

# EFPIA-EUnetHTA Advisory Group e-meeting May 09, 2014, 1:00 - 4:00pm CET

E-meeting  
Organised by EUnetHTA Secretariat  
Danish Health and Medicines Authority, Denmark



## Summary of Discussion

### **EUnetHTA Participants:**

Finn Børlum Kristensen, DHMA, Denmark, EUnetHTA Secretariat  
Julia Chamova, DHMA, Denmark, EUnetHTA Secretariat  
Johannes Tvilling, DHMA, Denmark, EUnetHTA Secretariat  
Mirjana Huic, AAZ, Croatia  
Wim Goettsch, ZIN, Netherlands  
Sarah Kleijnen, ZIN; Netherlands  
Simone Warren, ZIN, Netherlands  
Elisabeth George, NICE, UK

### **EFPIA Participants:**

James Anderson, GSK/EFPIA  
Edith Frénoy, EFPIA  
Eric Giesen, Bayer/EFPIA  
Adrian Griffin, J&J/EFPIA  
Ansgar Hebborn, Roche/EFPIA  
Milena Richter, Sanofi/EFPIA  
Franz Pichler, Eli Lilly/EFPIA  
Andrea Rappagliosi, SPMSD/EFPIA

### **DG-Sanco Participants:**

Jerome Boehm, DG Sanco

## **Agenda, May 9, 2014:**

1. Agenda approval and Introduction of the participants
2. Clarification of the remit and tasks of EUnetHTA as the scientific and technical mechanism of the European cooperation on HTA
3. Survey of the EFPIA member views on the REA pilots – Preliminary results
4. Discussion of the EUnetHTA – EFPIA workshop on REA pilots
  - Purpose, scope and programme
  - What are the relevant and appropriate audience of the workshop and how to reach them?
  - Industry views and suggestions on how to show the value of pilots to the companies
  - Other pertinent issues

### *Intermission during point 4*

5. Other issues
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#### **1. Agenda approval and Introduction of the participants**

The meeting started with a round of introduction.

All participants were welcomed and the agenda was approved.

#### **2. Clarification of the remit and tasks of EUnetHTA as the scientific and technical mechanism of the European cooperation on HTA:**

Slides were presented by the EUnetHTA secretariat explaining the differences between the HTA network and EUnetHTA. The HTA Network is the strategic and political platform whereas EUnetHTA is scientific and technical arm of the Network. There were clarifying questions from industry representatives. Discussion points are summarised below after points 3 of the agenda.

#### **3. Survey of the EFPIA member views on the REA pilots – Preliminary results:**

Slides were presented by EFPIA secretariat. The results presented are interim results. The final report of the results will be shared with EUnetHTA. Discussion points are summarised below

### ***Summary of discussion points:***

In addition to the slides from EFPIA on the survey results, the following reasons were discussed by industry representatives regarding the pharma companies' reluctance to engage in pilots:

#### **1. Adaptation / re-use by member states:**

- The major concerns revolve around questions about the relevance of pilots for decision makers. There seems to be uncertainty around the role of the joint report at national level and the political commitment of member states and limited awareness of the pilot reports in

national organisations.

- Industry needs a public statement by a number of EUnetHTA members and national decision-makers committing to effective use of the information contained in the pilot in the national decision-making process. Such a statement would be key for attracting further participation.
- There seems to be limited interest/ability for participation from bigger member states.

## 2) Duplication, scope and quality

- The pilots have proven that the HTA organisations can co-produce a report in a limited timeframe. However, what remains to be proven is that the pilots lead to reductions in duplications at the national level, as intended by Directive 2011/24/EU. At this stage pilots add uncertainty to the MAH and the benefits remain uncertain.
- There is concern that there is a mix of the scope of national and European level within the pilots, with extensive information requests that require a lot of work from participating companies which are finally not used in the pilot.
- Industry understands the constraints of the Joint Action 2 work plan but considers that a few pilots of high quality with a lot of attention to national implementation would be more beneficial than many pilots with no attention to national implementation.

## 3) Company decision making

- EFPIA continues to support the European collaboration in HTA
- Industry clarified that the company members most involved in making decisions on engaging in pilots are: Global Market Access teams, Product teams and business units, with a strong involvement of senior management. All internal company stakeholders need to endorse a proposal in order to engage in a pilot

It was concluded that concrete actions points to ensure national implementation would be the most relevant step to increase industry engagement.

Furthermore all agreed that the pilot process should evolve on the basis of lessons learned during the first 2 pilots, also taking into account the results of the EFPIA survey. Industry representatives would like this point to be discussed during the workshop.

### **The following was added to the discussion by HTA organisations:**

- Are the concerns from industry specific for this process or are they inherent to any new process?
- It was indicated that implementation of pilots into the national processes (which are often very rigidly adhering to defined national routines) takes some time and it is anticipated that the uptake of the later pilots will be higher than the first ones.
- Implementation will have a great deal of focus in the coming period (remaining 1,5 years of JA2 and JA3). This was confirmed also by the representative of the EC. Implementation as a key success factor is about to be endorsed in October 2014 in the HTA network. Moreover, there will be more emphasis on combined involvement of decision maker and HTA doers
- It was suggested to step away from using the term pilot if other wording is more appealing to industry
- Bigger member states are more and more involved in EUnetHTA activities, e.g. NICE for the submission file template and IQWIG for the guidelines.
- It has to be acknowledged that JA2 is a contract between EUnetHTA and the EC in which certain work has to be accomplished.

## **Other discussion points:**

- Industry representatives indicated that there was a lack of clarity regarding the overall outcome of EUnetHTA JA2: Internal process or reduction of duplication of efforts? It was responded that both will be measured and will be relevant outcomes of JA2. Industry representatives asked how it will be measured, i.e. what specific metrics will be used, where it will be measured, and how it will be presented. It was responded that each WP5 pilot is evaluated through a survey from author (including workload) AND readers perspective. Data are gathered on national implementation of reports from all EUnetHTA members including the way they are implemented. It was also indicated that it takes time to realise national implementation and that there is high commitment to implement currently produced products.
- Industry representatives asked whether it would be possible to have a voice in selecting the rapporteur and co-rapporteur. It was responded that there is a limited budget and that there should be different authoring organisations for different pilots for the learning experience. This limits the flexibility. It was added that for JA3 funding will hopefully be more flexible (easier to allocate budgets along the way to partners instead of pre-allocation at the beginning of the project).
- It was indicated that there is a high interest for early dialogues and it was questioned whether more should be invested in this area.

## **4. Discussion of the EUnetHTA – EFPIA workshop on REA pilots**

- **Purpose, scope and programme**
- **What are the relevant and appropriate audience of the workshop and how to reach them?**
- **Industry views and suggestions on how to show the value of pilots to the companies**
- **Other pertinent issues**

It was emphasised by industry that the workshop should not be a simple “sales pitch” for more pilots. Industry wants to get signals from end users (decision makers) that joint REA reports are useful for national processes, otherwise the pilots seem to be an academic exercise.

It was agreed upon by the meeting participants that the workshop should be a full-day workshop for a broad audience. This should include:

- Results of the evaluation of the first pilots conducted by EUnetHTA among WP5 members for authors and readers experience and among all EUnetHTA members for national implementation and an overview of the changes that will be made to methods/process for the next pilots based on the previous experience.
- Results from the EFPIA survey
- A specific section should be included on national implementation in which WP5 members show how they can/will use the report in national setting –
- How will WP5 move forward - discussion on common solutions for adaptations of the pilot process

It was suggested by WP5 to organise the workshop after the summer as it would be relevant to take on board the discussion from WP5 members at the next f-t-f meeting (10&11 June in Padova). It was emphasised by industry representatives that after the summer seems late if EUnetHTA wants to engage companies in pilots now.

WP5 indicated that an earlier workshop would be possible but this would influence the agenda and could not include the section on national implementation.