European network for Health Technology Assessment

Safe and Timely Access to Medicines for Patients
(European Commission’s STAMP expert group)
Brussels, May 6, 2015

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Chairman of EUnetHTA Executive Committee
Secretariat Director, EUnetHTA Secretariat
Danish Health and Medicines Authority, DHMA,
Copenhagen, Denmark
Participants in EUnetHTA JA2

EUnetHTA Partners and Associates

49 Partner organisations designated by Ministries of Health

Large number of regional agencies and non-for-profit organisations that produce or contribute to HTA
Some of the Partner Organisations in Joint Action 2 (2012-15), e.g.

- Germany, IQWIG, DIMDI (+GBA, Medical Valley – EMN)
- France, HAS
- UK, NICE, NETSCC (+HIS Health Improvement Scotland)
- Italy, AGENAS, AIFA, ASSR Emilia Romagna, Veneto Region
- Spain, ISCIII, AETSA, OSTEBA, Avalia-T, AQuAS (Spanish HTA Network)
- Poland, AHTAPOL
- Sweden, SBU, TLV
- Croatia, AAZ, CHIF Croatian Health Insurance Fund
- Portugal, INFARMED
- Austria, LBI, GÖG, HVB, Danube University Krems, UMIT
- Netherlands, ZIN
- Belgium, KCE, INAMI Institut National d'Assurance
- Bulgaria, NCPHP, NCPRMP, Medical University of Sofia
- Finland, THL, FIMEA
- Denmark, DHMA (Coordinator), CFK Region Midt; KORA
The Domains of the HTA Core Model® - assessing dimensions of value

SCOPE

Rapid REA

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects

HTA Core Model DOMAINS

Reliable, timely, transparent, information
EUnetHTA Tools

HTA Core Model Online
HTA Core Model for Rapid Relative Effectiveness
Submission template (undergoing piloting)
Planned and Ongoing Projects Database (POP)
Evidence database on new technologies (EVIDENT)
Adaptation Glossary & Toolkit
Contact Database
Intranet Groups
E-meeting facility
News Aggregator
WP5 – Joint Action 2 – Where are we now?

First pilot
- **Zostavax** for prevention of Herpes Zoster (Sanofi-MSD), author organisations: ZIN (NL) and A. Gemelli (Italy). Published Sept. 2013

Second pilot
- **Canagliflozin** for treatment of diabetes type 2 (J&J), author organisations: FIMEA (Finland), AAZ (Croatia) and Regio Veneto (Italy). Published Feb. 2014

Third pilot
- **sorafenib** for advanced thyroid carcinoma (Bayer), author organisations: AIFA (Italy) and IMFARMED (Portugal). Published March 2015

Fourth pilot
- **ramucirumab in combination with paclitaxel** for previously treated advanced gastric and gastro-oesophageal junction cancer (Eli Lilly), author organisations: NOKC (Norway) and AAZ (Italy). Published March 2015

Fifth pilot
- **Vorapaxar** for cardiovascular complications after MI (MSD), author organisations: HAS (France) and Ministry of Health (Slovakia). Expected publication: June 2015

Sixth pilot
- **New Hepatitis C treatments**, author organisations: KCE and RIZIV (Belgium), HVB (Austria), AAZ (Italy), A. Gemelli (Italy). Planned publication Dec. 2015
Organisation of Joint Assessments

Author organisation

Co-author organisation

Agency A

Agency B

Pool of dedicated reviewers

Agency C

Agency D

Agency E

Agency F

Agency G

WP5 members review
WP5 Strand A – Scoping Phase

Figure 2: Schematic overview of the Scoping Phase
It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific joint REA's.

**Timeline (days)**
- 180 days before CHMP opinion
- 90 days before CHMP opinion
- 0 days

<table>
<thead>
<tr>
<th>WP5 members</th>
<th>180 days before CHMP opinion</th>
<th>90 days before CHMP opinion</th>
<th>0 days</th>
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<tbody>
<tr>
<td>WP5 expression of interest on topic proposition*</td>
<td>Selection of 1 author + 1 co-author and 2-5 dedicated reviewers</td>
<td>Pre-scoping meeting</td>
<td>Receive final project plan</td>
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<th>Dedicated reviewers</th>
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<td>Request for authorship (2 weeks)</td>
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<td>Request for draft submission file</td>
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<th>Authors/Co-authors</th>
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<td>Feedback on draft submission file (2 weeks)</td>
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<td>Feedback from dedicated reviewers on draft submission file</td>
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<th>Coordination Team</th>
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<td>Scoping phase/draft meeting</td>
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<td>Scoping final meeting</td>
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<td>Ongoing EMA process (start of official MA process = 2-10 days / 150 days until CHMP opinion)</td>
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<th>Company applying for MA</th>
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<td>Expression of interest</td>
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<td>Final submission file (2 weeks)</td>
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Legend:  
- External products  
- EU net HTA products  
- Meetings

* Based on the list of applications for new human medicines under evaluation by CHMP
Scoping Phase

1. Expression of interest regarding topic by:
   - Pharmaceuticals company
   - HTA organisation (WP5 members)
2. Selection of Author/Co-Author organisation/Reviewers (WP5 internal process)
3. Receive draft submission file from MAH
4. Pre-Scoping E-Meeting
5. Scoping meeting with MAH (f-t-f)
6. Feedback from Author organisation on draft submission file
7. Receive final submission file
8. Finalisation of project plan including timelines
Assessment Phase

Figure 3: Schematic overview of the Assessment Phase
It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific joint REAs

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<th>timeline (days)</th>
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Legend: ![Legend Image]
Assessment Phase

1. Preparing the first draft of the assessment by the Author organisation and Co-Author organisation (35 days)

2. Review by dedicated reviewers (10 days)

3. Preparation of second draft of the assessment by author organisations (15 days)
Assessment Phase

4. Editorial review and layouting (15 days)

5. Consultation phase of all WP5 members and market authorisation holder (10 days)

6. Final version of the assessment (15 days)

7. Publication of final report and implementation into the national context (optional)
Survey on outcomes of HTA of sofosbuvir across Europe*

- questionnaires to EUnetHTA Partners and members of the Medicine Evaluation Committee (MEDEV) in 28 (30) countries
- information about
  - status of any assessment
  - final or preliminary assessment results on
    - clinical effectiveness
    - cost-effectiveness
    - budget-impact of sofosbuvir
  - reimbursement status
- willingness to share (preliminary) assessment report(s) on sofosbuvir

By early September 2014 28 responses were received from 26 countries

* Thanks to: Hedi Schelleman, Rudy Dupree, Finn Børlum Kristensen, Wim Goettsch
Survey results

- 26 out of 30 jurisdictions* responded
- 10 jurisdictions **no assessment started**
  - No application received (n=5)
  - No assessment needed
  - drug falls into the category of communicable diseases (n=2)
  - hospital drug (n=1)
  - Unknown (n=3)
- 9 countries assessment **ongoing**
  - Two jurisdictions provided interim results
  - Full report: England and Wales
  - No full report: Spain, Slovenia**

* EU plus Norway and Switzerland. For UK there were separate responses from England and Wales, and from Scotland. For Romania and Estonia no contact address was available N=28

** In Slovenia the assessment was done by National Viral Hepatitis Expert group
Survey results

7 jurisdictions assessment complete

- Full report: Denmark; France; Germany (IQWiG and G-BA*); Netherlands; Scotland

- No full report: Belgium; Portugal

*IQWiG and G-BA do not make two separate assessments: IQWiG is commissioned by the G-BA to assess the manufacturer dossier’s studies for the G-BA. The G-BA makes the final assessment for Germany after a hearing procedure consisting of written statements and an oral hearing with clinical experts, scientific medical societies and other stakeholders.
Survey results

Data available: full reports (6 jurisdictions)* and statements (4 jurisdictions)

Sofosbuvir effectiveness data:
- 8 RCTs (4 phase III and 4 phase II)
  5 non-randomised studies (2 phase III, 3 phase II)
  > 1500 patients

The outcomes most mentioned in the reports:
- **SVR12**: Sustained virological response
  12 weeks after the end of treatment
- QoL: Health-related quality of life
- Mortality
- Safety

*from one jurisdiction (Germany) there are two full reports (IQWIG and G-BA) available.
Thank you
Any questions?

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme