
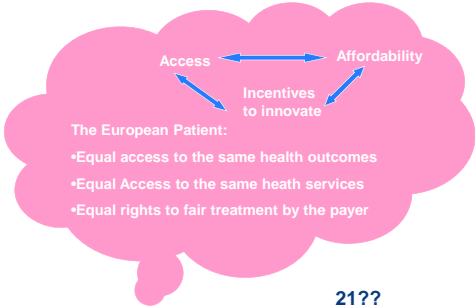


Clare McGrath
Senior director
HTA Policy
Pfizer Inc

An Industry Stakeholder Perspective




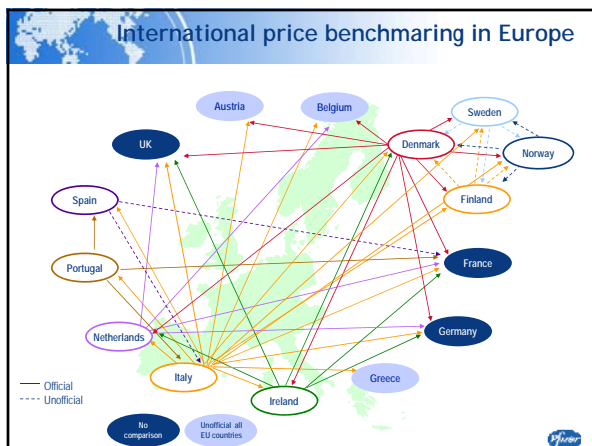
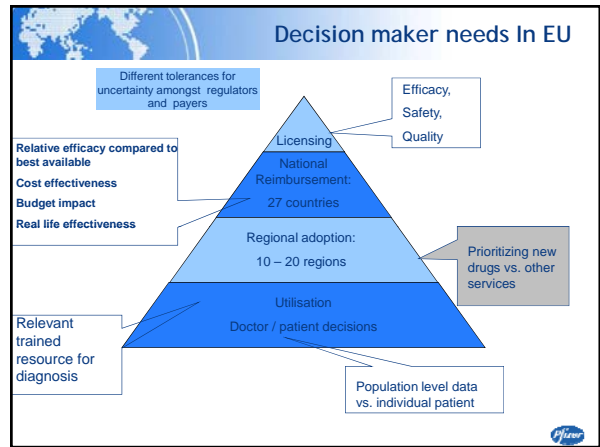
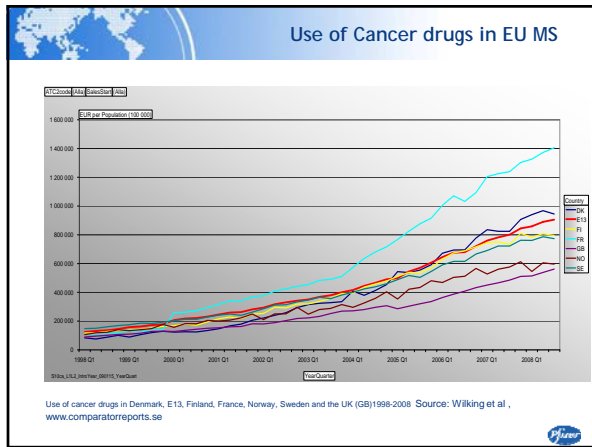
A Eurovision



The European Patient:

- Equal access to the same health outcomes
- Equal Access to the same health services
- Equal rights to fair treatment by the payer

21??

- ## R&D Industry as a stakeholder
- Focus on unmet medical need
 - *From blockbuster to niche buster*
 - Committed to demonstrate value
 - System wide, multiple perspectives
 - High users of the science of HTA without monopoly on bias
 - Innovation is a process in increments
 - Try to address efficiency of HTA
 - To manage scale, costs and **predictability**
 - Understand need to balance affordability, access and incentives to innovate
 - Global perspective
 - Regulatory decisions and multiple payers decisions world wide
- 

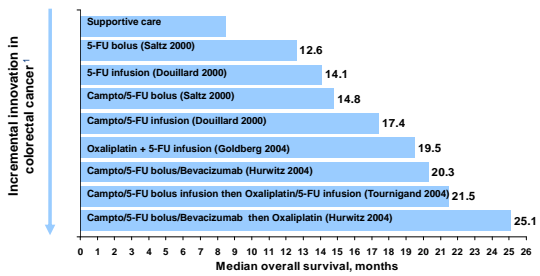
The challenge to industry

- How to address:
 - Serial R&D decision making vs. need to manage costs, time and effective patent life
 - efficacy vs. effectiveness;
 - short-term / surrogate endpoints vs. long-term / final outcomes;
 - future changes in disease management;
 - future variations on the cost side of the equation;
 - market response / drug uptake / budget impact;
- whilst:
 - directing research;
 - optimizing portfolio selection;
 - communicating value;
 - introducing certainty in securing ROI that supports further R&D and innovation...
- 10/15 years before it all happens!



Building knowledge about disease, treatment and disease management


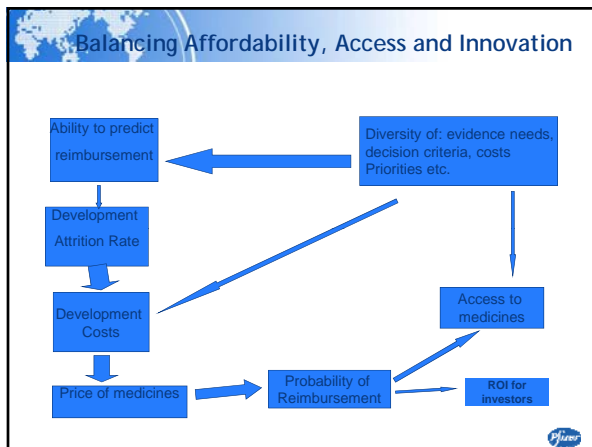
July 2010



Treatment	Median overall survival, months
Supportive care	12.6
5-FU bolus (Saltz 2000)	12.6
5-FU infusion (Douillard 2000)	14.1
Campto/5-FU bolus (Saltz 2000)	14.8
Campto/5-FU infusion (Douillard 2000)	17.4
Oxaliplatin + 5-FU infusion (Goldberg 2004)	19.5
Campto/5-FU bolus/Bevacizumab (Hurwitz 2004)	20.3
Campto/5-FU bolus infusion then Oxaliplatin/5-FU infusion (Tournigand 2004)	21.5
Campto/5-FU bolus/Bevacizumab then Oxaliplatin (Hurwitz 2004)	25.1

Incremental innovation in colorectal cancer has led to significant improvement in survival – 3-year survival rates are now over 50%*

*ABPI (2009), *Coccolini (2010)

Key principles and tools for successful Pan EU Assessment


★

Principles:

- the work and decisions by EMA are fully recognized and accepted;
- no additional layer of assessment for industry is added;
- assessments for marketing authorization and added therapeutic value remain separated;
- subsequent national assessments, in the proper national health-care context, include a broad and societal perspective of value and all stakeholder perspectives, while fully respecting previous assessments at the EU level.


Tools:

- Development of the EPAR
- Joint scientific advice from regulator and payer(s)
- Ongoing regulator, HTA dialogue (HTAi, Tapestry etc.)
- CAVOD pilot for Orphans
- EUnetHTA JA I and II
- Various MS experiments with conditional reimbursement
- Methods development for RE and cost effectiveness / value assessment
- More decision tools, MCDA,




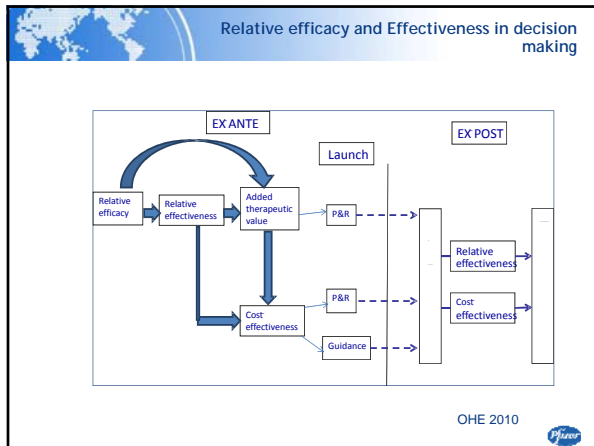
It's not just about the evidence....

- Address the pricing conundrum
 - Ability to pay and respecting the innovation process
- Harmonise the clinical evidence criteria
 - Add to the knowledge continuum don't duplicate unnecessarily
- Address sustainability of the whole system not just 10 to 20% of it
 - Understand the link between innovative technologies and system efficiency
- Align incentives accordingly
- Give clear signals about what will be valued and paid for



Backups





Different payer models...

HAS – SMR/ASMR

- SMR (Service Médical Rendu)
 - Medical benefit assessed by severity, clinical-effectiveness and public health impact.
- ASMR (Amélioration du Service Médical Rendu)
 - A comparison with existing treatments (same therapeutic class) for the improvement in medical benefit.

ASMR	Description
1	Major therapeutic improvement
2	Important therapeutic improvement
3	Modest improvement
4	Minor improvement
5	No improvement

SMC – Economics

- Cost-utility
- Budget impact
- Sensitivity analysis but not necessarily probabilistic
- No reference case but SMC suggests consideration of NICE reference case maybe helpful.

Bending et al 2010

Yield different Recommendations

SMC advice	HAS advice		
	To list advice	To list Minor Restriction	To list Major Restriction
To List advice	<ul style="list-style-type: none"> SMR1 (A, B) SMR2 (A, B) SMR3 (A, B) SMR4 (A, B) SMR5 (A, B) SMR6 (A, B) SMR7 (A, B) SMR8 (A, B) SMR9 (A, B) SMR10 (A, B) SMR11 (A, B) SMR12 (A, B) SMR13 (A, B) SMR14 (A, B) SMR15 (A, B) SMR16 (A, B) SMR17 (A, B) SMR18 (A, B) SMR19 (A, B) SMR20 (A, B) 	<ul style="list-style-type: none"> ASMR1 (A, B) ASMR2 (A, B) ASMR3 (A, B) ASMR4 (A, B) ASMR5 (A, B) ASMR6 (A, B) ASMR7 (A, B) ASMR8 (A, B) ASMR9 (A, B) ASMR10 (A, B) ASMR11 (A, B) ASMR12 (A, B) ASMR13 (A, B) ASMR14 (A, B) ASMR15 (A, B) ASMR16 (A, B) ASMR17 (A, B) ASMR18 (A, B) ASMR19 (A, B) ASMR20 (A, B) 	<ul style="list-style-type: none"> ASMR1 (A, B) ASMR2 (A, B) ASMR3 (A, B) ASMR4 (A, B) ASMR5 (A, B) ASMR6 (A, B) ASMR7 (A, B) ASMR8 (A, B) ASMR9 (A, B) ASMR10 (A, B) ASMR11 (A, B) ASMR12 (A, B) ASMR13 (A, B) ASMR14 (A, B) ASMR15 (A, B) ASMR16 (A, B) ASMR17 (A, B) ASMR18 (A, B) ASMR19 (A, B) ASMR20 (A, B)
List Minor Restriction	ASMR1 (A, B)	ASMR2 (A, B)	ASMR3 (A, B)
List Major Restriction	ASMR1 (A, B)	ASMR2 (A, B)	ASMR3 (A, B)
Do not list advice	ASMR1 (A, B)	ASMR2 (A, B)	ASMR3 (A, B)

What do Payers Value and Pay for?

Disease	Recommend	Recommend R*	Not recommended	Total Decisions
Cardio-vascular	19 (32%)	27 (45%)	14 (23%)	60 (100%)
Cancer	29 (22%)	51 (40%)	49 (38%)	129 (100%)
Total decisions	48 (26%)	78 (41%)	63 (33%)	189 (100%)

*R = Recommended decision with restriction to clinical classification or patient group.

Bending et al 2009