Collaboration in assessment of relative effectiveness of pharmaceuticals in the EU

INTERNATIONAL SCIENTIFIC AND PRACTICAL CONFERENCE “INTERNATIONAL EXPERIENCE IN HEALTH TECHNOLOGY ASSESSMENT AND PROSPECTS OF ITS IMPLEMENTATION IN RUSSIA”, Moscow, May 21, 2012

Wim Goettsch
Lead Partner EUnetHTA WP5 on REA of pharmaceuticals
CVZ, The Netherlands
Reasons for European collaboration

• Technologies become more ‘international’
  • Not only for pharmaceuticals (European market authorization) but also for medical devices, surgical procedures etc

• Patients become more ‘European’
  • EU Directive on cross-border healthcare, specifically mentioning HTA as a tool

• Decrease duplication on HTA assessments
  • For some technologies like drugs in oncology assessments are performed simultaneously by different national and regional organisations*

• Increase consistency between different national HTA assessments
  • Variety in type of assessments seems to be common: does this lead to different assessment results?#
BUT....

• No European health insurance

• Decisions on reimbursement should be made on a national level!
  • For instance for pharmaceuticals*
Levels of European HTA collaboration

Scenario 1: ICT platform
- Level of welfare effects

Scenario 2: Guideline development
- Common European guidelines

Scenario 3: Joint Assessments
- Common European assessments
- Sharing national assessment reports in Europe
Pharmaceutical Forum 2008 Recommendations

- Decisions on reimbursement on national level
- Relative effectiveness assessment (REA) vs cost-effectiveness assessment (CEA)
- Exchange of REA criteria/information
- Implementation of agreed good practice principles for REA
- More effectively done by existing networks

But also: “…Member States, with the involvement of the EMA, should continue their efforts to consider how European Public Assessment Reports can further contribute to relative effectiveness assessments..”
EUnetHTA was asked to take this work forward by the Steering Committee of the HL PF in autumn of 2008.

EUnetHTA WP on REA started in 2010

EUnetHTA decided to work with the definitions that had been agreed in PF2008

According to the Pharmaceutical Forum:
Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.
EUnetHTA - European Network for Health Technology Assessment

- 2006-2008 EUnetHTA project
- 2009 EUnetHTA Collaboration
- 2010-2012 EUnetHTA Joint Action 1
  - Workpackage on Relative effectiveness of pharma.
- 2012-2015 EUnetHTA Joint Action 2
  - Workpackage on Rapid assessments (pharma ao)
- 2015 and onwards >> sustainable network
The WP5 Partners JA1

1 Lead
CVZ
College voor zorgverzekeringen

1 Co-lead
HAS
HAUTE AUTORITÉ DE SANTÉ

17 Associated Partners

13 Collaborative Partners

Objective:
Development of HTA tools and methods for REA

Development of model for Rapid REA (CVZ)
Methodology guidelines for REA (HAS)
Collaboration with EMA (HAS)

Background review on national REA (CVZ)
Pilot of Rapid REA (CVZ)
# Background review on national REA#

**Objective:** provides an overview of the processes and methodologies used in national practice

29 countries included*  
Australia Austria Belgium Canada  
Czech Republic Denmark England & Wales (UK)  
Estonia Finland France Germany Hungary  
Ireland Italy Latvia Luxembourg Malta Netherlands  
New Zealand Norway Poland Portugal Scotland (UK)  
Slovakia Slovenia Spain Sweden Switzerland  
Turkey United States of America

*Separate data abstraction for England/Wales & Scotland  
Background review on national REA
Conclusions and challenges

- Most of countries carry out some form of REA to support national reimbursement decisions of pharmaceuticals
- The scope and the methodology used vary across countries to some extent, however not that much (TERMINOLOGY!)
- Rapid assessments are most common and relevant for reimbursement Purposes
- The differences between counties, as well as the reasons behind them, need to be considered in the development of a common European methodology for REA

Table 1: Most relevant challenges for a European model

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<thead>
<tr>
<th>Most relevant challenges</th>
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<td>Methodology to do assessments is often not explicitly reported</td>
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<td>Variation between jurisdictions in terminology and definitions</td>
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<td>How to handle lack of effectiveness data</td>
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<td>How to present unintended and intended effects</td>
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<td>Variance in usual care between jurisdictions</td>
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Development of REA model

*Should be based on HTA Core Model* (HTA Core Model = A structured manner of creating and presenting HTA information)

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WP5

- Multiple comparators
- Years after market authorisation
- Indication based

- Limited number of comparators
- Soon after market authorisation
WP5 pilot of a rapid assessment

Objective: Test the usability of the draft model for rapid REA and the draft guidelines

Topic selection:
- List was produced of all pharmaceuticals that received market authorization between June 2010 and February 2011
- Selection made based on exclusion criteria
- Manufacturers approached for willingness to provide submission file (2 out of 4 were willing)
- Pazopanib for the first-line treatment of metastatic renal cell cancer.

Basic documentation:
- Manufacturer submission file
- Rapid REA model
- Methodological guidelines developed in WP5
WP5 pilot of a rapid assessment

Experience

- Participation of 29 organisations requires intense coordination on several levels
- 3,5 months timelines for scope/assessment phase if possible but very intense
- Relevance of all research questions (assessment elements) for a rapid assessment?!
- Harm/benefit analysis is still in development (synthesis).
- This model of collaboration is not sustainable if rapid assessments needs to be done within three months
### Development of model for Rapid REA

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#### Last 4 domains replaced by checklist

**Principles:**

- **>> Limited timeframe:** Transparency Directive 89/105/EEC
- **>> Different collaboration model**
WP5 Joint Action 2 (2012-2015)

- Ten pilots on rapid REA of pharmaceuticals between 2012-2015

Collaboration model:
- One organisation is author and one organisation is co-author
- A number of WP5 partners will be dedicated reviewers
- Other WP5 partners will be consulted after this dedicated review
2015 & onwards

- EUnetHTA = permanent network

- Possible joint assessment of relative effectiveness of pharmaceuticals?
  - Short after or along with market authorisation
  - Rapid REA reports should be input for CFH
  - Formatting tools to transfer REA report into CFH report