Relative Effectiveness Assessment of Pharmaceuticals (WP5 – SG4)

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Update on activities WP5
SG4 – methodology guidelines

- **Objective: to produce a common documentation / methodology (HTA core information) for Rapid HTA focussed on relative effectiveness of pharmaceuticals in Europe**

- **Initiated in 2010**

Update on activities WP5
SG4 – methodology guidelines

Main topics of interest:

- **Comparators and comparisons**
  - Criteria for choice of most appropriate comparator(s)
  - Methods of comparison: direct and indirect comparisons
- **Outcomes**
  - Clinical endpoints
  - Surrogate endpoints
  - Composite endpoints
  - Endpoints relevant for patients
  - Health-related quality of life
  - Safety
- **Level of evidence**
  - Internal validity
  - Applicability

Update on activities WP5 : SG4
What has been done (1)

1st drafts: sent to WP5 consultation
(Jan. – March 2010)

1275 comments
from 12 HTA agencies

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Update on activities WP5 : SG4
What has been done (2)

- **All comments were analysed by the authors and the coordinator (HAS)**
- **Main (controversial) issues identified**
- **3 workshops to discuss 4 topics:**
  - May 3rd (KCE): HRQoL and patient-relevant outcomes
  - May 5th (HAS): External validity
  - June 10th (Oslo): Surrogate endpoints and Internal validity
- **Endpoints relevant for patients GL merged into the GL on clinical endpoints**
- **GL on grading experience in experts and experience has been dropped (after WP5 survey)**

Update on activities WP5 : SG4
What has been done (3)

Main comments

- Define the scope of the GL and the terminology used
- Structure of documents
- Consistency between GL
- Define the most important concepts
- Give clear recommendations, useful for HTA assessors and pilot authors

2nd drafts for the pilot assessment available in June 2011

Update on activities WP5: SG4
Next steps

- **End 2011 - Feb. 2012**: Guidelines review incorporating input from the rapid model pilot

- **3rd versions - WP5 and SAG consultation**:
  - First batch: March 2012
  - Second batch: April 2012

- **EMA and public consultation**:
  - First batch: April – June 2012
  - Second batch: June – August 2012

Update on WP5 activities
EMA – EUnetHTA collaboration

- **Guidelines**
- **EPARs**
- **Parallel scientific advice**

EMA – EUnetHTA collaboration

EPARs

- 2 meetings in 2010 (EMA, London) and 2011 (CVZ, Diemen): main topic: **adaptation of EPAR template** in line with comments from MEDEV/EUnetHTA

- **Aug. – Nov. 2011:** 10 EPARs “new template” evaluated by 10 HTA organizations with the same questionnaire used by the EMA to assess EPARs (parallel EMA – HTA review)

- **22 Feb. 2012 in Paris (HAS):** next meeting to discuss the EPAR review

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EMA – EUnetHTA collaboration

EPARs

EPAR review - HTA contribution

- AETSA (Teysuno / Halaven)
- AIFA (Teysuno / Jevtana)
- CAHIAQ (Pumarix / Xeplion)
- CMPT (Esbriet / Pravafenix)
- CVZ (Xiapex / Gilenya)
- NICE (Esbriet / Jevtana + Gilenya and Halaven)
- NOKC (Pumarix / Xiapex)
- HAS (Esbriet / Trobalt)
- HVB (Xeplion / Gilenya)
- UVT (Halaven / Pravafenix)

Status

All questionnaires have been filled in and returned
Analysis ongoing

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EMA – EUnetHTA collaboration
EPARs – Paris meeting (Feb 22, 2012)

Main topics proposed for discussion:

- Progress of relevant workpackages in EUnetHTA
- Evaluation of the new **EPARs**
- Guidelines
- Parallel EMA/HTA scientific advice

EMA – EUnetHTA collaboration

Parallel EMA/HTA SA

- **Pilot phase, pharmaceuticals only**

- **Upon companies request** (participating HTA agencies chosen by the company)
  - **Tapestry networks** (9 SA in total, 6 SA with HAS participation: 4 finished and 2 upcoming)
  - **Companies:** 3 companies, 4 SA

- **HTA input within the EMA SA procedure timeframe at the time of the discussion meeting only (minutes)**

- **No request for HTA bodies to produce written answers**

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EMA – EUnetHTA collaboration
Parallel EMA/HTA SA

Content:

- EMA - targeted questions
  - – product development plan
- HTA – targeted questions
  - – active comparisons, outcomes, added value, design of pragmatic trials
- Common questions

Parallel or joint advice?

- Separate advice by each HTA body participating in the exercise ?
- Compiled document?
- Exchange of final advices? (EMA, HTA?)

EMA – EUnetHTA collaboration

Parallel EMA/HTA SA

- **Excellent opportunity to test:**
  - Agreement on the choice of comparators and endpoints both for MA and REA
  - EUnetHTA and EMA guidelines recommendations in real examples of product development
  - Consistency with final decisions
    - **EMA: MA opinion**
    - **HTA: HTA guidance and reimbursement decision**
- **Possible benefits/consequences:**
  - Drug development adapted to the needs of both regulators and HTA bodies
  - Higher requirements?
  - Time to market: Faster or slower?

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