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Health systems and products
e-Health and Health Technology Assessment

Brussels, 22 May 2015

APPROVED MINUTES OF THE 4TH HTA NETWORK MEETING

MONDAY 23 MARCH 2015

Introduction

These minutes were 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 and the European Medecines Agency EMA were present. Iceland was excused. In addition, the five stakeholder representatives attended as observers and the organisations of MedTech Europe, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Innovative Medecines Initative (IMI) were introduced as speakers. No interests were declared during the assessment of a potential conflict.

The meeting was initially chaired by Andrzej Rys, Director of “Health systems and products” DG SANTE, during the morning session and was replaced by Tapani Piha, Head of Unit for "e-Health and Health Technology Assessment", during the latter half of the afternoon session.

Presentations are available on the HTA Network website[1].

1. 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 near future. Furthermore, Andrzej Rys highlighted the need to establish the HTA cooperation as a self-sustainable and permanent mechanism in line with the objectives of the Network.

The Chair suggested to change the order of the presentations under the second point of the agenda (Reflection paper on "Reuse of joint work in National HTA activities") and to begin the second point with the presentation by EFPIA on their internal survey on “Joint Work in national HTA activities”. The suggestion was unanimously approved.

No other changes to the Agenda were proposed.

[1] http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

2. REFLECTION PAPER ON “REUSE OF JOINT WORK IN NATIONAL HTA ACTIVITIES”

The Chair introduced the topic by thanking the Rapporteur and the Chair of the Working Group for their valuable contribution. The Chair then continued by introducing the first presentation, by the EFPIA.

2.1. EFPIA on internal survey "Joint Work in national HTA activities"- Andreas Rappagliosi, Co-Chair of the EFPIA HTA Task Force

The presenter introduced an internal survey by members of the EFPIA on the usage of Joint Work in relation to Health Technology in a sample of MS. Specifically, the presentation addressed the issue of how HTA reports at a European level may contribute to the avoidance of duplication of work, and to the greater efficiency of HTA in a national context.

As an example, the presenter showed a pilot report where Relative Effectiveness Assessments (REA) on the vaccine of Zostavax had been performed. The example highlighted that the reuse of the report had varied within different MS and in certain cases there had been instances of duplication. The presentation further highlighted the possible areas where Joint Work can replace certain elements of HTA in different MS.

The presentation further stressed the importance of having a discussion on joint scientific advice based on the SEED methodology with the approach of including the relevant actors downstream to upstream. The importance of the identification of downstream actors was highlighted.

Consensus on the dimensions of comparator, endpoints, patient population and study design were highlighted as very important to avoid duplication. Thereafter, other political realities and local considerations were exemplified.

Finally, the presenter suggested that the Network is in a position to assist the process of the re-use of Joint Work on HTA namely by facilitating the uptake of Joint Work at a national level, identifying the relevant actors (including downstream actors) and raising awareness of the HTA process.

2.1.1. Discussion:

Following the presentation, the following points were raised by participants:

- The idea of establishing Joint Work including specific conditions such as an established comparator was questioned; with the consideration that these specific conditions might be considered to be prescriptive and inhibit an inclusive process of Joint Work. As a response, the presenter stressed that it is important to be open to different approaches to address a medical need, but also underlined the importance of agreement on, for instance, comparators to facilitate cooperation. When other comparators will be used for meeting local needs, they need to be justified.

2.2. Presentation of the draft - Chair Francois Meyer and the Rapporteur Mirjana Huic of the Working Group

The Chair introduced the point by thanking the working group, its Chair Mr Francois Meyer (HAS) and the Rapporteur Mirjana Huic (AAZ) for their work and all members of the Network for their contribution. He welcomed the final draft and gave them the floor.

After their presentation, Flora Giorgio (DG SANTE) was given the floor and presented amendments and other suggestions that had been integrated since the last draft. The floor was then opened for comments.

2.2.1. Discussion:

Re-wording of certain paragraphs was proposed, where simplifications and clarifications were agreed. The following were some of the main points mentioned:

- An emphasis to respect the competencies of the MS.
- To clarify and emphasise the concept of quality assurance as it is an integral part of Joint Work on HTA.
- The importance of respecting Directive 2011/24/EU.
- Clarification of the elements of the HTA core model and its applications.
- Clarification on the concept of submission templates.
- Clarification regarding the reference to pricing and reimbursement.

2.3. Adoption and next steps

The reflection paper was unanimously adopted in principle with the condition that the clarifications and linguistic editing discussed were to be integrated. The Secretariat will aim to circulate the revised paper by 27 March and Members were invited to send comments before 10 April.

3) PRESENTATION OF A NATIONAL HTA STRATEGY

The objective of the session was to learn about HTA in a specific country (in this case Ireland) and discuss how Joint Work and EU cooperation in general can feed into national activities. Progress on the mapping exercise ongoing in the Secretariat was also reported. The Chair introduced the different presentations emphasising the importance of sharing experiences.

3.1 HTA in Ireland - Mairin Ryan, Managing Director Health Information and Quality Authority (HIQA), Ireland

This presentation gave an overview of the present landscape of HTAs in Ireland where there recently has been structural changes. Thereafter, the presentation further detailed the actual work done by HIQA and the different roles within their HTA division were explained.

As examples of Joint Work, the presentation showed that work regarding HTA on cost effectiveness as well as stakeholder guidelines had been reused. The presenter gave a further example of successful collaboration on Prion Filtration HTA; where the use of an UK economic model had been revised. This Joint Work had further been reused in Italy. Furthermore, systematic reviews of clinical effectiveness inspired by the HTA EUnetHTA core model have also been performed.

Subsequently, the presentation highlighted the importance of different HTA aspects such as implementation of HTA work and the usage of networking opportunities. Regarding implementation, there is inter alia a need for clear prioritisation criteria and networking may provide a good knowledge base for further organisational improvements.

A challenge presented, was that HTA of products may be launched with different timelines between different countries. In particular, the different reimbursement structures were seen as a contributor to the different timelines.

Finally, the quality assurance process for Joint Work was highlighted as key; where it was suggested that it should be a critical aspect in the proposed Joint Action 3. It is important to be confident in the quality of the outputs and aligning national priorities with Joint Work, as much as possible.

3.1.1. Discussion

Following the presentation, the following points were raised by participants:

- There was a query on how registries may be used by other parts of the organisation. It was explained, the main operation of HIQA is engaged in regulatory affairs where HTA can be used as a valuable input in for instance the use of clinical expertise.

- Furthermore, there was a query on how much of the work by HIQA is dedicated to pharmaceuticals. It was explained that HTA still remains to be a small part of the organisation and that there are other national initiatives for pharmaceuticals.

3.2. Mapping HTA in EU – progress – HTA Network Secretariat

This presentation highlighted the conclusions from a mapping exercise of HTA. The template used, focussed on licensing, HTA (appraisal, assessment and cost-effectiveness) and decision uptake. HTA was considered in the context of this exercise using a systematic evaluation of properties, effects, and/or impacts of health care technology.

There are different measurements of value used between different HTA bodies and between different MS. Cost effectiveness was presented to be commonly used in a number of MS, whilst some MS and regions use other methods, such as simple budgeting.

The Secretariat intends to continue this work provided that the MS are interested in the outcome and are willing to contribute.

3.2.1. Discussion

Following the presentation, the following points were raised by participants:

- The Chair emphasised that there is a need of continued work on mapping with the Network as literature reviews may have addressed some of the aspects underlined in the exercise, but may not have properly addressed the dynamic nature of the policy context.

- Certain participants highlighted other initiatives e.g. WHO, ISPOR that might complement future work on this exercise. Furthermore, it was concluded that there might be an interest for the Network to communicate with these initiatives.

- Representatives from industry explained that industry also possesses valuable information that possibly can be of help when considering this exercise.

- It was highlighted that this exercise is of interest for Work Package 5 of Joint Action 2 and they have already submitted material which could be of help.

- There was a query if this information will be public and it was agreed that it would be depending on the final result.

3.2.2. Conclusions and next steps

The Chair thanks for the valuable input on this discussion. He asked the Secretariat should look into other mapping initiatives and come back to this discussion at the end of the year.

4) HTA FOR MEDICAL DEVICES

The objective of the session was to discuss in depth HTA in the context of medical devices. In particular, the focus was on the ongoing revision of the legislative framework and the Joint Work already ongoing between HTA bodies. The view from industry was also addressed.

4.1. An example of Joint Work on Medical Devices- Rapid Effectiveness Assessment- Claudia Wild, LBI, Austria (EUnetHTA Work Package 5).

The presentation addressed Joint Work on HTA in relation to medical devices. Different challenges were highlighted namely: topic selection, timelines, timing of assessment, methods and quality assurance.

With regards to duplication of HTA, the presentation highlighted that the issue of duplication might be exacerbated over time and not necessarily at the same point in time as the national HTA is performed. The presentation then explained Work Package 5 of EUnetHTA and three ongoing initiatives.

Language barriers were mentioned as well as the opportunity of transparency, comparability and the adaption/reuse by other agencies. Finally, the benefits of Joint Work for HTA-agencies, health policy, patients and manufacturers were presented.

In the conclusions, it was highlighted that there is a high potential for efficiency gains if the reuse of joint assessments as well as other EUnetHTA tools are implemented on a national/local basis.

4.1.1. Discussion

Following the presentation, the following points were raised by participants:

- With regards to the POP database, it was questioned how often medical devices appear; where it was concluded that it was not very often.

- The specificity of medical devices versus pharmaceuticals; arguably pharmaceuticals have a clear entry point when HTA has to be performed; this is not necessarily the case for medical devices. Furthermore, how evidence can be better integrated in the assessment.

- The present timeline lasting an average of 8 months cannot be considered a rapid assessment; there is a need to reduce it to 4-5 months. Efforts should be made to achieve this objective, including more efficient exchange of information between relevant players.

4.2. HTA for medical devices- expectations and limits of the EU cooperation on HTA, the view of industry (MedTech and COCIR)-

Serge Bernasconi CEO Eucomed and EDMA, members of MedTech Europe

The presenter highlighted that Medical Devices have different specificities in comparison to pharmaceuticals. For example the development time is linked to evolution of materials, to other available technologies and to the skills needed to use the technologies. A timeline of developing a Medical Device can be around 18-24 months, versus tens of years for pharmaceuticals. This also raised the issue of when a medical device should be subject to HTA. Often a medical device receiving CE marking does not undergo a HTA for market access. Medical devices are relatively less costly over time but the upfront cost for ensuring updates in clinical practice may be high.

In view of the above, industry is neither against nor for HTA on medical devices, since the absolute trend is increased assessment of technologies. However, the industry insists that the specificities of the medial devices' market access pathways are well reflected in any HTA cooperation at EU level. This is a critical aspect.

There is an issue with the variability of systems put in place (differences in the HTA process/requirements and sometime multiple HTA even in the same country) which can be very challenging for small companies to handle. As a result, it was emphasised that there is a need for clear guidelines and understanding of the situation of certain companies

In the vision of the future the presenter reiterated that industry does not see current work on HTA at EU level fitting the context of medical devices , but is however keen to collaborate with the HTA Network to develop a better model.

COCIR- Dr. Geoff Wilson HTA Taskforce Leader

The presenter began by underlining the distinctive features of the industry sectors he represented: medical imaging, radiotherapy, electromedical equipment and Health ICT. Furthermore, the presenter supported the idea of further cooperation on HTA in order to primarily expedite benefit to patients, avoid duplication, increase efficiency, and reduce uncertainties on the manufacturers' side. However, it was stressed that the evaluation of medical technologies has to be different from pharmaceuticals

Many medical devices offer more than clinical benefits, which need to be taken into account, such as reduced absenteeism, and increased efficiency. HTA needs to recognise the full value of these benefits as well.

The presenter reiterated that decision makers need to put trust into an industry which has value to add and a role to play. It was also asserted that there is a need for effective coordination and to avoid mixing CE marking and HTA. Finally, the presenter put forward that industry struggles to meet the evidence requirements set by HTA agencies and thus there is a need for better coordination.

4.2.1. Discussion

Following the presentation, the following points were raised by participants:

- Mixing up CE marking and HTA. Certain participants questioned the possible incidence of mix ups.

- Industry affirmed that issues regarding safety should be related to CE marking and then performance should be assessed through HTA.

- Furthermore, it was stated by the speakers that there is usually a learning curve in order for professionals to be able to use certain products and that puts forward the question of the timing for the HTA of medical devices.

- COCIR emphasised that a partnership with the HTA network should be the way forward in order to address issues surrounding medical devices.

4.3. Update on the ongoing negotiation on the Regulation for Medical Devices- possible consequence on HTA- Mrs Sabine Lecrenier, Head of Unit, Health Technologies and Cosmetics, DG GROW, European Commission

The presenter explained the most recent progress with regards to consultations and recent dialogues. The focus is to update the legislation, the process and then the substance. On the 5th of November mandate was received to enter into trialogues.

There has been a process of examining the proposals, where 45 meetings have been held with the Council Working Party. The main issues have been related to scrutiny mechanisms, pre-market assessment of high-risk IVDs, reprocessing of single-use devices as well as counselling, informed consent and genetic testing.

The Latvian presidency is trying to find agreement in its present term to facilitate work on the controversial issues and discussions at the COREPER have been held recently. Medical devices are also an important topic for the coming Luxemburgish presidency and there is a hope to conclude the file. The aim is to establish a wider and clearer scope of EU legislation for medical devices.

Regarding possible implications for HTA, a number of aspects were mentioned. As one possibility, the involvement of panels of scientific experts for medical devices was highlighted; where opinions on the clinical data could potentially be used for the HTA stage. Arguably, further cooperation between authorities can facilitate the exchange of information further, also taking in to account the real-life performance of medical devices.

4.3.1 Discussion

Following the presentation, the following points were raised by participants:

- There was a discussion on what could be the more controversial topics of the future regulation. One of the more crucial points was to establish a viable scrutiny mechanism for medical devices. Furthermore, different devices and types of products face different challenges, such as implantable products versus injected products.

- The importance of knowledge management was raised as well as how to engage relevant actors in the regulation process as it is a very long process. In all, it is very important to strengthen the capacity of the regulatory field.

5) UPDATE ON EU INITAITIVES RELEVANT FOR HTA DEVELOPEMNTS

The objective of the session is to update Members of relevant developments which can be of interest for HTA both on national and European dimension.

5.1. Safe and Timely Access of Medicinal Products (STAMP) EC expert group – update – Olga Solomon, Deputy Head of Unit D5 - Medicinal Products - Authorisations, European Medicines Agency, DG SANTE, European Commission

The presenter explained the rationale and background of the recently established EC expert group named Safe and Timely Access of Medicinal Products (STAMP). The aim of the group is to discuss experience acquired so far with the implementation of the EU pharmaceutical legislation and national initiatives, and to identify ways to optimise the use of existing regulatory tools to further improve the safe and timely access and availability of medicines for patients. The work of the EMA, including the pilot project on adaptive pathways will be part of this discussion. The conclusions on innovative benefits for patients were also emphasised in the Council; where the issue of providing patients with rapid access to new innovative medicines remains an important issue.

There is, at the present, discussions on a pilot project referring to adaptive pathways by the EMA to provide accelerated assessments. Different features of accelerated assessment, conditional market authorisation, unmet medical need, rapid assessment as well as compassionate use were also mentioned. Compassionate use and unmet medical need are subject to national competences and are thus defined by the MS. A common denominator is to establish the evidence base that is needed in order to perform an assessment.

With regards to adaptive pathways, there is a need for real world data and to establish the ability to engage HTAs and other downstream stakeholders. Work of the STAMP will include discussions on how to provide solutions to facilitate harmonisation of data, adaptive pathways, issue off-label use, harmonise prescriptions and use national experiences both from a policy and regulatory point of view.

The presenter further explained that STAMP has no mandate to look at HTA as well as pricing and reimbursement issues, even though these are considered essential elements. There are possible synergies to be discussed such as that between CAPR and EMA, and how it can be conducted efficiently to increase understanding.

Finally, the first meeting on 27th of January was summarized. There had been a constructive exchange of experiences (e.g. Conditional Market Authorisation) and tools regarding accelerated assessments of innovative medicines, the use of existing regulatory tools and on perceived weaknesses within the present context of accelerated assessments.

5.1.1. Discussion

Following the presentation, the following points were raised by participants:

- There was a discussion on the importance of HTA in the first meeting where it was explained that there is a need to adopt a holistic approach.

- It was raised that even though the STAMP has no mandate to discuss issues such as pricing and reimbursement, it is important to still have an open discussion to establish the needs of others and to build bridges between other competences.

- It was underlined that at the next STAMP meeting on 6 May, HTA will be on the agenda where EUnetHTA has been invited to contribute.

5.2. Innovative Medicines Initiative (IMI) projects relevant for HTA-Nathalie Seigneuret Acting Director, IMI

This presentation summarised the IMI projects regarding European Partnership for health and its objectives. It was explained that the projects have a focus on patient and societal needs. Subsequently, these projects may further investigate topics such as the integration of healthcare solutions, support of the biopharmaceutical industry, regulatory matters, capacity building and to establish a platform to align both public and private interest. Thus, the importance of HTA was highlighted.

IMI 1 has been considered a success and there has been a process of identifying the success factors and also to identify new approaches. There are new changes in the coming IMI 2 programme which has a scientific focus oriented towards addressing healthcare priorities identified by the WHO, a strategic agenda on stratified medicines (prevention, treatment and health management) and the product life cycle. The financial details were also summarised.

Further changes, related to rules and procedures, mean that more entities are eligible for funding and also funding has become simpler with the rules being aligned with the Horizon 2020. Furthermore, there is collaboration across sectors in order to harness knowledge and technologies which can contribute to IMI 2.

The goals of the IMI 2 were presented as follows:

- Increase the success rate of clinical trials of new medicines & vaccines.
- Speed up the earlier stages of drug development.
- Develop new treatments for areas of unmet need.
- Develop new biological markers to diagnose diseases and assess treatments.
- Improve the drug development process by creating tools to assess the efficacy, safety and quality of medicines.

Finally, a number of performed projects and upcoming projects were presented in order to better understand the workings of the IMI 2 programme and its projects.

5.2.1. Discussion

Following the presentation, the following points were raised by participants:

- The possible interaction between IMI 2 projects and EUnetHTA was suggested as a possible topic for the proposed Joint Action 3.

- There was a discussion on the main differences between H2020 and IMI. It was explained that the IMI agenda is topic driven by industry; subsequently, different partner organisations are brought to the consortium and work in this neutral platform.

6) PROPOSED JOINT ACTION 3 ON HTA – UPDATE

Jerome Boehm of DG SANTE explained that there would be an informal meeting on 24 March on a possible future Joint Action 3 (JA3). The suggested layout of the Joint Action was presented with the main feature of 5 work packages (WP): WP.0: Overall coordination; WP.1: Production of joint assessments; WP.2: Evidence generation support; WP.3: Methodology and processes; WP.4. Implementation and impact.

There was also a summary of relevant information with regards to the process to adopt the Work Programme which includes the budget for Joint action on HTA. It was further encouraged that the Members of the Network liaise with their representatives to explain the importance of HTA further.

6.1. Discussion

Following the presentation, the following points were raised by participants:

- Stakeholders questioned if there is an opportunity for the stakeholders to make suggestions and get involved in the design of JA3. The EC secretariat explained that it will be discussed at the next informal preparatory meeting on 24 March

- It is expected that the Joint Action 3 proposal should be sent to CHAFEA by the end of the year, pending the review of the adoption of the Work Programme.

7) Any other business

The next meeting of the HTA Network will be held on 29 October in Paris and be hosted by the French Ministry of Health and Haute Autorité de Santé (HAS). As a celebration of the 10 year anniversary of the HTA capacity at HAS, a conference will be held on the next day jointly with the Commission to give an opportunity for the four FP7 research programs on HTA to present their projects.