REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

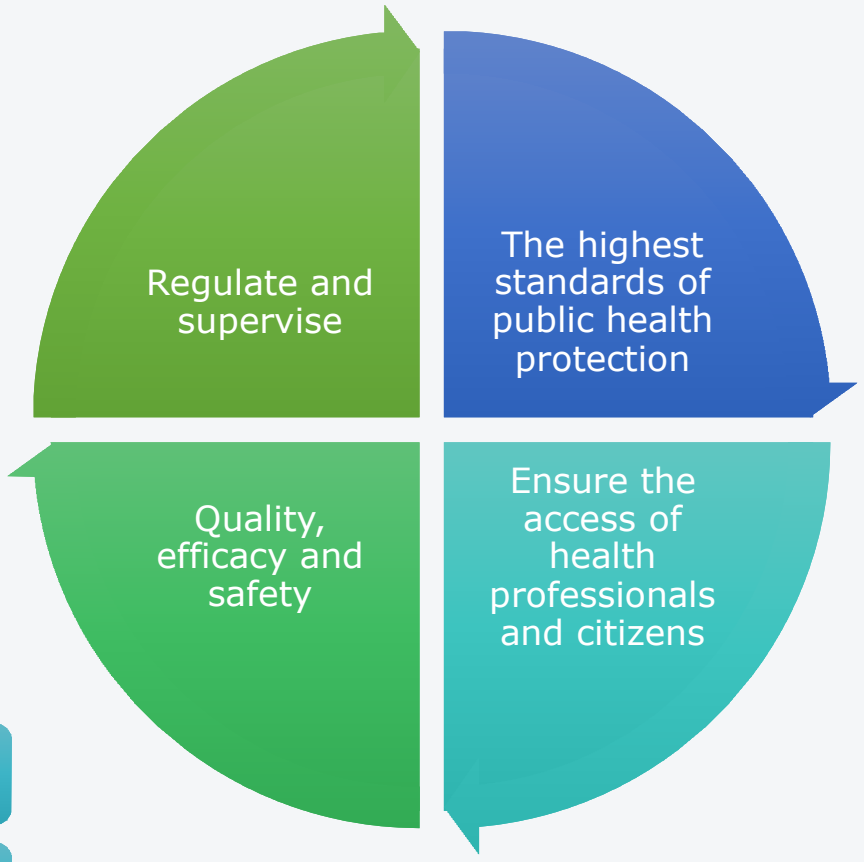
11th International Pharmaceutical Compliance and Medical Device Congress
May 15 - 17, 2017 Lisbon, Portugal

Welcome by INFARMED
The Portuguese National Authority of Medicines and Health Products

Rui Santos Ivo
Vice-President, Executive Board
National Authority of Medicines and Health Products (INFARMED)
Member of the Executive Board of EUnetHTA

About Infarmed

Mission and Areas of Activity



- **Human Medicines**
- **Medical Devices**
- **Cosmetics**
- **Evaluation, Authorisation**
- **Licensing**
- **Inspection**
- **HTA Pricing & Reimbursement**
- **Pharmacovigilance**
- **Supervision and Control**
- **Market Monitoring**

About Infarmed

Vision

To be a model of excellence in the provision of a quality public service…

… and a reference agency in the European Union…

…valuing its employees.

About Infarmed

Strategic Objectives

Sustainability of the Healthcare System

Market Surveillance and Risk Management

Development of Pharmaceutical and Health Products Sectors

Communication Strengthening

Continuous Improvement and Internal Efficiency

Strengthen the Positioning in the International Context

Congress topics

»» anti-corruption/anti-bribery compliance programmes

»» data privacy

»» new marketplace

»» transparency

»»next generation of ethics and compliance programmes

… focus on:

- *company compliance professionals*
- *regulators*
- *Lawyers*
- *consultants working in this interesting and expanding field*

National and EU trends

- PT: Transparency Platform since 2013, reviewed in 2017
- Specific rules applying to Portuguese National Health Service
  - Involving all parties, particularly *Ordens Profissionais*
- Key issues on health systems sustainability under discussion at EU level
- Transparency objectives at EU level
  - Council Conclusions – June 2016
  - Round Tables in The Hague, Lisbon and La Valletta: ongoing discussions between Ministers of Health and Pharmaceutical Industry
  - Multilateral initiatives at EU level
    - E.g. Declaration of La Valletta – 10 countries cooperating

The EUNetHTA project: the added value of collaboration on HTA in Europe

EUnetHTA JA3 one year later

Rui Santos Ivo
Vice-President of the Executive Board of INFARMED
Member, Executive Board of EUnetHTA

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eunethta

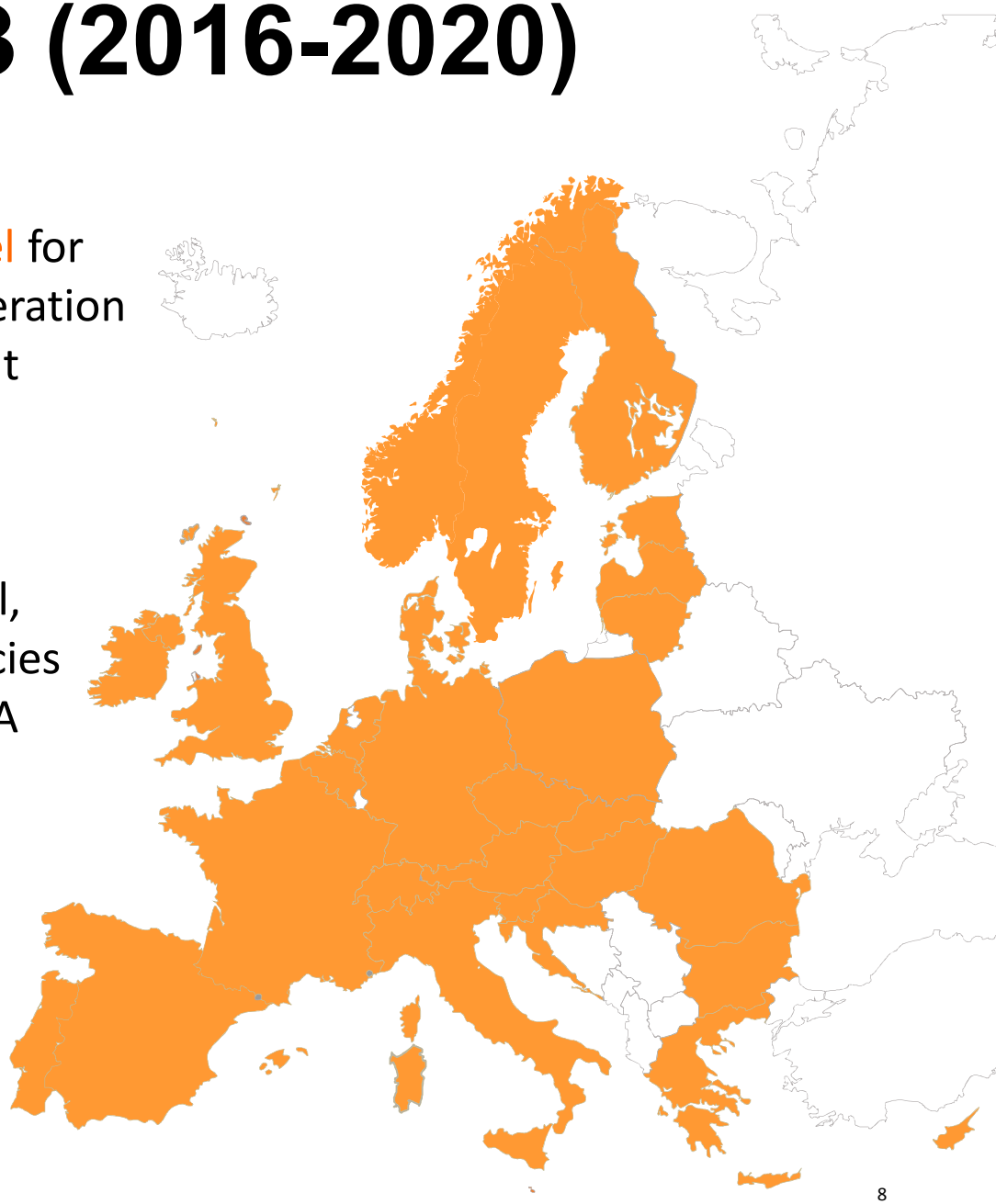
European Commission

EUnetHTA JA3 (2016-2020)

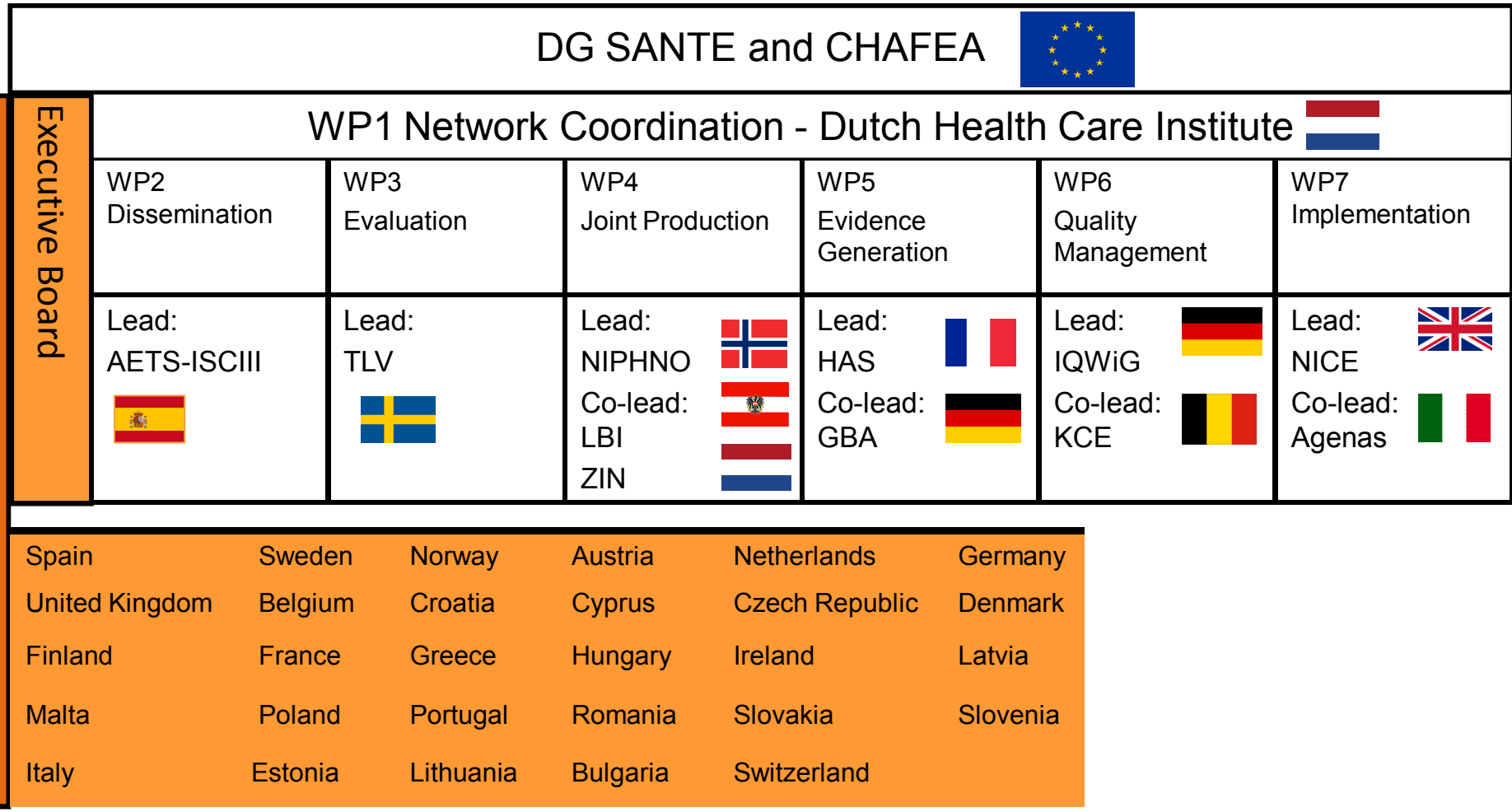
Aims to build a sustainable model for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe

80 partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

Project Coordinator:
Dutch National Health Care Institute (ZIN)



Organisational and Governance Structure



Specific Objectives

- To increase production of high quality HTA joint work
- To increase uptake and implementation of joint HTA work at the national, regional and local level
- To support evidence-based, sustainable and equitable choices in healthcare and health technologies

EU cooperation on HTA

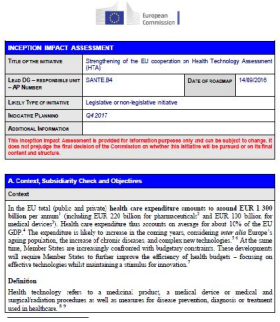
HTA Network

- **Policy and strategic cooperation**
- Art 15 Directive 2011/24
- Set up October 2013
- Multiannual work programme
- **Permanent**

Synergy and complementarity

EUnetHTA Joint Action

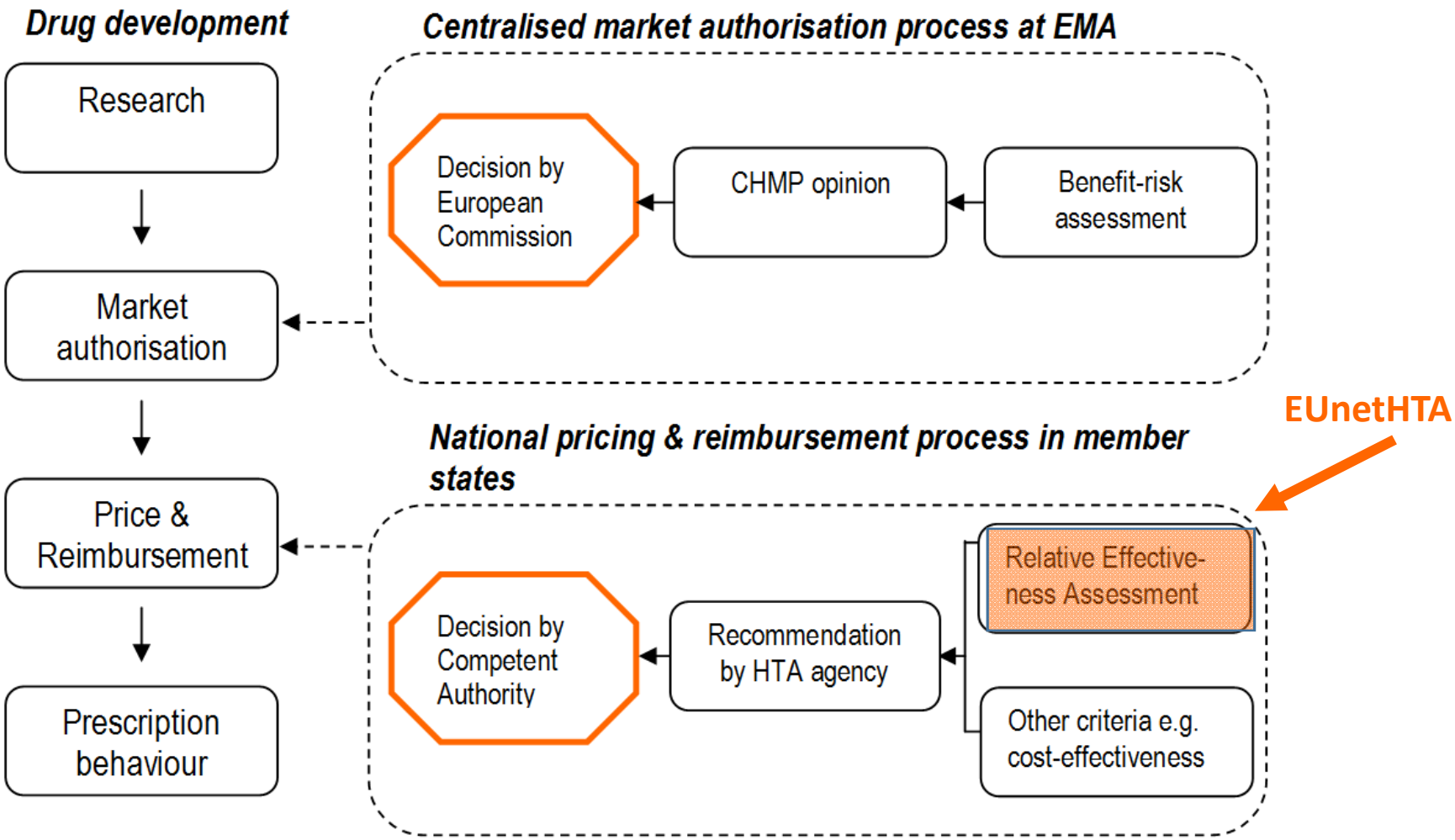
- **Scientific and technical cooperation**
- Started in the 1990's, later EUnetHTA
- Now Joint Action 3 – **2016 – 2020**



New HTA Initiative

- **Cooperation beyond 2020**
- Inception Impact Assessment
- Description of the status quo
- Options for the future

Market Access to Medicines in Europe



Key Benefits of Collaboration on REA

- **Efficiency**
  - Efficient collaboration and reduce duplications
- **Quality**
  - Guidelines and core model
- **Consistency**
  - Reliable and predicable outcomes
- **Timeliness**
  - Earlier access if added value (and value for money) is proven

Summary of select activities in JA3

WP4 Joint Production

- To produce **43** rapid REA on other technologies and **37** on pharmaceuticals
- To provide a system for topic selection and prioritization

WP5 Evidence Generation – life cycle approach

- To conduct Early Dialogues (joint HTA or parallel/joint with regulators)
- To link additional data collection to on-going activities

WP6 Quality Management, scientific guidance and tools

- To provide quality management for EUnetHTA joint products
- To further develop methodologies and tools for joint work if necessary

WP7 National implementation and impact

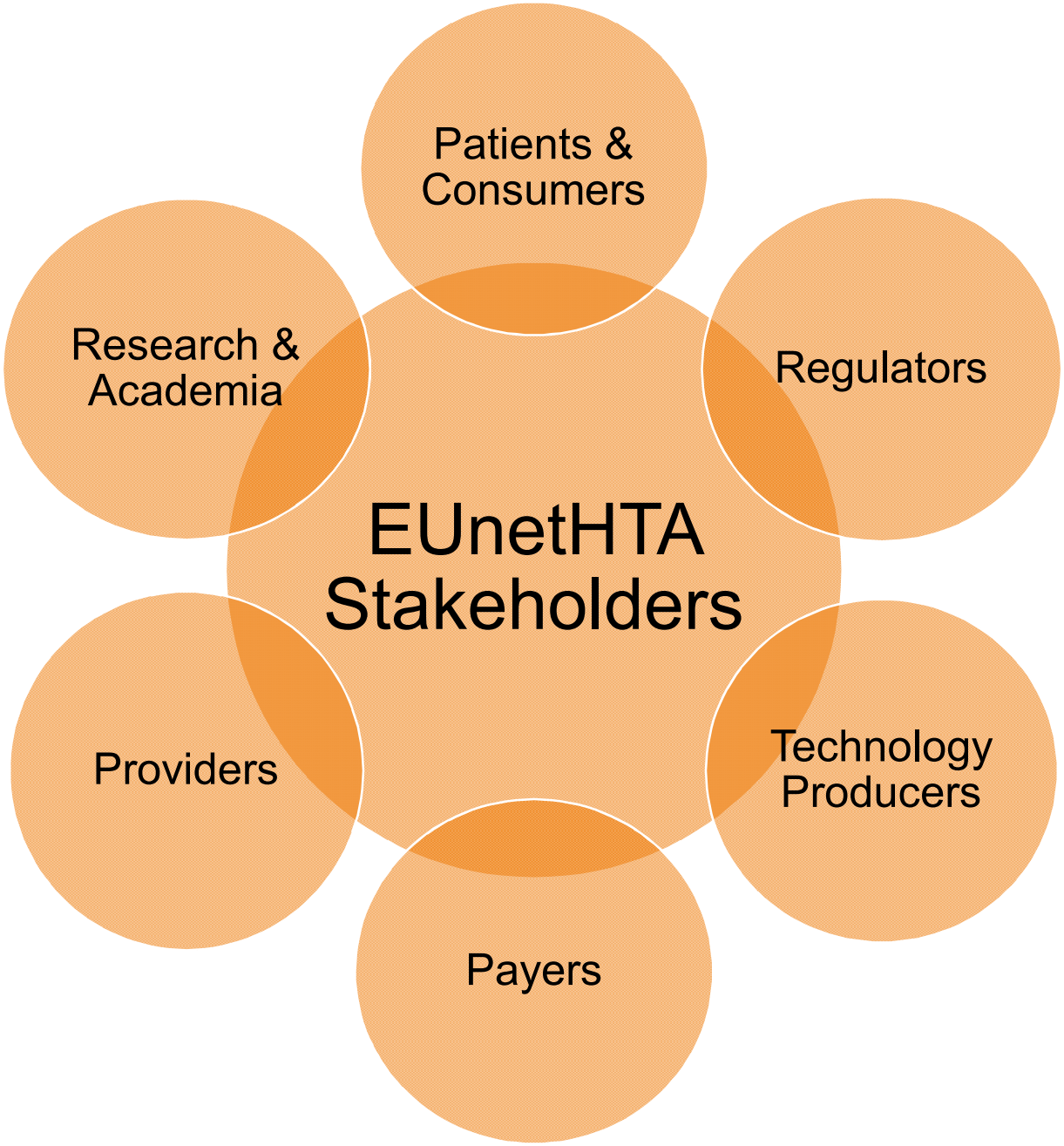
- To facilitate the uptake of joint products at the national/local level
- To measure the impact of joint work in collaboration with other work packages

Achievements EunetHTA

- Tools
  - –HTA Core model (full model and rapid REA)
  - –EUnetHTA Planned and Ongoing Projects (POP) database
  - –EVIDENT database
  - –Evidence submission templates
- •Methodology
  - –Guidelines for REA
  - –Handbook for full HTA

Achievements EunetHTA

- Products
- –Early dialogues (EUnetHTA and SEED, medical devices and pharmaceuticals)
- –Rapid REAs (pharmaceuticals, medical devices, surgical procedures)
- –Full core HTA’s (different types of interventions)


Patients & Consumers
Research & Academia
Regulators
EUnetHTA Stakeholders
Providers
Technology Producers
Payers

Stakeholder involvement in JA3

- Political and strategical involvement is moved to HTA Network

- Scientific and operational involvement will receive more attention in JA3
  1. Participation in the EC/EUnetHTA Forum
     - October 21st (yearly interactions)

  2. Participation in Work Packages
     - Facilitation of the provision of specific subject-matter information/knowledge on specific technical questions
     - Public consultations on deliverables
     - Interaction on the level of specific activities like the Early dialogues (WP5) and Joint Assessments (WP4)
     - Interaction on the level of methodologies, guidelines and procedures (WP6)

Practical examples of involvement

- Technology producers
  - Meeting with EFPIA on Joint Assessments (June 2016), EFPIA HTA WG, national associations
  - Meetings with individual pharma companies on pilots
  - Participation in meetings with medtech industry

- Patients organisations
  - See next slides

- Regulators
  - Half yearly meetings EMA-EUnetHTA
  - Development working plan for collaboration

- Health care providers
  - Meeting with ECCO, February 2017

- Relevant research activities
  - Meeting with IMI on involvement in IMI projects

Patient Involvement in JA3

- Meeting on March 8th
- WP4 (LP and Co-LPs); WP5 (LP); WP6 (Co-LP)

- Patient & Consumer Organisations
  - BEUC
  - EURORDIS
  - European Multiple Sclerosis Platform
  - European Patients' Forum
  - European Cancer Patient Coalition
  - IAPO (invited, did not attend)

- EUnetHTA Directorate
- DG SANTE

Views from WPs on Involving Patients

- WP4
  - Examples from on-going assessments were shared
  - Working group to be established & there will be consultation with patient & consumer orgs

- WP5
  - Build on experience with SEED (Shaping European Early Dialogues for health technologies)
  - Work with patient & consumer orgs to define possible approaches
  - Explore feasibility of leveraging tools available at EMA

- WP6
  - Build on experience from JA2

First joint REA of Pharmaceuticals 2017

1. midostaurin for acute myeloid leukemia (Novartis), authors are FIMEA (Finland) and NOMA (Norway). Started 2016 Q4

2. regofarenib for hepatocellular carcinoma (Bayer), authors are HAS (France) and IMFARMED (Portugal). Started 2017 Q1

But also:

- Collaborative assessments (decentralized assessments)
- Using the EUnetHTA REA core format to generate regional and national REA reports

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Trends

- EUnetHTA JA3 is progressing
  - Final signature agreement late; end of September 2016
  - Resource issues at the level of coordinator and some LPs
  - Complex because high number of (new) partners

- Link of EUnetHTA JA3 to Commission activities on post-2020 scenarios is crucial
  - Involvement of ExBoard EUnetHTA in the discussion on the post-2020 scenarios
  - Members of the ExBoard EUnetHTA JA3 involved as experts in the different studies by the Commission for the post2020 scenarios
  - First results from EUnetHTA JA3 are input for the Commission activities

Major Achievements (EUnetHTA JA1 and JA2)

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

Shortcomings of current EU cooperation on HTA

- **Low uptake of joint work** ⇒ duplication of work by HTA bodies and industry
- Differences in the **procedural framework** and administrative capacities of Member States
- Differences in national **methodologies**
- **No sustainability** of current cooperation model

Recommendation oncology drugs (MA 2011-2013) per country

Abbreviated indication	Brand name (generic)	HTA recommendation					
		GEMANY	THE NETHER-LANDS	FRANCE	ENGLAND/ WALES	SCOTLAND	POLAND
Bone metastases from solid tumours	1. Denosumab	Not assessed	Equal benefit	Added benefit Equal benefit	Positive	Not assessed	Negative
Breast cancer	2. Eribulin	Equal benefit Equal benefit	Added benefit	Added benefit	Negative	Negative	Negative
	3. Pertuzumab	Added benefit	Not assessed	Added benefit	Not assessed	Negative	Positive
Colorectal cancer	4. Aflibercept	Added benefit	Not assessed	Equal benefit	Negative	Negative	Positive
Gastric cancer	5. Tegafur / gimeracil / oteracil	Not assessed	Lesser benefit	Lesser benefit	Not assessed	Positive	Negative
Melanoma	6. Ipilimumab	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	7. Vemurafenib	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	8. Dabrafenib	Equal benefit	Not assessed	Equal benefit	Positive	Positive	Positive
Non-small-cell lung cancer	9. Afatinib	Added benefit Added benefit Equal benefit Lesser benefit	Not assessed	Equal benefit	Positive	Positive	Positive
	10. Crizotinib	Equal benefit	Not assessed	Added benefit	Negative	Negative	Negative
Prostate cancer	11. Cabazitaxel	Added benefit Added benefit	Added benefit	Added benefit	Negative	Negative	Negative
	12. Enzalutamide	Added benefit Added benefit	Not assessed	Added benefit	Positive	Positive	Positive
	13. Abiraterone	Added benefit	Equal benefit	Added benefit	Positive	Negative	Positive
Renal-cell carcinoma	14. Axitinib	Added benefit	Not assessed	Added benefit	Positive	Negative	Positive

Relative effectiveness assessments of oncology medicines for pricing and reimbursement decisions in European countries. Kleijnen S, Lipska I, Leonardo Alves T, Meijboom K, Elsada A, Vervölgyi V, D'Andon A, Timoney A, Leufkens HG, de Boer A, Goettsch WG. Ann Oncol (2016) 27 (9): 1768-1775.

Initiative on Strengthening EU cooperation on HTA

Inception Impact Assessment published on 15 September 2016

WHY?

- Support MS to ensure sustainability of healthcare
- Contribute to patient access to innovation
- Support innovation in EU

WHY NOW?

- Growing support to continue cooperation on HTA

  -Council Conclusions 2015, 2016

  -EP own initiative report 2016

  -HTA Network Strategy 2014
- No EU-funding mechanism foreseen beyond 2020

+ Addressing shortcomings

+ Responding to Member States needs

SUSTAINABLE COOPERATION BEYOND 2020 BASED ON THE SUCCESS OF THE CURRENT COOPERATION

Policy options

Inception impact assessment

Option 1	Option 2	Option 3	Option 4	Option 5
Status quo – **voluntary cooperation**	**Long-term voluntary cooperation** (beyond 2020)	Cooperation through the **collection, sharing and use of common tools and data**	Cooperation on **production of joint REA (relative effectiveness assessments) reports**	Cooperation on production of **joint Full HTA reports (REA+ Non-clinical: economic, ethical, legal, etc.)**
Non-legislative / *voluntary*		**Legislative / *voluntary* + *mandatory***		

+ Issues to be addressed

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Public consultation

- Launched: 21/10/2016
- Deadline: 13/01/2017 – extended end January

Total number of replies = 249

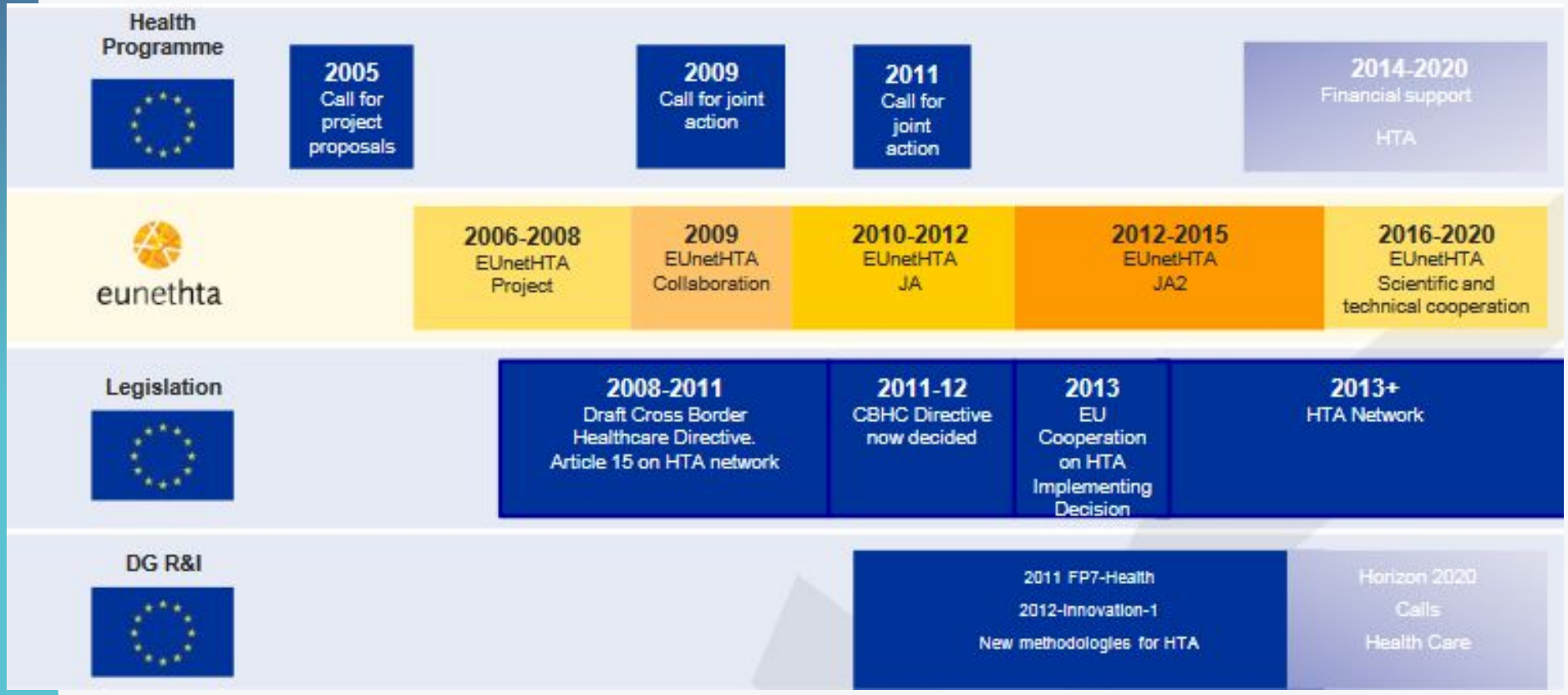
- **Questionnaire for citizens**: 63 (from 21 MS)
  - *Profile: Tertiary education; with background/working in HTA sector,*
  - *healthcare sector or industry*
- **Questionnaire for administrations, organisations, associations**: 150
- **Questionnaire for SMEs** (DG GROW – SME Network): 36 replies

Next steps

- - **Publication of the public consultation report** – 2nd quarter 2017
    - Full report on the public consultation published on EC website on Monday 15 May
- - **Conclusion of studies supporting the impact assessment** –2nd quarter 2017
- - **Consultation meetings** (Member States authorities, HTA Network, EUnetHTA, stakeholders) – on a continuous basis
- - **Impact assessment**
- - **Proposal**

European cooperation

The timeline of reaching a sustainable and permanent HTA network in Europe



https://www.ispor.org/meetings/montreal0614/presentations/IP13-WimGoettsch.pdf

THANK YOU

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Please see also

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