



Pharmaceuticals and health care : challenging need for transparency

Crosstalks 24/03/2009

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Change, we can !

During crosstalks:

- 2 KIWI'S, 1 harvested
- 2 “obligatory voluntary” price drops
- 2 “cheaper prescribing” measures
- 2 volume oriented measures in latest agreement between doctors / mutualities
- 2 professors working on a psychomedication report
- A chapter 2 reform
- Accelerated access (2 files)
- DRG based hospital drug budget
- CRM/CTG reports on the web
- Pharmaceutical taxes modulated
- Pharmaco economic guidelines introduced
- First contract negotiation started
- ADHD drug consumption went up (no wonder)

Change, we wanted ?

Where did 2005 – 2007 / budget growth go to ?

	<u>NET INAMI / RIZIV</u>			
Hospital	+ 136,6 mio €	+ 14,7 %		
Officina	+ 94,5 mio €	+ 4,3 %		
	+ 231,1 mio €	+ 7,4 %		
Oncology (ATL)	+ 141,1 mio €	= 61,00 %		
	NET INAMI / RIZIV	DDD	UNIT COST DDD	
Cardiology (ATC C)	+ 5,1 mio €	+ 182.531.388	- 0,05	
Officina	(+ 0,9 %)	(+ 12,9 %)	(- 12,5 %)	
Gastroentology (ATC A)	- 2,2 mio €	+48.031.021	- 0,08	
Officina	(- 0,89 %)	(+ 13,1 %)	(- 12,1 %)	
Neurology (ATC N)	+ 34,7 mio €	+ 43.24.335	- 0,03	
Officina	(+ 9,5 %)	(+ 12 %)	(- 3 %)	



Corporate Governance, Guy Peeters said

- Mr Verhofstadt's Health Forum: will he/it come back ?
- No agreements on drug budget concluded
- No mid term agreement on pharmaceutical policy
- CTG/CRM overall 90 % proposition made
 - but class 1 applications : only 68,5 %
 - Orphan drug applications only 75, 9 %
- Belgium : "bad boy" image still cultivated by some

STILL

- Belgium : therapeutic added value evaluation within best of European / American class
- Mutual trust grew and delivered (e.g. day 60 report on the web)



National Corporate Governance

Our business models

AUTHORITY

- Budgetary pressure
- Public opinion
- Controlling therapeutic freedom
(the accountability / professional autonomy paradox)
- Ideology and reality;
 - the power of “who likes a KIWI” ?
- Internal market driven Europe
- Silos in reimbursement fields.



National Corporate Governance

INDUSTRY

- HQ holds the ties
- Shareholders horizon 1 to 4 compared to authorities one
- Global business model under serious pressure

MEDICAL COMMUNITY

- Where is the leadership on making real choices and ethical sound priority setting ?

CITIZEN / PATIENT SIDE

- Price cuts avoid difficult choices but for how long ?
- Individual patient need versus collective defined priorities
- “What I need” ≠ “what society needs”

→ Our business models get stuck



Classical pharmaceutical pathway



Pharma company

Market authorization

EU / MS Regulatory Authority
e.g. EMEA

- Summ Prod Char
- Registered indication(s)
- Efficacy & safety in RCT target group

Pricing & Reimbursement

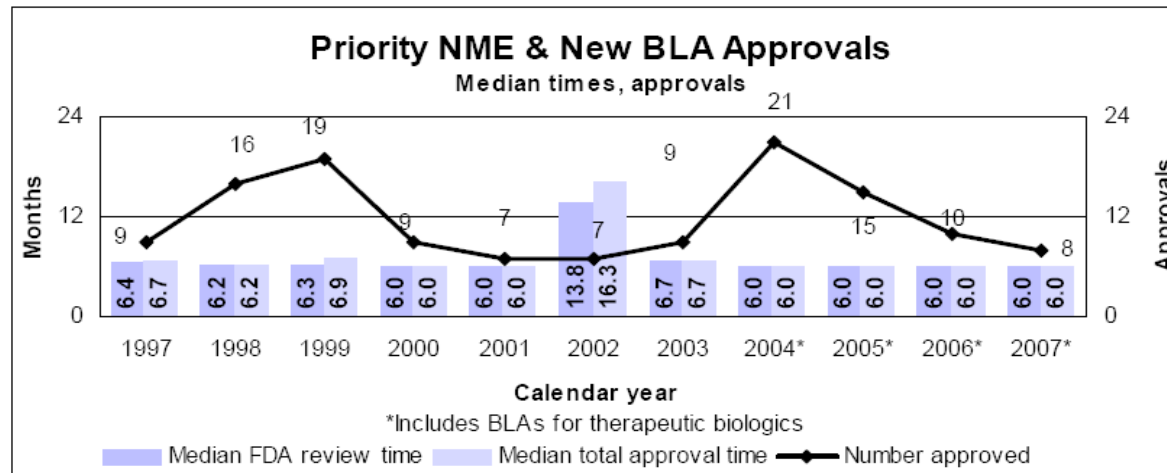
Payer
e.g. NIHDI

- [list] price
- reimbursement conditions
- access to patient population



Critical factors within actual pathway

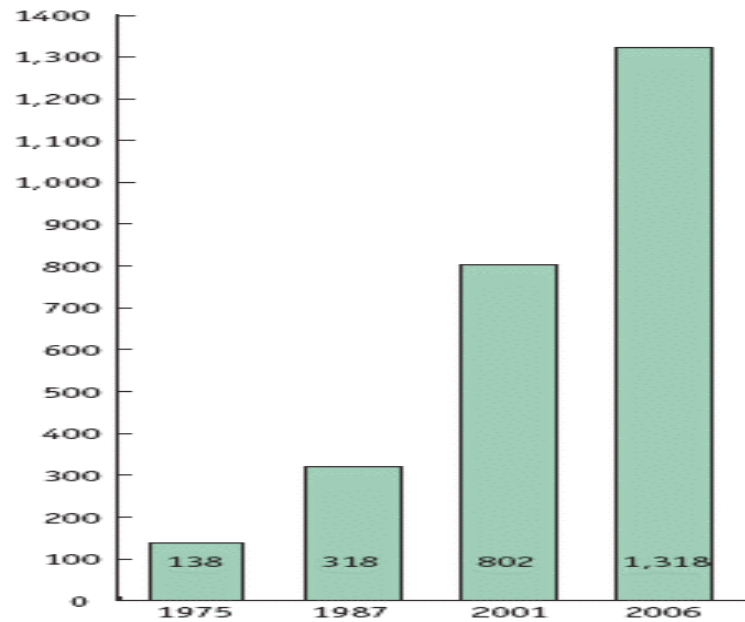
- **Pre market** authorization
 - Risky development: only 17% from clinical research products gets MA
 - R&D cost for 1 successful product > 1 billion Euro
 - Output : < 10 NMEs with priority review in 2007
 - Efficacy and safety in tested in a « GCP » selected study population





Critical factors within actual pathway

ESTIMATED FULL COST OF BRINGING A NEW CHEMICAL OR BIOLOGICAL ENTITY TO MARKET (\$ MILLION - YEAR 2005 \$)



Source: J.A. DiMasi and H.G. Grabowski, 'The Cost of Biopharmaceutical R&D: Is Biotech Different?', *Managerial and Decision Economics* 28 (2007): 469-479



- drop in NME despite increased financial resources is multifactorial problem:
 - Troublesome conversion of compounds with biological action into effective and safe medicines
 - Impact of business decisions considering ROI in the short term
 - Changing regulatory standards
 - Length of patent terms



GAO

United States Government Accountability Office
Report to Congressional Requesters

November 2006

NEW DRUG DEVELOPMENT

Science, Business,
Regulatory, and
Intellectual Property
Issues Cited as
Hampering Drug
Development Efforts





Critical factors within actual pathway (cont)

- **Post market access**

- 4th hurdle:

- Competence and budget = individual member states
- Extending HTA:
 - Relative Effectiveness > EU Pharmaceutical Forum
http://ec.europa.eu/pharmaforum/docs/ip-08-1451_en.pdf
 - USA : HTA in public spending (Medicare/Medicaid)
 - Multiplicity in (cost) effectiveness evaluations

- Effectiveness data after uptake of product in 'daily practice' population
e.g. safety issues, adherence in chronic conditions ...
- Unmet medical need :
 - Compassionate use, small markets, unregistered indications
- Efficiency: bevacizumab in AMD, trastuzumab treatment duration
- Silos : erlotinib and K-RAS
- Creeping market extension without lowering price



Elements for a new interactive model

- ***Sustainability of insurance mechanisms: value for money***
 - More and broader HTA, regular review if new evidence...
 - Efficiency: go beyond the pharmaceutical « silo » !
 - Economics and Ethics > efficiency and equity ! e.g. KCE report 100: no actual ICER threshold
- ***Managing uncertainty***
 - Risk-sharing mechanisms e.g.
 - value-based pricing
 - Early and accelerated conditional access
 - Cost- volume reimbursement conditions
 - Bio-markers and pharmaceutical target population



Elements for a new interactive model

- ***Efficiency of R&D:***
 - increase transparent exchange between basic – and applied research between university and industry
 - impact of translational research
- ***More independent research:***
 - Payer's perspective involved in design, conduct, analysis and reporting
 - Patient's perspective in off label unmet medical need:
 - Official recommendations to off label use (e.g. Dutch CBO) ?
 - Study driven new indication ?
- ***Synergy between assessors: mutual recognition of relative effectiveness assessments ?***



Thinking out of the box

- Let's move from on/off list decisions to drug reimbursement pathways
- Risk sharing: Buying more certainty through transparency premiums
 - Shared priority setting on R & D needs
 - Agreements on promising innovations
 - Maximimizing evidence / minimizing “narrow views”
- New tools :
 - Reinvest pharmaceutical taxes through independent bodies into research
 - Call for proposals on priority R & D



Thinking out of the box

- Use contracts on individual and ATC class level
- Develop integrated therapeutic - drug inclusive - programs
- Develop shared and visionary leadership taking innovation, added value, global health and equity on board and making “my health” again being part of “our health”.
- Innovate regulatory mechanisms
 - CTG / CRM :
 - Already to adapt ! (cell therapy, drug eluded stents,)
 - Be aware of information assymetry risk



Thinking out of the box

- Price controls & market competition
- Contracting framework
- Drop axiomas
 - In patent
 - Me too
 - Research leadership
 - Applicant driven ATM / ATR



Final remarks

- Cross talks opened windows for needed fresh air
 - Stakeholders around a tempting pool full of seducing secrets
 - We tiptoed the water
 - We felt that it might probally be worthwhile to jump
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WHAT KEPT US FROM DOING ?

TOO MUCH LOOKED AT FROM OUR BACKYARDS ?