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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
e-Health and Health Technology Assessment

Brussels, 20 January 2015

APPROVED MINUTES OF THE 5TH HTA NETWORK MEETING

THURSDAY 29 OCTOBER 2015

1. INTRODUCTION

These minutes are prepared by the Secretariat of the Health Technology Assessment Network ("HTA Network") in accordance with the rules of procedure.

All Member States (MS) and Norway, as well as the EUnetHTA secretariat were present. Iceland was excused. In addition, the five stakeholder representatives attended as observers.

The meeting was chaired by Andrzej Rys Director of Health Systems and Products with the European Commission.

The organisations of St Jude Medical, Reseau des Acheteurs Hospitaliers (RESAH) and the PARENT secretariat were introduced as invited speakers. They were only present during their individual presentations.

No interest was declared during the assessment of a potential conflict.

Presentations are available on the HTA Network website.

2. OPENING AND WELCOME

The Chair, Andrzej Rys, welcomed participants and underlined that cooperation on HTA is a high priority for the European Commission and will continue to be so for the future.

Professor Jean Luc Harousseau, President of HAS (Haute autorité de santé) hosting organisation of the meeting, made an opening speech.

The Chair continued by introducing the different topics of the day and stressed the importance of the discussion on medical devices and health economic aspects.

The Members were informed that representatives of Medical Technologies (MedTech) had sent a letter to the EC on 27 October (copy circulated).

The agenda was approved unanimously.

3. PREPARATION OF EUNETHTA JOINT ACTION 3 – LESSONS LEARNT FROM JOINT ACTION 2

The Chair introduced the topic by stressing the importance of bringing the knowledge from the previous EUnetHTA Joint Action 2 into the coming Joint Action 3 as well as discussing the preparatory work of the coming Joint Action. The topic was further elaborated by the presentations on "Lessons learnt" from the present coordinator of EUnetHTA JA2 Danish Health Authority (DHA) and the representatives of all stakeholders.

3.1. EUnetHTA coordinator report to the Network on lessons learnt from JA2 - Finn Børlum Kristensen, Director, EUnetHTA Secretariat

The EUnetHTA coordinator introduced the work of the present Joint Action while also stressing the important way forward. In particular, he emphasised the important question on where "we" want to be in 2019 regarding the EU cooperation on HTA. In that regard, it was stressed that the future system should have joint assessments that fit national processes and that local HTA reports should be in a format allowing efficient cross-border utilisation. A support structure is also needed including maintained tools and process support. In addition, there is a need to establish that the future cooperation finds appropriate ways on how to inform policy. His presentation identified challenges for establishing the robust and efficient network.

As regards the HTA Network development the presenter emphasised clarity and remit (political vs scientific and technical), engagement with stakeholders, diversity of nominated partners, respecting Member States' competences, and voluntary participation with an obligation to contribute. Finally, the vision of 'zero-duplication', integrated coordination, professionalism, mutual understanding and prioritisation were highlighted.

3.2. Stakeholder representatives report to the Network on lessons learnt from JA2

The input on "Lessons learnt" was presented by following representatives of stakeholder groups: Patients (Jamie O'Hara, European Haemophilia Consortium); Industry (by Andreas Rappagliosi, EFPIA); Payers (by Christine Dawson, European Social Insurance Platform); Providers (by Rosa Giuliani, European Society for Medical Oncology) and Stakeholder Forum EUnetHTA (by François Houÿez co-Chair EUnetHTA)

All stakeholders described the lessons learnt from their interactions with EUnetHTA Joint Action 2. A conclusion was presented by François Houÿez, EURORDIS co-Chair with the EUnetHTA stakeholder forum.

3.2.1. Stakeholder group - Patients

The presenter emphasised that HTA bodies should define appropriate methods by which they can obtain patients input. Patients should be at a minimum involved as observers at the appraisal phase. Assessment processes should have a timely launch, where Relative Effectiveness Assessment (REA) preparation should start at the submission of a marketing authorisation application with the inclusion of patient organisations.

Transparency was emphasised especially regarding the topic selection which potentially may include obsolete technologies. It was suggested to consider topic proposals by patients.

Finally, the presenter suggested that HTA reports include a general opinion on the added value for the health technologies assessed, and should be adapted to different audiences. Access to information on reimbursement, coverage and assessment status of promising technologies is key.

3.2.2. Stakeholder group Providers

The presenter emphasised the importance that health care providers (HCP) are recognized having a specific identity and are included in HTAs. Participation may be different since providers may consider other economic and technical criteria which may be associated to other assessment elements such as societal impact "on the field". Furthermore, the difficulty of integrating highly specific or specialised processes for providers coming from the concrete world of healthcare was mentioned. In that, the sometimes steep learning curves were presented and also how to ensure the appropriate presence of the providers.

On how to proceed in the coming joint action, the presenter asserted that the current platform of involvement of HCP in the Stakeholders Forum is good for sharing information and regular updates. However, the input of HCP as stakeholders may be limited. Therefore it is suggested that one should envisage the earlier and proactive contribution of health care providers in specific activities.

At scientific level, the inclusion of HCP at an earlier stage is suggested where a call of participation and specific assessment may be discussed and agreed at the Forum level. Potentially the development of the model of inclusion of stakeholders could be a deliverable per se.

3.2.3. Stakeholder group Payers

The presenter emphasised that the EU collaboration has become even more urgent where cost-effectiveness and relative effectiveness presents areas for strengthened collaboration. Preferably, the cooperation should include the EU 28. EU collaboration should never lead to a lowering of the quality of assessments.

For the continuation of collaboration, the presenter emphasised that the cooperation should have political support and that HTA is increasingly used for pricing and reimbursement decisions. Transparency of processes as well as quality monitoring is important. Furthermore, a focus should be on re-use of joint work.

Regarding, involvement of payers, it was suggested to shift from being a general observer to active involvement. In that, participation in priority setting as well as in the national implementation and impact evaluation was suggested. Furthermore, one called for being involved in the work on evidence generation and joint re-assessment post-reimbursement decision and possibly the development of coordinated access schemes.

3.2.4. Stakeholder group the Industry

The presenter introduced the presentation into two sections, one for medical technologies and one for pharmaceuticals.

2.2.4.1 Medical technologies

From the perspective of medical technologies presenter emphasised that the work in their respective sectors is challenging and specific. Furthermore, joint work is stressed to have not been widely taken up by Member States. It was further emphasised that one need to acknowledge the specificities of medical technologies. These include features of the existing different European access models where joint HTA should not duplicate by mixing with CE marking processes, but to keep focus on effectiveness or utility of medical technologies.

Joint EU HTA initiatives should be conducted based on policy and access related demands of MS. Development of appropriate methodologies that comprehensively assess their value. To achieve this, representatives of medical technologies call for the setup of a dedicated EU Commission supported multi-stakeholder dialogue platform with seats for the medical technologies at the HTA Network level, implemented through specific meetings and reflections on value and assessment of medical technologies

2.2.4.2. Pharmaceuticals

As for pharmaceuticals, it was reiterated that HTA agencies can work together; EUnetHTA Joint Action 2 showed that HTA agencies can successfully conduct European assessments of relative efficacy and effectiveness.

There was a call for that future joint work should focus on clinical aspects of HTA only (relative efficacy and effectiveness assessment) as other elements are context specific; general methodological guidelines could cover non-clinical domains.

There was also a call that Member States should commit to integrating European assessments. In that the future Join Action 3 will be an important instrument. It was iterated that this will reduce duplication and increase quality and efficiency. Any JA3 activity needs to support this overall goal.

3.2.5. Summary by co-chair of Stakeholder Forum of EUnetHTA

The presenter showed the common messages as regards process as well as content and output. On processes it was emphasised that engagement of stakeholders needs a dedicated framework led by HTA bodies and tools. Furthermore, it was stressed that one should move beyond current involvement mechanisms in order to develop collaborative processes including priority setting scoping, assessments, reports and reviews.

On the content and output, common features were that there is a need to allocate resources which generates the most added values. Furthermore, scientific work should be of good quality, recognised and appreciated. Joint Assessments should include a conclusion.

It was argued that there is a need for a common approach for cost and economic aspects. Finally, there was a call for that HTA timelines should be better aligned with the needs of decision makers.

3.2.6. Discussion

Following the presentations on “Lessons learnt” from JA2 by the coordinator and the stakeholders the following points were discussed.

- How to ensure timeliness of HTA and inclusiveness of stakeholders. Importance of timely HTA which accommodates the needs not only of national timing and priority settings constraints, but also to ensure patient access to true innovative treatments.

- The EU cooperation on HTA is moving rapidly both at the political level and scientific and technical level. In that regard, some members raised the need to ensure transparency and also the uptake of joint work and/or local reports.

- The European Commission would in line with the discussion on reuse also address the legal barriers of reuse in the respective MS.

- The European Commission also mentioned issues of topic selection among MS.

4. PREPARATION OF EUNETHTA JOINT ACTION3

In this session Wim Goettsch, the officially nominated coordinator of the EUnetHTA JA3 Zorginstituut Nederland (ZIN), reported on the preparations done so far .

The nominations by the MS for the future Joint Action was finalised on 9 October and 27 Member States have nominated in total 64 organisations. Following informal preparatory meetings during the first 3 quarters of 2015, a preliminary structure has been agreed on 15 October at the first formal preparatory meetings with the following work packages:

- WP1: Network Coordination
- WP2: Joint Production
- WP3: Evidence Generation
- WP4: Quality Management, Scientific Guidance and Tools
- WP5: National Implementation and Impact

The Joint Action will also include an executive committee as well as a liaison committee to facilitate interaction with national processes.
The Joint Action will follow the HTA Network strategy adopted in October 2014 and will constitute the scientific and technical arm of future EU cooperation.

The second formal preparatory meeting is planned for 26 November 2015. Submission deadline for the proposal is 17 December 2015 and the kick off planned for early in March 2016, during the NL presidency of the EU.

Summary of discussion points

- The members raised the importance of reuse and defining of the term "implementation".
- There was also a call to define the success factors on how to measure implementation and impact.
- The European Commission called for expression of views regarding scope and domains, notably on health economic aspects and medical devices. Possibilities for the reuse of results was raised as the key determining factor.
- A concern was raised regarding the liaison committee if it would duplicate other structures such as the HTA Network. It was stressed that the liaison committee should

not be considered a strategic committee, but a construct with the specific duty of commissioning the work and report on impact at national level.
- One Member raised the need of training particularly on the EUnetHTA core model for other actors, notably universities.
- The current EUnetHTA JA2 coordinator Danish Health Authority assured Members that the transition to the future coordinator of Zorginstituut Nederland (ZIN) had so far been very constructive and will continue so.

5. DISCUSSION PAPER "THE ADDED VALUE OF THE EUROPEAN COOPERATION IN THE JOINT HTA OF MEDICAL DEVICES"

Maria Grazia Leone, Italian Ministry of Health, summarised the paper addressing the added value of Joint HTA for medical devices (MD). The paper describes the context of MD and HTA, stressing the importance of MD regarding economic growth as well as the sustainability of health systems. The paper further calls for EU wide cooperation on MD stressing that medical devices need to be appropriately assessed to ensure the best outcome notably for patients. In that, EU cooperation was argued to bring about added value to the individual Member States in a number of ways. Inter alia the following are mentioned: the efficient use of resources, lowering the risk of introducing harmful technologies, and appropriate disinvestment.

6. STRATEGIC DISCUSSION ON SCOPE AND DOMAINS OF FUTURE JOINT ACTION 3

Following the presentations on lessons learnt from JA 2, state of play of future EUnetHTA JA3, and the discussion paper on medical devices, the EC initiated discussion on the scope and domains of the future Joint Action 3. In the discussion two important strategic issues following were raised:

- One member argued that there are a number of legal barriers that needs to be addressed regarding the implementation of joint work on medical devices.
- Appropriate methodologies were also stressed, especially regarding the long term performance of medical devices.
- There was a call to include public procurement actors and payers in the coming discussions as they face challenges on how to assess the MD.
- On cost effectiveness and health economic evaluations some members argued that this should be done if some MS wish to do so. Others argued such asssessments are country specific and possibly should not be part of the coming joint action.
- On health economic aspects, budget impact methodological issue was specified as an important area.

7. EU HTA COOPERATION ANSWERING NATIONAL NEEDS

The purpose of this presentation was to identify how the EU HTA cooperation and deliverables are answering national needs, from the perspective of HTA Bodies and Ministries of Health from Italy, Germany, Hungary and Belgium.

7.1. The Italian Experience

Marcella Marletta representative of the Italian Ministry of Health presented developments in the legal context in Italy especially regarding medical devices where Italy in recent years have aimed to establish a more centralised governance regarding HTA with "Cabina di Regia" providing a key role and forum for stakeholders as well as decision makers alike.

The present structure of HTA in Italy is aimed to establish a sustainable health system.

7.2. The German experience

Silke Baumann representative of the German Ministry of Health started by stating that there are important benefits of the EU cooperation.

The lack of appropriate data was mentioned to be one important challenge where data at the Market Authorisation level often is not adequate for the HTA. In that joint work on registries as well as early dialogues pose a very important common interest and something the German Ministry supports.

It was emphasised, that there are important challenges ahead. Healthcare systems of member states are very heterogenous and stay in national responsibility. Implementation, when understood as impact on national healthcare legislation, should not be a goal of JA3. Joint work should rather identify member state demands and focus on products that could assist national procedures. Coordination as well as how to identify what can be reused should be taken care of regarding future joint work. The country specific features were in that regard emphasised. In that, Full HTAs was recommended not to be a focus in the following Joint Action as these assessments require country specific expertise.

The presenter concluded that the focus should be to establish attainable goals.

7.3. The Hungarian Experience

Beatrix Horvath representative of the Hungarian Ministry of Health, presented experience gained in the previous Joint Actions. Hungary had benefited from strong competencies in the field of HTA; where working in an international environment had allowed them to receive positive and constructive feedback on contributions done.

Different challenges were described. Primarily, the main one is the limited national capacity with frequent change in staff. The speaker suggested to focus on developing effective communication with partners and also to establish a European HTA Agency, as a network organisation with the participation of the national HTA bodies.

7.4. The Belgian Experience

Raf Mertens, representative of Belgian Health care Knowledge Centre (KCE), made a presentation from the perspective of the HTA body. He also presented from the perspective of INAMI, the Belgian national insurance instituion, which emphasised that the payers constitute the customers of HTA.

The presentation showed the importance of the different steps from experimental research, case reports, cohort studies and RCTs and real world trials. An emphasis was put on the importance of cohort studies as well as real world trials: which are important for the work of

the "customers" meaning the payers. Registries were also stressed as an important feature of EU cooperation in that regard.

Thereafter, there was an explanation on the benefits of shared information at EU level. For instance, certain case studies showed how KCE reports as well as reports of other HTA bodies had been reused. KCE has adopted English as their primary scientific language and have facilitated the reuse of reports from for instance by NOKC. Language was used as an example of a success factor for reuse. Reuse is important and there are important synergies where one may inter alia identify a better division of labour.

7.5. Discussion

The following points were discussed.

- It is emphasised that there is willingness for joint work and that there is a need for political support.
- Focus should be on "low hanging fruits".

The Chair noted that at the meeting in March 2015, Ireland gave its perspective; now four more countries followed. Other Members will be invited to do so in upcoming meetings.

8. HTA MULTIANNUAL WORK PROGRAMME

The Commission introduced the topic by stating the importance of establishing of following two sub-groups:

- The new multi-annual work programme (MWP) for the HTA Network; and
- Regulatory issues and HTA.

The Commission presented the mandate and suggestions for the admission of the third parties (regulated by the Article 8 of Rules of Procedure of the HTA Network) for both sub-groups.

The Commission suggested further that the draft report for sub-group on MWP should be delivered in April 2016 with adoption in May 2016 at the next HTA Network meeting, and the sub-group on 'Regulatory issues and HTA' should delivered a report for a preliminary discussion in May, with adoption in October 2016.

The Commission invited MS to express their interest in participating in sub-groups by showing hands. Following MS have expressed their interest:

- MWP: UK, DE, HR, SWE and ES.
- Regulatory issues and HTA: SWE, DE, UK, IT, AT, PL, NL, NO and HU.

The “chair” and “rapporteur” were not appointed at the meeting. This task was delegated to the sub-group members to agree among themselves.

9. RECOMMENDATION ON THE USE OF PARENT JOINT ACTION DELIVERABLES ON PATIENT REGISTRIES

Marija Magajne, PARENT coordinator from Slovenian National Institute of Public Health, presented the PARENT Joint Action’s work and deliverables and their implications to HTA. The PARENT Joint Action (JA) produced several deliverables, which include a web-based

registry of registries, methodological guidance and recommendations for efficient and rational governance of patient registries, an IT-based knowledge-management platform. The JA produced recommendations for the dissemination of its deliverables.

MSs were invited to support the dissemination of the PARENT JA deliverables, once they are adopted in eHealth Network meeting that will be held on 23 November 2015.

The MS's took a positive note of the draft recommendation and passed the draft recommendation on to the eHealth Network.

10. HTA AND MARKET ACCESS ISSUES FOR A COMPLEX INTERVENTION

The complex intervention presented was on a pulmonary heart sensor for the telemonitoring of heart failure patients (CardioMEMS). The purpose was to address common challenges related to HTA and market access issues for complex interventions.

Sebastian Gaiser, representative of St. Jude Medical and producer of the sensor, and Marianne Klemp, representative of Norwegian Knowledge Centre for the Health Services (NOKC), presented the issues of clinical assessment, cost assessment and funding mechanisms for this type of intervention. Both agreed that industry and HTA bodies should work together.

Discussion:

- It was stressed that more such pilots should be done in JA3 as "learning by doing".
- The importance of involving different actors such as payers, hospitals and HTA bodies when performing HTAs for complex interventions.
- Issues such as high cost of interventions and scarce availability of real world evidence was raised.

11. HOSPITAL HTA

Charles-Edouard Escurat, a representative of RESAH (Réseau des Acheteurs Hospitaliers), presented how HTA is integrated into the procurement process in France and at EU level. Procurement process for technologies for hospital use is decentralised and decisions are taken at the level of the regions or hospitals.

Further he presented the work of EHPPA (European Health Public Procurement Alliance) and GPO (Group Purchasing Organization). It is recognized that assessment (HTA) is needed in the procurement process of step I (sourcing), step II (identifying need) and step IV (contracting).

RESAH and AdHopHTA provide experience of joint procurement which could be taken forward by the EUnetHTA JA3, notably in view of prioritisation of the work on medical devices.

12. CLOSING THE MEETING

The Chair closed the meeting by thanking all participants and speakers for their valuable contribution.

The next HTA Network meeting is planned for May 2016 (the date as updated after the meeting).