

Summary and Highlights

PPRI Network Meeting, Lisbon, 8-9 April 2025

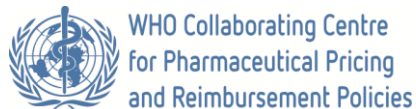
Margit Gombocz, Valentin Kandler, Katharina Kieslich, Verena Knoll, Sabine Vogler

PPRI Secretariat

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Pharmacoeconomics Department

Gesundheit Österreich (GÖG/Austrian National Public Health Institute)




Agenda

Day 1

- Welcome words
- PPRI updates
- Country poster sessions
- Group sessions & PPRI Network Queries
- Newcomer session

Day 2

- Hot potato session
- Pharmaceutical policy and impacts in Portugal
- Implementing pharmaceutical policies: What works?
- De-funding in pharmaceutical policy: Communicating unpopular decisions



PHARMACEUTICAL PRICING AND REIMBURSEMENT INFORMATION (PPRI)	
PPRI Network Meeting	
8 – 9 April 2025	
AGENDA	
Venue and host: Hotel HF Fénix, Praça Marquês de Pombal 8, 1269-133 Lisbon Hosted by INFARMED	
Working language: English	
Day 1: Tuesday, 8 April 2025, 8.30 – 17.30 h WET	
Facilitation: Verena Knoll (PPRI Secretariat)	
8.30 – 9.00	REGISTRATION
9.00 – 9.30	WELCOME AND INTRODUCTION <ul style="list-style-type: none">• INFARMED<ul style="list-style-type: none">Rui Santos Ivo, President of INFARMED, Portugal• Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection, Austria<ul style="list-style-type: none">Sarah Grabner, Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection, Austria• PPRI Secretariat<ul style="list-style-type: none">Sabine Vogler, PPRI Secretariat, GÖG, Austria• Round of introduction
9.30 – 10.30	UPDATES <ul style="list-style-type: none">• PPRI Secretariat<ul style="list-style-type: none">Sabine Vogler, PPRI Secretariat, GÖG, Austria• Update from the European Commission<ul style="list-style-type: none">François Janssens, DG SANTE (online)• Update from OECD<ul style="list-style-type: none">Valérie Paris, OECD (online)• Update from WHO HQ<ul style="list-style-type: none">Kiu Siang Tay, WHO HQ (online)

Highlights



72 participants
from
28 countries



Photo credits: Infarmed / GÖG

Thank you to our
colleagues at **Infarmed**
for hosting this meeting!

Highlights

Welcome words by **Rui Santos Ivo**,
President of INFARMED, Portugal
and
Sarah Grabner, Austrian Federal Ministry of
Labour, Social Affairs, Health, Care and
Consumer Protection



Photo credits: Informed / GÖG



3 interactive sessions
24 country posters



Day 1 – PPRI Updates

PPRI Secretariat gave a short overview of the PPRI Network, its membership, goals and activities.

Summary

- PPRI is a members-based network
- Membership limited to competent authorities; currently 50 countries; over 200 people as members
- Membership rules might need to adapt due to high influx of new members → Stay tuned 😊
- PPRI celebrates its 20th anniversary on 16 September 2025 in Vienna

PPRI Secretariat contact details (also for questions related to membership)



PPRI team @ GÖG
Stubenring 6
1010 Vienna, Austria

E-Mail: ppri@goeg.at
<https://ppri.goeg.at>

Day 1 – Presentation of PPRI country posters

- Posters on recent and planned developments in pharmaceutical policies in 2024/2025
- **Special topic:** Current advances in HTA (for EU Member States: Implications from the EU-HTA Regulation)
- Country posters can be accessed on the public PPRI website:
https://ppri.goeg.at/ppri_posters

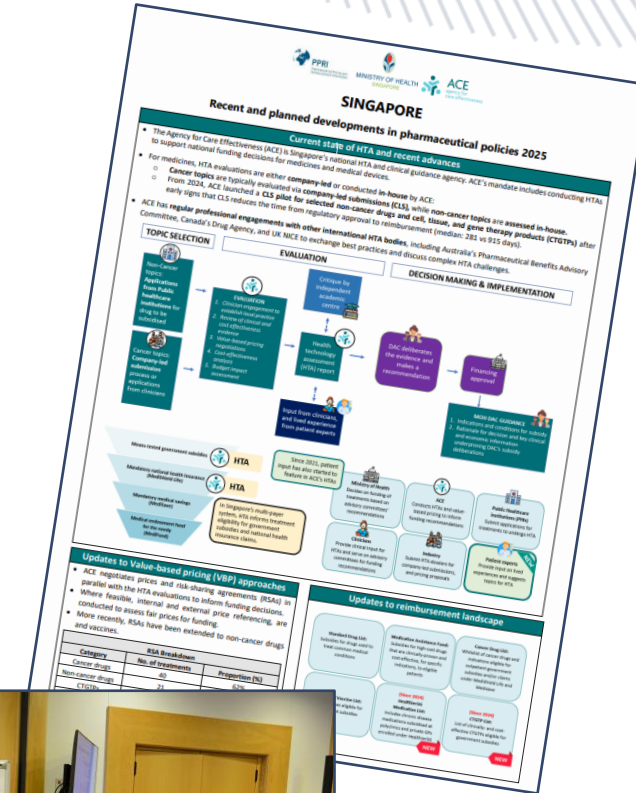
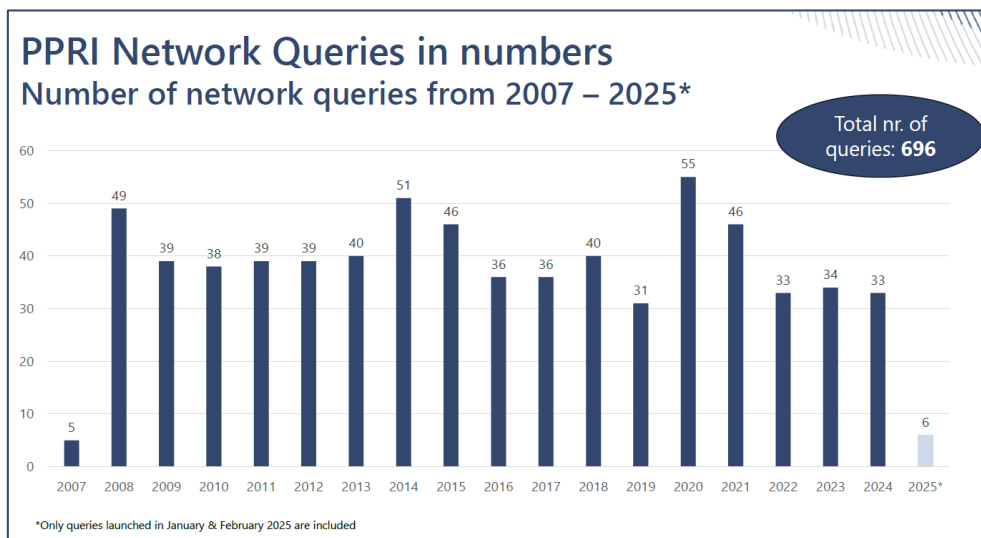


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Day 1 – PPRI Network Queries

Statistics on PPRI Network Queries were presented

- Since 2007: **696 queries** launched
- Number of responses per query varies among members.
- Leading countries: **Sweden, Malta, Austria & Switzerland**



Two members provided insights into PPRI Query compilations

- Query on the pricing & reimbursement of **Casgevy** (Sarah Grabner, AT)
- Query on the reimbursement of **Epinephrine (Epipen)** (Damien Byrne, IE)

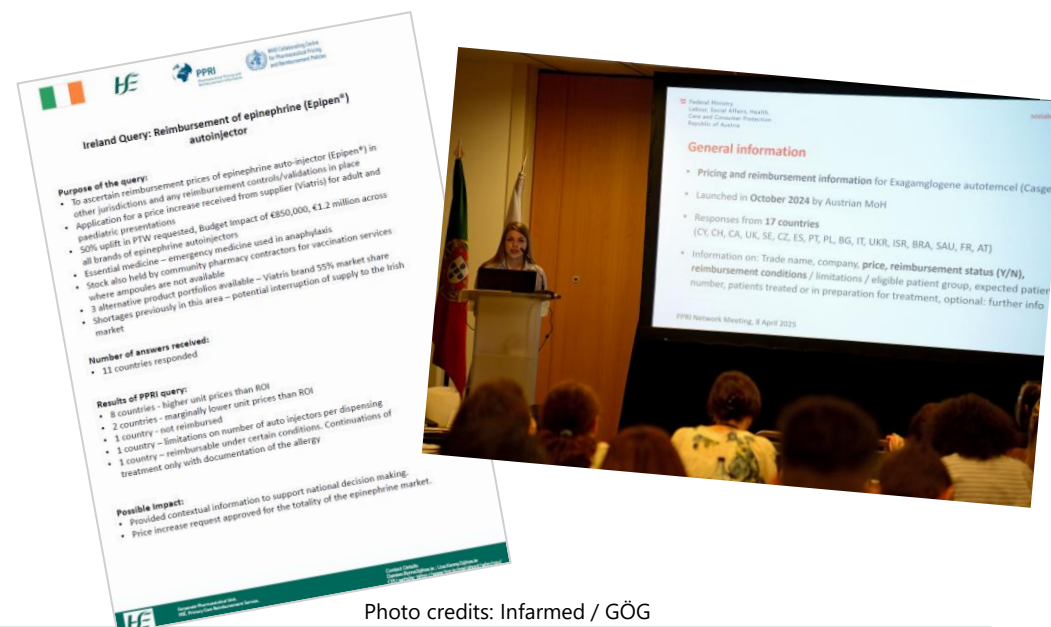


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Day 2 – Hot potato session



Published after the PPRI network meeting:
<https://www.sciencedirect.com/science/article/pii/S0168851025000739>

Topic: Early Access Schemes

(Session run by Sophie Lopes & Nadia Amer, CNAM, France)

Sophie and Nadia presented the results of a country study they conducted of EAS in England, France, Germany, Italy and Spain:

- Early access schemes: usually narrow indication scope
- EAS in most countries granted before marketing authorisation (MA)
- Early access cuts average access times
- France EAS experience: negotiation times are longer if a medicine has EA
- UK: Pharma-sponsored EA

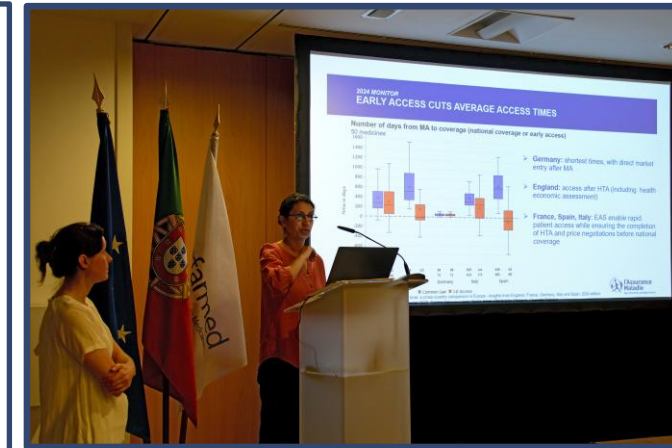
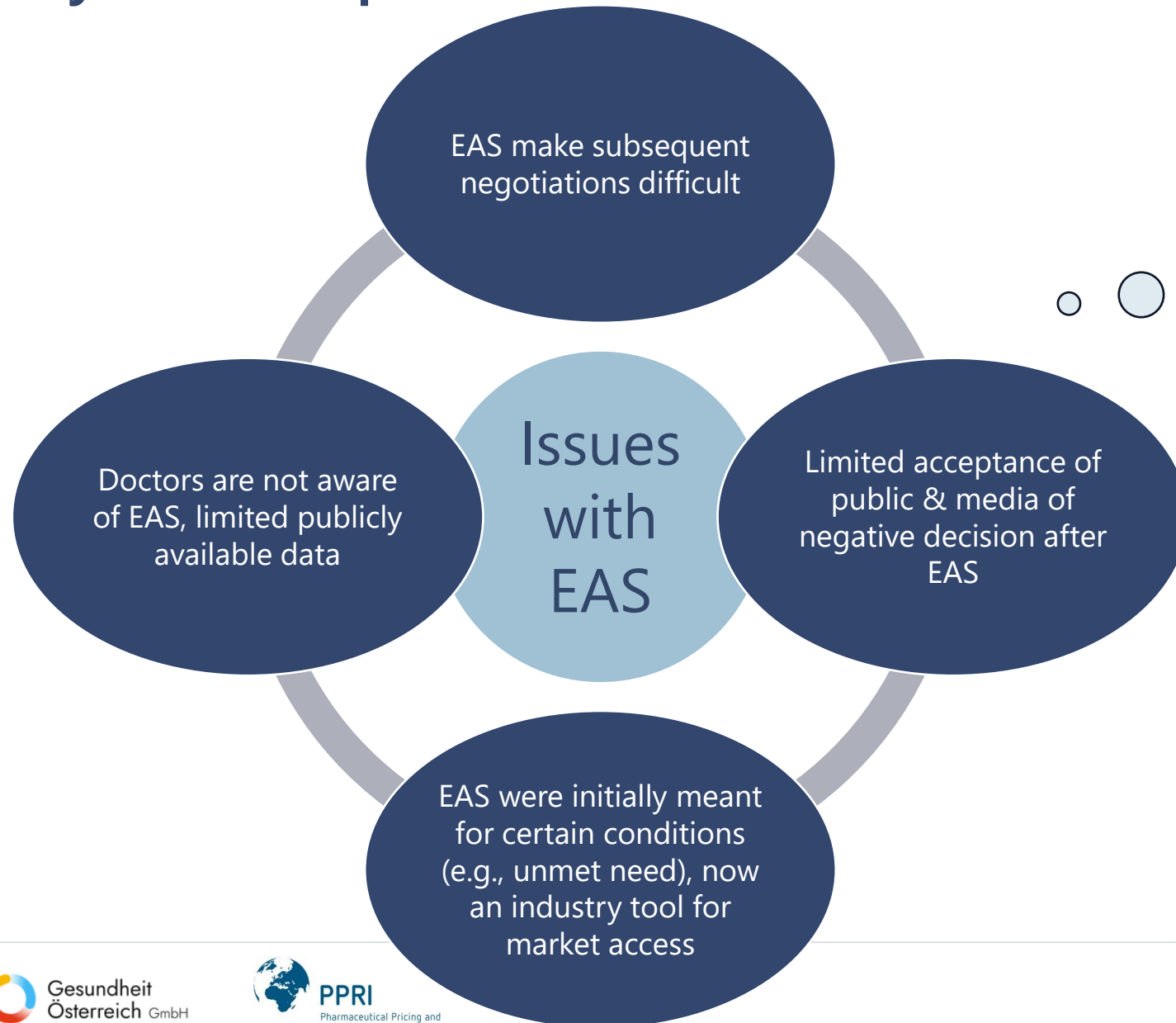


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Day 2 – Hot potato session



Day 2 – Pharmaceutical Policy and Impacts in Portugal





The Portuguese Pharmaceutical System: Structure and Challenges (Sónia Caldeira, INFARMED)

- PT: prices are considered to be low, in annual price review there is an option to increase price
- P+R policies support accessibility while maintaining financial stability
- Different reimbursement rates according to medicine types; special reimbursement schemes
- Lengthy evaluation process
- Co-payments are a revenue stream
- No special incentives for biosimilars

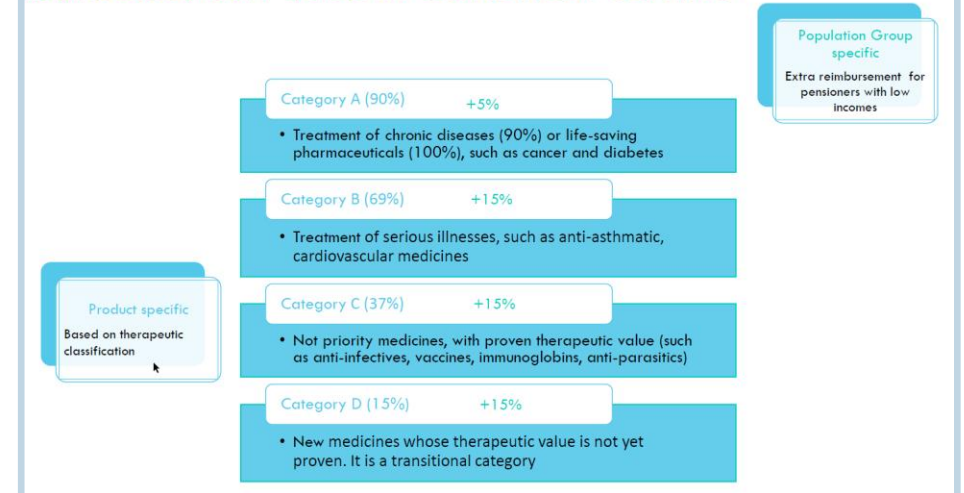
Challenges

- Delays in access to innovation despite EAS that are in place
- High co-payments for patients (co-payment rates of up to 67%)

NON-GENERICS – PRICE STRUCTURE

Outpatient	Inpatient
Maximum Retail Price (PVP) = ex-factory price (PVA)* + Wholesale margin + Pharmacy margin + Sales Tax (0.4%) + VAT rate (6%)	Maximum acquisition price (PVH) = ex-factory price (PVA) # + Sales Tax (0.4%) + VAT rate (6%)
Distribution Remuneration- 6 price tiers (fixed + variable components)	
* Average price of the 4 reference countries	# Lowest price of the 4 reference countries
 Spain	 France
 Italy	 Belgium

REIMBURSEMENT LEVEL IN OUTPATIENT SETTING



Day 2 – Pharmaceutical Policy and Impacts in Portugal

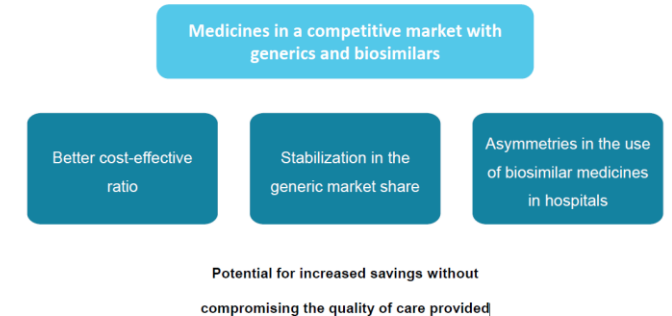
Rethinking Public Spending on Pharmaceutical and Medical Devices: The ongoing Reforms (Ana Correia, INFARMED)

- Current spending review (financial goals set by Ministry of Finance): Goal of identifying areas where efficiencies and savings can be made
- A current area for intervention identified for the current spending review was the generic and biosimilars market
- Idea is: Prescribers should feel the savings, otherwise they won't know their contribution
- Reduction of waste, e.g., in polypharmacy; point is not limiting access, but creation of consciousness about it
- Challenging process: Ministry of Finance wants 15% reduction; difficult to manage and reconcile expectations of Ministries of Finance and Health with each other.

The reimbursement process: Opportunities with the HTA-R regulation (Cláudia Furtado, INFARMED)

- HTA results now mostly in the "added value but non-quantifiable" category
- PT includes budget impact in their considerations
- Negotiation factors: Pharmacotherapeutic assessment; ICER and budget impact; affordability
- Robust HTA system but with delays; delays create pressures to do an EAS/programme, affects negotiations
- More efficient use of clinical experts through HTA-R
- Improve patient engagement in HTA assessment

INTERVENTION AREAS



With the Implementation....

We are taking opportunity to adapt the legislation:

- Introduce prioritisation criteria for drugs and MD
- Implement a differentiated approach (simplify in low-risk drugs)
- Improve patient engagement in HTA assessment (HTA Committee?)
- Promote an articulation between different entities from MoH and NHS to ensure a smoother adoption
- More transparency on decisions & timings

Day 2 – Implementing pharmaceutical policies: What works?

Introduction

Facilitators and barriers & relevance of evaluation studies (Sabine Vogler, PPRI Secretariat, GÖG)



Case study 1

Measures to mitigate medicines shortages in Portugal (Diogo Sobral, INFARMED)



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Case study 2

Measures to mitigate medicines shortages in Brazil (Diego Botelho Gains, ANVISA)



Day 2 – De-funding in pharmaceutical policy: Communicating unpopular decisions

Presentation 1

When evidence meets real-world limitations
(Katharina Kieslich, PPRI Secretariat, GÖG)

Presentation 2

Experiences from the PPRI network countries: Denmark
(Dorthe Bartels, AMGROS)

When evidence meets real-world limitations

In pricing & reimbursement we rely on scientific evidence, technical expertise and (ideally) good-quality data

Yet, evidence frequently meets real-world limitations such as...

- Uncertainty
- Unexpected crises, knowledge not yet available
- Lengthy timelines for assessment of evidence
- Unexpected or unpopular results
- Difficulty of communicating complex information to policymakers/public
- Unfavourable policy/political environment
- Role of the media
- Financial constraints
- Judicialization of decisions
- Public opinion
- Misinterpretation or misrepresentation
- Mistrust of experts and science



This is what you are up against!
Not just scientific limitations!



WHY IS THERE SO MUCH FOCUS ON THIS PARTICULAR DISEASE AREA?

MUSKELSVINDFONDEN

Marcus må ikke få den medicin, som er udviklet til ham

Stadig nej til medicin til børn med SMA over seks år, men lidt flere børn kan få

Grøn Koncert

09.04.2025 Amgro's PowerPoint presentation

FIRST RESULT ==> AND THEN A DIFFERENT APPROACH

Jan – Feb. 2023

- Amgro's publishes a tender with a deadline of February 15, 2023
- The tender is not like other tenders: it was divided into patient groups

- The Medicine Council continues to reject expanding the population - based on price

=> Encourages Amgro's and companies to renegotiate

April – June 2023

- Amgro's invites companies and the patient organization (Muscular Dystrophy Foundation) to joint **DIALOG** meetings about the disease and "ceasefire"

- Amgro's renegotiates price and agreement types with companies

- D. 21 juni 2023 approved DMC treatment with Spinraza and Evrysdi - patient up to 25 years

09.04.2025 Amgro's PowerPoint presentation

Evidence-based decision-making: Why is it so difficult?

Challenges for institutions in pricing and reimbursement

→ Even when evidence is favourable, a medicine might not be reimbursed, or access might be restricted due to funding challenges

→ Even when evidence is favourable, it is difficult to stop funding a treatment or medicine because patients, doctors and others do not like change

Can lead to **implicit or arbitrary forms of rationing or access restrictions**, which can have negative consequences on health equity



— Outlook and network events

Thank you to our colleagues
at **Wigev (Vienna
Healthcare Group)** for
hosting the next meeting!

In-person network meeting in Vienna on 15 September 2025

PPRI@20 anniversary meeting and celebration in Vienna on 16 September 2025