Poster #PT34

A transitional reimbursement mechanism for new medicinal products addressing high unmet clinical need in Greece: proposal for a Medicines Innovation Fund

ISPOR Europe 2025, Glasgow, UK; 9-12 November 2025

Kyriakos Souliotis[1,2], Christos Tsakalogiannis[3], Aris Angelis[4,5]

1 University of Peloponnese, Corinth, Peloponnese, Greece; 2 Health Policy Institute, Maroussi, Greece; 3 PWC, Maroussi, Greece; 4 Hellenic Ministry of Health, Athens, Greece; 5 London School of Hygiene & Tropical Medicines, London, UK

Introduction

- In Greece, high mandatory paybacks on pharmaceutical expenditure, particularly within the hospital channel, are deterring Marketing Authorization Holders (MAHs) from launching Advanced Therapy Medicinal Products (ATMPs) and Priority Medicines (PRIMEs) early on, if at all.
- Furthermore, high uncertainty around these therapies necessitates a real-world evaluation of their outcomes, if to differentiate negotiated levels of discounts /mandatory paybacks from other medicinal products, and, thus, "reward" their innovation (Figure 1).
- We propose the establishment of a Medicines Innovation Fund (MIF) in the context of ATMPs and PRIMEs in Greece to ensure a) early access to potentially innovative products and b) the value-for-money of these products and the long-term sustainability of the health care system (Figure 2).

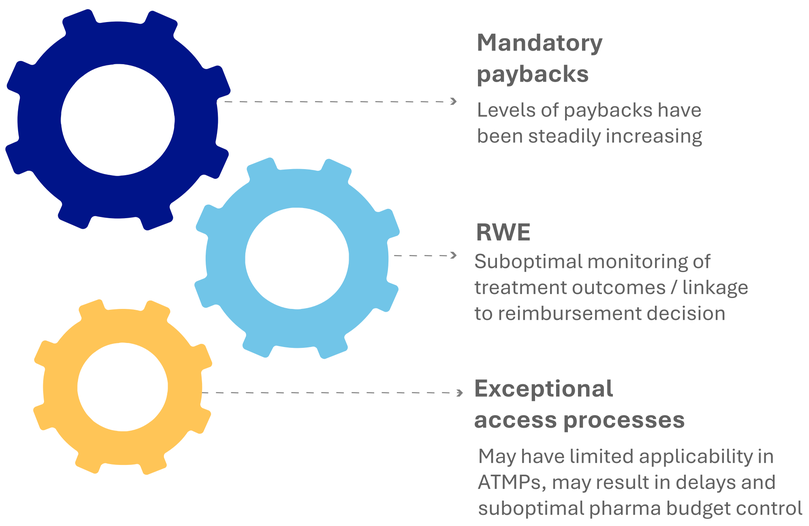
Methods

- We reviewed EU best practices on medicines innovation funds, particularly for ATMPs and PRIMEs.
- We identified elements of their mechanisms that would be fit-for-purpose in the Greek setting.
- We detailed all processes, roles, digital tools and timelines relevant to the establishment of a MIF.

Results

- Following EMA approval, MAHs of eligible products that want to enter the MIF should submit their products to the **annual horizon scanning** performed by the National Organization for the Provision of Healthcare Services (EOPYY).
- In their application to MIF, MAHs should submit **evidence on expected number of patients, budget impact implications, and clinical outcome and economic indicators** against which continuous data collection (including real-world data) will take place.
- Data collection indicators could fall under the following categories: **effectiveness, safety and resource use**, which should be agreed with the relevant HTA committee.
- **At agreed timepoints**, treating physicians will receive notifications to input data against these indicators in the **Electronic Preauthorization System**, required to keep patients on treatments.
- A **preliminary assessment report** will be produced at the midpoint of the plan, with a final assessment report produced at **3-6 months prior to the product exit from the MIF.**
- **The report will be assessed by the HTA and Negotiation Committees,** for their final opinion and reimbursement status.

Figure 1: Current challenges MIF aims to address

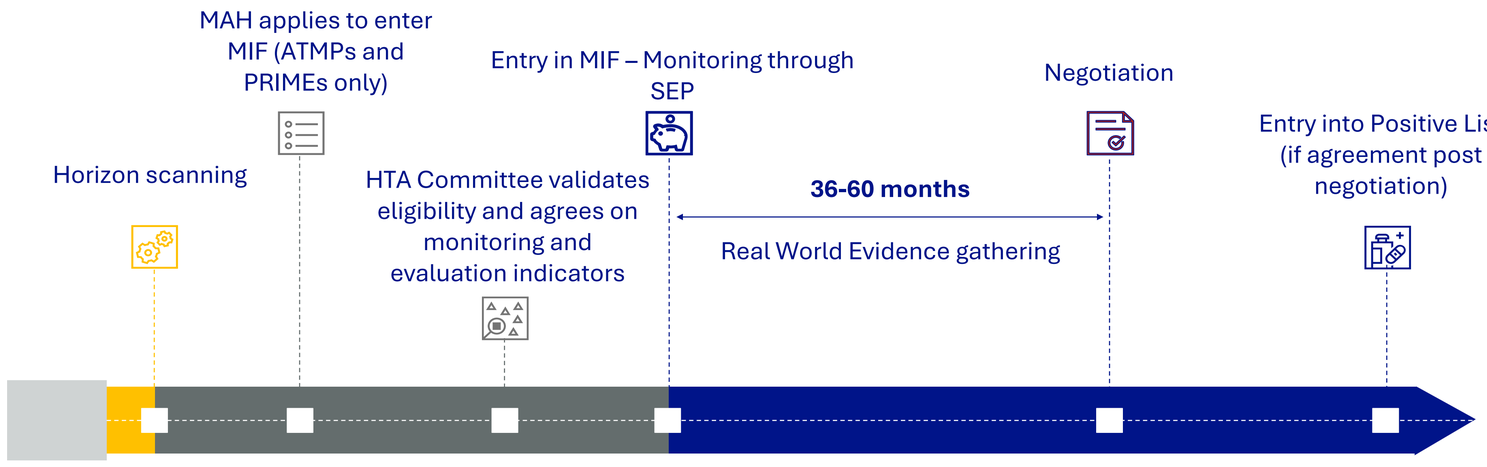


Abbreviations: ATMPs = Advanced Therapy Medicinal Products; MIF = Medicines Innovation Fund; RWE = Real World Evidence

Figure 2: Expected benefits of a MIF

Abbreviations: MIF = Medicines Innovation Fund

Figure 3: MIF process flow



Abbreviations: ATMPs = Advanced Therapy Medicinal Products; HTA = Health Technology Assessment; MAH = Marketing Authorization Holder; MIF = Medicines Innovation Fund; PRIMEs = Priority Medicines; SEP = System for Electronic Preauthorization

Figure 4: MIF proposed governance

- Supervised by Ministry of Health
- Financially managed by National Organization for Healthcare Services Provision (EOPYY)
- Real World Data are monitored and reported through the System for Electronic Preauthorization (SEP), in EOPYY
- In collaboration with the HTA and Negotiation Committees
- Phase 1: Only for PRIME & ATMPs

Abbreviations: ATMPs = Advanced Therapy Medicinal Products; HTA = Health Technology Assessment; PRIMEs = Priority Medicines

Key take aways

A MIF is expected to incentivize MAHs to launch ATMPs and PRIMEs earlier in Greece as well as act as a transitional reimbursement mechanism to ensure value-for-money

The proposed MIF expedites entry into the market, through a simplified application for inclusion in the MIF, which includes an agreement on indicators to be monitored for the duration of stay in the MIF

Monitoring is performed during clinical practice through the **System of Electronic Preauthorizatio**n, which is also used to request access to these treatments and can be modified to record agreed outcome indicators

Comprehensive monitoring of outcomes in the real world is used to **inform reimbursement decisions upon exit from the MIF** and reward innovation

Additional funding for the MIF through the State Budget ensures **sustainability for the MIF** and further **alleviates running levels of mandatory paybacks** on total pharmaceutical spending

Timeline to implementation