Unlocking the Value of Pharmaceutical Innovation for Patients, Healthcare Systems and Society

Romina Siaterli, Policy and Communications Excellence Lead, Roche Hellas
Member of the Policy Working Group, PhARMA Innovation Forum

Pharmaceutical innovation helps people live longer, healthier lives

And brings significant benefits to the economy, healthcare systems and society

Value of innovation for patients

Advancements in cancer treatments have **increased 5-year survival rates** for several cancer types.

Since the 1980s we have seen **death rates from HIV fall by over 80%**

COVID-19 vaccines have **reduced deaths by at least 57%**, in Europe (WHO)

Value of innovation for HC systems and society

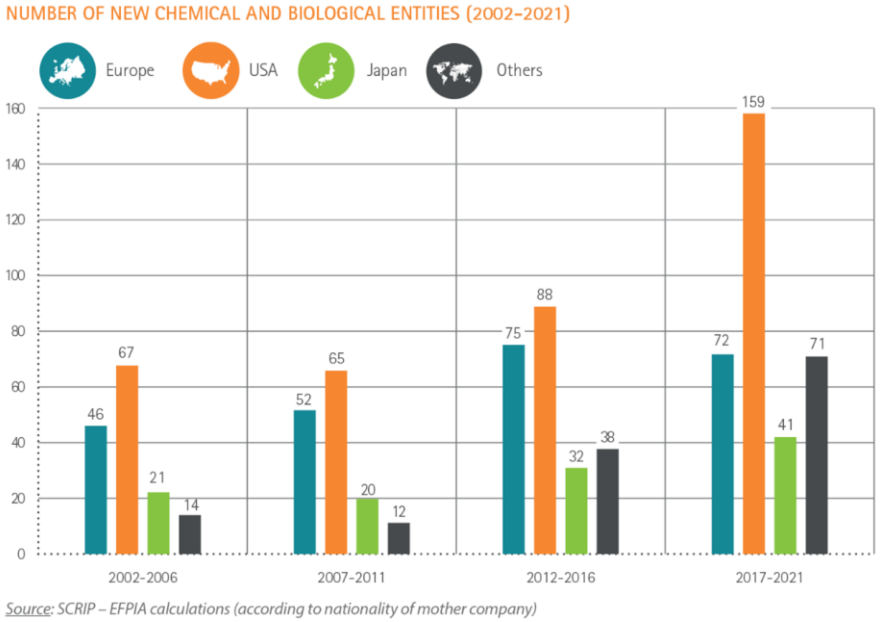
Innovative treatments **reduce the need for emergency treatment and hospitalizations**

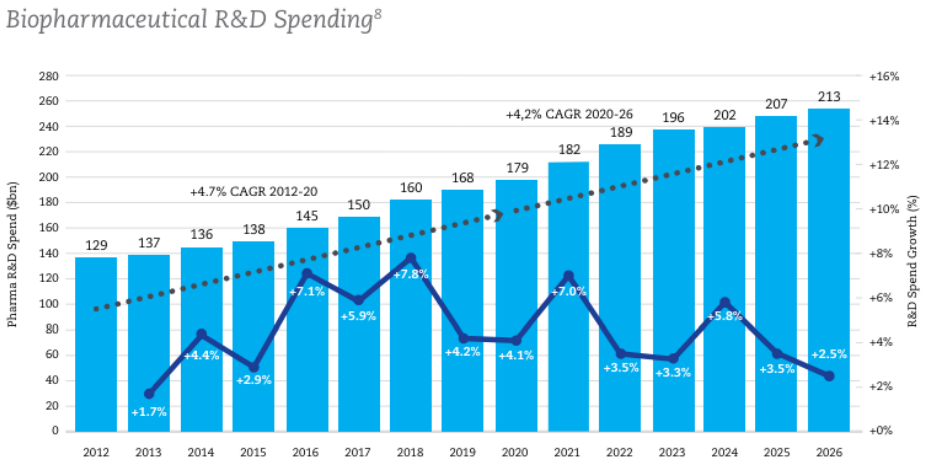
Innovative treatments may yield **increased productivity for patients and their carers** and decreased social benefits payments

Sources: 1) EFPIA, *Value of Medicines*, Available at: https://www.efpia.eu/about-medicines/use-of-medicines/value-of-medicines/ 2) World health Organisation (2024),COVID-19 vaccinations have saved more than 1.4 million lives in the WHO European Region, a new study finds], Available at https://www.who.int/europe/news/item/16-01-2024-covid-19-vaccinations-have-saved-more-than-1.4-million-lives-in-the-who-european-region--a-new-study-finds *3) EFPIA, Health gains and savings, Available at https://www.efpia.eu/publications/data-center/value-to-healthcare-systems/health-gains-and-savings 4)* Gill J. et al (2020), *Access to Personalised Oncology in Europe*, London School of Economics , [Online], Available at https://www.lse.ac.uk/business/consulting/assets/documents/Personalised-Oncology-in-Europe.pdf

Even greater value is expected…

As we are undergoing a scientific "revolution" in pharmaceutical R&D

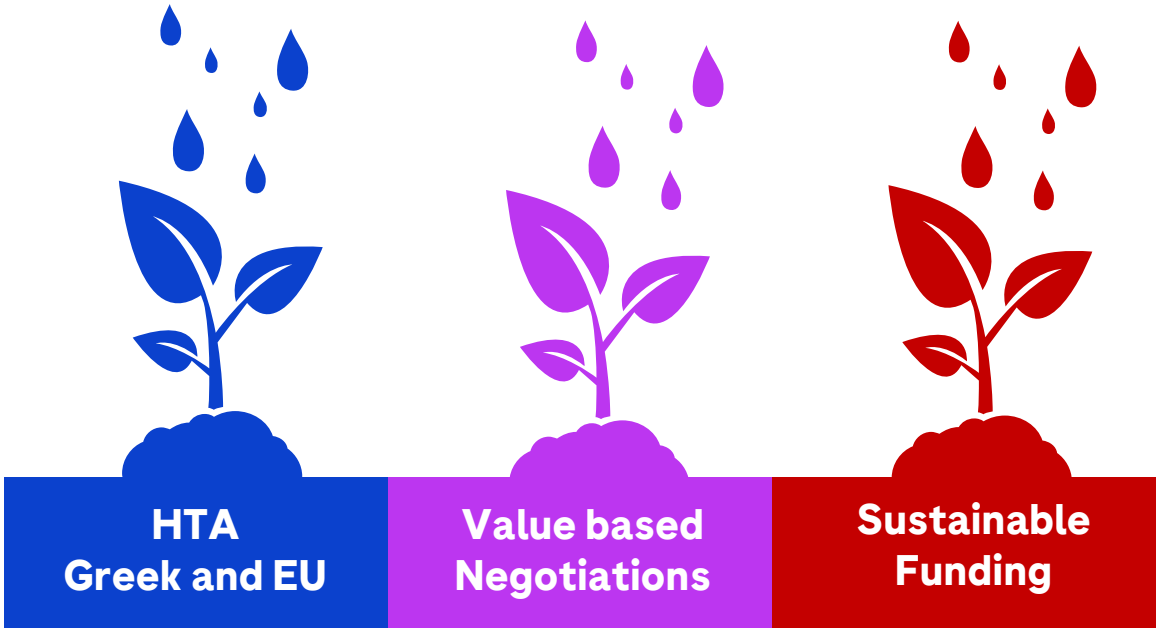




Science is evolving rapidly with new innovative technologies, such as gene therapies, delivering better patient outcomes

Sources: 1) EFPIA *New Chemical or Biological Entities*, Available at https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-rd/new-chemical-or-biological-entities *2) IFPMA (2022), The Pharmaceutical Industry and Global Health, Facts and Figures 2022,* Available at https://www.ifpma.org/publications/facts-and-figures-2022-the-pharmaceutical-industry-and-global-health/

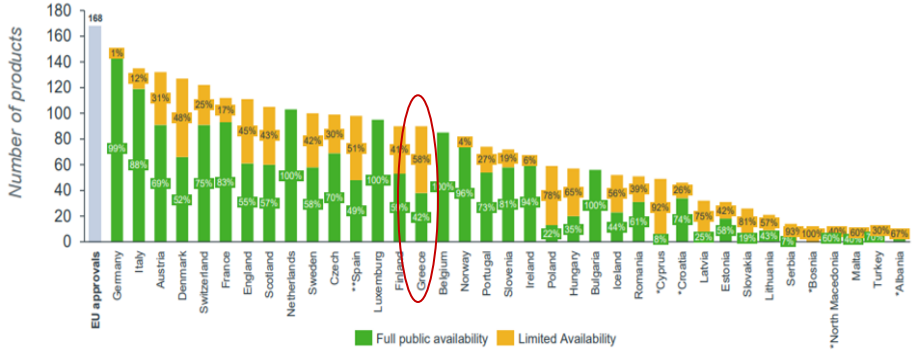
Unlocking the mechanisms that allow the value of innovation to reach patients, the healthcare system and society



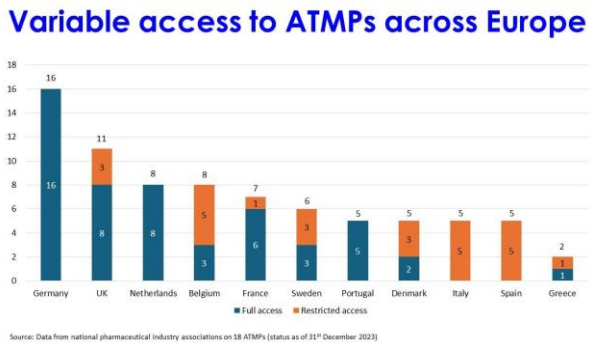
Health Technology Assessment (HTA)

Barriers to fast, full access to innovative therapies in Greece

42% rate of full availability (2018 - 2021)



Full access takes >18 months from EMA approval



- Empirically we see considerable improvement of HTA timelines since 2018
- However, Greece continues to lag behind in full availability

The 5/11 criterion causes significant delays in full access to innovative treatments

Source: 1) EFPIA (2023), *EFPIA Patients W.A.I.T. Indicator 2022 Survey,*] Available at https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf , 2) Danish Association of the Pharmaceutical Industry (Lif), 2023

HTAR presents an opportunity to redefine the HTA framework

Towards an inclusive, flexible and fast HTA

WHAT'S IN THE EU HTA REGULATION?

FRAMEWORK FOR JOINT HTA COOPERATION

- Joint clinical assessments (JCAs).
- Joint scientific consultations (JSCs).
- Identification of emerging health technologies.
- Common procedures and methodologies across the EU.

KEY PRINCIPLES OF THE HTA REGULATION

- Only on clinical domains of the assessment: No economic assessment or any conclusion on pricing and reimbursement.
- Driven by EU HTA bodies who remain responsible for drawing conclusions on added value for their health systems.
- High quality, timeliness and transparency.
- Use of joint work in national HTA processes.
- Input from independent experts.
- Stakeholder engagement and inclusiveness.
- Progressive implementation.

TIMELINE FOR MEDICINES

- 12 January 2025: New oncology medicines and advanced therapy medicinal products will be assessed at EU level.
- 13 January 2028: Orphan medicinal products to be added to the joint work.
- 13 January 2030: All new medicines will come under the scope of the regulation.

EXPECTED BENEFITS OF THE EU HTA REGULATION

For EU Patients	For Member States	For the Industry
• Improved transparency and engagement • Improved availability	• High quality, timely scientific reports • Supports evidence based decisions on national level • Less duplication of efforts	• Clearer, more coherent evidence requirements • More efficient clinical evidence generation and submission

Optimizing EU HTA in Greece

- **Abolition of the 5/11 criterion**
- **Official consultation** process between HTDs and the HTA Committee
- **Capacity and capabilities building** for HTA members, patients and HCPs
- Introduction of **a clear and flexible assessment framework**

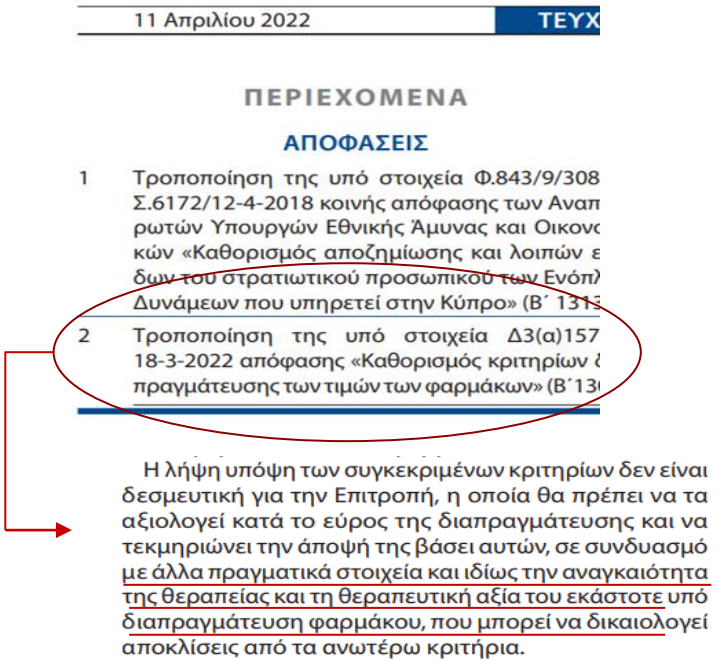
Open, inclusive, ongoing dialogue among all stakeholders on the required legislative, methodological and procedural amendments is key

Towards Value-Based Negotiations

The Negotiations process in Greece is suboptimal and in dire need of reconceptualization

Innovation is treated as a cost to society rather than an investment

From theory…



11 Απριλίου 2022 ΤΕΥΧ

ΠΕΡΙΕΧΟΜΕΝΑ

ΑΠΟΦΑΣΕΙΣ

1 Τροποποίηση της υπό στοιχεία Φ.843/9/308 Σ.6172/12-4-2018 κοινής απόφασης των Αναπ ρωτών Υπουργών Εθνικής Άμυνας και Οικονο κών «Καθορισμός αποζημίωσης και λοιπών ε δων του στρατιωτικού προσωπικού των Ενόπλ Δυνάμεων που υπηρετεί στην Κύπρο» (Β΄ 131

2 Τροποποίηση της υπό στοιχεία Δ3(α)157 18-3-2022 απόφασης «Καθορισμός κριτηρίων πραγμάτευσης των τιμών των φαρμάκων» (Β΄13

Η λήψη υπόψη των συγκεκριμένων κριτηρίων δεν είναι δεσμευτική για την Επιτροπή, η οποία θα πρέπει να τα αξιολογεί κατά το εύρος της διαπραγμάτευσης και να τεκμηριώνει την άποψή της βάσει αυτών, σε συνδυασμό με άλλα πραγματικά στοιχεία και ιδίως την αναγκαιότητα της θεραπείας και τη θεραπευτική αξία του εκάστοτε υπό διαπραγμάτευση φαρμάκου, που μπορεί να δικαιολογεί αποκλίσεις από τα ανωτέρω κριτήρια.

To practice…

- Negotiations **focus primarily on the level of paybacks (*one-size fits all approach*)**

  without adequate consideration of the necessity and therapeutic value of the treatment

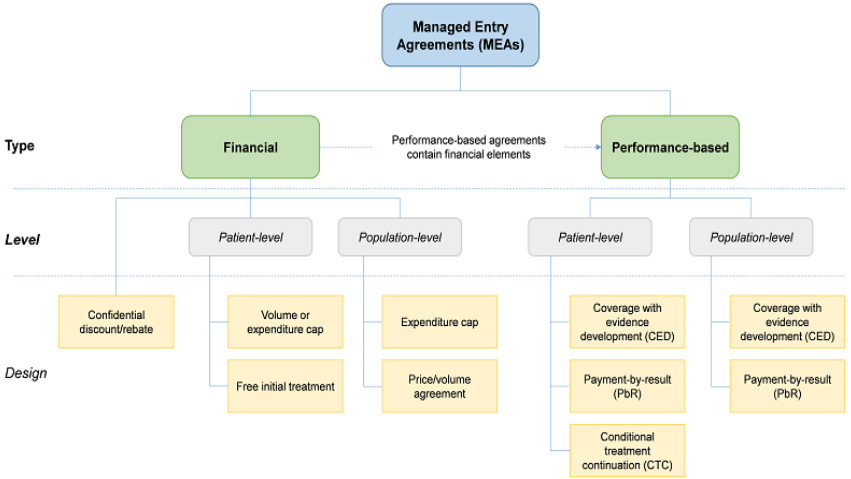
- ***Vacuum between the two Committees when it comes to the value of medicines***

Long-term: We need to consider the wider savings that a treatment brings to the healthcare system → holistic health budget approach vs pharmaceutical budget

Towards a Negotiations Model based on value rather than on cost

The use of **Performance-Based Agreements** allows for:

- Access to innovative treatments in light of clinical uncertainty due to their innovation level
- Better management of the budget impact of a new treatment and the realisation of the desired level of cost-effectiveness



Pre-requisites

1. Investment in digital infrastructure for gathering and utilising data:
   - Disease registries
   - Integrated Electronic Health Records
   - System Interoperability
1. Introduction of a legal framework for the secondary use of health data and the frequent reporting of data related to pharmaceutical expenditure

Sources: 1)OECD (2019), *Performance-based managed entry agreements for new medicines*, Available at https://www.oecd-ilibrary.org/social-issues-migration-health/performance-based-managed-entry-agreements-for-new-medicines-in-oecd-countries-and-eu-member-states_6e5e4c0f-en , 2) EFPIA (2020), *ADDRESSING HEALTHCARE CHALLENGES: Novel Pricing and Payment Models: New solutions to improve patient access*,, Available at https://www.efpia.eu/media/554543/novel-pricing-and-payment-models-new-solutions-to-improve-patient-access-300630.pdf

The Legal Framework allows for negotiations on the basis of value

Ministerial Decision Δ3(α) 19688, GG/ 1756/B/11-4-2022

‘The reimbursement decision can be based on outcomes, i.e. based on real clinical data (Real World Evidence - RWE).

MAH in this case must, if requested, provide the HTA Committee with data on biomarkers and biochemical analyses and not only data from clinical studies'

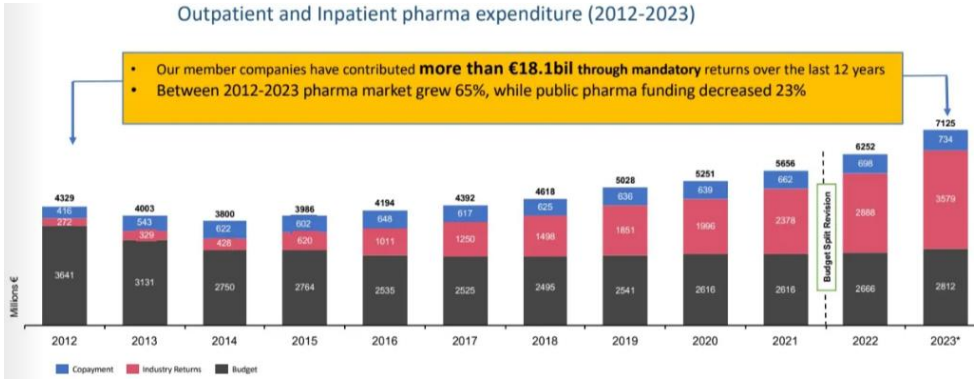
Law 4633/2019, Article 25

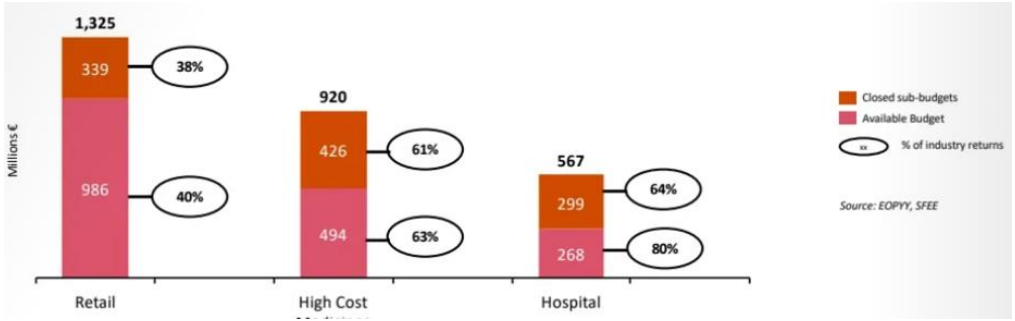
‘The Negotiations Committee may negotiate agreements that include rebates, volume-based tiered rebates, outcome-based agreements, therapeutic indication agreements, risk-sharing agreements, and agreements based on therapeutic endpoints over specific time periods.
'

Sustainable Funding

Budget challenges threaten the sustainability of the healthcare system

Even if the HTA & RMB framework changes, the system will not be endowed to welcome innovation





- Despite increase in population needs and scientific advancements, the **pharmaceutical budget has remained relatively stable** over the years
- In 2022, **the total industry's contribution was higher than that of the state**
- **Hospital products>30 euro are affected the most (est. 80% payback in 2023!!)**

Source: SFEE estimates, 2023

We need a long-term strategy regarding pharmaceutical policy and funding in Greece

Setting a sustainable funding structure

- Introduction of a **unified pharmaceutical budget** that meets the healthcare needs of the population
- **Gradually reduce the mandatory payback** level - introduction of **a jointly agreed clawback cap**
- **Alignment with the average EU standards** of pharmaceutical investment

Optimizing the efficiency of resources

- Intensification of **structural reforms**
- Link the value of interventions to **clinical practice** (eg biomarkers, prescription protocols)

A key success factor is the engagement of all relevant stakeholders in the design and implementation of a long term strategy

Key Takeaways

In a nutshell..

To unlock the value of innovation we need...

An inclusive, flexible and fast HTA Framework

- Abolition of 5/11
- Official consultation between HTDs and the HTA Committee
- Capacity and capabilities building
- Clear and flexible assessment framework

1

2

A value-based Approach to Negotiations

- Link HTA outcomes to negotiations
- Use of performance based agreements

3

A fit-for-purpose Pharmaceutical Budget

- Adequate, unified budget
- Structural reforms for more efficient use of resources

Doing now what patients need next