



Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

DG SANTE - Health Systems and Products
Medical Products: safety, quality, innovation

Outline

- **HTA Network Stakeholder Pool - background**
- **EU Cooperation on HTA - State of play**
- **HTA Legal Proposal - update**

Stakeholders' involvement – HTA Network

- HTA Network included stakeholders as observers (2013) – 4 representatives
- EUnetHTA JA2 – Stakeholder pool (biannual meetings)
- EUnetHTA JA3 – EUnetHTA Forum (2017-2018)
- HTA Network stakeholder Pool –set up (2017)
 - **Call of expression of interest to establish HTA Network Stakeholder Pool launched (December 2016)**
 - **Applications analysed (February 2017)**
- Stakeholders' involvement to the HTA Network: New RoP and from **4 to 8 stakeholders representatives** (2016-2017)
- **Update of the Stakeholder Pool** (during 2018)
- **Publication of a new Stakeholder Pool list** (November 2018)

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/stakeholderpoollist_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 Womens 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 Organisation for Research and Treatment of Cancer (EORTC) – NEW
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)

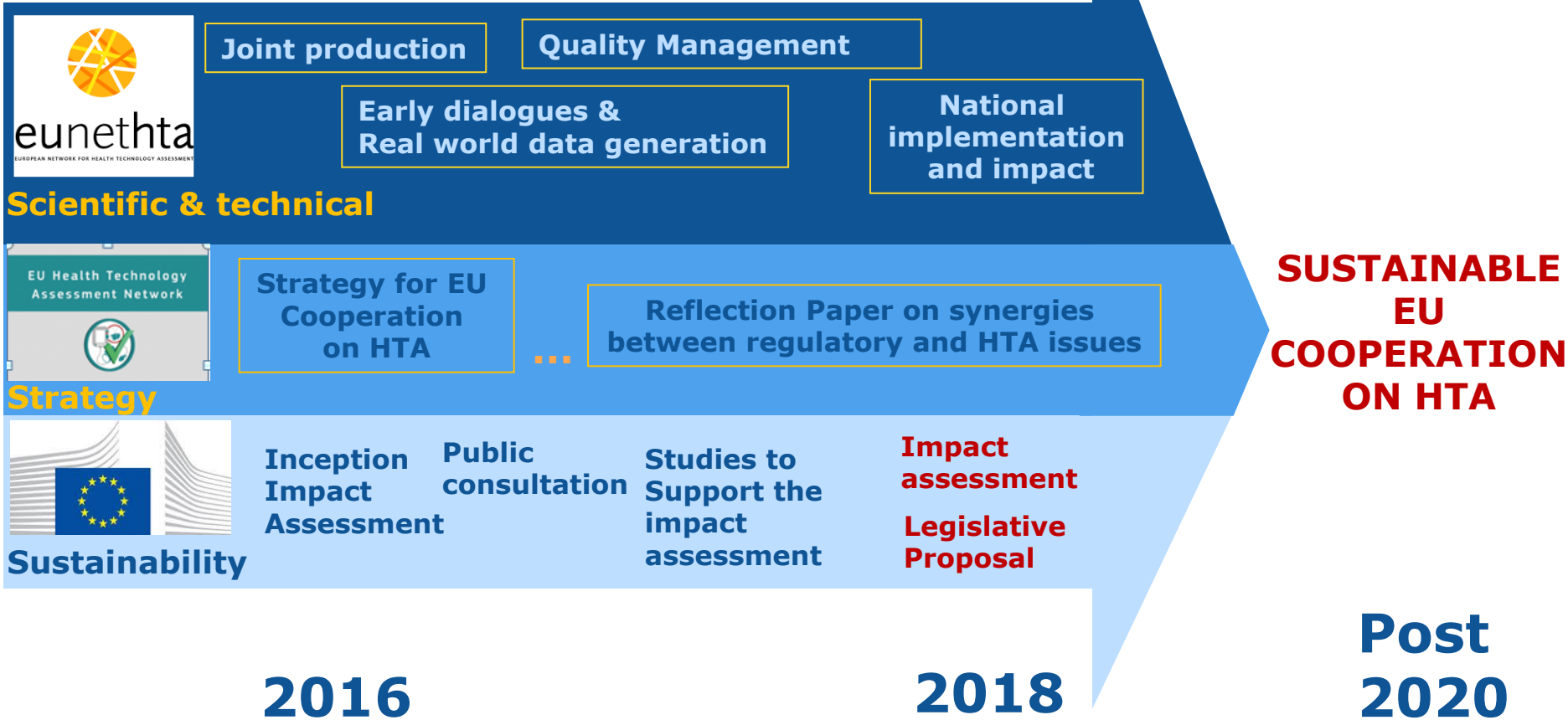
Industry:

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) -NEW

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.

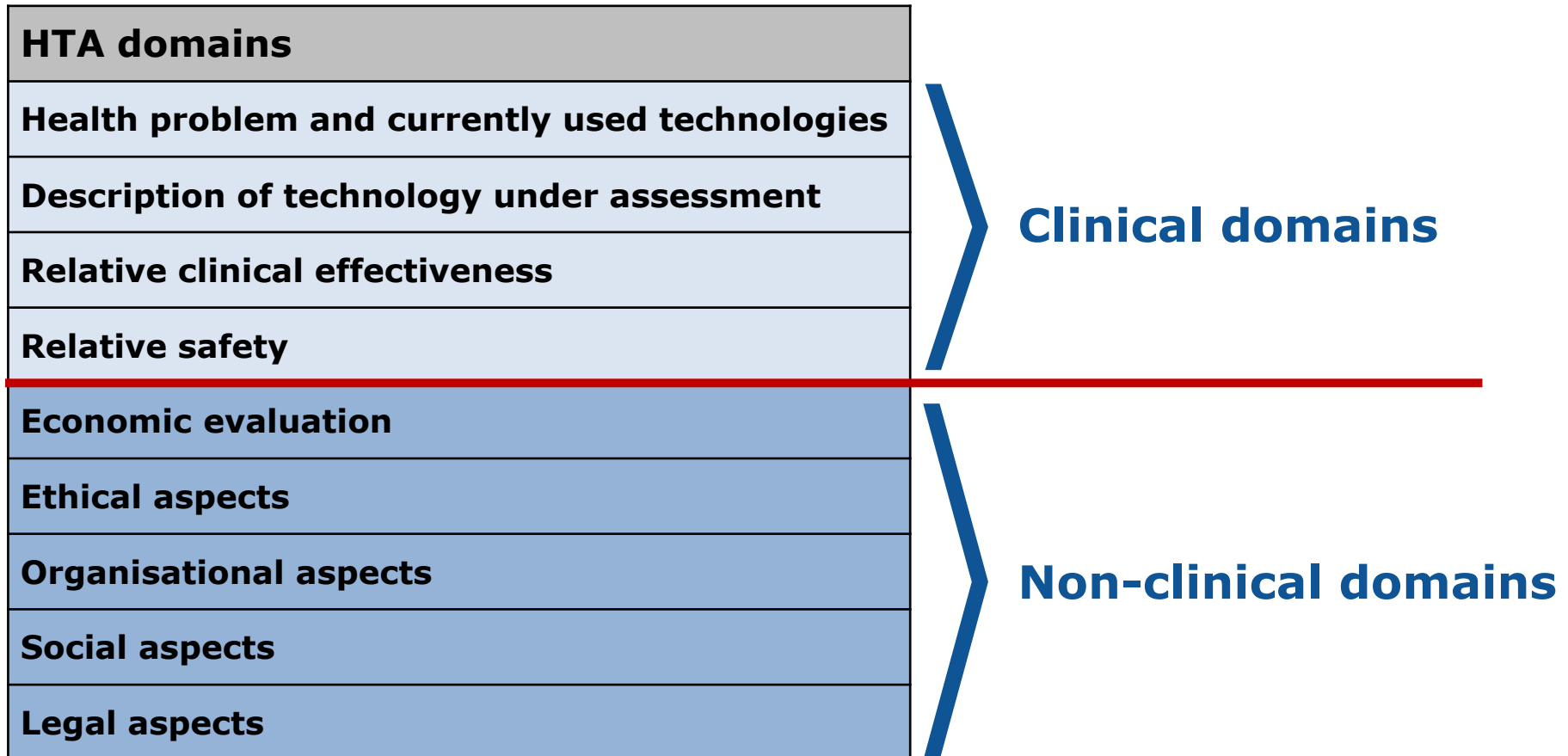
EU cooperation HTA STATE OF PLAY



What is Health Technology Assessment?

- **"Health technology"** comprises:
 - medicines,
 - medical devices,
 - in vitro diagnostics devices,
 - medical and surgical procedures, measures for disease prevention, vaccination, treatments - used in healthcare.
- **HTA an evidence-based process that assesses the added value (relative effectiveness)** of a given health technology/health interventions and compares it with other health technologies and / or the current standard of care.
- **HTA can cover different aspects:** from clinical domains (e.g. safety, clinical effectiveness) to non-clinical domains (e.g. economic, ethical, organisational).

Health Technology Assessment (HTA)



Why an HTA initiative?

More than 25 years of cooperation: joint actions, projects



ACHIEVEMENTS

- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP/EVIDENT databases, methodological guidelines)
- Piloting **joint work** (e.g. early dialogues, joint assessments)



LIMITATIONS

- **Low uptake of joint work** ⇒ duplication of work
- **Differences** in national **legal/procedural HTA frameworks** and administrative capacities of Member States
- **No sustainability** of current cooperation model

Expected outcomes

Member States

- **Pooling of resources** and **expertise**
- **High quality** and timely **reports**
- **Support** MS in **evidence-based decision-making**
- Contribution to sustainability of health systems

Patients

- Increased **transparency**
- Increased **engagement** in the HTA process
- Contribution to **improved access** to technologies with benefits for patients

Industry

- Positive impact on **business predictability** (innovation investments)
- Increased **efficiency** of evidence generation and submission (reduced duplication)

Key elements (1)

- **Provides support framework** and procedures for EU cooperation on HTA
- **Well defined scope** Article 5
- Focus on **clinical** aspects
- **Member States** driven approach Articles 3-7,13
- **High quality** – Member States experts
- **Timely output** Recitals 17-18
- **Transparency and independence** Article 22.1.
- Pragmatic **phase-in** approach Articles 33, 36

Key elements (2)

- Enable **synergies** between regulatory and HTA issues

Articles
11, 16

- **Defined areas of join work:**

- Joint clinical assessments/JCA (REA)
- Joint scientific consultations/JSC (early dialogues)
- Horizon scanning/Emerging health technologies
- Voluntary cooperation

Articles
5-11

Articles
12-17

Article 18

Article 19

Member State-driven approach

Articles 3-4

HTA Coordination Group (CG)

Joint work carried out by MS experts

CG Sub-groups

Joint clinical assessments (JCA)

JCA reports

MP

MD

Joint scientific consultations (JSC)

JSC reports

MP

MD

Identification of emerging health technologies

Input for annual work programme

MP

MD

Voluntary Cooperation

Collaborative assessments / non-clinical domains

Article 26

Stakeholder Network

Preparation of the annual work programme/annual reports, updates of the common requirements and guidance documents

EC Secretariat

Administrative support
(e.g. meetings, planning)

Scientific/technical support
(e.g. scientific secretariat to rapporteurs, quality management)

IT support
(submission system, databases, intranet)

Facilitate cooperation with EMA and other Union bodies



Involvement of patients and clinical experts – EC Proposal

- **Joint Clinical Assessments**

The designated sub-group shall ensure that stakeholders, including **patients and clinical experts**, are given an **opportunity to provide comments** during the preparation of the draft joint clinical assessment report

- **Joint Scientific Consultation**

The designated sub-group shall ensure that stakeholders, including **patients and clinical experts** are given an opportunity to provide comments during the preparation of the draft joint scientific consultation report

- Consultation of patients and clinical experts in clinical assessments carried out by Member States

The Commission shall adopt **implementing acts** concerning **procedural rules** for the consultation of patients, clinical experts and other stakeholders

Stakeholder Network – EC Proposal

- Established by the Commission through an **open call for applications** and a selection procedure (list of included stakeholder organisations is published)
- **Meetings** between **Stakeholder Network** and **Coordination Group** (updates and information exchange)
- **Support Coordination Group** in the **identification of patient and clinical expertise** for the work of its subgroups



Stakeholder Involvement

Ongoing discussion

- **Shared Objective :**

Involving stakeholders EU HTA cooperation - welcomed and acknowledged

- Involvement of stakeholders experts in products specific output
- Involvement of stakeholders representatives in overall/general output

- **Challenge :**

How to combine inclusiveness , high quality with timeliness and resources availability



Thank you

Contact: SANTE-HTA@ec.europa.eu

Parallel session rooms – 13.30-15.00

Group A - *Patient and Health Care Professional Experts Involvement Room* - **AB-3.04 -3rd Floor**

Group B PHARMA - *Identification and Prioritisation of Health Technologies for Joint Work* - **Room AB-4B – plenary room**

Group B MEDTECH - *Identification and Prioritisation of Health Technologies for Joint Work* - **Room AB-4B – plenary room**