



Council of the European Union
General Secretariat

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Brussels, 29 January 2019

WK 1315/2019 INIT

LIMITE

**PHARM
SAN
MI
COMPET
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CODEC**

WORKING PAPER

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WORKING DOCUMENT

From: General Secretariat of the Council
To: Working Party on Pharmaceuticals and Medical Devices (HTA)

N° Cion doc.: 5844/18 PHARM 6 SAN 49 MI 61 COMPET 53 IA 43 CODEC 133 + ADD 1 +
ADD 2 + ADD3 + COR 1

Subject: Working Party on Pharmaceuticals and Medical devices on 28 January 2019
- Presentation on Stakeholder Network, IT Platform and Stakeholder Pool

Delegations will find attached the presentation given on the topics mentioned above at the meeting of the Working Party on 28 January 2019.

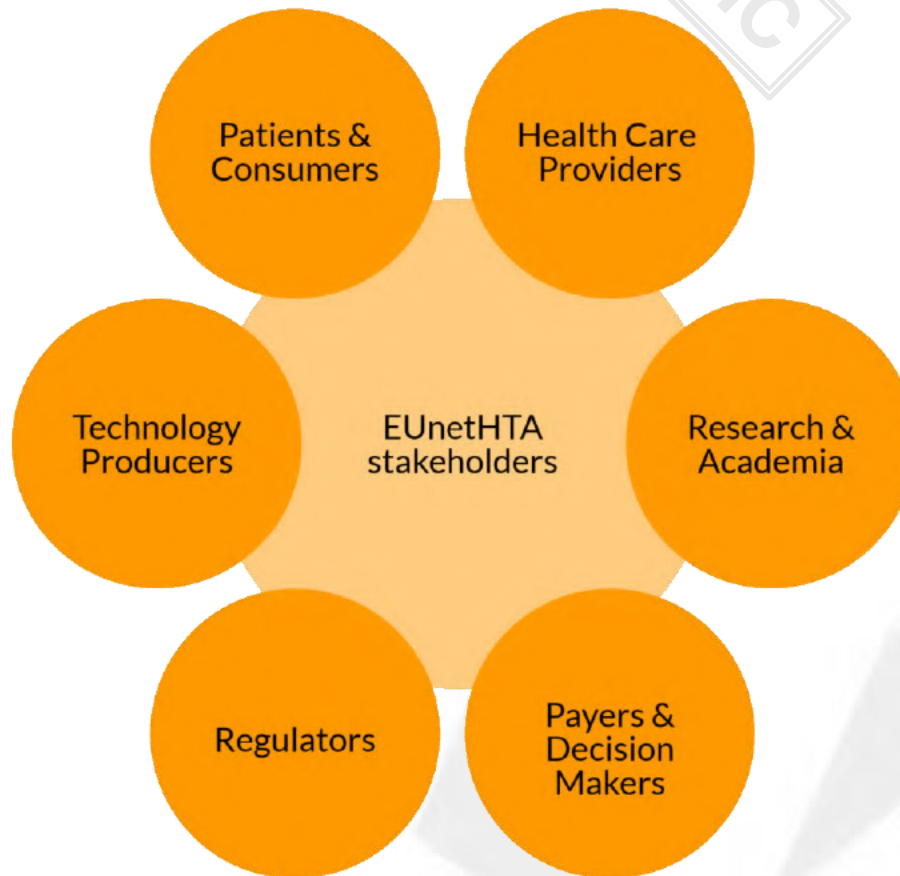
PUBLIC

EUnetHTA

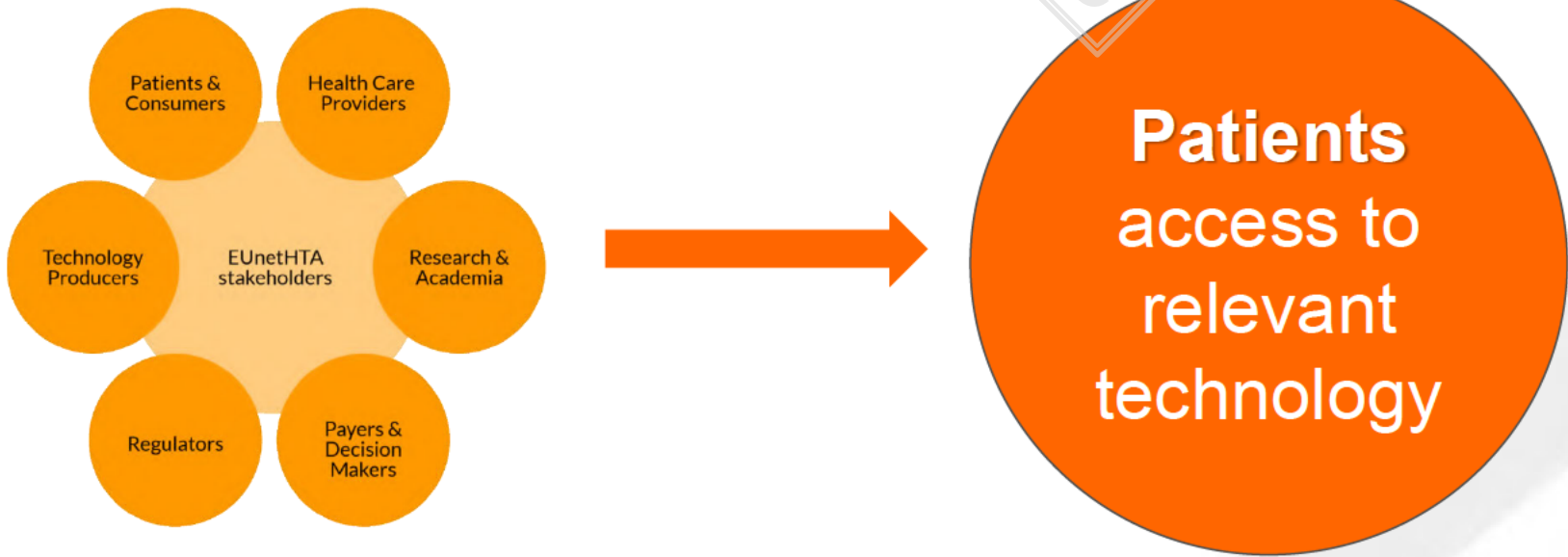
Stakeholder Network

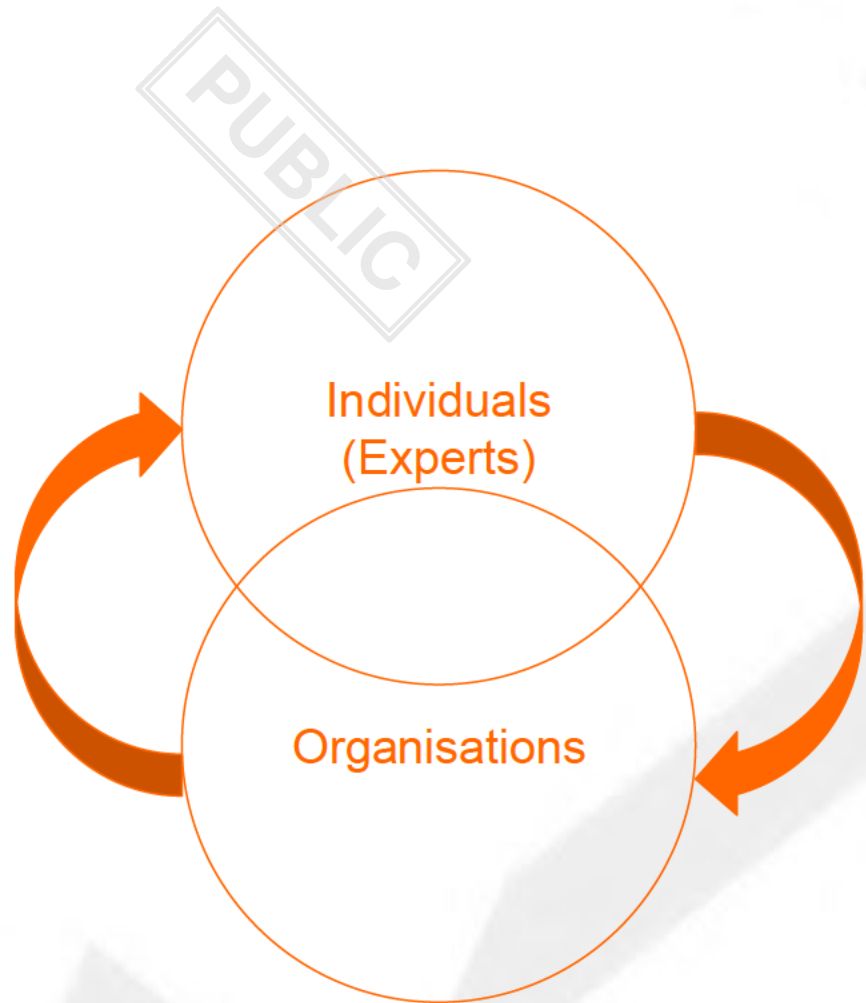
, Chief Operations Officer, EUnetHTA.

EUnetHTA “Stakeholder Family”

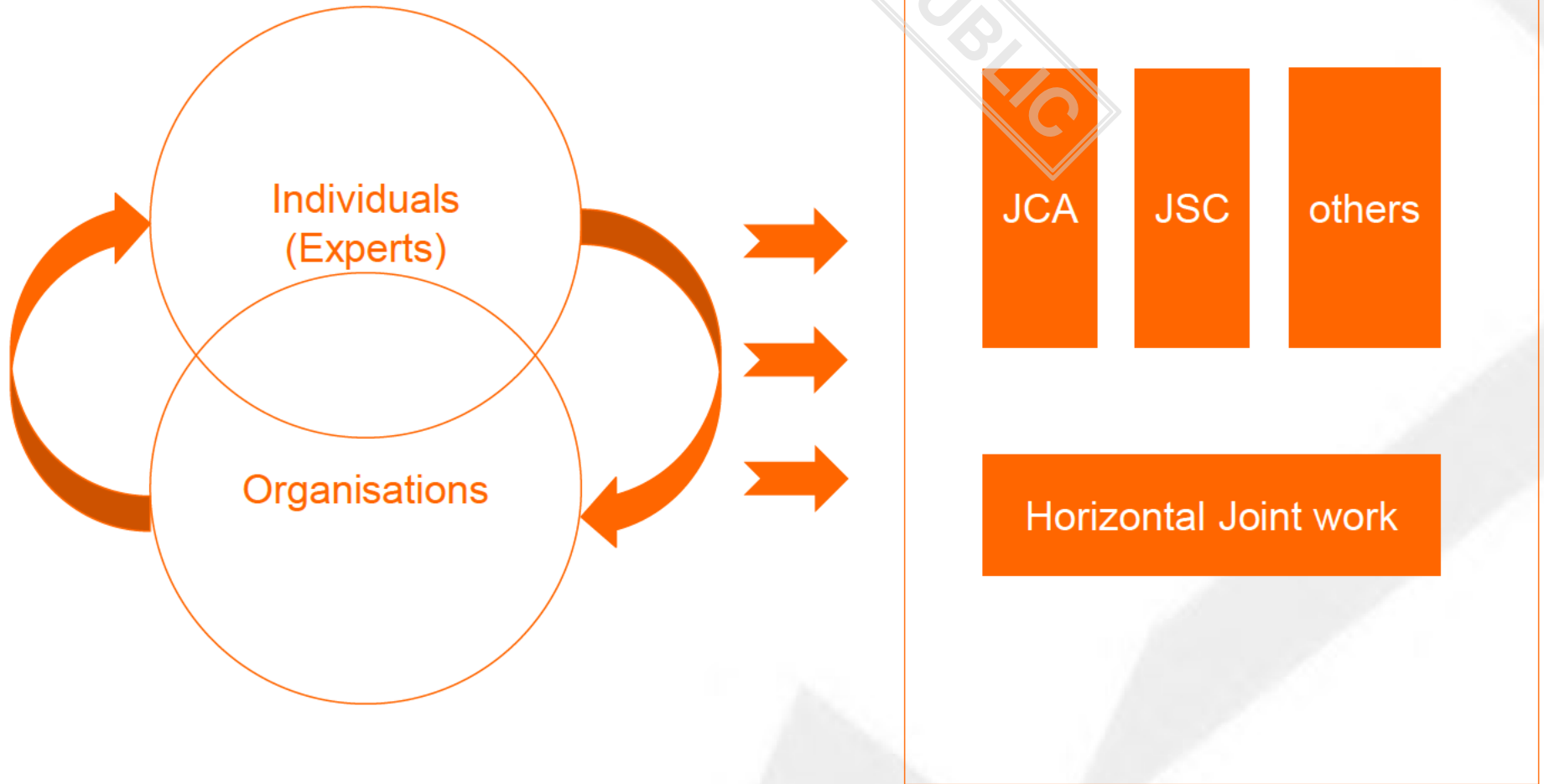


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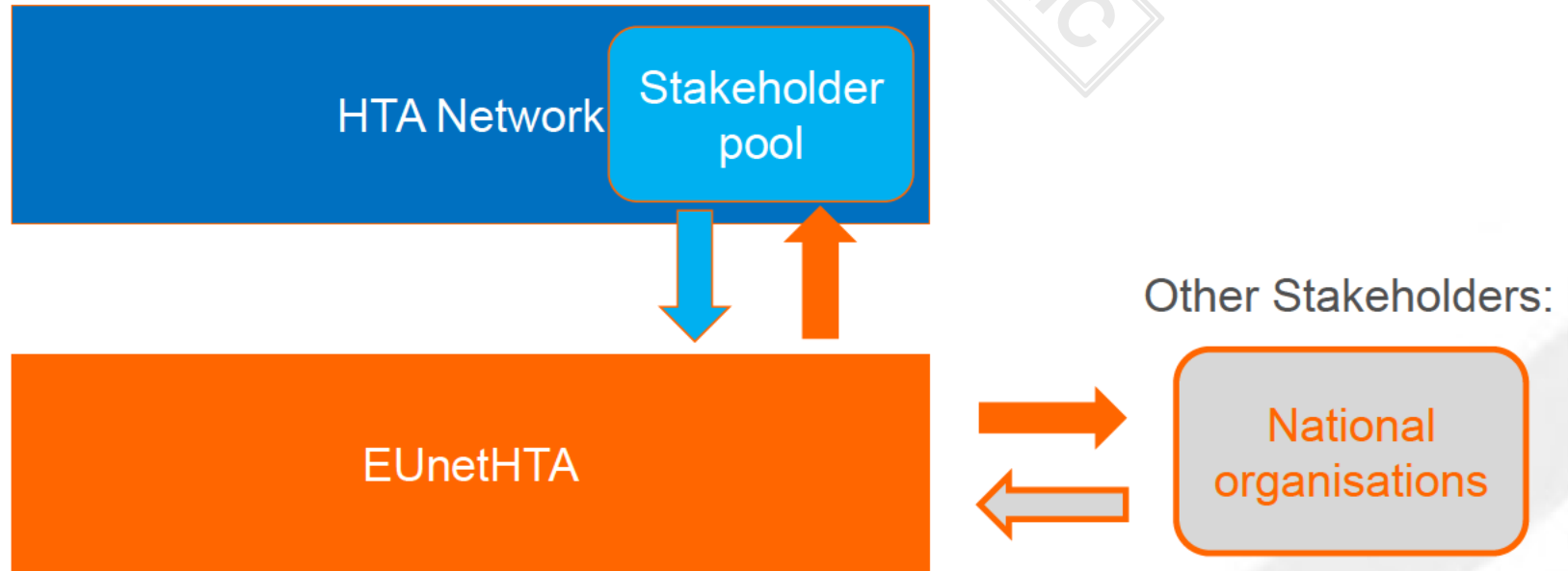




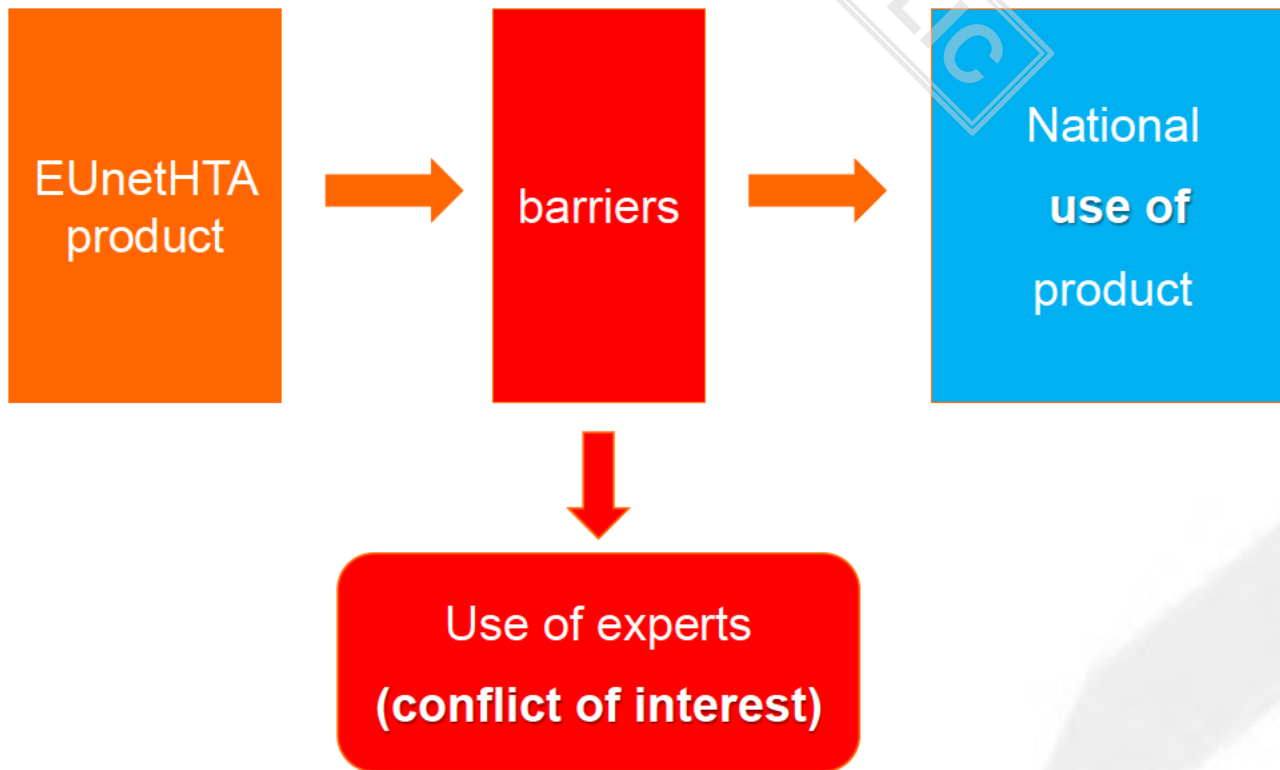
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Stakeholder Management during EUnetHTA JA3



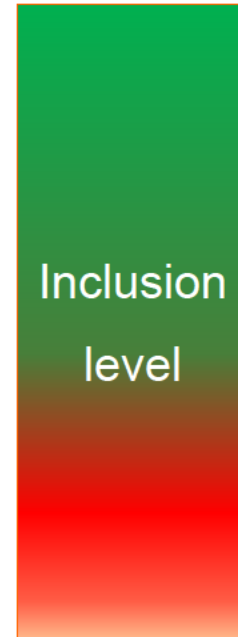
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per
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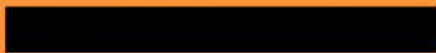
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EUnetHTA

IT Platform



Functionalities

Communication
/ Information

Collaboration

Data availability

Training

Data availability

JCA

JSC

Planned and
Ongoing Projects
(POP)

EVIDENT
(additional data
collection)

Experts database

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Principles

Compliance

Security

accessibility

sustainability

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Security

- Secure data exchange platform
- Room based access rights
- External validation / re-validation
- Activity monitoring
- Additional security features

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Thank you.





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HTA Network Stakeholder Pool History



Stakeholders' involvement - process

- **EUnetHTA Stakeholders' Forum (JA2-JA3)**
- Discussion and decision on stakeholders' involvement to the HTA Network: **8 stakeholders representatives** (May 2016)
- HTA Network new Rules of procedure adopted (Nov.2016)
- **Call of expression of interest** to establish HTA Network Stakeholder Pool launched (December 2016)
- Applications analysed (February 2017)
- Stakeholder Pool: 8 nominations (2 per each of the 4 Groups)
- **Vote** from the **HTA Network (March 2017)**
- **Update of the** Stakeholder Pool (during 2018)
- **Publication of a new Stakeholder Pool list** (November 2018)

Stakeholders' involvement - criteria

A. Eligibility criteria

Organisations representing interests of the following four groups: (1) patients/consumers' organisations, (2) healthcare providers, (3) payers, (4) industry and fulfilling all of the following criteria shall be eligible for the Pool:

- a legal entity (public organisation, foundation, association, etc.) representing the interests, at European level ('umbrella organisation'), of bodies involved in the production or use of health technologies, health services, health insurances (public/private), health care providers or health technology assessments;
- disclosing its membership and sources of funding on its own website;
- organisations applying must be registered in the [Transparency Register](#) before applying.

Membership of the Pool is organisation-based. Umbrella organisations that operate at the European level shall be given priority. International organisations and national or regional organisations are also eligible candidates, particularly in fields where European level organisations are few or do not exist.

B. Added value criteria

The EU services shall take the following criteria into account when assessing applications:

- demonstrated current or planned engagement in HTA development (activity reports, work plans, position papers, active working groups, EU-funded actions);
- professional expertise relevant to the aims of the Pool at EU level;
- geographical coverage of several MS, with preference for a balanced coverage;
- communication / dissemination capabilities.

These four groups were defined in the first EUnetHTA Joint Action "[Stakeholders' Involvement Policy](#)" [document](#) The group of health providers includes: health professionals and scientific community.

HTA Network Stakeholder Pool

**33 organisations selected
based on the Call's eligibility/added value criteria**

(e.g.: legal entity representing the interests at EU level of bodies involved in HTA; disclosed membership, demonstrated current or planned engagement in HTA)

https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/stakeholderpoolist_en.pdf

HTA Network Stakeholder Pool

Patients/Consumers:

Bureau européen des unions de consommateurs (BEUC)
European Cancer Patient Coalition (ECPC)
European Federation of Allergy and Airways Diseases Patients' Association (EFA)
European Institute of Women's Health (EIWH)
European Patients' Forum (EPF)
European Public Health Alliance (EPHA)
European Organisation for Rare Diseases (EURORDIS)
Health Action International (HAI)
International Diabetes Federation European Region (IDF)

Health providers:

Council of European Dentists (CED)
European Association of Hospital Pharmacists (EAHP)
European Forum for Primary Care (EFPC)
European Hospital and healthcare Federation (HOPE)
European Organization for Research and Treatment of Cancer (EORTC)
European Public Health Association (EUPHA)
European Society of Cardiology (ESC)
European Society of Medical Oncology (ESMO)
European Union of General Practitioners/ Family Physicians (UEMO)
Pharmaceutical Group of the European Union (PGEU)
Standing Committee of European Doctors (CPME)

Payers:

Association Internationale de la Mutualité (AIM)
European Social Insurance Platform (ESIP)

Industry:

Association of the European Self-Medication Industry (AESGP)
European Association for Bioindustries (EuropaBio)
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
Medicines for Europe
MedPharmPlast Europe (MPPE)
Medtech Europe (MTE)
Plasma Protein Therapeutics Association Europe (PPTA Europe)
The Alliance for Regenerative Medicine (ARM)

HTA Network Stakeholder Pool Objectives:

- to contribute to the policy development related to HTA at EU level,
- to ensure that the views of different stakeholders are reflected in the policy development in a balanced way,
- to create synergies between different stakeholders.