Time to access pediatric/adolescent vs. adult medicinal products in Greece

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Introduction

- Access to medicines is affected heavily by the national pricing, Health Technology Assessment (HTA) and reimbursement policy.
- Previous research has revealed that access to pediatric medicinal products may be delayed in a national level and 21%-31% of pediatric medicinal products were not marketed (1).
- Greece is among the late adopters of an HTA system in the decision-making for the reimbursement of medicinal products (2).
- This new framework was established in January 2018 and it started operating by the summer of the same year (3).

Objective

- The aim of the present study was to evaluate the time lag between marketing authorization, submission to the Greek Health Technology Assessment (HTA) Committee, and inclusion in the National Positive Reimbursement List of medicinal products intended for adult vs. pediatric/adolescent use in Greece, from January 2018 until December 2021.

Methods

- Data were collected from the European Medicines Agency (EMA), the Hellenic Ministry of Health websites as well as from the Hellenic HTA Committee's database.
- The dataset included all medicinal products which received a marketing authorization/indication extension from EMA over the study period.
- Median times for medicinal products with adult vs. pediatric/adolescent indications were calculated in calendar days.

Results

- A total of 385 and 213 products with adult or pediatric/adolescent indications respectively, were authorised by EMA, from which 146 (37.9% of total approved) and 43 (20.2% of total approved) medicinal products, respectively, were submitted to the Greek HTA Committee, over the study period (Figure 1).
- The median time (25th–75th percentile) from EMA approval to submission to the Hellenic HTA Committee was 312 (199-458) and 365 (246-508) days, for medicinal products with adult or pediatric/adolescent indications, respectively (Figure 2).
- Among medicinal products submitted to the Greek HTA Committee, almost a third (n=54) with adult and a fourth (n=11) with pediatric/adolescent indications were included in the National Positive Reimbursement List during the study period (Figure 3).
- The median time (25th–75th percentile) from EMA approval to inclusion in the National Positive Reimbursement List was 836 (598-982) and 738 (616-1015) days, for products with adult or pediatric/adolescent indications, respectively (Figure 4).

Conclusions

- The new HTA framework is an opportunity to ensure efficient allocation of the country's scarce resources as well as patient access to innovative therapies at affordable prices and in a timely fashion.
- The time interval from EMA approval to submission to the Greek HTA Committee was longer for pediatric/adolescent products, while the respective gap to inclusion in the National Positive Reimbursement List was shorter, compared to medicinal products for adults.
- The special needs of the pediatric/adolescent population should be taken into account in the marketing authorization procedure as well as in the overall HTA process.

Results

Figure 1. Number of products authorized by EMA and submitted to the Hellenic HTA Committee

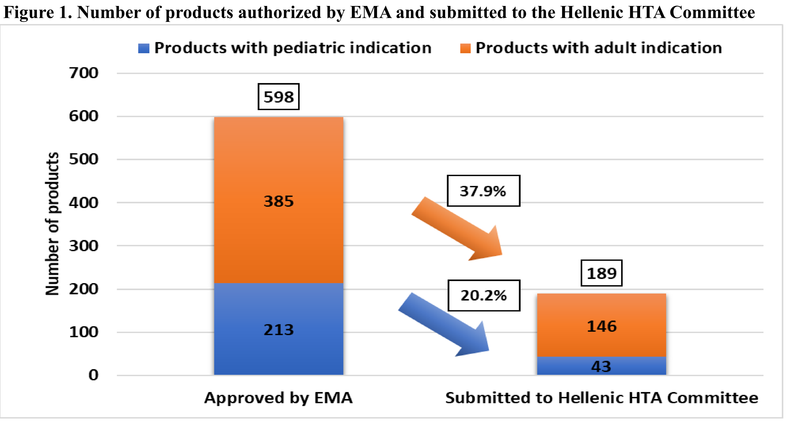


Figure 2. Median (25th-75th percentiles) time interval (in days) between EMA approval and submission to the Hellenic HTA Committee

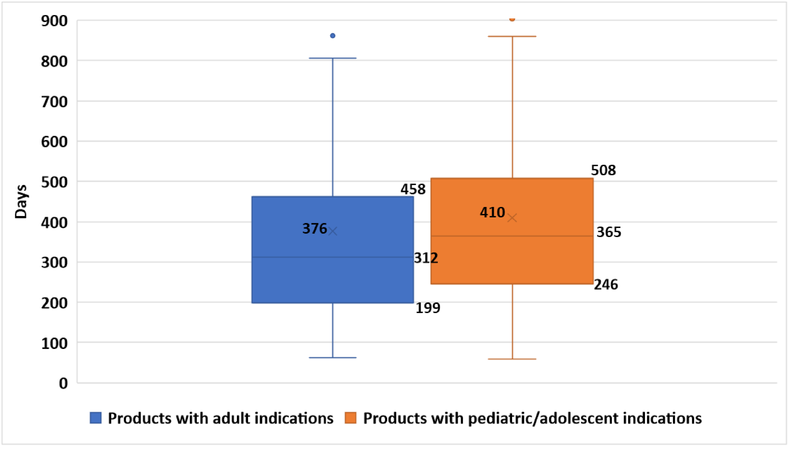


Figure 3. Number of products submitted to the Hellenic HTA Committee that were included in the National Positive Reimbursement List during the study period

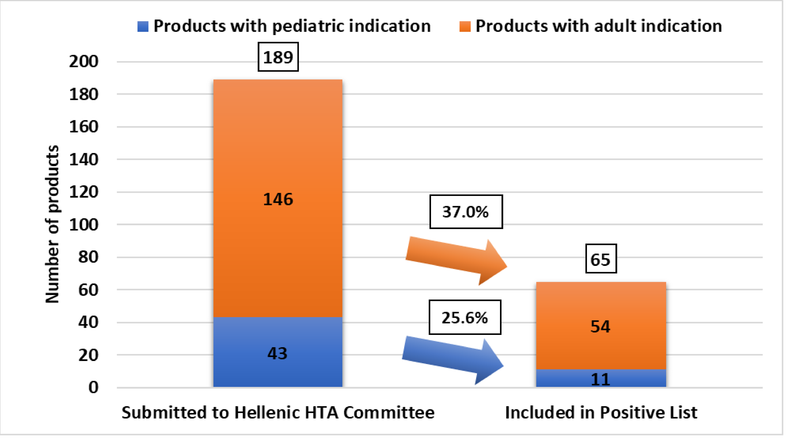
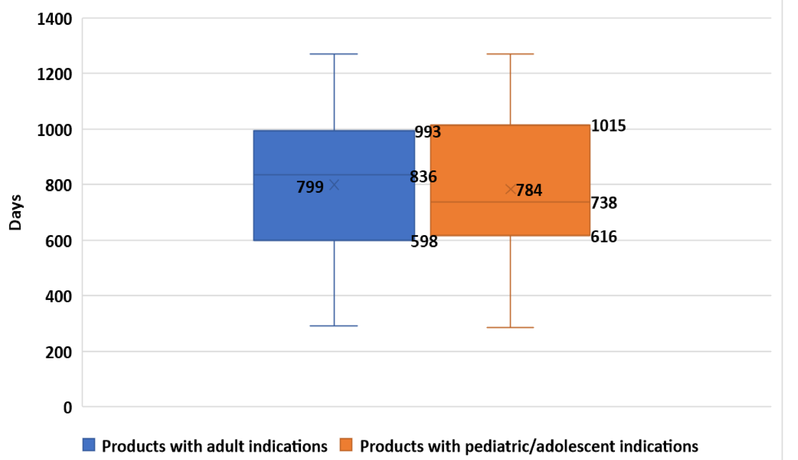


Figure 4. Median (25th-75th percentiles) time interval (in days) between EMA approval and inclusion in the National Positive Reimbursement List



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