Time to Health Technology Assessment of new medicinal products in Greece

Chantzaras A.[1], Margetis A.[1], Kani C.[1], Koutsiouris V.[2], Bacopoulou F.[1]

[1]Health Technology Assessment and Reimbursement Committee, Ministry of Health, Athens, Greece
[2]Ministry of Health, Athens, Greece

Introduction

- The importance of health technology assessment (HTA) in supporting healthcare decision-making has increased in recent years, as publicly-funded health insurance plans strive to find transparent and sustainable models for financing health care (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 purpose of the present study was to evaluate the time elapsed between Health Technology Assessment (HTA) application to completion of the clinical evaluation of new medicinal products (including orphans) in Greece, from July 2018 (establishment of the Greek HTA Committee) until April 2022.

Methods

- Data were collected from the Greek HTA Committee's database and other publicly available sources for medicinal products containing new active substances (including orphan drugs).
- This study concerned applications for new medicinal products, i.e. not included in the reimbursement list and not previously assessed.
- Median time intervals were computed in calendar days.

Results

- During the overall study period (July 2018-April 2022), a total of 177 applications concerning new active substances (140 excl. orphan drugs and 37 orphan drugs) were submitted to the Hellenic HTA Committee (Figure 1).
- The number of HTA recommendations for new active substance (incl. orphans) applications increased from 4, between July 2018 and July 2020 (HTA Committee first operation period), to 87 during the second operation period (July 2020 up to April 2022) (Figure 2).
- In July 2020, 45 applications concerning new active substances (incl. orphan drugs) were under clinical assessment, while, in April 2022, the backlog was reduced to 27 products (Figure 3). The corresponding backlog in the Negotiation Committee, i.e. products under price negotiations (i.e. following the clinical assessment stage), also decreased, from 34 to 24 products.
- The median time (25th-75th percentiles) from HTA application to HTA clinical assessment for new active substance (incl. orphan drugs) applications decreased from 200 (58-231) to 127 (84-178) days between the periods of July 2018-July 2020 and July 2021-April 2022), respectively (Figure 4); the mean interval also decreased from 167 to 153 days.

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.
- Since its establishment, a significant improvement in the performance of the HTA process has been observed by decreasing the backlog of medicinal products as well as the time of HTA clinical assessment.
- Further actions may be needed to optimize the HTA process at the national level.

Results

Figure 1. New active substance HTA applications by submission date period, and type of application

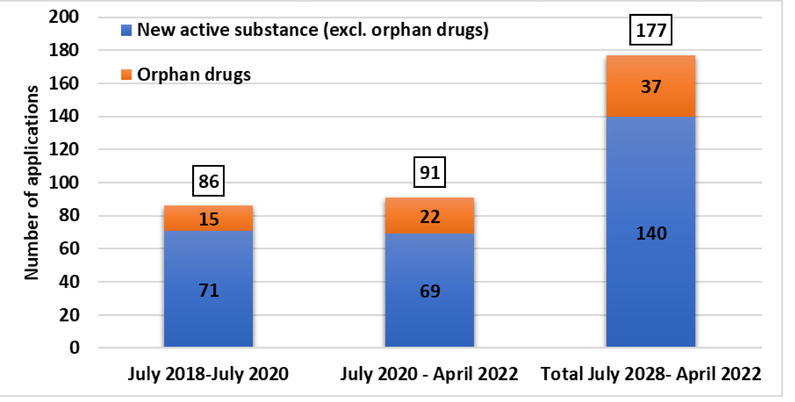


Figure 2. Number of HTA recommendations by period of operation

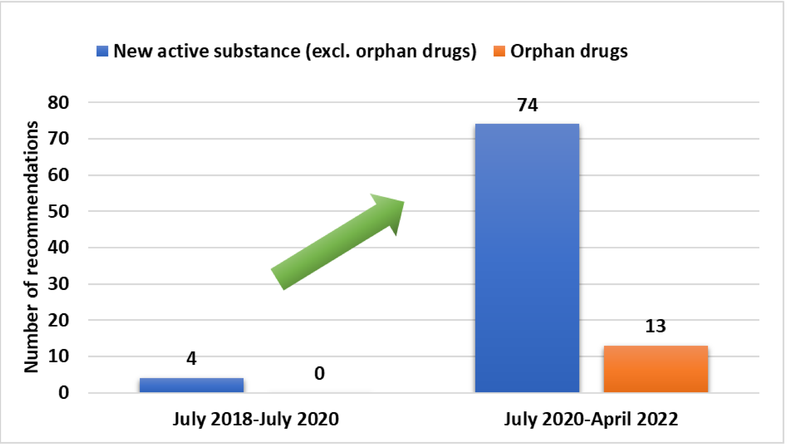


Figure 3. Number of applications concerning new active substances (incl. orphan drugs) under clinical assessment and under price negotiations over time

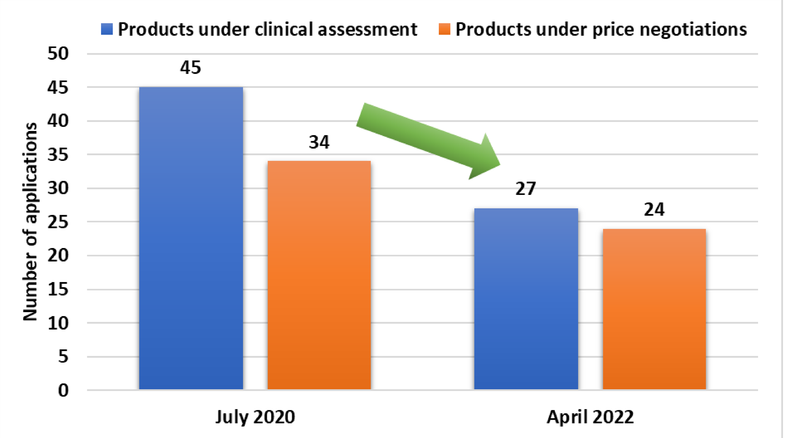
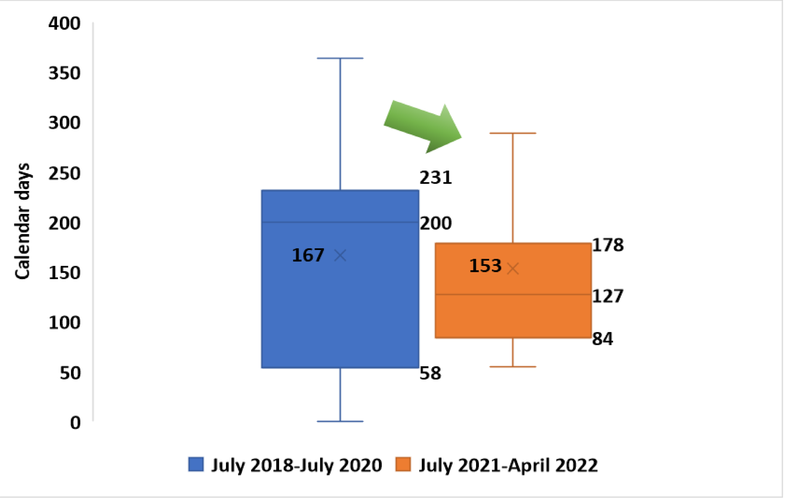


Figure 4. Median (25th-75th percentiles) time interval (in days) between HTA submission of application (new active substances & orphan products) and HTA clinical assessment of application by period



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