

# HTA implementation in Greece: A 3 years' experience from the industry perspective

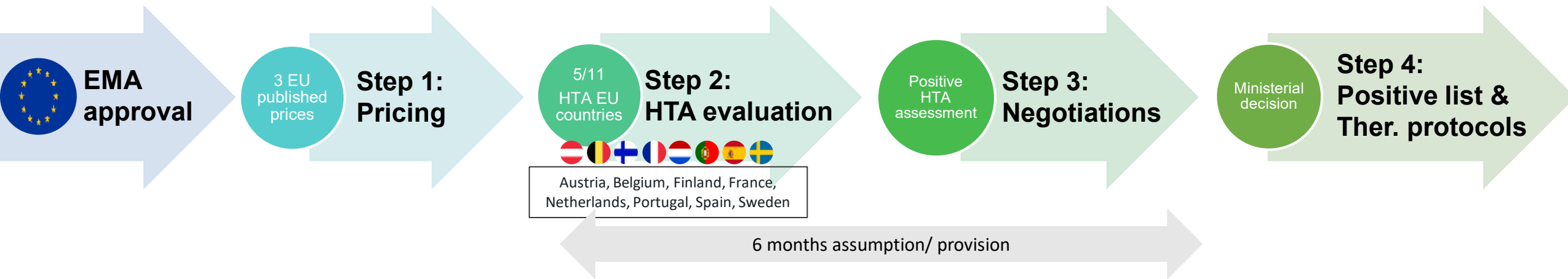


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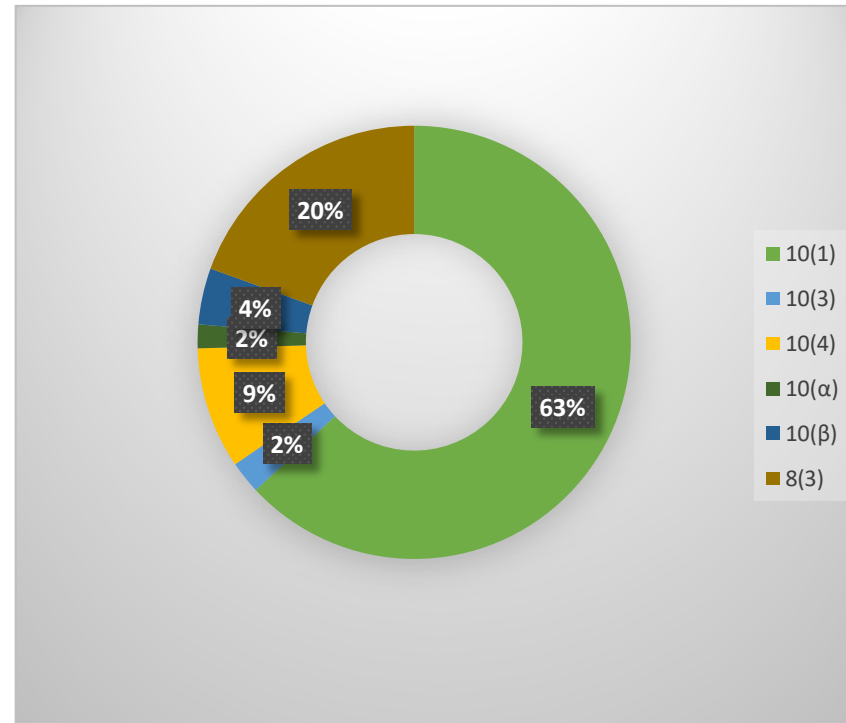
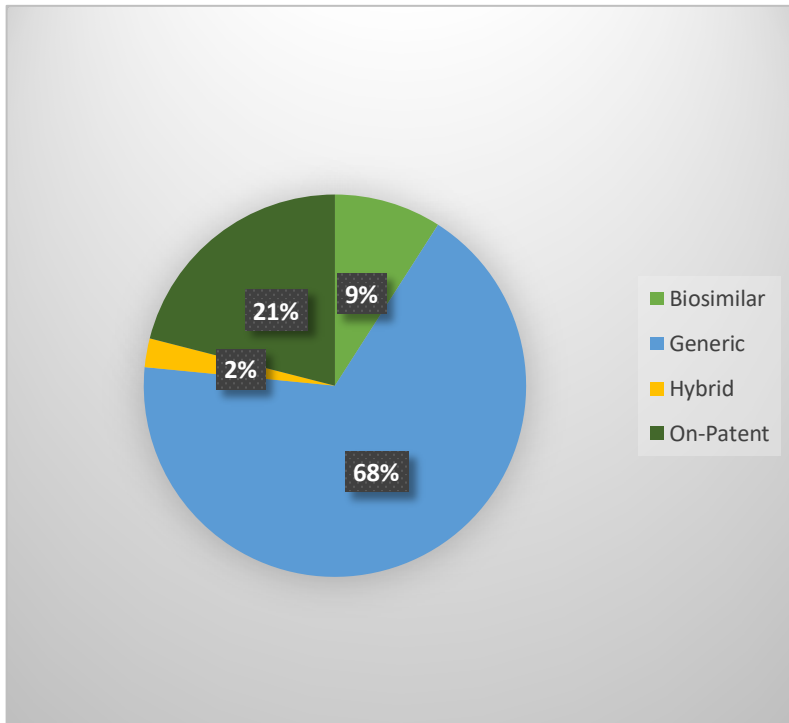
The HTA process was modified in 2019 aiming to speed up the approval process;  
Still improvements can be made



### Several improvements have been identified

- ✓ Exclusion of specific drug groups (e.g. orphan drugs, vaccines, etc.) from the 5/11 rule
- ✓ Exclusion of Generics, fixed combinations & package changes from the HTA process
- ✓ Abbreviated 1-month HTA process for vaccines & biosimilars
- ✓ Improvements in the negotiation process & prioritization

# Acknowledging wide leaps forward by the HTA and Negotiations Committees in 2019-2020: 452 reimbursement decisions (albeit 12 new active substances)



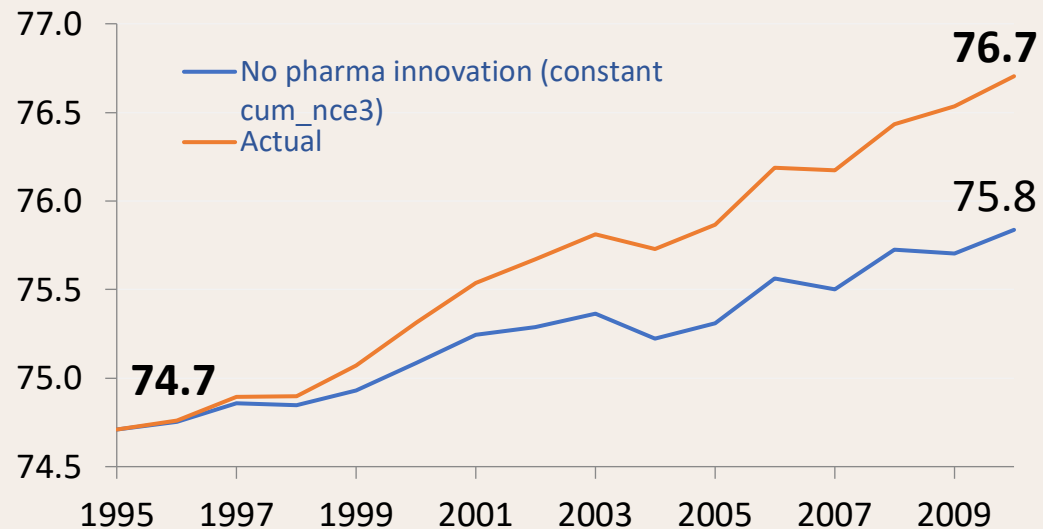
- IFET and SIP approvals **cannot substitute** for delays in reimbursement decisions:
- Named patient use applies **only to certain hospital products**, not in primary care and carries significant **access inequalities** between patients and regions

Source: MoH, Reimbursement decisions 2019-2021

# New treatments bring more health. Delaying treatment means investing in disease

**Timely and efficient access to innovative medicines has a significant impact both on the society and the economy's growth**

Pharmaceutical innovation increased 0,87 years out of 2 additional years of longevity in Greece in 1995-2010



Brings cost-effective treatments to market that save healthcare costs & contributes to productivity increase

**€ 27Bil.**



contributing in increased productivity for EU economies



**>10% of GDP**

The impact of effective COVID treatments and vaccines when approved

PIF's 3-year Pharmaceutical Policy Roadmap aims for a sustainable, high-quality healthcare system without inequalities and access barriers for patients

The 5 main pillars



Stable and predictable Pricing & Reimbursement system



Open & efficient HTA system and processes



Empowerment of clinical and biomedical research & fund for innovation

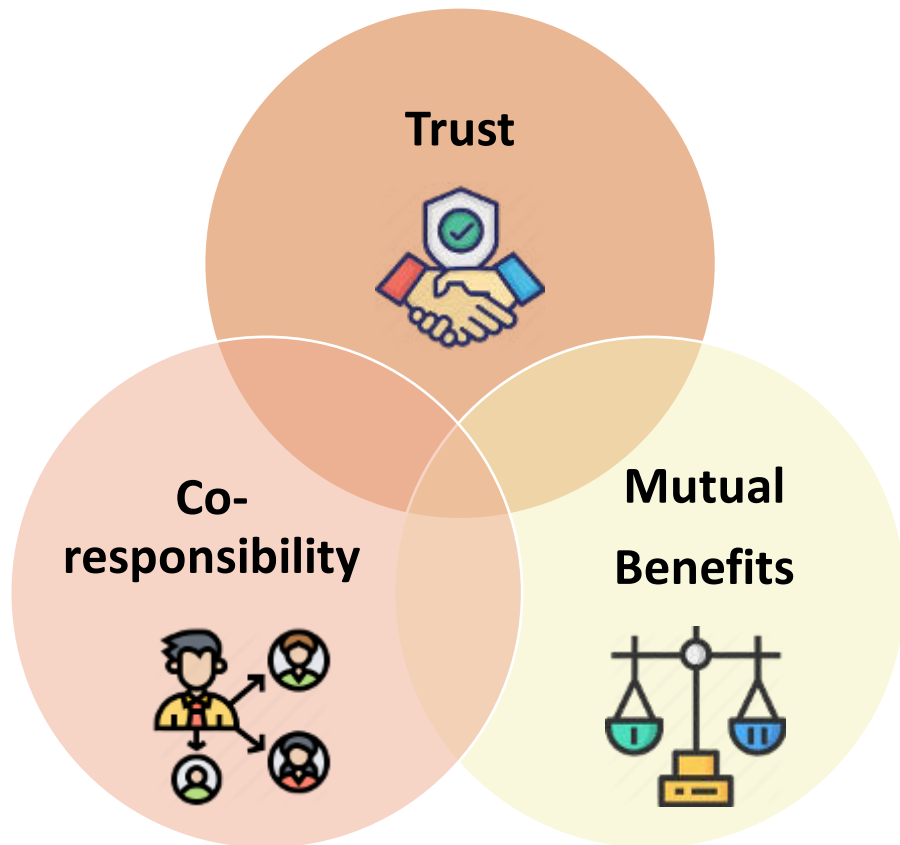


Transparency & Monitoring in prescribing and clinical protocols / registries implementation



Sustainable & predictable financing of pharma care

PIF's Pharmaceutical Policy Roadmap aims at strengthening the collaboration between the Greek government and pharma associations, allowing us to build...



**Focusing on the 2<sup>nd</sup> pillar the following suggestions were identified**

- 1** Timely access within 1-year from EMA approval
- Sharing of information during evaluation & negotiation processes
- Efficiency & appropriate coordination throughout the process
- Rewarding the value of innovation in a sustainable system



# Could reimbursement decisions for new products be achieved within 1 year after EMA approval ?



## HTA Submission stage

1. Submission at EMA approval
2. Abolishment of external criteria
3. Registry of HTA submissions & decisions



## Evaluation stage

1. Prioritization for products with EMA / FDA prime / breakthrough status
2. Active patient representation



## Negotiation stage

1. Negotiations should be finalized within 6 months from HTA referral
2. Negotiations process registry



## Operation / Implementation

1. Efficient monitoring and implementation of negotiation agreements
2. Link between HTA assessment and negotiation structure



Collaboration is the way forward...

**“Coming together is a beginning;  
keeping together is progress;  
working together is success.”**

**Henry Ford**



*Collaboration is the way forward*

A scenic landscape at sunset. A paved road with a white guardrail curves through a valley. To the left, a steep, grassy hillside rises. The sun is low on the horizon, casting a golden glow over the scene. The sky is filled with wispy clouds and a flock of birds is flying in the upper right corner.

*Thank you !*