



Relative efficacy and relative effectiveness


do regulatory agencies and reimbursement agencies have the same needs?

Wim Goettsch | ISPOR | November 8, 2010
Health Care Insurance Board (CVZ), The Netherlands and EUnetHTA lead partner WPS Relative Effectiveness Assessment of Pharmaceuticals




The issue

- What is the role of relative efficacy/ effectiveness assessment in defining the clinical value of a new medicine in routine national clinical practice across Europe?
- do regulatory agencies and reimbursement agencies have the same needs?




Who decides the clinical use of a new medicine?

- increasing debate about the roles of the regulatory agencies and the national reimbursement/HTA agencies:
 - is it acceptable that a new medicine is not reimbursed when the regulatory agency has granted a marketing authorisation?
 - clarification on the scientific work of defining the clinical value of a new medicine in the national health systems to inform reimbursement decisions;
 - the role of regulatory agencies.



Pharmaceutical forum definitions*


- 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;
- 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).



First plenary session of ISPOR, November 7, 2010.
Relative Effectiveness (WPS) Assessment of Pharmaceuticals,


Current challenge

- perceived need for EU-wide assessments of relative efficacy/effectiveness.
- Can this translate into EU-wide agreements on the clinical value of a new medicine in national clinical practice?
- The aim of the issue panel session:
 - to explore how such aspirations can be achieved in a way that meets the needs of all parties involved, and to explore practical solutions.



Questions

- Can decisions on the clinical value of a new medicine and its place routine practice be made on an international basis/ EU basis?
- Can REA be carried out across countries on an international basis/ EU basis?
- If so, how should this be done and who should be involved?



Our panellists

- Dr Elisabeth George (NICE, UK and EUnetHTA partner)
 - **The HTA perspective**
- Dr Eric Abadie (Président du CHMP, EMA, France)
 - **The Regulators perspective Vision**
- Dr Andrea Rappagliosi (EFPIA HTA Task Force, Belgium)
 - **The Industry Perspective**