EUnetHTA JA3
an update and future initiatives

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Director EUnetHTA JA3 Directorate

Brussel, February 15, 2018
Outline

• Update on WP activities

• Interaction with stakeholders/EMA

• Future perspectives/developments in EUnetHTA
  o Regional initiatives
  o Towards a permanent model
Summary of Activities in EUnetHTA JA3

• WP4 Joint Production
  o To produce rapid REA on pharmaceuticals and other technologies;
  o To provide a system for topic selection and prioritization, e.g. horizon scanning.

• WP5 Evidence Generation
  o To conduct Early Dialogues (joint HTA or parallel/joint with regulators);
  o To cooperate on additional post-launch data collection to be used in various contexts (such as MEAs, CED).

• WP6 Quality Management
  o To provide quality management for EUnetHTA joint products;
  o To further develop methodologies and tools for joint work if necessary.

• WP7 National implementation and impact
  o To facilitate the reuse and implementation of joint products at the national/local level;
  o To measure the impact of joint work in collaboration with other work packages.

• WP1 Coordination
• WP2 Dissemination
• WP3 Evaluation
WP4 Status Joint and Collaborative Assessments

Other technologies

- Planned: 2 CA
- Ongoing: 2 JA, 5 CA
- Published: 4 CA

Pharma technologies

- Published: 3 JA

Total: 13
Future relevant activities for WP4

• Changes to the pharma JA
  o Simplify the production process (no draft submission file, focus on PICO)
  o Adapt EUnetHTA JA templates (readability), simplify process
  o More actively contacting manufacturers on products of interest for HTA bodies

• Working group for Topic Identification, Selection and Prioritisation (TISP)
  o Both on pharma and non-pharma activities
  o Also links to horizon scanning activities

• Additional activities on Medical devices
  o EUnetHTA Task Force on HTA and medical device regulation (first meeting May 29)

• Interaction with regional initiatives (discussed later)
WP5A - Early Dialogues – Status since JA3 start

20 Letters of Intent
- 8 Oncology
- 2 Neurology
- 2 Immuno-inflammation
- 1 Ophthalmology
- 1 Vaccine
- 1 Metabolic disorder
- 1 Infectious disease
- 2 Hematology

3x withdrawn
- 1 Ophthalmology
- 1 Oncology
- 1 Vaccine

7x individual PCI (~2-3 HTABs)
- 4 Oncology
- 1 Neurology
- 1 Immuno-inflammation
- 1 Infectious disease

10x EDWP
3 multi-HTA EDs + 7 PCC
- 4 Oncology
- 1 Neurology
- 1 Metabolic disorder
- 2 Hematology
- 1 Infectious disease
- 1 Immuno-inflammation

- 4 Completed
WP5B: Post Launch Evidence Generation (PLEG)

• **B1- PLEG Pilots:**
  
  o **Disease specific pilots:**
    
    ▪ **Two ongoing:** two qualification of registries, in collaboration with EMA
  
  o **Product-specific pilots:**
    
    ▪ **Calls for pilots on drugs** about to be launched (two topics proposed by AIFA and TLV)
    
    ▪ **Calls for pilots on medical devices** expected in March

• **B2 - Quality standards tool to evaluate registries**
  
  o Second draft of the tool currently tested by three HTA bodies (AQuAS, avalia-t, INFARMED)
  
  o Third draft of the tool together with first draft of the Vision paper for independently accrediting or assuring registers: expected March 2018
WP 6 - Quality management, guidance and tools
The EUnetHTA Companion Guide - status

**How to create an SOP**

- **SOP-ID:** 1
- **Version:** 1.0
- **Assessment type:** Quality Management (QM)-related
- **Applicable to:** Pharma Collaborative Assessments

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For details on revisions, please refer to section 5 (Document History).

1. **Purpose and Scope**
   The following SOP describes the process on how to create a Standard Operating Procedure. This SOP belongs to the body of SOPs establishing EUnetHTA’s quality management control system.

2. **Roles and Responsibilities**
   Table 1 shows the roles of all persons holding responsibilities in the work process. Table 1: Persons responsible for the process steps.

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<tr>
<th>Responsible persons</th>
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<td>WPS Activity Centre A Lead</td>
<td>Call for Collaboration</td>
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**EUnetHTA Methodology Guidelines**

**Introduction**

The primary objective of EUnetHTA Methodology Guidelines is to focus on methodological challenges that are encountered by HTA assessors while performing relative effectiveness assessments of pharmaceuticals or non-pharmaceutical health technologies.

As such, the guidelines represent a consolidated view of non-binding recommendations of EUnetHTA network members and is no official opinion of the participating institutions or individuals.

The products of EUnetHTA Guidelines have been successfully coordinated by EUnetHTA JA3 (VIPS, ALE) and EUnetHTA JA3 (WHE) (WHE). Please have a look at the SOPs to identify where and how to use the guidelines.

**Published guidelines**

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## WP 7 Status of activities

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<th>Activity</th>
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<tr>
<td>Activity 1: Research and analysis</td>
<td>Final report Nov ’17 (deliverable)</td>
<td>• Final report is publically available on the EUnetHTA website</td>
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<td>Activity 2: Case studies</td>
<td>Ongoing throughout JA3</td>
<td>• Year 1 case studies published in the activity 1 report</td>
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<td>• Year 2 case studies to take place in April and May so as to</td>
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<td></td>
<td></td>
<td>include discussion of the EC proposal for a regulation on HTA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 4 countries have volunteered for year 2</td>
</tr>
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<td>Activity 3: Technical to support development</td>
<td>Delayed to account for publication of the EC</td>
<td>• Activity to be initiated following liaison with WP1</td>
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<td>of the model of HTA cooperation</td>
<td>proposal for a regulation on HTA</td>
<td></td>
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<tr>
<td>Activity 4: Implementation Network</td>
<td>Implementation reports to be published May 2018, Nov 2018, May 2019, Nov 2019</td>
<td>• Data collection procedures to gather experiences of using the EUnetHTA assessments in place</td>
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<tr>
<td></td>
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<td>• The first implementation report will include:</td>
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<td></td>
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<td>• a baseline to measure assessment use in JA3</td>
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<td></td>
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<td>• first implementation data from JA3 assessments</td>
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Future work

• Ongoing collection and publication of data (quantitative and qualitative) about use of the JA3 EUnetHTA assessments;

• Collaborative work with WP6B among HTA users about incorporating EUnetHTA tools and guidelines in their national procedures;

• Develop resources and run activities to support implementation of EUnetHTA outputs;

• Support the development of the model of HTA cooperation.
WP1 Output and Milestones in 2017

Participation, Contribution and Coordination

Reporting

Products and Services

Publication

Increased Technical and Network Capabilities
Assembly and Forum, HTA Synergy, EUnetHTA-EFPIA Technical Meeting, EUnetHTA-EMA bilaterals, Executive Board/Project Management Group Face-to-Face, involvement and contribution to European-wide symposiums and organizations

Submission of Interim Technical and Financial Report (81 partner organisations and institutions)

EUnetHTA-EMA Parallel Consultation Process (Early Dialogues) and continued production of REAs

Internal monthly summaries and quarterly EUnetHTA magazine; interview and publication pieces in journals and web

New Intranet infrastructure (400+ users): development of Project Management Tool (PMT), Advanced Address Book (AAB); 30% increase in social media base; launch of rebuilt website is imminent
WP2 activities

• Involvement in communication activities

• Dissemination registry

• Training:
  o Training Strategy
  o A virtual classroom with training materials for partners
  o A Welcome Package for newcomers

• Stakeholder Involvement activities
  o Overall Stakeholder Involvement SOP
  o Stakeholder Registry
WP 3- Evaluation

• In total 11 evaluation reports
• 3 reports have been delivered so far
  – Bi-annual report I and II
  – Yearly interim report I
• The WP has also carried out
  – Partner interviews
  – Stakeholder interviews
  – Partner survey
• 4 reports to be delivered 2018
  – Bi-annual report III, IV and V
  – Yearly interim report II
Progress Stakeholder involvement in JA3 (I)

• Cross-WP task group on involvement patient and consumers started fall 2017
  o Support involvement in WP4 and WP5 activities
  o Meeting F2F January 2018
  o Experiences with involvement shared and collected and proposal to move on

• Cross-WP task group on involvement healthcare providers will be initiated in 2018
  o Support involvement in WP4 and WP5 activities

• Interactions with pharma industry on WP4 and WP5
  o Link to Heads of Agency meeting in May 2017
  o Technical meeting with EFPIA in December 2017
    o Experiences are shared and proposals to improve were discussed
  o Individual MAH interaction in REAs
Progress Stakeholder involvement in JA3 (II)

- Interaction with MedTech industry
  - Individual MAH interaction in REAs
  - Planning a technical meeting with MedTech Industry in 2018

- Interaction with payers will be intensified
  - Based on some early interactions in a meeting with EMA in September
  - Meetings going to be planned to identify progress activities and identify gaps to progress on

- Involvement in EUnetHTA Forum 2017
  - Active contribution of stakeholders in different panels on involvement as such, horizon scanning and topic selection and role of additional data collection
EMA and EUnetHTA finalise joint work plan for 2017-2020

13 November 2017

Medicines regulator and network of Health Technology Assessment (HTA) bodies continue to strengthen their collaboration

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) have published a joint work plan outlining key areas of collaboration for the next three years.

The EMA-EUnetHTA collaboration, which began in 2010, aims to harness synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine whilst
EUnetHTA-EMA workplan

• early dialogue / scientific advice (WP5A)
• information exchange at market entry (WP4): the exchange of information on the CHMP opinion
• post-authorisation data generation (WP5B): post-licensing evidence generation tools, such as patient registries,

EMA and EUnetHTA will also further collaborate in a number of areas including:
• concepts of unmet medical need and therapeutic innovation in view of possible synergies;
• understanding the conceptual similarities and differences between the significant benefit of orphan medicines versus their added therapeutic value.

Structured through bi-annual meetings

BUT ALSO INTERACTION WITH Medical Devices Regulator (DG Grow)!
• On methodologies and guidance, starting with meeting May 29
Introduction: regional activities (Pharma)

1) FINOSE (Finland, Norway, Sweden)
2) Valletta (Cyprus, Greece, Italy, Malta, Portugal, Spain, Slovenia, Croatia, France (observer))
3) BeneluxA (Austria, Belgium, Luxemburg, Netherlands)
4) Visegrad +2 (Czech Republic, Hungary, Poland, Slovakia + Croatia, Lithuania)

- Collaborative approach to gathering information
- Mutual recognition; Joint HTA
- Best practices, registries, policy dilemmas
- Horizon Scan interpretation; Information exchange;
- Input for Joint Negotiations
Possibilities for collaboration with regional collaboration on Pharma

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<tr>
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Regional initiatives may also support EUnetHTA by fitting EUnetHTA and national systems, identify topics of interest and increase industry interest to participate in EUnetHTA joint REAs by offering clear pathways to national decision.
Specific activities planned with regional initiatives on Pharma

Actions from WP4 LP and CoLP Pharma + WP1 LP:

• Being involved in meetings with regional networks
  o Meetings with FINOSE;
  o Meetings and sharing workplans on HTA with BeneluxA;
  o Working on contacts with the other initiatives;
  o In close collaboration with the EC.

How EUnetHTA may support in HTA activities of regional initiatives:

• Project management of the joint clinical assessments (clinical evaluation) including quality management of the process incl. methodological guidelines, the use of tools and templates and methods for patient involvement

• EUnetHTA WP4 budget
Conclusions

• EUnetHTA JA3 has progressed in activities
  o Major achievements in terms of organisation but also collaboration with EMA (for instance the early dialogues);
  o Joint assessments of REA both for pharmaceuticals and other technologies are starting off, implementation is growing;
  o It is important that the current momentum regarding the joint REA both on pharma and other technologies will be kept!

• Discussion will start on the development of EUnetHTA JA3 activities until 2020 in relation to the future permanent model
  o Deliverable in EUnetHTA JA3 GA is to support the development of permanent EU cooperation on HTA (WP1 deliverable)
  o Stepwise approach starting with constructive discussions in the EUnetHTA Executive Board with input of the European Commission on the future scenario as described in the EC proposal
  o Linked to the progress of political discussions on the current proposal of the EC.
  o Taking on board experiences and views of the stakeholders
Thank you
Any questions?