WP8

Appendix 1:

SF-Executive Committee ftf meeting summary, June 2010, Dublin, Ireland

EUnetHTA Joint Action Stakeholder Forum meeting
Dublin, Ireland
June 9, 2010

Address of the meeting venue: Herbert Park Hotel, Ballsbridge, Dublin 4
tel. + 353 1 667 2200
Mobile +45 40 629357 (Julia Chamova, EUnetHTA Secretariat Manager)

Summary report

Agenda

1. **Opening, presentation of participants**

2. **EUnetHTA Joint Action – content, organisation governance**

    Presentation, Q&A

2. **EUnetHTA JA Stakeholder Policy and SOP**

    Presentation and discussion

Coffee break

3. **EUnetHTA Stakeholder Forum – tasks, organisation of work**

    Presentation and discussion

4. **Other issues**

    - *EUnetHTA Stakeholder Forum members' evaluation (WP3 Evaluation)*

Finn Børlum Kristensen, EUnetHTA Executive Committee Chair, welcomed the participants to the first face-to-face EUnetHTA Joint Action Stakeholder Forum meeting and presented the agenda for approval. He introduced Bert Boer, CVZ Executive Board member, who chaired the meeting. Participants introduced themselves (see List of Participants).

Finn Børlum Kristensen presented the content, organisation and governance structure of the EUnetHTA Joint Action (Appendix 1, slides 3-20) and Julia Chamova, EUnetHTA Secretariat Manager, presented the background for development of, the content and structure of the draft documents of the stakeholder involvement policy and standard operating procedures as well as the conclusions of the EUnetHTA Plenary Assembly meeting on May 20-21, 2010 in Ljubljana with regards to stakeholder involvement in the EUnetHTA Joint Action.

During the ensuing discussion the following comments and clarifications were made:

- the Stakeholder Forum members suggested to make changes in the presented documents eg, adjust the definition of stakeholder in the policy document, to reflect a more active role of stakeholders in the EUnetHTA Joint Action;
- with regards to the conclusions of the High Level Pharmaceutical Forum the Executive Committee clarified that the EUnetHTA Joint Action is taking forward the scientific recommendations from the Pharmaceutical Forum Working Group on Relative Effectiveness of Pharmaceuticals through the work performed in the

EUnetHTA JA Work Package 5 (Relative Effectiveness Assessment of Pharmaceuticals). It is not a continuation of the Pharmaceutical Forum in terms of its structural/governance organisation.

- the Stakeholder Forum members suggested stakeholders' direct involvement in the specific work package activities; the Executive Committee confirmed the intent and specific plans of involving stakeholders in the work of specific work packages as described in the 3-year EUnetHTA Joint Action 3-year Work Plan. The Executive Committee further indicated that the initial avenue for communicating with and identifying specific involvement in the Work Packages (WPs) is through the EUnetHTA Executive Committee that consists of the WP Lead Partners (LPs) (and 3 elected EUnetHTA Partners and Chair of the EUnetHTA Plenary Assembly).
- The LPs of WP 4, 5 and 7 welcomed the assistance from the members of the Stakeholder Forum to identify experts to be involved in the work of their respective work packages;
- The Stakeholder Forum members emphasised the importance of ensuring a dialogue with the EUnetHTA Joint Action Partners and feedback on the input they provide to the EUnetHTA Joint Action procedures. A mechanism for that should be developed. They further requested that the involvement of stakeholders on specific issues should take place prior to the final decisions within the EUnetHTA Joint Action
- The EUnetHTA Executive Committee confirmed that detailed feedback on the draft documents is welcomed and will be taken into consideration during the next Executive Committee e-meeting on June 30, 2010
- it was acknowledged that the pragmatic approach recognising the resource limitations for stakeholder involvement activities while providing fair opportunities of transparent stakeholder involvement should be the way forward
- It was agreed that that the time schedule of meetings and planned main outputs of the EUnetHTA Joint Action shall be made available to the members of the Stakeholder Forum
- It was agreed that in preparation to the first e-meeting the Stakeholder Forum members shall provide feedback on the EUnetHTA JA 3-year Work Plan so that the Executive Committee can clarify any questions on the work plans of respective work packages.

Eleanor Guegan presented the WP3 Evaluation and plans for surveying the members of the Stakeholder Forum (Appendix 2). One survey is planned for each of the years 2010-12.

The meeting was adjourned at 16:00.

Participants List

EUnetHTA Joint Action Stakeholder Forum

Attendee	E-mail	Organisation
Martin Višňanský	martin.visnansky@vszp.sk	**AIM (Association Internationale de la Mutualité)**
Sinead McMahon	health@beuc.eu	**BEUC (The European Consumers Organisation)**
Nicole Denjoy	denjoy@cocir.org	**COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)**
Ursula Hofer	ursula.hofer@baek.de	**CPME (Standing Committee of European Doctors)**
Robert Hudson	tom.hudson@ecpc-online.org	**ECPC (European Cancer Patient Coalition)**
Andrea Rappagliosi	andrea.g.rappagliosi@gsk.com	**EFPIA (European Federation of Pharmaceutical Industries and Associations)**
Martin Gallagher	mgallagher@clonmel-health.ie	**EGA (European Generic Medicines Association)**
Pascale Brasseur	pascale.brasseur@medtronic.com	**EUCOMED – Medical Technology**
Liuska Sanna	liuska.sanna@eu-patient.eu	**EPF, European Patients' Forum**
Jean Mossman		**Expert (at the request from EPF)**
Christian Peters	Christian.Peters@bv.aok.de	**ESIP (European Social Insurance Platform)**
François Houÿez	francois.houyez@eurordis.org	**EURORDIS (European Rare Diseases Organisation)**
Gloria Lombardi	sg@hope.be eco@hope.be	**HOPE (European Hospital and Healthcare Federation)**

EUnetHTA Executive Committee

Attendee	E-mail	Organisation	Country
Albert Boer	BBoer@cvz.nl	**CVZ (College voor zorgverzekeringen)**	The Netherlands
Wim Goettsch	wgoettsch@cvz.nl	**CVZ (College voor zorgverzekeringen)**	The Netherlands

François Meyer	f.meyer@has-sante.fr	**HAS, Haute Autorité de Santé**	France
Alric Ruether	alric.ruether@iqwig.de	**IQWIG (IQWIG, Institute for Quality and Efficiency in Health Care)**	Germany
Finn Børlum Kristensen	fbk@sst.dk	**EUnetHTA Secretariat, National Board of Health**	Denmark
Julia Chamova	juch@sst.dk	**EUnetHTA Secretariat, National Board of Health**	Denmark
Patrice Chalon	Patrice.Chalon@kce.fgov.be	**KCE (Belgian Health Care Knowledge Centre)**	Belgium
Andrew Cook	andrewc@soton.ac.uk	**NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre**	United Kingdom
Eleanor Guegan	e.guegan@soton.ac.uk	**NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre**	United Kingdom
Carole Longson	carole.longson@nice.org.uk	**NICE (National Institute for Health and Clinical Excellence)**	United Kingdom
Eva Turk	eva.turk@ivz-rs.si	**NIPH-RS, National Institute of Public Health of Republic of Slovenia**	Slovenia
Marianne Klemp	Marianne.Klemp@kunnskapssenteret.no	**NOKC (Norwegian Knowledge Centre for the Health Services)**	Norway
Urs Bruegger	brgu@zhaw.ch	**SNHTA (Swiss Network for Health Technology Assessment)**	Switzerland
Kristian Lampe	kristian.lampe@thl.fi	**THL, National Institute for Health and Welfare**	Finland

European Commission – DG SANCO

Attendee	**E-mail**	**Organisation**
Anders Lamark-Tysse	Anders-Lamark.TYSSE@ec.europa.eu	**DG SANCO, European Commission**

WP8

Appendix 1 for Appendix 1

Agenda

Opening, presentation of participants   **14:00**

EUnetHTA JA – content, organisation, governance **14:15**

EUnetHTA JA Stakeholder Policy and SOP   **14:40**

Coffee break   *15:40*

EUnetHTA Stakeholder Forum   **16:00**

Other issues   **16:45**
    EUnetHTA Evaluation (WP3)

EUnetHTA JA - content, organisation, governance

Stakeholder Forum meeting, June 9, 2010, Dublin

European network for HTA

Joint Action between European

Commission and EU Member States

A total of 34 government appointed organisations from 23 EU Member States, Norway and Croatia and a large number of relevant regional agencies and non-for-profit organisations that produce or contribute to HTA

What is HTA

- *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**

- **Its aim 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**

Main objective of Joint Action

The overarching objective of the Joint Action on Health Technology Assessment including work on relative effectiveness of pharmaceuticals is to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level
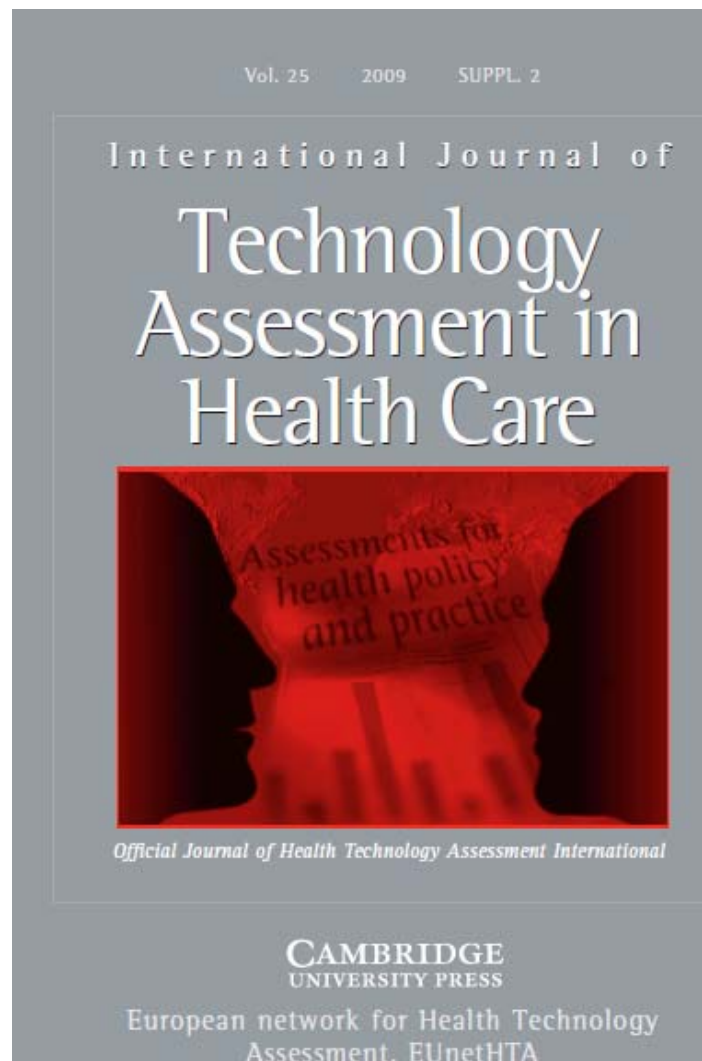
eunethta

Strategic position

- **All activities of the EUnetHTA Collaboration arise from the premise that its outputs will be used to inform but not mandate the content of national / regional / institutional HTA reports**

eunethta

How do we work?

- **Focus on methodology but ALSO on a working process (i.e. developing practical tools)**
- **Orientation towards results and continuity**
- **Strong emphasis on the management and organisational support structures for co-operation**

eunethta

How do we work?

- **Stakeholder involvement, openness to dialogue and inclusiveness**

- **Attention to the policy processes in European healthcare**

- **Continuous attention to delivering a unique and added value to partners and users**

EUnetHTA Joint Action 2010-12

- **Coordination**
- **Dissemination**
- **Evaluation**
- **Core HTA including adaptation**
- **Relative Effectiveness Assessment (REA) of Pharmaceuticals**
- **Information management system**
- **New Technologies. Facilitating Evidence Generation and Collaboration on (Pre-coverage) Assessments**
- **Strategy development (Business model for sustainability including capacity building to do HTA)**

eunethta

EUnetHTA JA organisation

WP1 – Coordination (Lead Partner (LP) – NBoH, Denmark)

WP2 – Dissemination (LP – IPH-RS, Slovenia; Co-LP – SBU, Sweden)

WP3 – Evaluation (LP – NETSCC, United Kingdom)

WP4 – Core HTA (LP – THL, Finland; Co-LP – AGENAS, Italy)

- 2 Strands – WP4A (electronic tool and Core Model development),WP4B (Core HTA production)

WP5 – Relative Effectiveness Assessment (REA) of Pharmaceuticals (LP – CVZ, Netherlands; Co-LP – HAS, France)

WP6 – Information Managment System (LP – KCE, Belgium, Co-LP – DIMDI, Germany)
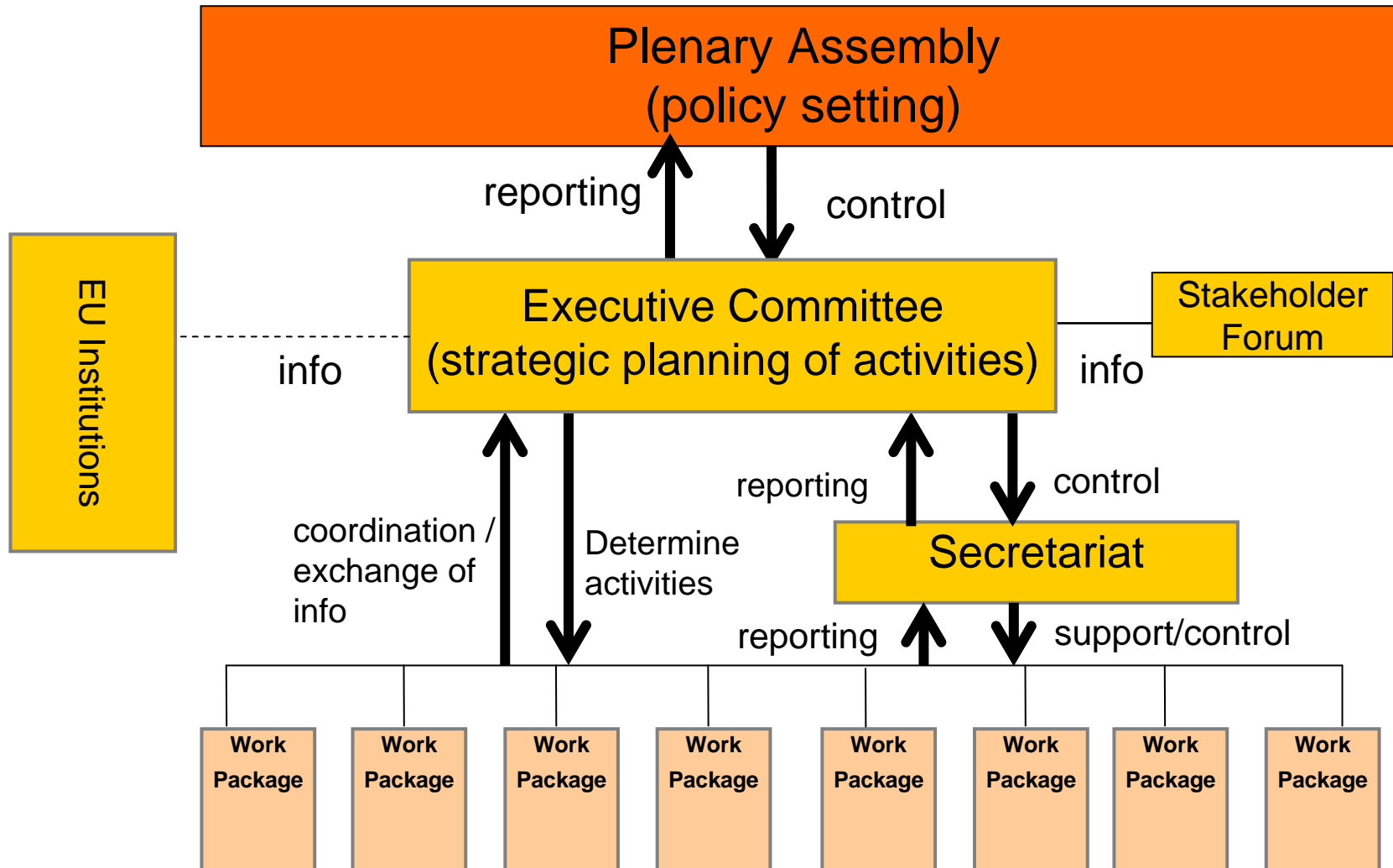
WP7 – New Technologies (LP – HAS, France, Co-LP – LBI-HTA, Austria)

- 2 Strands – WP7A (Facilitating Evidence Generation), WP7B (collaboration on (pre-coverage) assessments

WP8 – Strategy and Business Model Development (LP – NBoH, Denmark)

- specific lines of activities – a) HTA training and capacity building (focus on EUnetHTA tools) and b) facilitation of national HTA strategies.
- Responsible organisation for a) – ISCIII, Spain
- Responsible for b) – AHTAPol, Poland

eunethta

Plenary Assembly
(policy setting)

reporting   control

Executive Committee
(strategic planning of activities)

EU Institutions

info

Stakeholder Forum

info

reporting   control

coordination / exchange of info

Determine activities

Secretariat

reporting   support/control

Work Package
Work Package
Work Package
Work Package
Work Package
Work Package
Work Package
Work Package

eunethta

EUnetHTA Plenary Assembly

Composition: EUnetHTA Partners

Purpose: main policy setting body

Task examples: decision-making on EUnetHTA JA strategy, approval of work plans, changes in governance / organisational structure, advising on future development of the network, etc

EUnetHTA Executive Committee

Composition: EUnetHTA JA Lead Partners, 3 elected Partner organisations, Chair PA (non-voting position)

Purpose: strategic leadership, main executive body

Task examples: preparation and implementation of the work plan, developing strategy proposals, managing stakeholder involvement process, performance overview of the activities, etc

EUnetHTA Secretariat

Hosted by the EUnetHTA JA Coordinator NBoH Denmark

Purpose: operational leadership

Task examples: EUnetHTA JA coordination, financial management, facilitation of Executive Committee functions

EUnetHTA Stakeholder Forum

Composition: European umbrella organisations approved by PA

Purpose: information exchange

Task examples: to observe and comment on the EUnetHTA JA work and
to provide advice to overarching governance questions in the Joint Action

eunethta

The HTA Core Model

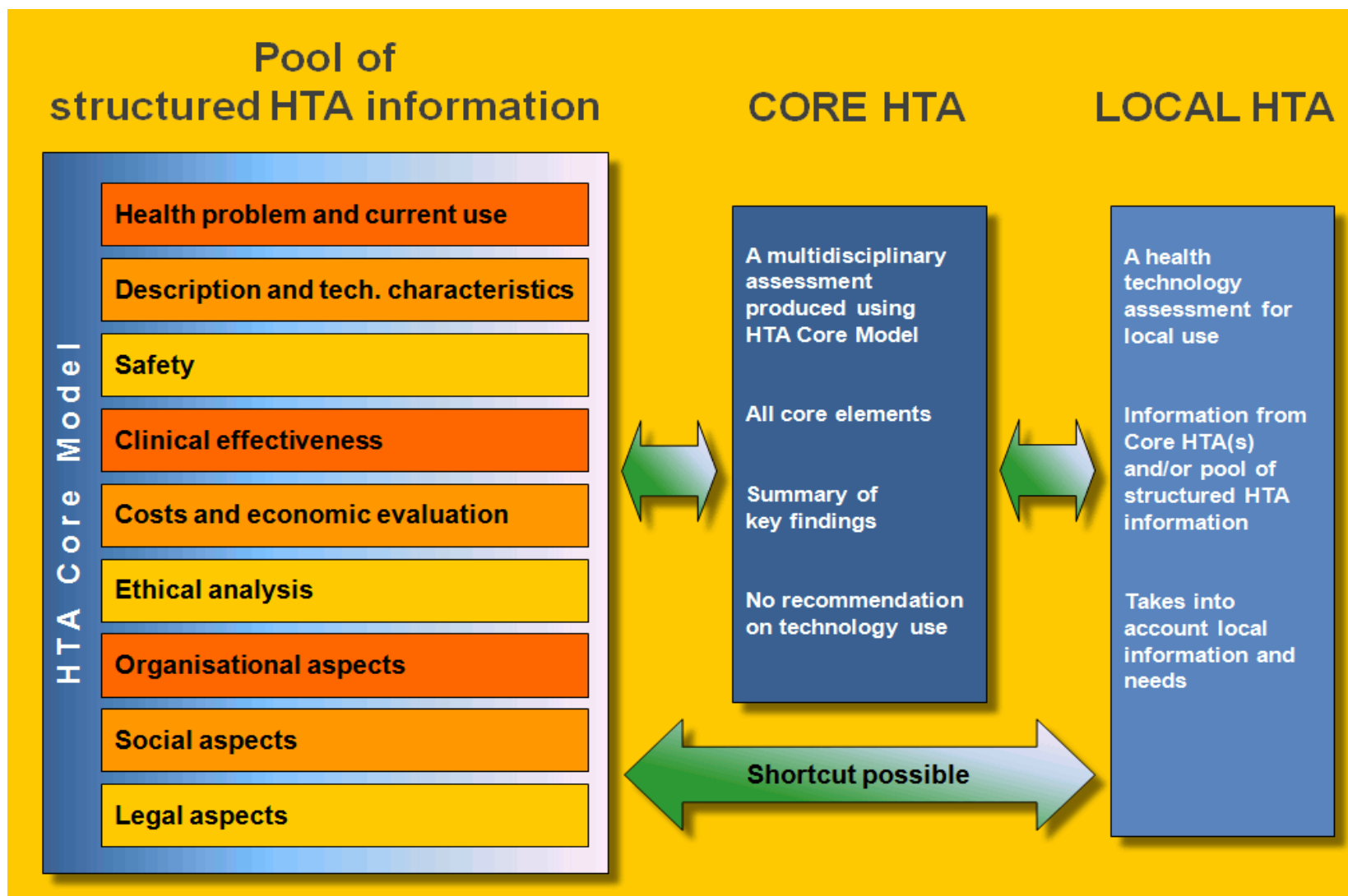# Domains of HTA

• Identified in previous EU projects, particularly EUR-ASSESS and ECHTA/ECAHI

• Promote the multidimentional nature of HTA

Health problem and current use of technology
Technical characteristics
Safety
Clinical effectiveness
Costs and economic evaluation
Ethical analysis
Organisational aspects
Social aspects
Legal aspects

eunethta

Core HTA Structure

EUnetHTA JA Stakeholder Policy, SOP and Stakeholder Forum

Stakeholder Forum meeting, June 9, 2010, Dublin

Outline

- Background
- Stakeholder policy
- SOP for policy implementation
- Discussion

EUnetHTA | European network for Health Technology Assessment | **www.eunethta.eu**   Joint Action 2010–2012

Background

- EUnetHTA Project 2006-2008
- EUnetHTA JA preparatory meetings 2009 (Feb 20, April 15)
- EUnetHTA/DG SANCO Nov 6 2009 meeting on stakeholder involvement
- EUnetHTA JA Executive Committee and Plenary Assembly discussions 2010

EUnetHTA Plenary Assembly May 20-21, 2010

Policy document:

• adjusted wording* of 1. Objective (p.2, par. 2):

  – *The EUnetHTA Joint Action partnership recognises that different groups and organisations bring key information and experience to the production of concrete Health Technology Assessments (HTAs). It further recognises the impact of HTA on the production, use and funding of various health interventions that could be subject to an HTA.*

* subject to final approval of minutes

EUnetHTA Plenary Assembly May 20-21, 2010

SOP document:
- 4 seats per stakeholder group
- the media stakeholder group has a different quality
- sharing information with all Stakeholder Forum eligible organisations
- non-selected eligible organisations can provide comments in writing and communicate them through members in their respective stakeholder group
- the Stakeholder Forum members are requested to communicate the views received from the non-selected eligible applicants
- terms of use of the information supplied by the EUnetHTA JA to the Stakeholder Forum members and eligible organisations to be developed
- communication with the WP Lead Partners is organised

through the mechanism of the Stakeholder Forum

EUnetHTA JA Stakeholder Involvement

Policy document:

- Purpose:
  - **core principles for stakeholder involvement in the EUnetHTA Joint Action**
  - **for the benefit of the decisions and governance of the EUnetHTA Joint Action**
  - **non-applicable to the national stakeholder involvement policies**

-Stakeholder definition
  - **consultative role**

- Forms of stakeholder involvement
  - **Stakeholder Forum**
  - **public consultations**
  - **answering specific questions emerging from the work of WPs**

eunethta

EUnetHTA JA Stakeholder Involvement

Policy document:

- Experts and EU institutions
    - outside the stakeholder involvement process
    - broad definition of an expert (to include patients)
    - EU institutions: terms of engagement to be agreed
- **Stakeholder Forum:**
    - part of the EUnetHTA JA governance structure
    - aim – to observe and comment on the EUnetHTA JA work and provide advice to overarching governance questions in the Joint Action
    - balanced representation of the five identified groups

EUnetHTA JA Stakeholder Involvement

Policy document – timeline till October 2010:

June: discussions in the Stakeholder Forum, preparation for the public consultation

July-August: public consultation

September-October: analysis of the comments, adjustment of the document for the final review and endorsement by the Plenary Assembly

End of October: final document (JA deliverable)

eunethta

EUnetHTA JA Stakeholder Involvement

SOP document:

- General provisions
- Stakeholder Forum procedures
- Work Packages procedures
  - Current WP work plans:
    - WP3 (survey), WP4 and WP5 (public consultation/engagement through SF), WP7A (targeted survey questions), WP8 (Stakeholder Forum/public consultation)
    - WP1, 2, 6, 7B - no stakeholder involvement planned

EUnetHTA Stakeholder Forum meetings 2010-2011 (proposal)

E-meetings: 14:00-15:30 CET

2010: September 22, November 24

2011: March 2, June 8, Sept 20, Nov 22

Face-to-face meetings:

2011: May 3, Brussels (SF)

Plenary Assembly meeting (5 observers from the Stakeholder Forum (1 per each group):

2011: May 25-26, London (PA) – *to be confirmed!*

Next steps

Till June 17: comments and suggestions on the 2 documents (writing)

June 21: minutes of the meeting (including comments received)

June 30: Executive Committee e-meeting, adjustment of the 2 documents

July 12: policy document going for the public consultation; adjusted SOP shared with SF

Sept. 8: Executive Committee e-meeting (finalisation of SOP and first review of public consultation results)

WP8

Appendix 2 for Appendix 1

WP3 Evaluation:

Stakeholder Forum members

Dr Eleanor Guegan, NETSCC, UK

Stakeholder Forum, 9th June 2010, Dublin

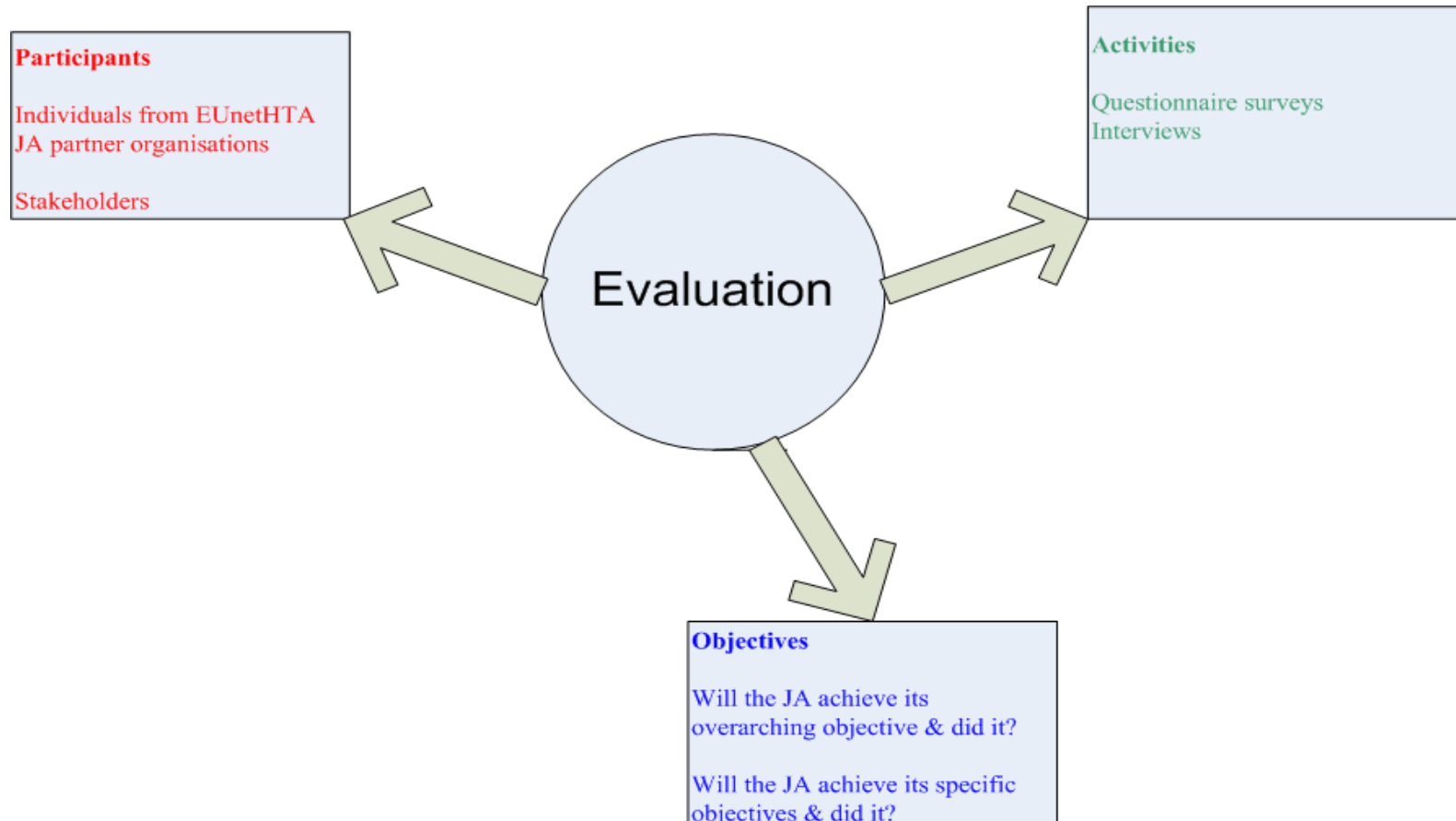**EUnetHTA** Joint Action 2010–2012 | **www.eunethta.eu**

NETSCC, UK

Participants

Individuals from EUnetHTA
JA partner organisations

Stakeholders

Activities

Questionnaire surveys
Interviews

Evaluation

Objectives

Will the JA achieve its
overarching objective & did it?

Will the JA achieve its specific
objectives & did it?

Milestones

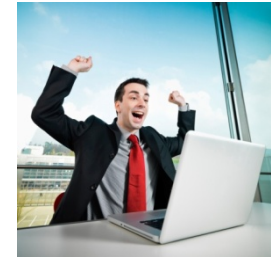| Ref	Milestone Description
M1	**Evaluation plan**
M12	**1st interim technical report**
M24	**2nd interim technical report**
M36	**Final evaluation report**

eunethta

Why is it important?

- **Early identification of issues**
- **Required by EU Commission**
- **Required by EUnetHTA JA**
- **Robust evaluation depends on high response rate**

Questionnaire surveys

- **Pre-notification**
- **Email invitation – for organisational response**
- **Format; web-based**
- **Time; 20-30mins**
- **Frequency; annual**
- **Follow-ups of non-responders**
- **Analysis of results; quantitative & qualitative**
- **Feedback**

Survey schedule

- **<u>Baseline</u>**

To evaluate start-up & identify initial concerns
July – August 2010

- **<u>Interim</u>**

To evaluate progress against plan & identify problems
May – July 2011

- **<u>Final</u>**

To evaluate if objectives met & problems resolved
March – May 2012

Many thanks for your help!

- Please watch out for our emails
- Please complete the surveys

eunethta