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## Industry involvement in HTA: Value or Bias?

ISPOR Madrid 2011

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## value or bias?

- **Health Technology Assessment:**  
“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” ... (EUnetHTA)
- **Who produces information? / who assesses the information?**
- “systematic, transparent, unbiased, robust manner” = valuable

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## Value or bias?

1. **At which stage of a HTA the industry involvement could be of value: scoping? assessment of evidences? appraisal? Implementation?**
2. **Can a systematic involvement of industry in HTA resolve controversies *upstream* in the process and reduce polarisation *downstream*?**
3. **What are the rules/principles that should guide between *who* produces information and *who* assesses the information?**

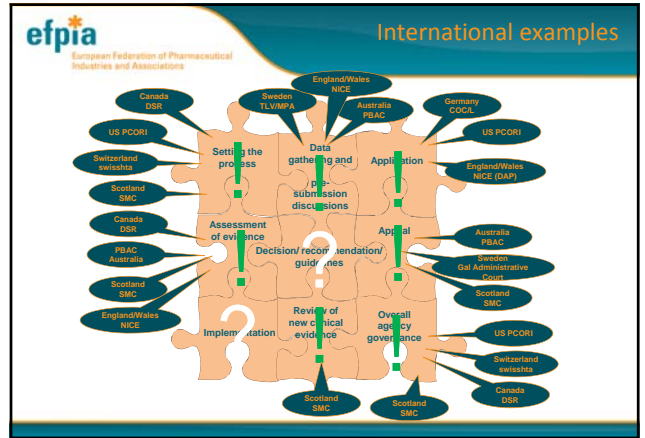
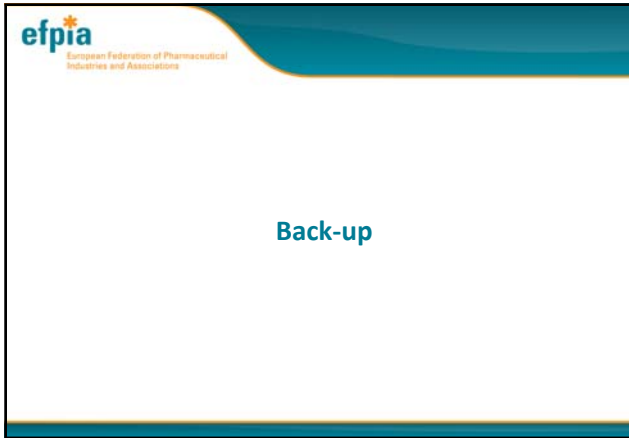
The question we should not forget...

Will a systematic and transparent involvement of the industry in decision on clinical value of a new medicines and relative effectiveness assessment improve patients access performances and overall system efficiency?

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## Speakers and Programme

- **Andrea Rappagliosi**, GlaxoSmithKline, Belgium and EFPIA - Moderator
- **Thomas Cueni**, Interpharma, Switzerland and EFPIA  
EQUAL PARTNERS IN BUILDING HTA: THE SWISS EXAMPLE
- **Meindert Boysen**, National Institute for Health and Clinical Excellence, UK  
CAPITALISING ON INDUSTRY EXPERTISE & EXPERIENCE: THE NICE EXAMPLE
- **Wim Goettsch**, Medicinal Products Reimbursement Committee, The Netherlands and EUnetHTA  
DEBATING THE OUTCOMES OF ASSESSMENT: THE DUTCH EXAMPLE & EXPERIENCES FROM EUROPEAN COLLABORATION ON HTA
- **Additional Speakers:**  
**Finn Børilum Kristensen**, EUnetHTA  
**Michael Schlander**, SwissHTA



**Motivation for Swiss Project on HTA**

**Growing pressure on social health insurance**

- Demographic change
- Chronic diseases
- Insufficient quality and efficiency in fragmented health care

**Need for**

- Better value for money
- Sustainable financing of health insurance
- Alternatives to rationing
- Alternative to oversimplifying methods and fixed thresholds

**Situation in Switzerland**

- Basic and fragmented use of HTA
- Political initiatives on federal and cantonal level to improve quality and cost-efficiency in health care
- Tradition of dialogue among stakeholders and pragmatism

SwissHTA – A Stakeholder Approach 8 November 2011 4 / XX

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## SwissHTA - A Stakeholder Project

**Initiated in 2010 by Interpharma and Helsana (sick fund)**


- Based on a proposal by Prof. Michael Schlander

**Aim of the project**

- Develop a consensus on the development of HTA in Switzerland
- Broad stakeholder involvement and support for consensus

**Supporters of SwissHTA**

- Santésuisse (association of Swiss sick funds)
- Interpharma (association of Swiss research based pharmaceutical companies)
- Federal Doctors Association of Switzerland (FMH)
- Swiss Academy of Medical Sciences (SAMS)
- Federal Office of Public Health (FOPH, as observer)



SwissHTA - A Stakeholder Approach

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## SwissHTA – Project Structure

Project Steering Group	Scientific Advisory Committee
<ul style="list-style-type: none"> <li><b>Sick funds:</b> Christian Affolter, Stefan Kaufmann (santésuisse), Pius Gyger (Helsana)</li> <li><b>Industry:</b> Thomas Cueni, Heiner Sandmeier (Interpharma), Ansgar Hebborn/Claude Cao (Roche)</li> <li><b>Physicians and Academy:</b> Daniel Herren (FMH), Peter Suter (SAMS)</li> <li><b>Federal Office of Public Health:</b> As an observer Andreas Fallner (FOPH)</li> <li><b>Project Leader:</b> Michael Schlander (Universität Heidelberg, InnoVal<sup>HC</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>Prof. Michael Schlander, University of Heidelberg, InnoVal<sup>HC</sup></li> <li>Prof. Gérard de Pouvourville, ESSEC Paris</li> <li>Prof. Robert Leu, University of Berne</li> <li>with participation of Prof. Urs Brügger, Zurich University of Applied Sciences</li> </ul>
	Iterative Consensus Process
	<ul style="list-style-type: none"> <li>International workshop, 5-6 November 2010</li> <li>seven retreats (1–1½ days) of Project Steering Group from January 2011 to September 2011</li> <li>Consensus paper (in German): finalized in October 2011</li> </ul>

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## Result of Consensus Process

**Learning experience for all involved**

- Open exchange of views (Chatham House Rule), tough discussions, constructive and productive dialogue

**Consensus Paper**

- Short Paper (30-pages, in German) finalized by Project Steering Group, October 19, 2011
  - Officially adopted by santésuisse, interpharma, FMH and SAMS, during November 2011
- Extended paper early 2012, with full scientific documentation



**Continuing collaboration**

- Members of SwissHTA renew engagement to support the Federal authorities in implementing and further developing SwissHTA

15.11.2011

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## Key Elements of Consensus

- HTA as effective decision support for benefit management in social health insurance for **new and established products, procedures and services (all technologies)**
- rHTA:** Rapid HTA process, primarily for new (single) technologies
- cHTA:** Complete HTA process, primarily for existing technologies / (complex) clinical pathways
- Broad stakeholder involvement throughout all stages of HTA process**
  - e.g. selection of topics, early consultation, scoping, assessments, appraisals, comments on recommendations, ...
- Transparency** of evaluation processes, criteria, and methods: key documents and rationales underlying decisions
- Implementation within existing legal framework**
  - Building on existing processes and methods

SwissHTA - A Stakeholder Approach 8 November, 2011 12 / xx

**“WZW-Criteria” in Swiss Health Insurance**

**Health Insurance Law**

- For reimbursement all benefits must comply with WZW-criteria
- Regular reassessment

**Wirksamkeit:** Efficacy / Effectiveness  
**Zweckmässigkeit:** Appropriateness  
**Wirtschaftlichkeit:** Economics / Efficiency

**Current Practice**

- WZW defined only in part and applied inconsistently, regular reassessment for drugs only
- Parliamentary Commission asked for remedy in 2009

SwissHTA: schweizerischer Konsensvorschlag 24.10.2011

**Assessment of Efficacy/Effectiveness: Added value, individual (patient) perspective**

**Clinical/ Therapeutic Effect** X **Confidence in Evidence** = **Categories for Added Value**

**Relevance for Patient**  
*e.g. life expectancy > faster cure > better compliance > quality of life*  
 X  
**Effect Size** (comparative)

**Level of Evidence**  
*compared to best possible evidence level for given context*  
 X  
**Relevance for Medical Practice** (in Switzerland)  
 X  
**Quality of studies**

**Categories**  
*Added Value compared to “Standard of Care” in Switzerland*

- Very high added value
- High added value
- Minor added value
- No added value
- Lower added value

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**SwissHTA – A frame to apply WZW-Criteria**

**Assessment**

	<b>W</b>	<b>Z</b>	<b>W</b>
Added Value for Patient Level of Evidence	Green	Z1	W1
	Yellow	Z (...)	W (...)
Societal Value	Yellow		
	Red		
Economic Evaluation			

**Appraisal**

Limits on Reimbursement (Rules)

Recommendation on Reimbursement

Yes  
conditional / MES  
No

**Decision**

Eligibility for Reimbursement

Negotiation Gvmt. - Applicant

Price / Tariff Limitatio;  
Evidence Development MES (Managed Entry Scheme)

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**Why a Stakeholder Approach?**

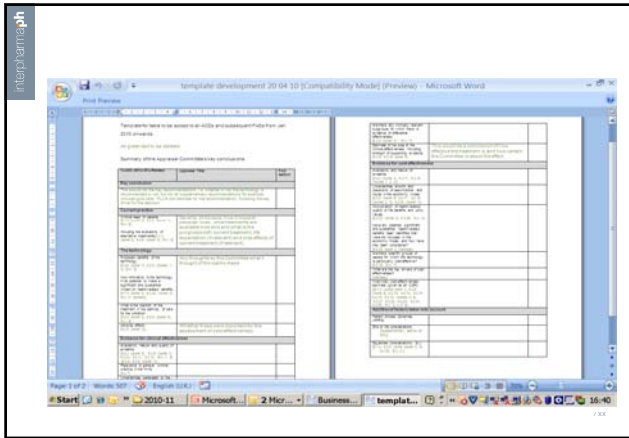
- Uncertain outcome
- Time consuming
- Risky to leave well known territory
- Schadenfreude in case of failure

„Wer nicht wagt, der nicht gewinnt“  
 „Nothing ventured, nothing gained“

- Shared analysis of major problems
- Building trust among stakeholders
- Common ground larger than expected
- Increased probability of implementation

SwissHTA – A Stakeholder Approach 9 November, 2011 16 / XX





## Patient Access Schemes

**“Patient access schemes are proposed by pharmaceutical company and agreed by DH to improve the cost effectiveness of a drug and enable patients to receive access to cost effective innovative medicines”**

*The Pharmaceutical Price Regulation Scheme 2009 between DH and the ABPI*

### Methodology

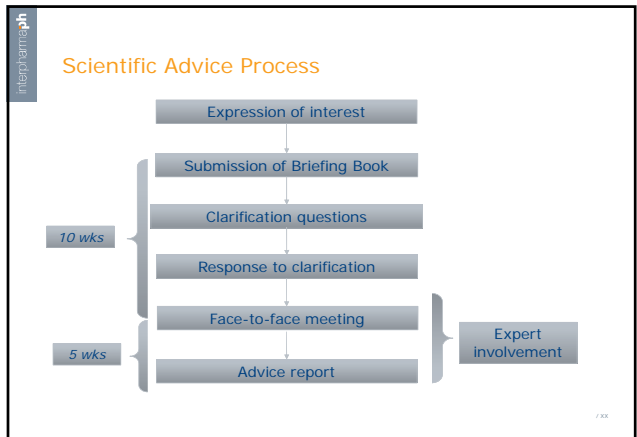
Table S.1 Summary of the reference case

Element of health technology assessment	Reference case	Section providing details
Defining the decision problem	The scope developed by the Institute	5.2.5 & 5.2.6
Comparator	Therapies routinely used in the NHS, including technologies regarded as current best practice	5.2.5 & 5.2.6
Perspective on costs	NHS and PSS	5.2.7 to 5.2.10
Perspective on outcomes	All health effects on individuals	5.2.7 to 5.2.10
Type of economic evaluation	Cost effectiveness analysis	5.0.11 & 5.2.12
Synthesis of evidence on outcomes	Based on a systematic review	5.3
Measure of health effects	QALYs	5.4
Source of data for measurement of HRQL	Reported directly by patients and/or carers	5.4
Source of preference data for valuation of changes in HRQL	Representative sample of the public	5.4
Discount rate	An annual rate of 3.5% on both costs and health effects	5.6
Quality weighting	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit	5.12

HRQL, health-related quality of life; NHS, National Health Service; PSS, personal social services; QALYs, quality-adjusted life years.

Annotations on the left side of the table:

- Patient Access Schemes Innovation (Kennedy) - points to 'Comparator' and 'Perspective on costs'.
- End of life & life extension - points to 'Quality weighting'.





### Supporting evidence submissions

**Making High Quality Evidence Submissions to NICE**

**ABPI and NICE Medicines**

Working together to improve patient care through the NHS Single and Multiple Licensing System (SLS) and the ABPI's Quality Standard (QS).

ABPI and NICE have agreed to work together to improve the quality of evidence submitted to NICE, and to the public, through the SLS and QS.

The initiative programme will allow the following to companies and members of the public:

- A clear and free to use quality standard for health technology appraisal (HTA) evidence submissions.
- A single point of contact for companies and members of the public.
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The initiative programme will begin in the second half of 2011.

**Technology appraisal process guides**

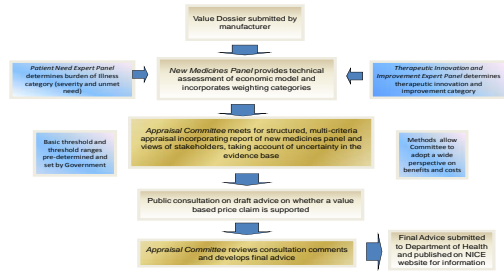
Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the National Institute for Clinical Excellence (NICE) on guidelines for the release of company data into the public domain during a health technology appraisal.

### NICE response to VBP

#### Retain key elements of the current system:

- A clear recommendation for the optimal use of new drugs, from NICE, in the form of technology appraisal guidance and through quality standards.
- A Funding Direction, which required NHS organisations to make available the resources necessary to allow new drugs, recommended by NICE to be used.
- The provision in the NHS Constitution that provides a right for patients to have access to new drugs recommended by NICE.

### Proposed New Value Based Pricing Appraisal Process





**Stakeholder involvement in HTA  
national and international experiences**

*Wim Goettsch PhD, Deputy secretary of the Medicinal Reimbursement Committee and Lead Partner EUnetHTA WP5 on REA of pharmaceuticals, CVZ*

**CVZ** College voor zorgverzekering

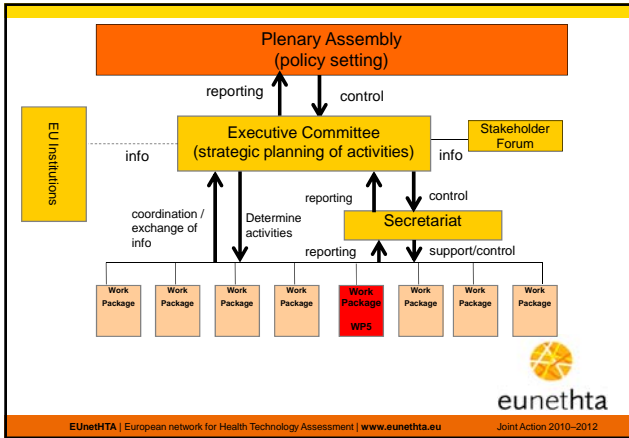
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## Two examples

- EUnetHTA, in specific WP5 on relative effectiveness assessment of pharmaceuticals
- The Netherlands, in specific CED intramural expensive drugs

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## EUnetHTA JA1 WP5 REA Pharmaceuticals

- Background review on national REA
- Guidelines for REA
- Development of (rapid) REA model
  - Including pilot on REA model

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## Stakeholder advisory groups (SAG)

- Input from experts from stakeholders (industry, patients, payers, healthcare providers)
- Before public consultation
- First involvement in background review



## Consultation background review

- **Stakeholder advisory group:**
  - 77 comments provided by Europa Bio/ EDMA/ EFPIA/ EPF/ ESIP/ AESGP/ Eucomed
  - Very content related
  - However SAG has indicated that review time (3 weeks) was very short
  - **positive experience!**

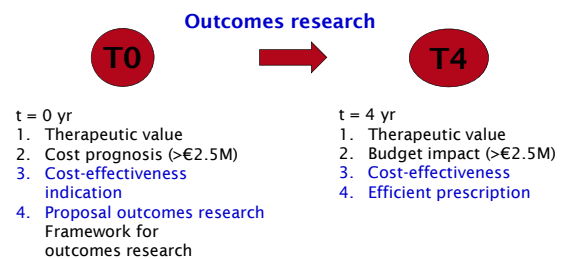


## Involvement MAH in pilot rapid REA

- **Pilot is limited to rapid assessment (after consultation of WP5 members)**
  - Based on rapid core model and draft guidelines
- **Selection pilot pharmaceutical by WP5 members for rapid assessment**
  - Consultation of SAG and EMA and product sponsors (for submission file)
  - Two product sponsors responded positively; first choice WP5 members.
  - MAH provided WP5 with submission file based on previous NICE submission
  - MAH will be consulted before other external parties (SAG, public consultation)
- **BUT main purpose pilot is methodology development**



## Example NL (CED intramural drugs)



## Assessments t=0 and t=4

- T=0 Jan 2006 - November 2011
- 45 appraisals (oncology, auto-immune diseases, macula degeneration, orphans)
- First T=4 December 2010
- Until now 11 definitive applications with data from outcomes research



## Involvement of stakeholders

- Consultation assessment t=0 and t=4
- In the actual outcomes research:
  - Setup and funding of outcomes research
  - Execution of outcomes research
  - Reporting of outcomes research
- Consultation appraisal t=4



## Reflection and questions on involvement

- Collaboration between stakeholders essential
- Who should **conduct** outcomes research (data collection and analysis)? Treating physicians, academics, industry, payers
- Who should **pay** outcomes research? Private (manufacturer) and/or public (Netherlands organisation for health research and development (Zon). MoH: budget for co-funding (50%))
- **Infrastructure** outcomes research including Patient registry
  - Setup registry publically funded
  - Maintenance registry also privately funded



## Conclusions

- **Involvement of stakeholders is essential**
  - Consultation phase
  - Input to the assessment procedure
  - Active contribution on how to perform research
  - Public/private co-funding (industry)
- **Less likely to have involvement in certain parts of HTA**
  - Actual assessment
  - Execution of outcomes research, observational studies



EUnetha Conference, Gdansk, December 8 and 9

**Focus on results JA1 and plans for JA2 (2012-2015)**


**Role of stakeholders**

**Implementation of European results in national practice**

Registration until November 15 (<http://www.eunetha2011.pl>)



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**European network for HTA**  
**Joint Action between European Commission and EU Member States**

A total of 35 government appointed organisations from 24 EU Member States, Norway and Croatia and a large number of regional agencies and non-for-profit organisations that produce or contribute to HTA

**EUnetha Joint Action 2010-2012 | [www.eunetha.eu](http://www.eunetha.eu)**

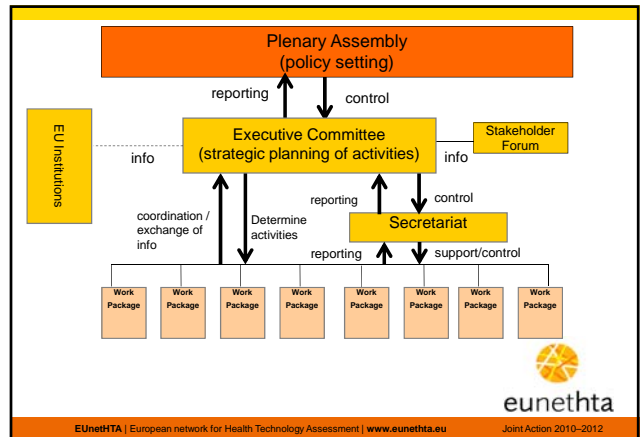


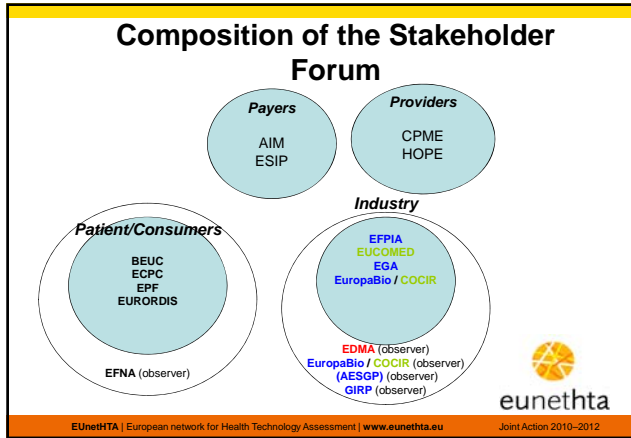
**The time-line of reaching a sustainable and permanent HTA network in Europe**

<b>Health Programme</b>	2005 Call for project proposals	2009 EUnetha Collaboration	2009 Call for Joint Action	2011 Call for Joint Action	2014+ European network for HTA
<b>Legislation</b>		2008-11 Draft Cross Border Healthcare Directive Article on HTA network	2010-12 EUnetha JA	2011-13 CBHC Directive Expert Group for HTA network implementation	2012-15 EUnetha JA2
<b>DG R&amp;I</b>					2011 FP7-Health 2012-Innovation-1 New methodologies for HTA

Legal basis: Cross Border Healthcare Directive  
Financial support: 1) EU Budget 2) Member States

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### EUnetHTA Conference, Gdansk

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