

Φαρμακευτική φροντίδα: ποιες πολιτικές πρέπει να εφαρμοστούν για την αξιολόγηση και αποζημίωση σε ένα περιβάλλον μεγάλων ρυθμιστικών αλλαγών;



Γιώτα Κοτσεκίδου

Corporate & Regulatory Affairs Director, AstraZeneca



Pharmaceutical Care: The impact of innovative medicines on health & social well being



New therapies significantly contributed to a decline in cancer deaths globally starting in 1991, with 2 out of 3 cancer patients now surviving at least 5 years

In the EU, prescription drugs added an estimated 2 million healthy years to patients' lives between 2007 and 2017

Medicines have reduced burdens on caregivers and families

**European citizens can expect to live up to 30 years longer than they did a century ago.
Life expectancy has doubled in both high-income and developing economies in the past century**

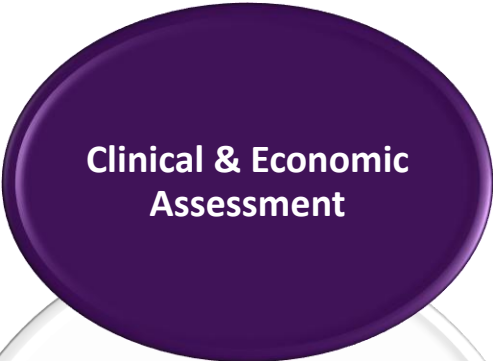
Medicines have increased quality-life years for people in the workforce

Medicines can substantially reduce costs in other areas of healthcare, including hospital stays and long-term care

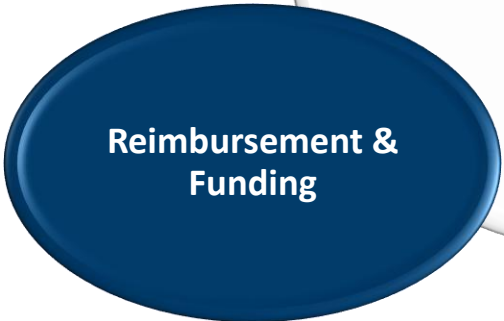
1) Oliver J Watson*, Global impact of the first year of COVID-19 vaccination: a mathematical modelling study, Lancet Infect Dis 2022; 22: 1293–302, 2) The Future of Patient-Centered Oncology Care in Europe, <https://www.efpia.eu/news-events/the-efpia-view/blog-articles/the-future-of-patient-centered-oncology-care-in-europe>, 3) The pharmaceutical industry in figures, Key data, 2023, EFPIA, 4) Research on rare diseases: ten years of progress and challenges at IRDIRC Lucia Monaco, Nat Rev Drug Discov. 2022 May 01; 21(5): 319–320, 5) The economic and societal footprint of the pharmaceutical industry in Europe, Technical Report, EFPIA, 2019, 6) Innovations in Health Care—A Conceptual Framework, Steffen Flessa, Int. J. Environ. Res. Public Health 2021, 18, 10026, 7) The offset effect of pharmaceutical innovation: A review study, Néboa Zozaya, Global & Regional Health Technology Assessment, Volume 2019: 1–10, 8) The Economic Consequences Of Mortality Amenable To High-Quality Health Care In Low- And Middle-income Countries, Blake C Alkire, Health Aff (Millwood). 2018 Jun;37(6):988-996, 9) The Economic and Human Impact of New Drugs, Frank R. Lichtenberg, J Clin Psychiatry 2003;64

Factors affecting patient access to medicines

HTA framework



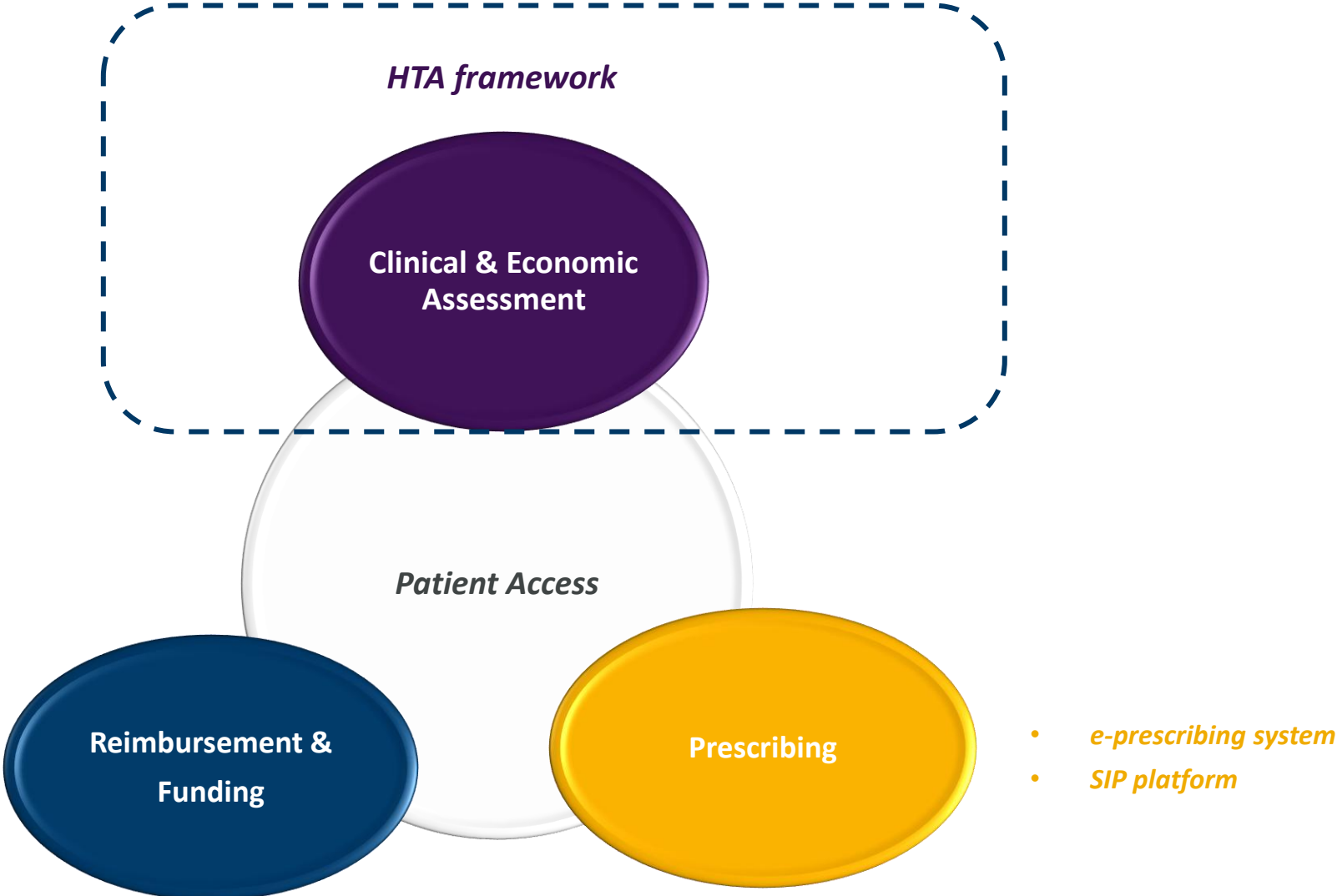
Patient Access



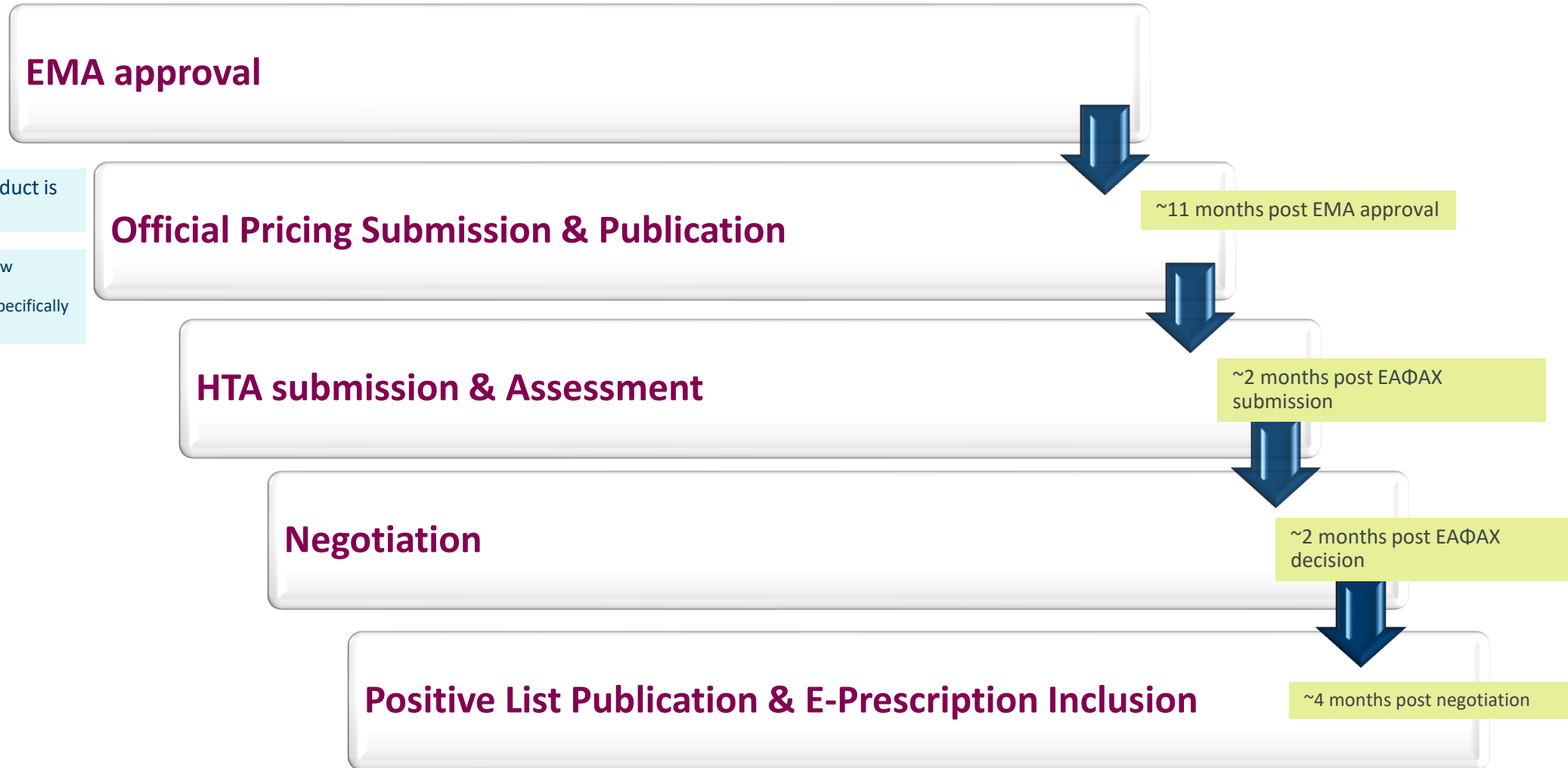
- *Legislated Budgets per channel*
- *Paybacks (Rebates/ Discounts/Clawback)*

- *e-prescribing system*
- *SIP platform*

Factors affecting patient access to medicines



Steps towards official new medicine reimbursement



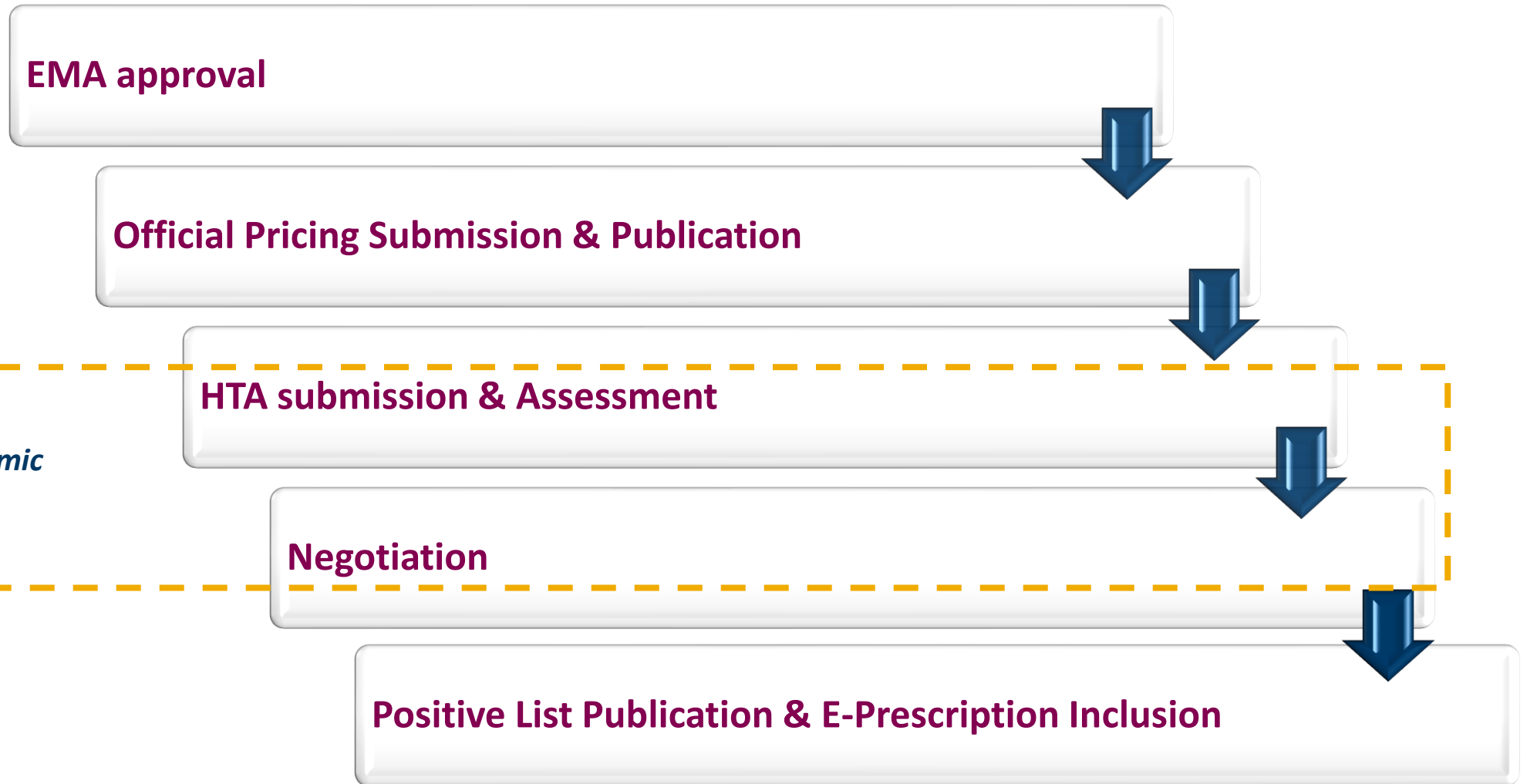
*orphan drugs pricing submission requirement: the product must be priced in 2 EZ countries

** 5/11 rule exemptions: orphan drugs, blood factors, vaccines, bio-similars,, drugs for Mediterranean anemia, clones well established use drugs

new product /new formulation// orphans excluded

depending on the time of the reimbursement list publication

Steps towards official new medicine reimbursement



An holistic approach is needed to highlight the full value innovative medicines bring

New medicines should not be assessed based solely on their price.

N. 4633/16Oct2019

Άρθρο 22 (Το άρθρο 249 του ν. 4512/2018 (Α' 5) αντικαθίσταται ως ακολούθως):

Κριτήρια και μεθοδολογία αξιολόγησης

«Άρθρο 249

1. Τα βασικά κριτήρια που χρησιμοποιούνται από την Επιτροπή για την αξιολόγηση των φαρμάκων είναι: α) το κλινικό όφελος, όπως αυτό αποτιμάται λαμβάνοντας υπόψη τη σοβαρότητα και το φορτίο της νόσου, την επίδραση πάνω στους δείκτες θνητότητας και νοσηρότητας, καθώς και τα δεδομένα ασφάλειας και ανεκτικότητας, β) η σύγκριση με τις ήδη διαθέσιμες αποζημιούμενες θεραπείες φαρμάκων, γ) ο βαθμός αξιοπιστίας των δεδομένων των κλινικών μελετών, δ) ο λόγος κόστους/αποτελεσματικότητας και ε) η επίπτωση στον προϋπολογισμό. Η αιτιολογημένη γνώμη της Επιτροπής Αξιολόγησης προς τον Υπουργό Υγείας για ένταξη ενός φαρμάκου στον Κατάλογο Αποζημιούμενων Φαρμάκων, περιλαμβάνει τη συγκεκριμένη θεραπευτική ένδειξη ή τις συγκεκριμένες θεραπευτικές ενδείξεις για την οποία ή για τις οποίες θα παρέχεται αποζημίωση, τις φαρμακευτικές μορφές, τις δοσολογίες και τις περιεκτικότητες. Μαζί με κάθε θεραπευτική ένδειξη αναφέρονται υποχρεωτικά τα κλινικά χαρακτηριστικά των ασθενών για τους οποίους το φάρμακο προτείνεται να αποζημιώνεται, το στάδιο της θεραπευτικής γραμμής (του θεραπευτικού αλγορίθμου) για το οποίο το φάρμακο προτείνεται να αποζημιώνεται, καθώς επίσης το μέγεθος του πληθυσμού, στο οποίο είναι δυνατόν να εφαρμοστεί η θεραπεία για να αξιολογηθεί η επίπτωση στον προϋπολογισμό.

Άρθρο 23/Διαδικασία αξιολόγησης

παρόντος, η έχουν πάρει καταρχάς οριστική αξιολογητική
βάσει συνοπτικής διαδικασίας αξιολόγησης. Η Επιτροπή
Διαπραγμάτευσης εκκινεί και ολοκληρώνει τη διαδικα-
σία διαπραγμάτευσης του φαρμάκου και γνωμοδοτεί
αιτιολογημένα, βάσει του αποτελέσματος της διαδικα-
σίας διαπραγμάτευσης, σχετικά με την επίπτωση στον
προϋπολογισμό από την ένταξη ή τη διατήρηση ενός
φαρμάκου στον Κατάλογο Αποζημιούμενων Φαρμάκων.



New EU-HTA Legislative Framework for Medicinal Products

Timely production of
high-quality results

Strengthening
collaboration among
member states within
the context of HTA/JCA

**Accelerate access to
innovation**

Reduction of parallel
assessments and
discrepancies in results
between member states

EU HTA regulation & Time-frame

For:

- *Centrally approved medicines*
- *Centrally approved new indications*
- *Medical devices*
- *In vitro diagnostic medical devices*

12 January 2025-Implementation date

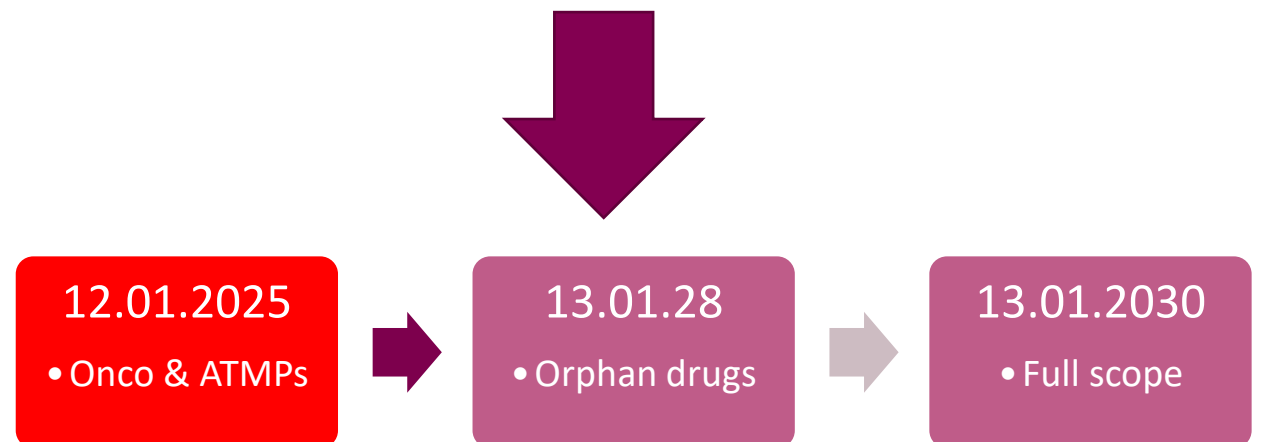
13 January 2026 -1st JCA

13 January 2027 – Submission of an implementation report from each state member

January 2028 - Progress report to be submitted to the European Parliament (assessment of the added value of JCA, funding, reduction of the administrative burden)

January 2030 - Full implementation of the EU HTA regulation

Up to 10-15 JCAs
initially annually



How are we getting prepared?

- Greek representation (MoH, HTA committee, EOPYY) in EU & Global working groups
- Meetings of the Greek representatives with Health Assessment organizations of Portugal, Italy, and France
- Ongoing project: “Strengthening the National Framework for the Implementation of the European Union Regulation on Health Technology Assessment 2021/2282”, is being carried out by the Ministry of Health in collaboration with the World Health Organization (WHO) and the European Commission’s Special Group for Reforms and Investments (SG REFORM)
- A practical ‘live’ guidance document for HTA methods and processes at national level, drawing on European best practices and ongoing engagement with HTA agencies across the Region, is under development.
- In this context, a pilot case study will be undertaken in the next phase of the project (2025 Q3/Q4) to operationalize the new methodology through the assessment of o medicinal products.

Proposals for a smooth harmonization of the Greek legislative framework with EU-HTAR

- Updated local procedures that enhance transparency & predictability (on-line tracking platform, provision for official consultation with the local MAH)

- Acceleration of Access → Acceleration of Reimbursement Procedures → Legislative adaptation
 - Abolishment of the external Criterion 5/11

- Initiation of the HTA Process upon Market Authorization

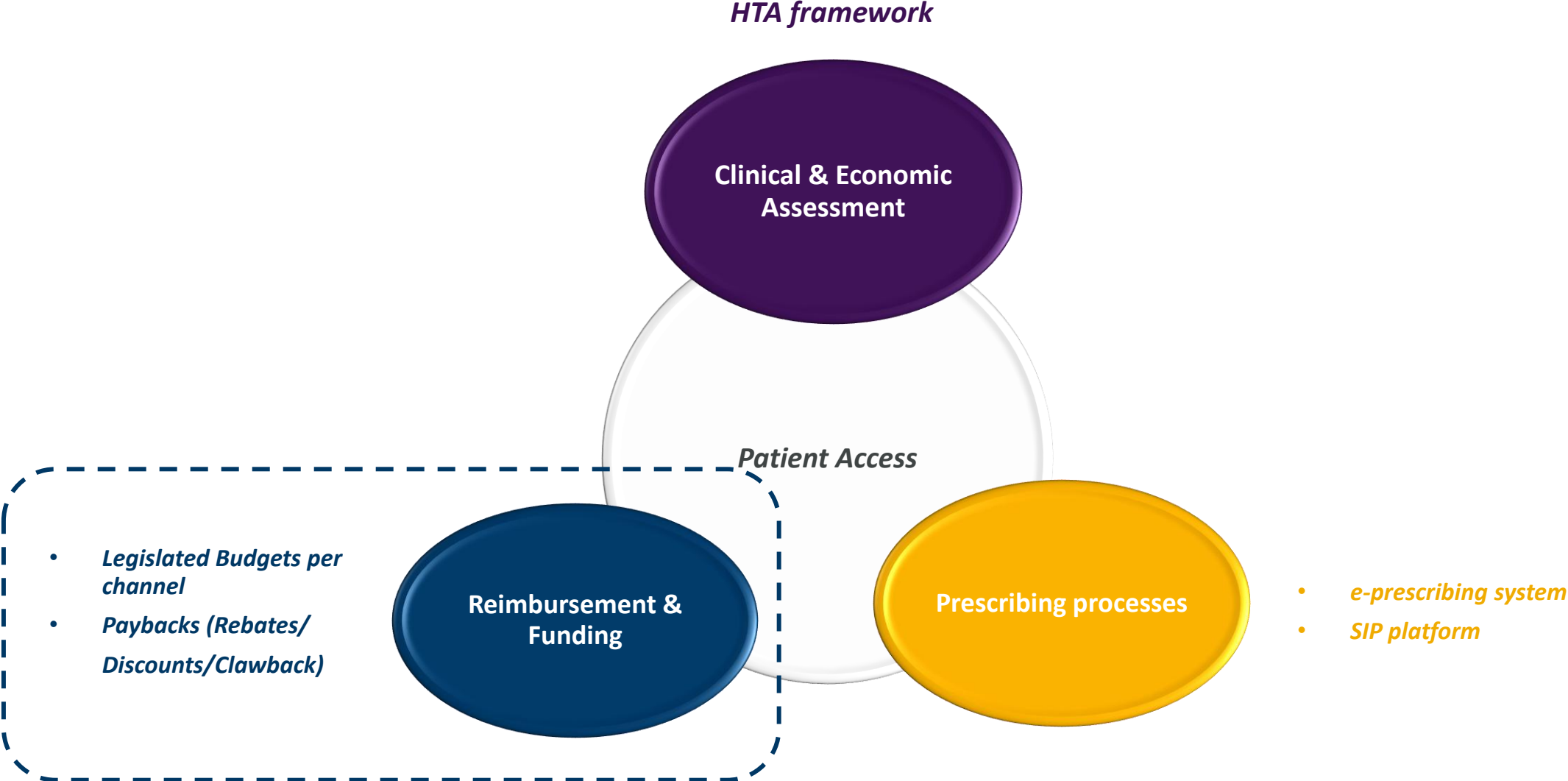
- May strengthen the role of patients in the national HTA process

- Bridging the gap towards the transition in the local HTA processes without delays and ensuring harmonized clinical assessment approach for medicines with and without JCA

Other structural reforms that drive efficiencies

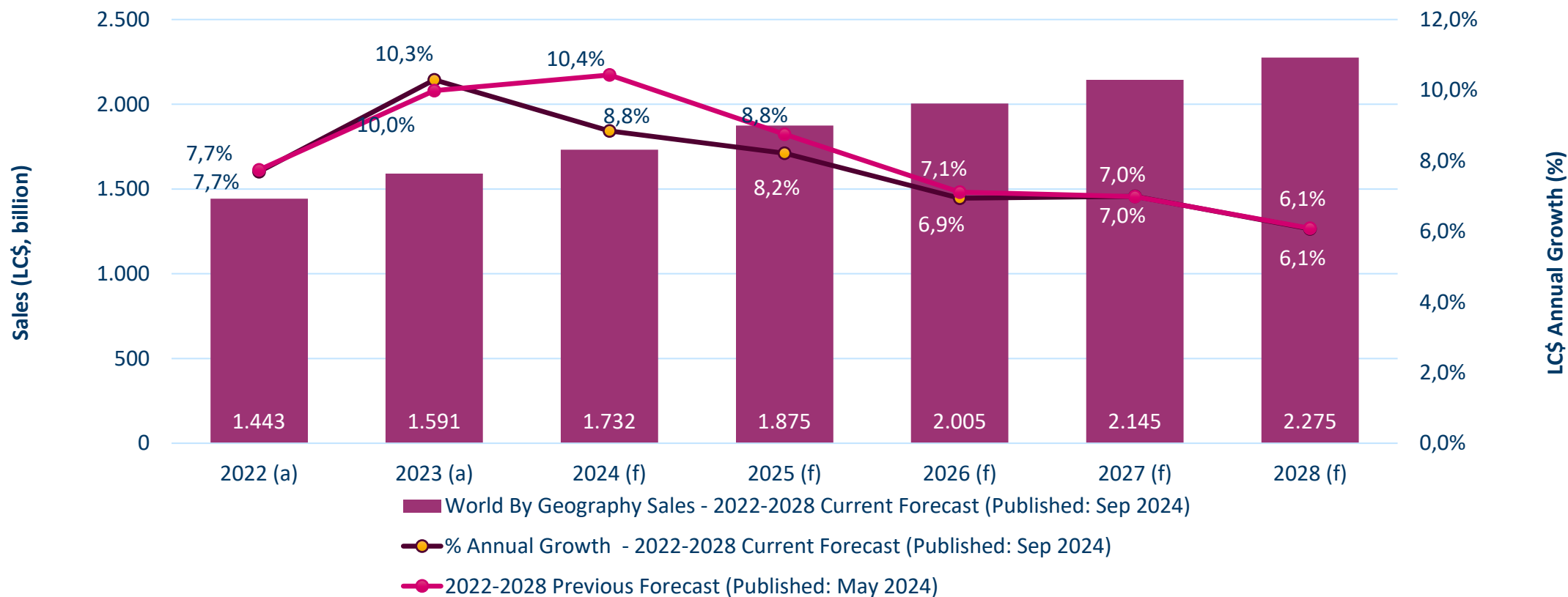
- Guideline guided Dx & Rx protocols
- Rx monitoring
- HTA org establishment
- Patients registries
- Enabling Managed Entry Agreements
- TRS

Factors affecting patient access to medicines



The global pharmaceutical market is forecast to grow at a CAGR of 7.4% between 2023 and 2028

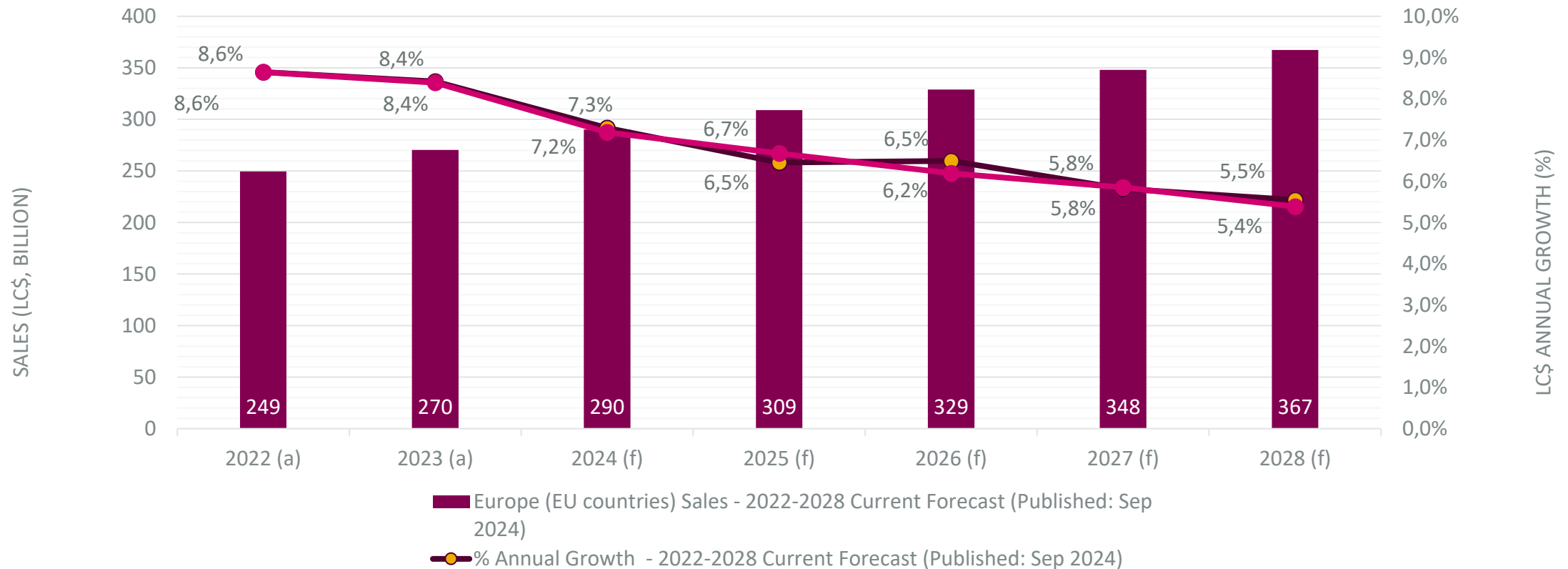
World Pharmaceutical Market Forecast – Sales and Growth (2022-2028)



14. Growth in the LATAM region is lifted by growth in Argentina, which is primarily driven by hyperinflation.
Market Prognosis Global 2024-2028

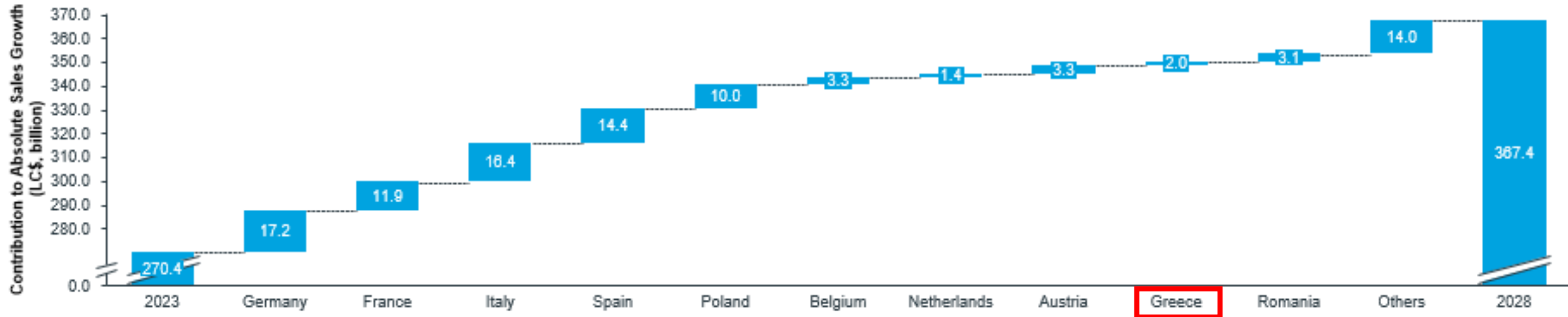
The European (EU countries) pharmaceutical market is forecast to grow at a CAGR of 6.3% between 2023 and 2028

Europe (EU) Pharmaceutical Market Forecast – Sales and Growth (2022-2028)



Greece with an estimated 2023-28 Expenditure CAGR of 5.5%

ExMNF Values



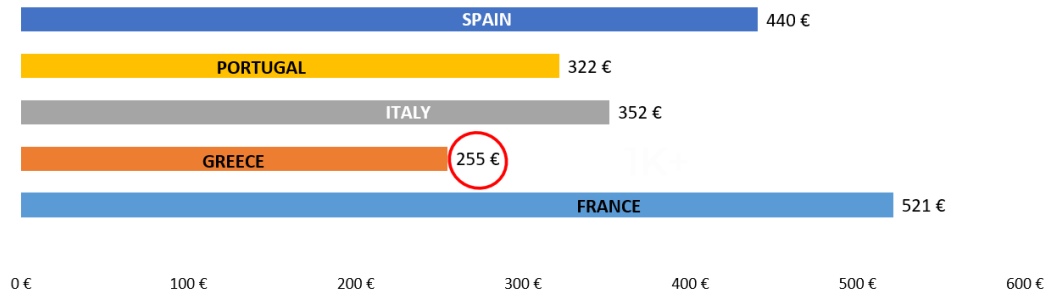
Region	Germany	France	Italy	Spain	Poland	Belgium	Netherlands	Austria	Greece	Romania	Others	Total
2024 Sales (LC\$, bn)	68.7	48.2	44.0	35.2	13.7	8.7	8.2	7.4	7.0	6.5	42.5	290.1
CAGR 2023-2028	4.9%	4.7%	7.0%	7.7%	12.9%	7.0%	3.4%	8.2%	5.5%	8.8%	6.3%	6.3%
Historical CAGR 2018-2023	6.6%	7.0%	5.8%	7.2%	10.5%	6.8%	6.4%	7.6%	4.6%	12.6%	7.0%	6.9%

Including Outpatient, Hospital and OTC sales

In terms of per capita total pharmaceutical public funding Greece is behind SE & WE Europe

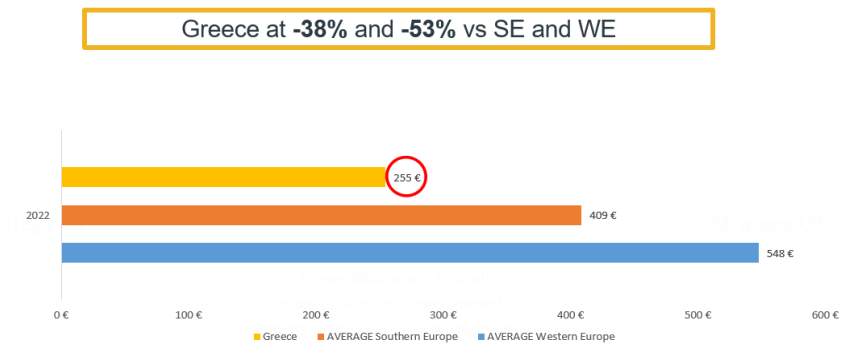
Comparison of per capita pharmaceutical State funding for Southern Europe (2022)

Total (**Outpatient & Hospital**) pharmaceutical State funding per capita



Source: FPPIA, 6/2024

Per capita pharmaceutical State funding (Hospital and Outpatient) 2022



Greece at **-38%** and **-53%** vs SE and WE

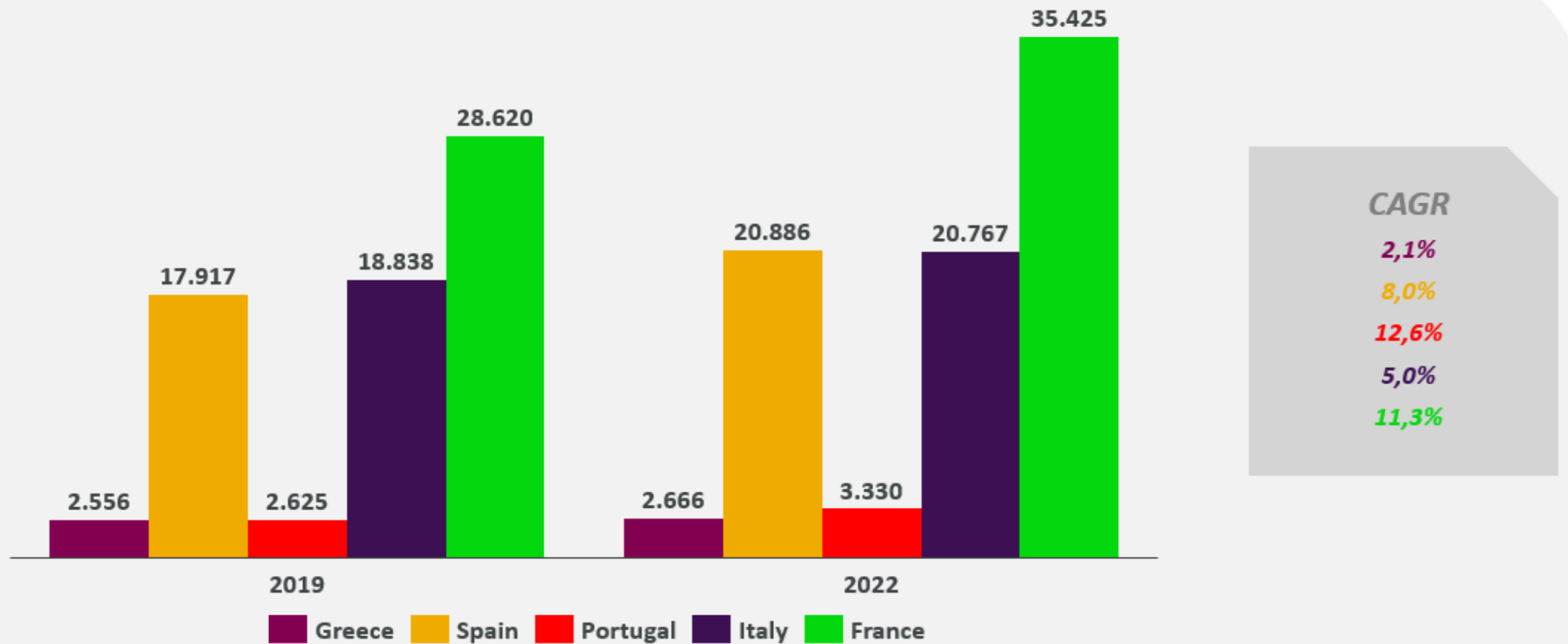
Greece lags behind Southern and Western Europe in terms of total pharmaceutical public funding

Source: EFPIA, 6/2024

* Note: The SE average consists of available data from 4 countries: Italy, Portugal, Spain, France, while the average WE average consists of available data from 7 countries: Belgium, Denmark, Ireland, Norway,



Benchmarks of total public pharma expenditure growth (mil. €)



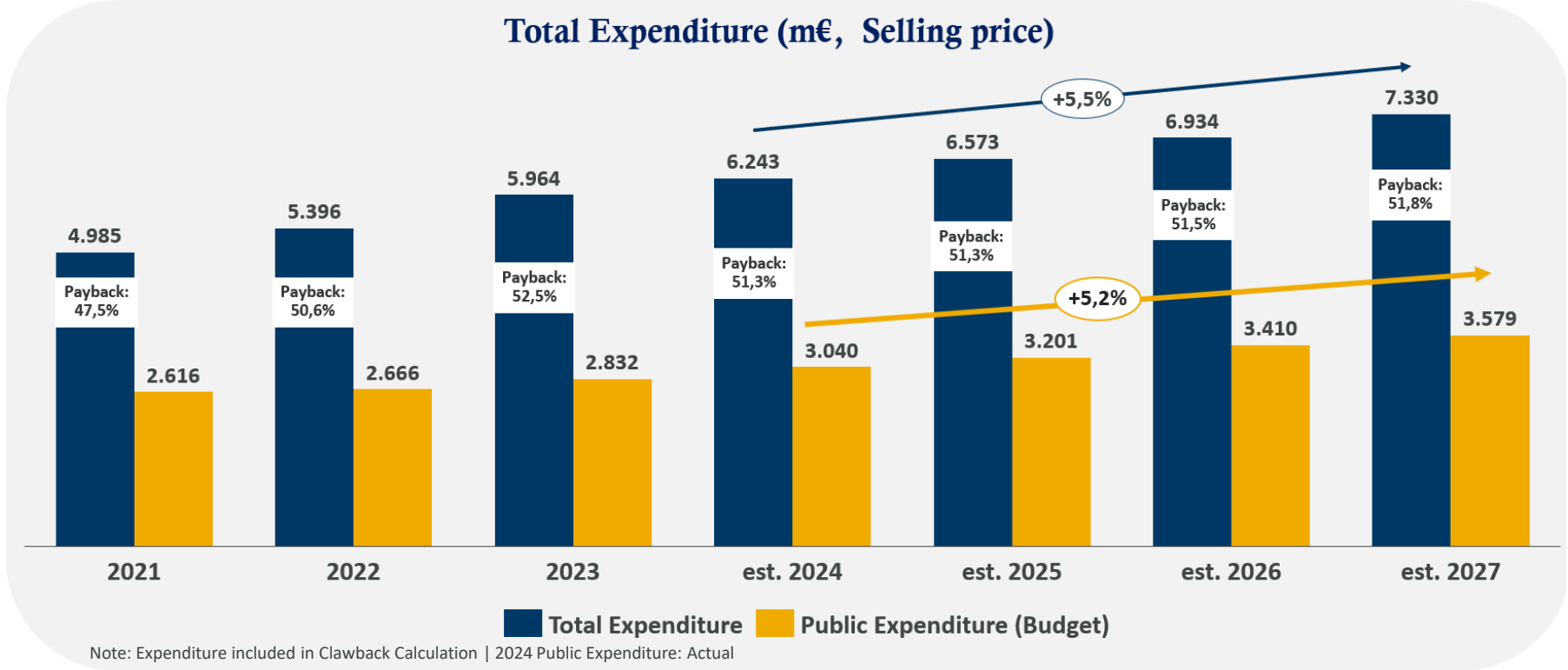
Source: EFPIA

Increasing returns in Greece | Expenditure Outstrips Budget growth

Announced Measures not leading to reduction of high payback burden

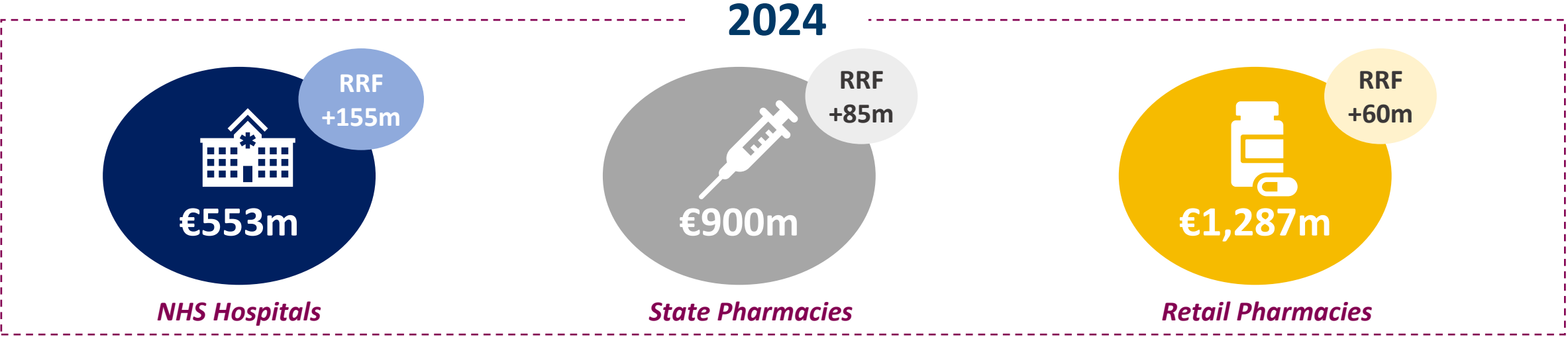
2025-27 Assumptions

- **Expenditure Growth:**
 - ✓ 5,5% per year
- **Annual Budget Growth:**
 - ✓ ~€170m per year
 - Incorporation of 2025 RRF funds
 - Budget increase according to GDP growth
 - + €100m in 2026
 - + €100m in 2027
 - + €50m TRS in 2026



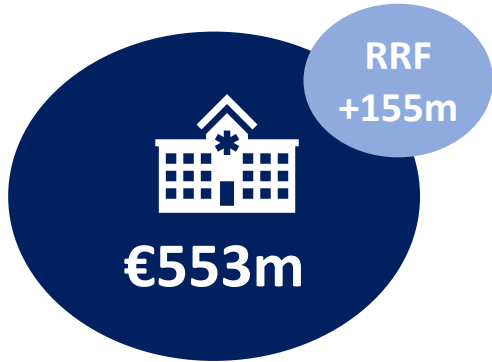
Budget increase rate should outpace Expenditure increase to reduce paybacks levels

Public Pharmaceutical Budget

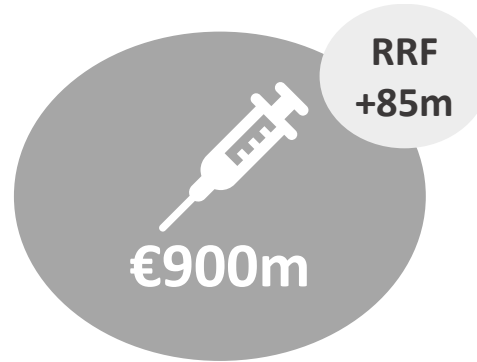


Public Pharmaceutical Budget

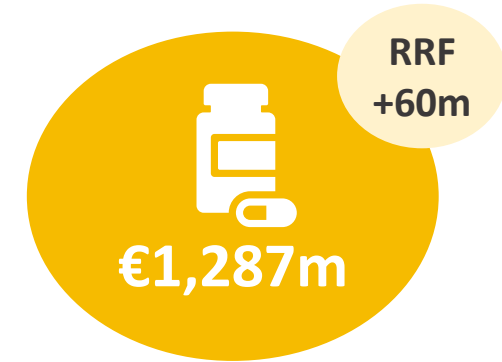
2024



NHS Hospitals



State Pharmacies

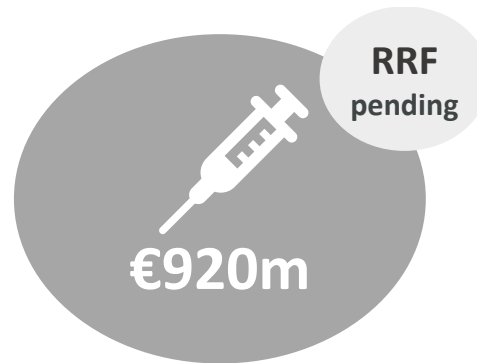


Retail Pharmacies

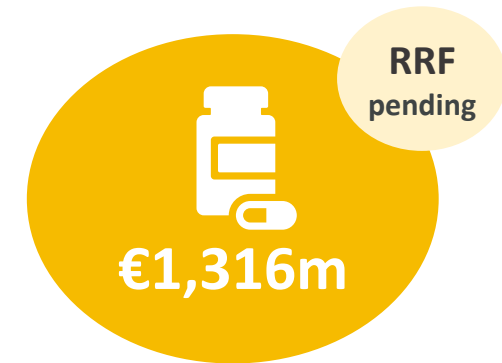
2025



NHS Hospitals



State Pharmacies

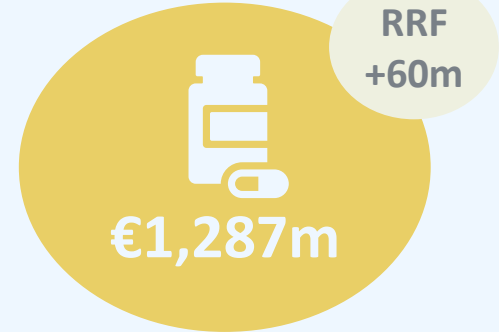
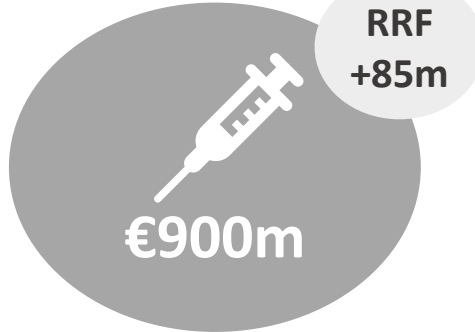


Retail Pharmacies

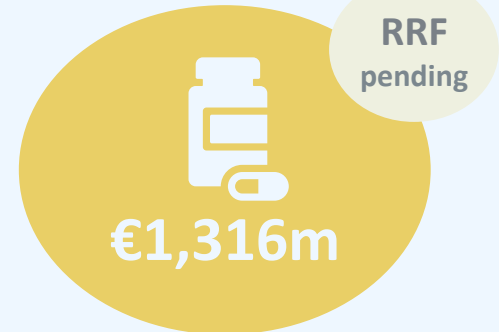
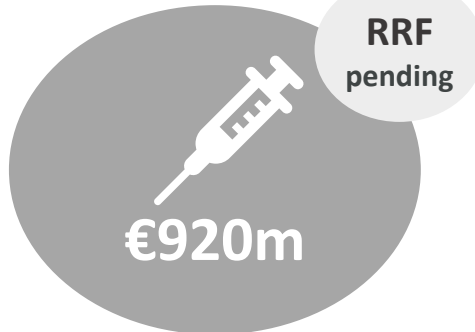
*Pending legislation

Public Pharmaceutical Budget

2024



2025



*Pending legislation

Retail Budget Split

ΦΕΚ Β' / 3949 / 23.07.2025



Retail Pharmacies



Medicines that never had patent protection

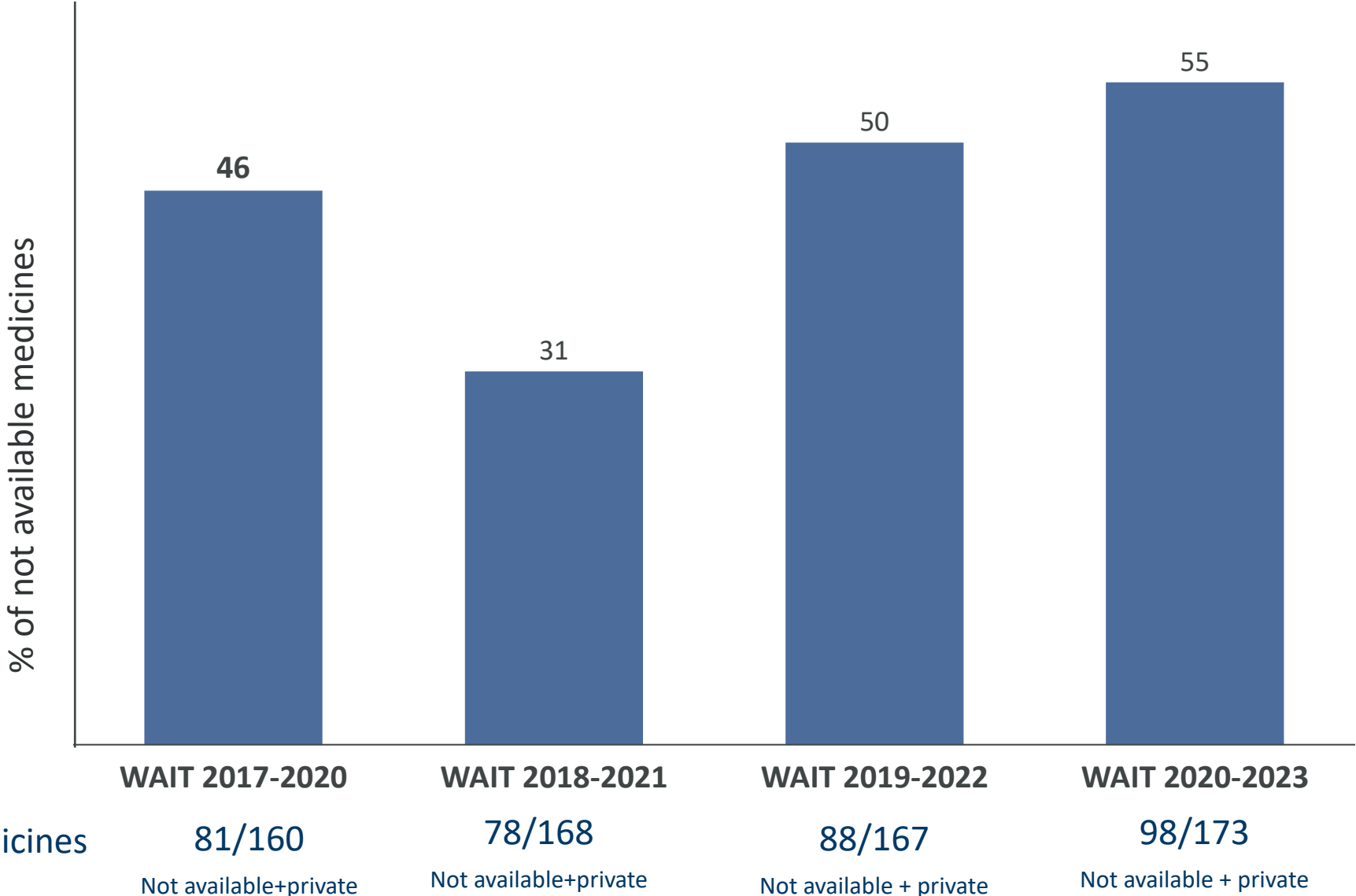
10(1), 10(3), 10(4), 10(α), 10(β), 8(3)β

This category covers products whose single active ingredients were not under substance patent protection at the time of approval, and whose indication is limited to substitution therapy in adult patients, where the individual substances are administered together at the same dose as a fixed-dose combination, but as separate products

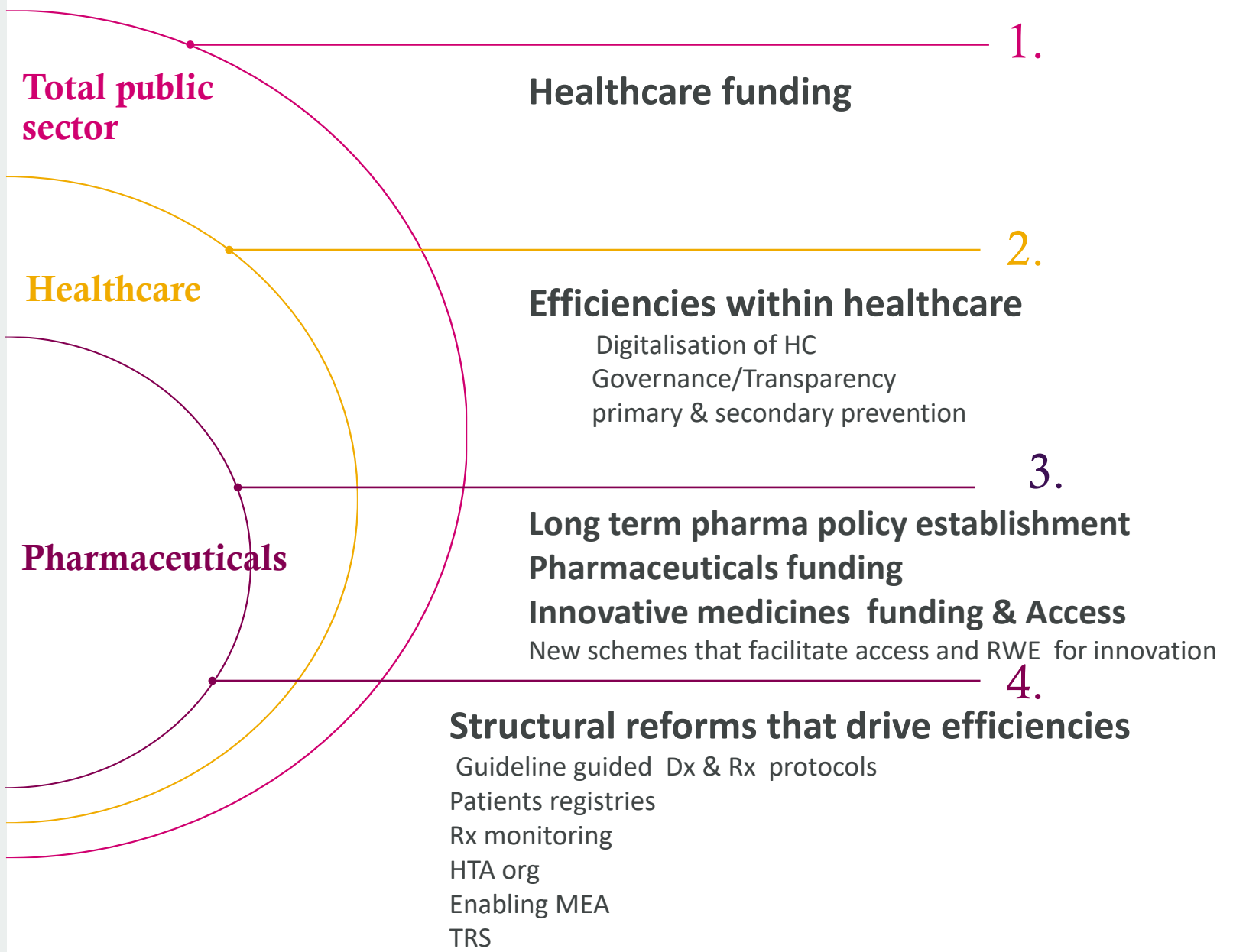


Medicines that had or have patent protection

The % of not available medicines in Greece increases



Need for a holistic long term strategic approach that put patient at the centre & drives sustainability for ALL stakeholders



Key principles

Transparency

Predictability

Collaboration

Open data

Commitment

Human Resources



Σας ευχαριστώ!!!