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Time to Access for Innovative Medicines in Greece: A Retrospective Analysis of Public Data in 2024-2025

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KEY FINDINGS

- Among the 17 eligible medicines reaching Positive List inclusion in each cohort year, mean time to reimbursement was descriptively 4% lower in 2025 versus 2024 (696 vs 723 days).
- Within the selected cohorts, orphan-designated medicines showed a larger descriptive difference in mean time to reimbursement (-23%), warranting further investigation into factors associated with their distinct access pathway.
- However, the small cohort sizes require cautious interpretation of year-on-year differences.

INTRODUCTION

- The EFPIA Patients W.A.I.T. (Waiting to Access Innovative Therapies) Indicator is used to assess the availability and timing of access to innovative medicines across European countries after European Union (EU) marketing authorization.[1]
- Findings from EFPIA Patients W.A.I.T. Indicator 2025 Survey which were published May 2026, highlighted substantial cross-country variation in time to availability.[2]
- Greece performed below the European average, demonstrating a mean time to availability of 641 days, compared with a European mean time to availability of 597 days.[2,3]
- In Greece, innovative medicines undergo a multistep pricing, health technology assessment (HTA) and negotiation process before achieving officially reimbursed access; collectively accounting for the overall time between marketing authorization and official reimbursement.[4]

OBJECTIVE

- This analysis aimed to evaluate the mean time from European Commission (EC) Decision [5] to official reimbursement, defined as Positive List (PL) [6] inclusion, for innovative medicines in Greece during 2024 and 2025, and to identify the key process intervals contributing to the overall time to reimbursed access.

METHODS

- A retrospective descriptive analysis of publicly accessible databases was performed applying predefined criteria.
- Data were retrieved from publicly accessible governmental sources, including European Medicines Agency records [5], Price Bulletins (PB) [7] , Positive Reimbursement Lists (PL) [6] , and Ministerial Decisions (MD) [6] on reimbursement, published through the official websites of the Greek Ministry of Health (MoH) and the DIAVGEIA transparency portal [8].
- Innovative medicines were defined as products authorized in Greece under Article 8(3) of Directive 2001/83/EC [9] with an EC Decision between 2021-2025, listed for the 1st time in one Price Bulletin (PB) [7] between 2022-2025 and included in the Positive List (PL)[6] of 2024 & 2025.
- New indications of previously authorized medicines and vaccines were excluded from the analysis.
- For comparable observation, products were analyzed by year of PL inclusion (2024 versus 2025) to assess temporal changes in the overall reimbursement timeline and its individual process intervals.
- The following eligibility criteria were applied:

a) 2025 PL cohort: PB inclusion from 1 January 2023 onwards and EC Decision from 1 January 2022 onwards and

b) 2024 PL cohort: PB inclusion from 1 January 2022 onwards and EC Decision from 1 January 2021 onwards.

- The overall time to reimbursement was divided into three consecutive intervals:

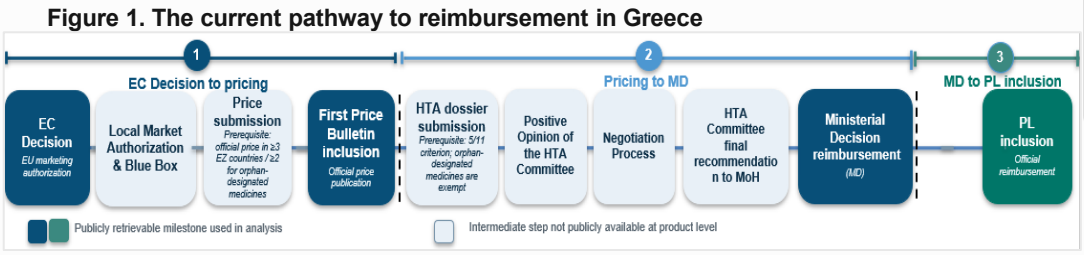
1) EC Decision to pricing: from the date of the EC Decision to the product's first inclusion in a Greek PB;

2) Pricing to MD: from first pricing to the issuance of the MD on reimbursement; and

3) MD to PL inclusion: from issuance of the MD to publication of the PL in which the product was first included, marking the official reimbursement (**Figure 1**).

- The time from EC Decision to official reimbursement in Greece, defined as inclusion in the PL, was calculated in calendar days for each medicinal product and summarized using the mean. Timelines were summarized using means and no statistical comparison was performed.

Figure 1. The current pathway to reimbursement in Greece



EC: European Commission, EZ: Eurozone, HTA: Health Technology Assessment, MD: Minesterial Decision, MoH: Ministry of Health; PL: Positive List

- A subgroup analysis was also conducted for orphan-designated medicines [10], applying the same methodology, given their specific regulatory pathway, including external price referencing based on two Eurozone (EZ) countries rather than three [11] and exemption from the 5/11 criterion (prior reimbursement in at least 5 of 11 specified EU countries) [12].

Limitations

- The analysis included only medicines meeting the predefined eligibility criteria.
- Medicines still awaiting reimbursement were not captured, while the eligibility criteria may have excluded products with longer access timelines.
- Product-level dates for intermediate HTA and negotiation timepoints are not publicly available; therefore, the pricing-to-MD interval could not be disaggregated into HTA application submission, assessment, negotiation, final recommendation, and decision-making steps.
- The analysis was descriptive. The annual cohorts were small, with 17 medicines per year, and the orphan-designated subgroups included only 7 medicines in 2024 and 6 in 2025; so, mean values and year-on-year differences should therefore be interpreted cautiously.
- The W.A.I.T. comparison was included for external context only, because the two analyses applied different methodological approaches.

Conclusions

- Mean time from EC Decision to PL inclusion remained approximately 2 years, with only an observed reduction of 27 days (−4%) in 2025.
- EC Decision-to-pricing remained the largest measured interval. Its improvement was partly offset by longer post-pricing intervals in 2025.
- Orphan-designated medicines showed a descriptively shorter mean time to reimbursement in 2025 (n=6) vs 2024 (n=7). Whether their distinct pricing and reimbursement provisions, including different external price-referencing requirements and exemption from the 5/11 criterion, contributed to shorter timelines warrants further investigation, particularly given the small subgroup size.
- Reducing time to reimbursement may require improvements across both pricing and post-pricing processes. More granular product-level data are needed to identify the contribution of individual HTA, negotiation, and administrative stages.
- Findings are directionally consistent with the broader timing reported by the EFPIA W.A.I.T. Indicator for Greece; however, methodological differences preclude direct comparison.
- Future research should assess whether national process reforms and implementation of EU Joint Clinical Assessment (a joint EU-level assessment of the relative clinical effectiveness of new medicines) are associated with measurable changes in time to reimbursement in Greece.

RESULTS

- A total of 373 and 424 SKUs entered the PL in 2024 and 2025, respectively. Based on the predefined eligibility criteria, 17 innovative medicines were included in the analysis in each year (**Figure 2**).

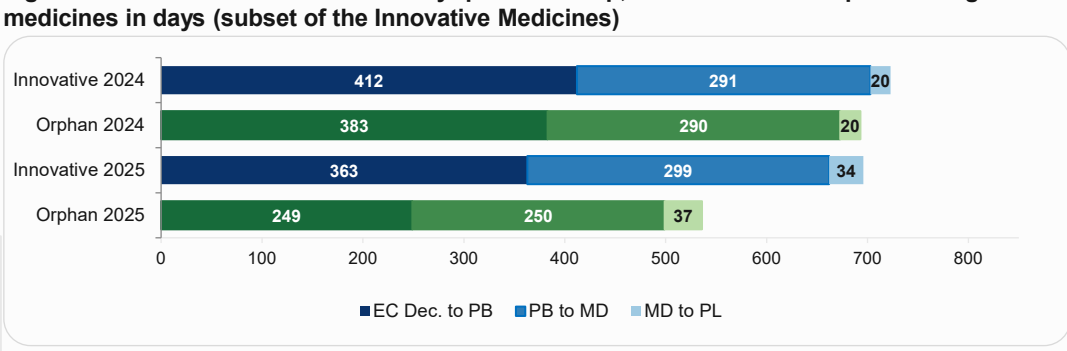
Figure 2: Cohort Selection Funnel for Innovative Medicines Included in the 2024 and 2025 Analyses



Important notes: the funnel changes unit at the final step—from SKUs to a brand-level sample. Excluded from the Innovative medicines analysis: vaccines and new indications. Orphan brands remain a subset of the final sample: 6 of 17 in 2025; 7 of 17 in 2024.
PL: Positive List, SKU: Stock Keeping Unit

- Among the 17 eligible medicines reaching PL inclusion in each cohort year, mean time from EC Decision to PL inclusion was 723 days in 2024 and 696 days in 2025, corresponding to a descriptive difference of -27 days (-4%) (**Figure 3**).

Figure 3. Time to reimbursement by process step, Innovative vs Orphan designated medicines in days (subset of the Innovative Medicines)



PB: Price Bulletin, **MD**: Ministerial Decision, **PL:** Positive List
Source: Price Bulletins [7] Positive Reimbursement Lists [6] and Ministerial Decisions for reimbursement inclusion [6] published on the official websites of the Greek Ministry of Health [13] and DIAVGEIA transparency portal [8]

- EC Decision-to-pricing remained the longest measured interval, decreasing from 412 to 363 days and accounting for 57% and 52% of the total reimbursement timeline in 2024 and 2025, respectively (**Table 1**).
- The MD-to-PL interval was the shortest component but showed the largest relative increase, from 20 to 34 days (+70%) (**Table 1**), which coincided with fewer PL publications in 2025 (n=3) than in 2024 (n=5).
- Consequently, the post-pricing interval (from pricing to PL inclusion) increased from 311 days in 2024 to 333 days in 2025 (**Table 1**), partially offsetting the improvement observed in EC Decision-to-pricing.

Table 1. Time to Reimbursement - Innovative Medicines

Year	Number of Medicines	EC Decision to PB (Days)	PB to MD (Days)	MD to PL (Days)	Post Pricing (MD+PL Days)	Total days
2024	17	412 (57%)	291 (40%)	20 (3%)	311 (43%)	723
2025	17	363 (52%)	299 (43%)	34 (5%)	333 (48%)	696
Change 2024→2025		-49 days (-12%)	+8 days (+3%)	+14 days (+70%)	+22 days(+7%)	-27 days (-4%)

PB: Price Bulletin, **MD**: Ministerial Decision, **PL:** Positive List, **HTA:** Health Technology Assessment
Source: Price Bulletins [7] Positive Reimbursement Lists [6] and Ministerial Decisions for reimbursement inclusion [6] published on the official websites of the Greek Ministry of Health[13] and DIAVGEIA transparency portal [8]

- Among orphan-designated medicines, mean time to reimbursement was 693 days in 2024 (n=7) and 536 days in 2025 (n=6), corresponding to a descriptive difference of -157 days (-23%). EC Decision-to-pricing decreased from 383 to 249 days, while post-pricing interval decreased from 310 to 287 days in 2025 (**Table 2**).

Table 2. Time to Reimbursement for Orphan-Designated Medicines (subset of Innovative Medicines)

Year	Number of Medicines	EC Decision to PB (Days)	PB to MD (Days)	MD to PL (Days)	Post pricing (MD+PL Days)	Total days
2024	7	383 (55%)	290 (42%)	20 (3%)	310 (45%)	693
2025	6	249 (46%)	250 (47%)	37 (7%)	287 (54%)	536
Change 2024→2025		-134 days (-35%)	-40 days (-14%)	+17 days (+85%)	-23 days (-7%)	-157 days (-23%)

PB: Price Bulletin, **MD**: Ministerial Decision, **PL:** Positive List , **HTA:** Health Technology Assessment
Source: Price Bulletins [7] Positive Reimbursement Lists [6] and Ministerial Decisions for reimbursement inclusion [6] published on the official websites of the Greek Ministry of Health [13] and DIAVGEIA transparency portal [8]

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