# EUnetHTA / Medical Technology[1] - HTA Expert meeting

**16 October 2015**, rue Joseph II 40, 1000 Brussels

## Summary of Discussions

## Agenda

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| **9:30 – 10:00** | **Registration and Coffee** |
| **10:00 – 10:20** | **Welcome and Introduction** |
| | **The value and impact of EUnetHTA JA2 concrete experiences** |
| **10:20 – 11:10** | **Rapid REA on medical devices including application of the submission template (WP5 strand B/WP7 SG4)** |
| **11:10 – 12:00** | **Core HTA (WP4)** - Core HTA on Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening & Core HTA on Structured telephone support (STS) for adult patients with chronic heart failure |
| **12:00 – 12:30** | **Methodological guidelines on medical devices (WP7)** |
| **12:30 – 13:00** | **Early Dialogue for IVDs (WP7)** |
| **13:00 – 14:00** | **LUNCH** |
| **14:00 – 15:00** | **Views on successes, value and impact of JA2 collaboration for non-pharma technologies** |
| **15:00 – 15:30** | **Coffee break** |
| **15:30 – 16:50** | **Teaming up for value - views on how the HTA cooperation could be of value and could be impactful in the next JA3 and beyond** |
| | • Introduction on the status of JA3 – latest developments (DG SANTE)<br>• Concrete suggestions of approaches and activities in the future European HTA cooperation and stakeholder involvement modalities in JA3 |
| **16:50 – 17:00** | **Conclusions and closing of the meeting** |

[1] Medical Technology = Medical Devices, In-vitro Diagnostics, Medical Imaging and Health ICT

## The value and impact of EUnetHTA JA2 concrete experiences

Alternate presentations were made by industry and EUnetHTA representatives:

Rapid REA: Adrian Griffin/Anna Nachtnebel and Zoe Garrett; Core HTA: Karsten Berndt/Tom Jefferson; Methodological guidelines: Pascale Brasseur/Jorg Lauterberg; Early Dialogue: Karsten Berndt/Francois Meyer

***Key comments on the experience:***

- Medical technology (MedTech) industry expressed a view that there is a lack of clarity on the justified differences in methodologies applied and consequent processes utilized to assess medical technologies (see definition of a "medical technology" in the footnote on p.1) in comparison to pharmaceuticals

- The MedTech industry associations are requesting to be more actively involved in the development of the methodological guidance regarding assessment of medical technologies. Establishing a "pool" of methodological experts on assessment of medical technologies could be helpful

- MedTech industry expressed high level of anxiety[2] regarding potential negative consequences of the EUnetHTA methodological guidance for medical technology assessments, ie, the guidance can be perceived as directly "prescriptive" and applicable for a concrete assessment of a specific type of medical technology and would lead to unfair and wrong HTA results / conclusions. The EUnetHTA representatives responsible for the guidelines work explained that the guidance provided in the current EUnetHTA methodological guidelines is at the general level and therefore, any perceived risk of inappropriate application of the guidelines' content by EUnetHTA is theoretical. These EUnetHTA representatives further clarified that the guidelines which were originally developed for REA of pharmaceuticals were reviewed, updated and adapted with a general approach to medical technology without aiming at giving very specific recommendations addressing the particular nature of a medical technology, ie, IVD, or medical devices or medical Imaging or health ICT. The meeting participants agreed that there is a necessity to develop methodological guidance for specific types of medical technology – a guidance that addresses with specificity the various medical technologies' types, eg, a specific methodological guideline on HTA of in-vitro diagnostics.

- MedTech industry expressed their perception of "confusion" in the logic and process of identification of topics for joint assessments of medical technologies. The MedTech industry highlighted that whilst there was a clear 'trigger' for the pilot REAs of pharmaceuticals (EMA approval), there was no similar 'trigger' applied to the pilots of medical devices. The devices selected for pilot REAs had been on the market for between 0 and 7 years, which meant it was impossible for companies to predict likely pilots, and more importantly, companies were often required to divert resources from other projects to resource the EUnetHTA pilot, with little indication on how the process may influence access decisions down the line.

- The definition of the "fit-for-purpose" HTA including joint assessment at the European level includes "timely informing decision-making on public health matters" as one of the features of the fit-for-purpose HTA. MedTech industry expressed their need to know assessment criteria early on to have data to inform such decision making.

- The MedTech industry questioned the need for the pilot process to deliver REAs in a proposed shorter timeframe than required for pharmaceutical REAs. It was highlighted that whilst 'rapid' is important for drugs, where the report is required within a specific time window of EMA approval, the device pilots were often taking place many years after receiving a CE-mark. It was therefore, argued by the MedTech industry that it is necessary for EUnetHTA to identify why the 'rapid' review was being undertaken for a particular device; what question was being addressed, and preferably, what decision was being influenced, so that the urgency, and therefore

[2] Specifically, EDMA pointed out that in vitro diagnostics were out of scope of the EUnetHTA eight-adapted-methodological-guidelines for relative-effectiveness assessment of medical technologies (adapted from the JA-1 guidelines intended to pharmaceuticals by using a methods of 'wording replacement' as stated by EDMA). Given that under EDMA's view the applied method of adaptation is not fit-for purpose to produce guidelines with the needed quality to support HTA assessors facing methodological challenges in the assessment of In Vitro Diagnostics EDMA suggested that the phrase "IVDs are out of scope of these guidelines' should be clarified in the scope section of the 8 guidelines

appropriate timeframe /duration of the review, could be appreciated by industry participants. It is necessary for both industry and HTAs to see the development of joint assessment process as an undertaking in motion – it is not yet stabilized as a fully standardized process. Changes in the process have been made during the 3 years of JA2 to implement learnings from the earlier pilots, eg recognition of the challenges and initial adjustments in process of scoping and joint assessment.

- Expectations to the joint assessments of non-drug technologies as being similar to the joint assessments of pharmaceuticals in its timing, start, composition of partners, etc are not appropriate. It is not appropriate to judge the process using the same criteria and parameters applicable to the joint assessment of pharmaceuticals

- Relevance of the joint assessment results on national level should be thoroughly considered during the scoping phase with an appropriate assurance of relevance of the topic and consequent research questions from the national decision-makers. Any (additional) information request to the manufacturers from HTAs should be supported by the requests' clearly established relevance to the national decision-making process

- Application of the HTA Core Model® should utilize its full potential as being a flexible framework. Not only "full" or "rapid" HTAs (in their current form at the time of JA2) should be produced – needs of the users of the HTA information and product characteristics should define the extent to which the "building-brick-structure" of the HTA Core Model is applied.

- Broader perspective on value offered by the HTA Core Model allows alignment of needs of HTAs (to have required evidence to perform assessment) and interests of the manufacturers (to provide appropriate evidence supporting their value claims on a specific technology). Such alignment facilitates cooperation between the two parties in joint assessments provided there is a clear link of the joint assessment to the decision-making at national level

- Clear governance for stakeholder engagement and its consistent application across all European activities associated with the joint work/assessment on medical technologies is needed for a success of the European cooperation on HTA

- Proactive, collaborative, inclusive stakeholder involvement is needed to define sustainable modalities and activities of the HTA cooperation in Europe for medical technologies.

## Views on successes, value and impact of JA2 collaboration for non-pharma technologies. Teaming up for value - views on how the HTA cooperation could be of value and could be impactful in the next JA3 and beyond

The European Commission representative presented an update on the developments at the HTA Network level (Sevala Malkic), the EUnetHTA Secretariat representative shared some considerations on the approaches to stakeholder involvement in JA3 (Julia Chamova), and industry representatives provided MedTech industry perspective on the next steps (Yves Verboven (EUCOMED), Nicole Denjoy (COCIR), Victoria Wurcel (EDMA), Sophie Cross (EUCOMED) and Marcus Ott (EUCOMED)

***Key comments from the discussion:***

- Scaling up of joint assessment production must be carefully weighed against operational readiness of all parties – not least HTA organisations themselves – to fully and committedly engage in these activities. Joint production process seems to need further improvement to achieve the overall goal of improving efficiency of HTA. However, improvement of the joint production process should not be a goal in itself – national utility of the joint production results for the national HTA and decision-making purposes must be the primary objective of the joint assessment production. It was further suggested by the MedTech industry that they would be ready to collaborate on describing the links between HTA and decision-making in various national settings

- EUnetHTA partner organisation representatives at the meeting indicated that the medium and small size EU countries have already experienced the value added of the European cooperation on HTA, not least in the area of assessment of medical technologies, demonstrated via adaptation of the results of joint assessments growing each year of JA2 – examples of it can be found at the EUnetHTA public website

- Engagement of the MedTech industry – both at the level of umbrella organisations and individual technology producers – in the joint assessments and in other activities of EUnetHTA is affected by the EUnetHTA ability to clearly demonstrate benefits of such engagement compared to costs associated with such participation (eg, opportunity costs of engagement of companies' staff, sharing of confidential information on technologies to be assessed in a joint process, etc)

- Efficiency gains due to joint assessments and establishment of clear value-added at the national level should be among the focus points of the JA3 (the official start of the JA3 proposal development was on October 15)

- MedTech industry reiterated that appropriate process and procedures associated with handling confidentiality issues, timelines and study design are important factors for the industry when assessing their readiness to get practically engaged in the joint assessment process at the European level. The joint assessment process should be improved on these parameters and appropriate standardization of procedures should be implemented

- With regards to the process and content of the Early Dialogues activities, it was suggested to further look into the requirements and implementation details regarding evidence requirements, confidentiality, application of the HTA Core Model structure, and clinically relevant endpoints.

- It was suggested that clear coherence and consistency in European activities from early dialogues, to joint assessments to additional evidence generation could bring further understanding and contribute to the improved medical technology companies' willingness to engage. It was strongly supported that the HTA Core Model is a pragmatic framework and a tool for practical implementation of such consistency and coherence along the life cycle of technology.

- MedTech industry requested in the next phase of development, ie, JA3, more targeted effort by the European cooperation on HTA, specifically its scientific and technical level, to address in their joint activities and processes the issues of predictability and "fit-for-purpose" with regards to national decision-making processes

- It was discussed that rapid technological change leading to development of integrated solutions in medical technologies combining IT, pharmaceuticals, telecommunications, etc will pose the next real challenge to HTA processes

- Recognition of the specificity of various medical technologies through differentiated practical approaches when assessing these technologies and finding effective practical ways of engagement in a constructive dialogue is needed

- Representatives from both HTA organisations and medical technology companies that collaborated in JA2 expressed general willingness to further cooperate based on the lessons learned from the experience of JA1 and JA2[3]

- It is important to identify concrete end goals of the European cooperation on HTA and ambitions at the EU level that are shared by all stakeholders in this cooperation, not only by the HTA organisations participating in the network activities

[3] EUCOMED representative strongly expressed the view of little if any value achieved in JA2 regarding medical technology assessment and a perceived increased request on resources which SMEs were not able to address – moreover, SMEs allegedly commented on "increased burden of access to innovation".

- It was further commented that defined goals at EU level need to be translated into concrete actionable tasks and objectives where pragmatic approach to feasibility of implementation leading to positive impact at national level will dictate setting of priorities for action

- Transparency on which decision-makers and how their needs are served by the joint action at the EU level is important to deliver in JA3

- Specifically, HTA at hospital level and relation to the standardization and cooperation efforts at EU level would need to be pragmatically addressed in JA3

- MedTech industry was explicitly requested to come up with specific solutions that would improve their engagement and involvement in the European cooperation on HTA. The target "population" for these solutions should not include only the HTA organisations as the ones to be responsible for implementation but also the medical technology industry itself in order to share the responsibility and increase ownership for improvement steps and support the industry's own drive to become an "equal partner at the table" of the EU cooperation on HTA

- The MedTech industry proposed establishment of a dedicated platform at the strategic level of the European cooperation on HTA, ie, the HTA Network, to discuss medical technology issues. Specific proposal will be shared with the HTA Network Secretariat in the nearest future

Presentations made at the meeting are available as stand-alone documents at www.eunethta.eu (except the one about early dialogues from the IVD industry perspective).

## List of participants

**EUnetHTA secretariat and WP leaders or co-leaders**

1. Lidia Becla, EUnetHTA Secretariat / DHA, Denmark
2. Julia Chamova, EUnetHTA Secretariat / DHA, Denmark
3. Tom Jefferson, WP4: Agenas, Italy
4. Gottfried Endel, WP4/5: HVB, Austria
5. Mirjana Huic, WP4/5: AAZ, Croatia
6. Claudia Wild, WP5: LBI-HTA, Austria
7. Anna Nachtnebel, WP5: LBI-HTA, Austria
8. Francois Meyer, WP7 SG1: HAS, France
9. Naomi Fujita-Rohwerder, WP7 SG3: IQWIG, Germany
10. Jörg Lauterberg, WP7 SG3: IQWIG, Germany
11. Petra Schnell-Inderst, WP7 SG3: UMIT, Austria
12. Nick Crabb, WP7 SG4: NICE, UK
13. Zoe Garrett, WP7 SG4: NICE, UK

**European Commission**

14. Sevala Malkic, European Commission

**COCIR, EDMA, and Eucomed**

15. Nicole Denjoy, COCIR
16. Yves Verboven, Eucomed & EDMA
17. Victoria Wurcel, EDMA
18. Pascale Brasseur, Medtronic
19. Sophie Cros, Abbott Vascular
20. Karsten Berndt, Roche Diagnostics
21. Adrian Griffin, Johnson & Johnson
22. Bernd Hofmann, Siemens
23. Seong Chen, Roche Diagnostics
24. Markus Ott, Bayer
25. Christine Muzel, Philips
26. Geoffrey Wilson, GEHC
27. Zuzana Pisano, Eucomed
28. Colin Hopley, BD
29. Marcus Simon, SJM
30. Magdalena Madolska, COCIR