

European collaborations on patient access to medicines – Lessons learned and implications for national pricing policies such as external price referencing

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DoI, disclaimer and credits

Declaration of interest:

- Austrian National Public Health Institute
- WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (“PPRI WHO CC”)
- Beneluxa Initiative
- PPRI (Pharmaceutical Pricing and Reimbursement Information) network

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Credits go to:

- Co-authors of WHO Cross-country collaborations study (at “PPRI WHO CC” & WHO CC at Utrecht University)
- The members of the PPRI network (= competent authorities for pharmaceutical pricing and reimbursement) for providing information on their country

Publications: – see PPRI website → Publications <https://ppri.goeg.at/publications>
– selection at the end of this presentation

Outline

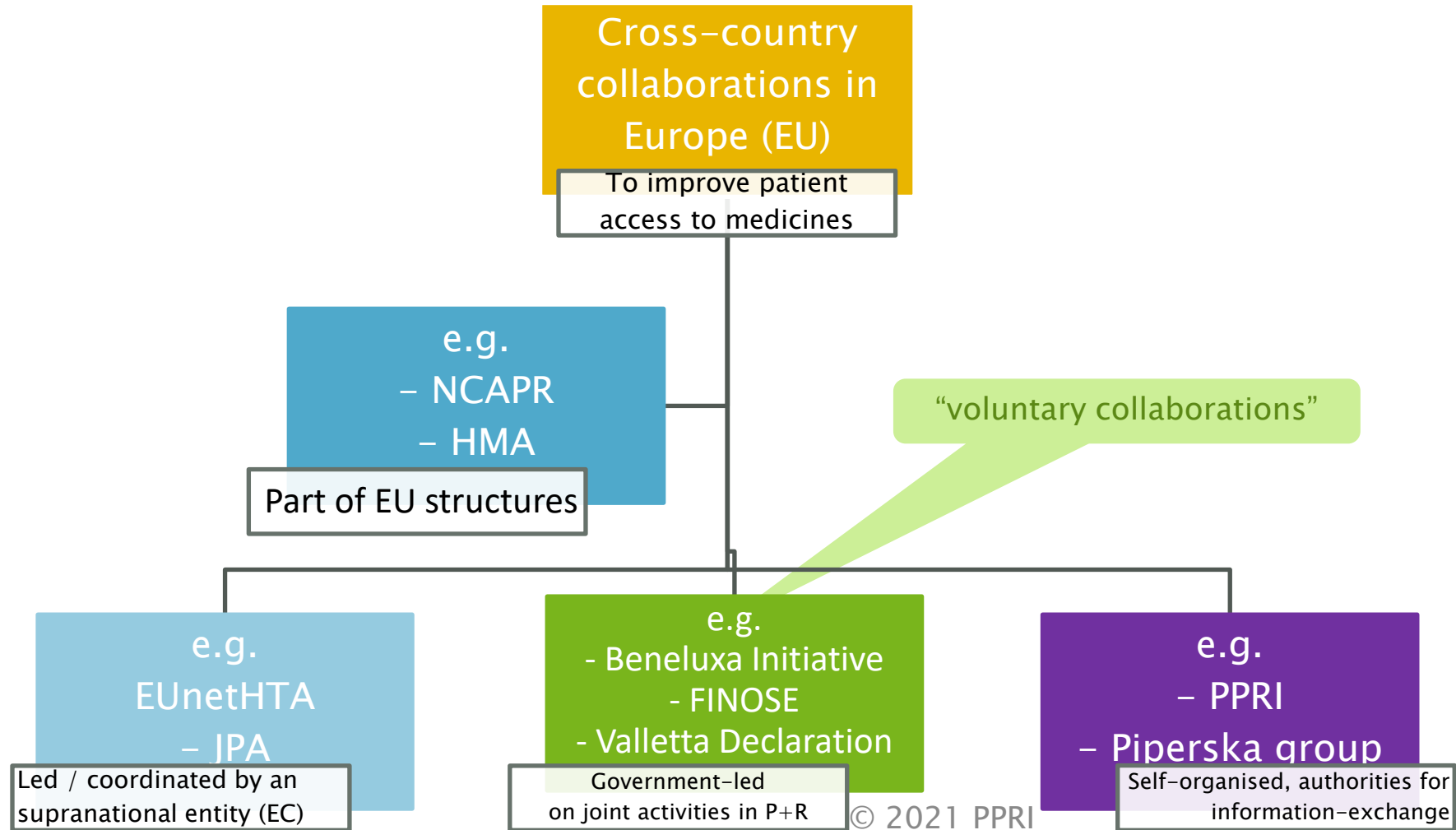
Cross-country collaborations in Europe

Lessons learned

Implications for national pricing policies (such as EPR)

Conclusions

Cross-country collaborations in Europe



Cross-country collaborations

**Baltic
Procurement
Initiative
(May 2012)**
Estonia, Latvia,
Lithuania

**Beneluxa Initiative
(September 2015)**
Belgium, Luxembourg,
Netherlands; 2016:
Austria; 2018: Ireland

**FAAP
(March 2017)**
Hungary, Lithuania,
Poland, Slovakia; 2019:
Czechia



**Nordic
Pharmaceutical
Forum
(January 2015)**
Denmark, Iceland,
Norway, Sweden
(Finland: observer)

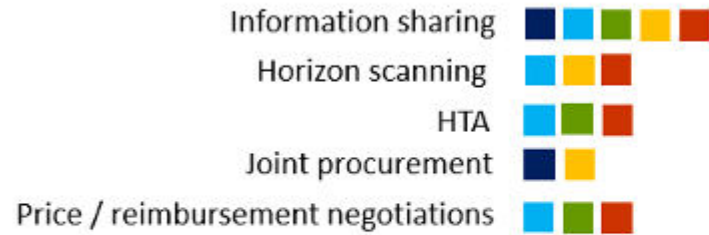
**Valletta
Declaration
(May 2017)**
Cyprus, Greece,
Ireland, Italy,
Malta, Portugal,
Romania, Spain;
2018: Slovenia,
Croatia

WHO Europe study

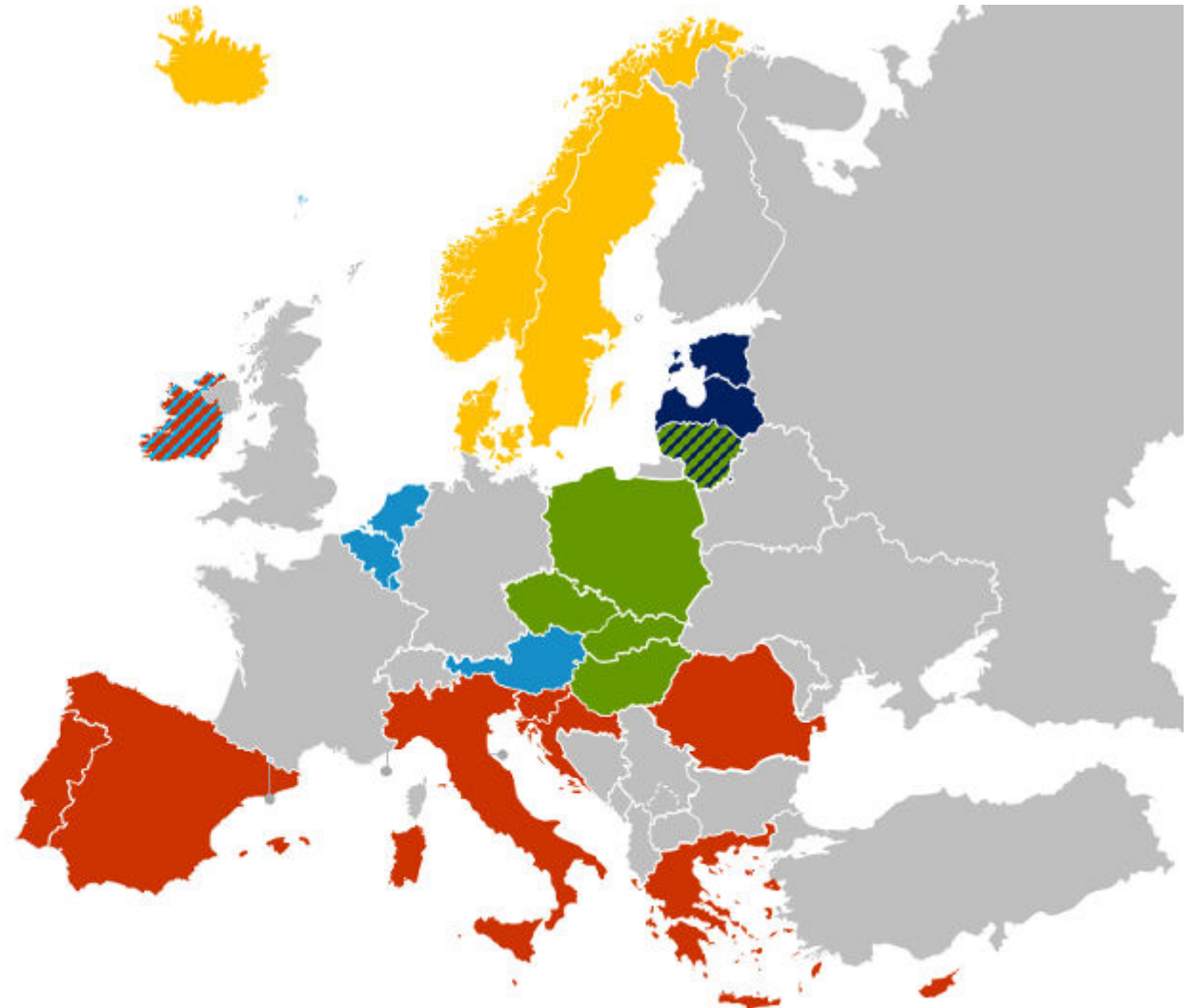
Vogler S, Haasis MA, van den Ham R, Suleman F, Humbert T, Garner S.: Cross-country collaborations to improve access to medicines in the WHO European Region. WHO Regional Office for Europe. Copenhagen 2020

https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Cross-country%20collaborations_final.pdf

Cross-country collaborations



Source: Vogler S et al., Cross-country collaborations to improve access to medicines in the WHO European Region. WHO Regional Office for Europe. Copenhagen 2020



Lessons learned: was it successful?

- » All unanimous that the collaborations are successful:
 - Difficult to measure the results of collaboration so far, but worth the effort
 - A move in the right direction → too early to assess success
 - Early benefits of the collaboration (information exchange and initiation of some assessments)

- » Monitoring and evaluation
 - Process indicators
 - “Tangible successes”

Facilitating factors and challenges

Facilitating factors

- » Trust
- » Enthusiasm and commitment
- » Highly qualified technical experts
- » Based on long-term collaboration
- » **Political commitment**
- » Structure within which to work
- » Information technology
- » Language

Challenges

- » Language
- » **Different P+R systems**
(standardization of procedures, rules)
- » Legal barriers
- » Reluctance of industry to negotiate
- » Identifying right people to work in the collaboration
- » Communication to the public
- » **Resources** (particularly time resources)
- » Fragmentation of system (hospital sector)
- » Lack of concrete results
- » To identify products and lead partner

Major lessons learned

- » Importance of political commitment
- » High expectations within collaboration and pressure from “outside”
- » Need to produce “tangible results”
- » Information and experience sharing is (considered) key
- » Processes take time
- » Collaboration requires (time) resources
- » Monitoring and evaluation processes should be planned in
- » Communication is a challenge (language issue)

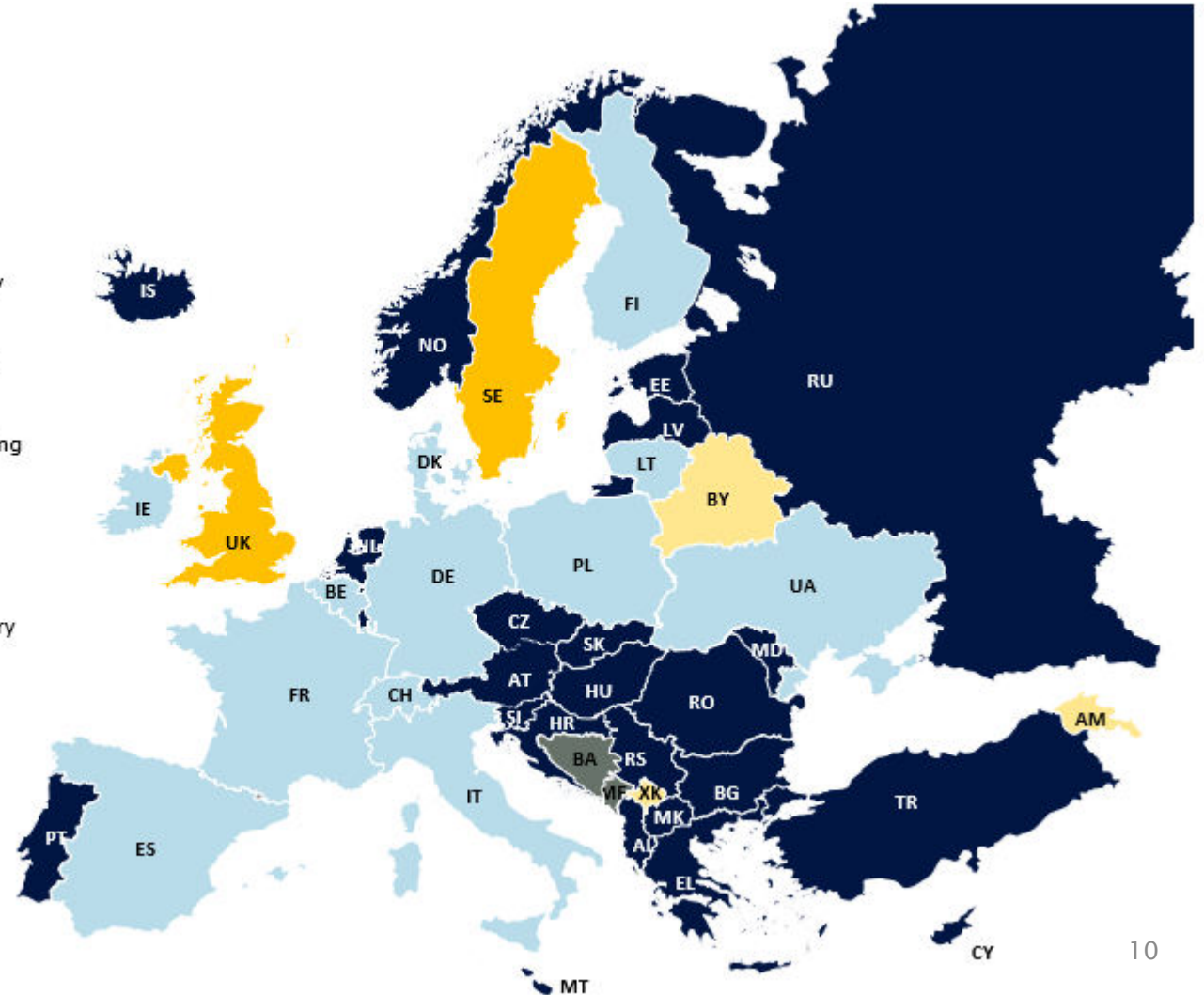
External price referencing is still a major (starting) pricing policy

External price referencing:

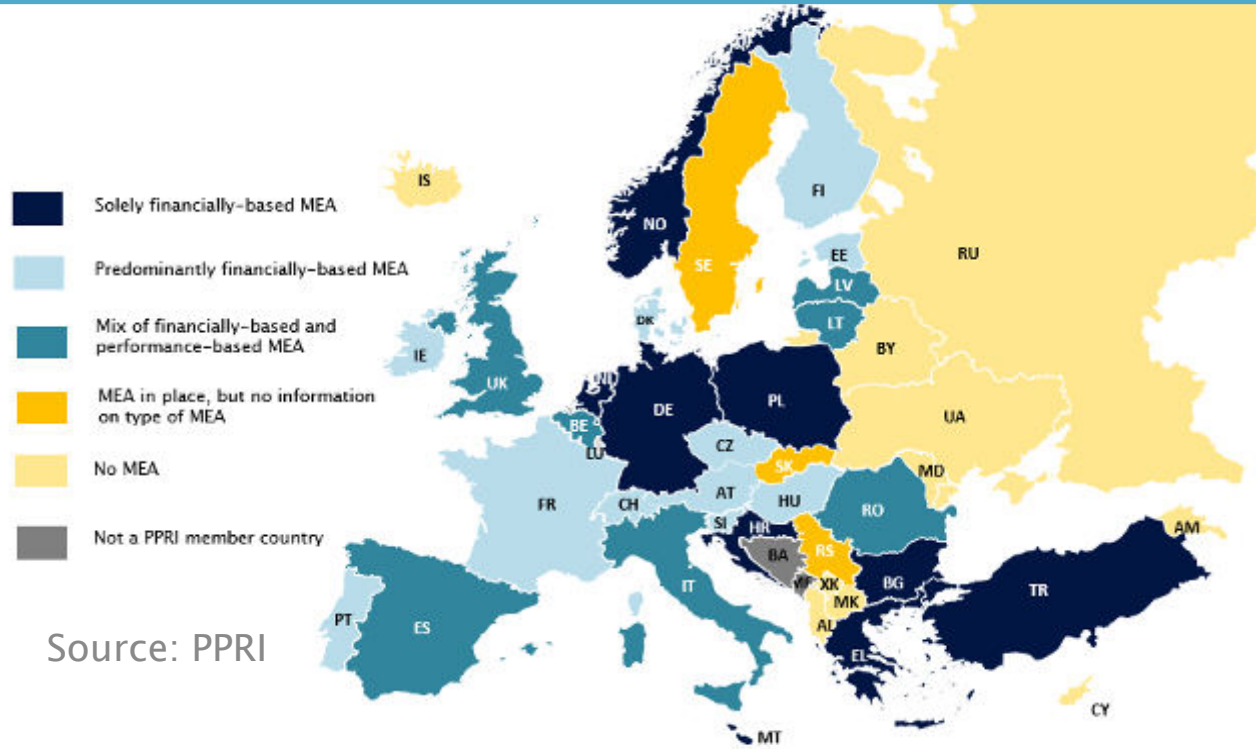
The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.

-  EPR as main pricing policy
-  EPR as supportive pricing policy
-  No EPR; use of other pricing policies
-  No price regulation
-  Not a PPRI member country

Source: PPRI



From EPR to managed-entry agreements (MEA)



Source: PPRI

Other EPR-applying countries ...

price level

impacts

access
(strategic launch)

Use of EPR (consideration of prices)

To determine a benchmark price

TOO HIGH

To negotiate a more affordable price (confidential discount)

To publish the higher list price

Managed entry agreements (MEA) – Impacts

- » Very limited knowledge on the impact of MEA
- » Earlier access
- » High administrative burden
- » Collecting and using new clinical data
- » Tend to increase list price



Implementing managed entry agreements in practice: The Dutch reality check

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SPECIAL ISSUE PAPER

The impact of managed entry agreements on pharmaceutical prices

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Abstract
Managed entry agreements (MEAs) have been used for several years, with the aim of curbing the growth of pharmaceutical expenditure and enhancing patient access to innovation. Yet, much remains to be understood about their economic implications. This paper studies the impact of MEAs on list prices, that is, prices before the deduction of any discount. Using a theoretical model, we show that, under most price setting regimes, the introduction of an MEA leads to a higher list price. This is confirmed by our empirical analysis of a sample of 35 medicines in six countries, providing a conservative estimate of the increase in price due to the MEA of 5.9%. A relevant policy implication is that papers may overestimate the financial gains that can be achieved through this tool.

KEYWORDS
managed entry agreements, pharmaceutical prices, risk-sharing agreements

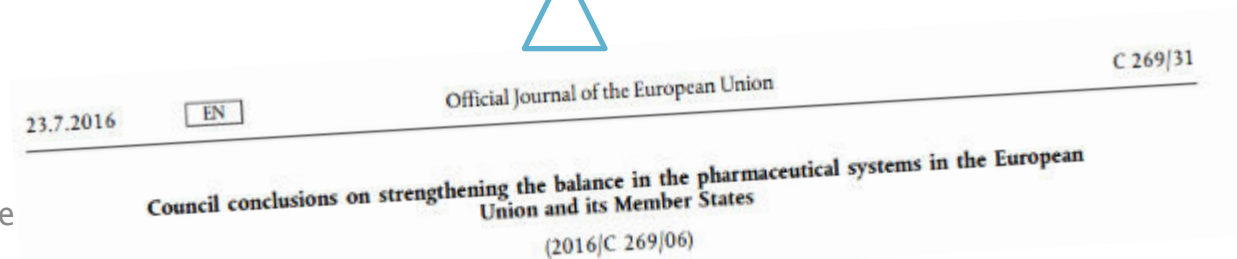
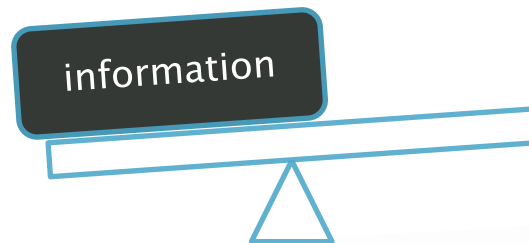


Determinants of price negotiations for new drugs. The experience of the Italian Medicines Agency

Federico Villa^{a,b,*}, Michaela Tutone^{a,c,2}, Gianluca Altamura^a, Sara Antignani^a, Agnese Cangini^a, Ida Fortino^{a,2}, Mario Melazzini^{a,2}, Francesco Trotta^a, Giovanni Tafuri^{a,1}, Claudio Jommi^{a,1}

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Implications of cross-country collaborations on pricing policies



Transparency



SEVENTY-SECOND WORLD HEALTH ASSEMBLY

WHA72.8

Agenda item 11.7

28 May 2019

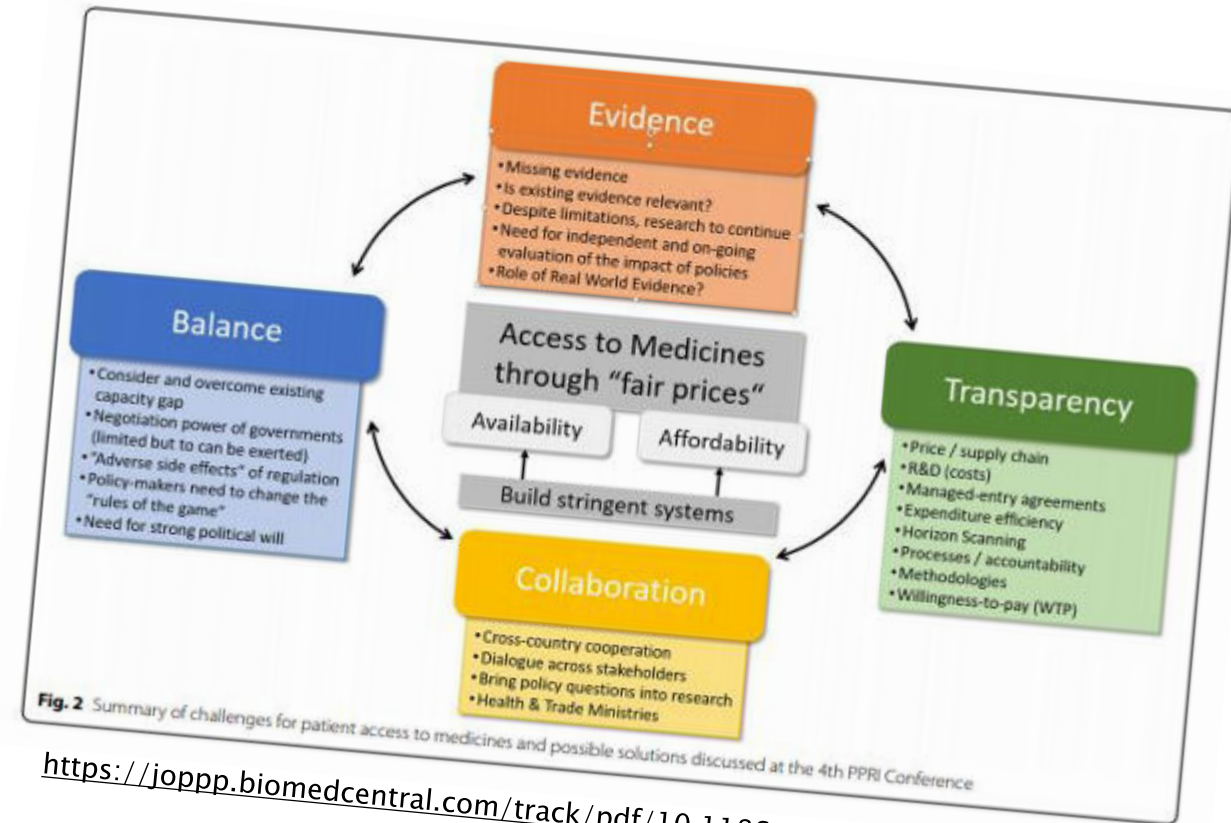
Improving the transparency of markets for medicines, vaccines, and other health products¹

https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

- » Take appropriate measures to **publicly share information on the net prices of health products**;
- » Take the necessary steps [...] to **support dissemination of** and enhanced availability of and access to aggregated **results data** and [...] **costs from human subject clinical trials** regardless of outcomes [...];
- » Work collaboratively to **improve the reporting of information by suppliers** on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;
- » Facilitate improved public reporting of **patent status** information and **marketing approval** status of health products

Conclusions

- » National pricing policies will continue to exist
- » Need for a holistic approach along the value chain
- » HTA – continued importance, adapted methodologies
- » More transparency is needed (price transparency and further)
- » Ensure the balance in the pharma. sector
- » **Collaboration of country collaborations**



<https://joppp.biomedcentral.com/track/pdf/10.1186/s40545-021-00300-3.pdf>

Thank you for your attention!

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Keywords

ABOUT - EXPERTISE - SERVICES - PUBLICATIONS - GLOSSARY - EVENTS - DE - ES - RU - MEMBERS

PPRI networks

We aim to contribute to affordable, equitable and sustainable access to safe, effective and quality essential medicines in Austria, Europe and globally.

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Experts of the Pharmacoeconomics Department conducted a survey in 24 countries on measures that governments implemented to address medicines shortages. Common policies include a notification...

More

PPRI Pharma Brief on Spain published

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More

Online Summer School Pharmaceutical Pricing and Reimbursement Policies 2021

5-9 July 2021 The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies is pleased to announce the first Online Summer School on Pharmaceutical Pricing and Reimbursement...

More

QUICKLINKS

- PPRI
- WHO CC
- PPI
- GÖG

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