HTA agencies in Europe: Knowledge and experience from ten years of European cooperation

Professor Finn Børlum Kristensen, MD, PhD
Chairman of the EUnetHTA Executive Committee
Director, EUnetHTA Secretariat,
Copenhagen, Denmark

Outline

- General Information about HTA
- EUnetHTA Achievements and Tools
- HTA in Selected countries

What is Healthcare Technology ?

- **Healthcare technology** is defined as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the *systems* within which health is protected and maintained

INAHTA

HTA definition

HTA **is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner**

HTA aim

The aim of HTA is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value

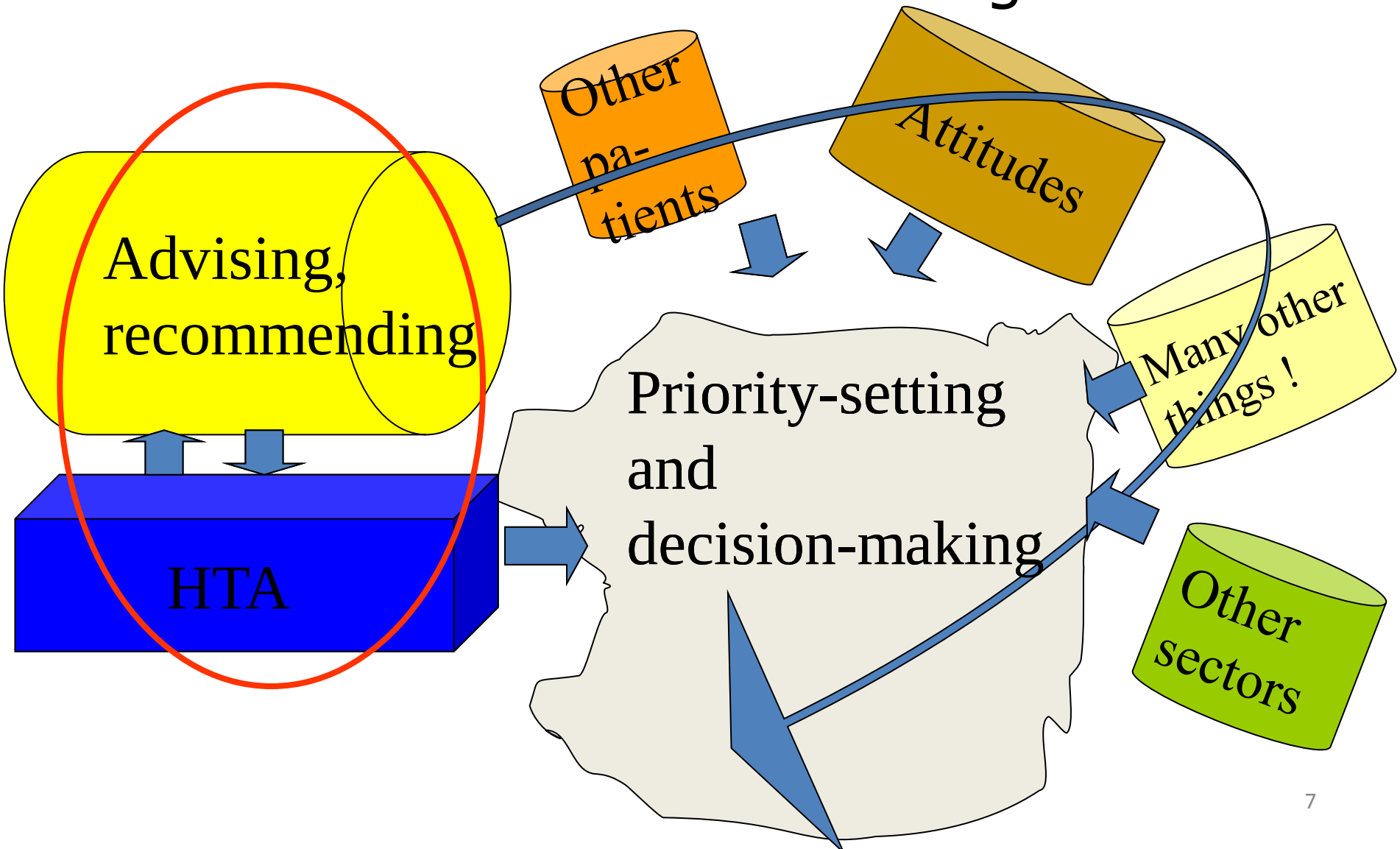
Despite its policy goals, HTA must always be firmly rooted in research and the scientific method

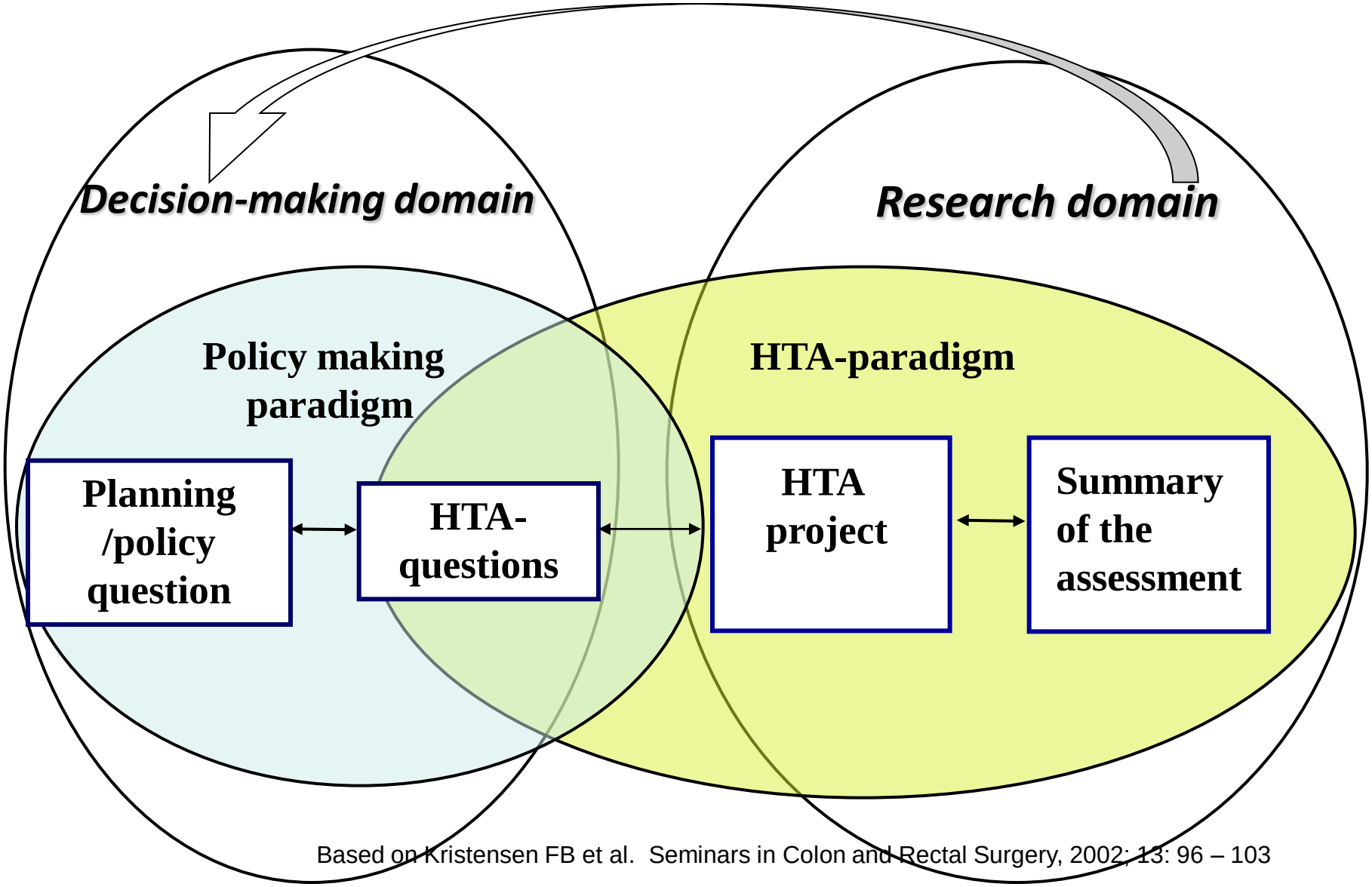
Eclectic, holistic (multidisciplinary)

Four main streams of applied research methodology have contributed to the development of HTA

- *policy analysis*
- *evidence based medicine*
- *health economics*
- *social and humanistic sciences*

HTA as an input to priority-setting and decision-making





Based on Kristensen FB et al. Seminars in Colon and Rectal Surgery, 2002; 13: 96 – 103

EUnetHTA

European network for
Health Technology Assessment

Developments in HTA in Europe

Professor Finn Børlum Kristensen, MD, PhD
Chairman of the Executive Committee
Director, EUnetHTA Secretariat
Danish Health Authority (EUnetHTA Coordinator),
Copenhagen, Denmark

EUnetHTA Objectives in 2005

- **To establish an effective and sustainable European network for Health Technology Asessment – EUnetHTA – that informs policy decisions**

- To **reduce overlap and duplication** of effort and hence promote more effective use of resources
- To **increase HTA input to decision-making** in Member States and the EU and hence to increase the impact of HTA
- To **strengthen the link between HTA and health care policy making** in the EU and its Member States
- To support countries with limited experience with HTA

Scope of EUnetHTA's work

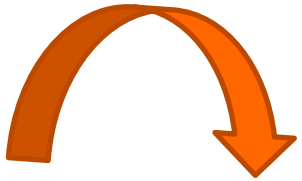
EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through

- **facilitating efficient use of resources available for HTA**
- **creating a sustainable system of HTA knowledge sharing**
- **promoting good practice in HTA methods and processes**

HTA and context – the **dynamics enabled by EUnetHTA**

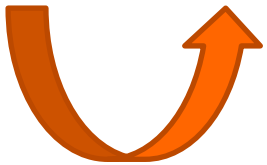
Globalize the evidence, localize the decision

J.M. Eisenberg



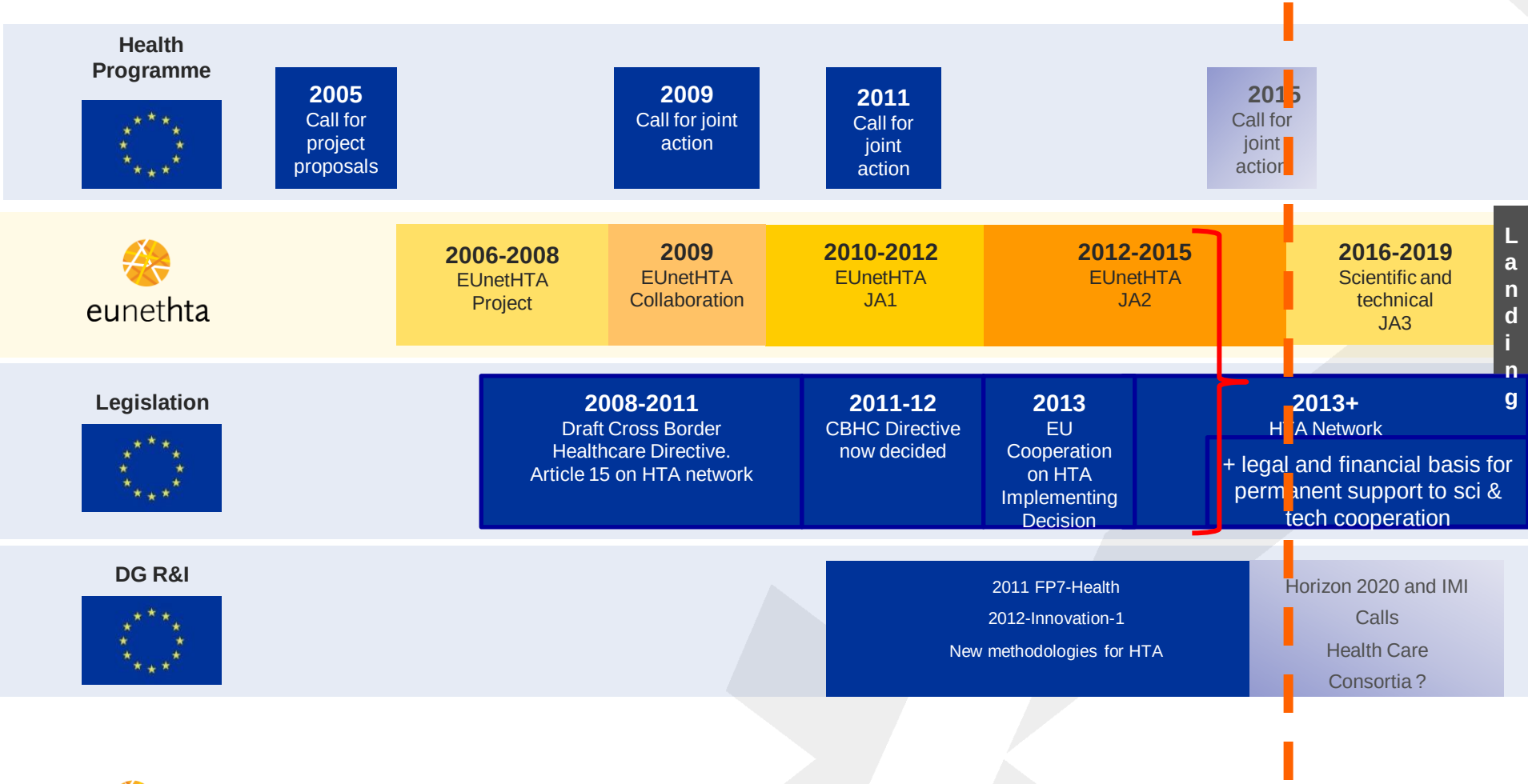
Locate the decision, globalise the evidence, localise the reporting

EUnetHTA



Project → JA1 → JA2 → JA3

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



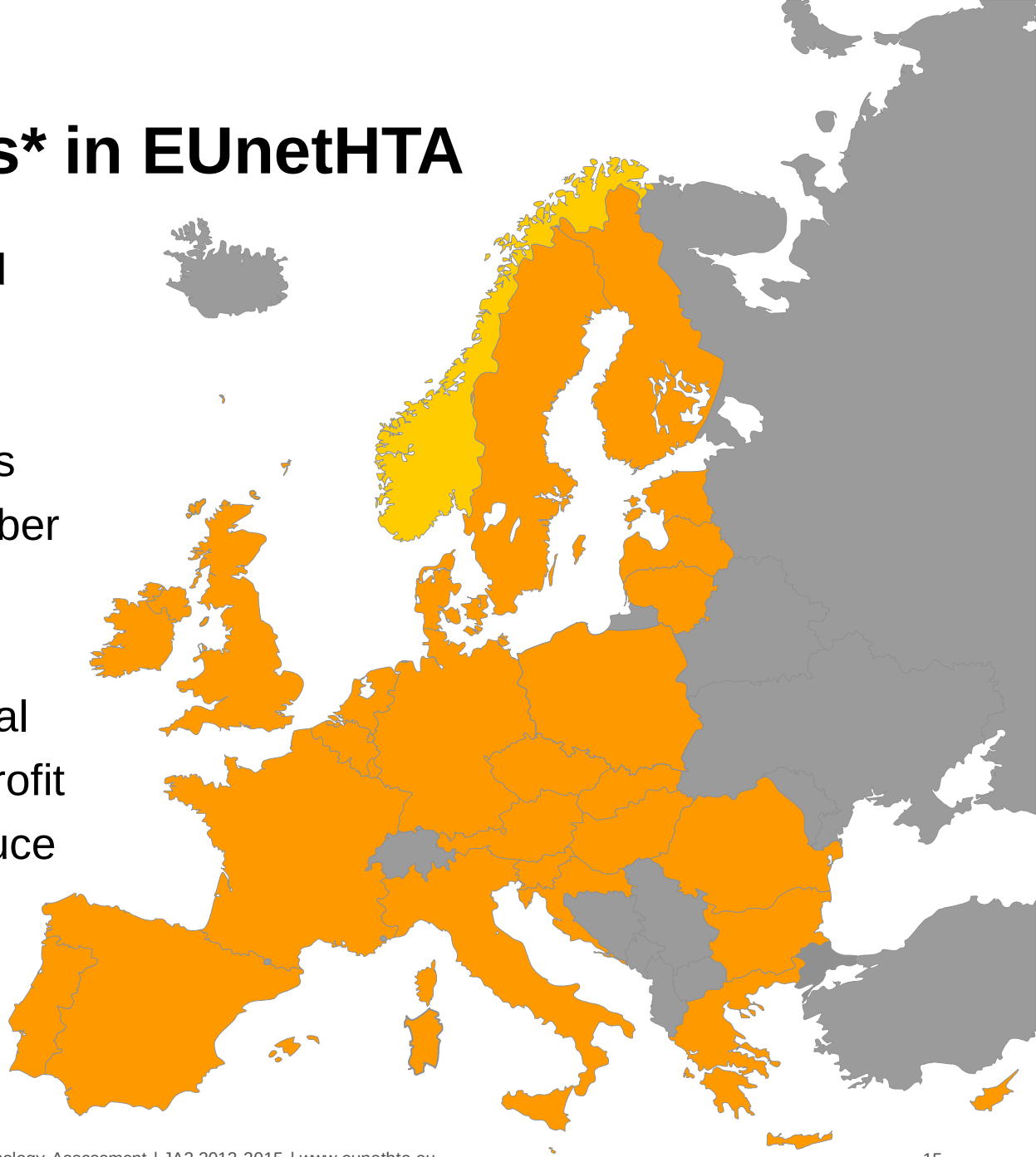
EU Participants* in EUnetHTA

EUnetHTA Partners and Associates in JA2

44 Partner organisations designated by EU Member States

Large number of regional agencies and non-for-profit organisations that produce or contribute to HTA

*) Norway participates in the Third EU Health Programme (2014-2020)



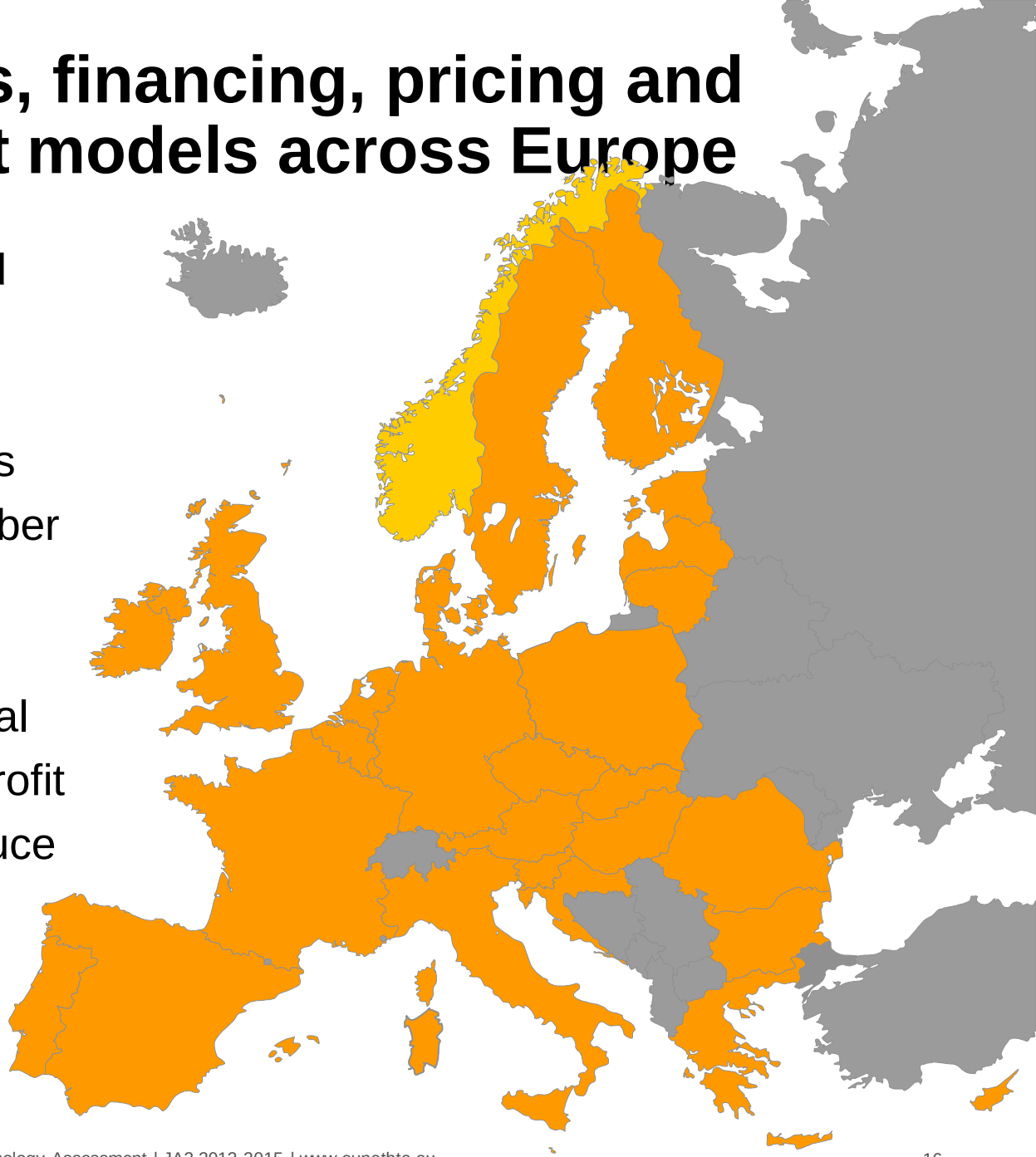
Health systems, financing, pricing and reimbursement models across Europe

EUnetHTA Partners and Associates in JA2

44 Partner organisations designated by EU Member States

Large number of regional agencies and non-for-profit organisations that produce or contribute to HTA

*) Norway participates in the Third EU Health Programme (2014-2020)



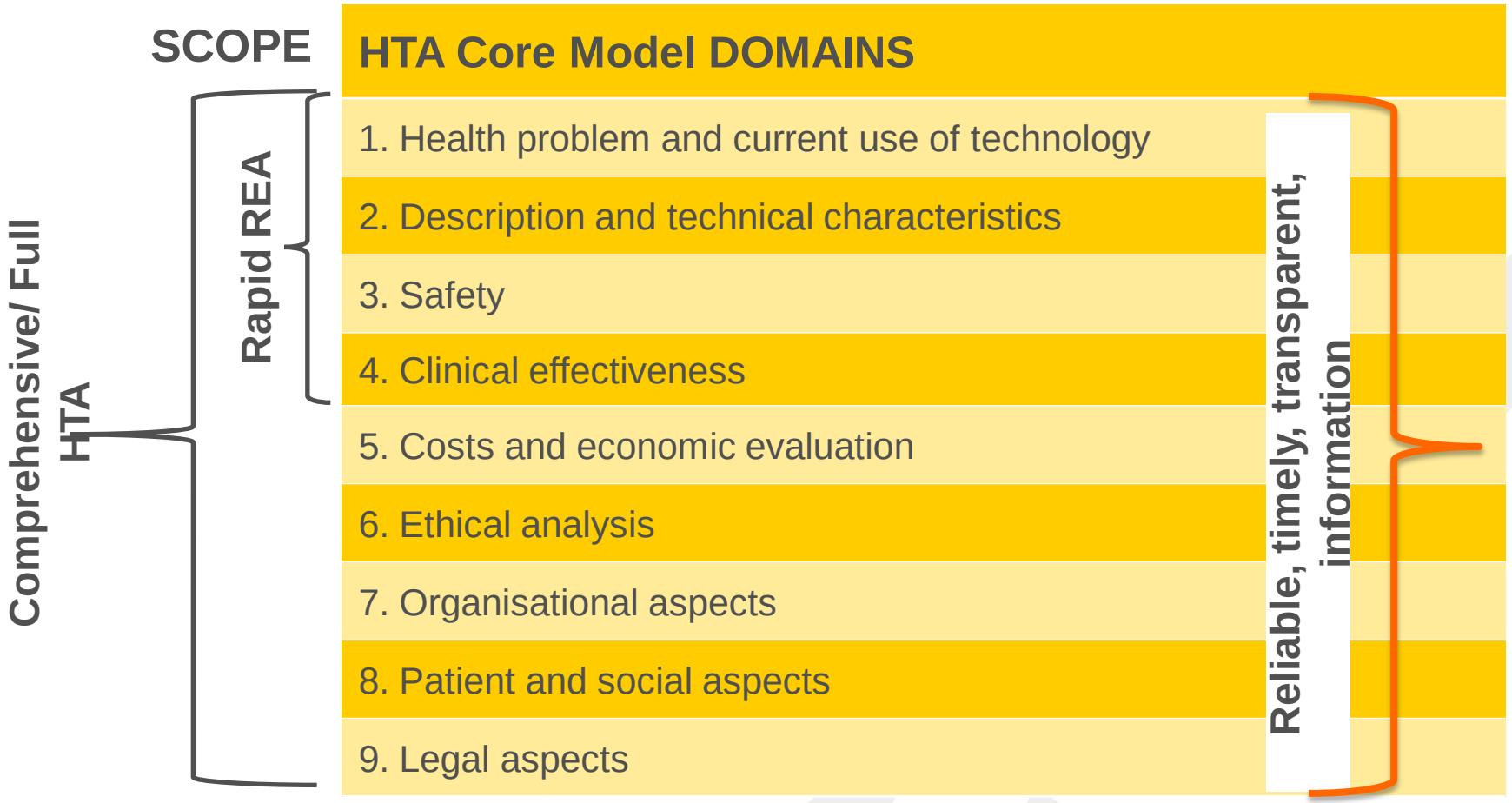
Some of the Partner Organisations in Joint Action 2 (2012-15), e.g.

- GBA, IQWIG, DIMDI, Medical Valley - EMN, Germany
- HAS, France
- NICE, NETSCC, HIS, United Kingdom
- AGENAS, AIFA, ASSR, Veneto Region, Gemelli Hospital, Italy
- ISCIII, AETSA, AQuAS, Avalia-T, IACS, OSTEBA, SESCS, UETS, Spain
- AOTMiT, Poland
- NSPH MPD, Romania
- ZIN, Netherlands
- KCE, INAMI, Belgium
- INFARMED, Portugal
- SBU, TLV, Sweden
- LBI, HVB, GÖG, UMIT, Austria
- THL, FIMEA, Finland
- AAZ, CHIF, Croatia
- NHS, Latvia
- DHA, Denmark (Coordinator), CFK, Central Region, KORA

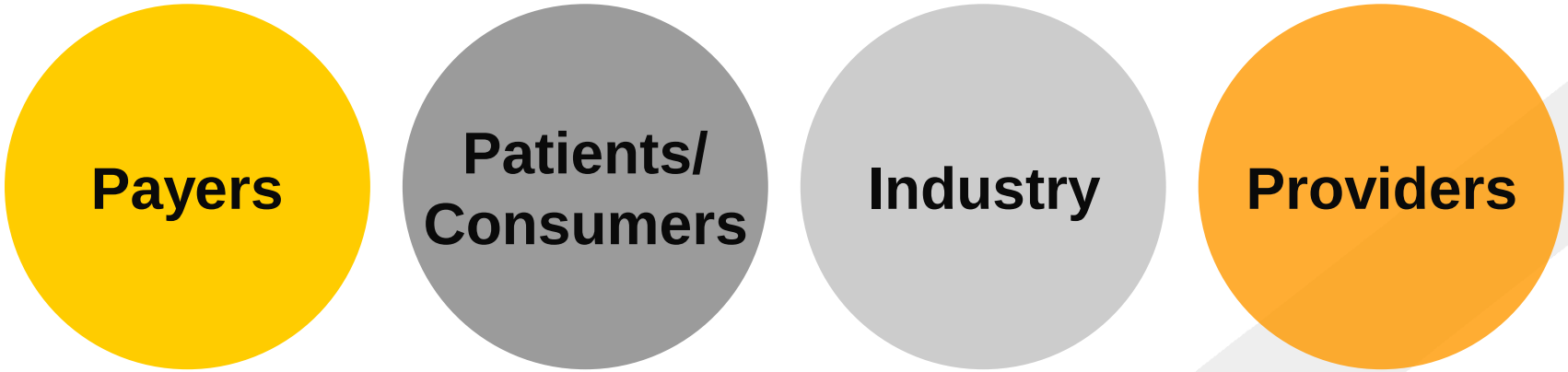
EUnetHTA (2005-2016)
Key outputs

- The **HTA Core Model** for early and comprehensive assessment - and **Evidence Submission Templates** – available to anyone
- **Pilot assessments** (relative effectiveness and full)
- **Pilot Early Dialogues**
- **Procedures and Policies** - including for Declaration of Interest and Confidentiality Undertaking – SOPs, Governance and Management Principles and project management structure
- **P**lanned and **O**ngoing **P**rojects **Database**
- **Recommendations** on the implementation of a **sustainable** European cooperation on HTA
- **Additional Evidence Generation** clarifications
- Fulfilling the three-year plan for **EMA – EUnetHTA Cooperation**
- Input by EUnetHTA JA2 **Executive Committee Task Force on JA3** to the **development of the JA3 proposal**

The Domains of the HTA Core Model® - assessing dimensions of value



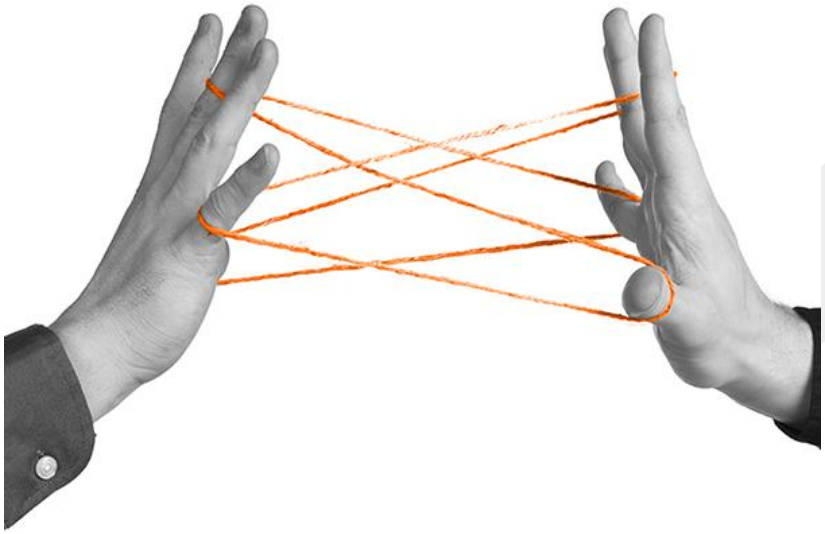
Composition of the Stakeholder Forum



Purpose of the Stakeholder Forum

To provide stakeholders with the opportunity

- to participate as stakeholder representatives in the EUnetHTA Joint Actions
- to observe and comment on the EUnetHTA Joint Action work
- to provide advice to overarching governance questions in the Joint Actions, and
- to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies in line with the aims of the EUnetHTA Joint Actions



“Dimensions” of variation between countries and systems in Europe

National < SYSTEM > Regionalised

Tax based < FINANCE > Premium based

Public health < INSURANCE > Statutory

No < HTA BODY > Yes, well-defined role

No - unclear < ARM’S LENGTH > Defined

England
(United Kingdom)

Value assessment in NICE Technology Appraisals

- A review of clinical and economic evidence leading to recommendations on the appropriate use of **new and existing medicines** for the NHS in England
- Regulations for funding
- Recommendations are appealable

Methods – reference case

Element of health technology assessment	Reference case	Section providing details
Defining the decision problem	The scope developed by NICE	5.1.4 to 5.1.6
Comparator(s)	As listed in the scope developed by NICE	2.2.4 to 2.2.6, 5.1.6, 5.1.14
Perspective on outcomes	All direct health effects, whether for patients or, when relevant, carers	5.1.7, 5.1.8
Perspective on costs	NHS and PSS	5.1.9 and 5.1.10
Type of economic evaluation	Cost–utility analysis with fully incremental analysis	5.1.11 to 5.1.14
Time horizon	Long enough to reflect all important differences in costs or outcomes between the technologies being compared	5.1.15 to 5.1.17
Synthesis of evidence on health effects	Based on systematic review	5.2
Measuring and valuing health effects	Health effects should be expressed in QALYs. The EQ-5D is the preferred measure of health-related quality of life in adults.	5.3.1

Methods – reference case

Element of health technology assessment	Reference case	Section providing details
Source of data for measurement of health-related quality of life	Reported directly by patients and/or carers	**5.3.3**
Source of preference data for valuation of changes in health-related quality of life	Representative sample of the UK population	**5.3.4**
Equity considerations	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit	**5.4.1**
Evidence on resource use and costs	Costs should relate to NHS and PSS resources and should be valued using the prices relevant to the NHS and PSS	**5.5.1**
Discounting	The same annual rate for both costs and health effects (currently 3.5%)	**5.6.1**

Considering cost effectiveness

Costs

- Drugs
- Resource use and technology/tests
- Cost of managing adverse events

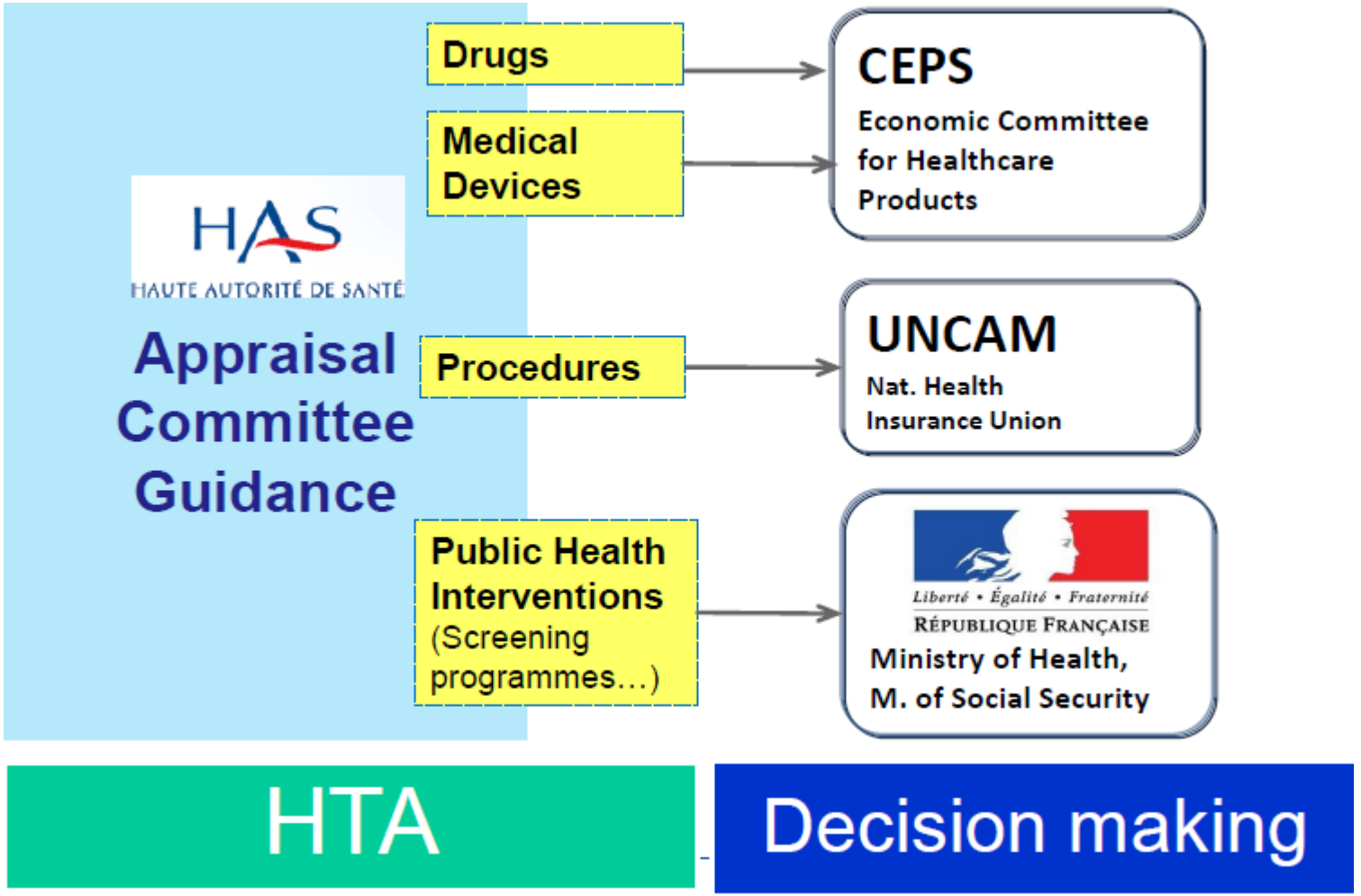
Benefits

- Length of life
- Quality of life
- Impact of adverse events

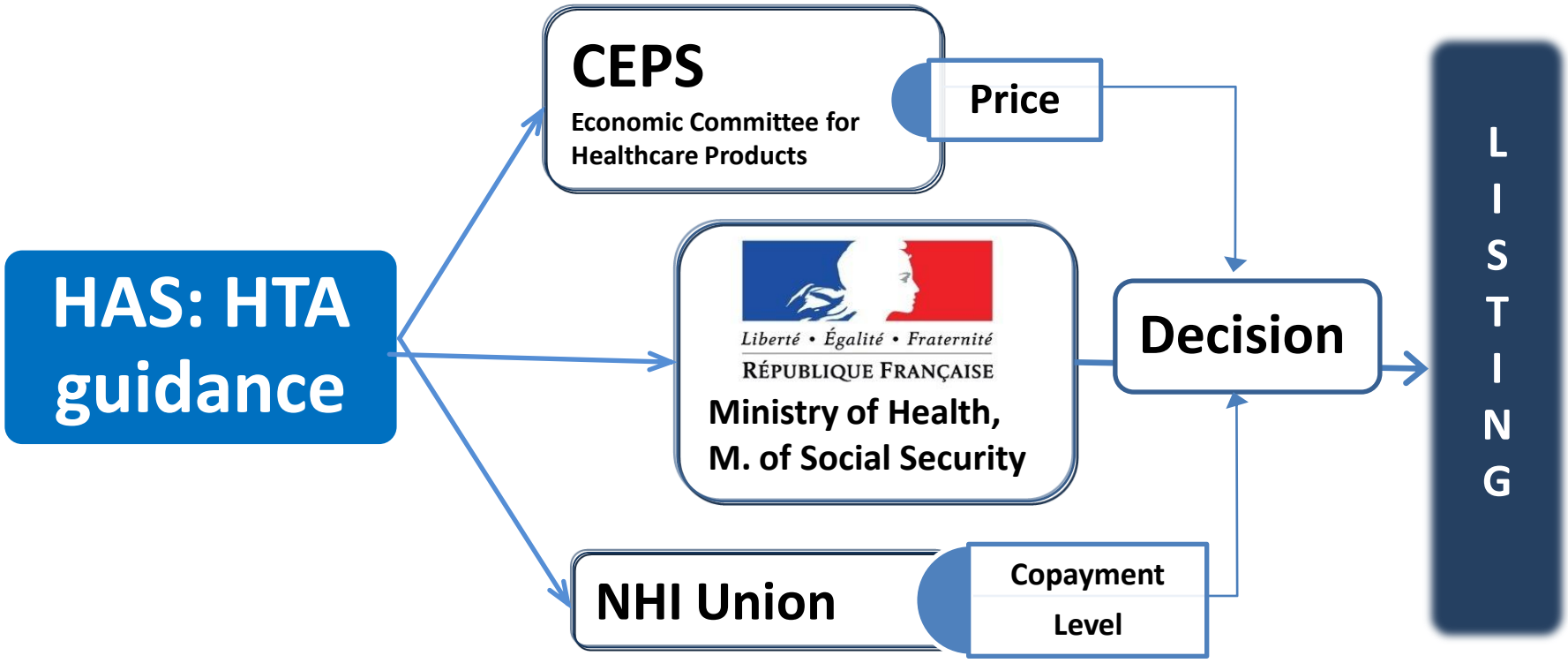
$$\text{ICER} = \frac{\text{difference in cost}}{\text{difference in effect}}$$

France

From HTA to reimbursement



HTA in France
Reimbursement and Pricing
The actors



ACTUAL BENEFIT (SMR): reimbursement and copayment level

SMR	Level of reimbursement by NHI
Important	65%
moderate	30%
minimal	15%
insufficient	NO REIMBURSEMENT

Medical Benefit (SMR)

Niveau de SMR	Nombre de SMR N (%)
Important	**177 (71.7%)**
Modéré	**21 (8.5%)**
Faible	**21 (8.5%)**
Insuffisant	**27 (10.9%)**
Commentaire / non précisé	**1 (0.4%)**
TOTAL	**247**

Si un médicament a plusieurs indications avec le même SMR, celui-ci n'est comptabilisé qu'une fois.
S'il possède des SMR différents, ils sont comptabilisés une fois dans chaque catégorie concernée. En 2012, 17 avis ont comporté 2 SMR différents et 7 ont comporté 3 SMR différents ce qui explique que le nombre de SMR formulés (247) soit plus élevé que le nombre d'avis rendus (216).

Economic evaluation for first listing and relisting of drugs and medical devices

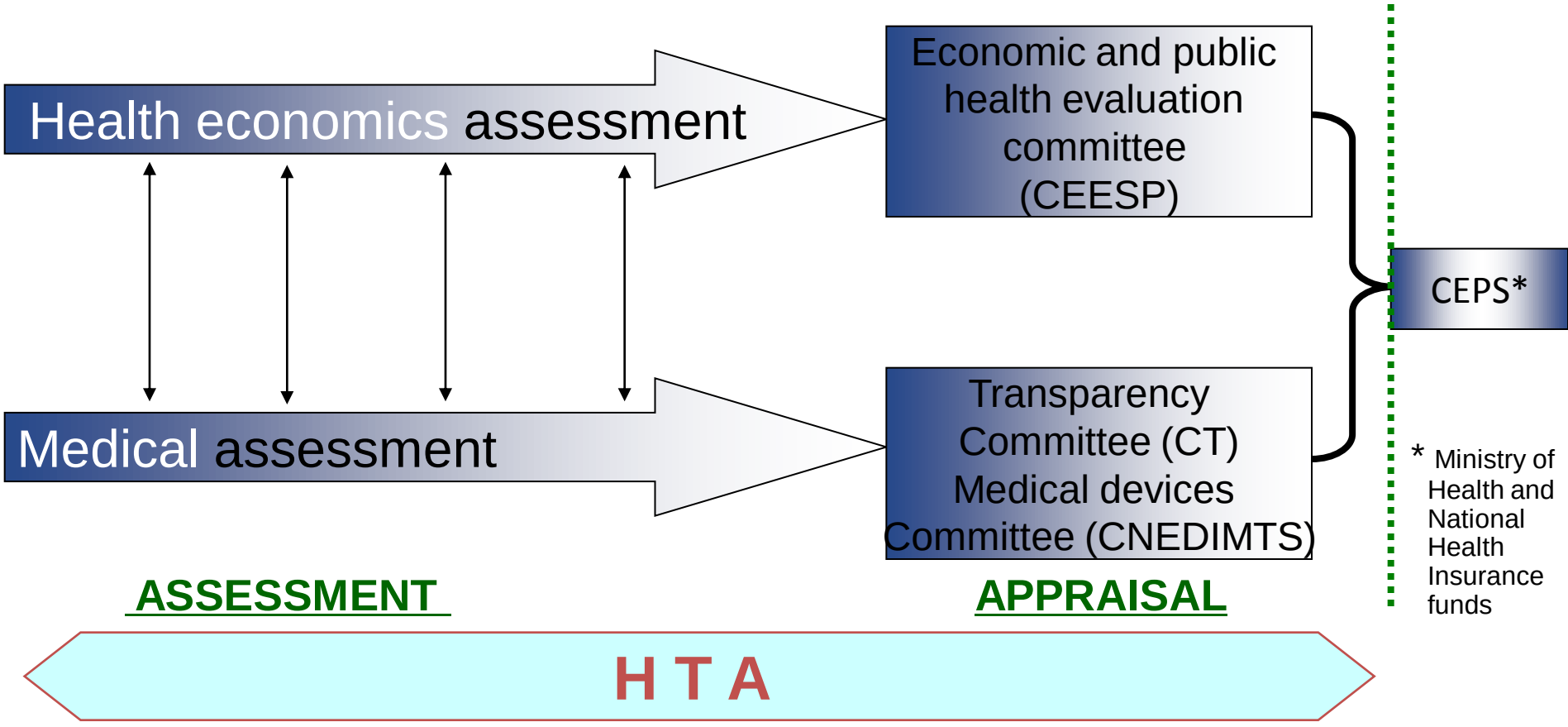
- **Required since 3/10/2013 (decree)**
- **For innovations (i.e. claim by the company of an improvement of clinical benefit (ASRM) of level 1 to 3)**

  AND

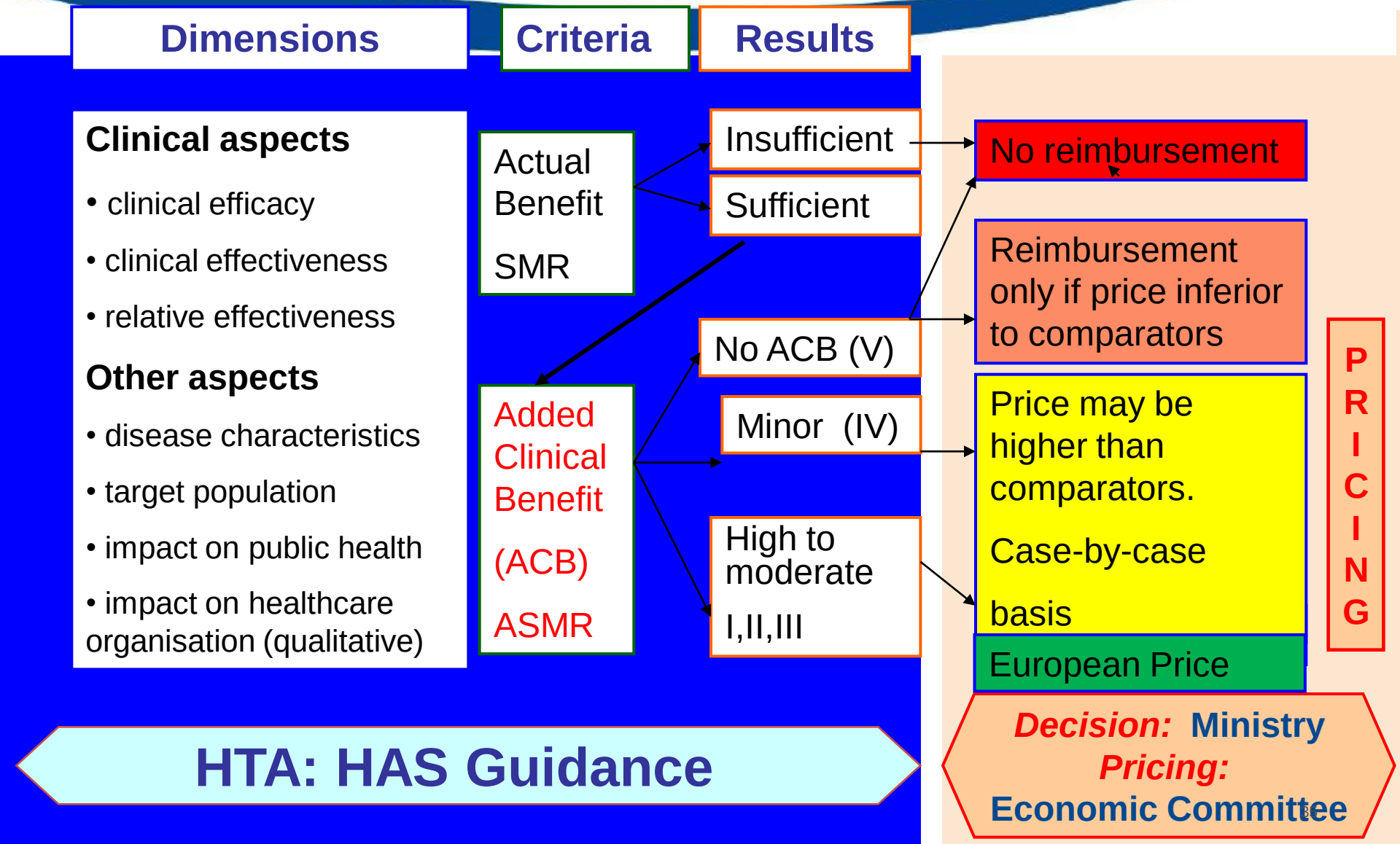
  « significant impact on health insurance expenditures »
- **An « economic opinion » must be produced within 90 days**

Coordinated assessment/appraisal

To provide the pricing committee (CEPS) with an assessment of the improvement of the clinical benefit and an economic opinion



Initial listing: From HAS guidance to CEPS pricing



Rules governing price setting

- Primary considerations when setting prices:
  - **added clinical benefit** (ASMR),
  - prices of **comparators**,
  - forecast **sales volumes** (clawback payments in case of overshooting)
- Link between ASMR and price
  - drugs that provide **no added clinical benefit** ('ASMR 5') as assessed by HAS and **no savings** on treatment costs **cannot be reimbursed**

Rules governing price setting

- Spending objective: ONDAM
  - Parliament adopts every year a national health spending objective (ONDAM),
  - indicative, not compulsory.
- CEPS' task is to obtain
  the most advantageous price
  and financial conditions for the NHI system,
- whilst taking into consideration
  - both the pharmaceutical market as a whole
  - and the limitations of the ONDAM budget,
  - as well as public health needs
  - and the obligation to treat all the companies equally.

Why did France introduce pharmaco-economic assessment of drugs and devices ?

1. The economic context

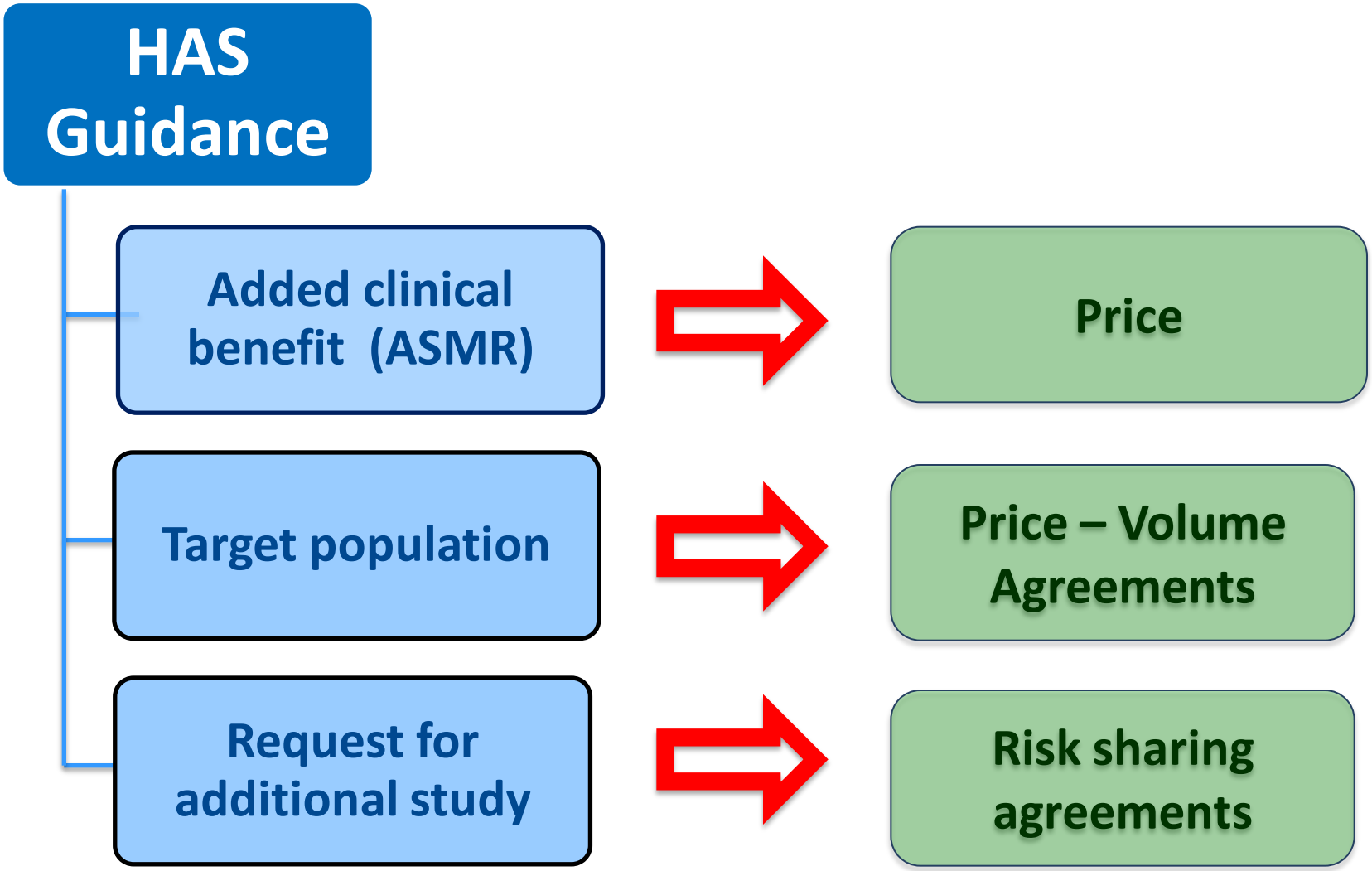
2. Increasing costs of expensive therapies without clear clinical superiority

3. Very high cost of new therapies (including targeted therapies , orphan drugs)

4. At all levels of the health-care system
   - health technologies (reimbursed drugs: <20% of healthcare costs)
   - appropriateness of medical choices and practices
   - organization of patient pathway

CHOICE is becoming necessary

Link between guidance and decision



Germany

HTA in Germany – collaboration between G-BA and IQWiG

- Decision-making body of the self-governing health care system in Germany
- Representatives of statutory health insurance (GKV), physicians, hospital federation and patients constitute G-BA and submit proposals
- Specification of services provided by statutory health insurance (decisions on reimbursement at a system level)

Appraisal

Gemeinsamer Bundesausschuss (Federal Joint Committee)

Commissions

Recommendation

IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Institute for Quality and Efficiency in Health Care

Assessment

- ambulatory (out-patient) and hospital (in-patient) care

Decision: on directives

Legal Supervision

Bundesministerium für Gesundheit (Federal Ministry of Health)

GKV Die Gesetzlichen Krankenkassen

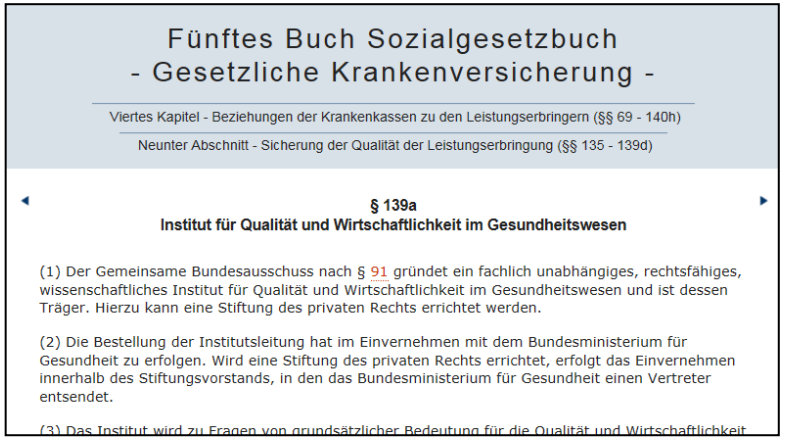
Health services funded by statutory health insurances (coverage ~90% of German population)

Based on B. Wieseler, IQWiG

IQWiG – Some facts I

- independent scientific institute
- founded in 2004 under the Health Care Reform by the Federal Joint Committee (G-BA)
- legal basis: Art. 139a Social Code Book V (SGB V) – Statutory Health Insurance

- solely commissioned by the Federal Joint Committee (G-BA) and the Federal Ministry of Health (BMG)
- in addition, IQWiG can select topics for scientific evaluation independently (no approval by G-BA or BMG required)



Fünftes Buch Sozialgesetzbuch
- Gesetzliche Krankenversicherung -

Viertes Kapitel - Beziehungen der Krankenkassen zu den Leistungserbringern (§§ 69 - 140h)

Neunter Abschnitt - Sicherung der Qualität der Leistungserbringung (§§ 135 - 139d)

§ 139a
Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

(1) Der Gemeinsame Bundesausschuss nach § 91 gründet ein fachlich unabhängiges, rechtsfähiges, wissenschaftliches Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen und ist dessen Träger. Hierzu kann eine Stiftung des privaten Rechts errichtet werden.

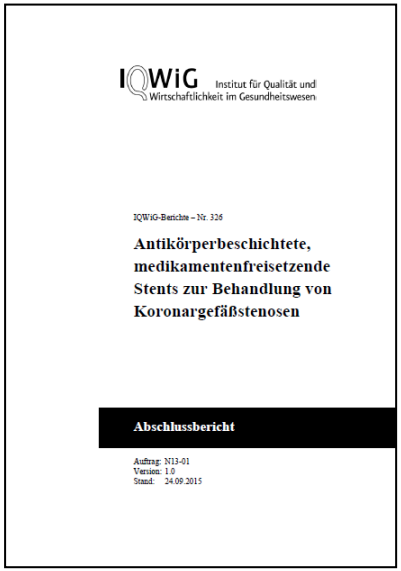
(2) Die Bestellung der Institutsleitung hat im Einvernehmen mit dem Bundesministerium für Gesundheit zu erfolgen. Wird eine Stiftung des privaten Rechts errichtet, erfolgt das Einvernehmen innerhalb des Stiftungsvorstands, in den das Bundesministerium für Gesundheit einen Vertreter entsendet.

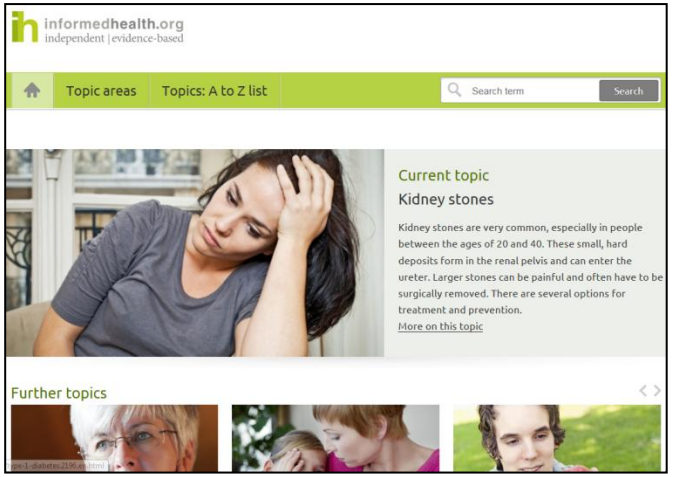
(3) Das Institut wird zu Fragen von grundsätzlicher Bedeutung für die Qualität und Wirtschaftlichkeit

see for example: http://dejure.org/gesetze/SGB_V/139a.html

IQWiG – Responsibilities according to Art. 139a SGB V

- independent, evidence-based reports e.g. on:
  - Drugs (benefit and cost-benefit assessment)
  - Non-drug interventions (e.g. surgical procedures, medical devices, diagnostic and screening methods)
  - Clinical Practice Guidelines (CPGs) and Disease Management Programmes (DMPs)





http://www.informedhealth.org

- Easily understandable health information for patients and the general community (originate from IQWiG reports + further topics addressed)

Early assessment of new pharmaceuticals (AMNOG)

- The benefit of a pharmaceutical is the patient-relevant therapeutic effect, in particular in respect of
  - longer survival
  - improvement in the state of health
  - reduction in the duration of the disease
  - improvement in the quality of life
  - reduction in side effects.

- The **added benefit** of a pharmaceutical is a benefit according to §1, which is qualitatively or quantitatively higher than the benefit of the appropriate comparator.

Challenge: benefit-based pricing

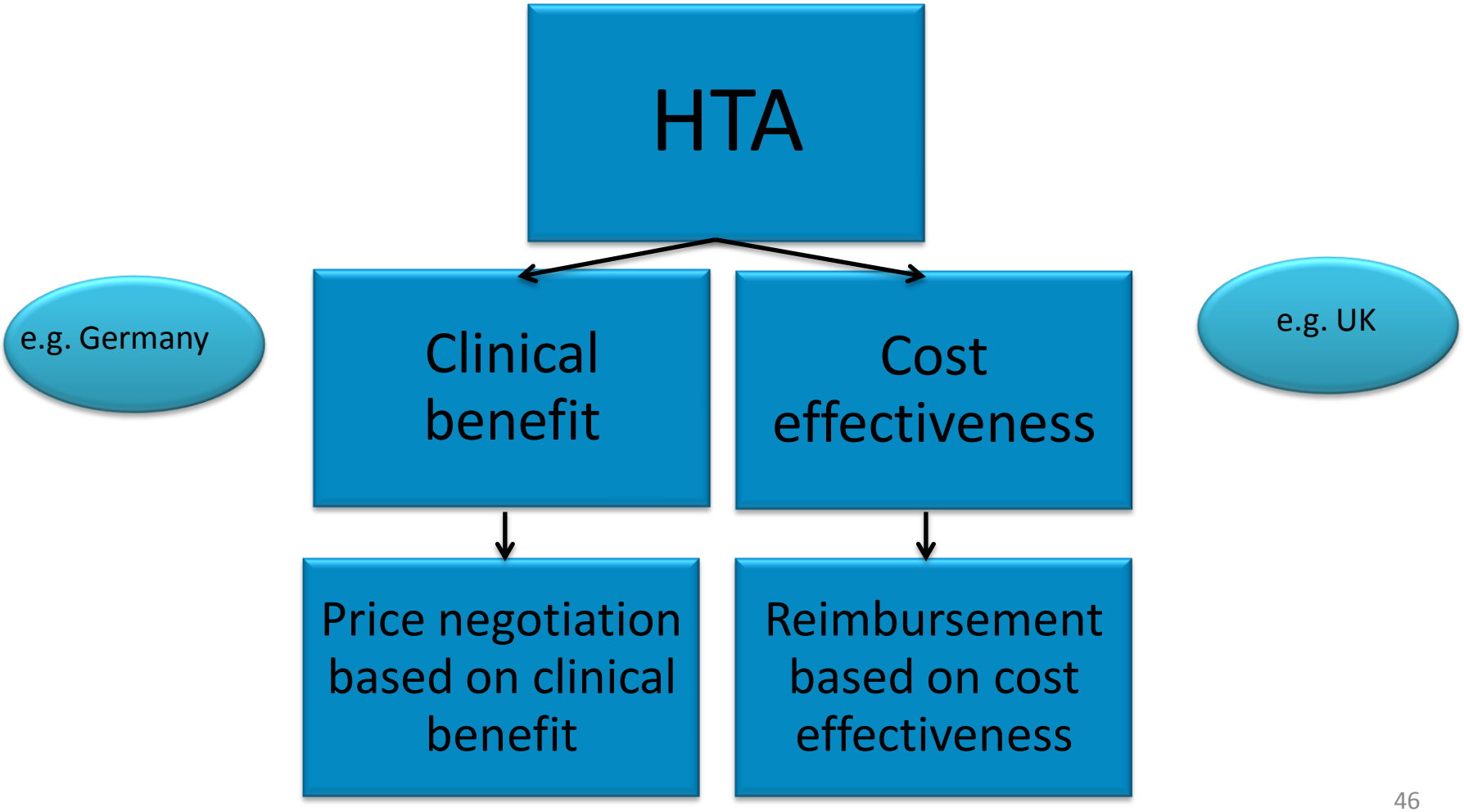
Regulation on the Benefit Assessment of Drugs*, § 5 (7)

'… the extent of the added benefit … has to be quantified as follows:

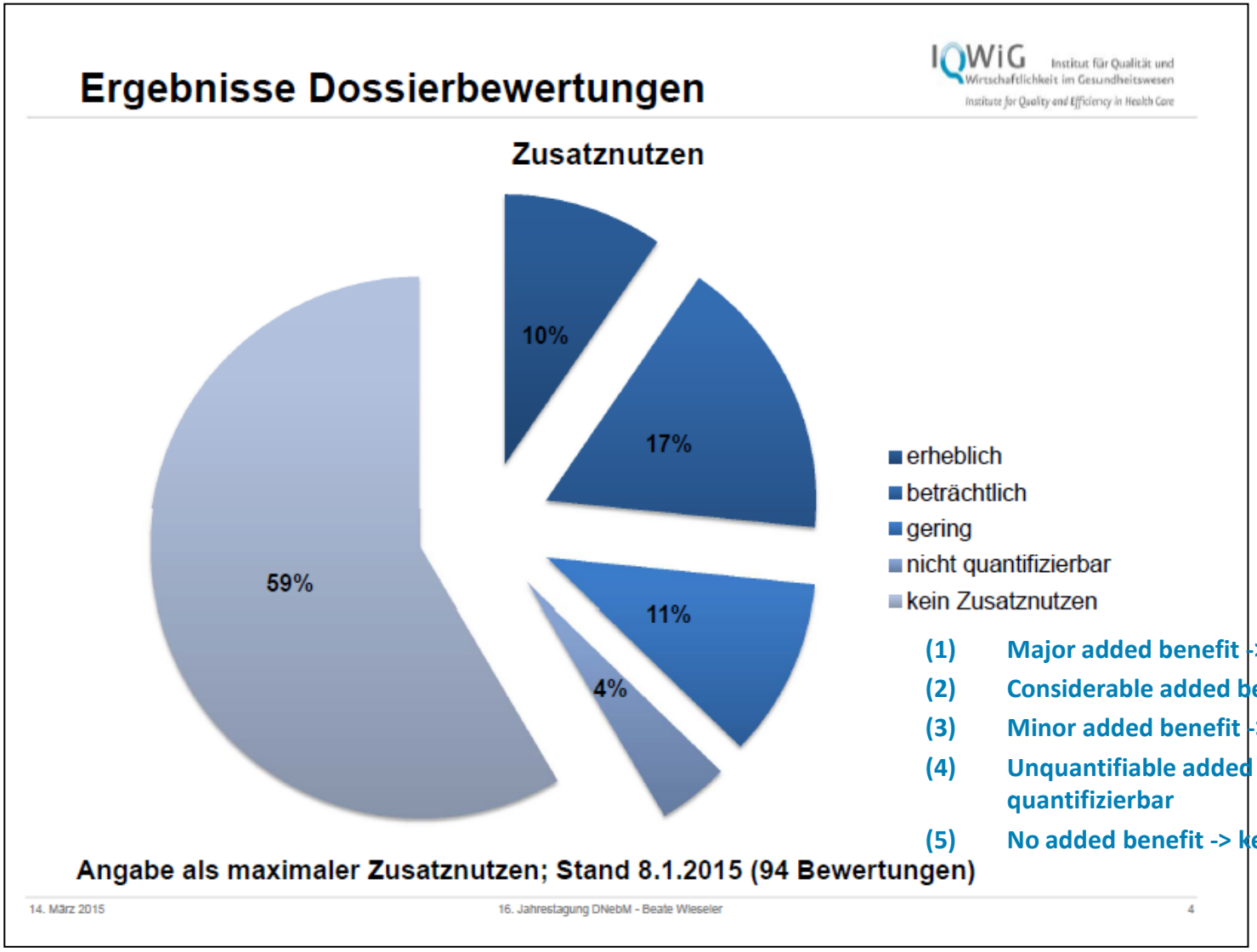
(1) Major added benefit
(2) Considerable added benefit
(3) Minor added benefit
(4) Unquantifiable added benefit
(5) No added benefit
(6) Less benefit

*According to § 35a (1), S. 6+7, SGB V

Paths of Decision Making based on HTA in Europe



Results AMNOG (2012-2015)



(1) Major added benefit -> erheblich

(2) Considerable added benefit -> beträchtlich

(3) Minor added benefit -> gering

(4) Unquantifiable added benefit -> nicht quantifizierbar

(5) No added benefit -> kein Zusatznutzen

Situation in Germany: German Law

Social Code Book V (SGB V) § 35b, 1

"***All insured persons receive access to treatments which are necessary to reduce mortality or morbidity or to increase health-related quality of life.***"

Simply assessing costs?

Example Cost effectiveness….

- **Statement of German Ministry of Health (12.06.2008):**
  - **Exclusion from reimbursement of drugs whose costs lie above a set uniform threshold value is incompatible with German law.**
  - **Legal mandate: ascertain a fair price for innovative drugs that corresponds to the additional therapeutic benefit.**

- For IQWiG
  - i.e. Concept of efficiency frontier

The Pharmadialog may change the AMNOG and market access in Germany

The results of the Pharmadialog, an extended discussion involving three government ministries, the leading pharmaceutical industry associations and several academic bodies, are now in the public domain (April 2016)

Thank you !

Any questions?

The objectives of pharmaco-economic assessment

- Not just for reducing health-care expenses
- Not just for indicating the costs
- But to inform decision makers on possible disproportions between incremental costs and incremental effectiveness
- And provide them with a scientific and accurate guidance

Pharmaco-economic assessment in France

- New Law (PLFSS 2012) and Decree (Oct 2012) to strengthen HAS' role in documenting the collective added value of technologies
- When ?

  - first listing or reevaluation (relisting)

3. Which products ?

   - Drugs and medical devices

   - Innovations: ASMR I to III claimed by the company

   and - Significant impact on health care expenses (health care organization, price, professionnal practices)

4. How ?

   - Based on data provided by the company

   - Expected or observed efficiency (comparison with existing drugs or technologies)

Practical details

- Documentation of “significant impact” on health expenditure (>20 million €/year)
  - To be provided by the company
  - To be checked by the HAS board of directors
- Submission of the economic evaluation by the company

Economic opinion process (90 days)

(National early dialogue meeting)

- Submission
- Administrative compliance
- Scientific/methodological compliance
- Internal analysis + economics sub-committee rapporteur
- Complementary technical requests
- Opinion draft
- Economics sub-committee assessment
- CEESP validation
- Sending of the economic opinion to the company
- Hearing (phase contradictoire)
- Publication of the final opinion

Template of the economic opinion

- Economic Opinion of the CEESP
- Appendix 1 - Context of the request
- Appendix 2 - Critical analysis of economic evaluation
- Appendix 3 - Critical analysis of budgetary impact
- Appendix 4 - Synthesis of the critical analysis
- Appendix 5 - Exchange with companies

Content of the economic opinion

- Administrative completeness of the submission
- Compliance with the HAS guidelines for economic evaluation
- Assessment on the robustness of the ICER*
- Potential need for additional data for reassessment within 5 years to verify ICER in real world

*) Incremental Cost-Effectiveness Ratio

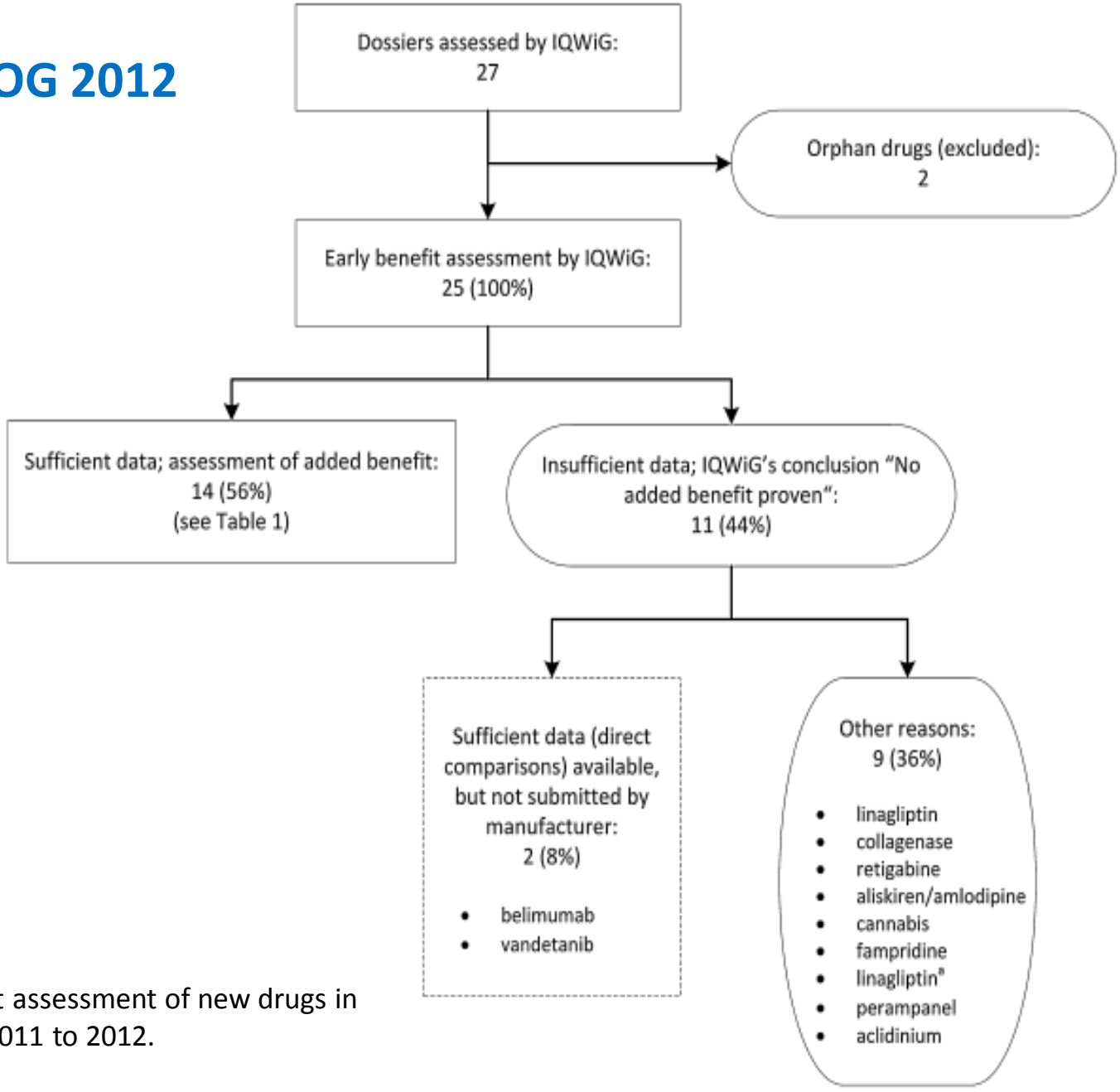
Commissions and Reports

n = 262

Department	AMNOG-Dossiers	Final Reports	Preliminary Reports	Report Plans	Project already started
Drug Assessment	95	42	-	1	6
Non-Drug Interventions	-	40	4	7	3
Quality of Health Care	-	25	1	-	3
Health Information	-	13	-	-	-
Health Economics	95 + 7	5	-	2	3
Medical Biometry	-	4	-	-	1
Total	**102**	**129**	**5**	**10**	**16**

Last update: May 12th, 2014

Results AMNOG 2012



Hörn H, et al. Early benefit assessment of new drugs in Germany – Results from 2011 to 2012.
Health Policy (2014)