HPR84

The Price Negotiation Phase of the Reimbursement Process In Ireland

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BACKGROUND

Ireland has a well-established reimbursement process for new medicines[1]. Like other countries in Europe, the reimbursement process includes an evaluation and a price negotiation phase[2]. Submissions are evaluated by the National Centre for Pharmacoeconomics (NCPE), while price negotiations are conducted by the Health Service Executive (HSE) Drugs Group[2]. The HSE Drugs Group is a national committee whose role involves making recommendations to the HSE Executive Management Team (EMT) in relation to each individual application having considered the criteria under the 2013 Health (Pricing and Supply of Medicines) Act[3]. The HSE Drugs Group considers the NCPE assessments (both Rapid Reviews and health technology assessments (HTAs)), the outputs from commercial engagements, patient interest group submissions and other pertinent information in advance of providing its recommendation to the HSE EMT[3].

In some case, the HSE Drugs Group recommend restrictions to reimbursement in the form of a managed access protocol (MAP). A MAP imposes the eligibility criteria attached to reimbursement support of a medicine. Criteria applied include controls on prescribing authority, clinical diagnostic and severity criteria, previous lines of treatment, concomitant treatments, outcome data collection, and validations within the reimbursement claims system. Using the guidance from the HSE Drugs Group, the HSE is able to take account of the challenges faced by patients in terms of unmet need and the potential budget impact of the drug, alongside considerations of cost effectiveness[3].

The outcomes and the timelines associated with the assessment phase and overall reimbursement timelines has been well documented for Ireland but there is a dearth of information on the price negotiation phase.

OBJECTIVE

The objective was to examine the price negotiation phase in terms of timelines such as the average time between the different stages of the price negotiation phase, number of items reviewed by the HSE Drugs Group each year and what percentage of drugs with a MAP in place.

METHODS

We developed a database derived from all evaluations conducted by the NCPE from January 2015 until December 2023. This database includes data on full indication, therapeutic area, oncology/orphan status, Rapid Review and HTA start and end date. Data from the HSE Drugs Group meetings were added to the database, including date of first HSE Drugs Group meeting, number of meetings required and date of reimbursement recommendation4. Furthermore, information from the Medicines Management Programme (MMP) on MAPs were added to the database. This database was fed into a Power BI dashboard, and descriptive statistics were applied.

RESULTS

Over the 2015-2023 period, 244 drugs were reviewed by the HSE Drug Group. The number of drugs reviewed at HSE Drugs Group meetings has decreased in recent years reflecting the complexity of medicines under review.

The average time from Rapid Review/HTA end to securing the first HSE Drug Group meeting was 194 days (6.4 months) over the 2015-2023 period. The time to secure a meeting peaked at 276 days (9.1 months) in 2022 before reducing to 236 days (7.8 months) in 2023. The average time taken for the HSE Drugs Group to make a recommendation has decreased from 83 days (2.7 months) in 2015 to 36 days (1.2 months) in 2023 (see figure 1). In addition, the average time taken from HSE Drugs Group reimbursement recommendation to actual reimbursement was 248 days (8.2 months). Figure 1 shows that this part of the price negotiation phase has been highly variable over the 2015-2023 period peaking at 495 days in 2019 before reducing to a 79 days in 2023.

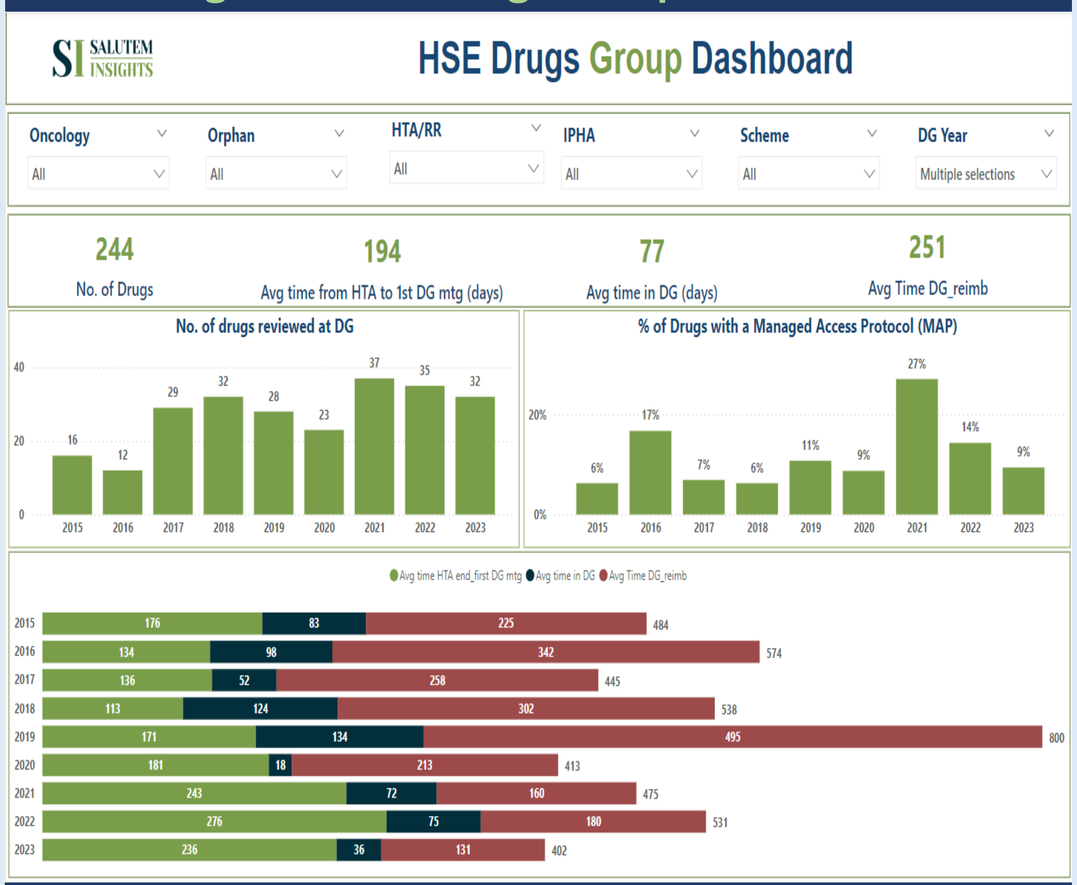
MAPs are becoming an important feature of the HSE Drugs Group recommendation with on average 12% of drugs subject to a MAP (see figure 1). A MAP typical adds to reimbursement timelines following the HSE Drugs Group recommendation as shown in figure 2.

Figure 3 presents the dashboard for oncology medicines, which represent 53% of all drugs reviewed at HSE Drugs Group. The figure highlights that MAPs are relatively new to the oncology space and that average timelines for oncology medicines are typically longer than all medicines. A similar picture emerges from a review of orphan medicines (not shown).

CONCLUSION

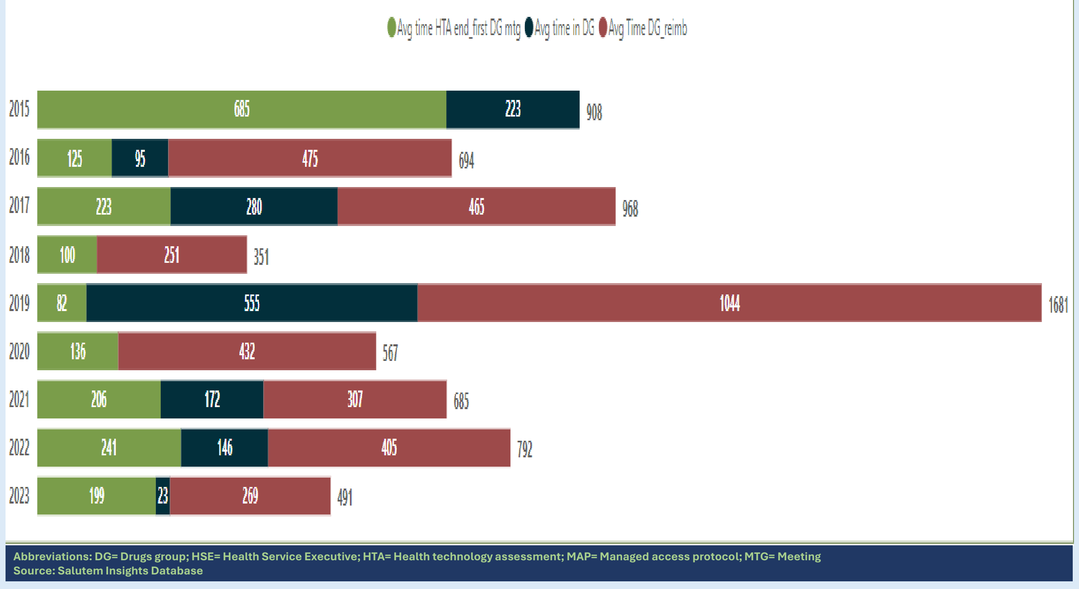
The HSE Drugs Group plays a crucial role in the reimbursement of new medicines in Ireland, and it is essential that pharmaceutical companies seeking market access, especially those in the oncology and rare disease domains are prepared for this stage of the process and the timelines. The results above coupled with current and expected future trends of high-cost drugs and delays in access to medicines, highlights that price negotiations through the HSE Drugs Group will play a pivotal role in shaping access to drugs in the future1.

Figure 1: HSE Drugs Group Dashboard



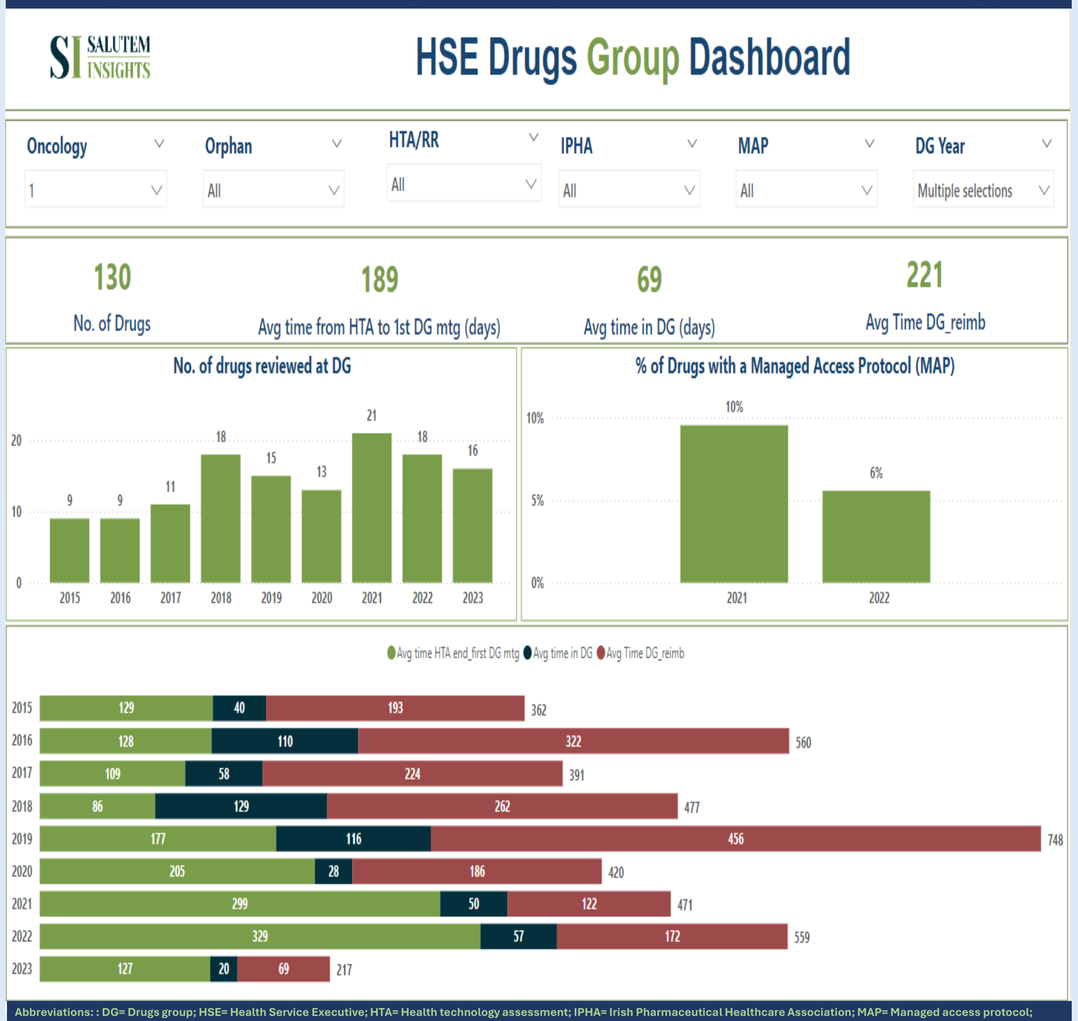
Abbreviations: DG= Drugs group; HSE= Health Service Executive; HTA= Health technology assessment; IPHA= Irish Pharmaceutical Healthcare Association; MTG= meeting; RR= Rapid review
Source: Salutem Insights Database

Figure 2: Timelines with a MAP



Abbreviations: DG= Drugs group; HSE= Health Service Executive; HTA= Health technology assessment; MAP= Managed access protocol; MTG= Meeting
Source: Salutem Insights Database

Figure 3: HSE Drugs Group Dashboard: Oncology



Abbreviations: : DG= Drugs group; HSE= Health Service Executive; HTA= Health technology assessment; IPHA= Irish Pharmaceutical Healthcare Association; MAP= Managed access protocol; MTG= meeting; RR= Rapid review
Source: Salutem Insights Database

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