



European
Life Science Circle

17. April 2007
Brussels



WELCOME

“Pharmaceuticals and the Future of Cost-Benefit Assessment in the EU”

17. April 2007

Dr. Jorgo Chatzimarkakis MEP

Cost- Effectiveness in the Pharmaceutical Forum

Working Group on Relative Effectiveness

- supports Member States to apply relative effectiveness systems
- allows containment of pharmaceutical costs
- as well as a fair reward for innovation
- in terms of clinical efficiency
- and cost-effectiveness
- helps set a fair price for these medicines

Definitions

Efficacy is proven in well controlled randomized (regulatory) trials which must demonstrate whether a technology works when all other influencing factors are controlled for.

Effectiveness refers to the effects of technologies under conditions which reflect real life (daily practice care, daily life compliance etc).

Definitions

Efficiency refers to the relationship between costs and effects and is often expressed through cost-effectiveness ratios (eg. cost per bad event avoided), cost-utility ratios or cost-benefit ratios.

Definitions

Cost-Effectiveness considers both medical *and* cost consequences of technologies and calculates cost-effectiveness ratio's which reflect the cost per unit of health effect gained.

Definitions

Relative Effectiveness considers the medical effects (effectiveness and side-effects) of a technology in comparison to existing treatments.

Definitions

Health Technology Assessments (HTA) are broad evaluations which (should) consider medical, ethical, political, economic, and social aspects of new technologies to guide their optimal implementation in the health care market.

HTA Bodies

- The most known National Health Technology Institutes are:
 - NICE in the UK (since 1999)
 - IQWiG in Germany (since 2004)
 - HAS in France (since 2004)
 - LFN in Sweden (since 2002)

Table 2: Criteria for HTA assessment

Criteria	AT*	AU	BE	CA	CH	DE	FI	FR	NL	NO	SE	UK
Therapeutic benefit	●	●	●	●	●	●	●	●	●	●	●	●
Patient benefit	●	●	●	●	●	●	●	●	●	●	●	●
Cost-effectiveness	●	●	●	●			●		●	●	●	●
Budget impact		●	●	●			●	●	●	●		●
Pharmaceutical/innovative characteristics	●		●	●				●	●			●
Availability of therapeutic alternatives	●	●							●		●	●
Equity considerations				●						●	●	●
Public health impact				●				●				
R&D		●					●					

Source: Adapted from Zentner et al. (2005) and case studies.

From: ENSURING VALUE FOR MONEY IN HEALTH CARE: THE ROLE OF HTA IN THE EUROPEAN UNION January 2007

Since 01.04.07 cost-effectiveness is new criterion for IQWiG

Questions

- European HTA bodies have different approaches, principles and values
 - Do we need a common approach for a European solution?
 - What should be the underlying criteria?
 - How do we get principles for transparency of process and results?

Questions

- Decisions of NICE are mainly based on cost per Quality Adjusted Lifeyear (QALY)
 - How much can a Quality Adjusted Lifeyear cost?
 - On what considerations should a Quality Adjusted Lifeyear be decided?
 - Are peoples´ preferences really reflected through the concept of Quality Adjusted Lifeyear?

Questions

- A European NICE?
 - Do we need 27 different institutes or is it better for a common market to have one common institute?
 - Would it be possible to have a main provider for a specific disease in one member state?
 - E.g. cardiovascular disease for NICE
 - e.g. diabetes for IQWiG
 - etc

Questions

- What is the impact of HTA bodies on technological innovations?- I
 - How can we prevent a too early refusal of technological innovation before they become more cost-effective?
 - Does a refusal of reimbursement of new technologies introduce a two class health system?

Questions

- What is the impact of HTA bodies on technological innovations? - II
 - How restrictive can HTA decisions be?
 - Should it be possible to reimburse despite of a refusal by HTA bodies like e.g. in Germany?

Speakers

- Prof. Sir Michael Rawlins, NICE
„NICE and it's Methodology – an International Benchmark for Cost-Benefit Assessment?“
- Prof. Dr. Peter Sawicki, IQWiG
„Benefit Assessment in Germany and the European Context“

Speakers

- Dr. Steffen Wahler, VFA
„Cost-Benefit Assessment – Industry's Perspective“
- Philippe Brunet, Cabinet of Commissioner Kyprianou
„The High Level Pharmaceutical Forum: The Future and the Perspectives of Cost-Benefit Assessment in the European Union“