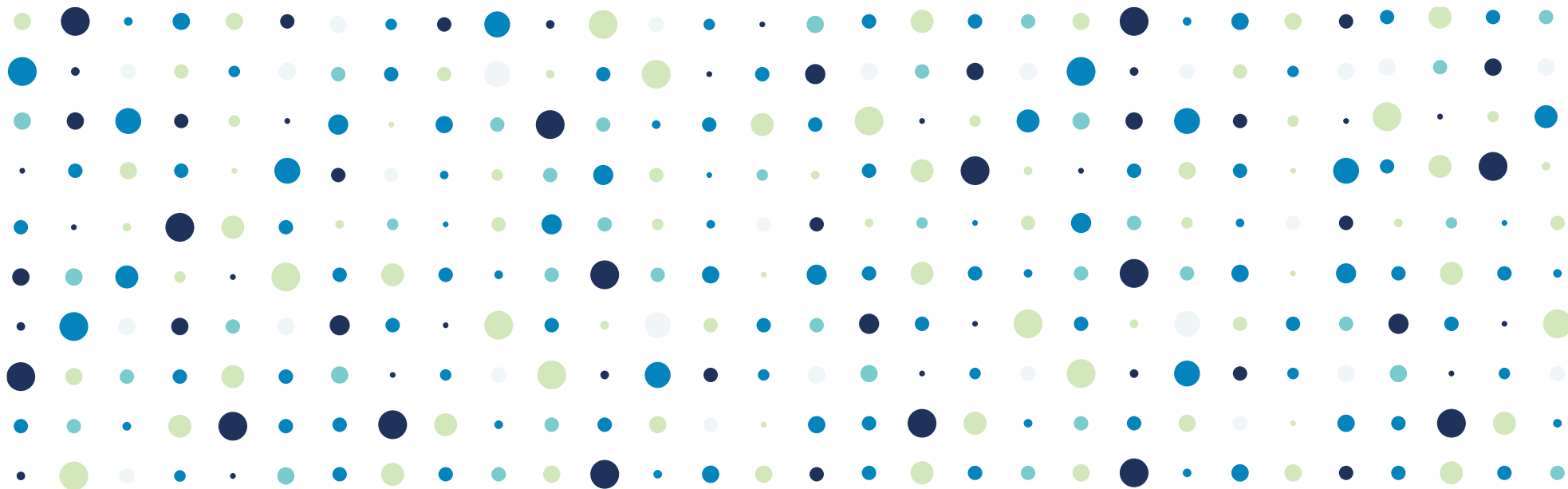


## Strategic recommendations to ensure healthy competitiveness and economic viability of generic medicines in Europe

21-MFE01GNR

14/06/2022

Version 1.0



The key objective of the study is **to demonstrate the inefficiency associated with current price regulations of generic medicines and evaluate how new pricing models could lead to greater efficiency.**

1

This study consists of two parts. The aim of the first - diagnostic part of the study is **to present current knowledge and experience of the impact of direct and intense price regulation of generic medicines on dynamic price competition among generic competitors in Europe.** Additionally, the impact of the implementation of systems regulating the reimbursement rate, particularly through reference pricing and similar tools, is reported.

2

The second part of the study **is aimed at new pricing models, their value and applicability for generic medicines in Europe.** The feasibility and applicability of these new models across Europe are presented using the country archetypes. These are groups of countries which share similarities in approach toward generic medicines price regulation.

The study is based on **Systematic and Targeted Literature Reviews** and **interviews and ad-board with experts** from five countries (Belgium, Portugal, Spain, Romania and Greece) representing four country archetypes.



# Strategic recommendations to ensure healthy competitiveness and economic viability of generic medicines in Europe

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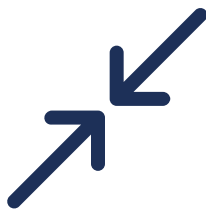
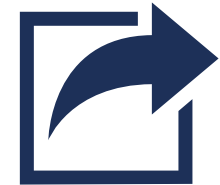
1. Recommended activities for country decision-makers in regard to competition-sensitive approach.
  - A. Revise existing policies whether they enable actions towards improving competitiveness.
  - B. If existing policies are insufficient to improve competitiveness, implement new or adjust existing pricing models taking into account your country archetype.
  - C. Reconsider composition of reference groups to fully reflect real-life competition conditions.
  - D. Monitor and analyze competitiveness level in reference groups based on sales data.
  - E. React to deteriorating competitiveness level.
2. When considering policy changes relating to generic medicines, apply holistic approach considering both general and market specific aspects.
3. A proper balance has to be achieved and maintained between generating savings for the system and revenue for manufacturers with the ultimate goal to ensure access to affordable medicines for patients within the available budget.



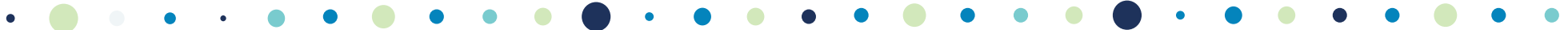
# 1A Revise existing policies whether they enable actions towards improving competitiveness



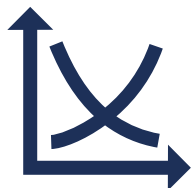
- Most European countries regulate generic medicines prices using policy tools (external and internal reference pricing or mandatory market entry discounts) or budget management tools (clawback and payback), mainly to reduce medicines expenditures and generate savings which could be used to expand access to both innovative and generic medicines.
- Although widely used, **External Reference Pricing is not perceived as a proper tool to ensure competitive pricing in the off-patent market**, since off-patent medicines already operate in a highly competitive market environment and other policies are more appropriate to stimulate competition in the off-patent market.



- **Internal Reference Pricing** is the classical tool most widely used to harmonize prices of products with the same or similar therapeutic effect (the reference group), working best in association with other tools supporting appropriate use of generic medicines.

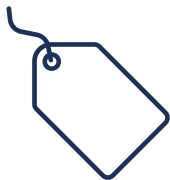


# 1A Revise existing policies whether they enable actions towards improving competitiveness



- As much as they are effective to generate short-term savings, **the mandatory rebates, discounts, extraordinary contributions, clawback and payback policies can easily be overused and severely impact economic viability and sustainability of supply**, especially if are unlimited and lack differentiation to account for which products actually contributed to excessive spending. Today, only 2 countries have differentiated payback for generics and innovative medicines (Netherlands and Romania).

- At this point there is **no evident (clearcut) universal approach that would systematically solve challenges facing by generic market in Europe**. Fundamental mindset shift is required to implement competition-sensitive approaches in policy models applied to generic medicines. New pricing policy models are adequate to address this requirement.

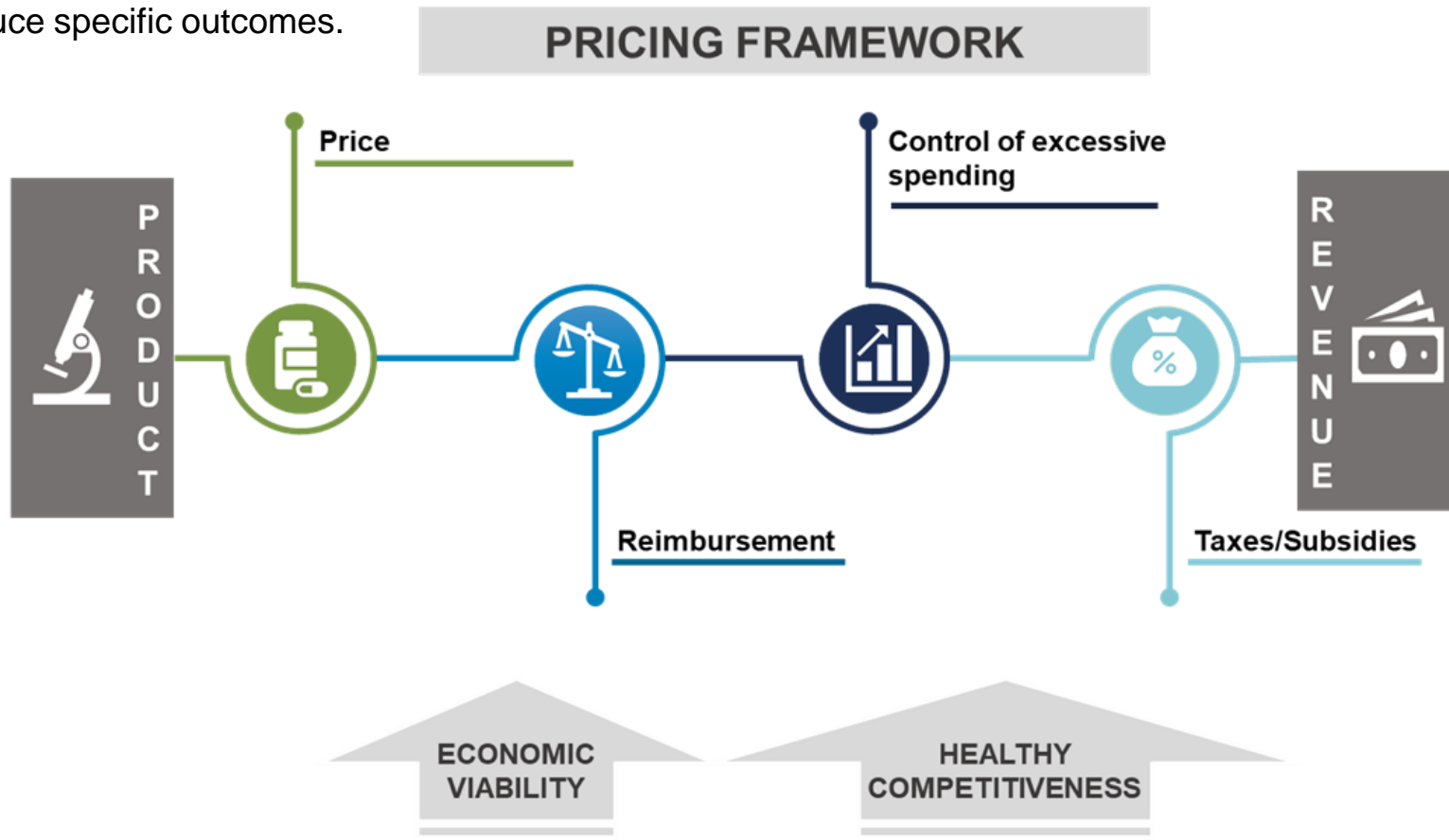


- **Highly resilient and future proof strategies should be promoted to counteract raising inflation** (price adjustment might be needed according to inflation level)

# 1B Implement new pricing models

## Points of impact for new pricing models

In total there are eleven new pricing models proposed that can be utilized to promote healthy competitiveness and enhance economic viability. These models can have different points of impact (price, reimbursement, excessive spendings, taxes/ subsidies) within the presented pricing framework (product to revenue chain) and thus produce specific outcomes.

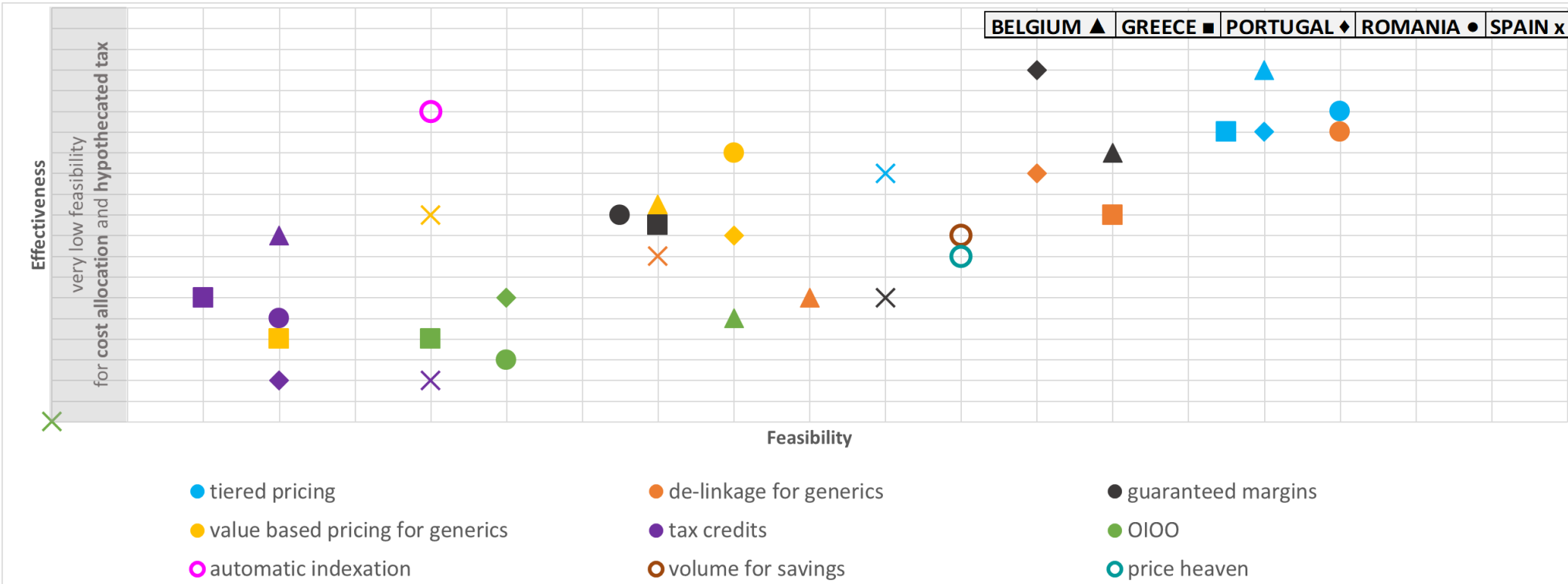


# 1B Implement new pricing models

## New pricing models pair-wise comparison (implementation potential)

Experts from five countries (Belgium, Portugal, Spain, Romania and Greece) representing four country archetypes were asked to assess new pricing policy models\* in terms of their perceived effectiveness and feasibility. The models that scored the highest on feasibility and effectiveness parameter based on new pricing models pairwise comparison, represent the highest implementation potential in a certain country archetype (A).

European countries were assigned to five country archetypes based on shared similarities in approach to generic medicines price regulation and restrictiveness of existing policies (see each country archetype characteristics on the next slide). Countries with free-pricing policies (A1) for generic medicines were not considered.



\*excluding end-user fee models (cost allocation, hypothecated tax) as they were unequivocally assessed for very low feasibility; automatic indexation, volume for savings and price heaven were assessed by internal team only.

# 1B Implement new pricing models

## Proposed new pricing models

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11 new pricing models for generic medicines:

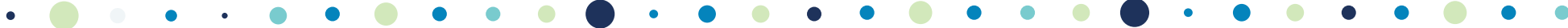
- Tiered pricing
- De-linkage from originator price
- Guaranteed margins/ fees
- Tax credits
- One-in-one-out (OIOO)/ One-in-X-out (OIXO)
- Value based pricing (VBP) for generics
- Hypothecated tax
- Cost allocation
- Automatic indexation
- Volume for savings
- Price heaven

Preliminary two top ranked models, with tiered pricing being undisputedly seen as the one with the highest implementation potential.

Models that are not perceived as pricing models per se but rather as strategic mindset changer by switching narrative from “generics provide savings” to “generics provide treatment benefits

End user fee models that are excluded from further analysis due to being assessed as not feasible even before new pricing models pair-wise comparison performed by experts

Models proposed for Belgium – country that represents archetype A2.





# 1B Implement new pricing models

## Characteristics of country archetypes

Archetype	Countries	Explanation
A1	UK, Netherlands, Denmark, Germany, Sweden	<ul style="list-style-type: none"> <li>• Free pricing</li> <li>• Retail tender market for generic medicines</li> </ul>
A2	Finland, France, Italy, Hungary, <b>Belgium</b>	<ul style="list-style-type: none"> <li>• No ERP</li> <li>• % below originator price as main criteria to set the price of generic medicines</li> <li>• Clawback/ payback</li> </ul>
A3	<b>Portugal</b> , Ireland	<ul style="list-style-type: none"> <li>• Pricing mechanisms without the main objective to obtain the lowest price possible               <ul style="list-style-type: none"> <li>○ ERP: country basket with comparable countries + average price approach</li> <li>○ Clawback/ payback</li> </ul> </li> </ul>
A4	Austria, <b>Spain</b>	<ul style="list-style-type: none"> <li>• Price alignment between the originator and the generic medicine</li> <li>• No clawback/ payback</li> </ul>
A5	Bulgaria, Czech Republic, Poland, Slovakia, <b>Romania</b> , <b>Greece</b> , Lithuania	<ul style="list-style-type: none"> <li>• Pricing mechanisms with the main objective to obtain the lowest price possible (downward price spiral)               <ul style="list-style-type: none"> <li>○ ERP: large country basket + lowest price approach</li> <li>○ Burdensome clawback/ payback</li> <li>○ Price negotiations</li> </ul> </li> </ul>



# 1B Implement new pricing models

New pricing models in certain country archetypes - effectiveness and feasibility ranking

## 1) Tiered pricing model (1/4)

The main objective of the tiered pricing model is to establish a price based on the number of generic manufacturers ready to compete on the market within a given generic medicine category. *“Essentially, the design of the tiered pricing scheme is such that it imitates competitive pricing”.*

- Different prices based on numbers of players/suppliers on the market (number of suppliers determines a tier with a given maximum level of acceptable price)

The more generic manufacturers supplying the market, the lower the generic price falls. Generic manufacturers enter the market as long as the price exceeds their expected average cost of production and distribution (reservation price). Manufacturers put on hold or resign completely from entering the market once the price drops to the level near the reservation price.

- Tiered pricing system is linked to variable costs of production and distribution to generate prices close to the efficient level.

PROS	CONS
mimics competitive pricing and boosts economic viability	difficult to efficiently set margins between pricing tiers
incentives market entries (to some extent)	new competitors entering the market deteriorates pricing conditions for all manufacturers causing price drop
provides predictability and stability of generic market	infrastructure (IT, monitoring systems) required for implementation success







# 1B Implement new pricing models

New pricing models in certain country archetypes - effectiveness and feasibility ranking

## 1) Tiered pricing model (4/4)

### Canadian Tiered Pricing Framework (TPF)

Generic Medicine Category / Tier	% of Brand Reference Pricing	Notes
Tier 1: Single source (i.e. only one manufacturer of a generic medicine)	<p>75% of brand reference price if product listing agreement (PLA) or pricing agreement for brand exists in any jurisdiction.</p> <p>Priced at 85% of brand reference price if PLA or pricing agreement for the brand product does not exist</p> <p>Maybe reassessed after 2 years following their initial assessment</p>	Option for jurisdiction to retain PLA or pricing agreement with the brand if provides better value
Tier 2: Dual source/Two generics	50% of brand	
Tier 3: Multi-source/ Three or more generics	<p>25% of the brand (oral solid)</p> <p>35% of the brand for all dosage forms other than oral solids (e.g., liquids, patches, injectables, inhalers, etc.)</p>	



# 1B Implement new pricing models

New pricing models in certain country archetypes - effectiveness and feasibility ranking

## 2) De-linkage from originator price (1/3)

- Breaking the link between the fluctuating price (reference price) of the originator and a generic price

There are three possible variations of the de-linkage from the originator prices model for generic medicines (complete de-linkage from the originator price, partial de-linkage from the originator price and competition maturity de-linkage). The partial de-linkage seems to be the most feasible variant.

- The partial de-linkage model suggests breaking the link between the fluctuating price of the originator (used as reference) and a generic price, after the initial price (reimbursement) is established for a new generic medication entering the market.



PROS	CONS
generic manufacturers focused on competing with one another regardless of originator's prices changes	lack of ability to improve competitiveness if it is already disrupted
facilitates market stability and predictability	application might be limited to countries with high generic market volume and multiple generic manufacturers
incentivise market entries	only for new market entrants

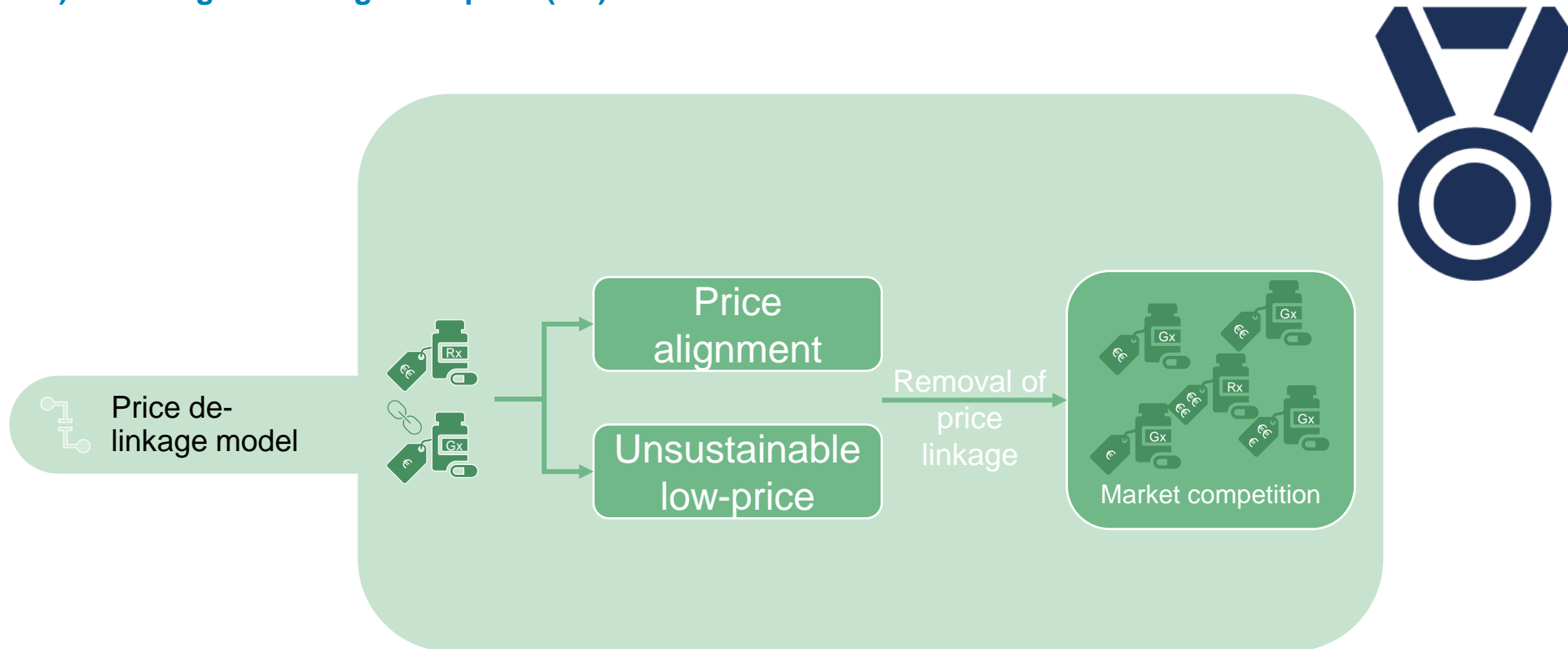




# 1B Implement new pricing models

New pricing models in certain country archetypes - effectiveness and feasibility ranking

## 2) De-linkage from originator price (3/3)





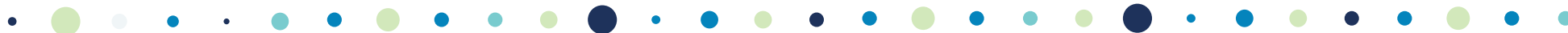
# 1B Implement new pricing models

New pricing models in certain country archetypes - effectiveness and feasibility ranking

## 3) Automatic indexation

- Automatic indexation models assume that a value impacted and eroded by inflation will be protected against such impact with automatic adjustment based on fluctuations in the prices of goods.
- Related indexes:
  - CPI – Consumer Price Index
  - PPI – Producer Price Index
- Is assessed as highly effective but with low feasibility. The more budgetary means are available, the more acceptable automatic indexation would be (e.g., Germany). The main concern for feasibility would be to what extent to share the risk of inflation between the payer and medicines manufacturers. It may be claimed that such model should be considered as **transient measure** to address the economic cycles with higher inflation levels
- **Additional research is needed to evaluate its potential as it was not assessed by experts**

PROS	CONS
alleviate negative impact of inflation	difficult to determine shared risk
directly correlated with economic situation (responsive to dynamic changes) and minimize the risk of medicines shortages	lack of stability and predictability (not sustainable), risk of system being abused by medicines manufacturers
considers consumer and producer perspective (CPI and PPI)	there is a need to secure budgetary means in advance



# 1B Implement new pricing models

New pricing models in certain country archetypes - effectiveness and feasibility ranking

## 4) Value based pricing for generics (VBP)

The next best model is Value-Based Pricing for Generics: it is ranked as extremely effective for countries A5 (Romania) and mid-values for archetypes A2-A4 whereas it is ranked mid- to low- for feasibility for all archetypes. Similarly to One-In-One-Out model, Value-Based Pricing for Generics is perceived more as a strategic mindset changer by switching narrative from “**generics provide savings**” to “**generics provide treatment benefits at exceptionally affordable cost**” much lower than current innovative treatments. The biggest challenge universally would be to perform value-based assessments in countries with limited HTA capacity and extensively for whole therapeutic classes/indications including all available treatment options.



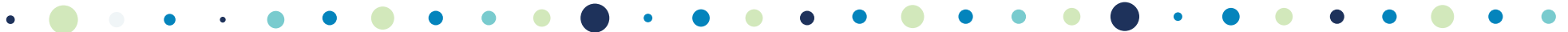
# 1B Implement new pricing models

New pricing models in certain country archetypes – effectiveness and feasibility ranking

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The remaining two models have been assessed internally and their relative position on the diagram reflects this internal assessment.

- **Volume for savings** and **price heaven** have been proposed in archetype 2 country where systematic price cuts are in place (Belgium). It appears that volume for savings would be relatively effective and feasible however in practice achieving volume increases might be a challenge. Price heaven has both effectiveness and feasibility measures similar to volume for savings and appears to be a temporary tool to address medicines needs during the COVID-19 pandemic.



# 1C Reconsider composition of reference groups to fully reflect real-life competition conditions

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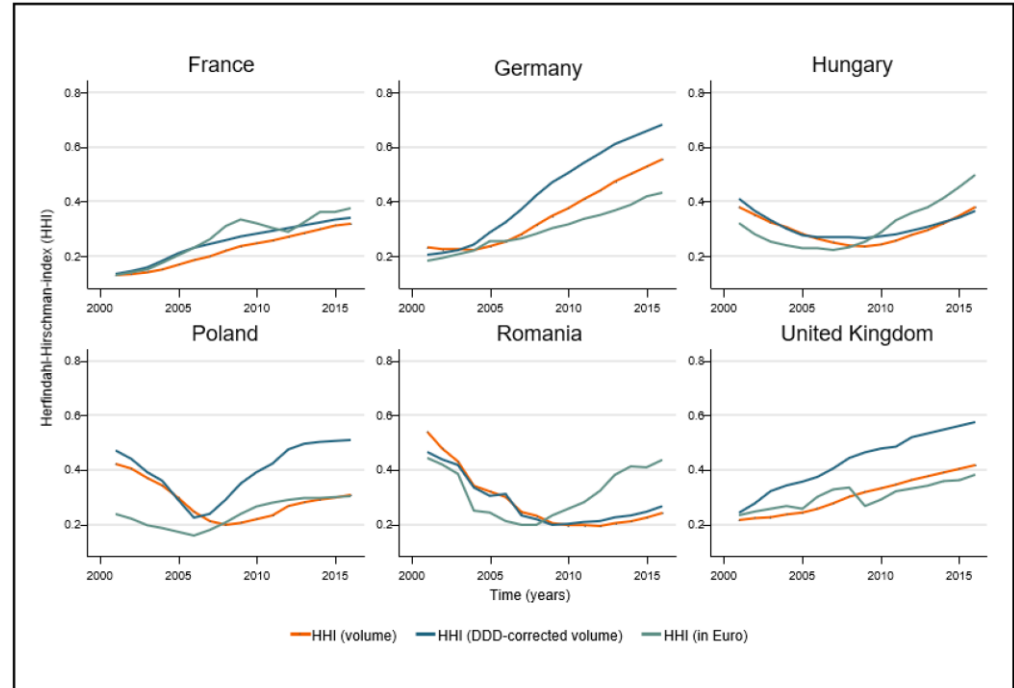
- Major issue mentioned by experts is **lack of dynamic approach to create a link between the reference price and the level of competition within a certain reference group**: if there are few competitors, the reference price can be increased, if there are many – reduced.



# 1D Monitor and analyze competitiveness level in reference groups based on sales data

- The most fundamental recommendation for decision and policy makers would be **to start consistently monitoring the level of competitiveness in reference groups** (using Herfindahl-Hirshman Index), notice the changes in negative direction and take actions when deterioration of competition is considered a threat to continued supply instead of waiting inactively until medicines are no longer supplied.

Market concentration of ACE inhibitor active ingredients in six European countries from 2001 to 2016<sup>1</sup>



**Herfindahl-Hirschman Index (HHI)** (HHI, also known as Herfindahl index, or sometimes HHI-score) is the most popular concentration measure in the competition literature that informs about the size of the firms in relation to the industry and is an indicator of the amount of competition among them. It is calculated as the sum of the squares of the market shares (expressed as fractions) of the companies within the industry (market). **Numbers closer to 1.0 are deemed non-competitive** (smaller number of players and/or concentrated market share, a single monopolistic producer), **numbers closer to 0.0 indicate a huge number of very small firms** (share spread evenly across many players).

# 1D Monitor and analyze competitiveness level in reference groups based on sales data

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- The lower the value of HHI the higher is level of competitiveness. The changes in the reference price can either drive the prices up or push them down. The number of generic manufacturers on the market ultimately impact both prices and competitiveness level.



- Analogically, the high HHI value indicates decreased competitiveness level with increased market power.



# 1E React to deteriorating competitiveness level



- Most often in current policies in European countries the objective is to generate savings regardless of impact on competition. **If savings are imposed too aggressively, it is certain to backfire in a form of medicines shortages.** For example, in case of austerity measures assuming blind repetitive price cuts with a competition-sensitive approach you would monitor the competition level and put on hold further price cuts in a certain reference group when competition level significantly worsens in repeated measurements. Usually, the first affected parties would be smaller competitors. The reason for stopping the price cuts would be that you may be getting close to the point beyond which price levels are unsustainable.

- **Be proactive to prevent competitiveness deterioration to a level of medicines shortages.** Reassure if generic medicines generated savings **do not create threat to medicines supplies** (too restrictive price cuts). The efficient generic medicines policies facilitate access to affordable medicines and provide substantial healthcare savings at the same time.



## 2 Holistic approach

### Generic medicines as an integral part of a healthcare system – helicopter view

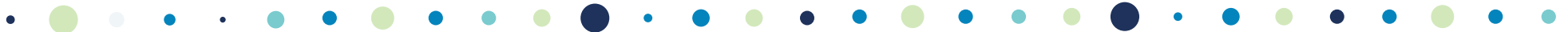
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A holistic approach should be adopted while discussing implementation strategy of new pricing/ policy models for generic medicines in Europe. Not only should the general aspects like:

- GDP,
- size of the country,
- maturity of pharmaceutical market,
- restrictiveness of existing medicines pricing policies,
- healthcare system specificities,
- impact on innovative products,
- flexibility in allocating funds for healthcare,
- social acceptance,
- attitudes towards generic medicines

be addressed, but also market specific such as:

- volume market share - high/low,
- number of molecules suppliers,
- number of medicines manufacturers and their capacities).



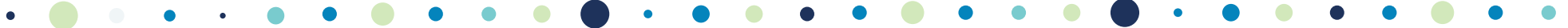


## 2 Holistic approach

### European geographical regions (general information)

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While reflecting on generic market in Europe it is important to notice the polarization between the role generics play in European countries (there are some exceptions). There is a distinctive difference between countries in Western and Eastern Europe in the context of access to medicines. In Western Europe generics' role is to generate savings without the need to expand access (because it is generally secured), while in Eastern Europe generics enable or expand access to medicines otherwise with limited availability.

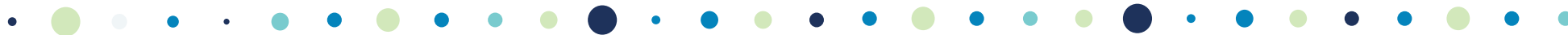
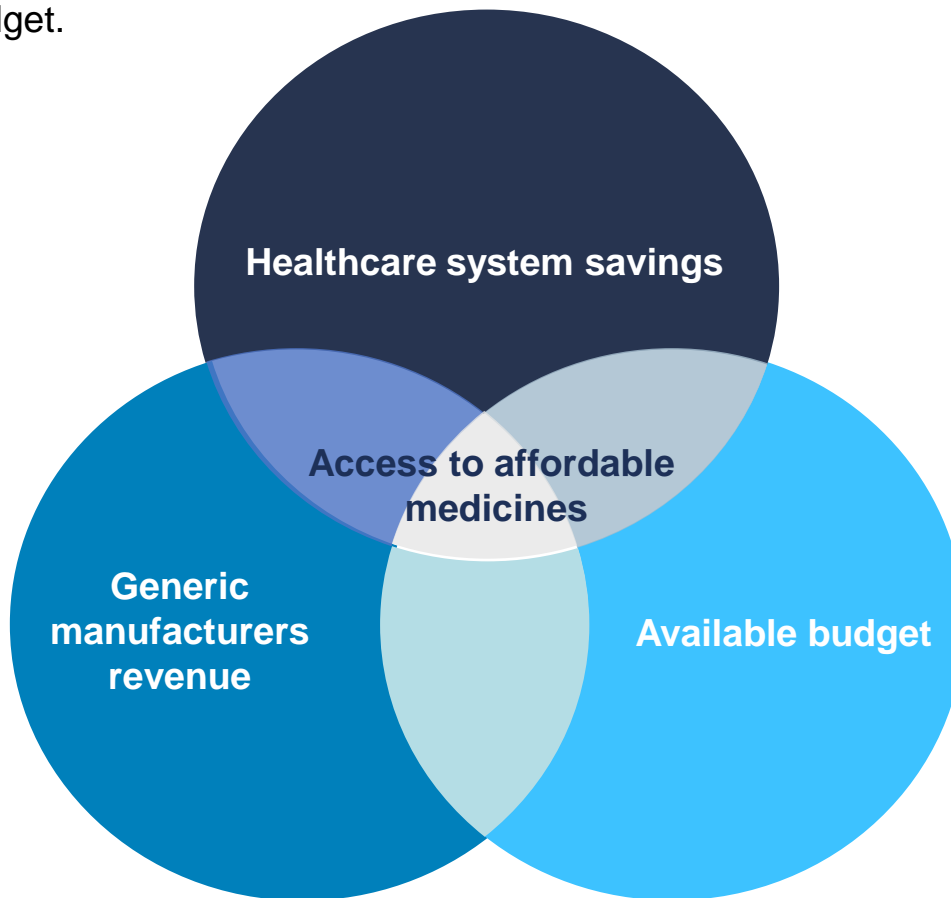


# 3 Balance

Representing interest of multiple stakeholders and leading towards sustainability

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A proper balance has to be achieved and maintained between generating savings for the system and revenue for manufacturers with the ultimate goal to ensure access to affordable medicines for patients within the available budget.



# Thank you

