

The patient perspective on the new EU HTA Regulation

CDDF webinar, 28 September

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The importance of HTA for patients

1. Patients are the **ultimate users** of health technologies
2. Decisions taken on the availability and reimbursement of technologies have **an impact on access to quality healthcare**
3. HTA can prevent the funding of **technologies with limited or no added value**

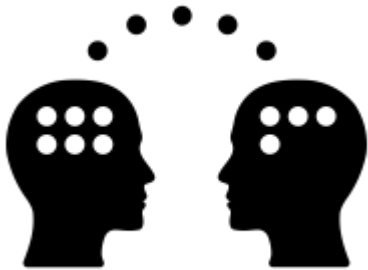


Patient involvement in HTA

Nothing about us without us



- Democratisation of the decision-making process



- Experiential knowledge of living with a chronic or lifelong condition



- Contribution to robust evidence to support informed decision-making

Patient involvement in HTA at national level

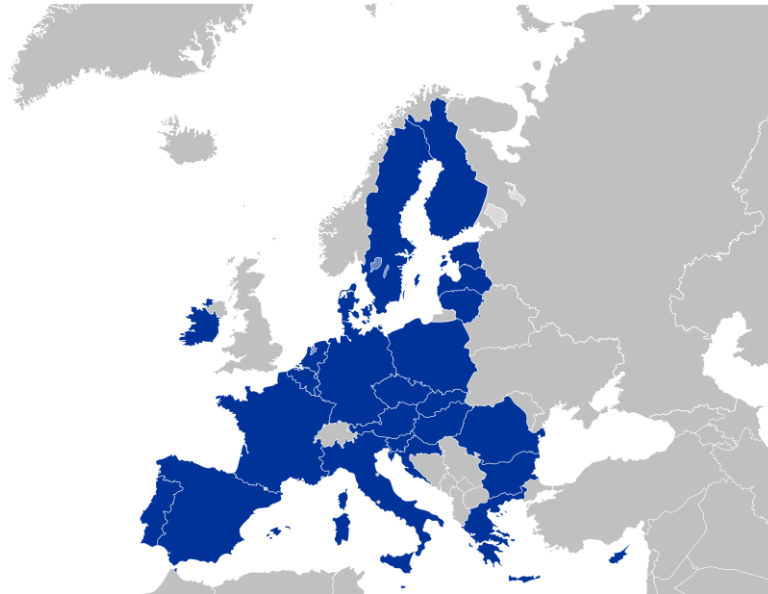
- 27 different processes leading to disparities
- Uneven involvement of patients

**Health
Technology
Assessment
(HTA)**



Patient involvement in HTA at EU level

- 2006-2023: **European Network for Health and Technology (EUnetHTA)** and the Stakeholder Forum
- 2021: **EU HTA Regulation** with mandatory patient involvement



The HTA Regulation & patient involvement



- Patient experts in:
 - Joint Clinical Assessment
 - Joint Scientific Consultation
- Patient representatives in the HTA Stakeholder Network

But who, what, when, where and how?

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EUnetHTA 21 deliverable & patient involvement



eunetha

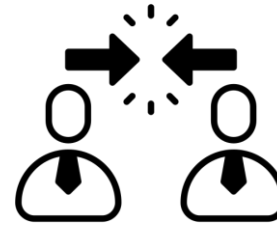
Stage	Individual patients	Patient organisations
Joint Scientific Consultation	Input	
Scoping	Input	Input
Joint Clinical Assessment	Input	Input
Appraisal process at national level	If relevant in national legislation	If relevant in national legislation
Emerging technologies		Through the Stakeholder Network and for those outside, only if requested by the Coordination Group
Annual Work Programme		Through the Stakeholder Network

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Involvement of patient expert

Challenges

- Lack of profiles
- Lack of clarity on conflict of interest criteria
- Unavailability of relevant profiles
- Timely involvement



Enablers

- Clarifying the concept of expert patient
- Anticipate the search for relevant expert patients
- Constructive interpretation of conflict of interest criteria (as is done at the EMA)
- Involve POs constructively in identifying potential profiles.

Involvement of patient organisations

Challenges

- Lack of clarity on conflict of interest criteria
- No mention of financial support for POs
- The role of national POs still needs to be clarified



Enablers

- Predictability of PO involvement
- Clearly define conflict of interest criteria
- Clarify the governance framework to represent the voice of national POs
- Recognise the capacities required by POs



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What is EPF doing to prepare the patient community?

- Advocacy activities
- Representatives in the EU HTA Stakeholder Network
- European Capacity Building for Patients (EUCAPA) project



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