EUnetHTA Joint Action 3

EUnetHTA MedTech Technical meeting

May 27th, 2019: 12:30–17:15

Local Host: LBI-HTA (Ludwig Boltzmann Institute for Health Technology Assessment)
Meeting Venue: LBI-HTA: 1090 Vienna, Garnisongasse 7/20

Minutes

Participants

	Participant	Agency
HTA	Chantal Guilhaume	HAS, France
	Ingvil Sæterdal	NIPHNO, Norway
	Helene Arentz-Hansen	NIPHNO, Norway
	Claudia Wild	LBI-HTA, Austria
	Petra Schnell-Inderst	LBI-HTA, Austria
	Sabine Ettinger	LBI-HTA, Austria
	Marcus Guardian	ZIN, Netherlands
	Emmanuel Gimenez Garcia	AQUAS, Spain
	Nicola Vicari	AGENAS, Italy
Industry	Francesca Barron	Liva Nova
	Christine Muzel	Philips
	Gordon Goodall	Edwards
	Yves Verboven	MedTech Europe
	Marcus Ott	Roche
	Jessica Imbert	MedTech Europe
	Aline Topouchian	Siemens

Additional: Stefan Sauerland (IQWIG) and Orsi Nagy (EU commission) excused
Miriam Luhnen IIQWiG) participated via zoom for the WP6 update

Agenda

Time	Description
13:30 – 13:50	**Welcome, introductions**
13:50 – 14:30	**Horizon scanning**
14:30 – 15:15	**Life cycle approach to improve evidence generation**
15:15 – 15:45	**Coffee/tea break**
15:45 – 16:30	**Production of EUnetHTA assessments. Gap analysis**
16:30 – 16:45	**National implementation of EUnetHTA assessments**
17:00 – 17:15	**Take-Home messages**

1. Horizon Scanning (HS)

1.1. EUnetHTA introductory explanation: The current status of the EUnetHTA pilot TISP (Topic Identification, Selection and Prioritisation) procedure was presented by Helene from NIPHNO. The draft recommendations for TISP were written between June and September 2018. This was followed by Project Plans in 2019 for the two pilots in 2019: one for "Other Technologies" (OT) and another one for Pharmaceuticals (PT). The TISP for OT identified 95 topics through topics sent from EUnetHTA partners with existing horizon scanning (HS), topics suggested by stakeholders and the POP database. 74 were selected for Minimal DataSet (MDS) and 58 were finally included to the Call for Collaboration (Final deadline for EUnetHTA partners to reply was 24-May). The Project Plan for OT can be accessed via this link.

1.2. Main issues and dialogue HTA-Industry

a. *How many responded to send topics?* Answer: 9 within the deadline.

b. *Which were the specific criteria to pass from 95 to 58 topics?* Predictability is desired. Answer: To have a CE Mark, or being a Medical Device or an In-Vitro Diagnostic, among others.

c. *Was "Unmet need" a criterion?* Answer: Not directly. Each country has its own criteria to suggest topics and unmet need can be one of these.

d. *Industry positioning is positive (appreciation and acknowledgement) towards "Horizon Scanning". Nevertheless, Europe´s perception about HS is very heterogenic across countries (systems). Among OT the landscape is very different and maybe the HS should be done by differentiating some categories where "unmet need" and lifecycle is defined in different*

ways: it is not the same to look for the future on implants, stents, imaging technologies or diagnostics. The patent period is not the same. A common thing that differs between OT and PT market dynamics is that, after 3 years or even less, two thirds of the products are renewed. There is also a different market access pathway including CE mark and a different reimbursement-HTA process. A differential relevant variable to understand what is relevant to be assessed and the product value is the learning curve (skill set), but also the value at changing the standards of care at different stages of the patient pathway, data privacy adjustment, patient data, the use of resources or the mode of therapeutics. Industry believes those topics should be taken in consideration in a HS method. Answer: the current status is a pilot for TISP. The aforementioned impact criterion like "unmet need" could be considered in the future.

e. *How do you decide that a topic is interesting enough to start an EUnetHTA assessment?* Answer: At least 3 HTA agencies must declare interest.

1.3. Rooms for collaboration: EUDAMED will be good from a CE marking perspective, but maybe sometimes HS should have information before that (majority of technologies already assessed in EUnetHTA are perceived to be already in the market). But, it is not possible for Industry to share a unique list of future products as per using in the HS process. Maybe a first-in-class approach or at some companies level this could be done. But. First of all, the list does not exist, so even if it was wanted to share. Moreover, it is difficult for confidentiality reasons, which is more relevant in OT than in PT because of the faster lifecycle competition. Finally, sometimes, the adoption of the HTA in, e.g., coverage with evidence, by final financing decision-makers is not seen, so more risks than benefits are seen. In this sense, EUnetHTA could try to build a framework to provide a safe environment for industry to share information (so that no competitor receives this information). EUnetHTA presents evidence-based collaborative conclusions so to support recommendations and decision-making for reimbursement on national level.

2. Scientific Advice and Life Cycle

2.1. EUnetHTA introductory explanation: Chantal from HAS presented what corresponds to the WP5 of EUnetHTA. The tasks in this workpackage are divided in the "scientific advice" or "early dialogues" (ED) and the "post-launch evidence generation". There has been one pilot in ED of a Medical Device in JA3. The ED working party is formed by RER, NICE, HAS and AVALIA-T, agencies that have already experience in Medical Devices ED in the past. The ED has a Scientific Coordinator, a procedure of 4.5 months and a Briefing Book requirement process that has been continuously improved. More information and several related links including the eligibility process for ED is in the end of the following link. HTA quality of registers can be assessed through the REQueST® tool, which is available at the following link.

2.2. Main issues and dialogue HTA-Industry

a. *Industry is very interested in the ED. For example to discuss about patient segmentation based on value-based healthcare. Sometimes there can be a discussion about the evidence that can be brought up at the latest part of a lifecycle (for example in the treatment of epilepsy or vagal nerve) and Industry feels to have problems adapting the (type of) evidence and move from one indication to another (topic for another meeting). Sometimes there are also ethical problems that cause not having a demanded RCT in OT (who would want to be operated in some treatment arms?). Moreover, sometimes, each country thinks differently. How do HTA agencies as a group manage questions about which methodologies are expected to accept to prepare for launch?*

   Answer: the Scientific Coordinator tries to achieve a common position. Nevertheless, obviously, this can be followed by specific technical opinions from the different agencies, who have, among others, specific design knowledge. Before the afternoon Face-to-Face meeting with agencies, these meet in teleconferences and the corresponding morning. Stakeholders from different countries are included in different ways (including patient views) and these are shared with the ED requester.

b. *How is the structure of the dossier for ED? Answer:* There is a template and briefing book defined after several experiences and feedback.

c. *Are ICHOM variables in consideration?* Answer: They are relevant, as are also the COMET criteria for selection of outcomes.

d. Additional issue raised by industry: *There are different types of products. ED with HTA make more sense in implantable devices than in CT, MRI or other imaging technologies, which have difficult coverage/access problems because the extension of use of OT in new therapeutic areas by doctors, radiologists and end-users is difficult.*

e. *Industry foresees that standards of care and clinical pathways are different across countries and we start opening the market for Germany and Austria (for example) and later, we find that we didn't cover the situation from Spain. And covering all of them is difficult. Synchronization would be desirable…* Answer: EU level Early Dialogue is a proper way to approach these problems. It is also stated that EUnetHTA agencies involved in ED have a professionals with a technical profile that corresponds, not only to "review" but to "advice". Nevertheless, it is impossible to avoid different opinions among 27 Member States.

2.3. Rooms for collaboration: There is a lot of interest from industry in Early Dialogues and a desire/wish to have more experiences. Industry wants much stronger guidance, especially on trial designs

3. Evaluation production

3.1. EUnetHTA introductory explanation: Sabine from LBI-HTA (WP4) and Miriam Luhnen from IQWiG remotely (WP6) present how EUnetHTA performs assessments on Medical Devices, diagnostics, screening… Topics for assessments usually come from national work programmes of EUnetHTA partners (i.e. a request from the Ministry of Health at national level). Then a call for collaboration is sent to EUnetHTA partners and if there is sufficient interest (in addition to the author, a co-author and 2 dedicated reviewers are needed), the assessment is done within EUnetHTA. A specific slide on manufacturer involvement was presented (out of 13 OT published assessments): 3/13 had scoping meeting involvement, 8/13 factual accuracy check of draft project plan, 12/13 factual accuracy check of draft assessment, 12/13 submission dossier, 1/13: unsuccessful involvement. Various manufacturers might have been involved via different methods within each assessment (depending on their willingness to participate).

3.2. Main issues and dialogue HTA-Industry

a. *Internal thoughts are made about the 1 case without successful involvement. It is seen as strange by the industry not to answer requests from HTA agencies. Nevertheless, even though it is true and disappointing, capabilities of the industry to deal with HTA issues can be limited due to the company's size and available resources. The established timeframes sometimes are difficult to keep because of the same reason.*

b. *An opinion is given by an industry representative, who had been involved in a EUnetHTA assessment, that the stakeholder relevance, would be higher having more professionals involved*

c. *Industry also stated that their portfolio is diverse and that sometimes the products can even transfer between categories. E.g. from diagnostics to monitoring/e-health or imaging could be used with pharmaceuticals.*

d. *Industry also comments that the traditional market-access had been in the hospital, and once marketed, if product was not violating safety and was cost-effective, it could be used. Now there are requirements for reimbursement from national agencies… and now there are assessments from EUnetHTA….* Answer. Hospitals access path will remain and EUnetHTA assessments should not be an add-on to the national assessments (more on that in part 4). Also, through EDs and internal communication within industry country departments, resources could be saved.

3.3. Rooms for collaboration: MedTech Europe will internally discuss if they could potentially help EUnetHTA (in certain cases, where needed) to identify manufacturers of the intervention/technology that is included in an OT EUnetHTA assessment. Nevertheless it is not seen an easy/simple task. An example is the OTCA22 EUnetHTA assessment on

"Clinical utility and diagnostic accuracy of Point-of-care Tests (POCT): D-Dimer and Troponin"-T where around 20 manufacturers were already found.

4. Implementation of the assessments

4.1. EUnetHTA introductory explanation: Nicola (AGENAS) presented WP7 activities which include analysing the implementation of the EUnetHTA assessments. The WP includes 55 agencies, almost from all the EU countries who reported more than 100 uses. 52 cases of non-use were reported and the reason stated for most of them (90%) was "timing", including the problem that the opportunity arrived late.

4.2. Main questions and dialogue HTA-Industry

a. *What is considered as "use"? A translation can be?* Answer. 46 in assessment support/alterative for existing procedures and 57 dissemination to support and evidence informed action.

b. *Is there a reduction in the total number of assessments per product? Is it an add-on or is it replacement?* Answer. Two agencies reported that they had less needs to assess some products thanks to EUnetHTA

4.3. Rooms for collaboration

EUnetHTA WP7 can further analyse the last point raised.

Take home messages from Claudia (LBI-HTA) as closure

- Horizon scanning is not the same for HTA and industry. Horizon scanning within EUnetHTA is mainly topic identification. Some companies might be willing to share their pipeline topics (under safe conditions) but there is no way to get such a list for all high-risk; this list does not exist.
- There is a lot of interest in EDs and the desire/wish to have more experiences. Industry wants much stronger guidance, especially on trial designs and on what data would be required
- Collaboration in assessment production is resource intensive for OT industry
- There is still an open question whether EUnetHTA assessments are used at national level or if it is an add-on
- Industry asks EUnetHTA to have constructive dialogues
- EUnetHTA should do more marketing/communication of success stories (with regard to uptake of EUnetHTA assessments)
- If HTA agencies work in English, implementation also comes over time.