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First Plenary Session
Pros and Cons of a Centralized European Pricing & Reimbursement Agency



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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pros and cons of a centralised EU Pricing & Reimbursement Agency


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Hans-Georg Eichler

An agency of the European Union 


Disclaimer

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Declaration of Conflict of Interest


Agenda

- What's broken that needs fixing?
- What's different (or not so different) across Europe?
- What could (or could not) be harmonized?
- Conclusions

The EU dilemma



- *One* standard for drug approval
- *One* application, *one* assessment
- *One* decision valid in 27 EU + 3 EFTA countries

- single payer, solidarity-based healthcare - but:
- 30+ different HTA methodologies and interpretations
- 30+ independent decisions about whether the medicine should be paid for

Same license, different coverage decision



Coverage status of pazopanib, Sept 2011

Pazopanib was approved for treatment of advanced renal cell carcinoma by FDA, EMA, TGA, Health Canada.

In the USA (VA PBMS) and in Australia (PBAC) it is **not covered**. **No decision yet** in Canada.

In 6 EU countries (Germany, Netherlands, Portugal, Slovakia, Spain and Sweden) **fully covered**. In 5 EU countries (Austria, Denmark, France, Norway and Poland) **not covered** or **covered only on an individual basis** after prior approval. In 3 EU countries (Belgium, Czech Rep. and UK) **reimbursed with limitations**. In Finland it is **partially (42%) covered**. In 2 EU countries **covered under a Managed Entry Agreement (MEA)**; (UK, Italy).

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Transparency is here, comparisons are happening



Is this a risk to payers/ HTA bodies?

“equitable and timely access to approved Orphan Drugs for rare diseases patients remains an issue”

EURORDIS Proposal ... to Improve Access to Orphan Drugs in the EU
http://www.eurordis.org/sites/default/files/publications/Position_PaperCAVOD_2009.pdf

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What's different (or not so different) across Europe?

- Biology, pharmacology
- Science
- Healthcare environment
- Economics
- Politics

Crise de foie, Spasmophilie, Hypotension, EQ-5D

Variation in acceptance of SO across disease areas and HTAs

Disease	SO	HAS	NICE	IQWiG	AHRQ	CADTH/ CDR	PBAC	SMC
Diabetes	HbA1c							
	BP			N/A	N/A			
CVD	LDL			N/A	N/A			
	TTP			N/A	N/A			
Oncology	TTF			N/A	N/A	N/A	N/A	N/A
	PFS			N/A				
Osteoporosis	BMD		N/A	N/A	N/A		N/A	
HIV	Viral load CD4 count		N/A	N/A	N/A			

Accepted Accepted with reservations Not accepted No comment given N/A: No appraisal reporting outcome identified

SO = Surrogate outcome
Heron Evidence Development Ltd. Sedelnikova M, Lock K, Modha R.; Used with permission

Summary of payers' advice (comparators and other trial design features)

Attribute	Advice						
	Agency 1	Agency 2	Agency 3	Agency 4	Agency 5	Agency 6	Agency 7
Comparator(s)							
Methotrexate - continuous	✓	✓	✓	✓	✓	✓	✓
Cyclosporine - induction or intermittent	✓		✓	✓	✓	✓	✓
Injectable biologic - intermittent or continuous		✓	✓		✓	✓	✓
Placebo					✓	✓	✓
OK not to compare directly to all relevant drugs	✓			✓		✓	✓
Other trial design features							
Allow preselected topical agents during the trial			✓				
Switching allowed using likely treatment pathway	✓			✓			
Intermittent treatment would be useful					✓		
Reconsider rationale for 2 maintenance doses in trial	✓						
Perform separate induction and maintenance trials			✓	✓			
PASI 100/90	✓	✓	✓		✓		✓
Maintenance							
Time to relapse - 50% reduction in PASI gain	✓						
Measure impact of withdrawal from treatment					✓		
Measures of productivity and other activity losses						✓	✓
Measure adherence and impact on outcomes						✓	✓

Backhouse ME et al, Value in Health 2011; 14: 608

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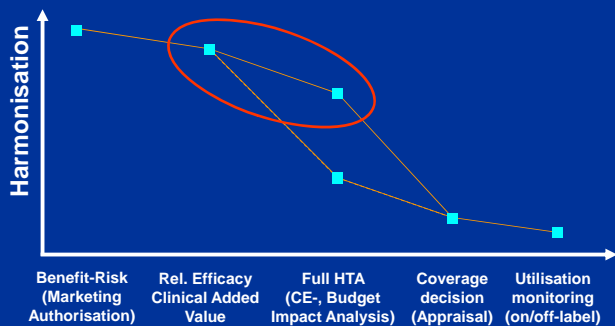
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Access to Drugs: What can be harmonised in the EU?




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**“Nothing is more powerful than
an idea whose time has come”**
attributed to Victor Hugo


**“Nothing is more doomed to
failure than a good idea that’s
premature”**


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Conclusions

- A bit of a déjà vu debate
- It’s not a matter of pros and cons or choice,
...
- ...it’s about timely response to the forces of
evolution
- near term: harmonisation of methodologies,
common assessment of Relative Efficacy /
Clinical Added Value; drugs first, other
technologies later
- mid-term: some common full HTA’s of high-
profile technologies
- long-term: ?

Thank you!



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