EUnetHTA – EFPIA Expert Meeting

October 7, 2015

Zorginstituut Nederland (ZIN), ZorgEekholt 4, 1112 XH, Diemen, Netherlands

Summary Report

Agenda

Chair and Co-chair: Finn Boerlum Kristensen (EUnetHTA Secretariat) / Adrian Griffin, (EFPIA/ Johnson & Johnson)

1. Welcome and objectives of the meeting
2. Overview of EUnetHTA joint assessments
3. Experiences from first 5 pilots
   - Industry experience with joint European assessments
   - EUnetHTA experience based on 5 pilots (perspective of the authors)
4. Discussion on pilot processes
5. Discussion on the future of joint European Assessment
   - JA3
   - HTA Network
6. Update on EUnetHTA Joint Action 3 and conclusion

Purpose of the meeting:

The Expert Meeting was jointly organised by EUnetHTA and EFPIA and hosted at the premises of Zorginstituut Nederland, the lead partner in EUnetHTA JA2 Work Package 5 which focused on the production of rapid joint assessments. Members of EFPIA, as well as EUnetHTA stakeholders, representatives from the partner organisations, including rapid joint assessment authoring agencies, from the European Commission and participants from HTA bodies in Member States gathered to discuss lessons learned from JA2 rapid REA production, possible improvements to the process, and the future of the rapid joint assessments in the European HTA collaboration focusing on JA3.

Opening Remarks

The participants were welcomed by Arnold van Halteren Head of the Health Care Department, National Health Care Institute of the Netherlands on behalf of ZIN. He highlighted the objectives of the meeting, that contributes to continuation and improvement of collaboration on HTA in Europe.

Overview of EUnetHTA joint assessments

Simone Warren presented the EUnetHTA Joint Assessments (see Appendix 2). The presentation mainly covered joint assessments of pharmaceuticals (5 completed pilots).

Experiences from first 5 pilots

Tim Wilsdon, Charles River Associates, presented the outcomes of an analysis of the first five completed pilot assessments on pharmaceuticals from an industry perspective, focusing on process, methods, outcomes and re-use (Appendix 1).

Agnese Cangini, AIFA (Italy) presented the EUnetHTA joint assessment authors' perspective on the pilots (Appendix 1).

Both speakers indicated an overall positive experience with the process of the pilots and identified several areas in need of further improvement.

Key discussion points and comments:

EFPIA Point of View:

- The current timetable of the pilots seems to work and should continue to be followed. However the timely start of assessments could help increase usability of the results.

- In the 5 pilots, from the "Scoping meeting" onwards, timelines were met to a great extent.
- In the first part of the procedure, time can be gained. For example the procedure for choice of authors sometimes led to details. The procedure should be clarified, and more transparency regarding the division of work among authors and reviewers. It was also recommended to clearly communicate the goal of the individual pilots to the participating market authorisation holder.
- Overall this resulted that the 5 pilots were delayed when compared with the ideal EUnetHTA timelines (i.e. publication of the report within 10 days after publication of the EPAR).

- The current "scoping meeting" is useful but could be improved. It was felt that currently, the scoping meeting is too late to really scope the work but to early to review the draft submission. The recommendation was therefore given for having the "scoping meeting" between the MAH, the Coordination Team (CT) and the Authors (if already selected) earlier in the process, to discuss PICO), and to add a final draft submission review meeting later. A confidentiality agreement in place early in the process would also help the interaction.

- EFPIA members feel that re-use could be improved by better timeliness. Re-use of high quality joint assessments is the key issue for EFPIA members. Experience with the five pilots shows that there was no re-use as defined by substituting parts of the rapid REA pilot for the national process.

- Further information can be accessed in the CRA report (available on the EFPIA website at http://www.efpia.eu/uploads/Modules/Documents/cra-efpia---analysis-of-rapid-rea-pilots-final-report-december-2015-stc.PDF).

EUnetHTA authors Point of View:

Discussion items pre-scoping phase:

- The letter of intent should be submitted earlier
- Consideration of the difference between a letter of intent (submitted by the pMAH) and the letter of interest (submitted by EUnetHTA to pMAH)

Suggestions for scoping phase

- Ensure equal involvement of all authors in scoping phase. Early feedback from Coordination Team and Dedicated Reviewers is appreciated, to avoid inefficiency later on.
- Scoping Meeting: minutes could be produced by MAH and checked by authors and CT
- Word version of submission file would be greatly appreciated, taking into account copyright issues etc. Often the submission file is provided in PDF, but can be challenging to work with, and a word file is easier to use for most computer users.
- Earlier selection of PICO and completion of project plan
- More information regarding authors and author roles

Suggestions for assessment phase:

- Flexible working Agenda, such as the possibility to lengthen time to first draft, or shorten time to second draft depending on workload and author needs.
- The first version of the assessment should be consolidated to avoid major changes in the second version
- To improve timeliness: review process could be more efficient (to avoid duplication of work or changes in a later stage).

National uptake:

- Agreement on improvement of timeliness, this would help national use of the EUnetHTA reports.
- Not all contributing countries received submission from MAH. Improved topic selection process would increase efficiency.

Action points:

The feedback received both from industry and HTA agencies that participated in JA2 joint assessment pilots will be taken into account in the update of EUnetHTA procedures and templates at the end of JA2 / the beginning of JA3.

Discussion session 1: The Process

The discussion on the joint REA process was jointly moderated by Marianne Klemp, NOKC, and Adrian Griffin, Johnson & Johnson

Key discussion points and comments:

Improvements to pilot process:

- Decide upon/provide advice on PICO earlier in process (in an earlier scoping meeting)
- Begin discussion of pilot participation with industry earlier (up to 280 days prior to estimated CHMP opinion)
- Pre-scoping meetings are encouraged

- Consider process development on how to handle changes in indication during pre- and scoping phase
- Begin scoping earlier than in the current timeline procedure

Improvements from industry perspective regarding provision of input to pilot process:

- Allow for more input regarding choice of authors, such as selection based on relevance to submission or indication.
- Industry suggested consideration of REAs that are developed with a subset of MS or a particular "expert group" of MS
- Industry suggested the need to decide upon a common set of assessment elements that can be used across Europe (harmonised submission template focusing on aspects relevant across Europe).
- Assistance from EUnetHTA as well as engaged stakeholders and the member states in encouraging re-use of joint assessments.

National implementation and next steps:

- Important to encourage more MS providing input in terms of participation and information regarding HTA needs and engaging in participation in pilot process through authorship, topic selection, dedicated review and uptake. Important that MS identify in the national access pathways where joint assessments can fit and what they can replace.
- Embedding the joint work into a routine work process in national/regional HTA agencies by increasing the familiarity at national level via dissemination and awareness/capacity building on joint work and helping integrate interaction with joint assessments into a normal part of daily work.
- Plan a post assessment planning meeting (prior to finalisation of the assessment) to facilitate national adaptation
- Plan a national implementation meeting at the start (scoping phase) of the process with the coordination team, authors, MAH and relevant stakeholders

Ways to enhance REA processes:

- Consideration of further development/refinement of process to handle confidential and/or unpublished data in JA3
- Structured process to be defined, including consideration of pre-scoping and post assessment
- Assess the need for core common protocols, such as those produced in EUnetHTA JA2 WP7 particularly in areas of rare disease.

Ways to enhance exchange and cooperation on national implementation

- The national implementation of joint work should be a key focus in JA3
- The importance of political support and buy-in from the MS
- Consideration for the creation of an implementation working group at both industry level and MS level
- Guidance on how to re-use joint work and data from joint assessments (such as safety data, tables, outcomes, etc).
- Clarify the role and consider involvement of payers as stakeholders
- Consider assessing not only the implementation but the impact of the implementation
- Importance of collaboration among stakeholders and EUnetHTA to define access pathways to decision

makers.

Action points:

The suggestions will be brought forward to Joint Action 3 to be addressed

Discussion session 2: the future of joint European Assessment

The discussion on pilot processes was moderated by Jérôme Boehm (European Commission)

EUnetHTA views on the future were presented by: Wim Goettsch (ZIN/EUnetHTA)

Industry views on the future were presented by: Edith Frénoy (EFPIA)

Key discussion points and comments:

National implementation issues and next implementation steps in JA3:

- Test the applicability of joint products in the national contexts, such as barriers to uptake and how to overcome said barriers.
- Need for clear definition of what constitutes “re-use”
- Consideration that joint production is two-way, both joint products produced at the European level (EUnetHTA joint REA) and those produced at the national level (collaboration among a small number of MS or re-use of national assessments at European level)
- Importance of buy-in and support from reimbursement decision makers to allow for the inclusion of joint products in national process

Clarify how various discreet activities lead to a seamless process of joint assessment production geared towards meeting the national HTA needs that input into access decisions:

- It will be important to define a structured process of joint production that functions beyond a pilot phase based upon the existing structure of JA2, and refined for continuous joint production.
- Have an implementation meeting also early in the joint production process, such as during scoping phase

Attention to the operational and technical issues of the process for the companies and HTA bodies to be prepared to effectively engage in the process:

- Consideration of the timing, the process, the buy-in, and the uptake at national level, as well as re-use of evidence submission to be considered to facilitate engaging in the joint production process for companies as well as HTA bodies

Gain understanding of processes at national level as well as the processes at the level of industry in order to facilitate implementation and re-use:

Identify bottlenecks in the processes (joint and national) as well as internal processes in companies

- Should MS be classified into subsets that can more or less easily re-use joint work?
- Joint work must take into careful consideration the national processes to ensure more effective national uptake
- Importance of having "line managers"/national assessors engaged in EUnetHTA and joint work – not only top management representatives or technical/academic personnel.

Action points:

The suggestions will be brought forward to Joint Action 3 to be addressed

Concluding remarks and update on JA3:

Wim Goettsch presented the meeting conclusions and update on JA3. (Appendix 2)

Action points:

Plan expert meetings and discussions in JA3 to continue dialogue on the process of joint production and collaboration in HTA across Europe.

The meeting was concluded with a networking reception.

Follow-up action point	**Who**
1. Share lessons learned from JA2 joint production in the final reporting from JA2	EUnetHTA JA2 partners
2. Take suggestions for development of processes for joint production in the future into consideration	EUnetHTA JA3 partners
3. Identify bottlenecks in the processes (joint and national) as well as internal processes in companies and assess ways to overcome bottlenecks	EUnetHTA JA3 partners and Industry Stakeholders (EUnetHTA stakeholder group members)
4. Form a "value network" to improve the production of joint work and the uptake at the national level	EUnetHTA JA3 partners, EFPIA members, Stakeholders, and Member States
5. Plan additional meetings and discussions in JA3 to continue dialogue on the process of joint production and collaboration in HTA across Europe.	EUnetHTA JA3 partners, EFPIA members, Stakeholders, and interested representatives of Member States

Participant list

Name	***Organisation***
Agenese Cangini	AIFA, Italy
Adrian Griffin	Johnson&Johnson
Andrew Bruce	Amgen
Beate Wieseler	IQWIG, Germany
Christoph Künzli	Swiss HTA Network
Christelle Saint Sardos	SP-MSD
Dorottya Dudas	OGYEI, Hungary
Edith Frénoy	EFPIA
Eric Giesen	Bayer
Finn Børlum Kristensen	DHMA, EUnetHTA Secretariat, Denmark
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Franz Pichler	Eli Lilly
Jérôme Boehm	European Commission
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Tim Wilsdon	CRA
Tomas Tesar	Ministry of Health Slovak Republic
Tina Orben	VfA (Germany)
Tuomas Oravilahti	FIMEA, Finland
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