Reimbursement Decisions for Innovative Drug Technologies in Poland: Duration of Reimbursement processes and Impact of HTA recommendation

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Introduction

In Poland, the reimbursement process is detailed in the Act on the Reimbursement of Medicines, Foodstuffs for Particular Nutritional Uses, and Medical Devices[1] (Reimbursement Act). The process is initiated by the drug Marketing Authorisation Holder (MAH) submitting an application to the Ministry of Health (MoH). The health technology assessment (HTA) done by the Agency for Health Technology Assessment and Tariff System (AOTMiT) is a part of the process and results in a recommendation on the public funding of the drug, which is the starting point for negotiations of the price and reimbursement conditions with the Economic Commission. Upon the conclusion of price negotiations, the MoH decides on the appropriateness of the drug's reimbursement. A drug that has obtained reimbursement is placed on the reimbursement list, which is regularly updated (every three months from 2024).

According to the reimbursement law, the application is considered within 180 days, but decision-making practice shows that processes in Poland take significantly longer. The last amendment to the Reimbursement Act (November 2023)[2] introduces a requirement to supplement the application with additional "conditions" presented in the conditionally positive recommendation of ATOMiT, subject to verification by AOTMiT and extends the time of assessment.

Objectives

The purpose of this study is to evaluate the duration of reimbursement processes for innovative drug technologies in Poland divided by drugs available within the hospital (under drug programs & chemotherapy) and retail availability categories. Describing the impact of HTA recommendations (number of positive, negative, and conditional assessments) on reimbursement decisions made by the MoH, expressed in the number and percentage of positive decisions implemented.

Methods

The analysis was carried out on two data sets: process covers all reimbursement applications regarding innovative drugs evaluated by AOTMiT from January 1, 2021 to December 14, 2023 and analysis of all positive decisions published from March 2021 to January 2024. We analyzed over 250 applications for reimbursement for innovative drugs, including those in the mature phase (with issued HTA recommendation & at least 180 days passed since the date of the order's submission to AOTMiT). Reimbursement decisions are not published, therefore the analysis was based on publicly available data, namely: documentation published on the AOTMiT website and reimbursement lists published by the Ministry of Health. The duration of the processes was calculated based on the adopted assumptions (1) the starting point is the date of submission of the application for evaluation by AOTMiT[3]; (2) decisions are identified through the analysis of reimbursement lists[4]; (3) the lack of recognition of a positive decision means that the process is ongoing, has been suspended, or ended with a denial of the requested reimbursement; (4) the endpoint of the process is the effective date of the reimbursement decision.

Results

According to the results of the analysis, in the years 2021-2023, 254 unique applications for innovative drug technologies reimbursement were submitted in Poland. Among all applications, 226 were identified as mature applications. 80% of mature applications were successful - received the requested reimbursement and were made available to Polish patients (Fig. 1). In drug programs, the success rate was 82%, and in retail reimbursement, it was 75%.

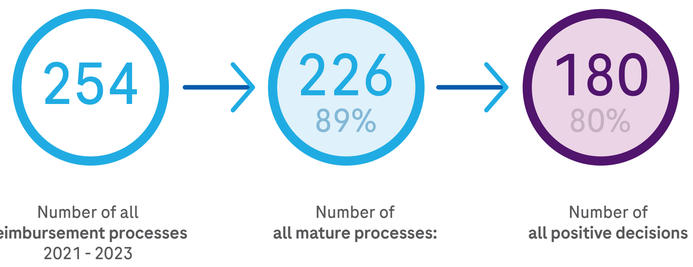

Figure 1. Summary of reimbursement processes in 2021 – 2023 included in analysis

In the years 2021-2023, 268 positive reimbursement decisions were made and implemented, of which 204 (76%) concerned reimbursement under the drug program, 61 (23%) in retail, 3 in chemotherapy catalog. Most new decisions within the drug program were made for drug technologies used in oncology (49%) and immunosuppression (21%).

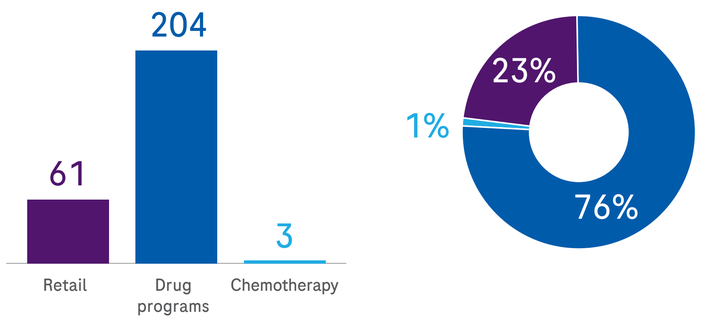

Figure 2. Reimbursement decisions according reimbursement category – retail, drug program, chemotherapy catalog

The duration of reimbursement processes (from submitting an application for HTA assessment to reimbursement decisions) in 5 categories - retail, drug program, catalog of chemotherapy, oncology and orphan drugs shows an accelerating trend. The analysis of all decisions indicated that the average process duration was 566 days (median 449 days) in 2021 and 316 days (median 269 days) in 2023. In the drug program category, process duration in 2021 was on average 616 days, the vast majority of processes (76%) lasted longer than a year. In 2023, the duration of the process was shortened to an average of 315 days.

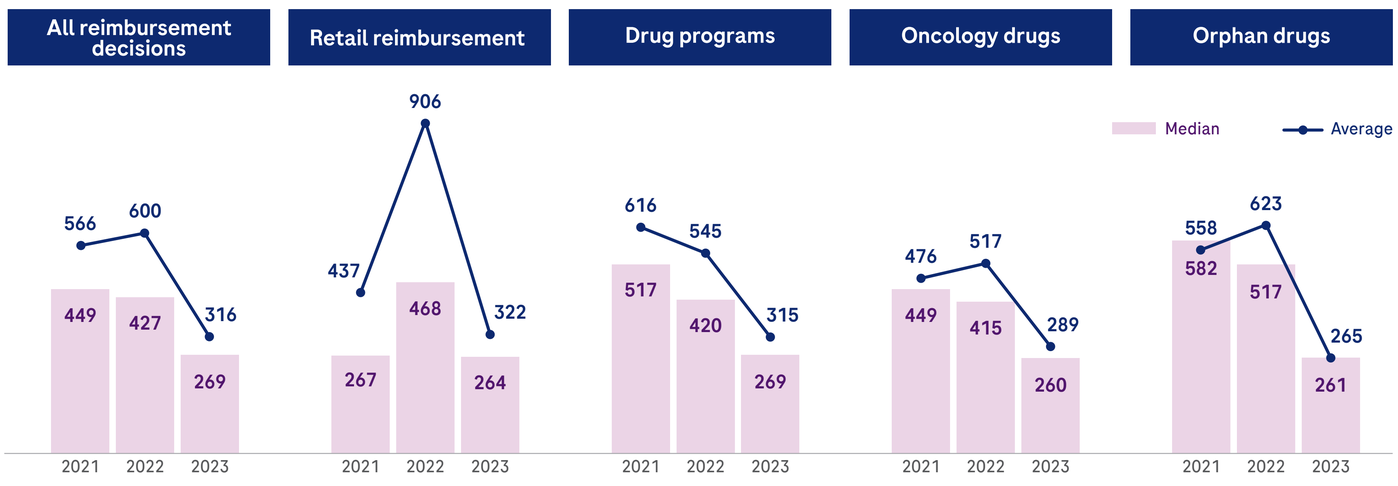

Figure 3. Duration of reimbursement processes according reimbursement category – retail, drug program, chemotherapy catalog and therapeutic areas

Among all positive reimbursement decisions from the last 3 years, only 13% were preceded by an unconditionally positive HTA recommendation, 13% were successful despite negative reimbursement recommendation, and the majority of drugs received a conditional recommendation - positive with conditions or negative with a chance in certain circumstances (Fig. 4).

Positive recommendation (POS) - the validity of the reimbursement was indicated in the summary of the recommendation
Positive recommendation with conditions (POS-) the summary indicates the validity of the reimbursement under certain conditions
Negative recommendation with a chance (NEG+) the summary negates the validity of the reimbursement, while the justification indicates the circumstances under which a reimbursement is possible
Negative recommendation (NEG) - the validity of the reimbursement was denied

Figure 4. Type of AOTMIT recommendation issued for innovative drugs that received positive reimbursement decisions

Conclusions

- In Poland, in the years 2021 - 2023, the success rate of reimbursement processes for innovative drugs was 80%.
- The average duration of the reimbursement process has been shortened by 250 days over the last 3 years, ultimately, the process is to last one year.
- The vast majority of positive reimbursement decisions were based on a conditional HTA recommendation. The need to meet the condition included in the recommendation is particularly important in the context of the new Reimbursement Act, which increases the importance of the HTA stage and, transferring the shaping of the financial offer to an earlier stage, even before the start of price negotiations.

References:

1. Act of 12 May 2011 on the reimbursement of medicines, foodstuffs for particular nutritional uses and medical devices
2. Act of 17 August 2023 amending the Act on the reimbursement of medicines, foodstuffs for particular nutritional uses and medical devices and certain other acts
3. Date of HTA assessment orders to AOTMiT available at: https://bip.aotm.gov.pl/zlecenia-mz-2024
4. Reimbursement lists available at: https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych

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