Pharmaceutical Policy in Greece: In search of rationality amidst cumulative distortions over the 2010-2023 period

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THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

Agenda

1. Context and Pharmaceutical Spending Development; 5 areas causing distortion
2. The Clawback Mechanism
3. The Pricing System
4. The HTA and Negotiation Mechanisms
5. The lack of Prescribing Guidance
6. The IFET Channel
7. Recommendations and ways forward

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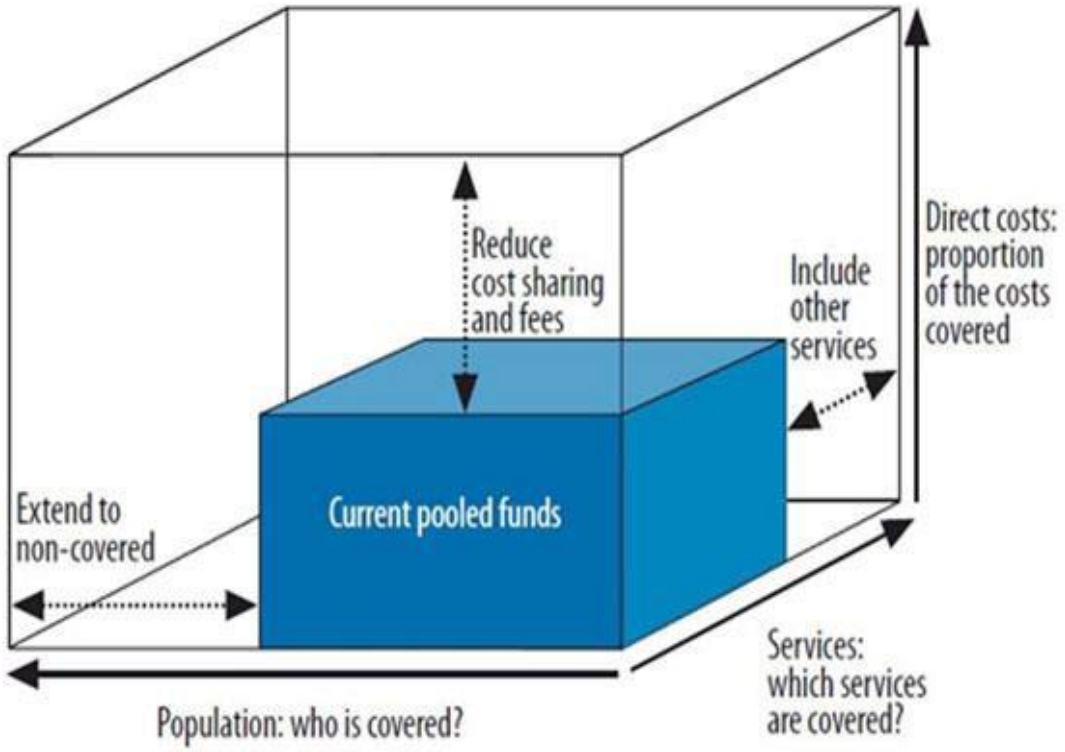
Rational Pharmaceutical Policy – Improving access, promoting rationality, ensuring financial sustainability

Objectives of pharmaceutical policy

- ***Macroeconomic-efficiency*** (keep within a fixed budget; financial sustainability)
- ***Microeconomic-efficiency*** (resource allocation, optimal prescribing, therapeutic pathways)
- ***Equity*** (leave no one behind)
- ***Choice*** *and* ***responsiveness***
- ***Rational drug use*** (providing the most appropriate treatment and monitoring its effects)

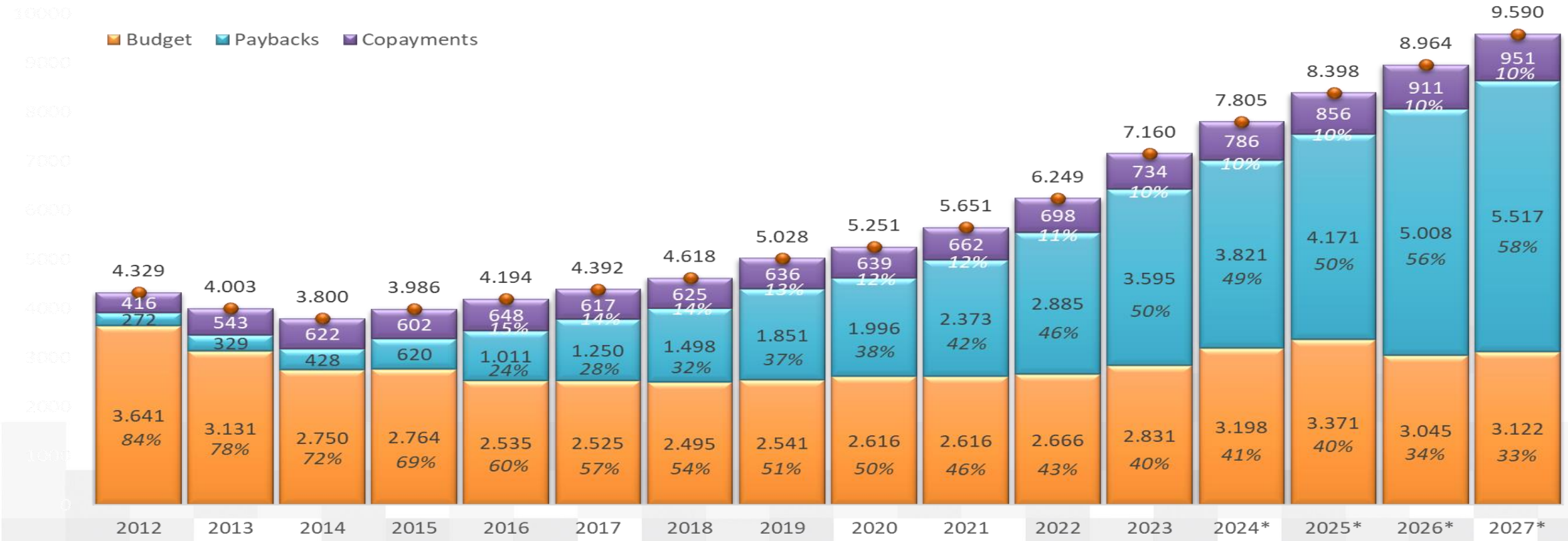
Role of value assessment system

- Improve efficiency in resource allocation
- Encourage rational prescribing through clinical & cost-effectiveness guidance
- Contribute to the achievements of Universal Health Coverage (UHC)



Source: World Health Organization, 2017

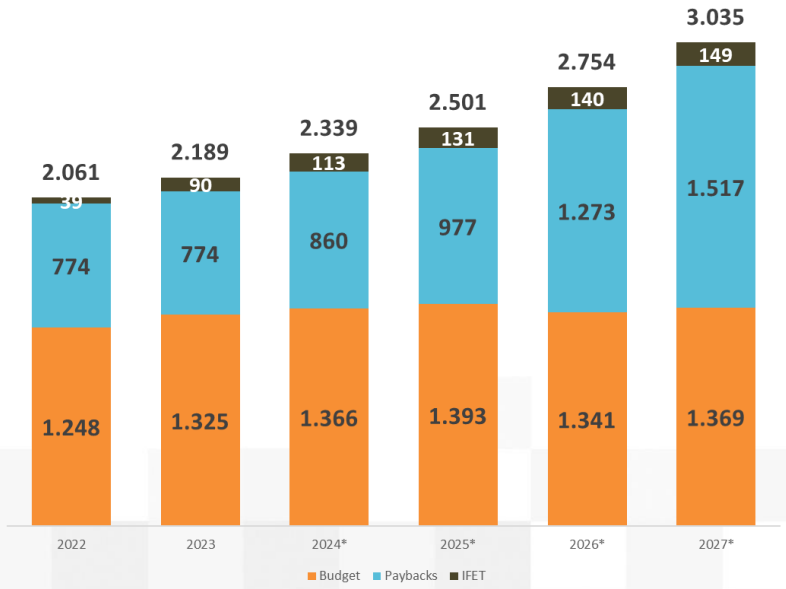
The evolution of pharmaceutical expenditure, 2012-2027



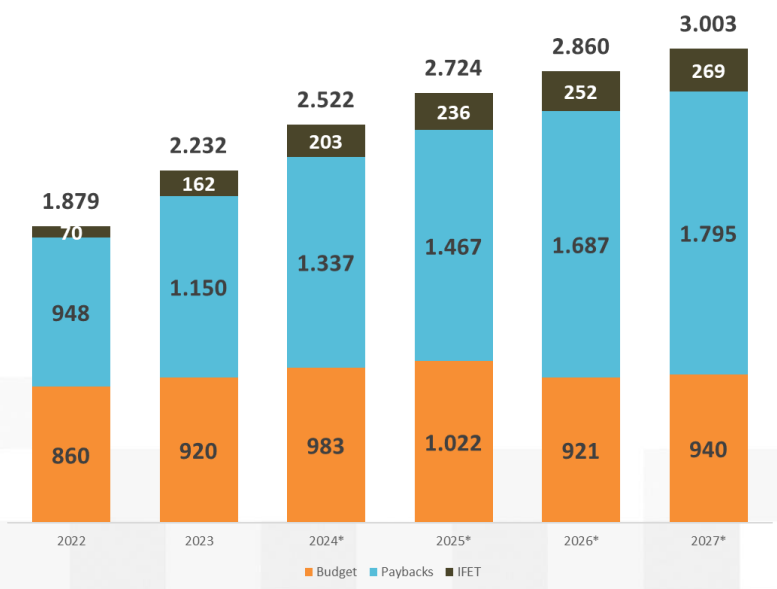
Source: IOBE, ΣΦΕΕ Facts and Figures *Own Estimations

The evolution of pharmaceutical expenditure per distribution channel, 2022-2027

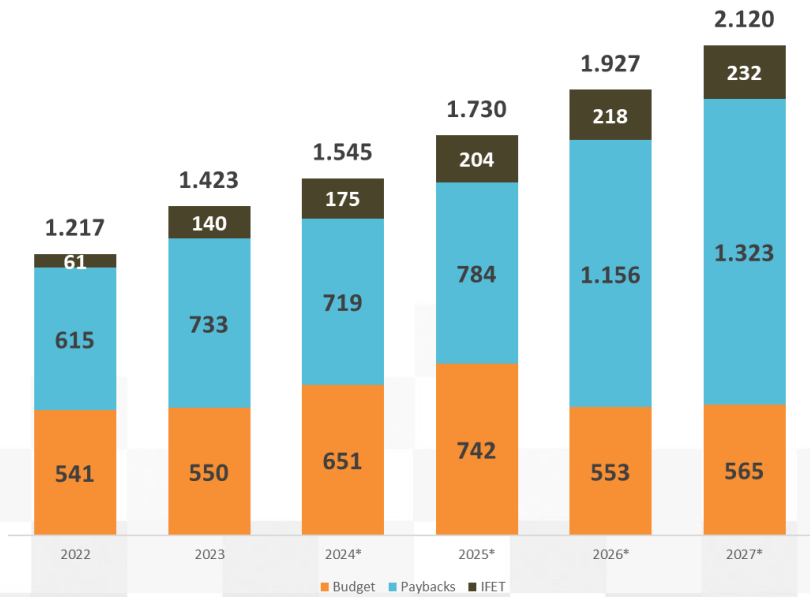
Retail



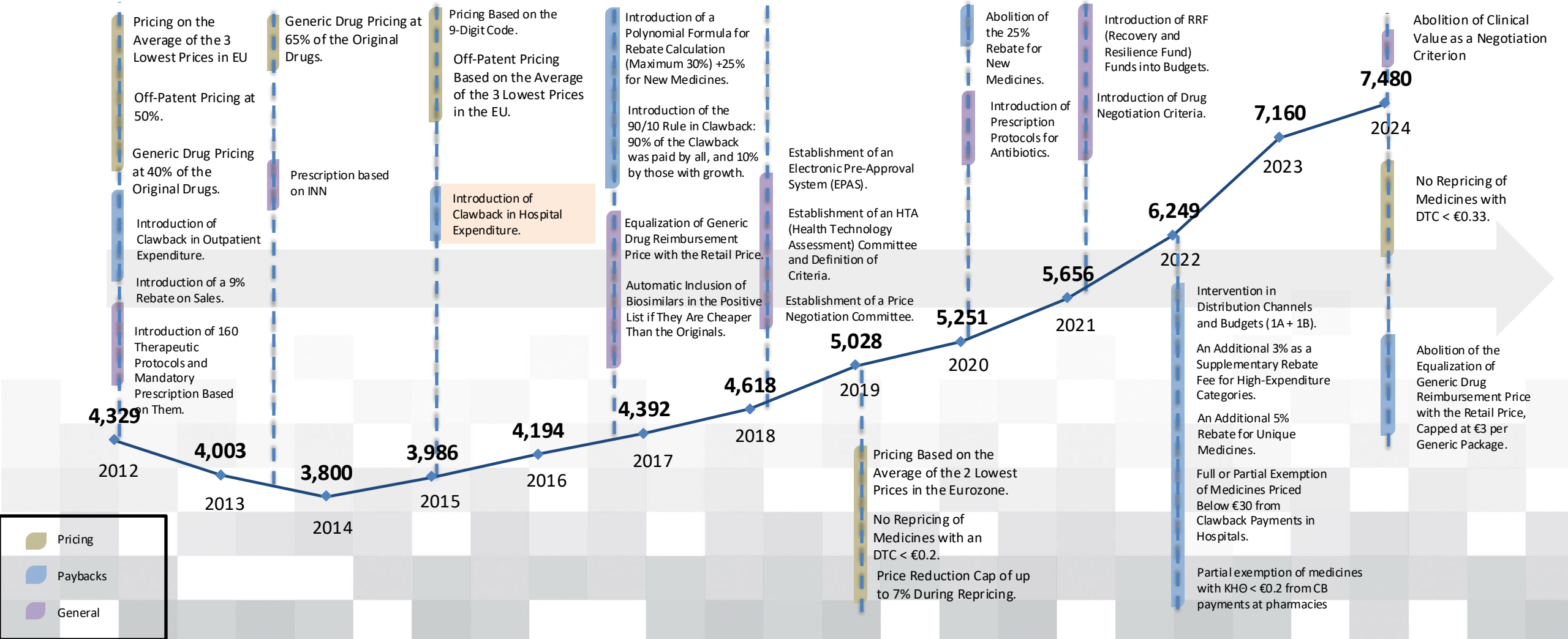
EOPYY



Hospital



Evolution of pharmaceutical legislation and pharmaceutical spending 2012 – 2024



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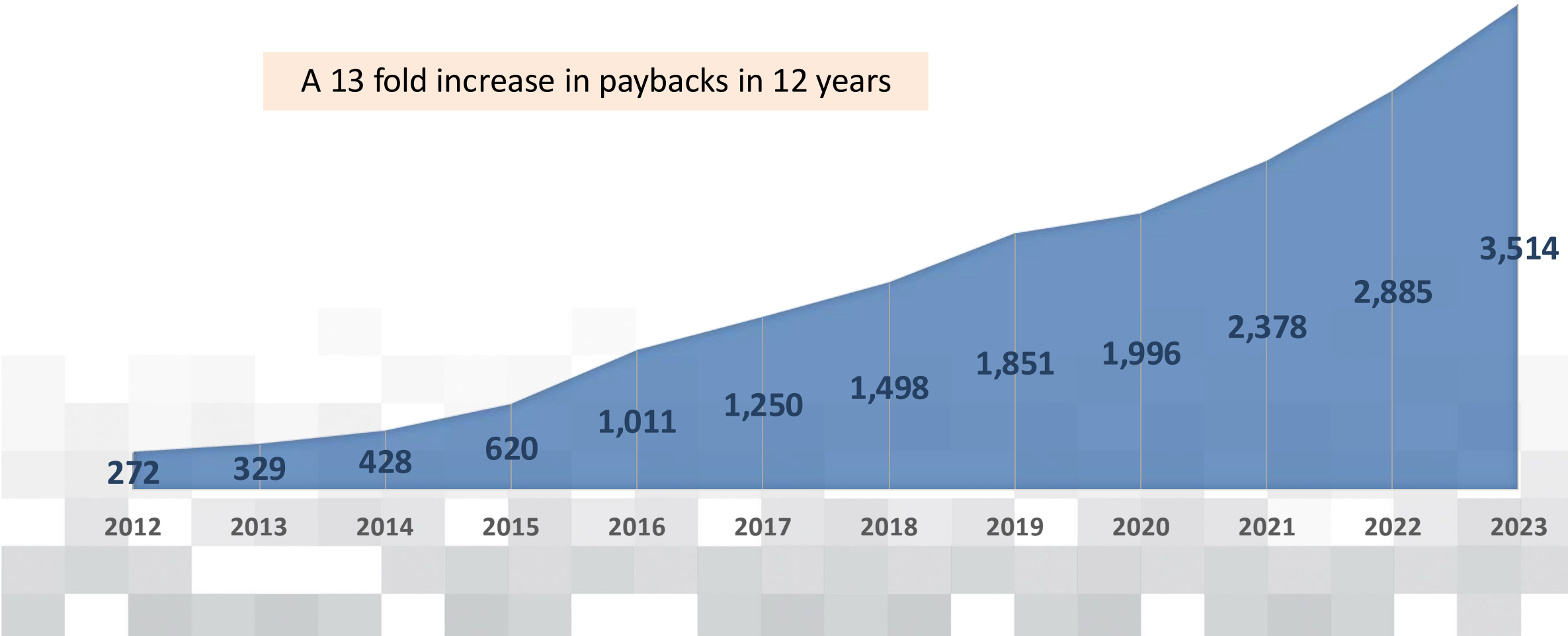
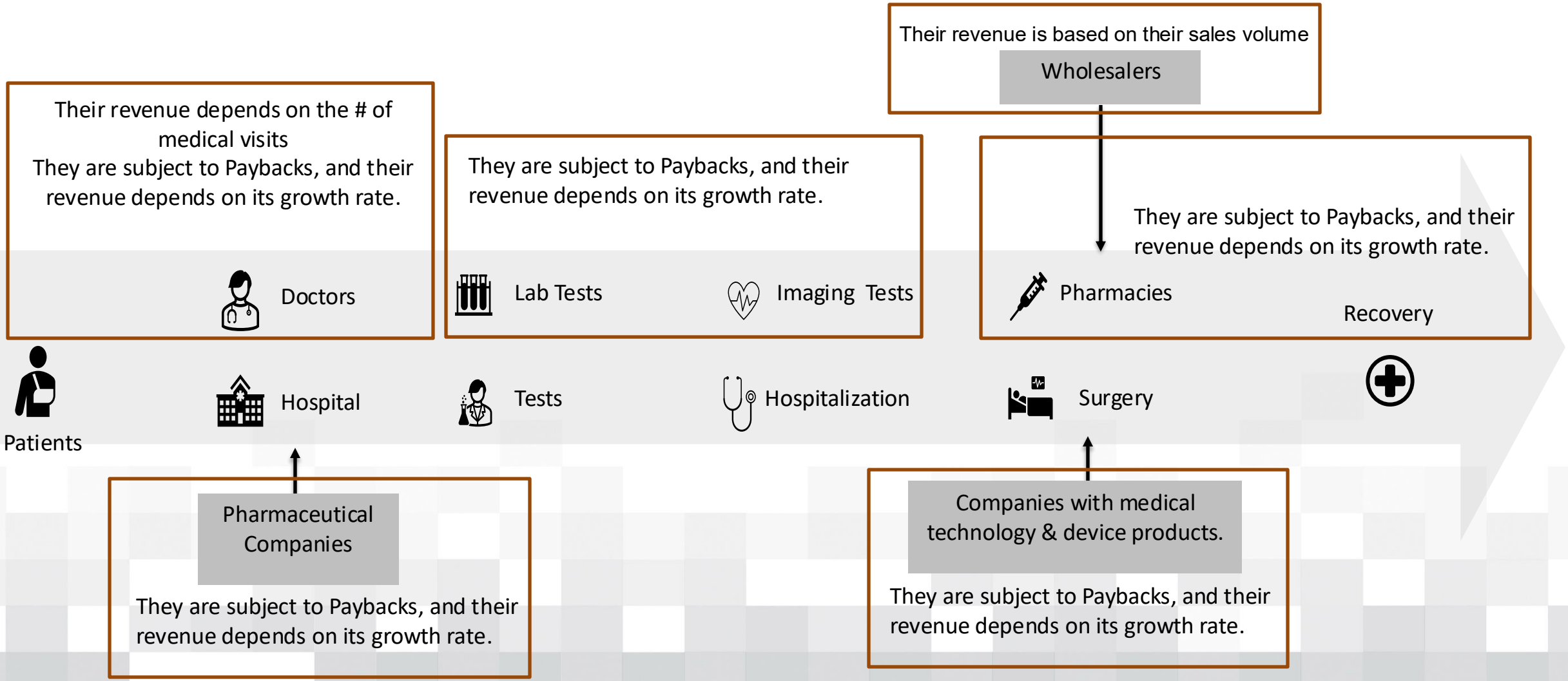
Evolution of Total Industry Paybacks (€ m., 2012 – 2023)

A 13 fold increase in paybacks in 12 years

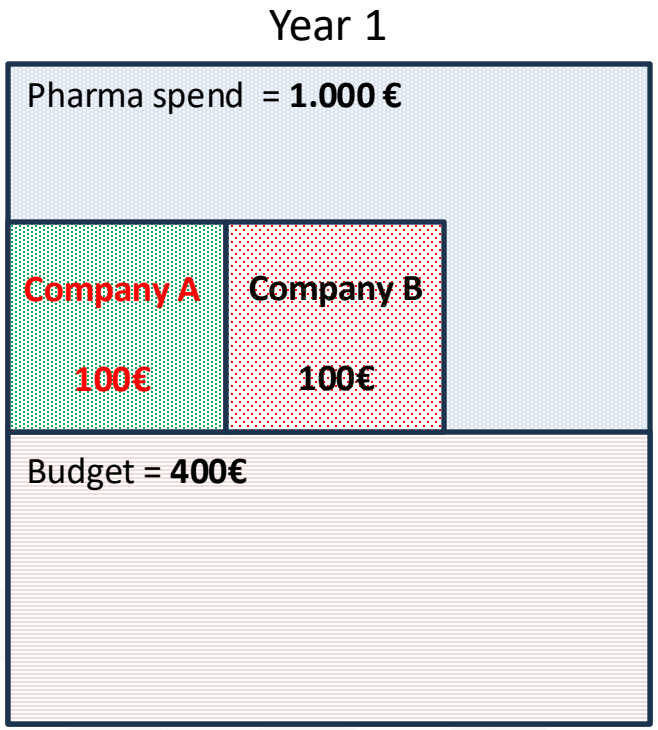


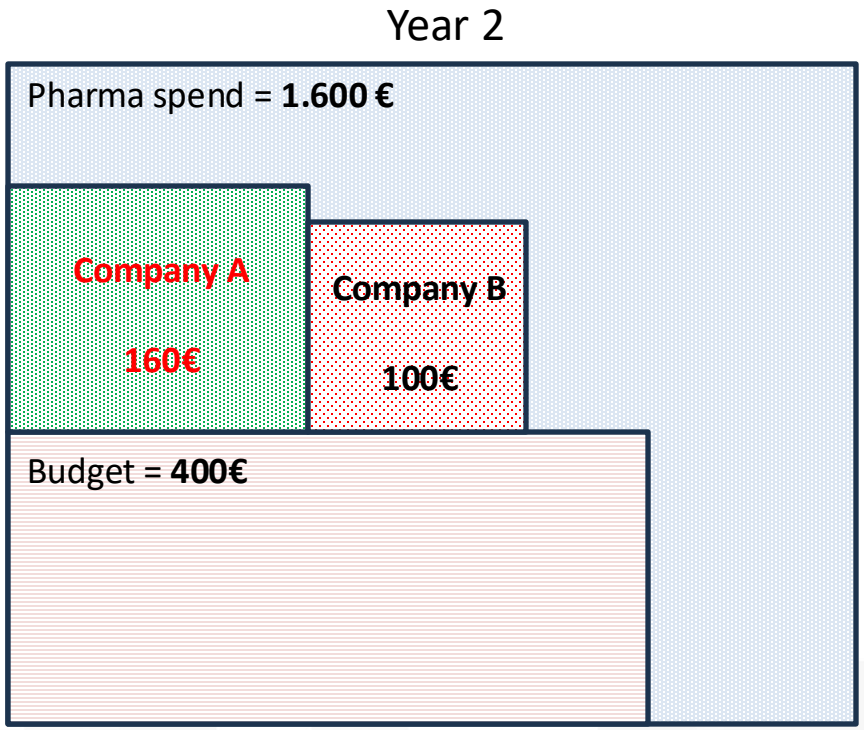
The current health system rewards increased consumption only



The Inflationary Nature of the Clawback

Increasing company sales less than market average growth rate leads to lower net sales and lower net price



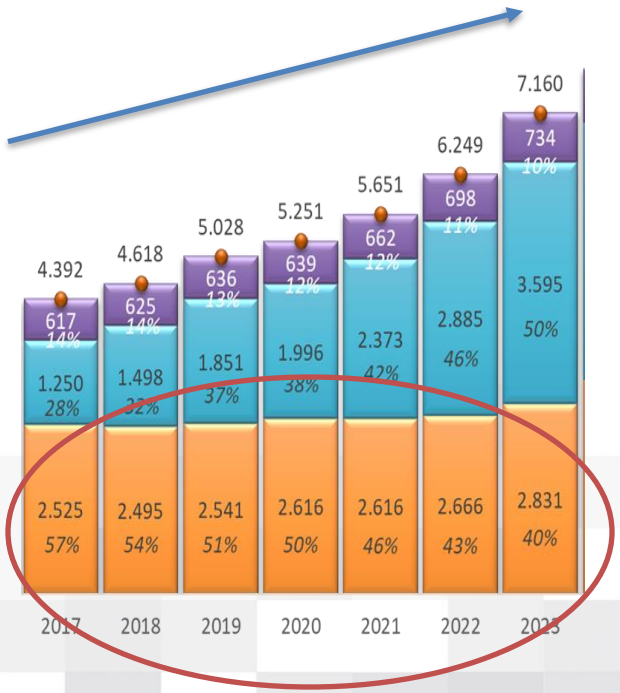


	Gross Spending	Paybacks	*Net Spending*
Market	**1.000**	**-60%**	***400***
Company A	100	-60%	*40*
Company B	100	-60%	*40*

Gross Spending	Paybacks	*Net Spending*
1.600	**-75%**	***400***
160	-75%	*40*
100	-75%	*25*

Focus on payback redistribution rather than spending control creates patient access inequalities

Pharma Expenditure and paybacks evolution



Redistribution Interventions

2017
- Implementation 90/10 rule for Outpatient Clawback (10% CB paid by companies with growth)
- Equation Retail Price of Generics with Reimbursement Price

2018
- Change 90/10 rule to 80/20 for Outpatient Clawback (20% CB paid by companies with growth)

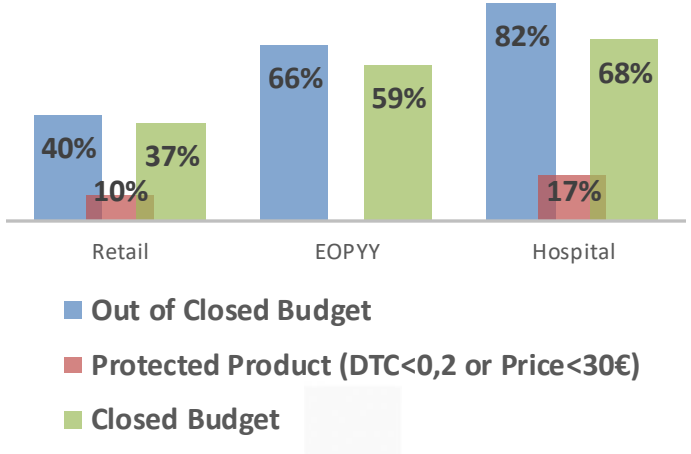
2019
- Change 90/10 rule to 80/20 for Hospital Clawback (20% CB paid by companies with growth)
- Price decrease cap of 7% of annual price reassessment

2022
- Full or Partial Exemption of Medicines Priced Below €30 from Clawback Payments in Hospitals, the rest allocated to other companies
- New rebate 5% for Innovative Products

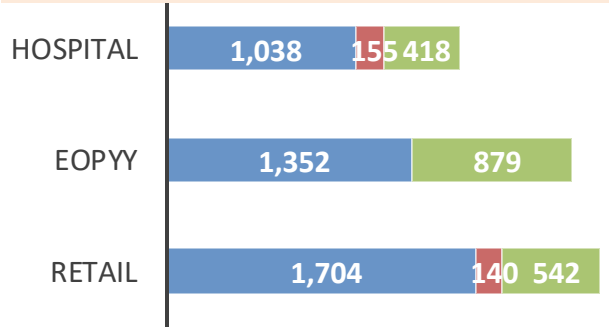
2023
- Drugs with DTC<0,2€ will pay 10% maximum CB, the rest allocated to other companies

2024
- No repricing of Drugs with DTC<0,33€

Total returns (in %) Patients and Products with varying levels of access



Spending Levels and Payback Ratios per Channel



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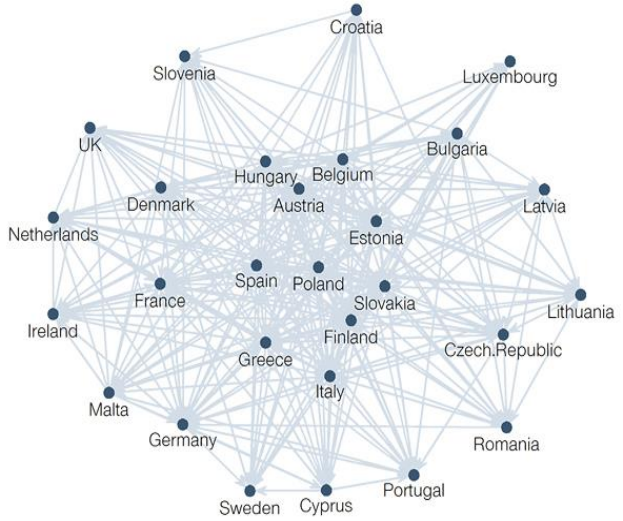
External Price Referencing: What are the pricing rules?

- **External Price Referencing** (EPR) is a pricing mechanism where the price of a drug in one country is set/adjusted in relation to the price of the drug in other countries.
- There is no fixed method as to how EPR is applied in the drug pricing process, and as a result, every country has unique IRP rules with their own selection of reference countries and frequency of price revisions



Greek Basket (EU – Eurozone Countries)

On – Patent/ Off Patent/ Combinations/ Biologics/ Biosimilar/ Hybrid

Ex- Factory price defined as the average of the 2 lowest different price in Eurozone Countries

Generics

EX- Factory price defined as 65% of reference product

What are the pricing distortions?

EX-Factory/Reimbursement Price

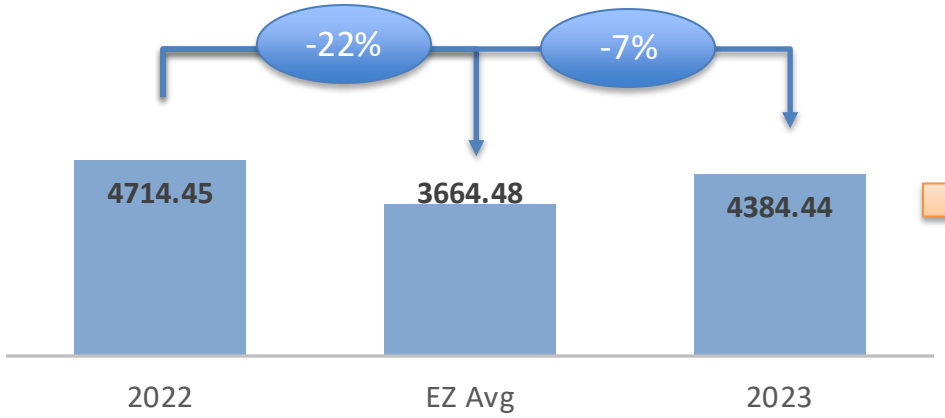
- 7% Cap on Price List Reduction
- Pricing based on the 9-digit code
- No price adjustments for medicines with DTC < 0,33€
- Automatic reimbursement for biosimilars if they are cheaper than the reference medicine
- Generic pricing at 65% of the reference medicine's price
- Reimbursement for generics at retail price with a cap of 3€

NET Price (after paybacks)

- It depends on the distribution channel
  - Retail
  - EOPYY Pharmacies
  - Public Hospital
- It depends on price protection rules
  - Public Hospital < ή > 30€
  - Retail < or > 0.2 DTC
- It depends on the time of negotiations
  - How much money has been added (e.g. RRF penalty) and when?
  - How many agreement have been made?

Price Reduction Cap of up to 7% at Annual Price Reassessment

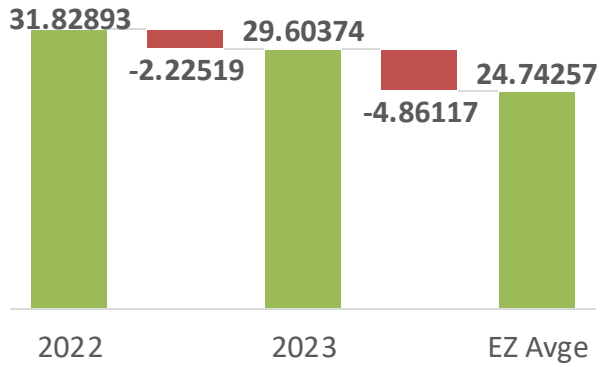
Product A: Biologic with data protection (originator)



Sales 2023

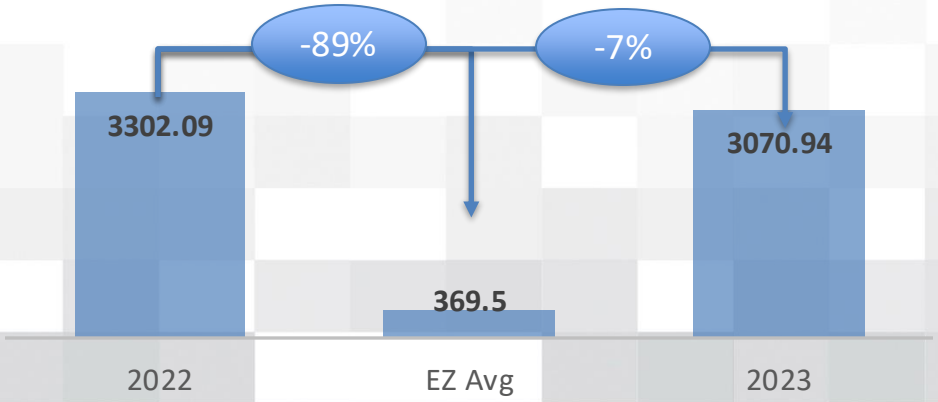
6,752

Purchases 2023

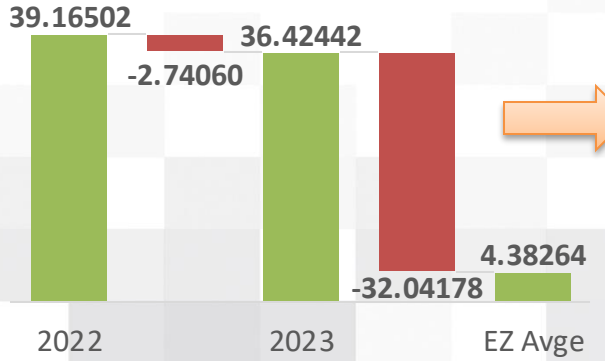


SAVINGS:
4.864.172 €

Product B: Biologic without data protection (originator)



11,861

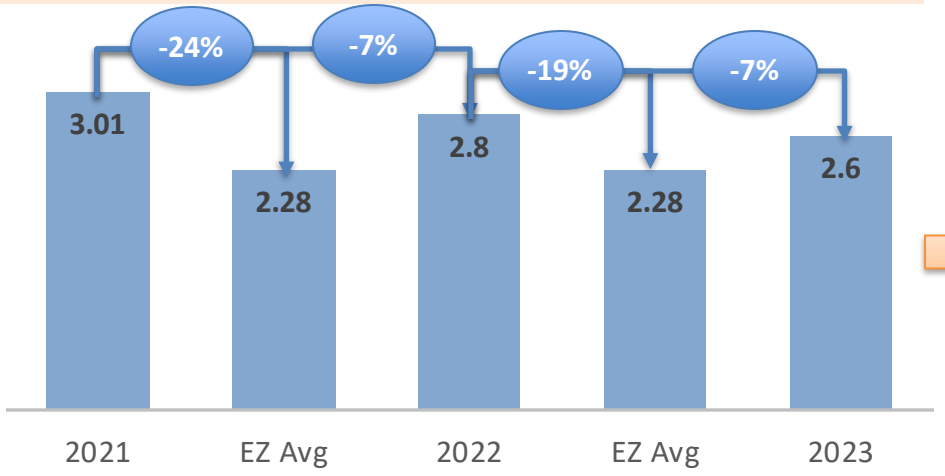


SAVINGS:
32.043.486 €

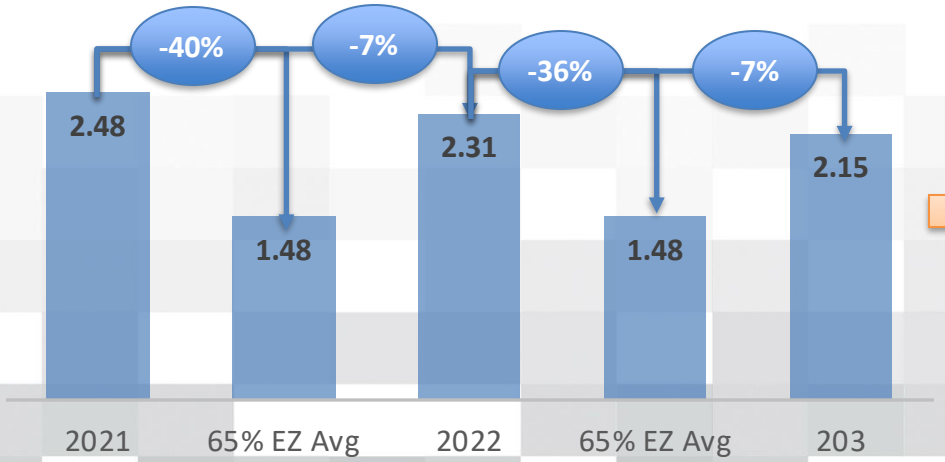
Source: IQVIA, Price Bulletin MoH

Price Reduction Cap of up to 7% at Annual Price Reassessment

Product A Off – Patent Originator



Product B: Generic



Source: IQVIA, Price Bulletin MoH

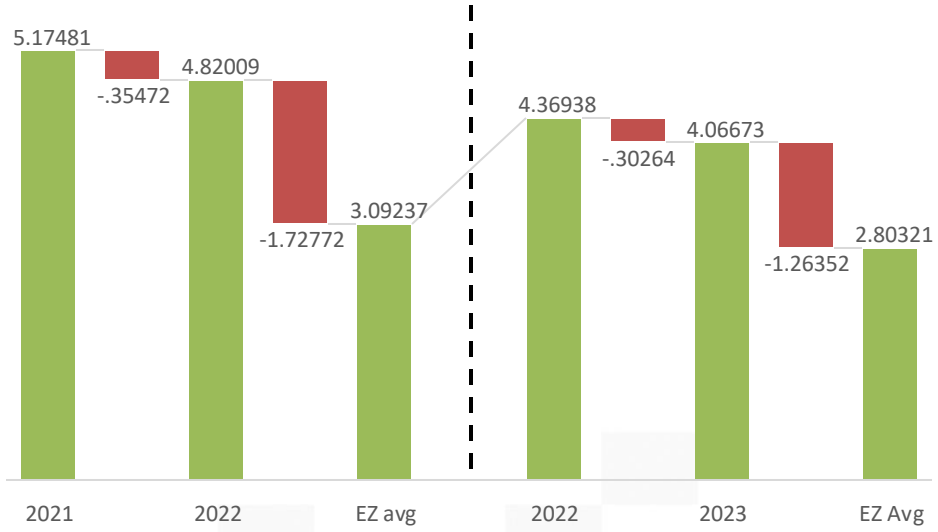
Sales 2023

2022
24,464
2023
22,332

2022
2,086,617
2023
1,891,505

*Factorized Units

Purchases



SAVINGS 2022:
1.732.490 €

SAVINGS 2023:
1.264.629 €

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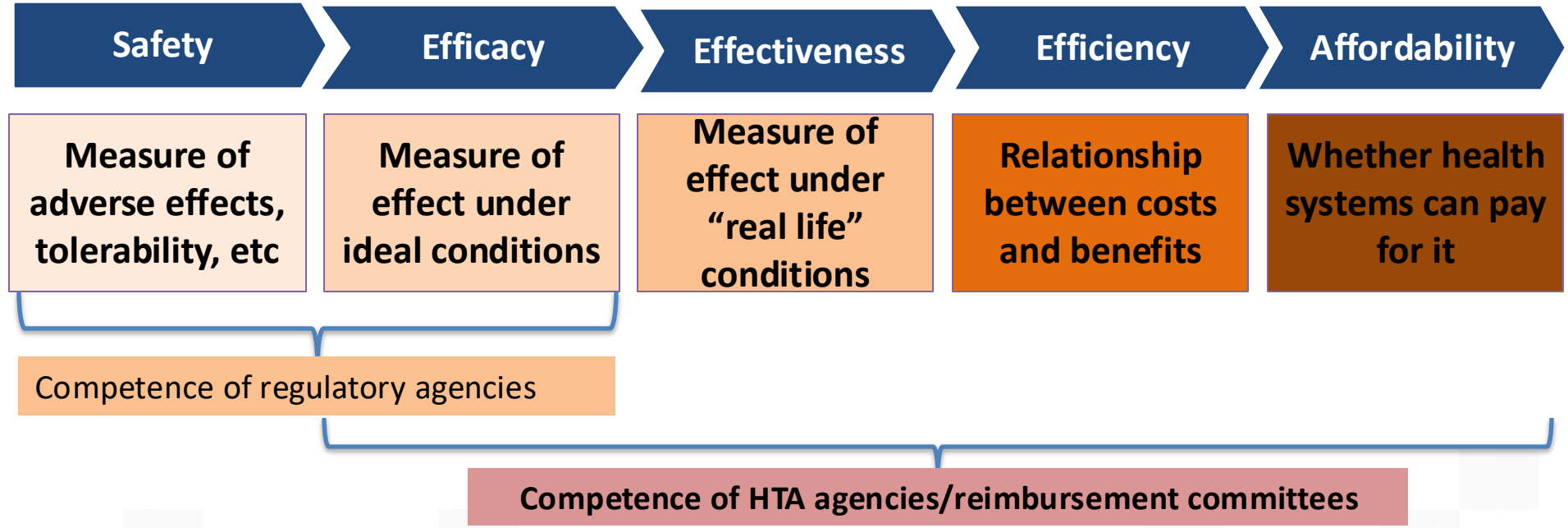
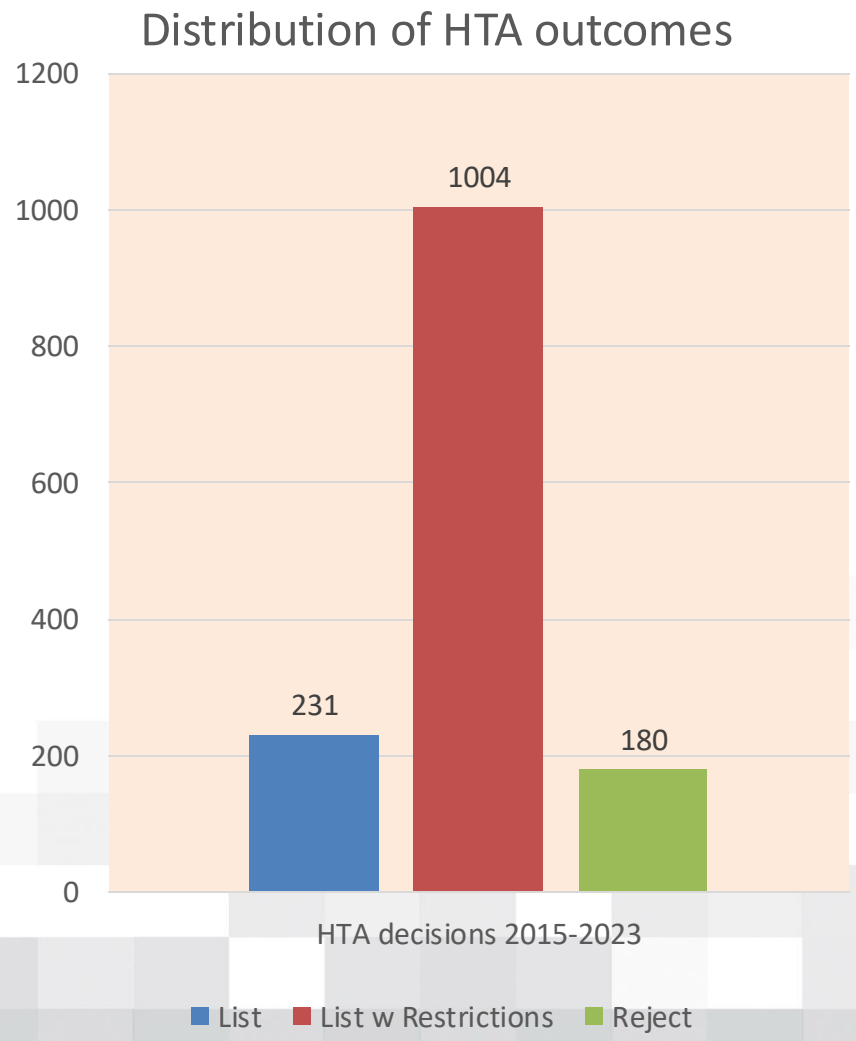
Value Assessment and Health Technology Assessment: Why?



Models of HTA → **Cost-effectiveness** (England, Sweden) | **Clinical Benefit Assessment** (France, Germany) | **Value-based assessment** (England, France)

International evidence shows that >70% of drugs submitted to HTA undergo **restriction of indication**, through **population restrictions** and/or **prescribing restrictions**

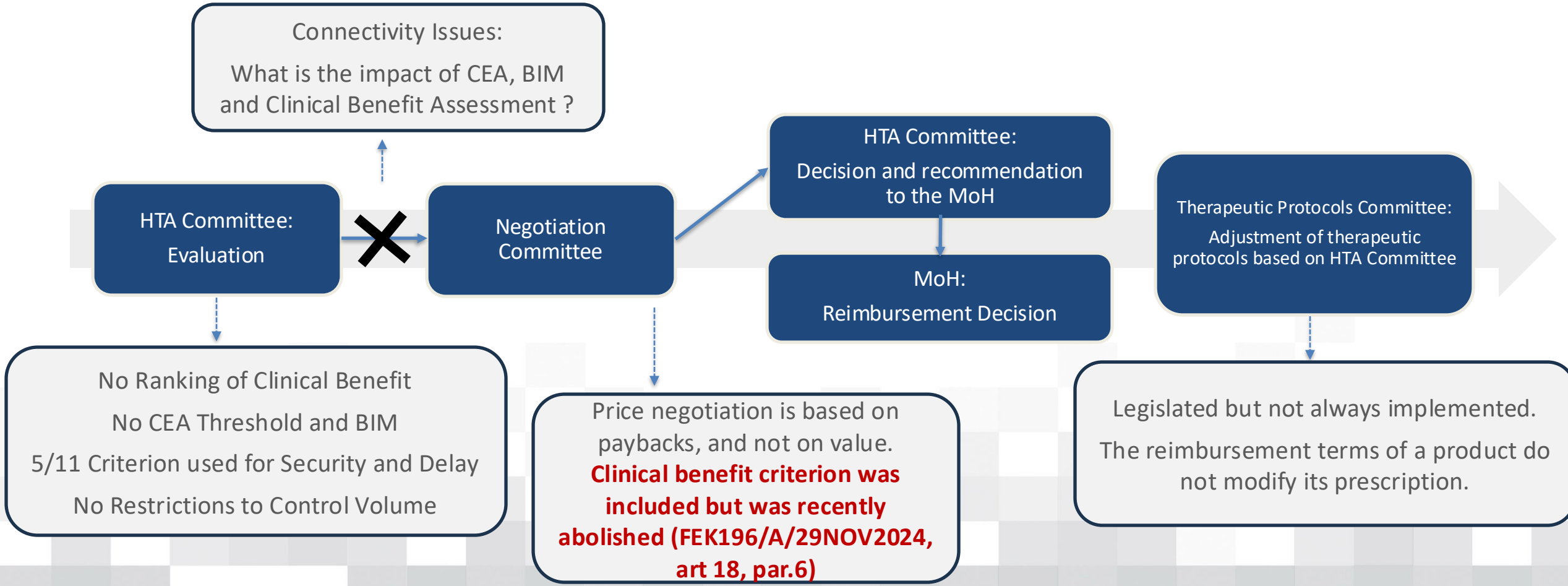
- **HTA processes**: informing (a) ***coverage decisions*** and (b)health system-wide ***uniform prescribing guidance***
- **Sample**: **N=1,415** drug-indication pairs across 7 countries*
- **Listing**: Only a fraction (16%) of submissions to HTAs are approved as applied for (as per approved indication)
- **Listing with restrictions**: 71% of all drugs have been approved with some form of population or prescribing restriction (amounting to **restriction of indication**)
- **Rejection**: 13% of all drugs had at least one prior rejection; most have been LWC when re-submitted



* Australia, Canada, England, France, Germany, Quebec, Scotland, Sweden.

Kanavos et al, Social Science and Medicine, 2023.

Reimbursement process:
Absence of value assessment and restrictions



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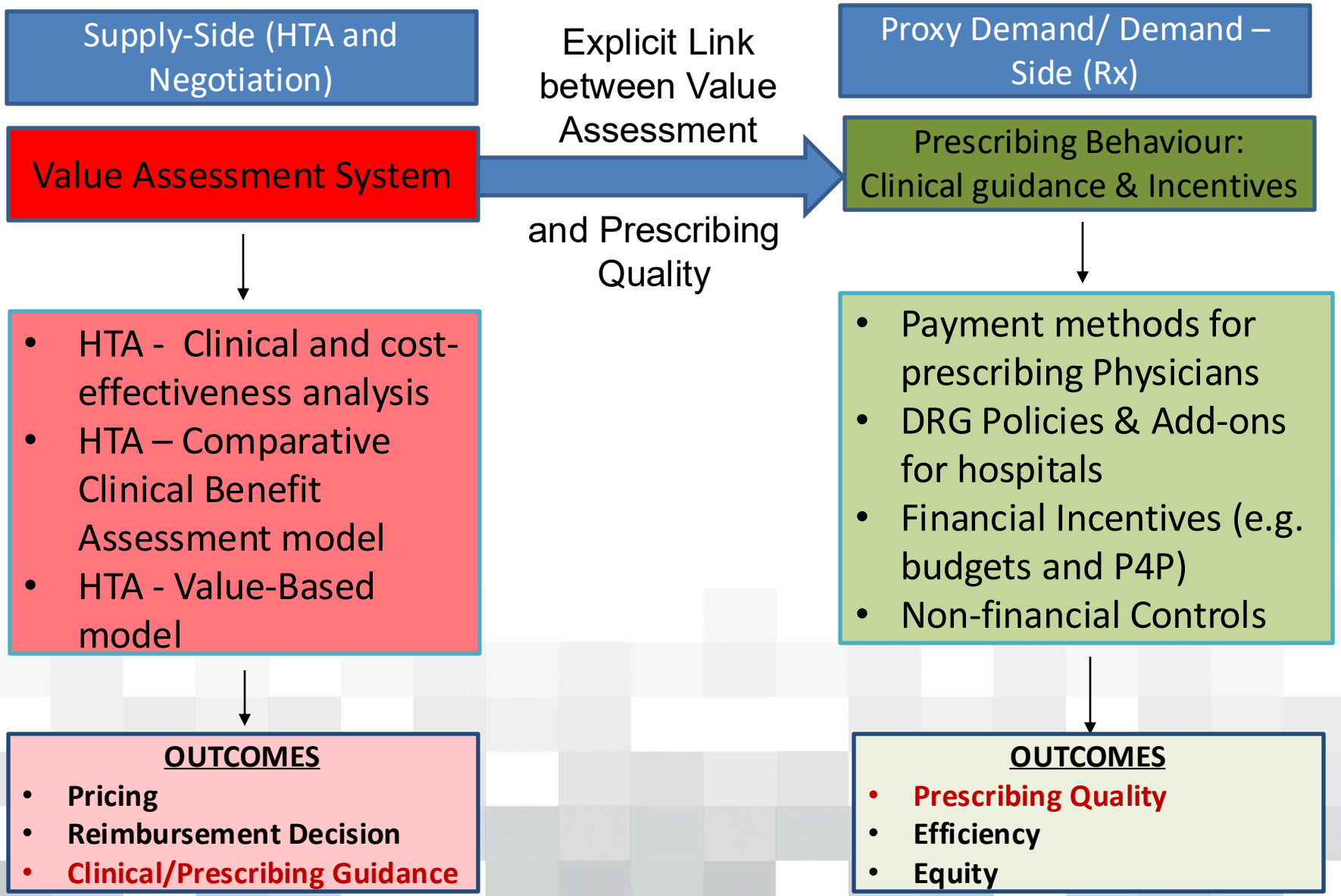
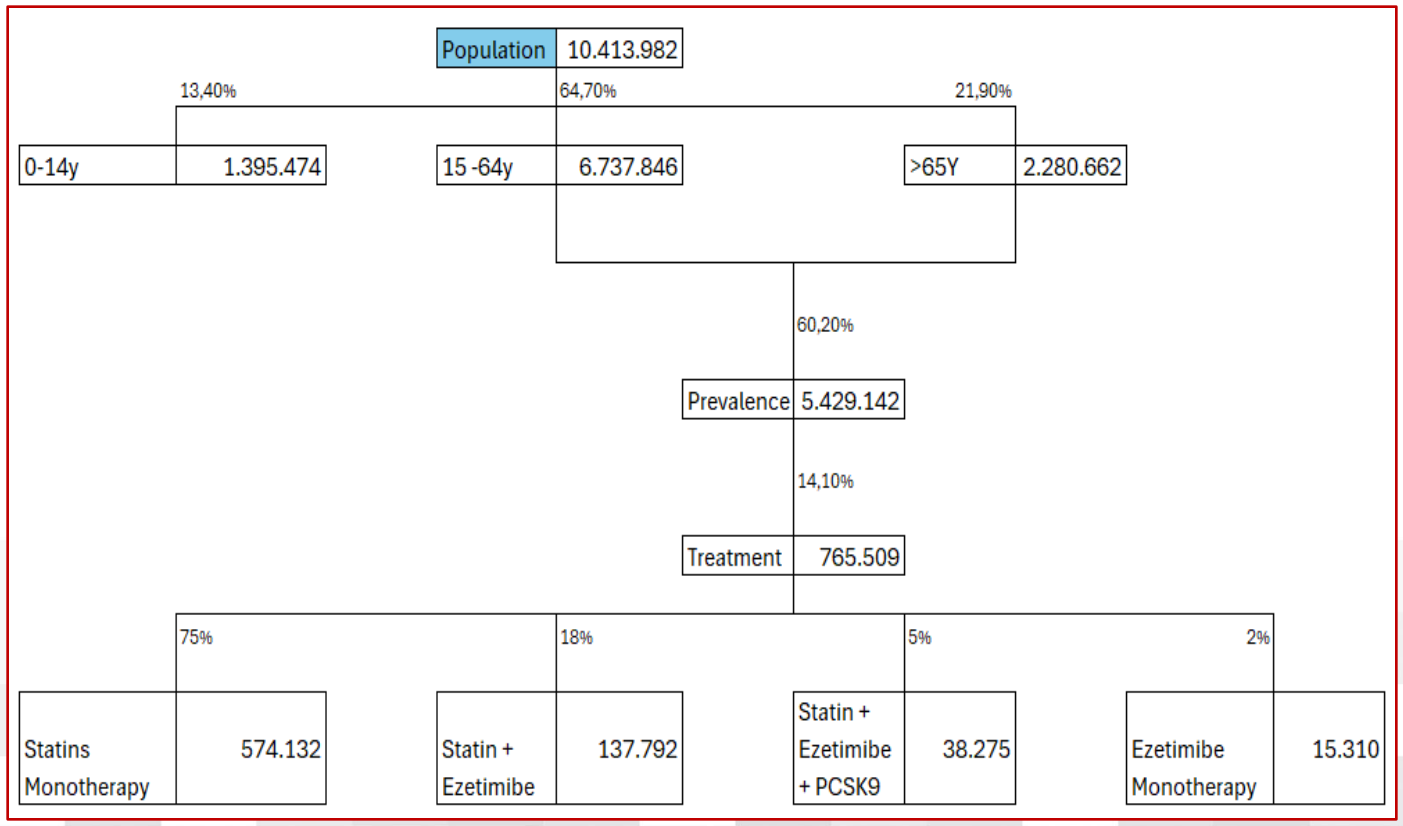
Strengthening HTA and Negotiation Committees can result in rationalizing prescribing & optimizing spending

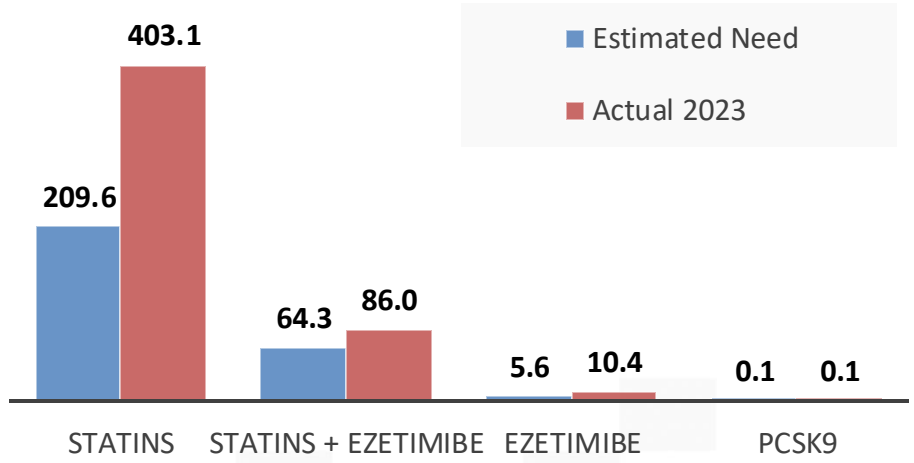


The case of dyslipidemia protocols: Savings for the health system?

Treatment Algorithm based on the new protocol of dyslipidemia and adapted to the total Greek Population



Actual Consumption (million pills) 2023 vs estimated consumption based on treatment algorithm



SAVINGS: 105.930.188 €

SAVINGS without price distortions: 147.840.901 €

Source: MoH, 2024; IHME, 2024 ; Touloumi, G., Karakosta, A., Kalpourtzi, N. *et al.* High prevalence of cardiovascular risk factors in adults living in Greece: the EMENO National Health Examination Survey. *BMC Public Health* **20**, 1665 (2020). https://doi.org/10.1186/s12889-020-09757-4

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The IFET channel

The new distribution channel without Paybacks

What happened until 2019

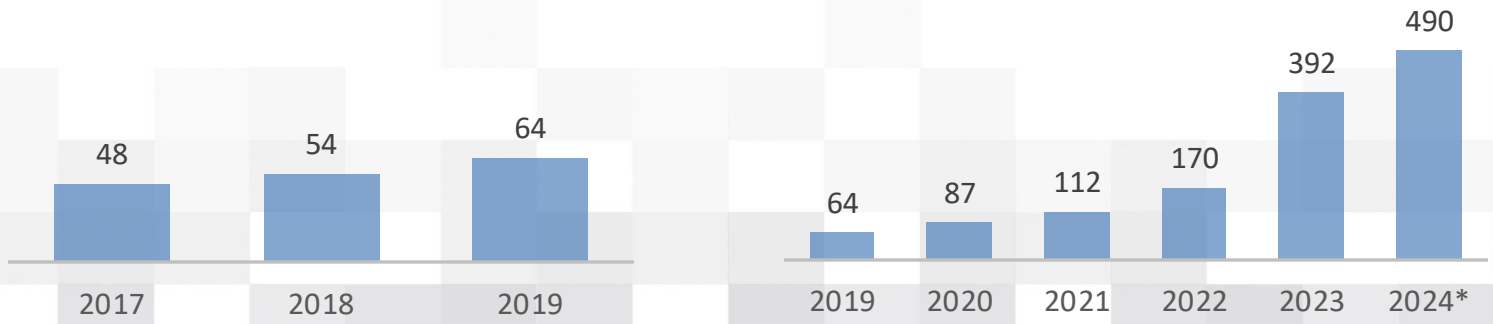
What happened after 2019

IFET Drug List based on purpose

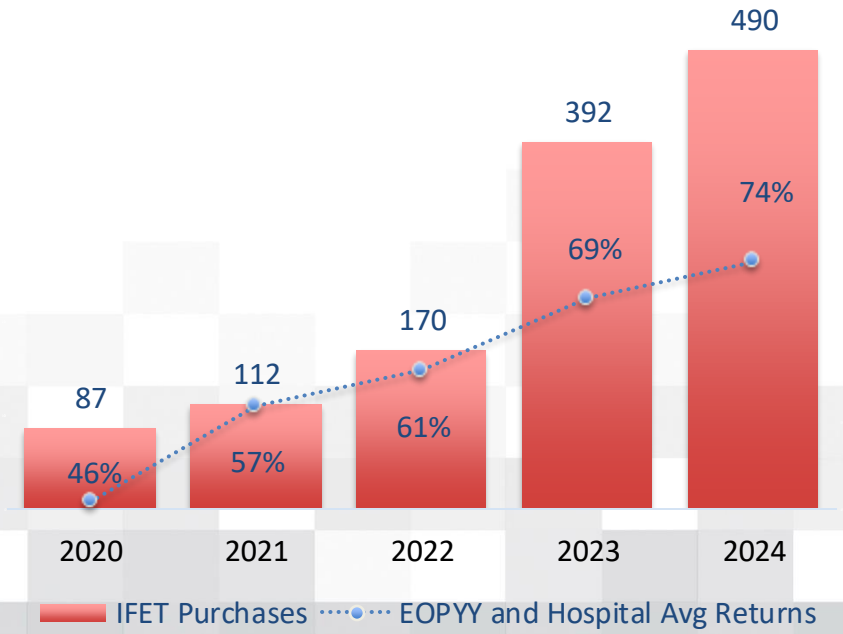
- Emergency Coverage Medicines
- Particular Hospital Coverage Medicines
- Medicines for Individual Orders

List of medications available through IFET

- Medicines pending EMA approval
- Medicines without a price
- Medicines under agreements
- Medicines on the Positive List
- Medicines approved by EMA for more than 1 year



Link between IFET purchases and "The Clawback"



Sources: EOPYY, KMES, hospital spending data/model

IFET Impact

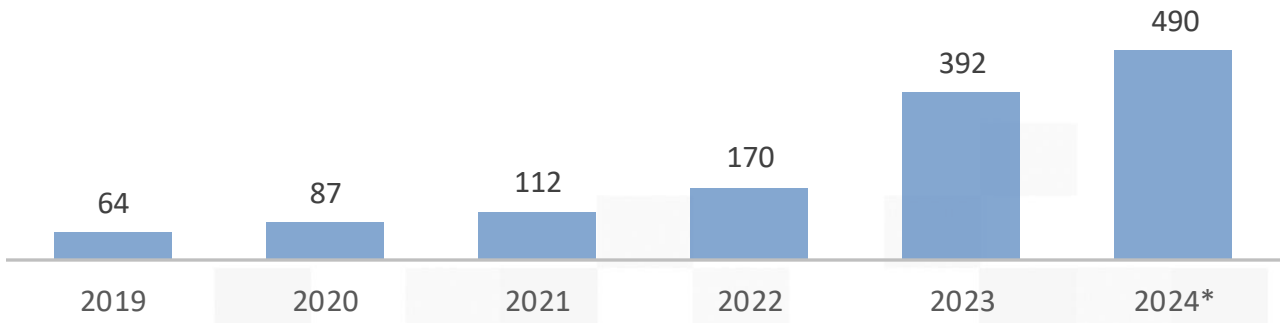
Price Impact

	List Price	Invoice Price (hospital: minus 13.3%)	Actual Purchase Price	Difference
Product A	6,123.24	5,308.67	23,329.14	439%
Product B	19,550.95	16,950.09	25,108.20	148%
Product C	552.99	479.43	407.81	85%
Product D	624.34	541.28	1,135.35	210%
Product E	1.38	1.20	49.53	4,140%
Product F	77.52	67.21	308.31	459%

Fiscal Impact

Fiscal Impact

- The purchases of IFET are financed by the Ministry of Health's budget.
- IFET charges paybacks are not returned, creating a fiscal gap.



Purchases	64	87	112	170	392	490
Paybacks	26	37	61	99	239	319
Fiscal Impact	90	124	173	269	631	809

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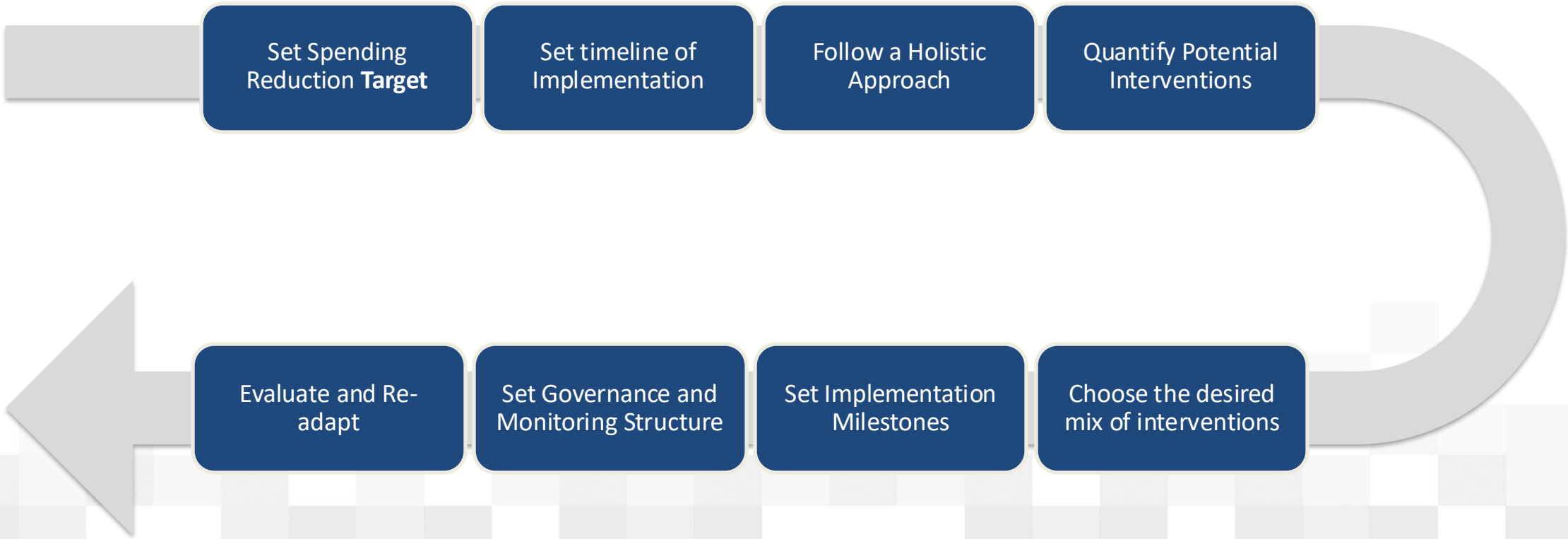
Some suggestions about the ways forward



Thank you for your attention!

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