EU Health Technology Assessment Regulation Can it improve access to medicines?

Iga Lipska MD PhD MPH

The Chairwoman of the Board

Health Policy Institute

Poland, Warsaw-Gdańsk

Czech ISPOR Chapter, 22nd Febr 2023

Health Policy Institute

Health Technology Assessment

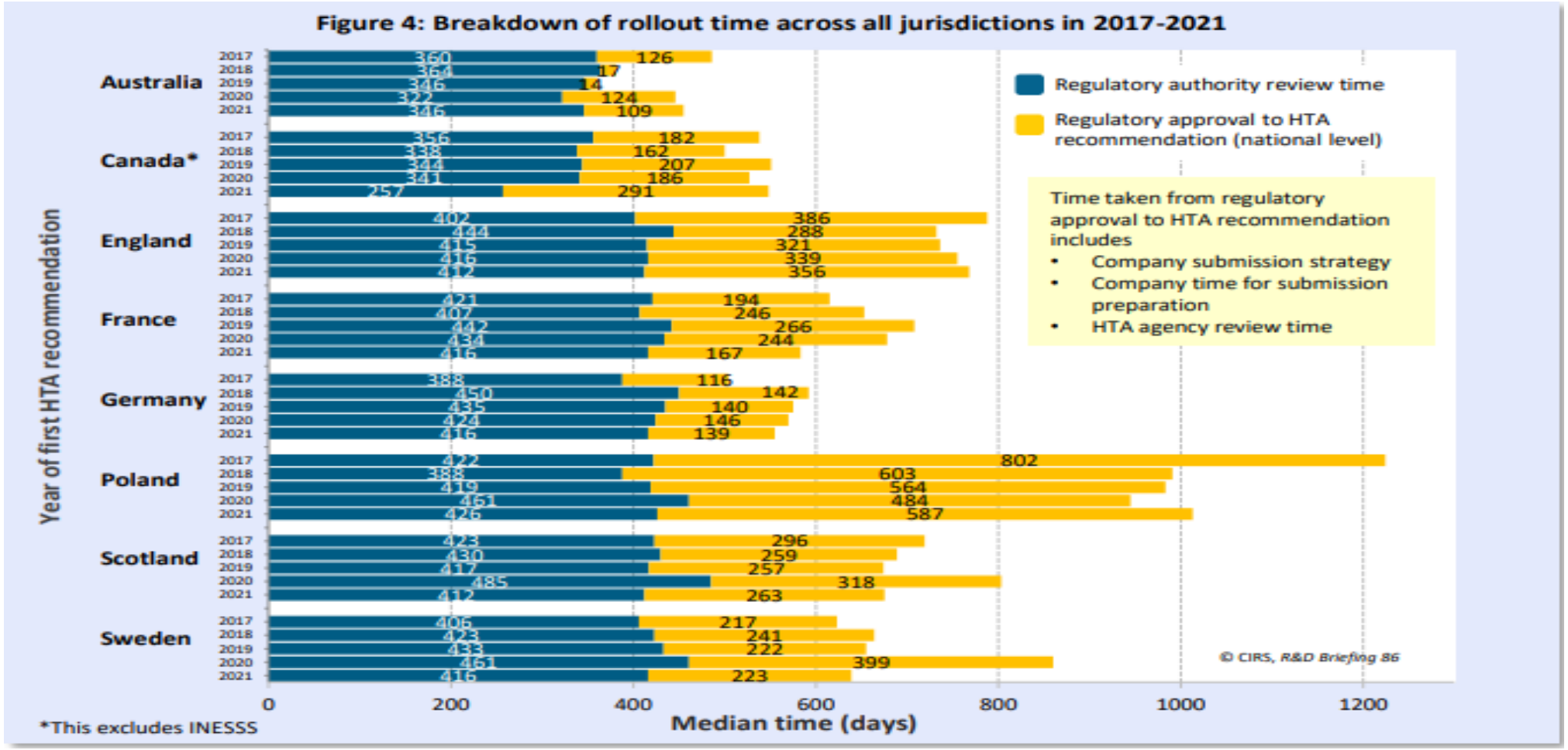
- **Let's start from the definition**
  - *HTA is a **multidisciplinary process** that uses explicit methods to determine the **value** of a health technology at different points in its **lifecycle**. The purpose is to inform **decision-making** in order to promote an **equitable, efficient, and high-quality health system****
- ***Past – long history of EU collaboration (eg. EUnetHTA)***
- ***Presence***
- ***Future***

** O'Rourke B, Oortwijn W, Schuller T, the International Joint Task Group (2020). The new definition of health technology assessment: A milestone in international collaboration. International Journal of Technology Assessment in Health Care 1–4. https://doi.org/10.1017/ S0266462320000215*

Current landscape HTA

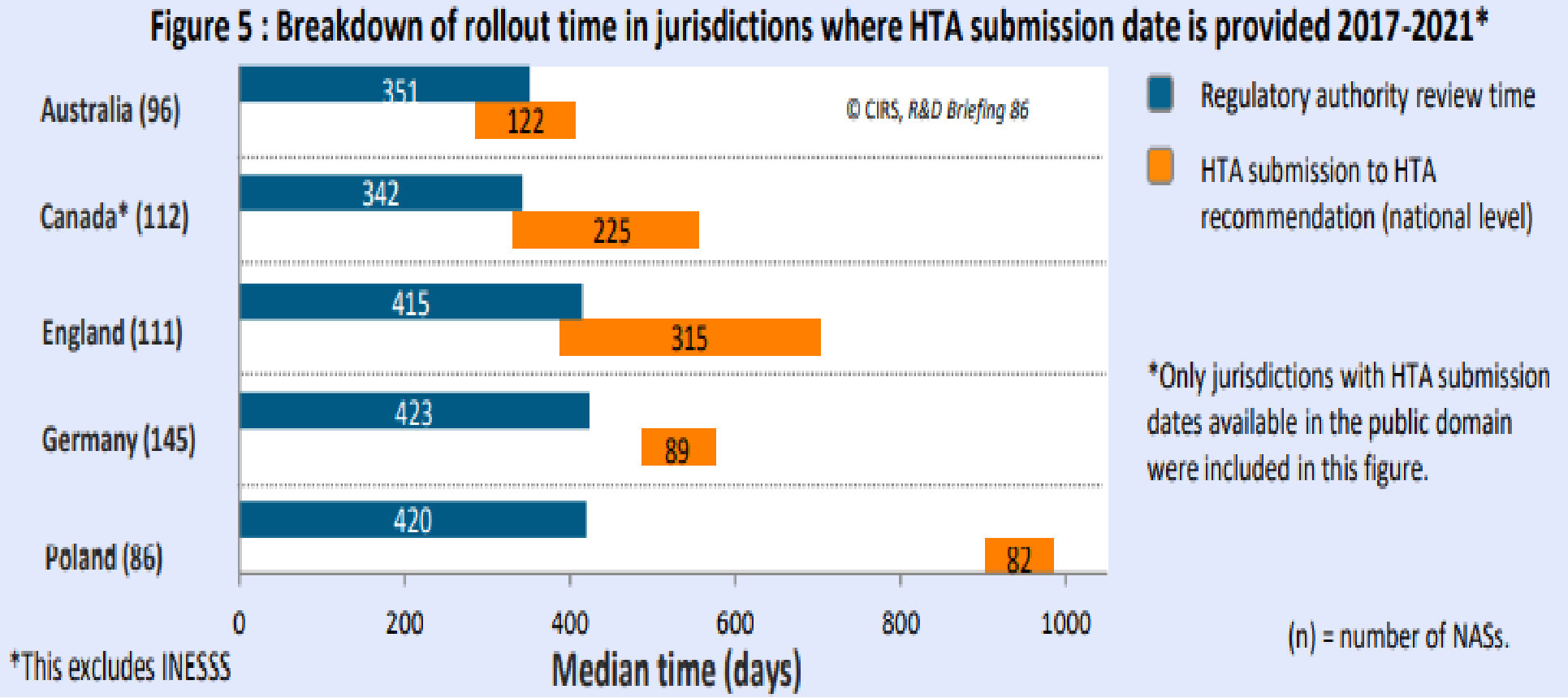
- Access gap
- New EU legislation framework
- EUnetHTA21
- Update on the implementation of Regulation (EU) 2021/2282 on HTA

Access gap



Sola B, Wang T, McAuslane N. 2022. R&D Briefing 86: Review of HTA outcomes and timelines in Australia, Canada and Europe 2017 -2021. Centre for Innovation in Regulatory Science. London, UK.

Breakdown of rollout time



Sola B, Wang T, McAuslane N. 2022. R&D Briefing 86: Review of HTA outcomes and timelines in Australia, Canada and Europe 2017 -2021. Centre for Innovation in Regulatory Science. London, UK

New legislation framework

- EU HTA Regulation
- Parliament and Council - Dec 2021
- Came into force Jan 2022
- Apply from Jan 2025

EU HTA Regulation / Rationale

Health Policy Institute

The objective is to improve patient access by

reducing duplication of assessment effort (clinical!)

Appraisal at Member State level!

EU HTA Regulation

- Joint Clinical Assessment (JCA)
- Joint Scientific Consultation (JSC)
- Horizon Scanning (see *IHSI*)

(Nearest) Future

- **Jan 2025**
  - **oncology drugs & ATMPs**
- **Jan 2028**
  - **orphan drugs**
- **Jan 2030**
  - **full scope**

Update on the implementation of Regulation (EU) 2021/2282 on HTA

Health Policy Institute

REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

This rolling plan contains a list of key activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the "HTAR"). The plan is subject to regular review to provide national authorities and stakeholders with the most updated information.

The HTAR entered into force on January 11, 2022. It will be applicable as of January 12, 2025.

Latest update: December 2022

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) HTAR Article 3				
Third meeting of the HTACG	HTAR Article 3		**20 March 2023**	Planned
Meetings of the HTACG		To be updated as dates are confirmed	Q2 2023 – Q4 2024	
Call for nominations - subgroup for the development of methodological and procedural guidance	HTAR Articles 3.3; 3.7 (k)	Designation of member institutions and their representatives by Member States (as well as observer institutions and their representatives by EEA countries), covering expertise in both medicinal products and medical devices.	Q1 – Q2 2023	Planned
Meetings of the subgroup on methodological and procedural guidance		To be updated as dates are confirmed	Q2 2023 – Q4 2024	
Call for nominations - subgroup for Joint Clinical Assessments	HTAR Articles 3.3; 3.7 (k)	Designation of member institutions and their representatives by Member States (as well as observer institutions and their	Q1 – Q2 2023	Planned

** European Comission DG SANTE https://health.ec.europa.eu/system/files/2022-12/hta_htar_rolling-plan_en.pdf*

Update on the implementation of Regulation (EU) 2021/2282 on HTA

		expertise in both medicinal products and medical devices.		
Meetings of the subgroup on identification of emerging health technologies		To be updated as dates are confirmed	Q2 2023 – Q4 2024	
Implementing acts				
Adoption	Articles 15.1(a) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medicinal products	by Q4 2024	Planned
Adoption	Articles 15.1 (b) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medical devices	by Q4 2024	Planned
Adoption	Article 20.1	Joint Scientific Consultations for medicinal products	by Q4 2024	Planned
Adoption	Article 20.1	Joint Scientific Consultations for medical devices	by Q4 2024	Planned
Adoption	Article 25.1(a)	Conflict of interest management	by Q4 2024	Planned
Adoption	Articles 15.1 (a) and (b); 20.1 (c) and (d)	Cooperation by exchange of information with the European Medicines Agency (EMA)	by Q4 2024	Planned
Stakeholder network HTAR Article 29				
Publication of the list of stakeholder organisations	HTAR Article 29.4	Following the call for applications to join the HTA stakeholder network on 12 December	Q1 2023	Planned

** European Comission DG SANTE https://health.ec.europa.eu/system/files/2022-12/hta_htar_rolling-plan_en.pdf*

Update on the implementation of Regulation (EU) 2021/2282 on HTA

Health Policy Institute

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Second and Third releases	HTAR Article 30.1(b) HTAR Article 30.1(c) HTAR Article 30.1(d)	Setup of a secure intranet for the exchange of information between members of the Coordination Group and its subgroups, including exchange of information with health technology developers and experts, with the European Medicines Agency and the Medical Device Coordination Group; as well as between members of the stakeholder network	Q4 2024	Planned
EU support for HTA (capacity building, training, awareness raising, etc.)				
EUnetHTA 21	Third EU Health Programme	Provision of joint HTA work supporting the continuation of EU cooperation on HTA	2023	Final year of the contract
Training of patients and clinical experts contributing to joint health technology activities	EU4Health Work Programme 2022	Capacity building of patients and clinical experts	2023-2024	Planned
Raise awareness of Member States authorities and stakeholders about the HTAR	EU4Health Work Programme 2022	Dissemination activities in Member States	2023-2024	Planned
Training of national assessors and HTA national authorities	EU4Health Work Programme 2023	Capacity building of HTA national authorities	2024	Planned

** European Comission DG SANTE https://health.ec.europa.eu/system/files/2022-12/hta_htar_rolling-plan_en.pdf*

HTAR implementation rolling plan

European Commission

** European Comission DG SANTE https://health.ec.europa.eu/system/files/2022-12/hta_htar_rolling-plan_en.pdf*

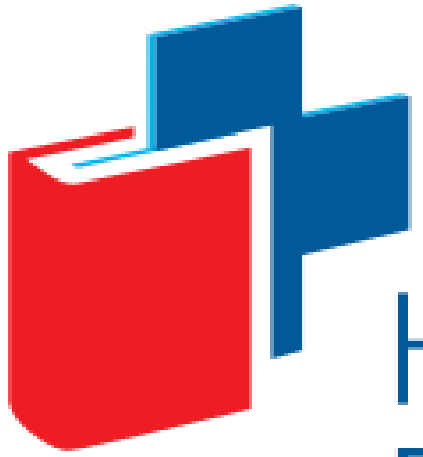
Future – call for action!

Health Policy Institute

- Stakeholders' involvement
- Actively participate in EUnetHTA21 work
- The urgent need to **map legislation** at national level
- To **adopt national legislation** to EU HTA Regulation

Thank you!

iga.lipska@healthpolicy.institute



Health Policy Institute