WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

Gesundheit Österreich GmbH

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

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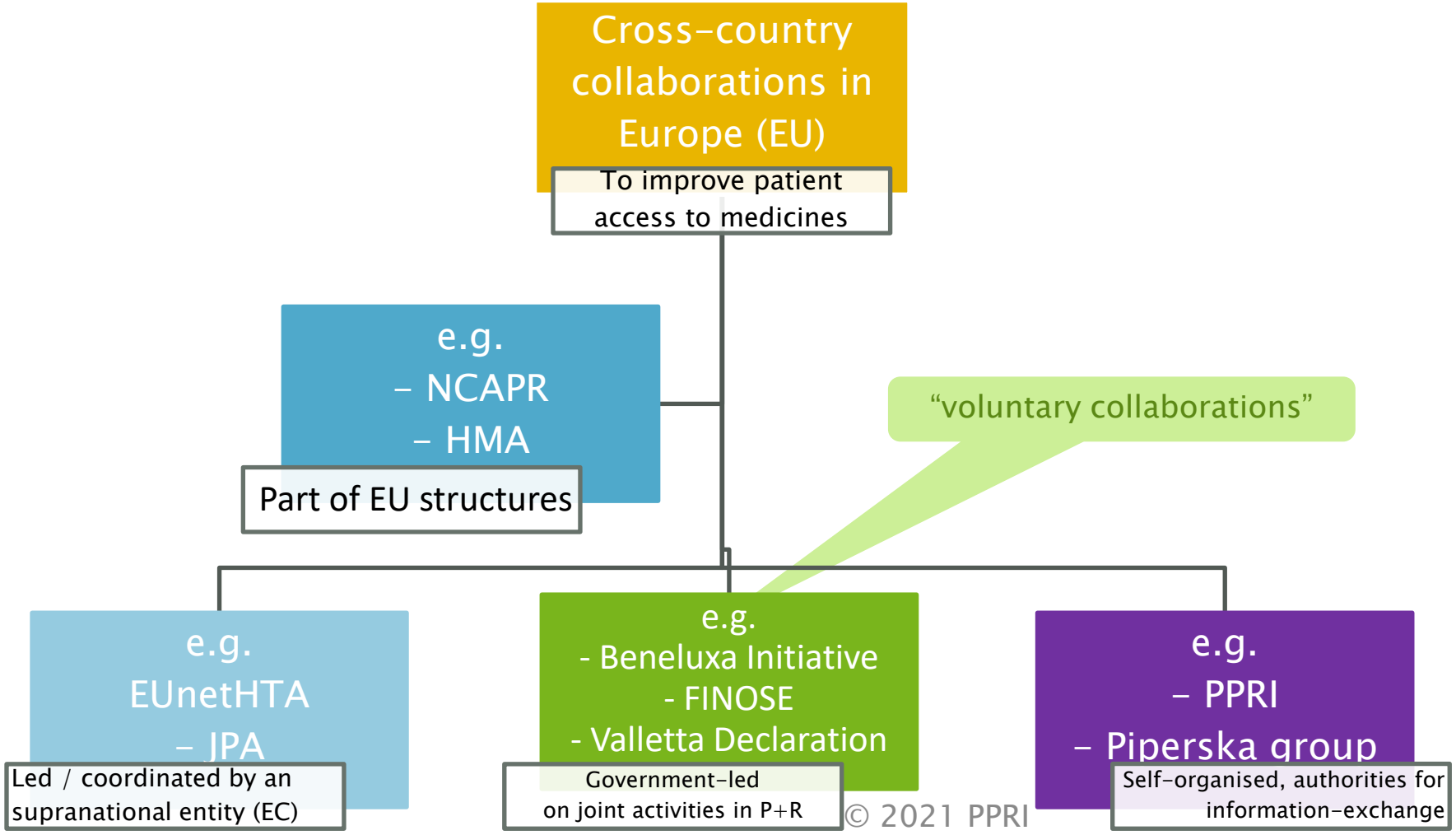
- Co-authors of WHO Cross-country collaborations study (at "PPRI WHO CC" & WHO CC at Utrecht University)
- The members of the PPRI network (= competent authorities for pharmaceutical pricing and reimbursement) for providing information on their country

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

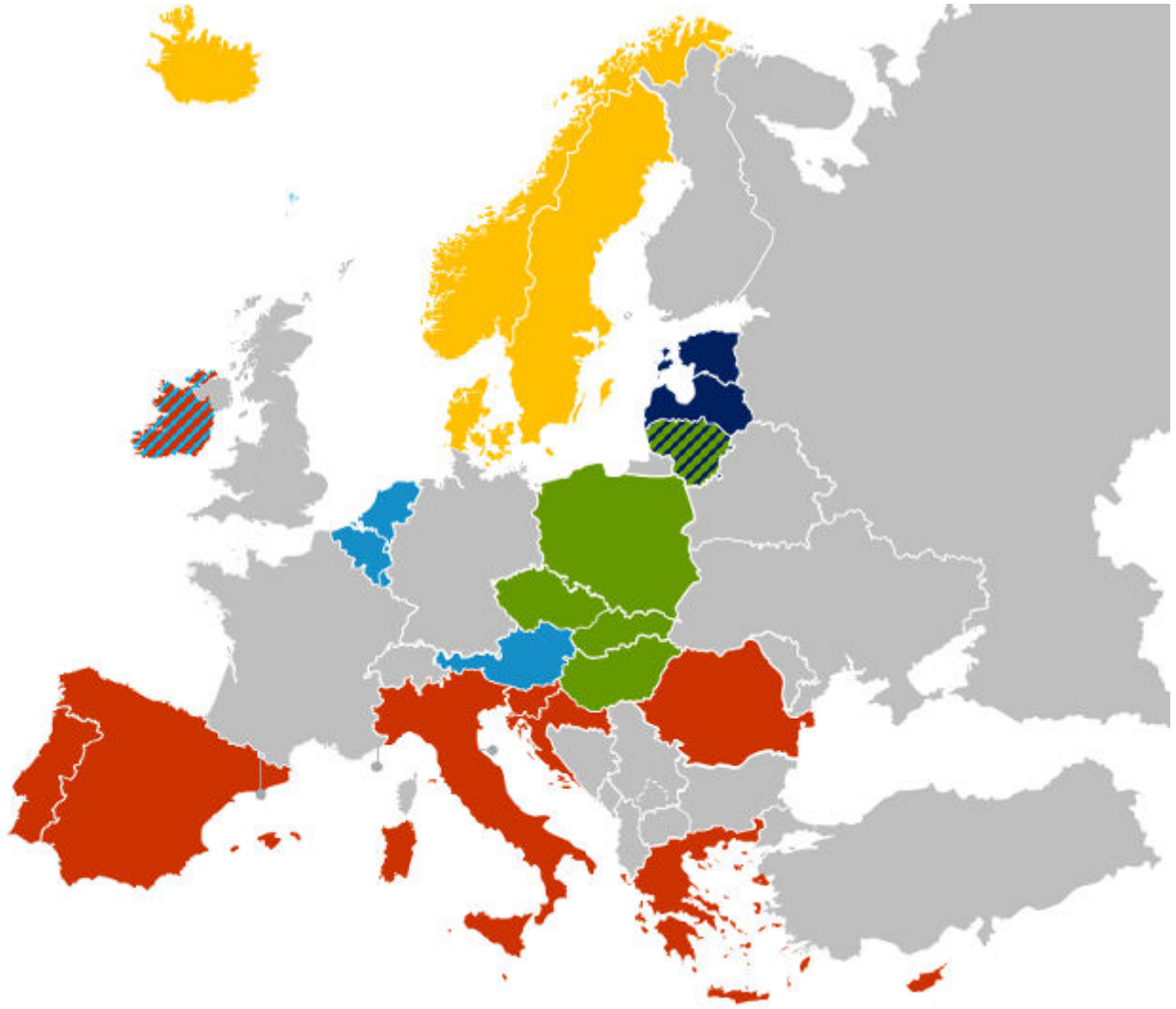
WHO Europe study

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

Information sharing
Horizon scanning
HTA
Joint procurement
Price / reimbursement negotiations



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

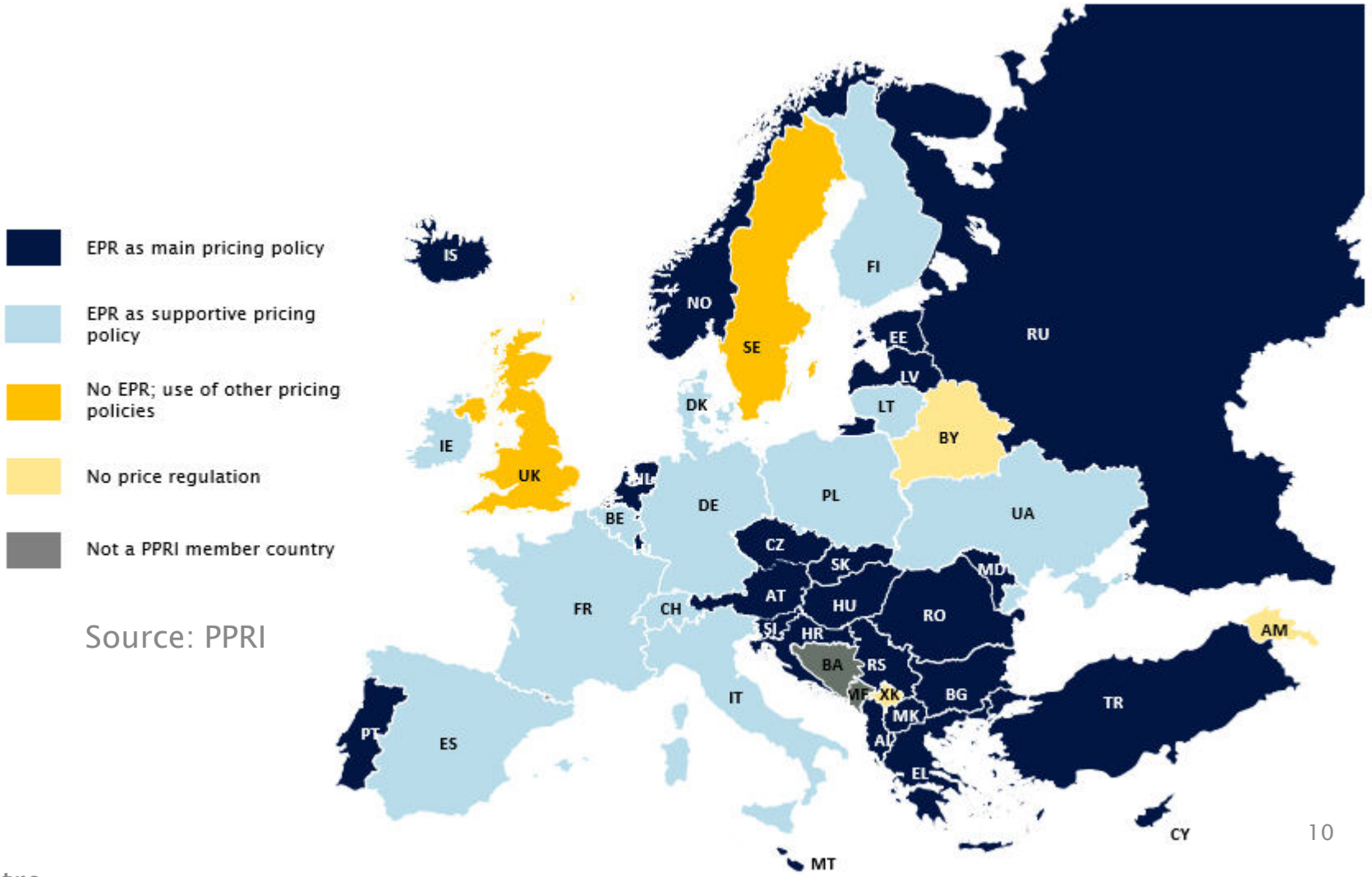
Major lessons learned

- 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

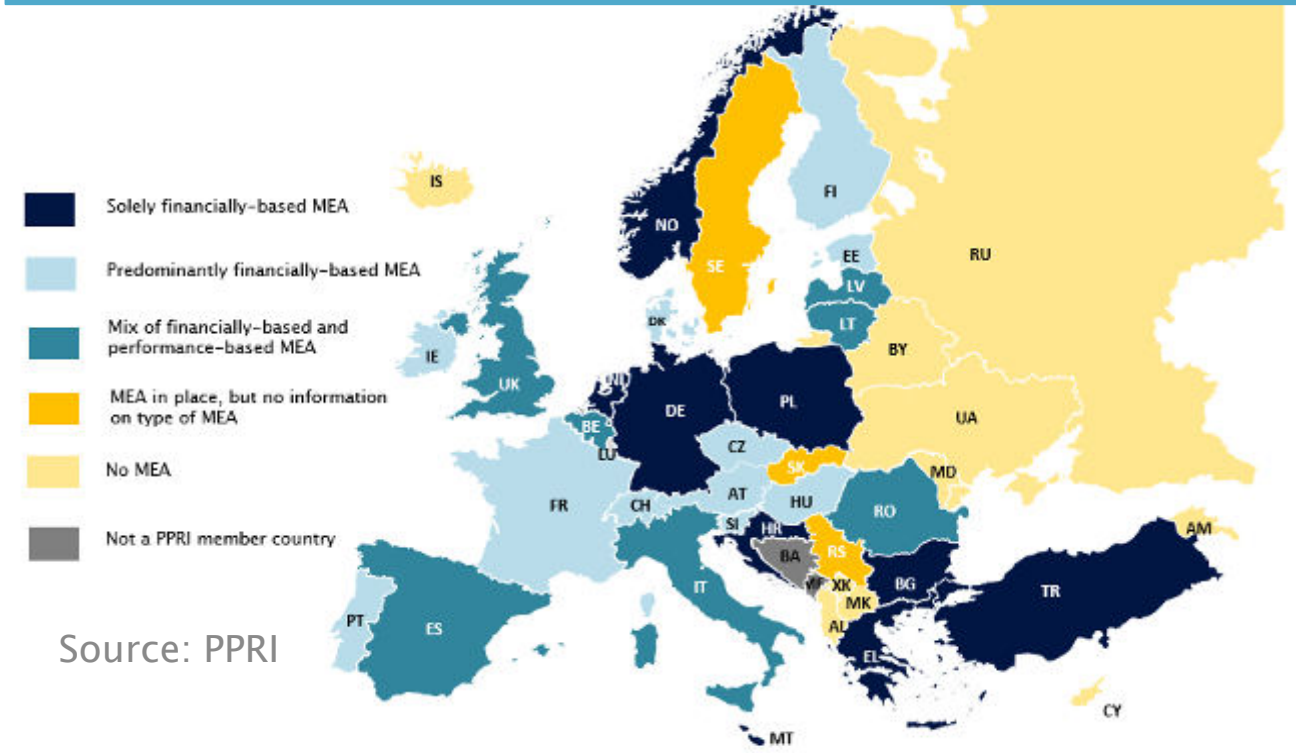
External price referencing:

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.



Source: PPRI

From EPR to managed-entry agreements (MEA)



Source: PPRI

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

Other EPR-applying countries …

price level

impacts

access (strategic launch)

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

A. Makady, A. van Veelen, A. de Boer, H. Hillege, O.H. Klungel, W. Goettsch

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

Federico Villa, Michaela Tutone, Gianluca Altamura, Sara Antignani, Agnese Cangini, Ida Fortino, Mario Melazzini, Francesco Trotta, Giovanni Tafuri, Claudio Jommi

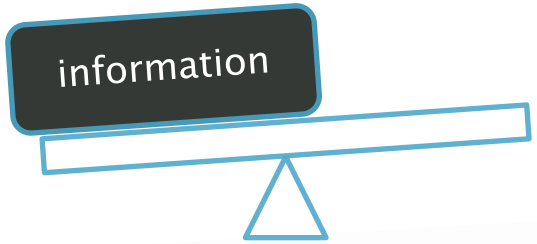
Implications of cross-country collaborations on pricing policies

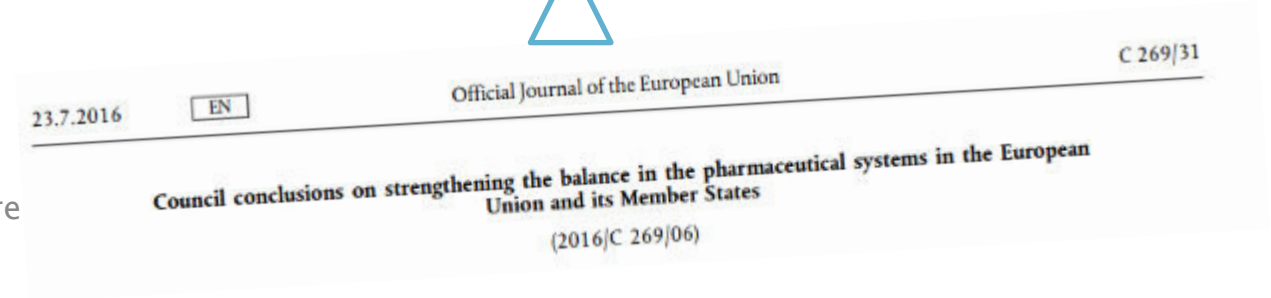
Cross-country collaborations

?

IMPACT

National pricing policies




23.7.2016 EN Official Journal of the European Union C 269/31

Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States

(2016/C 269/06)

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 products[1]

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**

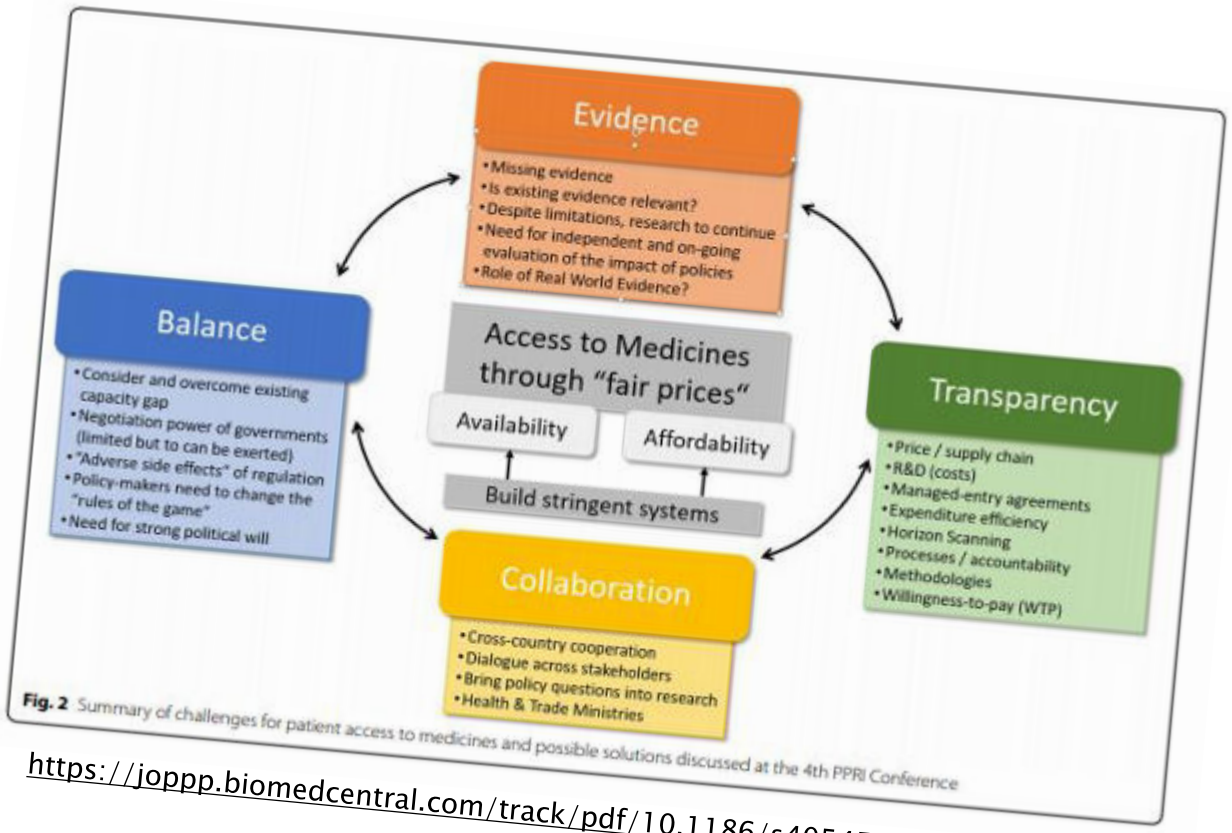


Fig. 2 Summary of challenges for patient access to medicines and possible solutions discussed at the 4th PPRI Conference

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

Thank you for your attention!

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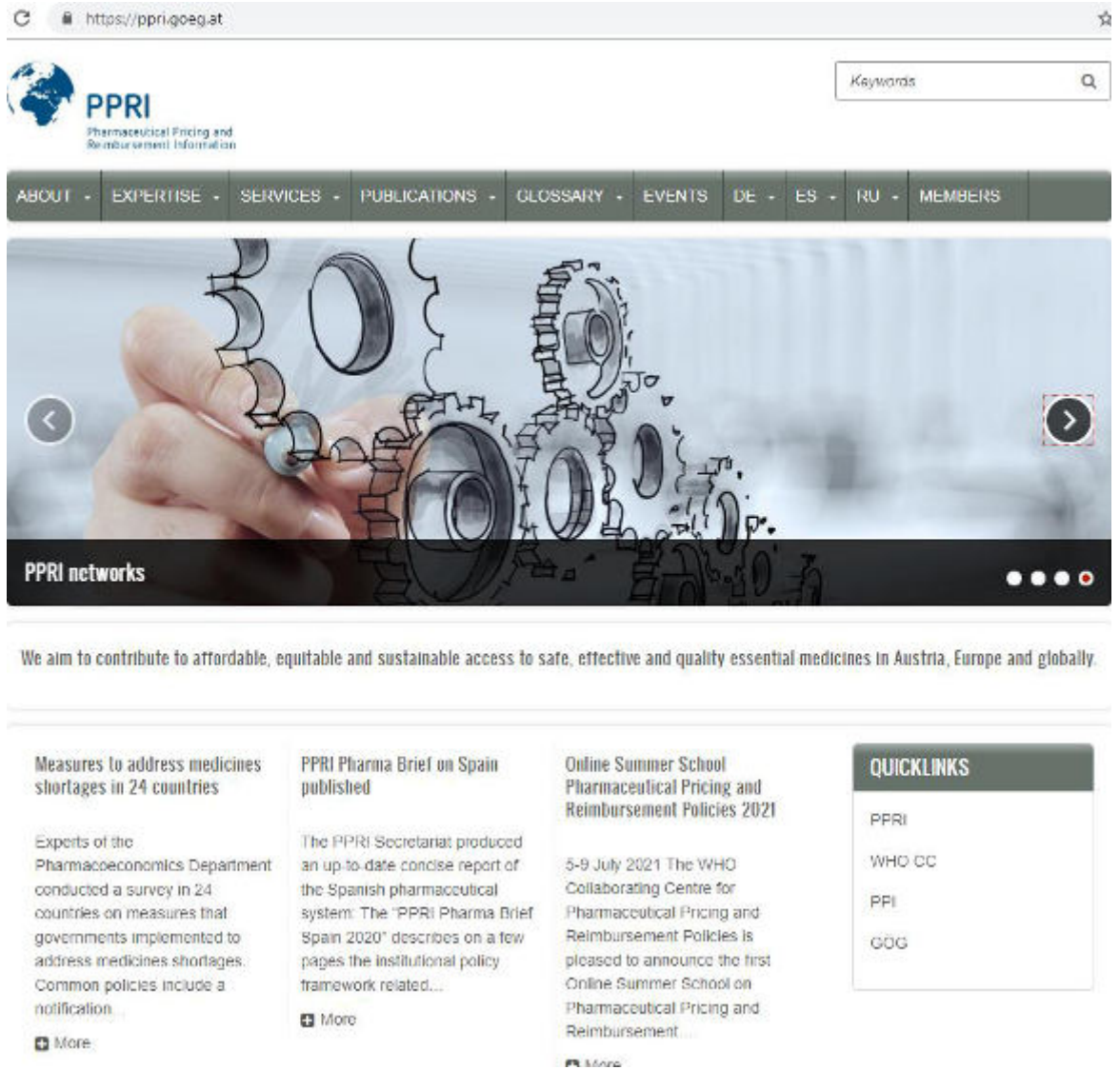

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