

Relative Effectiveness Assessment (REA) of Pharmaceuticals in Europe

ISPOR, Prague, 2010
Wim Goettsch
Lead Partner EUnetHTA WP5 on REA of pharmaceuticals
CVZ, The Netherlands

EUnetHTA Joint Action 2010–2012 | www.eunetha.eu




Background on activities 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

- EUnetHTA was asked to take this work forward by the Steering Committee of the HL PF in autumn of 2008.
- EUnetHTA decided to work with the definitions that had been agreed in PF2008
- EUnetHTA WP on REA started in 2010



2 EUnetHTA | European network for Health Technology Assessment | www.eunetha.eu Joint Action 2010–2012

Partners Workpackage REA

Lead partner CVZ **Co-lead partner** HAS

- 17 Associated Partners
- 12 Collaborative Partners




3 EUnetHTA | European network for Health Technology Assessment | www.eunetha.eu Joint Action 2010–2012

(Relative) effectiveness or efficacy?*

According to the Pharmaceutical Forum:

- Efficacy: is the extent to which an intervention does more good than harm under ideal circumstances. (MARKET AUTHORISATION)
- Relative efficacy: can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions. (MARKET AUTHORISATION?)
- Effectiveness is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice.
- 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. (REIMBURSEMENT)

*RELATIVE EFFICACY AND RELATIVE EFFECTIVENESS: DO REGULATORY AGENCIES AND REIMBURSEMENT AGENCIES HAVE THE SAME NEEDS? IPB 8-11, 10-15-11-15, George, Abadie, Pappalardo, Goettsch



4 EUnetHTA | European network for Health Technology Assessment | www.eunetha.eu Joint Action 2010–2012


Relative effectiveness assessment (REA) vs. HTA

- 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

= THERAPEUTIC (ADDED) VALUE

versus


- Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner



5 EUnetHTA | European network for Health Technology Assessment | www.eunetha.eu Joint Action 2010–2012

Topics

Clinical effectiveness	Health problem and current use of technology
Topic 1: Mortality	Technical characteristics
Issue 1: What is the effect of the intervention on overall mortality?	Safety
Issue 2: What is the effect of the intervention on mortality caused by the target disease?	Clinical effectiveness
Issue 3: etc...	Costs and economic evaluation
	Ethical analysis
	Organisational aspects
	Social aspects
	Legal aspects



EUnetHTA | European network for Health Technology Assessment | www.eunetha.eu

Topics/domains for REA

- **Positive effects (most topics of domain clinical effectiveness)**
- **Negative effects (most topics of domain safety)**
- **Ease of use (topic Features of the technology of domain Description and characteristics of the technology)**
- **Innovation versus me-too (topic principal questions... of domain ethical analysis)**
- **Centralisation vs decentralisation (topic structure of domain organisational aspects)**



Rapid vs full REA model

- Rapid model is relevant for countries that need to assess directly after market authorisation (in 90 days, transparency guideline)
 - **Rapid model will only use selected domains/topics from the core-HTA**
- Full model is relevant for countries that want to assess groups of pharmaceuticals a longer period after market authorisation (indication-based)
 - **Full model will probably use most domains/topics from the core-HTA.**



Methodological guidelines

- For each subject a guideline will be elaborated
 1. *comparators & comparisons*
 - criteria for choice of the best comparator(s)/ methods of comparison/ direct and indirect comparison
 2. *outcome*
 - patient relevant outcomes/ clinical outcomes/ surrogate markers/ quality of life outcomes/ safety/ composite endpoints
 3. *level of evidence*
 - internal and external validity/ grading confidence in experts and experience/ extrapolation from efficacy results to real life situation (effectiveness)
- Coherence and link between topics/subjects will be ensured
- In subject groups members from the HTA organisations but also external experts will participate



*TOOLS AND METHODS FOR CROSS-BORDER COLLABORATION IN HTA
Educational Symp 7-11, 19.00-20.00, Kissmann, Pasternack, d'Andon, Meyer

Interaction

- Exchange of information with EMA (2 meetings in 2010)
 - **Adaptation of EPARs; further contribute to REA**
- Cooperation with MEDEV organizations (2010-onwards)
- Outside EU with organizations like AHRQ(USA), CADTH/CEDAC(Canada), PBAC(Australia) (in future)
- Stakeholders
 - **Public consultation**
 - **Stakeholder Advisory Groups (SAG)**
- Experts (Academic)



Conclusion: PF2008 recommendations will be addressed.

- Exchange of REA criteria/information
 - Overview of the processes, the scope and the scientific methods CURRENTLY used for REA of pharmaceuticals in European countries/US/Canada/ Australia&New Zealand (34 countries)
- Implementation of agreed good practice principles for REA
 - Rapid and full models for REA based on core-HTA available before the end of 2012
 - Methodological guidelines in concept available in 2011
- More effectively done by existing networks
 - Based on the EUnetHTA network
 - In cooperation with EMA, MEDEV and others

