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

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Gordana Kalan Zivcec	Gordana.KalanZivcec@zzs-mcs.si	**CPME (Standing Committee of European Doctors)**
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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