Time to Access Orphan Medicines in Greece

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Introduction

- Approximately 30 million individuals in Europe and 300 million people globally are living with rare diseases. Timely access to orphan drugs remains an on- going challenge in most European countries (1)
- The need of Health Technology Assessment (HTA) in facilitating healthcare decision-making has grown in recent years, especially as publicly-funded health insurance plans seek transparent and sustainable healthcare financing models (2).
- Greece in 2018 implemented an HTA system for decision-making regarding the reimbursement of medicinal products (MPs) including orphans (3).

Objective

- The purpose of the present study was to compare the time elapsed from market authorization to reimbursement of new MPs with or with- out orphan designation, in the current year in Greece.

Methods

- Data were obtained from the Greek HTA Committee's database and other publicly available sources for MPs containing new active substances that were included in the national Positive Reimbursement List in February 2023.
- Median time intervals were computed in calendar days.

Results

- The national Positive Reimbursement List in February 2023 encompassed a total of 53 newly approved for reimbursement MPs containing new active substances, among which 13 had an orphan designation (Figure 1).
- Approximately 20% of new active substances, excluding orphan drugs, and 15.4% of orphan drugs were approved with restrictions.
- For non-orphan MPs, the median time (25th-75th percentile) between market authorization and the submission of the HTA dossier was 420 days (260-856). On the other hand, for orphan MPs, this period was slightly longer at 457 days (360-832), as indicated in Figure 2.
- In terms of the median time from HTA application to reimbursement, non-orphan MPs took 228 days (200-442), while orphan MPs had a notably longer time frame at 417 days (376-570), as shown in Figure 3.
- Finally, the overall median time from market authorization to inclusion in the national Positive Reimbursement List in February 2023 was approximately 666 days (485-1215) for non-orphan MPs and 1032 days (826-1635) for orphan MPs.

Conclusions

- Longer time to access orphan (vs. non-orphan) drugs was attributed to delays both in the dossier application for HTA and in the time from HTA to reimbursement.
- Orphan MPs are a priority of the new European HTA regulation to facilitate timely access across the EU.
- Further actions may be needed to optimize the HTA process for orphan MPs at the national level.

Results

Figure 1. Number of medicinal products approved for reimbursement in February 2023

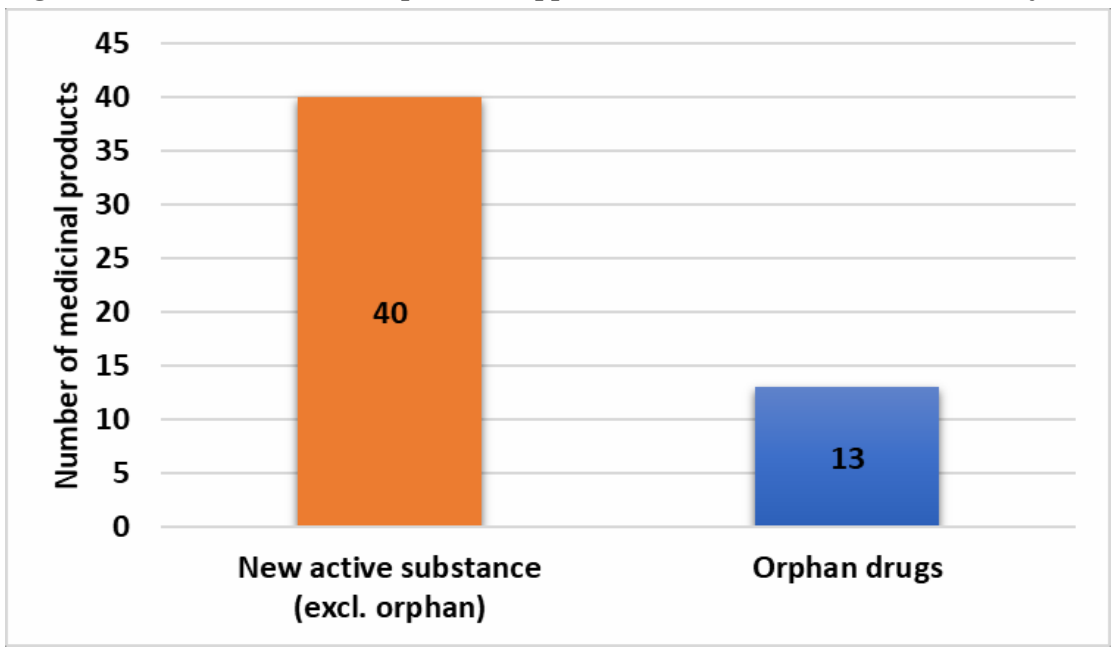


Figure 2. Median (25th-75th percentile) time interval between market authorization and HTA dossier application

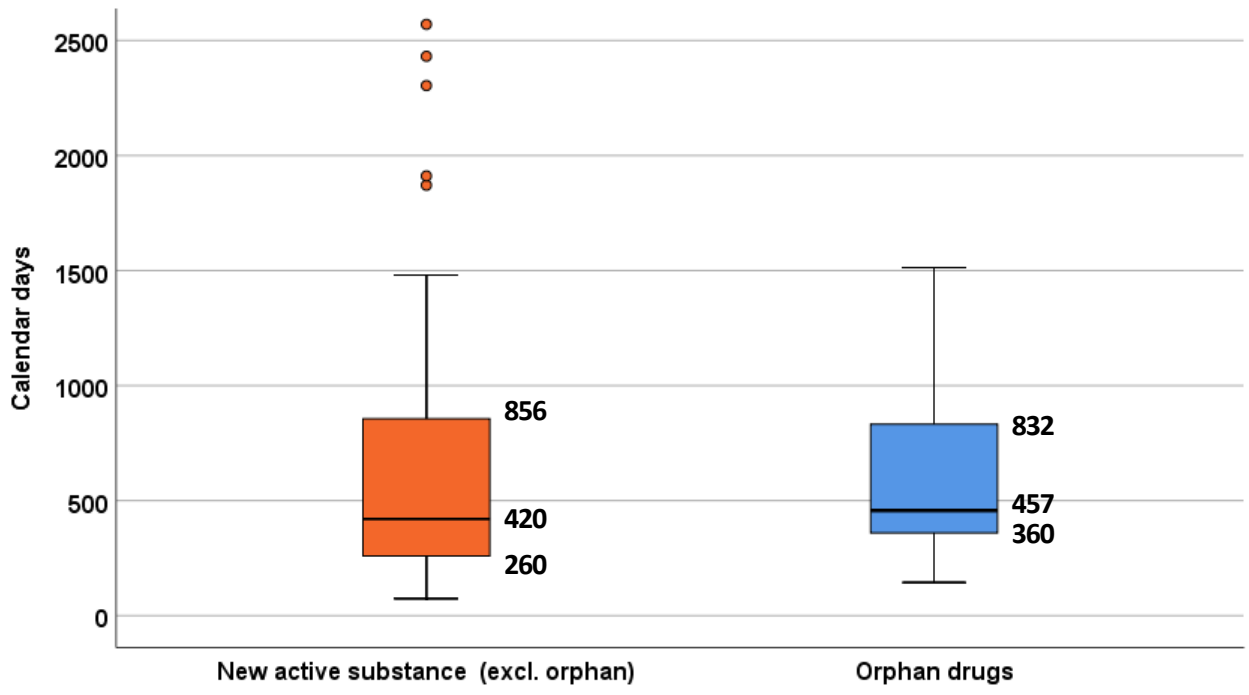


Figure 3. Median (25th-75th percentile) time interval between HTA dossier application and inclusion in the national Positive Reimbursement List in February 2023

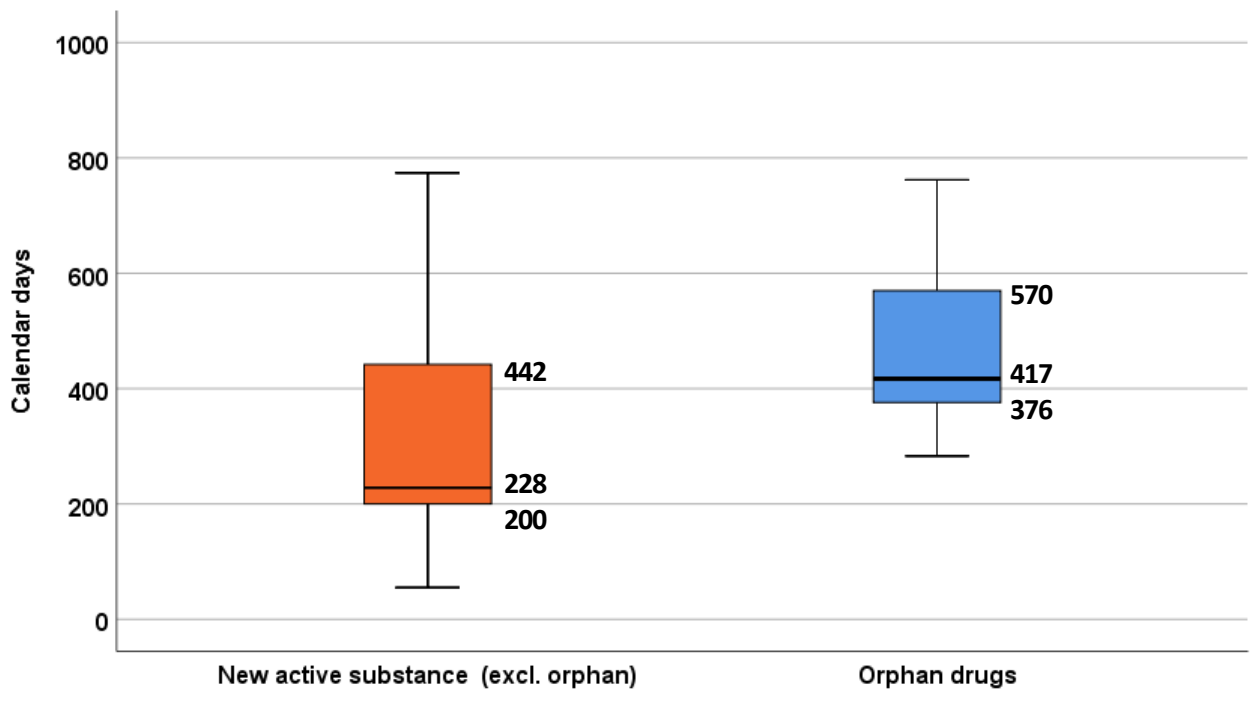
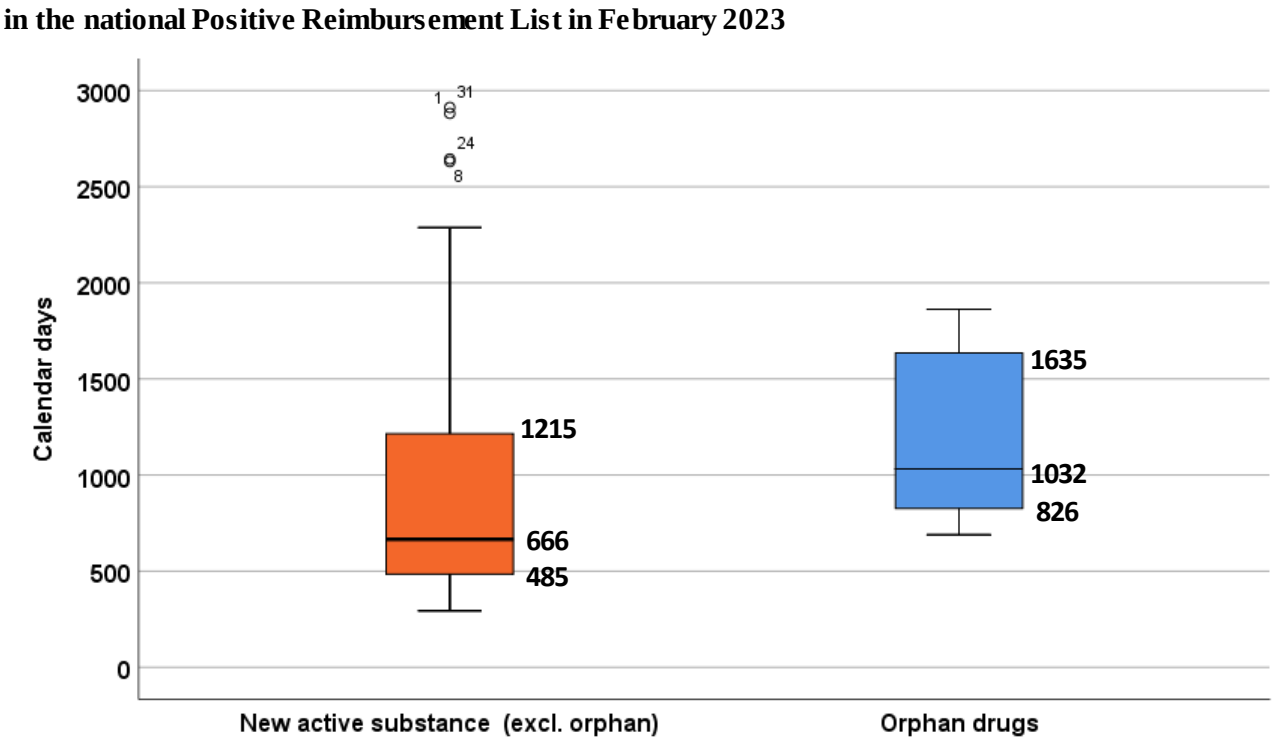


Figure 4. Median (25th-75th percentile) time interval between market authorization and inclusion in the national Positive Reimbursement List in February 2023



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