HAUTE AUTORITÉ DE SANTÉ

EUnetHTA JA2 WP7
Multi-HTA Early Dialogues

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Collaborative EUnetHTA actions

Mandate for EU collaboration in HTA*

Relevant EUnetHTA* ongoing actions

- Raise standards in assessment **(general methodology guidelines)****
- Improve the quality and appropriateness of the data produced
  - Initial evidence generation **(early dialogues)** and disease-specific guidelines***

(*) Voluntary network of HTA bodies in Europe
(**) Article 15 **DIRECTIVE on the application of patients' rights** in cross-border healthcare
(***) Pharma Forum Recommendations

Early dialogues

Early Dialogue/scientific advice between HTA bodies and developers

- Scientific advice (SA) in place for a long time at regulatory agencies
- National HTA advice (e.g. NICE, GBA, AIFA..)
- Parallel Regulatory + HTA SA

Current initiatives: Multi HTA early dialogue

- Supported by European Commission
  - Part of EUnetHTA JA2 (2012 – 2015)
  - Call for tender for additional EDs

Multi HTA early dialogues
Current process

Main characteristics of the multi-HTA EDs:

- Confidential
- Non binding
- For new products with expected **added benefit**
- One indication per procedure

Main procedural steps:

- Letter of intent for selection
- Briefing book
- Face-to-face meeting

Content of the Briefing book:

- Development strategy, cost-effectiveness studies: **planned** studies
- **Prospective questions** and company's position for each question relevant to the development plan

Multi HTA early dialogues
Current process - Timelines

D0 = Face to face meeting

- **D-60: Briefing book sent to participating HTA bodies**
- **D-45:** Teleconference between HTA **bodies before FTF meeting to identify missing information in the dossier**
  - **list of issues** to be addressed by the company either in writing and/or at the FTF meeting
- D-30: Clarification by the company sent to HTA bodies
- D-7: HTA bodies send written answers to company's questions

Multi HTA early dialogues
Current process – Timelines

D 0: Early Dialogue FTF Meeting

- Preliminary discussion (without the company) on key issues
  - agreement and possible disagreements among HTA bodies
- FTF meeting with the company and HTA organizations – 3hrs
  - Each question discussed by each HTA body
  - Open dialogue, discussion on alternative approach
- Conclusions (without the company)

D+7: Detailed minutes

- including common answers/positions and positions of each HTA body on each question
- to be provided by the company, validated by all participants

Multi-HTA Early dialogues
JA2 WP7 ED pilots

10 EDs: 2 pre-pilots in 2012 / 8 pilots in 2013 (all on drugs)

- Coordinated and hosted by HAS, France
- **HTA participants:** AIFA, ASSR, IQWIG, GBA, NICE, HVB, CVZ, KCE/INAMI, GYEMSZI, TLV and HAS
- **EMA** invited as observer
- **All documents remain confidential** (unless explicit company's request)
- Various therapeutic fields
- Small and big companies
- One or 2-day FTF meeting (one product/day)
- Successful experience: improvement of collaboration between partners and process **efficiency**

Multi-HTA Early dialogues
JA2 WP7 ED pilots - Survey

Ongoing survey on process (WP7JA2 deliverable)

- Sent to the representatives of HTA organisations, observers and developers which participated to at least one ED
- **45 Questions** on all aspects of the process including objective and scope, candidate selection, confidentiality and roles and responsibilities of participants, collaboration, evolution, resources
  - ***Consolidated answers:*** *1 per HTA organisation and company*
- Analysis ongoing
- **Will be used to improve the process for additional EDs financed by EC**

EUnetHTA survey on ED
First answers received

12 HTA bodies (9 countries), 9 companies

- Analysis ongoing

When to get advice?

- Before phase 3, sometimes before phase 2 (choice of endpoints)
- Product with a supposed added benefit

Optimal number of HTA bodies?

- At least 5, but 10 would be too much (meeting too long)
- Mix of agencies focused on clinical relative effectiveness or on cost-effectiveness

Areas to cover (recommended, not compulsory):

- One indication per meeting
  - more than one line of treatment within the indication suggested
- Primary and secondary E, patient relevant benefit, added benefit,
- RE and CE

EUnetHTA survey on ED
First answers received

Key for successful EDs (companies perspective)

- Guidance needed on information to include in the BB
- Not more than 10 Q to be addressed during FTF
- Proposal: discuss only problematic issues during FTF; other issues may be answered by writing
- HTA bodies should always justify their answers
- Responses to be summarized by the chair after each Q
- Expertise in the field should be ensured (external expert)
- Importance of discussion

EUnetHTA survey on ED
First answers received

Key for successful EDs (HTA bodies perspective):

- Quality and level of detail in company's position for each question
- TC : discuss completeness of data and key issues
- Company's participation to the TC:
  - *Yes (companies)*
  - *No (HTA bodies)*
- HTA bodies' argued written answers exchanged one week before FTF meeting
- Internal FTF discussion of HTA bodies
- Maximum of 10 questions to be addressed during FTF

EUnetHTA survey on ED
First answers received

- **HTA agencies have different focus (e.g. some focus on RE, some on CE)**
  - **Chair to lead the discussion and combine, summarize consensus and divergences**
- **HTA written answers to be sent to the company?**
  - **Split answers – written answer should stay an internal document; if not – should be reviewed and sent to the company after FTF**

EUnetHTA survey on ED
First answers received

- **EMA as observer/active partner in ED?**
  - **Yes, to better understand HTA goals**
  - **Too much time on regulatory issues that EMA should cover**
  - **Companies: split answers**
    - Very much supported (some)
    - If EMA is observer, this may lead to a bias towards certain elements of the development program not relevant from a regulatory perspective (some)
    - Confidentiality issues (all)
- **Companies: importance of harmonisation of opinions among HTAs (and with EMA)**
- **Parallel EMA/HTA advice generally supported by HTA bodies**

Next step: additional EDs (2014)

EC Call for tender 2013

- **In addition to EunetHTA EDs**
  - At least 10 EDs : 7 drugs and 3 medical devices
  - Conducted by a consortium of at least 10 HTA organizations
- **Consortium selected by the Commission**
  - Call for tender published (April), deadline for submission (June), Selection by Commission (August), Contract signed (October).
- **Selected project :**

SEED consortium

Additional EDs (2014)
SEED consortium

SEED: Shaping European Early Dialogues

- HAS (lead) + 13 partners
- Regulators, payers, patient representatives as observers.
- Sustainable process to put in place, including collaboration with EMA
- Kick-off meeting (D1): October 21, 2013
- Preliminary work : procedures and templates for Briefing Books (medicines, MDs)
- All EDs in 2014, interim report after 5 EDs

Scenarios to test

- Independent advice and
- Parallel EMA-HTA advice

Model for permanent ED activity to be proposed

SEED consortium
Call for expression of interests

- **Selection of candidates - DRAFT criteria:**
  - **Solid assumption of added benefit:** in a target population, compared to one or more intervention alternatives (standard of care) for achieving the desired results, when provided under the usual circumstances of health care practice
  - To be assessed with appropriate patient-relevant clinical endpoints, relevant to main characteristics of the disease/condition to treat, the target population, and the aim of treatment.
- **First come first served basis**
- **Call for EOI to be published very soon !**

SEED consortium
Procedure

- **Topics to be covered :**
  - Relative clinical effectiveness and cost effectiveness
- **Procedure**
  - Derived from the EUnetHTA procedure
  - Improvements to be proposed following completion of analysis of survey results
  - To be discussed and adopted by *SEED* partners
- **Free of charge for companies**
- **Dates of the meetings**
  - between March and December 2013

Early dialogues/Scientific advice Permanent model

- EMA/HTA and multi-HTA EDs
  - Useful initiatives, may be optimised
- Several scenarios within the EC call for tenders
  - Pros and cons for each scenario
  - Survey results after each ED to improve the following one
- Towards a parallel EMA – EUnetHTA advice?
  - SEED results
  - Will depend on all actors views
    - HTA bodies – EUnetHTA
    - EMA (drugs)
    - Companies
    - Payers?