WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

Gesundheit Österreich GmbH

# Addressing high drug prices: What can be learned from European policies?

## Ensuring access to medicines

### How to redesign pricing, reimbursement and procurement?

Policy Brief No. 30 of the
European Observatory on Health Systems and Policies

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Webinar of the Knowledge Network for Innovation and Access to Medicines,
A project of the Global Health Centre, Graduate Institute of Geneva
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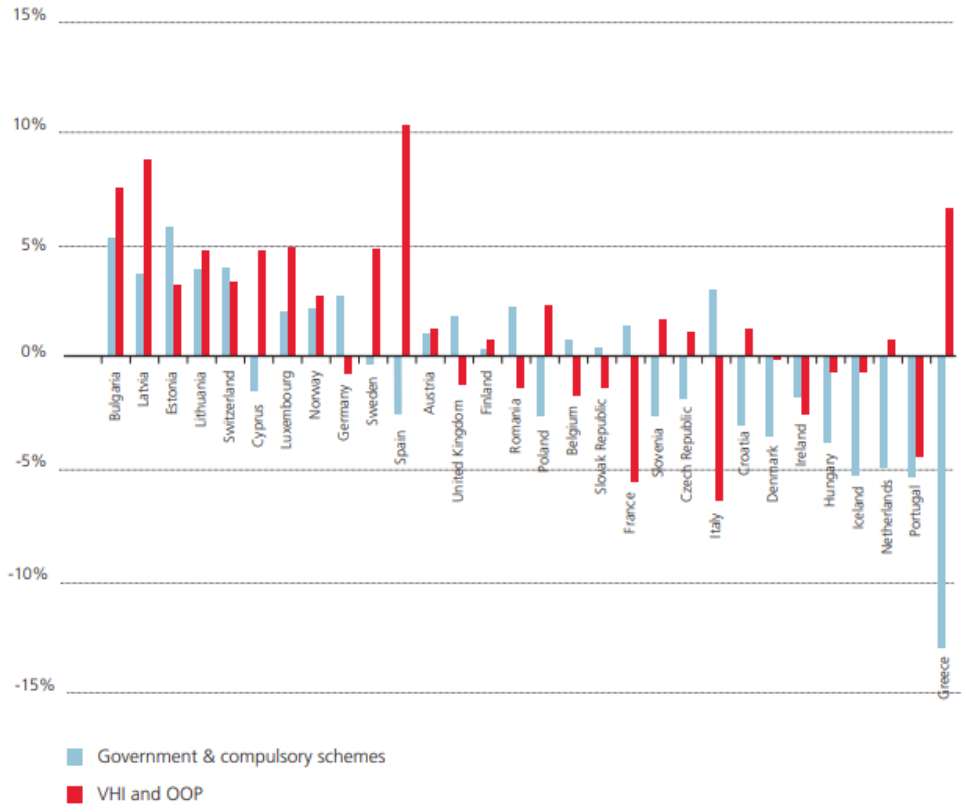
# Outline

- Introduction
- Policy Brief – Research questions
- Results
- Conclusions

# Introduction

- High prices challenge the
  - affordability of new medicines &
  - financial sustainability
- Increases in pharmaceutical expenditure
  - particularly in hospitals (lack of data)
- Concerns about
  - high prices and
  - limited or additional therapeutic benefits

## Annual growth rate of retail pharmaceutical expenditure 2011–2016




*Note:* VHI: voluntary health insurance; OOP: Out-of-pocket expenditures: United Kingdom 2013-2016; Bulgaria 2012-2016. There are breaks in the series for Czech Republic, Italy and Slovakia. Countries are listed according to the annual growth rate of total retail pharmaceutical.expenditures.

Source: OECD Health Data 2018

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# Introduction

» Affordability and sustainability concerns have been on the agenda of previous EU Presidencies

C 438/12 EN Official Journal of the European Union 6.12.2014

**Council conclusions on innovation for the benefit of patients**

(2014/C 438/06)

30.6.2017 EN Official Journal of the European Union C 206/3

**Council conclusions on Encouraging Member States-driven Voluntary Cooperation between Health Systems**

(2017/C 206/02)

Council of the EU

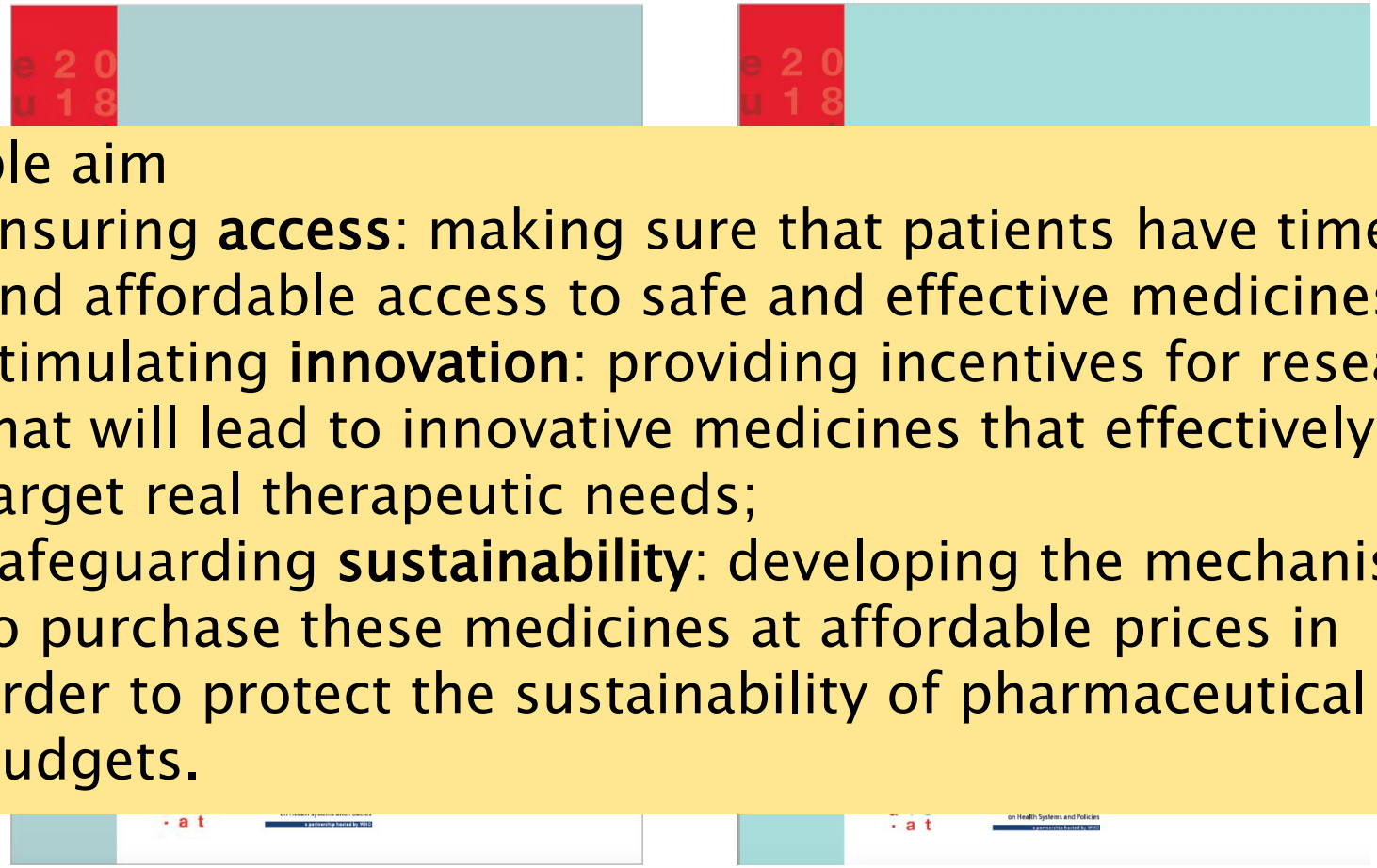
PRESS EN

PRESS RELEASE
350/16
17/06/2016

**Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States**

» Policy brief(s) in support of the Austrian Presidency

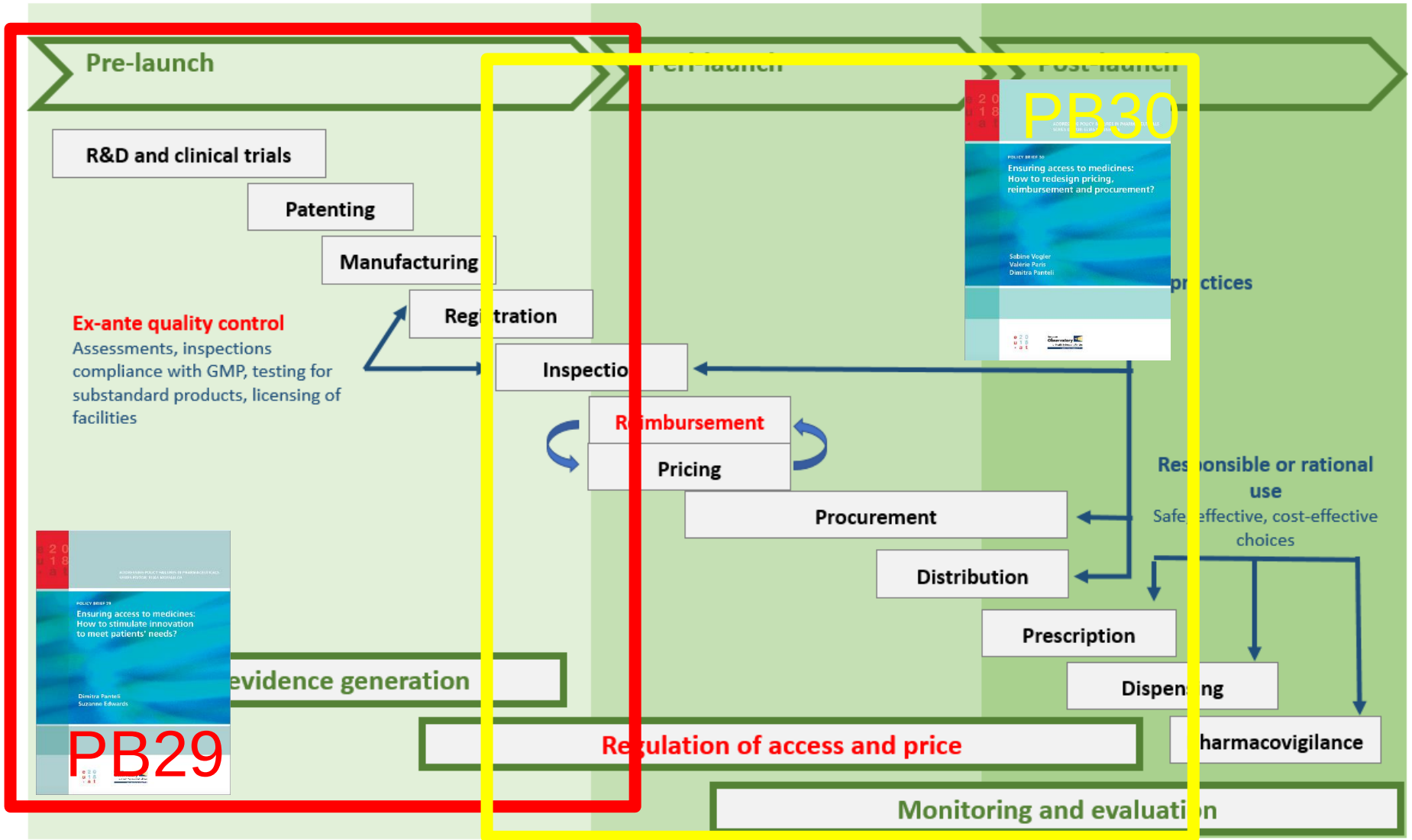
# Policy briefs on ensuring access to medicines under the auspices of the Austrian Presidency



Triple aim

- Ensuring **access**: making sure that patients have timely and affordable access to safe and effective medicines;
- Stimulating **innovation**: providing incentives for research that will lead to innovative medicines that effectively target real therapeutic needs;
- Safeguarding **sustainability**: developing the mechanisms to purchase these medicines at affordable prices in order to protect the sustainability of pharmaceutical budgets.

# How the policy briefs fit together



# Research que

Act or process of determining a price (price-setting practices in the context of price regulation

Covering the cost of HC services by a third-party payer

Process of purchasing goods, works or services (e.g. medicines) through a formal process (e.g. tender)

- **How can pharmaceutical pricing, reimbursement and procurement be redesigned to ensure affordable and sustainable patient access to new medicines?**
  - Which policies for pricing, reimbursement and procurement of new medicines are **currently** in place in EU Member States?
    What are their **strengths** and **limitations**?
  - Which **alternative approaches** to these policies might help improve affordable and sustainable patient access to new medicines?
    Are they **feasible**?
  - How could increased **transparency** on prices and **cooperation** between EU Member States provide a contribution to more affordable and sustainable patient access to new medicines?

# Results – Frequently used PRP policies for new medicines

| Policy | Definition | Use in EU MS | Benefits | Limitations |
|---|---|---|---|---|
| External price referencing (EPR) | Practice of using price(s) of a medicine in other countries | 26 of 28 EU MS, IS, NO and CH<br>Usually accompanied by other pricing policies<br>Differences in methodology | Evidence for cost-containment (savings), particularly in the short run<br>Methodology strongly impacts the results | Availability concerns ("strategic launches")<br>Reference to list prices (overpaying, information asymmetry) |
| Managed entry agreements (MEA) | Agreement between manufacturer and payer to enable access to a medicine | Increasingly used for high-priced medicines (oncology, OMP)<br>Mainly financial-based MEAs (no complete picture of use) | Facilitate access to medicines otherwise unaffordable<br>Outcome-based MEAs could enable collection of RWD | Confidentiality of prices and clinical data → weakening of negotiation power<br>MAH requests higher initial prices<br>High transaction costs & admini-strative efforts |

# Results – Tools to support decision-making

| Policy | Definition | Use in EU MS | Benefits | Limitations |
|---|---|---|---|---|
| Health Technology Assessment (HTA) | Multidisciplinary process that summarises info. about medical, social, ec. & ethical issues of HT to inform policy-makers | Use varies between MS (e.g. one government agency, more than 1 HTA agency) EUnetHTA | Provides robust data to inform PR decisions | Technical tool that cannot, in isolation, make decisions |
| Horizon scanning | Systematic identification of HT that are new & have the potential to affect health, health services and/or society | Traditionally done by research institutions, HS systems being built up | Supportive tool for budget impact preparedness → supports prioritization process for allocation of funds | Establishment and maintenance is extremely time-intensive and costly Limitations of (public) information |

# Results – Selected funding models for new medicines

| Policy | Definition | Use in EU MS | Benefits | Limitations |
|---|---|---|---|---|
| Amortization | Mechanism for paying for a large upfront cost by making smaller payments over time | – | Allows payers to fund expensive therapies while balancing the budgets within a year | Might postpone sustainability issues<br>No evidence on ability to improve affordability |
| Specific funds | Alternatives to established rules and enable R for defined medicines | In some MS<br>E.g. Cancer Drug Fund (England), funds for innovation (Italy) | Improve to medicines otherwise non-funded | Risk of funding medicines that are not cost-effective<br>Incentive for MAH to charge higher prices<br>Funds tended to increase over time |

# Results – Selected funding models for new medicines

| Policy | Definition | Use in EU MS | Benefits | Limitations |
|---|---|---|---|---|
| Tendering | Procurement approach based on a formal and competitive procedure | In the hospital sector for some high-priced medicines<br>Increased collaboration between hospitals, shift to regional and national levels | Substantial savings | "Race to the bottom" → too low prices?, availability issues |
| Measures to increase uptake of biosimilar medicines | Measures targeted at prescribers, pharmacists | Switching at prescribers level is supported in several MS. Substitution of biosimilar medicines at pharmacy level not widely used | Savings | – |

# Results – Barriers & limitations for PRP in the existing framework

- Intransparency of prices and further (R+D costs)
  - Payers have to trust the promise of getting "the best deal"
  - Unavailability of "real prices" → negative impact on EPR
  - Weakening of the bargaining power
  - Industry argument of return for investment of R+D cost

- Imbalances in negotiation power
  - Linked to the intransparency
  - Local payers/authorities meet global market players
  - Staffing level of authorities low (additional pressure due to financial crisis)
  - Capacity and qualification

# Results – Barriers & limitations for PRP in the existing framework

- Fragmentation of the pharmaceutical sector
  - Small markets (not attractive for industry)
  - Fragmentation between out-patient and in-patient sectors
  - Little contact between authorities along the life-cycle

- Legal and organisational barriers
  - E.g. tendering only allowed under certain conditions
  - Parallel trade
  - …

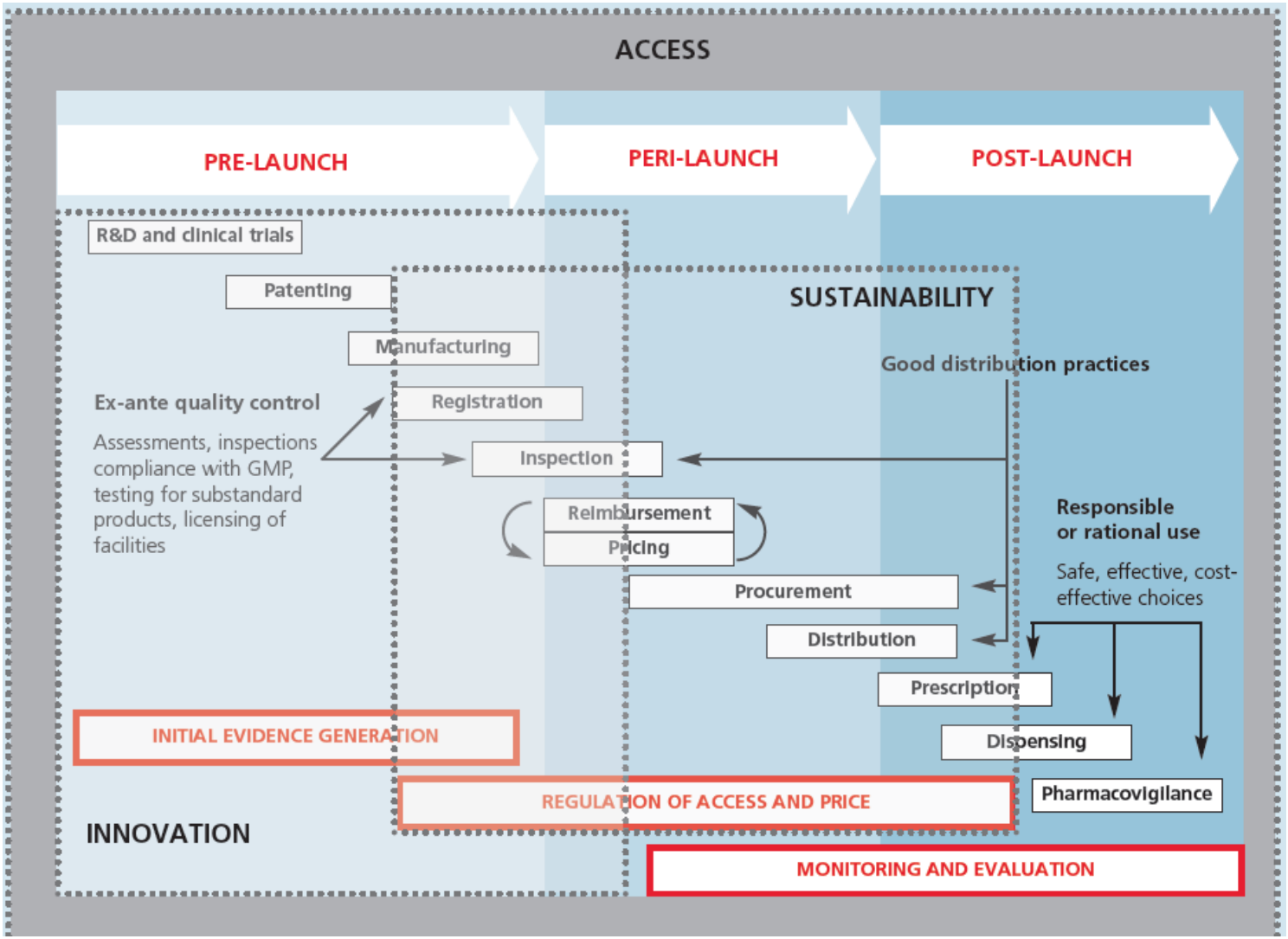
# Solutions

# Solutions

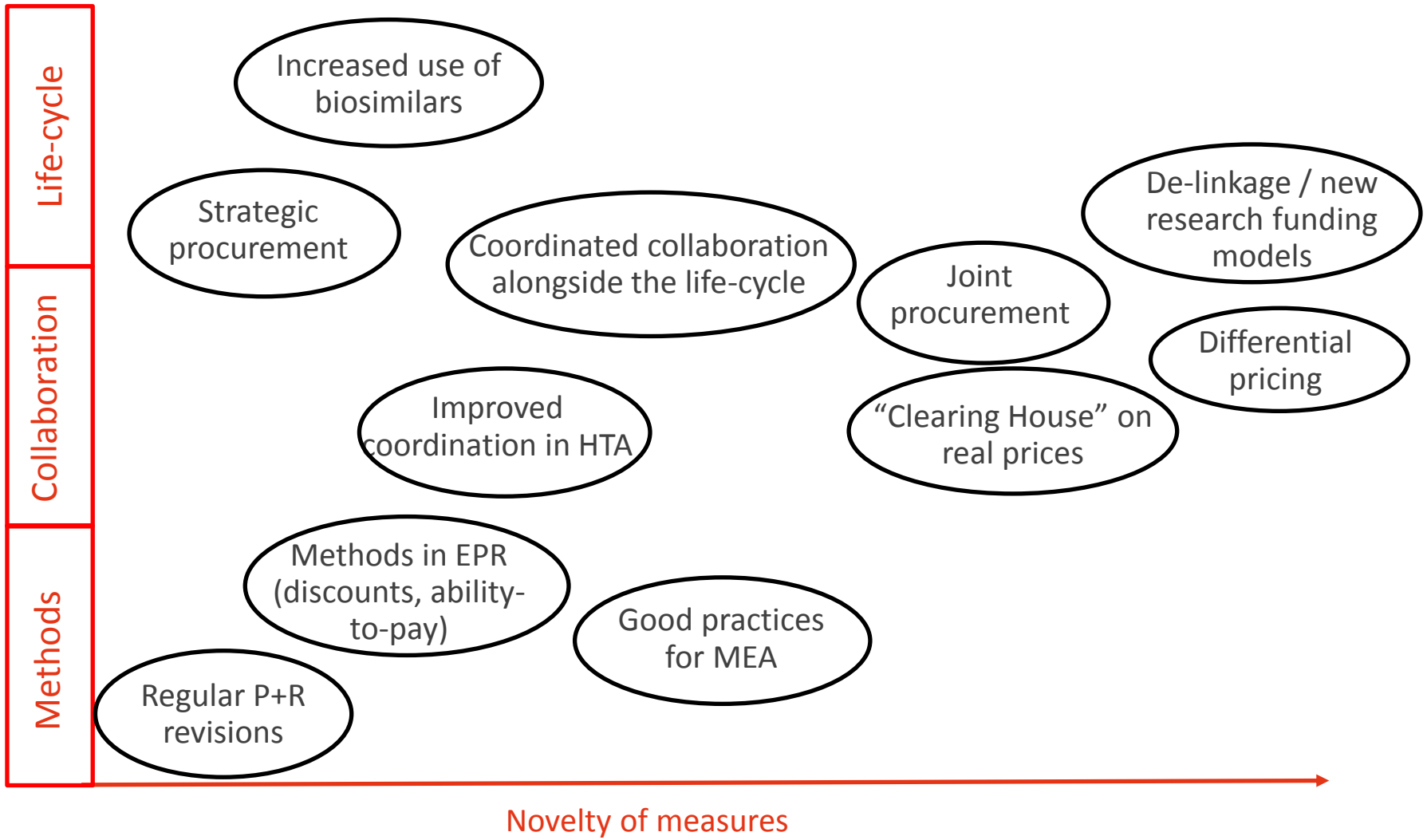
Pharmaceutical life-cycle

Collaborative approaches

Methodological advances



# Solutions


Life-cycle
Collaboration
Methods
Increased use of biosimilars
Strategic procurement
Coordinated collaboration alongside the life-cycle
De-linkage / new research funding models
Joint procurement
Differential pricing
Improved coordination in HTA
"Clearing House" on real prices
Methods in EPR (discounts, ability-to-pay)
Good practices for MEA
Regular P+R revisions
Novelty of measures

# Conclusions

- **How can pharmaceutical pricing, reimbursement and procurement be redesigned to ensure affordable and sustainable patient access to new medicines?**
  - Which policies for pricing, reimbursement and procurement of new medicines are currently in place in EU Member States? What are their strengths and limitations?
  - Which alternative approaches to these policies might help improve affordable and sustainable patient access to new medicines? Are they feasible?
  - How could increased transparency on prices and cooperation between EU Member States provide a contribution to more affordable and sustainable patient access to new medicines?

- EU MS use a range of PRP policies
- Variation in use and in methodologies
- Each policy has strengths and limitations
- Limitations of existing policies have become increasingly clear
- Alternative approaches range
  - from policy options with high feasibility, building on existing measures to
  - options expanding on existing experience and introducing new elements
- Collaborative approaches have been proposed as a way forward
- Measures to overcome information asymmetry and fragmentation and to strengthen the bargaining power of payers appear key
- Limited evidence on new initiatives → need for systematic evaluations

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# Thank you for your attention!


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