EFPIA and EUnetHTA Exploratory Meeting

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Taking an opportunity of attending the ISPOR Annual European Congress, delegations of EUnetHTA and EFPIA representatives met for an exploratory meeting to discuss specific issues of EUnetHTA WP5 'Strand A' pilots implementation.

Goals of the meeting:

- to share experiences on first two pilots and discuss learnings for future pilots
- to speed up the realization of the EUnetHTA WP5 pilots;
- to increase effectiveness in the engagement of the companies.

Introduction & main issues:

- Overall, the idea of joint relative effectiveness assessment pilots is receiving positive reactions from industry and stakeholders.
- However, despite this positive reception, there are ongoing issues with getting industry engaged and participating in subsequent pilots
- As a result, EUnetHTA are now facing the risk of not reaching the target of 10 pilots that must be produced by the end of 2015
- Representatives of the Lead partner of WP5 attend a lot of meetings with pharmaceutical companies. While feedback on the first two pilots during the meetings is generally positive, even when companies have compounds that could be reviewed, there seems to be internal barriers to participation.
- EUnetHTA needs pilot volunteers now.

Action Points

- WP5 shares the first draft of the submission file template to interested companies to give an idea of how the submission could be structured.
- EFPIA will facilitate the EUnetHTA communication with industry peers
- EUnetHTA and EFPIA will work together to identify opportunities to make pilots more relevant to companies, e.g. by improving pilot processes and ensure company concerns are appropriately addressed; this includes demonstrating how the process will reduce

duplication across countries and lead to meaningful efficiency gains for companies; discussing and agreeing on a relevant format for the EUnetHTA template for submission is an important part in that context. After testing the first draft of the template, there will be an official comment period, wherein EFPIA can provide further input.

- When promoting the WP5 pilot reporting to EUnetHTA partners, EUnetHTA will promote the acceptance of company submissions from WP5 pilots to support national justification of relative effectiveness, and so potentially reduce unnecessary duplication between countries in terms of relative effectiveness assessment.

Challenges to uptake from Industry Point of View:

- **The value perspective:**
    - It is not clear to many companies how participation in the pilots will bring possible efficiency gains to their already complex market access processes and what is the likelihood of the EUnetHTA process to improve market access conditions for their products over and above the status quo.
    - Despite the fact that industry in general shares a similar vision as EUnetHTA as to the potential of joint relative effectiveness assessments, it is unclear to industry if this vision will be effectively translated into efficiency gains to the market access processes. EFPIA indicated that it would help that there is clear buy-in from all EUnetHTA members in the implementation of EUnetHTA results in national practice. EUnetHTA indicated that this is a voluntary process and buy-in of individual countries is wished for but can not be forced.
    - There is a need to make this process more visible; for example, there was lack of awareness of the LBI zostavax national report uptake.
    - Value and policy change need to be demonstrated.
- **The need to address the risks and benefits:**
    - What is the risk for manufacturers?
    - Is the risk high or low?
    - What is the benefit?
    - Does the benefit outweigh the risk?
- **The issue with getting acceptance by individual manufacturers has different levels:**
    - Companies are so structured that any engagement in a pilot needs to involve several colleagues, including product teams and management teams; they will closely consider the opportunities and risks for engagement.
    - It is therefore a challenge to not only gain involvement at 'higher' levels in the company, but also to gain involvement laterally.

Additional issues from the EFPIA point of view:

- EFPIA mentioned that for the European Commission, there is acknowledgement that the EU environment for access to innovative medicines is not optimal.
    - Such an acknowledgement at a recent EFPIA board meeting attended by members of the EC was a breakthrough for many CEOs.
- There is clear logic in improving the whole system (IMI project, prospective assessment, registries, access plan for orphan drugs).
- Important to involve EMA in the process. At the time when the company goes for a pre-submission meeting with the CHMP - that is the moment that EMA could direct the company to the WP5 pilots, to streamline the process
- The importance of this process needs to be highlighted starting from the meetings at EMA.
- EFPIA advocates finding better ways to explain & communicate: i.e., to make it clear what happens with data, who uses data, so we don't have bloated submission files with

everything contained within.

Additional issues from the EUnetHTA point of view:

- From the EUnetHTA secretariat and WP5 lead partner perspective there are some doubts about the need to have 'physical' meetings at the EMA, as EUnetHTA and HTA are not an extension of EMA.
- We focus on the alignment with EMA.
- Therefore, from the EUnetHTA perspective any focus on putting things into the hands of EMA at this time point is not beneficial for the process and will certainly not increase the willingness of HTA agencies to participate in these joint assessments.
- Combined market authorization and REA in collaboration with EMA is not feasible in the near future. The arguments for this are well-known.
    - However, 3 year work plan of collaboration with EMA will be published soon, which contains concrete actions for moving forward in coordination and collaboration
- It would be very important to have a workshop for EUnetHTA pilot producers and industry to explain the process, experiences, risk uptake, etc. There is also need for EUnetHTA to promote REA and to inform on the Manufacturers' submission template among agencies to increase uptake.
- EUnetHTA Conference in Rome (October 30-31, 2014) next year will be important forum to present and discuss number of products that EUnetHTA is working towards

The pilot experience:

SPMSD shared experiences in the first pilot:

- SPMSD had a positive experience in the WP5-SA-1 zostavax pilot, which they are now sharing with colleagues in industry.
- In the case of SPMSD, the scoping meeting was earlier, and this allowed a chance to decide if we still want to commit.
- It was clearly stated that scope and process is European and not country specific.

Example: zostavax age groups – the Dutch figures of 70+ were not used, but rather 50+

Lessons learned based on the second pilot (input from J&J):

- →to have the scoping meeting even earlier in the EUnetHTA process, soon after it has been tentatively agreed to proceed with a rapid REA (In the ideal setting, this may even result in a scoping meeting soon after the CHMP process)
- →Consistency: who owns the process? I.e., different agencies? Will working with one set of authors yield a totally different experience and process when working with another set? The objective is a review on behalf of EU-member states that needs to be relevant to all, and therefore requires consistency (in methods, process and format): It should not be the 'national process of the lead author' being offered to other national agencies. This must be clear and acknowledged.
- It is an evolving process: this must also be clear
- Benefits and risks of the involvement of companies in the REA pilots to be shared with companies (different channels are needed to share this).
- Even if REA is not used by everyone; (it is not expected to be that efficient yet - pilot uptake is more a future benefit/goal) it would be beneficial for the companies to have the submission dossier become more accepted and used by more countries.
- Time saving is a major advantage of participation in the pilot for the company.

Lessons learned based on first two pilots from the EUnetHTA perspective:

→ <u>The process of Scoping of the review is a highly beneficial and crucial part of the</u>

assessment process and should take place as early as possible
- → Pilots are run by coordination office (WP5) – project management
- → The current format of the pilot process is not entirely effective – discussions with EUnetHTA
- → A new template will possibly incorporate submission template

Conclusions based on lessons learned:

- While EUnetHTA cannot force organizations to use the Manufacturer submission template on the national level, we can continue to encourage uptake and promote possible future use in national practice
- While it may be easier and more feasible for smaller and mid-size countries to uptake the use of the EUnetHTA submission templates and files in the near future, it is important to promote the use of these tools on a European level, as some countries could be eager to have such tools and materials and be more able to incorporate them within national process.
- For the company, even if they have to use national submission files, if they are allowed to use the material contained in the EUnetHTA submission dossier as well, that will amount to an increase in the practical use of participating in the EUnetHTA WP5 REA process.
- We need to be concrete about the monitoring of the uptake of national reports.
- However, there was discussion on this point as monitoring was not included in (WP5) work plan.

Moving Forward

Suggestions from EFPIA:

- The creation of 'shared space' and 'sequentiality' i.e., a company moves from Early Dialogues (led by HAS) to the submission dossier and to a REA pilot. This would accelerate the REA process and avoid duplications. Whilst this might not be achievable in JA2 because of timelines this could be a goal for future activities; in that case it should be discussed to which extent the same agencies would be involved in different steps of the process
- Important to move earlier in the pilot process and involve companies earlier in the CHMP approval, preferably involve companies as early as 12 months before expected market authorization.
- For companies it is important that EUnetHTA promotes among EUnetHTA partners to accept company submissions from WP5 pilots to support national justification of relative effectiveness, and so reduce duplication.

Future Steps and Action Points from EUnetHTA:

- EUnetHTA JA3 will have different goals.
- There is a need to work out the logistics, ensure better communication in a more holistic fashion and some alignment with regulatory bodies is necessary (e.g. there is cooperation with EMA on additional data collection).
- Key issue to be solved now is how to discuss getting scientific discussion for CHMP report and who is responsible for sharing? EMA? Industry?
- Share submission file template latest version with EFPIA (as they participated in the production of the submission file template)

Suggested solutions to overcoming obstacles:

Suggested action points:

- → **to improve communication**

- → **to engage in promoting national uptake**
- → **to sell the potential for faster uptake**
- → **to address the issue of investing resources and rewards (ie, accelerated regional uptake)**
- → **avoid controversies**
- → **Stress the sequentiality of the process i.e., the alignment with EMA. Early Dialogues → submission template → REA →Accelerated uptake**
- → **make the products and process more visible, not only from the company point of view but the point of view of EUnetHTA and industry together (to prevent people think it's one-sided)**
- → **to address the risk factor for companies and that benefits outweigh the risks.**
- → **to address EUnetHTA agencies' willingness to use the submission file/ REA report at the national level.**

Example: there is high interest in the early dialogues because the benefits outweigh the risks. There is actually more interest than there is capacity. For WP5 we have the capacity but lower interest in involvement. We have to address the perceived risk for the involvement by companies in these REA pilots

- → **to figure out how to address this at the company level.**

Ex: the issue of communicating what WP5 wanted with regards to the CHMP.

Action point (EUnetHTA):

- → Information regarding involvement in the REA pilots will be shared with a broader representation of companies during a workshop that should be organized preferably in the first half of 2014 in Brussels. EFPIA suggests that this expert workshop should be held before the broader workshop to address some issues regarding the template and pilot process. EUnetHTA responds that the focus should be first on the testing of the template, which was already extensively discussed in the development phase with EFPIA, in some pilots before going into a next phase of consultation and discussion. In the workplan of WP5 it is indicated that such an expert workshop will be used to discuss the template and pilot processes after some experience with the pilots.

Action point (EFPIA)

- **Stimulate industry to participate in EUnetHTA pilot**
- **Continue to promote information regarding EUnetHTA WP5**
- **Facilitate workshops between EUnetHTA and Industry**
- **Work with EUnetHTA to continuously improve pilot processes**

SUMMARY/Main action points:

1. Benefits and risks of involvement in the REA pilots: improve the awareness of the benefit/risk ratio and make it visible for companies
2. Scoping Meeting earlier & stressing voluntary nature to companies
3. Opportunities to monitor & exchange findings of national/local uptake. Make it more visible to our partners. EFPIA indicated that they would welcome a formal commitment from EUnetHTA on the uptake. EUnetHTA responded that there is a formal commitment to have at least 30 national reports based on the EUnetHTA pilots. However, as indicated before EUnetHTA can encourage, promote and facilitate the national/local uptake of the results of the EUnetHTA pilots but can not commit partner organizations.
4. Shared space to secure sequentiality and the sense of continuity. We do not need necessarily have the EMA integration and use the EMA space, but we should link the process and the outcomes, i.e., through the process of early dialogues, moving to REA and from REA to national uptake.

5. Organize a workshop for companies in order to provide more information on EUnetHTA processes and address possible issues through knowledge building. Try to find participation from different groups within companies in order to increase the knowledge within companies on the EUnetHTA process. EFPIA indicated that they would like to agree on an improved process, data elements and outcomes of a joint of REA before moving forward. EUnetHTA indicated that the current process and assessment should be tested in some more pilots and based on the results of these pilots further communications with stakeholders should be planned to optimize the process and assessment.

Task Distribution:
It was agreed that WP5, with the guidance of the secretariat, will take a lead on the action points in discussion with the other EUnetHTA participants and EFPIA.

End of meeting.