR across seven European Countries and the UK



Source: Post et al (2023), Salutem Insights

Figure 4: Proportion of time for stages of reimbursement for reimbursed medicines in Ireland



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1. Post HC, Schutte T, van Oijen MG, van Laarhoven HW, Hollak CE. Time to reimbursement of novel anticancer drugs in Europe: a case study of seven European countries. ESMO open. 2023 Apr 1;8(2):101208.

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