WP8

Appendix 3:

SF-Executive Committee ftf meeting summary, September 2012, Venice, Italy

EUnetHTA Stakeholder Forum Meeting
Venice, Italy
September 3, 2012, 10:00 -16:00

Meeting venue: Palazzo Balbi, Dorsoduro 3901 - 30123 Venezia
Organised by: Regione Veneto and the EUnetHTA Secretariat

Summary Report

Agenda

1.	**Opening**	**10:00 – 10:20**
2.	**EUnetHTA Joint Action 1 (2010-2012)**	**10:20 – 12:30**
	a) Update on the developments **b) Experience gained in JA1 regarding stakeholder involvement** **c) Presenting EUnetHTA JA WP3, SF Survey results** ***Update and presentations by the Secretariat, WP4, 5 and 7*** ***Open discussion***	
		12:30 – 13:30
Lunch		
3.	**EUnetHTA Joint Action 2 (2012-2015)**	**13:30 – 14:30**
	a) Objectives, structure, planned activities **b) Stakeholder involvement modalities (including policy)** ***Presentation, Q&A***	
Coffee break		***14:30 – 15:00***
		15:00 – 15:30
4.	**EUnetHTA JA2: Stakeholder expectations and involvement** ***An open discussion, Q&A***	
5.	**Perspectives on the stakeholder involvement in the view of the Directive on cross-border health care** ***An open discussion***	**15:30 – 15:50**
6.	**Other issues and closing of the meeting**	**15:50 – 16:00**

1-2. Opening, presentation of participants and Update on the developments in the EUnetHTA Joint Action

The meeting was opened by the chairman of the Stakeholder Forum (SF), Bert Boer, (BB) Member of Board, CVZ. He welcomed the participants and presented the agenda for approval and emphasised that the SF is supposed to provide recommendations to the EUnetHTA Executive Committee.

Participants introduced themselves (see List of Participants).

1. Finn Børlum Kristensen (FBK), EUnetHTA Executive Committee Chair, EUnetHTA Secretariat (DHMA), outlined the **general status and developments in the work of the EUnetHTA Joint Action** (JA) (Appendix 1, slides 1-9).

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

Frank Bongers (FB), EGA, raised the issue of how a revised European legislation in the field of pharmaco-vigilance could influence EUnetHTA activities? He found that EMA and EUnetHTA each measure safety in a different way, and that there generally is a need to clarify and align objectives. Questions will arise if companies can use existing data on safety for HTA. He also expressed concerns about lack of clarity about responsibilities (EMA and national medicines agencies vs. EUnetHTA) and underlined the need for transparency.

FBK responded that for HTA and EUnetHTA the focus lies on real life benefits and risks for patients. From a more limited scope on efficacy, risk and side effects EMA will now also look at efficacy / effectiveness in real life application. Thus, there is a certain approximation here, but the different roles are clearly defined (EUnetHTA is not regulator, not an agency, it is a network). The meetings between EMA & EUnetHTA held twice a year are a forum for reaching this clarity and developing cooperation further.. EMA will increasingly possess a lot of post-launch (post-market approval) prospective information (e.g. pharmaco-vigilance data) that could be of interest to HTA.

Mira Pavlovic (MP), HAS, underlined that it is still rather unclear what post market data EMA will actually ask for, and more clarity will probably be achieved next year
Wim Goettsch (WG), CVZ, emphasised that EMA's regulatory work can be of help for EUnetHTA's assessments. By way of the regular meetings, we can check which methodologies are applied in regulation and HTA, and how this can be aligned.

Gordana Zivcec (GZ), CPME, raised the issue of using the concept "European Umbrella Organisations" that might be a misleading concept if others associated it with exclusivity.

FBK responded that EUnetHTA use ''European Umbrella Organisation" to indicate that an entity is an association of national organisations, e.g. a certain industry or patient group, and that it was quite prevalently used in relation to European matters.

FB found that EUnetHTA should pay more attention to HTA on existing products and how they can have a new/different usage with improved outcomes. This aspect of an improved/better usage of existing drugs should be reflected in all documents. HTA should also be applied when an existing drug is used in a new environment. It's important to emphasise this as an essential part of the HTA programme.

FBK commented that it is indeed true that there is a tendency to focus on new technologies, and that we should go beyond that and also look at existing technologies to keep the balance. Some existing technologies might be outdated, and should be left behind to free up resources. European HTA should dedicate more resources to the comparison of existing drugs and other interventions.

2.b FBK opened the **discussion on experience gained in the JA regarding SF involvement** with a short presentation (Appendix 1 slides 10 – 14) including a long list of examples of how stakeholders have contributed to the JA (Slide 14).

GZ commented on a bullet point in slide 14 that said: "unclear how stakeholders could contribute". To her it was not unclear: EUnetHTA asks concrete questions, SF gives answers. If there is uncertainty we should clarify for the future.

Ilaria Passarani (IP), BEUC, found that the different backgrounds and resources of SF members should be better taken into account. EUnetHTA should clarify what they expect from each of the participants to avoid that no feedback was received at all (e.g. from patients and consumers).

Pascale Brasseur (PB), EUCOMED, requested that a detailed "lessons learned" on stakeholder involvement be included in the final JA report including a discussion of how the experience could translate into changes and improvements for JA2. The reporting should reflect where we learned how to operate.

PB referred to the recent joint letter from all SF stakeholder organisations to DG Sanco and EUnetHTA of April 2012 suggesting to be more closely involved in specifying the criteria for selection of topics that EUnetHTA would work on (Appendix 2 and reply, Appendix 3). This was supported by GZ, IP, and FB. Update presentations were then given by Lead Partners of WP4, 5 and 7.

WP4, Iris Pasternack (IP), THL: **Stakeholder involvement in WP4 of JA1 HTA Core Model and Core HTAs** (Appendix 4).

GZ emphasised the lack of balanced evidence on screening, and mentioned particularly breast cancer screening.

Christian Peters (CP), ESIP, commented that there is a problem of excessive screening in some countries.

The presentation of the pilot HTA on prognostic genetic testing in breast cancer lead to a short discussion on "personalised medicine". IP said that she doubted that HTA institutions currently are sufficiently equipped on a methodological level to assess genetic tests to guide the use of specific drug therapies. WP4 experiences some problems with getting the information from the sponsors of the tests who seemed not used to disclose certain information (e.g. rate of misclassification).

PB requested that if one of the two pilot reports is ready before the other the reports should be sent for comments in two rounds to reduce time pressures.

WP5, WG: **WP5 Joint Action: Stakeholder involvement, second pilot** (Appendix 5). The background survey and the first pilot were presented. Four out of four market authorisation holders chose not to be involved after having been invited to volunteer a compound for the planned second pilot Relative Effectiveness Assessment (REA). The companies found that they didn't have sufficient information to decide to cooperate. The timelines were found to be too short. Besides they were uncertain how EUnetHTA's pilot assessment would influence assessment at the national level. WG found that EUnetHTA needs to discuss with industry how successful recruitment for the pilots in JA2 could be facilitated. How could EUnetHTA make it easier for them to get involved? Such discussion would first need to be made with industry directly. Participation in the scoping of the assessment before start might be helpful to increase interest to volunteer. It was good that we now have three years in JA2, but timelines remain an important issue. Besides, it would be a challenge for the Stakeholder Advisory Groups (SAGs) to be involved in all 14 rapid assessments in JA2.

BB found that the concept of rapid assessment was a challenge in itself for everyone involved.

FB found that hardly any company would take the risk of collaborating on a pilot when each HTA and decision is still done country by country.

Andrea Rappagliosi (AR), EFPIA asked about the feedback given by the agencies involved in the pilot.

WG said that there had been general agreement to base the REA on the full HTA Core Model. The partners felt afterwards that this might not have been the best model to base the REA on. Only some of the domains (e.g. safety, effectiveness) were found necessary from REA. The work in JA2 will be limited to most relevant information (four, and not all nine, domains). A full assessment cannot be done in two months.

Luciana Ballini (LB), ASSR, found that reluctance to engage might undermine any role industry might take in priority setting. She agreed that more technical discussion, primarily with industry, was needed.

WP5, MP: **SG4 Joint Action 1 Stakeholder involvement** (Appendix 6)

Mira Pavlovic (MP) informed that the public consultation on the nine methodological guidelines was on-going, and that work was progressing well to be finished according to plans. MP informed that the two SAG members had provided extensive feed-back before the public consultations, but she found that there had not been enough response from industry and the SF participants in general. Academia was more active in responding. She also informed that EUnetHTA was trying to set up a meeting with EFPIA on the issue of endpoints in REA.

AR said that EUnetHTA was still relatively new on the scene while industry has long-standing relationship with EMA that has produced guidelines for regulatory processes for years.

Sigurd Vitols (SV), SBU, asked into possible difficulties in agreeing on choice of comparators with industry to reach consensus.

MP agreed that this is indeed very complex; there is no technical “gold standard”.

WP7, MP: **JA1 WP7 New Technologies Stakeholder involvement** (Appendix 7)

MP presented the activities in WP7 Strand A that were as of early September progressing according to plans.

2c. FBK referred to the EUnetHTA **JA WP3 Stakeholder Forum survey results** that had been distributed beforehand. He presented highlight from the survey (Appendix 1 Slides 16-22).

PB found that it would be interesting to see the evolution of survey results over time.

CP found the SF to be a very heterogeneous group and wanted to know if the results differ between the different stakeholder groups.

FBK said that WP3 will be asked to answer to these two points.

Irina Odnoletkova (IO), AIM, found that the survey had been a good exercise. The survey reflects the SF’s discussion on how stakeholders can add value. It is crucial that EUnetHTA answers why the network needs stakeholder involvement and makes the methodology of involvement explicit. WP LPs value and need involvement, but experience tells that a different level of involvement might be needed for different tasks and activities. IO asked about what is really the need for involvement of the different stakeholder groups – and which groups are EUnetHTA targeting. Some stakeholders are involved informally. Mapping of roles and significance of stakeholders would probably clarify how we can optimise our involvement. In her view, the objective of SF involvement should be: Feedback, ensure sustainability of network and dissemination of results.

BB underlined that we have to be more specific about expectations. There is a learning curve for stakeholder involvement in EUnetHTA.

IP asked if the SF met the expectations of EUnetHTA (WPs).

WG said that WP5 was happy with what they got from SAGs. They also valued very much the experience with individual stakeholders. Value is created at the working level.

FBK found that developments have been positive during the JA. The Joint industry paper at the time of the EUnetHTA conference in Gdansk and letter from all stakeholders had been very helpful as they indicate general support of the overall process. The Secretariat had developed a template to be used at start-up of activities within EUnetHTA JA2 and was developing a revised template for WP 3-year Work Plans. These explicitly ask for description of SF and wider stakeholder and public involvement.

IO suggested mapping the decision makers that are expected to use HTA. This will become more and more important under the framework of the Directive 2011/24 EU. There is a need for transparency of the decision-making across Europe. This is the first step for every citizen to understand what is the rationale and the aim of HTA and EUnetHTA.

BB concluded that the SF agrees that it's important to develop criteria for the selection of technologies to be assessed (priority setting).

BB concluded on the morning session:
The "learning curve" concept is very important as is the "glass half full or half empty" consideration. He found that the glass "was getting fuller". However, with the increased experience there is a need to clarify aims and objectives of stakeholder involvement in the decision-making process. It is a value in itself to have this clarification. EUnetHTA wants to be transparent. Perhaps with JA 2 we should open a phase where we need to make SF involvement more specific. Certain stakeholders in healthcare could contribute to raising and answering specific questions - i.e. EUnetHTA should address specific questions to specific groups.

The meeting participants' general conclusion was that stakeholder involvement is working. The reports from the WPs were rather enthusiastic. There is an invitation to contribute more - involvement can still be further improved.

Lunch

3-4. EUnetHTA Joint Action 2 (2012-2015)

- Objectives, structure, planned activities
- Stakeholder involvement modalities including policy
- Stakeholder expectations and involvement

FBK opened this point with a presentation of key issues in JA2 and slides describing the principles of stakeholder involvement in JA2 (Appendix 1 slide 23–31). The presentation was followed up by slides describing the correspondence (Appendix 2 and 3) with the SF stakeholder members (slide 32-40).

IP (Appendix 8), WG (Appendix 5 slides 7-10) and MP (Appendix 7 slide 7) presented JA2 plans for stakeholder involvement for their respective WPs.

Victor Lino Mendonca asked if the JA2 WP7 will cover different stages of the lifecycle of technologies.

MP replied that WP7 covers the life cycle from development (Early scientific advice) to the phases after the application in clinical practice (Evident database, guidelines). Early scientific advice is prospective in nature and is non-binding for European agencies, and it should be applied before phase three clinical trials.

Andrea Rappagliosi (AR) found that 2012 Plenary Assembly in Lisbon marked a moment of transition. However, the slides did not include any new forms of collaborating with Stakeholder Advisory Groups (SAGs). He recommended that the lessons from today's discussion on how to apply methods of involvement were carried forward. He found that there is lack of clarity on EUnetHTA's direction and expectations from the stakeholders. HTA often is too oriented towards pharmaceuticals only, but decision makers must take decisions on the entire healthcare sector, so HTA should also cover medical devices, interventions, services, etc. He also found that stakeholders should be more involved in informing about EUnetHTA.

IP encouraged collaboration with EMA. For example, EMA collects as much information as possible to communicate a risk profile of products to general public. In view of the pharmacovigilance legislation this gives possibility to align scopes of EUnetHTA and EMA. As mentioned before, SF in JA2 should take more account of differences amongst stakeholder groups. Level of expertise differs even within stakeholder groups (e.g. strategic (SF) vs. technical expertise (SAGs)). EUnetHTA should be more specific in requests for feed-back and proposals. There is a possibility to learn from EMA on stakeholder involvement. Besides, EMA has a strong conflict of interest policy. There are good examples of how patient and consumer groups are consulted by EMA: BEUC has longstanding experience from participation in EMA Committees. IP also emphasised that EUnetHTA should be as specific as possible when the network launches consultations (e.g. indicate level of workload).

IO said that non-industry members of the SF have had some considerations on developing HTA position statement. She also mentioned that there were other approaches to Informing policy than HTA around, and particularly mentioned the EVIDEM Collaboration.

FB asked why and how has the collaborative model been modified in WP5? Would that have consequences for the HTA Core Model?

WG replied that the challenge with applying the full HTA Core Model in rapid assessments is that the formation is taken from many different domains, and difficult to synchronise it within the time period given. A different model is required for rapid assessment because all domains are not equally relevant. This is an important learning but it does not affect the full core model at all.

FB asked which parameters would change for stakeholder involvement under JA 2.

FBK replied that there would be no "two tier" model with regard to SF membership. There would again be preference for European umbrella organisations over national ones, but national organisations would also be accepted if the umbrella organisation turn-out was too limited.

Jens Schneider (COCIR) emphasised that there was a need to clarify expectations (expertise, time) so that his organisation COCIR can set up a group with the right people to support the SF work.

BB encouraged dialogue between the Executive Committee and stakeholder groups in SF to understand how we can move forward faster.

WG found that EUnetHTA should involve several stakeholder groups, specialists but also e.g. cancer patients in its concrete work.

CP found that it should be acknowledged that each stakeholder group may be heterogeneous itself, e.g. payers are a heterogeneous group. There are many different insurance schemes in Europe: Some insurers pay for more or less everything, others only cover certain procedures. AOK, a German member organisation in AIM, could indeed deliver a long list of obsolete medical procedures if EUnetHTA so wanted. But AOK would not want to impose the list on EUnetHTA. It's EUnetHTA's role to tell what is feasible and what is not.

BB concluded that the points raised would be taken into account in the planning of JA2.

5. Perspectives on the stakeholder involvement in the view of the Directive on cross-border healthcare

The text of Article 15 on HTA was presented by FBK (Appendix 1, slides 41-44).

Anders Tysse, European Commission, DG Sanco presented the Commission's plans for establishing a permanent European HTA network ((Appendix 1, slides 45-52).

The formal adoption of the implementing act shall be finished before 25 October 2013. Member states will then be asked to appoint their representatives to the HTA network. The current perception is that the network will convene to adopt own rules of procedure. If there were overlap with EUnetHTA meetings, then the two meetings should be linked to each other. The network should build on outcomes/learning of EUnetHTA JA2.

AR asked the Commission to clarify the role, value, weight of JA2 in shaping the implementation act and after that the role and design of the future network. We need to look at this holistically, not just analyse isolated words of article 15 (e.g. stakeholder involvement). We should act in the spirit of the document keeping transparency, good governance, independence in mind.

FB emphasised that article 15 defines a voluntary cooperation of member states. How much can we really expect from this network? When it comes to real decisions, the European collaboration needs to go forward.

FBK reminded the SF of the development of Article before it was finalised by the Parliament and Council. On the involvement of stakeholders, wording was really discussed. Member States could agree only on "appropriate involvement", not "involvement in all activities". He agreed that it is a good point to look at all the other aspects too: independence, transparency etc. "Voluntary" is the only form of dealing with healthcare at EU level due to national versus EU competence. There will be a phase of clarifying in this setting whether the different tools that EUnetHTA develops can be brought into use at the member state level.

FB said that there still remain some questions how to move forward and identify next steps, really applying the EUnetHTA spirit in all 27 member states in a voluntary way.

GZ said that stakeholder involvement in the network must be appropriate and based on good governance.

IO emphasised that the status of experts and stakeholder representatives in the SAGs needed to be revisited. She found that the confidentiality issue hindered contact to others so that the work ended up being quite isolated.

FBK said that EUnetHTA should look at EMA, how do the Agency structure good governance, transparency, etc. How exactly does EMA perform consultations? On the issue of agencies that were involved in JA2 but may not be nominated by their member state for the permanent network it should be explored if they could join as associates.

GZ raised the issue that EMA is an agency and we are network. Is EUnetHTA moving in the direction of being an agency?

FBK replied that this question often comes up when presenting EUnetHTA to various audiences. An agency for HTA is not on the horizon. It may end up there eventually - or may not. This will also depend on challenges for Europe in a more global setting. We will continue trying to find tools and develop common standards, because most probably decisions will still be taken at member state level.

FB stressed that in some markets, HTA is seen from a different angle. There it's more the role of professionals to define (clinical practice) guidelines, evaluate interventions etc. How does that fit in with the network?

FBK replied that the focus lies on HTA at European level, not on development of clinical practice guidelines. If development goes more in that direction in the future, then we'll need to adapt.

AR stressed that there currently is a momentum for shaping the development of the permanent network. There is a strong interest from the Commission and Member States. It is important to "go for it" and see how the permanent network will develop. We cannot at this time be sure how it will end in terms of power, structure etc. This will also depends on how we will do things in JA2. AR further underlined that EUnetHTA should learn from the EMA development rather than from the development of EFSA (European Food Safety Authority).

6. Other issues and closing of the meeting

The Stakeholder Forum thanked Regione Veneto for hosting the meeting in Palazzo Balbi at Canal Grande and the local team for assisting the Secretariat with organising the meeting.

Note:
This overdue summary of discussion was produced by FBK on the basis of note-taking by Vanessa Pott, observer at the meeting for EDMA, by Mira Pavlovic, and himself due to a sick-leave in the Secretariat.

Participants List - As of September 3, 2012

EUnetHTA Stakeholder Forum

Attendee	E-mail	Organisation
Irina Odnoletkova	irina.odnoletkova@mloz.be	**AIM (Association Internationale de la Mutualité)**
Ilaria Passarani	ipa@beuc.eu	**BEUC (The European Consumers Organisation)**
Jens Schneider	jens.js.schneider@siemens.com	**COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)**
Gordana Kalan Zivcec	Gordana.KalanZivcec@zzs-mcs.si	**CPME (Standing Committee of European Doctors)**
Andrea Rappagliosi	arappagliosi@spmsd.com	**EFPIA (European Federation of Pharmaceutical Industries and Associations)**
Frank Bongers **Victor Lino Mendonca**	bogin@planet.nl victor@egagenerics.com	**EGA (European Generic Medicines Association)**
Pascale Brasseur	pascale.brasseur@medtronic.com	**EUCOMED – Medical Technology**
Christian Peters	Christian.Peters@bv.aok.de	**ESIP (European Social Insurance Platform)**
Observer	**E-mail**	**Organisation**
Vanessa Pott	v.pott@edma-ivd.eu	**EDMA (European Diagnostic Manufacturers Association)**

EUnetHTA Executive Committee

Attendee	E-mail	Organisation	Country
Wim Goettsch **Bert Boer**	WGoettsch@cvz.nl bboer@cvz.nl	**CVZ (College voor zorgverzekeringen)**	The Netherlands
Mira Pavlovic	m.pavlovic@has-sante.fr	**HAS, Haute Autorité de Santé**	France

Marina Cerbo	cerbo@agenas.it	**AGENAs (Agenzia Nazionale per i Servizi Sanitari Regionali)**	Italy
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Teresa Gasparetto	teresa.gasparetto@regione.veneto.it	**Regione del Veneto**	Italy
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Sigurd Vitols	vitols@sbu.se	**SBU (Swedish Council on Technology Assessment in Health Care)**	Sweden
Iris Pasternack	iris.pasternack@thl.fi	**THL, National Institute for Health and Welfare**	Finland

European Commission – DG SANCO

Attendee	Organisation
Anders Lamark-Tysse	**DG SANCO, European Commission**

Apologies:

AHTAPol, Poland; AQAHC, Croatia (Plenary Assembly Chair); DIMDI, Germany; KCE, Belgium; LBI-HTA, Austria; NETSCC, UK; NICE, UK; NIPH, Slovenia;
ECPC, European Cancer Patient Coalition; EURORDIS, European Rare Diseases Organisation; HOPE, European Hospital and Healthcare Federation; EPF, European Patients Forum

WP8

Appendix 1 for Appendix 3:

EUnetHTA Stakeholder Forum

Meeting

September 3, 2012

Venice, Italy

Agenda

Opening, welcome address	**10:00**
EUnetHTA JA1 (2010-2012)	**10:20**
Lunch	*12:30*
EUnetHTA JA2 (2012-2015)	**13:30**
Coffee break	*14:30*
EUnetHTA JA2: Stakeholder expectations and involvement	**15:00**
Directive 2011/24/EU, Article 15	**15:30**
Other issues	**15:50**

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EUnetHTA JA1 (2010-2012)

Update on developments; experienced gained with stakeholder involvement, WP3 survey results

Main objective of Joint Action 1

The overarching objective of the Joint Action 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

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Summer 2012

- 43 Partners
  - **25 EU MS, Croatia, Norway, Switzerland**
    - **Slovakia, Romania, (Czech Republic)**
- 20 Associates
  - **11 EU MS, Serbia, Turkey, USA**
    - **Russia**

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Summer 2012:
JA Deliverables progress

- HTA Core Model Online Tool and Service (*first pilot ready*)
- HTA Core Model on Screening (*1st public draft*)
  - Policies for HTA Core in review with the Executive Committee
- A set of 2 Core HTAs (*topic selection, domain teams, survey of manufacturers, drafts*)
- EVIDENT Database (*IT implementation*)
- Criteria to select new technologies for additional evidence generation (*delivered*)

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Summer 2012:
JA Deliverables progress

- Electronic POP Database (*1st version*)
- Quarterly communication protocol based on POP data (*ongoing according to schedule*)
- REA of Pharmaceuticals (*final publication scheduled for September 2012*)
- Methodology guidelines for REA of pharmaceuticals (*public consultation, review, publication in 2012*)
- Communication and Dissemination Plan (*completed*)
- Business Model (*completed*)
- 2nd Interim Report (*accepted without comments*)

Summer 2012: Activities and developments besides deliverables

Methods/tools/reports:

- Topic selection procedure for Core HTAs
- Background review on REA of pharmaceuticals
- HTA Core Model for rapid REA of pharmaceuticals
- Report on national HTA strategies
- Report on training needs followed by
  - **a training workshop on EUnetHTA tools**
- Early scientific advice pilots lead by HAS

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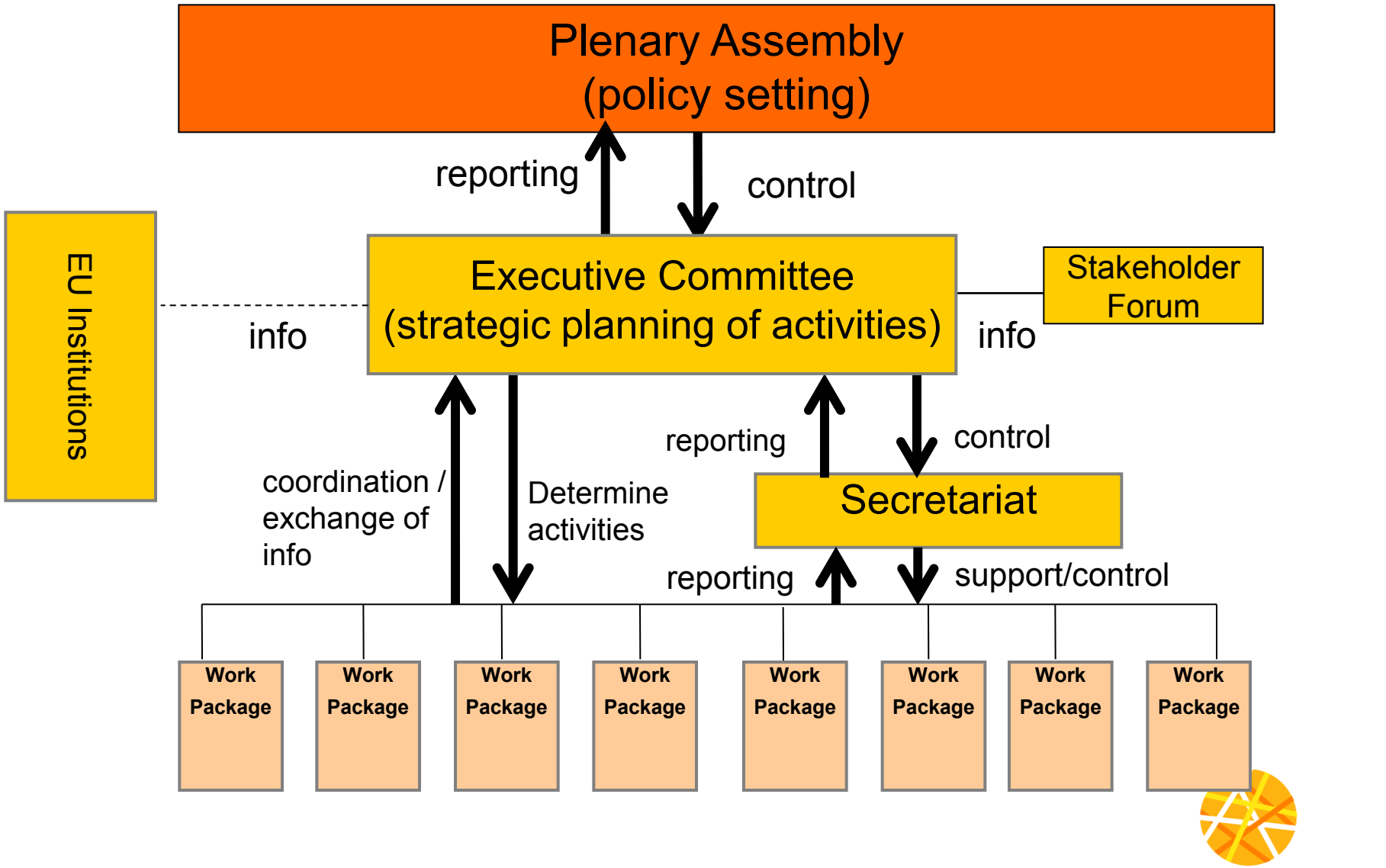
Summer 2012: Activities and developments besides deliverables

Communication:

- EUnetHTA Conference (Gdansk, December 2011)
- Informational Video
- LinkedIn group ”HTA in Europe” (800 members)

Collaboration with European/international institutions:

- EMA (improvement of EPARs, a widening field of topics)
- DG SANCO (Directive 2011/24/EU, Article 15 implementation; JA2 grant agreement)
- Memorandum of Understanding with INAHTA


Plenary Assembly
(policy setting)
reporting
control
EU Institutions
Executive Committee
(strategic planning of activities)
Stakeholder Forum
info
info
reporting
control
coordination / exchange of info
Determine activities
Secretariat
reporting
support/control
Work Package
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Work Package

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Stakeholder involvement JA1

- Stakeholder Forum
- Stakeholder Advisory Groups (SAGs)
  - **WP 4, 5, 7**
  - **Stakeholder Forum members and participants**
  - **Confidentiality undertaking**
  - **Early consultations on drafts**
- EUnetHTA Pilots
  - **Contribution from the technology developers in concrete pilot work (eg, Core HTAs, REA of pharmaceuticals)**
  - **Contribution from the SF in early dialogue pilots**

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EUnetHTA Stakeholder Forum

Composition: European (international, national, regional) umbrella organisations approved by PA

Aim: to provide stakeholders with the opportunity

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

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How Stakeholders have contributed to the EUnetHTA JA

How Stakeholders have contributed to the EUnetHTA JA

- Nomination of experts
- Participation in Stakeholder Forum meetings
- Organisation of a joint industry opinion on matters
- Disseminating JA information to members
- Giving feedback to the JA
- Participating in discussions about the future of EUnetHTA JA
- Representation at the EUnetHTA JA Conference
- Answered questionnaires
- Membership of SAGs
- Regular contact with workpackage leaders
- Unclear how they could contribute
- Through consultations

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Stakeholder involvement JA1

Details on the experienced gained in WP4, 5 and 7

Responses to the 2012 survey of Stakeholder Forum organisations (members and participants)

Results of the WP3 survey

- Response rate – 65% (17/11)
- Non-responders; ECPC, EPF, EGA, EUCOMED, EFNA, EUROPABIO
- Not all respondents answered all questions!
- ‘Don’t know responses’ often high - eg 30%
- a few highlights presented today
- **Executive Summary will be shared with the Stakeholder Forum**

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Stakeholder involvement

- The **SF** fulfilled its purpose; **36% disagree, 27% don't know**
- The **SAGs** have been a good way of being involved; **63% agree/strongly agree & 27% don't know**
- Organisation **kept updated** by our representative (for those not in SF); **100% agree/strongly agree**
- The Stakeholder Forum **meetings** have been useful; **75% agree**
- Stakeholders' **views** have been adequately considered; **20% strongly disagree/disagree, 30% don't know**

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Answered by both members of the Stakeholder Forum and those outside it

	Strongly disagree	Disagree	Agree	Strongly agree	Don't Know	Total n
The EUnetHTA JA Stakeholder Forum has fulfilled its purpose	-	4 (36%)	4 (36%)	-	3 (27%)	11
The appropriate organisations were included in the Stakeholder Forum	-	2 (18%)	6 (55%)	2 (18%)	1 (9%)	11
The formation of a Stakeholder Forum was an effective way of organising Stakeholder input into the EUnetHTA JA	-	2 (18%)	8 (73%)	-	1 (9%)	11
The Stakeholder Advisory Groups (SAGs) have been a good way of being involved in the EUnetHTA JA	-	1 (9%)	5 (45%)	2 (18%)	3 (27%)	11

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EUnetHTA Joint Action 2012-2015

	Strongly disagree	Disagree	Agree	Strongly agree	Don't Know	Total n
The EUnetHTA JA has achieved what my organisation hoped	-	3 (30%)	7 (70%)	-		10
Stakeholders' views have been adequately considered in the EUnetHTA JA	1 (10%)	1 (10%)	5 (50%)	-	3 (30%)	10
Adequate feedback from the EUnetHTA JA has been provided to Stakeholders	-	2 (20%)	7 (70%)	-	1 (10%)	10
My organisation's expertise has been appropriately used in the EUnetHTA JA	-	5 (50%)	3 (30%)	-	2 (20%)	10
It would be useful to have a EUnetHTA conference on a regular basis	-	1 (10%)	5 (50%)	4 (40%)	-	10

Anticipated success of JA meeting its objectives

	No	Yes	Don't Know	Total n
Development of a general strategy & business model for sustainable European collaboration on HTA	1 (10%)	6 (60%)	3 (30%)	10
Development of HTA tools & methods	-	6 (60%)	4 (40%)	10
Application and field testing of developed tools & methods	-	5 (50%)	5 (50%)	10

Concerns about the involvement of external stakeholders

	No	Yes	Don't Know	Total n
The principles of stakeholder involvement in the JA (Stakeholder involvement policy and SOP)	3 (30%)	5 (50%)	2 (20%)	10
The actual involvement of stakeholders in the JA	2 (20%)	7 (70%)	1 (10%)	10
The level of commitment of stakeholders in the JA	3 (30%)	4 (40%)	3 (30%)	10

EUnetHTA JA2 (2012-2015)

Objectives, structure, planned activities; stakeholder involvement modalities (including policy)

General information

- **38 Associated Partners (DHMA - Coordinator) from 26 EU MS, Croatia, Norway**
- **15+ CPs (Luxembourg, Switzerland, ….)**
- **October 1, 2012 - Sept 30, 2015 (36 months)**
- **General objective: strengthen the practical application** of tools and approaches to cross-border HTA collaboration bringining it to a higher level of understanding for the Commission and MS of ways to establish a sustainable structure for HTA work in the EU

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Specific objectives - I

• Test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network).

• Implement, pilot and further develop models and tools as well as production processes to support collaborative production of core HTA information with reinforced secretariat and coordination function.

• Produce recommendations on the design and running of the EU HTA cooperation process based on analysis of various coordination capacities for the permanent secretariat function and further testing of involvement of stakeholders in network activities

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Specific objectives - II

• Provide a conceptual and information management infrastructure and related services to support the piloting of collaborative production of HTAs by partner agencies, and facilitate the tasks and team working of the other WPs

• Increase awareness and understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholders.

• Develop and test a methodological basis for European cooperation on HTA including guidelines for distinct methodological issues and quality improvement of evidence generation for HTA.

WP	Deliverable
WP1	Final Report; Recommendations on the implementation of a sustainable European network for HTA
WP2	Report on yearly training courses on EUnetHTA tools and methodology
WP3	Report on evaluation of project completion including assessment of impact on secondary users of HTA information
WP4	Full Core HTAs
WP5	Pilot rapid assessments
WP6	Report on Information Management Infrastructure and Services
WP7	Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation; Methodological guidelines and templates to support production of core HTA information and rapid assessments
WP8	Upgraded and updated application package of HTA Core Model

Stakeholder involvement

The **Governance Structure** as well as the **EUnetHTA JA Stakeholder Involvement Policy** developed during the EUnetHTA Joint Action 2010-2012 continues to apply during the EUnetHTA JA2 (EUnetHTA JA2 Grant Agreement conditions apply where necessary and appropriate)

IN ADDITION

The following adjustments in the procedures were agreed and approved by the EUnetHTA Plenary Assembly to be applicable in EUnetHTA JA2 stakeholder involvement activities…

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Stakeholder involvement

- Increase the number of organisations per stakeholder group from 4 to 6 in the EUnetHTA Stakeholder Forum (SF)
- All applying organisations found eligible for participation in the SF receive a status of a SF member
- The stakeholder group members are responsible to organise themsleves for the participation in the SF meetings (with the maximum number of meeting participants per stakeholder group limited to 6)
- New forms of stakeholder involvement (in additon to the SF and Stakeholder Advisory Groups (SAGs) eg, expert meetings, may be introduced
- Earlier involvement of stakeholder expertise to be considered
- Adequate time to provide input to be allowed

Stakeholder involvement

The 3-year Work Plan (to be developed for final approval by the EUnetHTA Plenary Assembly in March 2013) will include specification of activities and adequate timing for stakeholder involvement:

- SAGs
- Stakeholder Forum
- Other types of stakeholder involvement to specify (eg, expert meetings,modality of involving in pilots, etc)

JA2 Stakeholder Forum

- Current Stakeholder Forum is working until the end of JA1 (ie, December 31, 2012)
- Stakeholder Forum for JA2 – operational from January1, 2013
  - October 2012 – open call for expression of interest to participate in the Stakeholder Forum; to be announced on the EUnetHTA website
    - **Current members to apply if wishing to be considered for participation in JA2 Stakeholder Forum**
  - November – Executive Committee to make a decision on membership; PA to approve
  - December – the applicants will be informed on the decision
  - January- February – forming JA2 SAGs

EUnetHTA JA2 (2012-2015)

Stakeholder expectations and involvement – open discussion

Letter from stakeholder organisations to EUnetHTA and DG Sanco

April 26, 2012

Suggestions for involvement of Stakeholders in JA2

- strengthening the role of the Stakeholder Forum. This pool of experts can be consulted and can provide advice according to the different perspectives and experiences represented, in addition to its role of receiving and disseminating information;
- increasing clarity with respect to the roles and responsibilities of all EUnetHTA bodies within the governance structure of the Joint Action, including the role of the Stakeholder Forum therein;

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Suggestions for involvement of Stakeholders in JA2

- securing timely, transparent and equitable access to the process and outputs of the Joint Action at all levels;
- adapting the forms of stakeholder involvement to the altered objectives and tasks of the Joint Action and future network;
- increasing stakeholder consultation on strategic issues (e.g. long- and short-term objectives and priorities);

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Suggestions for involvement of Stakeholders in JA2

- acknowledging the different nature of the various stakeholders and the different kind of input they can provide both in terms of content and resources to contribute to the work of the Joint Action and facilitate their equal participation as necessary;
- exploring new forms of dialogue such as experts' meetings and other discussion fora not limited to written comments or responses to consultations;
- involving stakeholders early and providing them with adequate time to provide input.

Reply from EUnetHTA to the letter from stakeholder organisations

June 15, 2012

The following items to take effect from beginning of Joint Action 2

- The number of organisations per stakeholder group in the EUnetHTA Stakeholder Forum meetings will be increased from 4 to 6
- The current two-tier system of members and participants in the Stakeholder Forum will be discontinued, i.e., all eligible organisations will have the status of Stakeholder Forum member

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The following items to take effect from beginning of Joint Action 2

- The Stakeholder Forum members of a specific stakeholder group are charged to organise themselves for participation in the meetings (face-to-face and e-meetings) (with the maximum number of participants per stakeholder group limited to 6)
- New forms of stakeholder involvement (in addition to the Stakeholder Forum and SAGs) may be introduced – e.g. expert meetings – according to need

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The following items to take effect from beginning of Joint Action 2

- Earlier involvement of stakeholder expertise in the specific processes of the joint actions to be considered and adequate time to provide input to be allowed while respecting the EUnetHTA joint action timelines.

Directive 2011/24/EU

Perspectives on the stakeholder involvement

Article 15
Cooperation on health technology assessment

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

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2. The objectives of the health technology assessment network shall be to:

(a) support cooperation between national authorities or bodies;

(b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;

(c) support the analysis of the nature and type of information that can be exchanged;

(d) avoid duplication of assessments.

3. In order to fulfil the objectives the network on HTA may receive Union aid. Aid may be granted in order to:

(a) contribute to the financing of administrative and technical support;

(b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;

(c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;

(d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;

(e) facilitate the consultation of stakeholders on the work of the network.

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Establishing a permanent European HTA network

EUnetHTA Plenary Assembly

25 May 2012

Anders Lamark Tysse, DG Sanco

Presented and amended for Stakeholder Forum with permission

State of play – Directive 2011/24/EU

- **Entry into force:** 24 April 2011
- **Transposition period:** 30 months **(25 October 2013)**
- **Bilateral discussions** with 27 Member States:
  - COM questionnaire on the transposition of the measures provided for in the Directive (May – October 2011)
  - COM bilateral visits in all 27 Member States (2011 – 2012) to discuss particular issues related to transposition
- **Committee on Cross-Border Healthcare**
  - **Formal forum** created by the Directive where all 27 MS meet regularly to discuss and vote on implementing acts
  - Has already voted on the draft act setting up the eHealth network, which is now formally established.

Ongoing activities - HTA

- Kick-off meeting in Gdansk December 2011
- Spring: Bilateral meetings with interested Member States
- March-June: Ecorys study on alternative models for hosting the HTA network (governance, synergies, costs)
- May-July: Stakeholder consultation on the modalities of stakeholder consultation in the HTA network

Ecorys study

- Feasibility study necessary as future network is eligible to Union aid
- Ecorys will consider alternative hosting of the secretariat (Commission services, Member State, other)
- The study serve as a background document for future decision-making possible scenarios

Stakeholder consultation

The network shall consist of members appointed by the Member States, however…

- its work "…shall be based on […] appropriate consultation of stakeholders…" (Article 15.1)
- and Union aid may be granted to the network "…in order to […] facilitate the consultation of stakeholders on the work of the network…" (Article 15.2(e)).

- Stakeholder consultation necessary to ensure that also stakeholders outside EUnetHTA and its Stakeholder Forum have a chance to provide input

Stakeholder consultation (ii)

Duration: 2 May – 1 August

Purpose:

- Map *interest* and *capacity* of stakeholders
- Get input on possible ways/methods to consult stakeholders on the HTA network's activities
- HTA agencies can reply – see section 4 of the questionnaire

Next steps

- A consultation summary and the Ecorys study will serve as background papers for the Committee on Cross border Care
- The Committee will discuss the HTA network autumn/winter 2012/2013 (start 22 October), and vote on a draft Commission decision spring 2013
- The Commission aims at formally adopting the implementing act before 25 October 2013
- Member States will then be asked to appoint their representatives to the HTA network

Next steps (ii)

- The Network will convene and adopt its own Rules of procedure.
- If overlap with EUnetHTA members, meetings should be linked to existing EUnetHTA meetings
- Should the network's scope and working methods be re-discussed based on JA2 experience???

Other issues

WP8

Appendix 2 for Appendix 3:

Brussels, 26 April 2012

Stakeholder involvement in the Second EU Joint Action on health technology assessment (HTA)

Dear Mr. Rys,

Dear Mr. Kristensen and Mr. Rüther,

Based on the experience gained to date in the current framework of the EUnetHTA Joint Action Stakeholder Forum, we write to share our views and expectations in relation to the involvement of stakeholders in the second Joint Action on HTA.

First and foremost, it is important to stress that HTA bodies and networks should be independent. An HTA intended to support healthcare decision-making must remain independent from stakeholders' interests, whilst taking into account all relevant available information.

Nevertheless, we believe the second Joint Action on HTA could benefit from more extensive, transparent and focused consultations with stakeholders, who contribute based on their different expertise and experience, by:

- strengthening the role of the Stakeholder Forum. This pool of experts can be consulted and can provide advice according to the different perspectives and experiences represented, in addition to its role of receiving and disseminating information;
- increasing clarity with respect to the roles and responsibilities of all EUnetHTA bodies within the governance structure of the Joint Action, including the role of the Stakeholder Forum therein;
- securing timely, transparent and equitable access to the process and outputs of the Joint Action at all levels;
- adapting the forms of stakeholder involvement to the altered objectives and tasks of the Joint Action and future network;
- increasing stakeholder consultation on strategic issues (e.g. long- and short-term objectives and priorities);
- acknowledging the different nature of the various stakeholders and the different kind of input they can provide both in terms of content and resources to contribute to the work of the Joint Action and facilitate their equal participation as necessary;
- exploring new forms of dialogue such as experts' meetings and other discussion fora not limited to written comments or responses to consultations;

- involving stakeholders early and providing them with adequate time to provide input.

We believe that these principles fully reflect the concept of stakeholder consultation foreseen in Art.15 of the Directive on the application of patient's rights in cross-border healthcare (Directive 2011/24/EU).

All undersigned organisations involved in the EUnetHTA Joint Action Stakeholder Forum remain committed to bringing a valuable contribution to the EUnetHTA Joint Action and to any future EU initiatives on HTA.

We look forward to hearing from you.

Yours sincerely,

- AESGP, The Association of the European Self-Medication Industry
- AIM, Association Internationale de la Mutualité (International Association of Mutual benefit societies)
- BEUC, The European Consumers' Organisation
- COCIR, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- CPME, Standing Committee of European Doctors
- ECPC, European Cancer Patient Coalition
- EDMA, European Diagnostic Manufacturers Association
- EFPIA, European Federation of Pharmaceutical Industries and Associations
- EGA, European Generic Medicines Association
- EPF, European Patients' Forum
- ESIP, European Social Insurance Platform
- Eucomed, Medical Technology
- EuropaBio, European Association of Bioindustries
- EURORDIS, European Organisation for Rare Diseases
- GIRP, The European Association of Pharmaceutical Full-line Wholesalers
- HOPE, European Hospital and Healthcare Federation

WP8

Appendix 3 for Appendix 3:

June 15, 2012

Dear EUnetHTA Stakeholder Forum Members and Participants,

Thank you for your letter of April 26, 2012. We would like to express our appreciation of your joint effort in developing a valuable input to further improve the process of stakeholder involvement in the EUnetHTA joint actions. We acknowledge your continued commitment to bringing valuable contribution to the EUnetHTA Joint Action and to any future EU initiatives on HTA.

Your suggestions were presented at the Plenary Assembly meeting in Lisbon on May 24, 2012. As the outcome of the discussions at the meeting, where the representatives of the industry, provider and payer stakeholder group took active part, the following items were agreed upon – to take effect from beginning of the second Joint Action:

- The number of organisations per stakeholder group in the EUnetHTA Stakeholder Forum will be increased from 4 to 6
- The current two-tier system of members and participants in the Stakeholder Forum will be discontinued, i.e., all eligible organisations will have the status of Stakeholder Forum member
- The Stakeholder Forum members of a specific stakeholder group are charged to organise themselves for participation in the meetings (face-to-face and e-meetings) (with the maximum number of participants per stakeholder group limited to 6)
- New forms of stakeholder involvement (in addition to the Stakeholder Forum and SAGs) may be introduced – e.g. expert meetings – according to need
- Earlier involvement of stakeholder expertise in the specific processes of the joint actions to be considered and adequate time to provide input to be allowed while respecting the EUnetHTA joint action timelines.

We look forward to a continued productive cooperation with the stakeholders.

Yours sincerely,

Finn Børlum Kristensen
Chair, EUnetHTA Executive Committee

Mirjana Huic
Chair, EUnetHTA Plenary Assembly

Cc. Mr. Andrzej Rys, DG SANCO

WP8

Appendix 4 for Appendix 3:

Stakeholder involvement in **WP4 of JA1**

HTA Core Model and Core HTAs

THL and Agenas

Stakeholder Forum in Venice September 3rd 2012

HTA Core Model

- **Policies for using the Core Model**
  - At the moment in internal discussion (WP4 and excom)
  - After that they will be sent for SAG consultation (Oct-Nov 2012)
  - Public consultation in November 2012

- **HTA Core Model Online Tool**
  - In March 2011 some SAG members tried and provided comments for Online tool
  - There will be another opportunity in this month (Sep 2012)
  - There will be no public consultation

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Screening model received substantial input from SAG and public (1/2)

- **SAG consultation for draft report in February 2011**
  - 11 out of 12 SAG members responded
    - **Out of the 17 general comments**
      - 4 (24%) resulted in immediate or pending change in the screening model document
      - 2 were taken as suggestions for online tool and REA model developers and Core HTA coordinators
      - 5 resulted in no change
      - 6 were comments with no request for change
    - **Out of the 175 domain specific comments**
      - 108 (64%) resulted in immediate change in the screening model document
      - 7 (4%) were listed as pending improvement for the next update of the screening model
      - 10 were taken as suggestions for online tool and REA model developers and Core HTA coordinators
      - 39 (23%) resulted in no change
      - 5 were comments with no request for change

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Screening model received substantial input from SAG and public (2/2)

- **First public draft submitted for public consultation in Oct-Nov 2011**
  - 8 individuals (7 organisations) responded: 3 HTA agencies, 4 industry,
    - **Out of the 96 comments**
      - 41 (43%) resulted in immediate change in the screening model document
      - 15 (16%) were listed as pending improvement for the next update of the screening model
      - 15 were taken as suggestions for online tool and REA model developers and Core HTA coordinators
      - 12 resulted in no change
      - 13 were comments with no request for change
- **Responses were provided for each comment and communicated back to the consultees**
- **Second public draft published in March 2012**

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Core HTAs

- **Two Core HTAs**
  - *Prognostic tests for breast cancer recurrence (Oncotype DX, MammaPrint, FEMTELLE)"*
  - *Screening for abdominal aortic aneurysm (AAA)*
- **In June 2011 their protocols (the selection of assessment elements) where sent for SAG consultation.**
  - 7/12 responded to breast cancer
  - 8/12 responded to AAA

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Manufacturers' involvement during Core HTA production

- In the breast cancer Core HTA there was a need for specific information from the manufacturers of the technologies assessed (Oncotype DX, MammaPrint, FEMTELLE)
- Specific questions were collected from each domain team and then sent by the Core HTA coordinators to each manufacturer

Questions for Manufacturers

Questions about health problem and current use of the technology

Questions about technical description and characteristics of the technology

Questions about safety issues

Questions about clinical effectiveness of the technology

Questions about market and regulation

Questions about prices

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Manufacturers' involvement ctd

- All 3 Manufacturers responded actively to the questions,although providing mostly advertising information

- Information were then shared among domains and included in the Core HTAs

Upcoming activities of WP4 involving stakeholders

- **In Sep 2012 validation (involving also SAG) of**
  - The two core HTAs
  - HTA Core Model online tool
- **In Oct-Nov 2012 SAG consultation for the Core Model policies**
- **In November 2012 Public consultation of the two Core HTAs and the Core Model policies**

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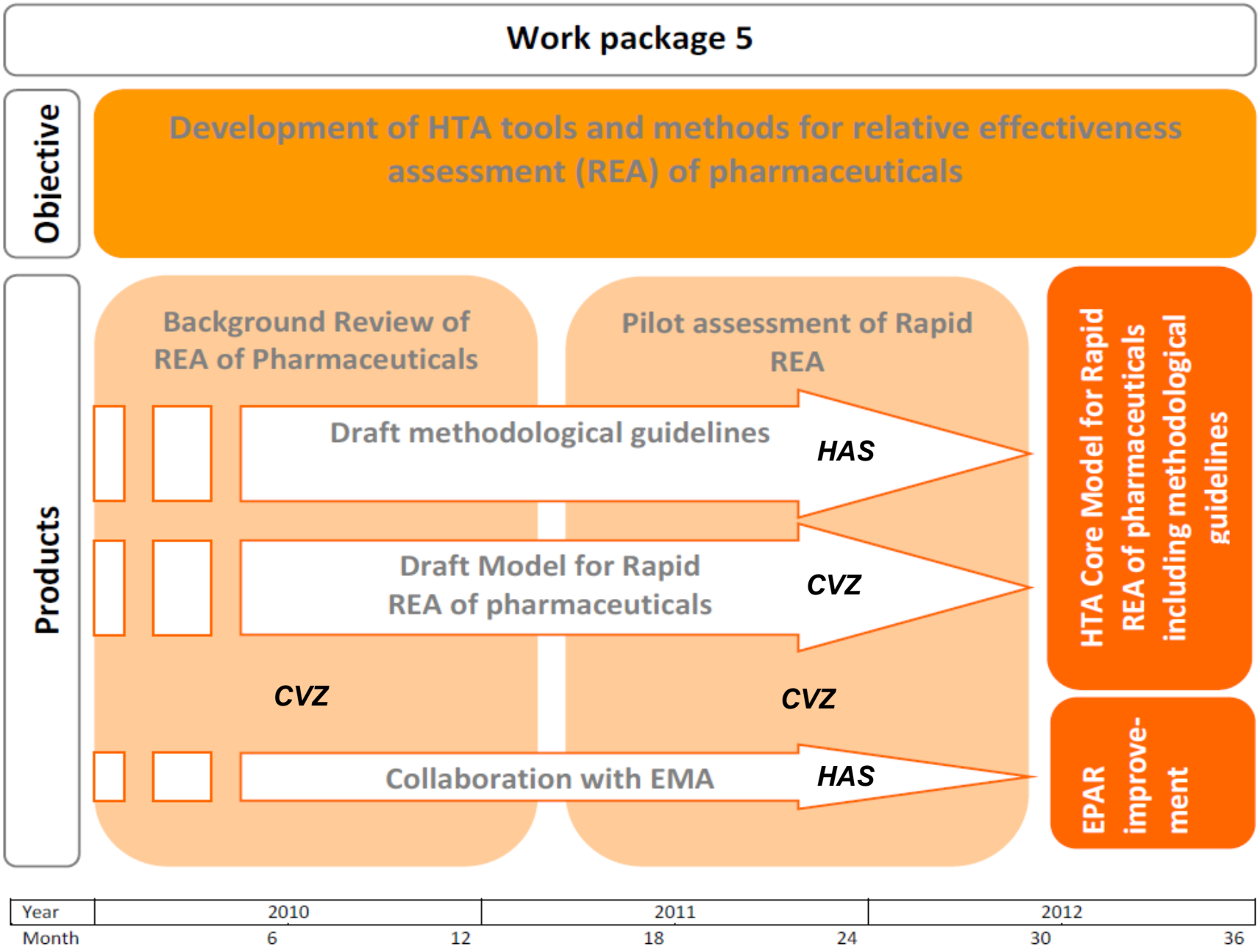
WP8

Appendix 5 for Appendix 3:

WP5 Joint Action: Stakeholder involvement

Stakeholder Forum, Venice, 3 September 2012


Work package 5
Objective
Development of HTA tools and methods for relative effectiveness assessment (REA) of pharmaceuticals
Products
Background Review of REA of Pharmaceuticals
Pilot assessment of Rapid REA
Draft methodological guidelines
HAS
Draft Model for Rapid REA of pharmaceuticals
CVZ
CVZ
CVZ
Collaboration with EMA
HAS
HTA Core Model for Rapid REA of pharmaceuticals including methodological guidelines
EPAR improve-ment
Year
2010
2011
2012
Month
6
12
18
24
30
36

Background review

- **Objective of review: To explore the main similarities and differences in the major methodological aspects of REA in multiple jurisdictions**

- Input from experts in 29 jurisdictions
- SAG consultation: 7 responses >> content related
- Public consultation: 10 responses >> content related & political statements

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Pilot Rapid REA

- **Objective of pilot: To test the draft HTA Core Model and Guidelines for Rapid Relative Effectiveness Assessment of Pharmaceuticals**

- Submission file provided by Marketing Authorisation Holder (MAH)
- MAH consultation including f-t-f meeting >> content related
- SAG consultation: 4 responses >> content related
- Public consultation: 5 responses >> content related & political statements

- **No 2nd pilot: >> topic selection procedure did not lead to topic for which we can receive a submission file. 4/4 marketing authorisation holders decided not to be involved in a pilot!!**

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HTA Core Model for Rapid REA

- **Objective of Model: develop a structured framework for Rapid Relative Effectiveness Assessment of Pharmaceuticals**

- SAG consultation: 4 responses >> content related
- Public consultation: will start 1 October 2012

Overall conclusion

+ + Valuable content related input from stakeholder advisory group that contribute to improved products

+ + Positive experience on collaboration with marketing authorisation holders for pilot

- Various consultation rounds are challenging for timelines

For WP5 Joint Action 2 input from marketing authorisation holders will be very important!

WP5 Joint Action 2: Planned Stakeholder involvement

Stakeholder Forum, Venice, 3 September 2012

WP5 Joint Action 2

- **Objective: Production of structured rapid core HTA information**

- >20 organisations
  - Lead: CVZ
  - Co-lead: LBI-HTA
- Fourteen pilot rapid assessments
  - 10 pharmaceuticals (CVZ), 4 other health technologies (eg, medical devices, interventions, diagnostics) (LBI-HTA)

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WP5 Joint Action 2

Basic principles for conducting rapid assessments:

- Other collaborative model from traditional Core HTAs:
  - 1 organisation is author, 1 organisation is co-author (thorough reviewer), Pool of reviewing organisations
- Based on submission files from MAH
  - Input from individual MAH is essential

Stakeholder involvement

- Input from SAG for specific products:
  - **Procedure manuals for JA2**
  - **Rapid assessments: All 14 or a selection?**
  - **Final procedure documents and final model for Rapid REA of pharmaceuticals**
  - **To be discussed more in detail**

- Input from marketing authorisation holders by submitting information files will be essential!

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WP8

Appendix 6 for Appendix 3:

WP5 – SG4 Joint Action 1

Stakeholder involvement

Stakeholder Forum, Venice, 3 September 2012

Mira Pavlovic (HAS, France)

WP5-SG4 Methodology guidelines

9 Guidelines:

- Criteria for choice of most appropriate comparator(s)
- Methods of comparison: direct and indirect comparisons
- Endpoints used for REA of pharmaceuticals:
  - **Clinical endpoints**
  - **Surrogate endpoints**
  - **Composite endpoints**
  - **Health-related quality of life**
  - **Safety**
- Levels of evidence:
  - **Internal validity**
  - **Applicability**

Objective:

- **Harmonise methods of assessment in Europe**
- **Help HTA assessors in rapid assessment of pharmaceuticals**

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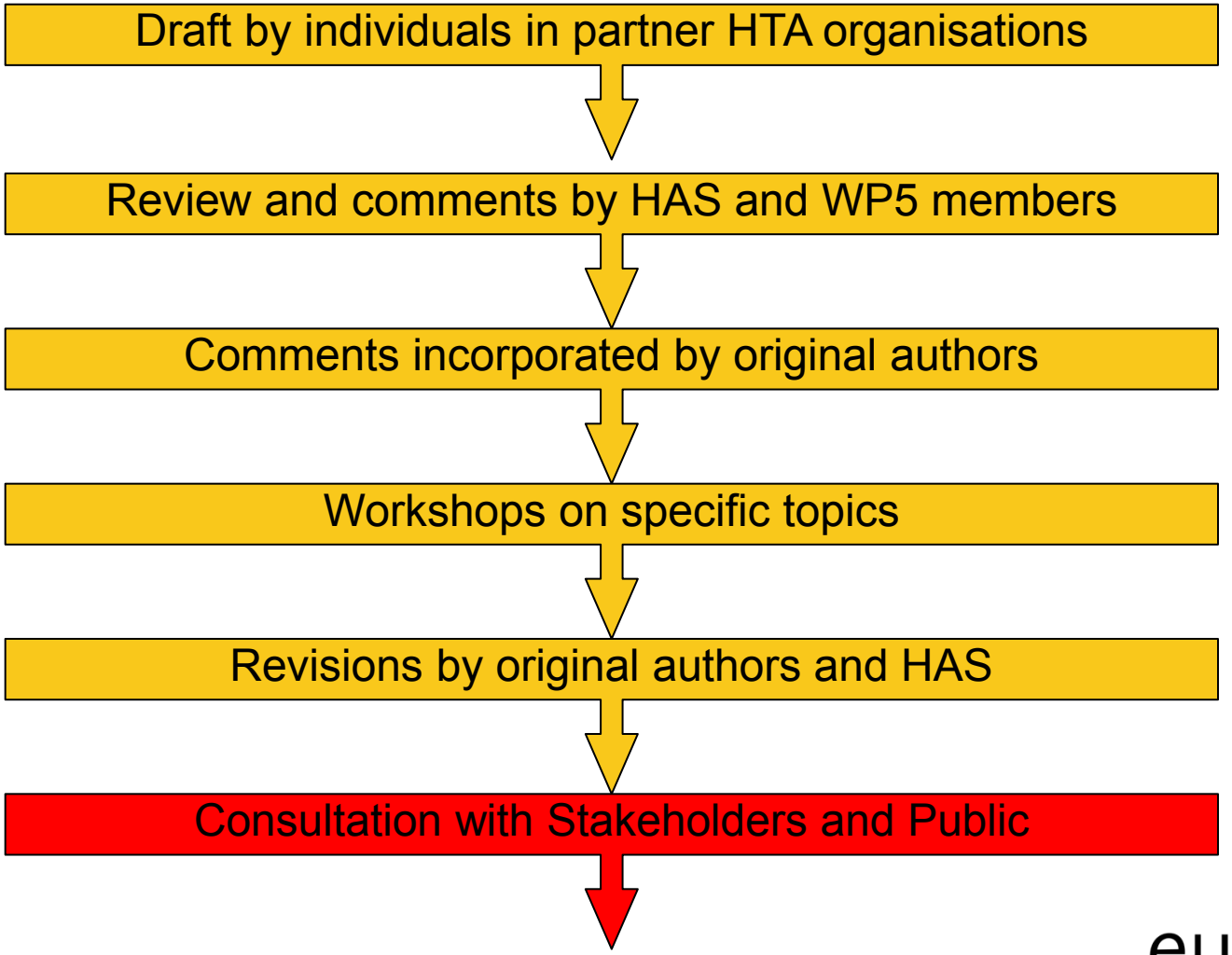
Stakeholder involvement in the process of development of Methodology GLs



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Stakeholder involvement in the process of development of Methodology GLs

WP5 and SAG consultation: Finished

1st batch (4 guidelines): 7 March – 13 April 2012

2nd batch (5 guidelines): 18 April – 21 May 2012

- Huge number of comments
- Some comments from SAG will be addressed at the same time as EMA and public consultation comments

EMA and Public consultation (including alert to MEDEV, AHRQ, PBAC, Vancouver group): Ongoing

1st batch: Choice of comparator, composite EP, surrogate EP and applicability: **29 June – 10 Sept.**

2nd batch: Direct and indirect comparisons, clinical EP, HRQoL, safety and internal validity: **3 Sept. – 30 Oct.**

Final guidelines: end of 2012

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Stakeholder involvement

- **Valuable comments** from SAG contributed to improved methodology draft guidelines before public consultation
- **Further input** expected from SAG and Industry during EMA and Public consultation
- **Possible meeting on endpoints** with EFPIA and stakeholders to discuss common endpoints-related issues before finalisation of GLs: date TBD

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Early dialogues

- **Part of EUnetHTA JA2**
- **JA2 WP7 "improvement of evidence generation for all HT":**
  - early dialogue
  - disease-specific guidelines for technology developers
  - general methodology guidelines
  - additional evidence generation
- **2 preparatory early dialogue pilots conducted before start of JA2**
  - 1st pilot early dialogue meeting: **30 May 2012**
  - 2nd pilot early dialogue meeting: **2 July 2012**

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Preparatory early dialogue pilots

- **Coordinated and hosted by HAS**
- **Participating HTA organisations: IQWIG, GBA, KCE, INAMI, HVB, CVZ, AIFA and NICE**
- **Experience on 2 drugs in oncology with participation of one small and one big company**
  - New HT with supposed added benefit for patients
  - Prospective questions (and position) pertaining to clinical relative effectiveness, economical and other aspects, relevant for the development plan
  - Development strategies, cost-effectiveness studies
  - Non binding and confidential

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Preparatory early dialogue pilots Gained experience

Successful experience

Excellent possibility to test

- Feasibility
- HTA bodies collaboration/governance issues,
- HTA prospective thinking on evidence requirements based on 2 examples
- Draft procedure

Help define how we want to work in future (JA2) including cooperation with EMA

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WP7 Joint Action 2: Planned Stakeholder involvement

Development of consensus on HTA methodologies

EunetHTA JA2 (2012-15): lead HAS, co-lead IQWIG

- **WP7 : Increase the quality of evidence generation (all HT)**
  - Initial evidence:
    - Early Dialogue
    - Disease-specific guidelines
  - Additional evidence : Common core protocols
- **Harmonise methods of assessment (all HT)**
  - Methodology guidelines
  - « Core HTA information »

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Methodology and disease-specific guidelines

Methodology guidelines extended to all HT

- Coordinated by IQWIG
- Topics TBD
- Involvement of stakeholders in the development process

Disease-specific guidelines

- Coordinated by HAS
- Topics TBD
  - With treatments involving not only pharmaceuticals
  - With large impact on Public Health
- Involvement of stakeholders in the development process

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Early dialogues

Drugs AND non-drug technologies

- **5 pilots for drugs** planned for end 2012-13 (meeting schedule in process)
- **1 pilot for a medical device/procedure**

→ Feed-back and input from companies expected to improve the process

Extended number of involved HTA bodies

Cooperation with EMA

Possibility to test

- EUnetHTA methodology GLs in real examples of product development
- Consolidated view/agreement on the choice of comparators and endpoints for REA

→ Help in the development of disease-specific guidelines

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WP8

Appendix 7 for Appendix 3:

JA1 WP 7 New Technologies

Stakeholder involvement

Mira Pavlovic (HAS, France)

WP 7 Objectives

- **Strand A (HAS, Fr)**
  Facilitating evidence generation on new HT

  3 deliverables:
  - criteria to select new technologies in need of further evidence
  - minimum dataset to share information on policy relevant clinical studies in development (developped by NETSCC)
  - database (EVIDENT) to share information & facilitate collaboration on additional evidence generation

- **Strand B (LBI-HTA, At)**
  Facilitating exchages on current assessment projects

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Stakeholder involvement in WP7

- Only for Strand A
- 15 representatives from 12 organisations (CPME, HOPE, AIM, ESIP, AESGP, COCIR, EDMA (2), EFPIA (2), EUCOMED, EuropaBio (2), EPF and EURORDIS)
- Stakeholders involved in two different ways:
  1. through Stakeholder advisory group (SAG): reviews of the first drafts of the 3 WP7A deliverables
  2. through Public consultation on final versions of deliverables on EUnetHTA's website

Experience from JA1

- Development of the 3 WP7 A deliverables was based on literature review, surveys and testing among WP7A partners and consultation

- Overview of Stakeholders' involvement in the development of the 3 deliverables:

  1) Selection criteria:

  - SAG consultation on the first draft (April 2011):

    8/12 responses (representatives of industry, health care providers and payers)

  - Public consultation on the final draft (June 2012):

    6/12 members participated (representatives of industry, health care providers and payers)

Experience from JA1 (ctd)

2) Dataset (developed by NETSCC)

- SAG consultation on the dataset proposal (May 2011):

4/12 responses (representatives of industry and payers)

3) EVIDENT database

- SAG consultation on the first proposal (September 2011):

8/12 responses (representatives of industry, health care providers and payers)

- Public consultation on the final proposal (December 2011):

4/12 SAG members participated (industry representatives)

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Experience from JA1 (ctd)

- All tasks were performed according to the Workplan and the Standard procedure for stakeholder involvement
- Responses were heterogeneous: from short-ones to very elaborated-ones
- Feedback helped improve the deliverables
- Great interest expressed for the deliverables, especially by industry representatives

* Update on WP7A deliverables

- Dataset: delivered to HAS in June 2011 and integrated into EVIDENT database
- Criteria: published on EUnetHTA's website in August 2012
- EVIDENT: launch planned for the end of September 2012

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Plans for JA2

WP7: Methodology development and evidence generation: guidelines and pilots production

- **General information:**

- Lead: HAS; co-lead partner IQWIG
- 17 associated partners
- developed on the basis of JA1 WP7 and WP5 actions

- **Specific objectives and deliverables:**

– to develop, implement, and pilot models, tools and processes to support collaborative production of HTA and improve quality of assessments:
  - o guidelines on the assessment of drug and non drug technologies
  - o process to updating the guidelines regularly

– to develop methodological basis for EU collaboration on HTA and to improve quality of initial and additional evidence generation for HTA
  - o Early dialog and therapeutic area specific advice : overview, guidelines and pilots
  - o Additional evidence generation : guidelines on how to formulate a research question, on how to request appropriate trial design, pilot on common core protocol

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WP8

Appendix 8 for Appendix 3:

Stakeholder involvement in **WP4 of JA1**

HTA Core Model and Core HTAs

THL and Agenas

Stakeholder Forum in Venice September 3rd 2012

HTA Core Model

- **Policies for using the Core Model**
  - At the moment in internal discussion (WP4 and excom)
  - After that they will be sent for SAG consultation (Oct-Nov 2012)
  - Public consultation in November 2012

- **HTA Core Model Online Tool**
  - In March 2011 some SAG members tried and provided comments for Online tool
  - There will be another opportunity in this month (Sep 2012)
  - There will be no public consultation

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Screening model received substantial input from SAG and public (1/2)

- **SAG consultation for draft report in February 2011**
  - 11 out of 12 SAG members responded
    - **Out of the 17 general comments**
      - 4 (24%) resulted in immediate or pending change in the screening model document
      - 2 were taken as suggestions for online tool and REA model developers and Core HTA coordinators
      - 5 resulted in no change
      - 6 were comments with no request for change
    - **Out of the 175 domain specific comments**
      - 108 (64%) resulted in immediate change in the screening model document
      - 7 (4%) were listed as pending improvement for the next update of the screening model
      - 10 were taken as suggestions for online tool and REA model developers and Core HTA coordinators
      - 39 (23%) resulted in no change
      - 5 were comments with no request for change

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Screening model received substantial input from SAG and public (2/2)

- **First public draft submitted for public consultation in Oct-Nov 2011**
  - 8 individuals (7 organisations) responded: 3 HTA agencies, 4 industry,
    - **Out of the 96 comments**
      - 41 (43%) resulted in immediate change in the screening model document
      - 15 (16%) were listed as pending improvement for the next update of the screening model
      - 15 were taken as suggestions for online tool and REA model developers and Core HTA coordinators
      - 12 resulted in no change
      - 13 were comments with no request for change
- **Responses were provided for each comment and communicated back to the consultees**
- **Second public draft published in March 2012**

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Core HTAs

- **Two Core HTAs**
  - *Prognostic tests for breast cancer recurrence (Oncotype DX, MammaPrint, FEMTELLE)"*
  - *Screening for abdominal aortic aneurysm (AAA)*
- **In June 2011 their protocols (the selection of assessment elements) where sent for SAG consultation.**
  - 7/12 responded to breast cancer
  - 8/12 responded to AAA

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Manufacturers' involvement during Core HTA production

- In the breast cancer Core HTA there was a need for specific information from the manufacturers of the technologies assessed (Oncotype DX, MammaPrint, FEMTELLE)
- Specific questions were collected from each domain team and then sent by the Core HTA coordinators to each manufacturer

Questions for Manufacturers

Questions about health problem and current use of the technology

Questions about technical description and characteristics of the technology

Questions about safety issues

Questions about clinical effectiveness of the technology

Questions about market and regulation

Questions about prices

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Manufacturers' involvement ctd

- All 3 Manufacturers responded actively to the questions,although providing mostly advertising information

- Information were then shared among domains and included in the Core HTAs

Upcoming activities of WP4 involving stakeholders

- **In Sep 2012 validation (involving also SAG) of**
  - The two core HTAs
  - HTA Core Model online tool
- **In Oct-Nov 2012 SAG consultation for the Core Model policies**
- **In November 2012 Public consultation of the two Core HTAs and the Core Model policies**

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WP8

Appendix 9 for Appendix 3:

EUnetHTA Joint Action 2
Work Package 4

Lead Partner : Agenas

September 3rd, 2012

EUnetHTA JA2-WP 4

Testing collaborative production of HTA information for national adaptation and reporting

1. Partners

- ***17 ASSOCIATED PARTNERS***
- ***7 COLLABORATING PARTNERS***

EUnetHTA JA2-WP 4

2. Objectives

- ***Test the capacity of national HTA bodies to produce structured core HTA information together and apply it in national contexts***

3. Deliverables

- ***3 Full Core HTAs***

EUnetHTA JA2-WP 4

4. Methods

1. *A methodological guidance for partners collaboration will be produced on the basis of JA1 experience.*
2. *Topic selection and prioritisation procedures will be set up and tested to capture topics of common interest with the aim to facilitate collaboration among the partners without overloading them.*
3. *Clusters of agencies/researchers will be organised according to the preferences and specific expertise so that all partners can be involved and will collaborate to produce Core HTAs and Core HTA structured information.*
4. *Simultaneous pilot production of local/national reports using Core HTAs and core HTA information will be carried out to combine core information with locally produced information.*

EUnetHTA JA2-WP 4

5. Stakeholder Involvement (preliminary)

Timing (preliminary)	Type of involvement	Topic	Notes
Fall 2012-2013	SAG	Topic selection and prioritization procedures draft	Feedback will be used to improve methodology
2013	SAG	1st draft of 1st core HTA protocol	Feedback will be used to improve document .Experts from stk groups can be invited during activities according to the needs
2014	Public	1st core HTA	
2014	SAG	1st draft of 2nd core HTA protocol	Feedback will be used to improve document .Experts from stk groups can be invited during activities according to the needs
2014-2015	Public	2nd core HTA	
2015	SAG	1st draft of 3rd core HTA protocol	Feedback will be used to improve document. Experts from stk groups can be invited during activities according to the needs
2015	Public	3rd core HTA	
2013-2015	SF	Updates on ongoing activities	