Access to Orphan Pediatric and Adolescent Medicinal Products in Greece over 4 Years (2018-2021)

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INTRODUCTION

Despite the framework established by the Pediatric Regulation in the European Union back in 2007 (EC 1901/2006), there is still a significant unmet clinical need for developing medicinal products (MPs) specific for pediatric use.[1]

Additionally, prices, Health Technology Assessment (HTA) and reimbursement policies, all have a significant impact on access to medicinal products. The variability in the time needed for national reimbursement from 133 to 899 days in Europe reflects the disparity in access to medicinal products.[2]

OBJECTIVES

The aim of the present study was to estimate the the time needed to access orphan medicinal products (MPs) for children and adolescents after the establishment of the national HTA and Reimbursement Committee and over a 4-year period (January 2018-December 2021) in Greece.

METHODS

Data were collected from the European Medicines Agency (EMA) and the Greek Ministry of Health websites, as well as from the HTA Committee's database

- Extracted dataset included MPs with a clear reference in their Summary of Product Characteristic (SPC) to pediatric and/or adolescent use

- Data on the orphan status and the therapeutic category (ATC3) of the active substances were also collected

- Median times for MPs with pediatric/adolescent indications and according to their orphan status were calculated based on the marketing authorization date, dossier submission to the Greek HTA Committee and inclusion in the national Positive Reimbursement List

RESULTS

Over the study period, from 54 MPs with orphan pediatric/adolescent indication submitted to EMA, only a fourth, 13 MPs with orphan designation were submitted to the national HTA and Reimbursement Committee (Figure 1)

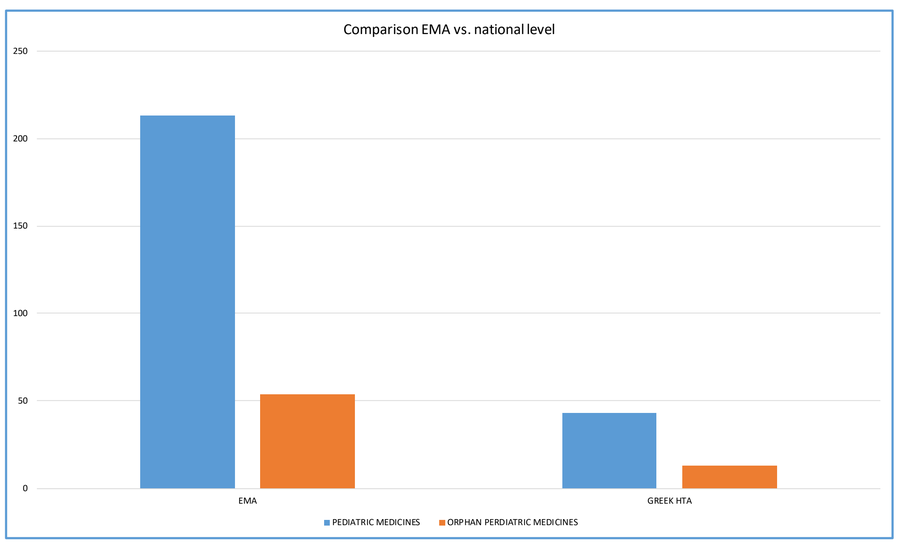
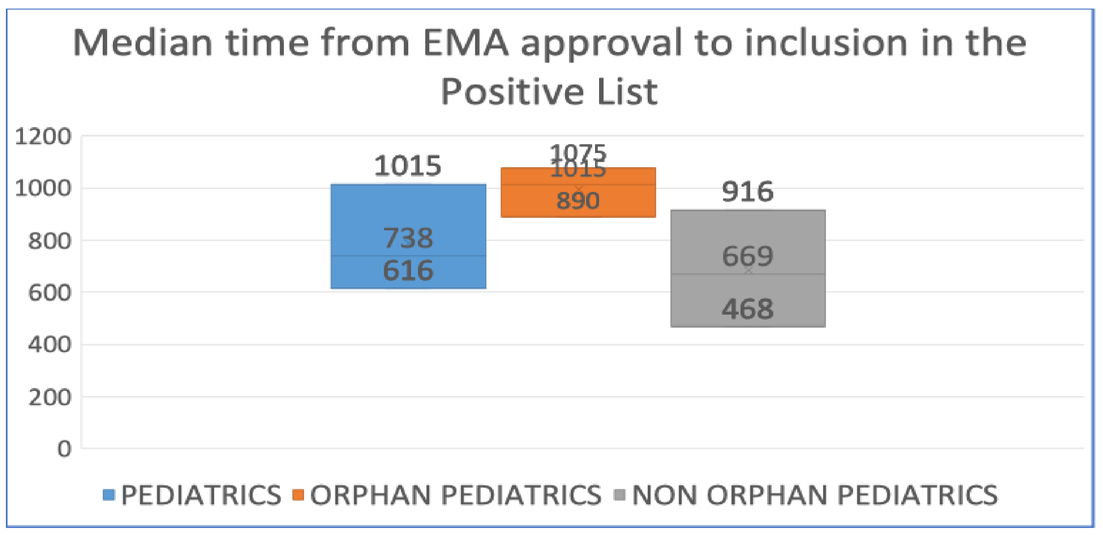
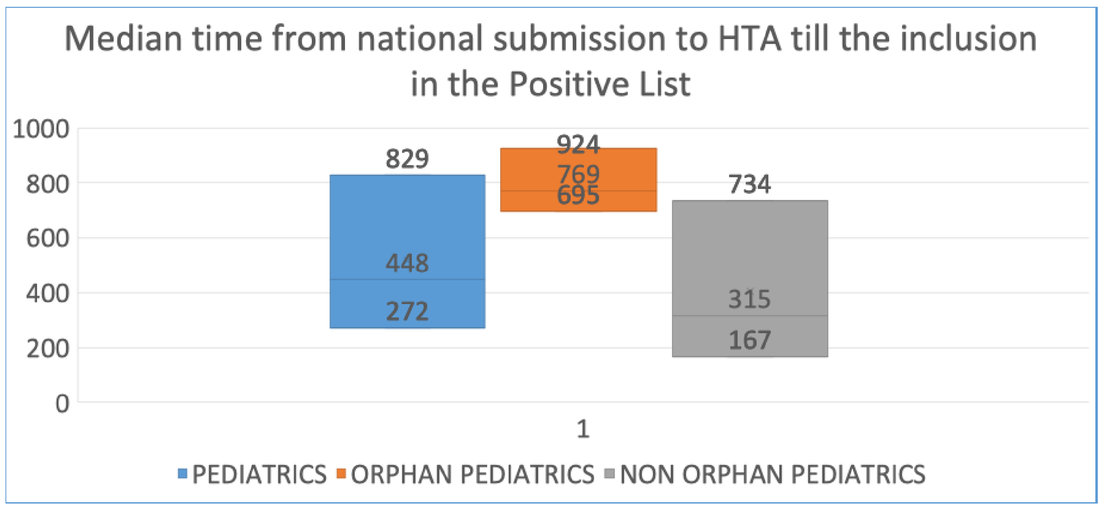


Figure 1. Comparison between submitted applications at national level and marketing authorizations issued for pediatric/adolescent and orphan pediatric/adolescent MPs

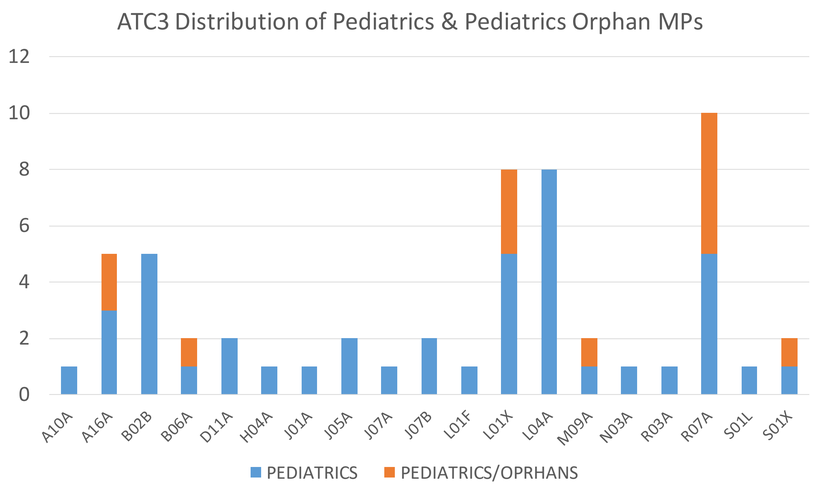
Median time (25–75 percentile) from marketing authorization to national HTA submission was 365 (246-508) days for pediatric/adolescent MPs in general and 393 (203-521) days for orphan pediatric/adolescent MPs and from marketing authorization to inclusion in the Positive List was 738 (616-1015) days for pediatric/adolescent MPs in general and 1015 (890-1075) days for orphan pediatric/adolescent MPs.



Median time (25–75 percentile) from submission to the national HTA to inclusion in the Positive Reimbursement List was 448 (272-829) days for pediatric/adolescent MPs in general and 769 (695-924) days for orphan pediatric/adolescent MPs



The majority of pediatric/adolescent MPs referred to immunosuppressants (ATC3: L04A) while orphans pertained to other respiratory system MPs (ATC3: R07A)



CONCLUSION

Orphan status could be a contributing factor to delayed access to pediatric/adolescent MPs in Greece

Reforms and incentives for pediatric and adolescent therapies should be taken into consideration in the upcoming revisions of the European pharmaceutical legislation

REFERENCES

1. Regulation (EC) No 1901/2006 of the European Parliament and ... - EUR-Lex. https://eur-lex.europa.eu/legal content/EN/LSU/?uri=CELEX:32006R1901.

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