

Introduction to: IMPLEMENTING PHARMACEUTICAL POLICIES: WHAT WORKS? Facilitators and barriers & relevance of evaluation studies

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New publication

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How to implement the **perfect pharmaceutical policy?**

The Guide Book for ensuring
sustainable access to affordable
medicines within five months



Outline of this introductory talk

- Barriers to policy implementation → turning them to facilitators
- Prerequisites for policy implementation
- Reasons for lack of data & evaluations
- Learnings



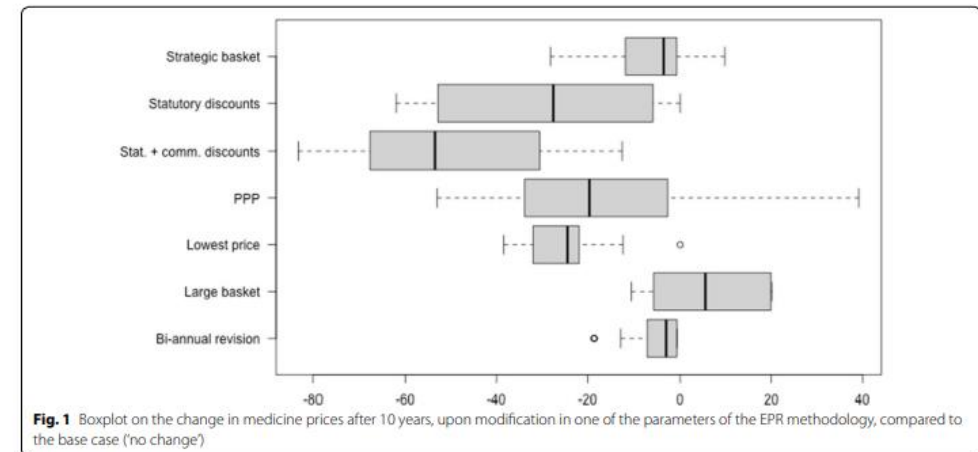
Learning from other countries is important, but be aware of ...

COUNTRY CONTEXT

Case study on generic substitution as a collaborative bottom-up pilot initiative in Denmark in the late 80-ties



POLICY DESIGN



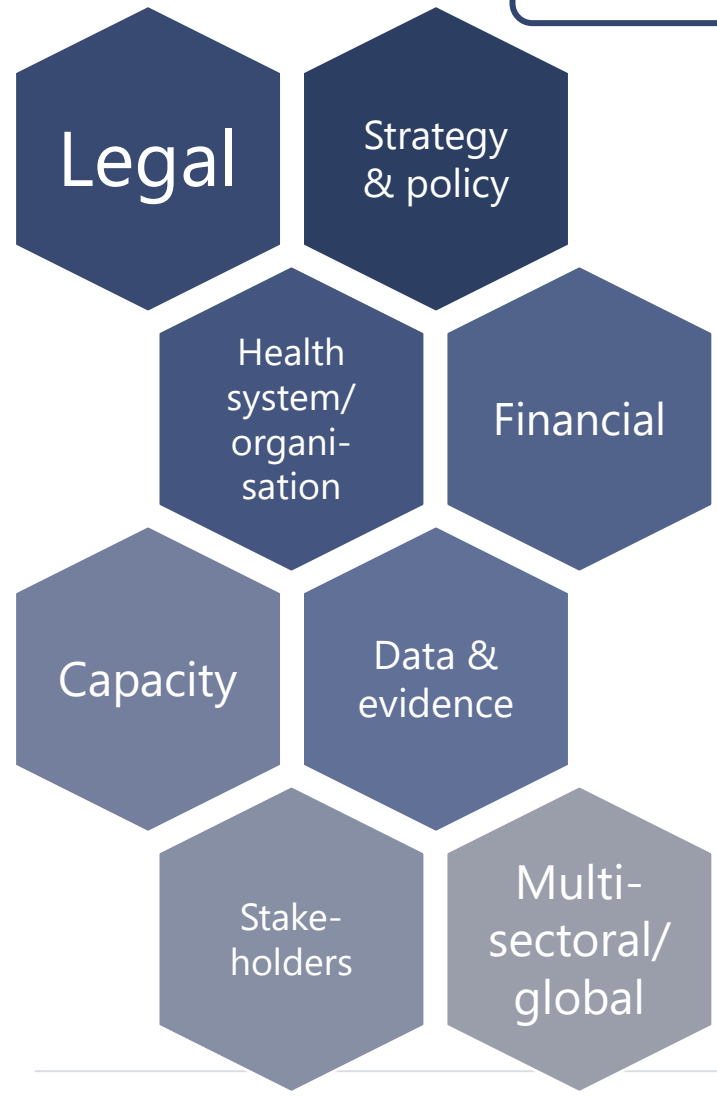
Habl C, Vogler S, Leopold C, et al. [Referenzpreissysteme in Europa](#). GÖG, Vienna 2008 ([Executive Summary in English](#))

Vogler S, Schneider P, Lepuschütz L: [Impact of changes in the methodology of external price referencing on medicine prices: discrete-event simulation](#). Cost Effectiveness and Resource Allocation 2020; 18(51)

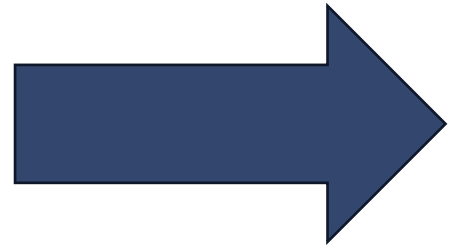
Key potential barriers that hinder successful policy implementation

= effective to achieve the defined policy objectives

Savings: 1 million DKK per day



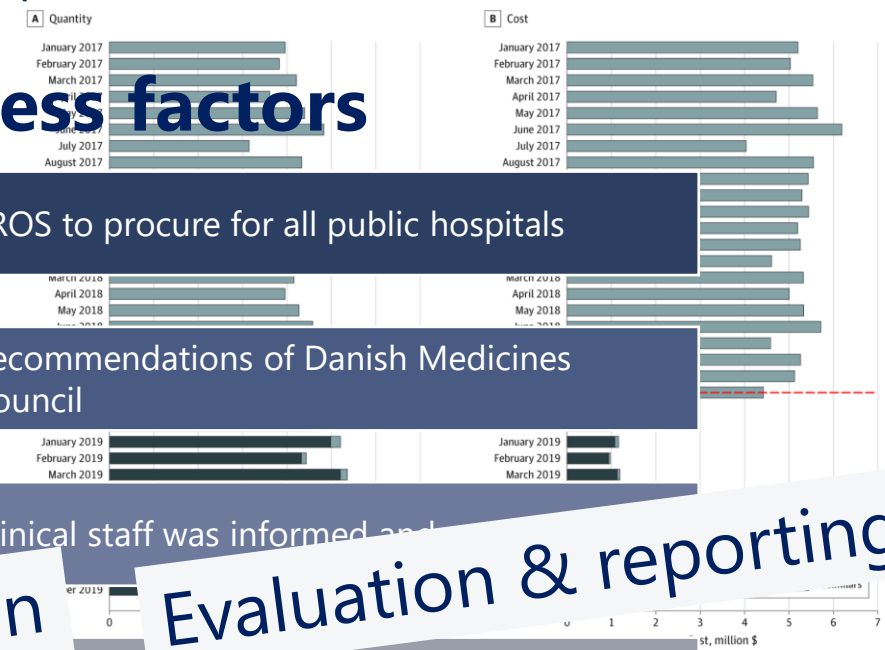
Identify and actively address these barriers (as far as possible)



Turn them into facilitators!

Good practice example of adalimumab switch in DK
(90% ada. use switched within 3 weeks)

Success factors



AMGROS to procure for all public hospitals

Recommendations of Danish Medicines Council

Clinical staff was informed and

Biosimilar TF prepared info materials for patients, dialogue with patient organisations

Preparedness

Communication

Evaluation & reporting

— Policy implementation should be well prepared

**SWOT
analysis**

**Stake-
holder
analysis**

**Commu-
nication
strategy/
plan**

**Imple-
menta-
tion plan**

Policy implementation should be based on evidence & should be monitored and evaluated (and published)

"What is the best pricing policy?"



Recommendations

1. External reference pricing
2. Internal reference pricing
3. Value-based pricing
4. Mark-up regulation across the pharmaceutical supply and distribution chain
5. Promoting price transparency
6. Tendering and negotiation

Based on a SLR: with limited findings

7. Promoting the use of quality-assured generic and biosimilar medicines
8. Pooled procurement
9. Cost-plus pricing for setting the price of pharmaceutical products
10. Tax exemptions or tax reductions for pharmaceutical products

Strong recommendations for the policy

Conditional recommendation against the policy

Conditional recommendations for the policy

coherence, specificity, clear purpose, transparency, integrated framework, relevance, compliance, collaboration

Eight principles for developing and considering policies



<https://apps.who.int/iris/bitstream/handle/10665/335692/9789240011878-eng.pdf?sequence=1&isAllowed>

Why is there lack of data & evidence?



Confidentiality



https://kce.fgov.be/sites/default/files/atoms/files/KCE_288_Improve_Belgian_process_managed_entry_agreements_Report.pdf

1.3 A difficult process due to data confidentiality and threat of legal proceedings

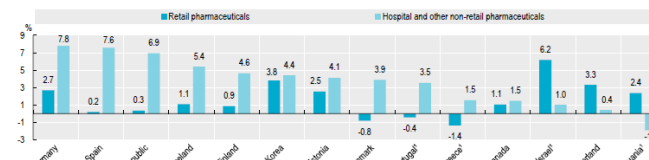
KCE's main priority was to evaluate the existing conventions to provide well-considered advice to the policy makers to improve their policy. The analysis was nevertheless limited by the confidential character of the appendices of the conventions, encompassing the precise outcome of the negotiation process (for instance the exact amounts or percentages of discounts, budget caps, etc.). KCE committed from the beginning of this project to respect the confidential nature of the conventions (with anonymous aggregated reporting and with a final check by the RIZIV – INAMI to verify the respect of the confidentiality and the validity of all observations and statements).

This was nevertheless not approved by the representatives of the pharmaceutical industry. Even after having invited them to participate in the study as external stakeholders, in full transparency, Pharma.be, a Belgian organisation representing part of the (non-generic) pharmaceutical industry, threatened to take legal action against KCE if the study was continued. We unfortunately had no other choice than to stop the collaboration and to base our analysis on public information only. Details on the compensation mechanisms available in the appendices of these conventions could not be used (neither directly, nor indirectly).



No routine data (other sectors)

Figure 9.3. Annual average growth in retail and hospital and other non-retail pharmaceutical expenditure, in real terms, 2011-21 (or nearest years)



1. Includes medical non-durables.
Source: OECD Health Statistics 2023.

https://www.oecd.org/en/publications/health-at-a-glance-2023_7a7afb35-en/full-report/pharmaceutical-expenditure_a58c1da0.html

Public funding for R&D?



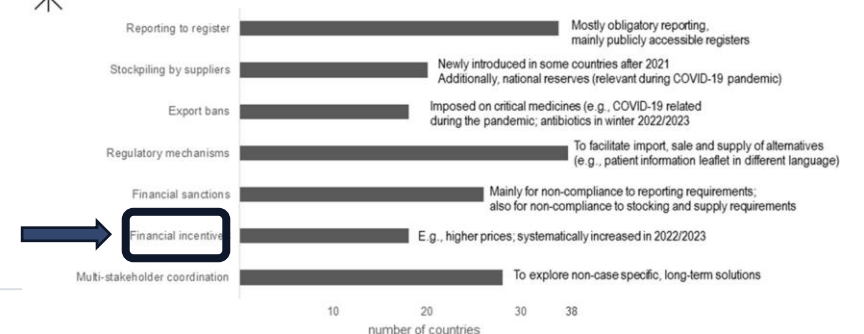
Measures to manage and mitigate medicine shortages in 38 countries



Survey with national public authorities for pharmaceuticals
33 European countries, Australia, Brazil, Canada, Israel and Saudi Arabia



Commonly applied governmental policy measures in 2023

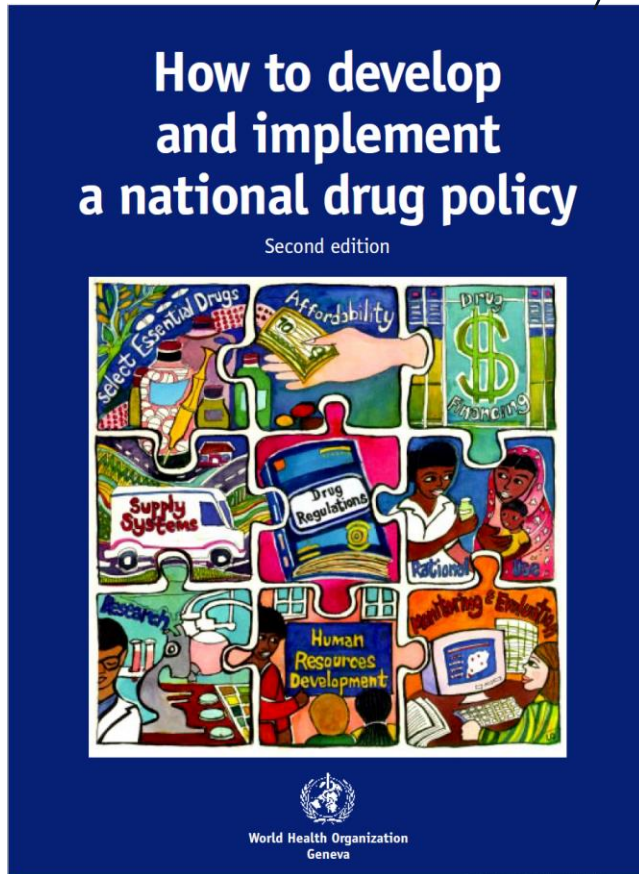


Medicine shortages:

- Multi-factorial problem is acknowledged
- But narrative of low generic prices

Learnings

2001



Preparation

Evaluation

Adaption of policy

**Introduction of
policy**
(after potential pilot)

<https://www.who.int/publications/i/item/924154547X>

Thank you for your attention

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