19TH European Health Forum Gastein
Demographics & Diversity in Europe
New Solutions for Health
EUnetHTA
A vision on voluntary European HTA collaboration

European network for Health Technology Assessment
Wim Goettsch, Director EUnetHTA JA3 directorate, Zorginstituut Nederland

European Health Forum, BadGastein, September 28, 2016
Health Technology Assessment

• Health Technology Assessment (HTA) is a systematic evaluation of the properties and effects of a health technology, aimed mainly at informing decision making regarding health technologies
  – For instance being used for making decisions on reimbursement of pharmaceuticals, medical devices etc.
  – Includes an assessment of relative effectiveness (REA), the clinical value of a (new) technology compared to standard care
European collaboration on HTA

Technologies become more ‘international’
Patients become more ‘European’

Decrease duplication on HTA assessments
Increase consistency between different national HTA assessments

– Variety in type of assessments seems to be common: does this lead to different assessment results?
<table>
<thead>
<tr>
<th>Abbreviated indication</th>
<th>Brand name (generic)</th>
<th>HTA recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>GERMANY</td>
</tr>
<tr>
<td>Bone metastases from solid tumours</td>
<td>1. Denosumab</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>2. Eribulin</td>
<td>Equal benefit</td>
</tr>
<tr>
<td></td>
<td>3. Pertuzumab</td>
<td>Added benefit</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>4. Aflibercept</td>
<td>Added benefit</td>
</tr>
<tr>
<td>Gastric cancer</td>
<td>5. Tegafur / gimeracil / oteracil</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Melanoma</td>
<td>6. Ipilimumab</td>
<td>Added benefit</td>
</tr>
<tr>
<td></td>
<td>7. Vemurafenib</td>
<td>Added benefit</td>
</tr>
<tr>
<td></td>
<td>8. Dabrafenib</td>
<td>Equal benefit</td>
</tr>
<tr>
<td></td>
<td>10. Crizotinib</td>
<td>Equal benefit</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>11. Cabazitaxel</td>
<td>Added benefit</td>
</tr>
<tr>
<td></td>
<td>12. Enzalutamide</td>
<td>Added benefit</td>
</tr>
<tr>
<td></td>
<td>13. Abiraterone</td>
<td>Added benefit</td>
</tr>
<tr>
<td>Renal-cell carcinoma</td>
<td>14. Axitinib</td>
<td>Added benefit</td>
</tr>
</tbody>
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Directive 2011/24/EU on cross-border healthcare

The Directive provides a detailed legal framework focused on three main areas:
• rules concerning the reimbursement of costs of cross-border healthcare
• responsibilities of the Member States with regard to cross-border healthcare
• cooperation between healthcare systems

EU Objectives in HTA Article 15 Directive 2011/24:
• Support cooperation between national HTA Authorities
• Support MS in the provision of objective, reliable, timely, transparent, comparable and transferable information […] to enable effective exchange of information
• Avoid duplication of assessments
Historical timeline of EUnetHTA

**EUnetHTA Collaboration**

**2006**
- **EUHTA Project**

<table>
<thead>
<tr>
<th>2016</th>
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<tbody>
<tr>
<td><strong>Joint Action 1</strong></td>
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<tr>
<td><strong>Joint Action 2</strong></td>
</tr>
<tr>
<td><strong>Joint Action 3</strong></td>
</tr>
</tbody>
</table>

- **Inception**
  - Putting into practice
  - Strengthening practical application
  - Turning pilots into standard practice
Possible key benefits of collaboration on HTA (focus on pharmaceuticals and relative effectiveness)

- **Quality**

- **Consistency**
  - May also indirect influence decisions and support price negotiations

- **Timeliness**
  - Earlier access if added value (and value for money) is proven

- **Efficiency**
  - Reduce duplications
Quality
EUnetHTA methodological (clinical) guidelines*

JA1 (2010-2012)
- Choice of comparator
- Composite EP
- Surrogate EP
- Applicability
- Direct and indirect comparisons
- Clinical EP
- HRQoL
- Safety
- Internal validity

- Internal validity of non-randomised studies (NRS) on interventions
- Meta-analysis of diagnostic test accuracy studies
- Economic evaluations
- Medical Devices
- Personalised Medicine
- Information retrieval in study registries and bibliographic databases
Consistency
What is the overlap between joint and national assessments?

Can a Joint Assessment Provide Relevant Information for National/Local Relative Effectiveness Assessments? An In-Depth Comparison of Pazopanib Assessments

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Abstract
Timeliness
Process for Rapid REA of Pharmaceuticals*

<table>
<thead>
<tr>
<th>EU Regulatory Process</th>
<th>WP4 HTA Process</th>
<th>Local HTA Process</th>
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<tbody>
<tr>
<td>EMA Process</td>
<td></td>
<td></td>
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<tr>
<td>CHMP opinion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expression of interest from pMAH</td>
<td>Preparation of draft submission file from pMAH</td>
<td>Scoping meeting with pMAH</td>
</tr>
<tr>
<td>Receive draft submission file</td>
<td>Finalization of project plan</td>
<td>Receive final submission file</td>
</tr>
<tr>
<td>Co-production of 1st version of REA</td>
<td>2nd version of REA Including editorial review</td>
<td>Consultation With WP4 members, MAH &amp; other stakeholders</td>
</tr>
<tr>
<td>Final version of REA</td>
<td></td>
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</tr>
</tbody>
</table>

Local REA’s (e.g. national, regional)
Efficiency
Joint pilots on REA of pharmaceuticals 2013-2015

First pilot
- Zostavax for prevention of Herpes Zoster (Sanofi-MSD), authors are ZIN (NL) and A. Gemelli (Italy). Published in September 2013

Second pilot
- Canagliflozin for treatment of diabetes type 2 (J&J), authors are FIMEA (Finland), AAZ (Croatia) and Regio Veneto (Italy). Published in February 2014

Third pilot
- sorafenib for advanced thyroid carcinoma (Bayer), authors are AIFA (Italy) and IMFARMED (Portugal). Published in March 2015

Fourth pilot
- ramucirumab in combination with paclitaxel for previously treated advanced gastric and gastro-oesophageal junction cancer (Eli Lilly), authors are NOKC (Norway) and AAZ (Croatia). Published in March 2015

Fifth pilot
- Vorapaxar for cardiovascular complications after MI (MSD), authors are HAS (France) and Ministry of Health (Slovakia). Published in June 2015

Sixth pilot
- Review of new Hepatitis C treatments. Authors are KCE and RIZIV (Belgium), HVB (Austria), AAZ (Croatia), A. Gemelli (Italy). Planned publication in December 2015
EUnetHTA JA3 Participants

78 partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

Project Coordinator: Dutch National Health Care Institute (ZIN)
EUnetHTA Joint Action 3 (2016-2020)

Aims to contribute to a **sustainable model** for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe in close collaboration with the stakeholders and the European Commission.
Specific Objectives

• To increase production of high quality HTA joint work

• To increase uptake and implementation of joint HTA work at the national, regional and local level

• To support evidence-based, sustainable and equitable choices in healthcare and health technologies
Summary of activities in EUnetHTA JA3

- **WP4 Joint Production**
  - To produce 37 rapid REA on pharmaceutical and 43 on other technologies
  - To provide a system for topic selection and prioritization, e.g. horizon scanning

- **WP5 Evidence Generation**
  - To conduct Early Dialogues (joint HTA or parallel/joint with regulators)
  - To link additional data collection to several activities (adaptive pathways, MEA, etc)

- **WP6 Quality Management**
  - To provide quality management for EUnetHTA joint products
  - To further develop methodologies and tools for joint work if necessary

- **WP7 National implementation and impact**
  - To facilitate the reuse and implementation of joint products at the national/local level
  - To measure the impact of joint work in collaboration with other work packages
HTA in the life cycle of technologies

Presenting and discussing requirements studies in ED*

Collecting evidence in early development.

Preparing submission files for EMA and HTA

Assessment for market authorization

Rapid REA

Additional data collection

Comparative or full HTA / REA

Use of technology in health care

Time line of innovation

*Early dialogue
Thank you
Any Questions?