



Keynote address

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Ega-Event 17-11-2010

European pharmaceutical policy 2010

- Organizational:
 - Shift EMA from DG Industry to DG Sanco
 - EMA roadmap
- Regulatory: Pharmaceutical package:
 - Counterfeiting medicines
 - Pharmacovigilance
 - Information to patients
- New initiatives:
 - General: Europe 2020 and pilot European Partnership active and healthy ageing
 - Specific:
 - Process on corporate responsibility
 - Conference on innovation and solidarity

Health topics and Belgian Presidency

- Central theme: “Innovation and solidarity”
- Three specific issues
 - Work force
 - Pharmaceuticals
 - Chronic care

Innovation and solidarity: Proposal for council conclusions

- Updating priority medicines report 2004
- Strengthening of coordination and prioritization allocation resources pharmaceutical research
- Priority to revision clinical trials directive
- Use possibilities to request post marketing authorization studies
- Reduce duplication of assessments
- Include information regarding relative effectiveness as early as possible in the process
- Fostering dialogue regarding access to and affordability of valuable innovative pharmaceuticals throughout the EU
- Enabling cross-border exchange of clinical data and interoperable registries (e.g. rare diseases)
- Support voluntary co-operation on HTA
- Acknowledge the review of Council Directive 89/105/EEC

Value-for-money In health spending (OECD, 2010)

” A strategy for increasing value-for-money in pharmaceutical spending is to expand the market for generic drugs... However, in several OECD countries, generic markets remain underdeveloped suggesting that appropriate economic incentives for providers, physicians, pharmacists and patients are lacking. Moreover, in several countries, price competition has been weak or has not benefitted consumers and third-party payers. More aggressive use of tendering processes (...) has led to immediate and sometimes huge price reductions. However, the approach is not without risks: experience shows that calls for tender need to be carefully designed in order to avoid the problem of supply shortage and excessive market concentration in the longer term.”

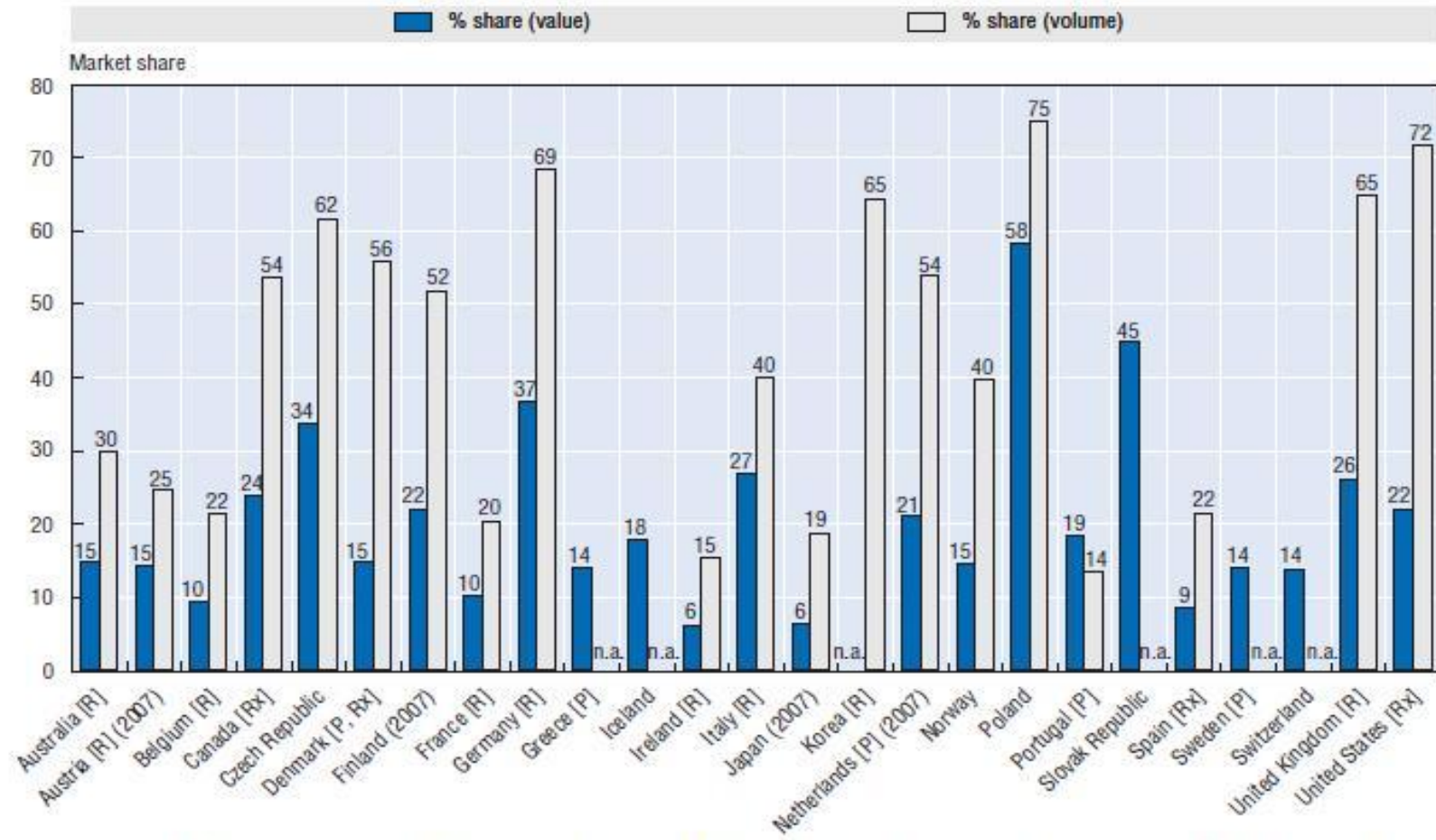
Value-for-money in health spending

Table 6.1. Policies to promote the use of generic drugs

Prescription in INN			Generic substitution			Incentives to prescribe/ dispense/ purchase generics (or cheap drugs)			Pricing and reimbursement policy	
Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory	Incentives for pharmacists	Incentives for patients	Incentives for physicians	Reference price system	Price linkage (discount for 1st generic entrant/ originator's price)
Australia	X			X		F	F	—	Y	−12.5% ¹
Austria	X		X			N	n.a.	NF	N	−48%, −15%+S
Belgium		X	X			NF	F	F&NF	Y	−30%
Canada ²		X ²		X ²	X ²	F ²	F ²	N ²	Y/N ²	2
Chile				X		N	F	NF ³	N	N
Czech Republic	X			X		n.a.	F	F	Y	−20%
Denmark	X				X	NF	F	NF	Y	N
Finland		X			X	NF	F	NF	Y	−40%
France		X		X		NF	F	NF&F	Y	−55%+S
Germany		X			X	NF	F	F	Y	N
Greece	X		X			N	F	N	Y	−20%+S
Hungary		X		X		NF	F	N	Y	−30%, −10%, −10%
Iceland				X		n.a.	F	n.a.	Y	n.a.
Ireland		X		X ⁴		N	F	NF	Y ⁴	S
Italy		X		X		F	F	NF	Y	−20%
Japan		X		X		F	F	⁵	n.a.	−30% ⁵
Korea		X		X		F	F	n.a.	n.a.	−32%, −15%
Luxembourg		X	X			n.a.	n.a.	NF	N	n.a.
Mexico			X	X			F	NF	N	N
Netherlands		X		X		F	F	n.a.	Y	N
New Zealand		X		X ⁶		F	F	NF	n.a.	n.a.
Norway		X		X		F	F	NF	N	S
Poland		X		X		NF	F	N	Y	−25%, −25%
Portugal			X	X		N	F	N	Y	−35%
Slovak Republic		X			X	NF	F	NF	Y	N
Spain		X			X	NF&F ⁷	F	NF&F ⁷	Y	−30%
Sweden		X			X	NF&F	F	NF	N	N
Switzerland		X		X		F	F	N	N	−20% to −50% ⁸
Turkey	X			X			F	—	Y	−20%
United Kingdom		X	X			F	N	NF	N	N
United States ⁹						F ⁹	F ⁹	N	N	N

Value-for-money in health spending

Figure 6.6. Generic drug market shares in 2008



EU-initiative:

Process on Corporate Responsibility in the field of Pharmaceuticals

- Transparency and deontology in the sector
- Access to medicines in the least developed countries
- Access to medicines in Europe, in the context of pricing and reimbursement

EU-initiative:

Process on Corporate Responsibility in the field of Pharmaceuticals

- Facilitating the **supply in small countries**
- Promoting a **good governance** for **non-prescription drugs**
- Market access for **biosimilars**

Belgian policy and generics

3 building blocks:

- Reference price system
- Low cost prescription quota
- New remuneration system for pharmacists

Belgian policy and generics

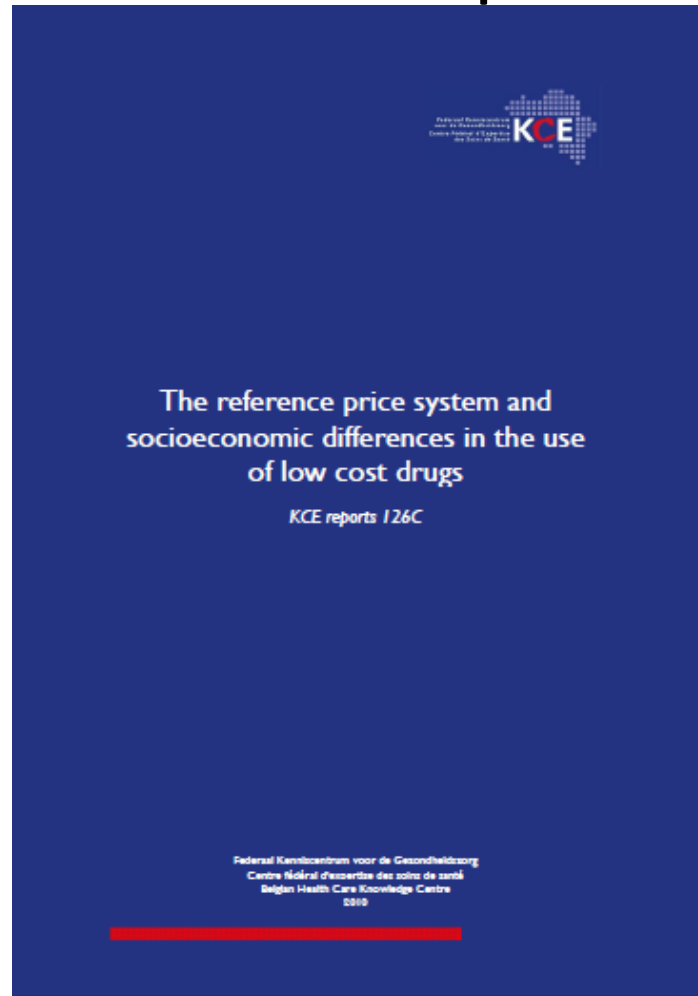
Evolution 2000 – 2009 – ambulatory care (Share in value and volume in %)		
	Value	DDD
2000	0,7	1,2
2001	2,5	4,2
2002	3,4	6,6
2003	4,9	8,9
2004	6,9	12,1
2005	9,1	17,8
2006	10,8	22,2
2007	11,0	23,1
2008	10,8	24,0
2009	12,1	25,4

Belgian policy and generics

(Share in ATC 1 in %)		
	Value	DDD
A Alimentary tract	34,1	48,2
B Blood and bloodforming organs	0,6	0,2
C Cardiovascular system	13,2	24,0
D Dermatological	12,7	15,0
G Genito - urinary	20,4	37,5
J Antimicrobiotics	18,3	33,6
M Muscoloskeletal system	24,9	39,2
N Nervous system	11,0	27,9
R Respiratory	4,0	15,3
Share in all ATC categories	12,1	25,4

Belgian policy and generics

- Evaluation of reference price system



Belgian policy and generics

- Evaluation of reference price system: research questions
 - How is the reference price system implemented in Belgium, and how can it be compared to reference pricing organized in other countries.
 - Is there evidence of socio-economic differences associated with the use of low cost drugs?
What is the impact on patient costs? How to avoid differences?

Belgian policy and generics

- Evaluations of reference price system: findings (1)
 - The Belgian reference price system is different from other countries on two points:
 - Reference price level is calculated on the price of the originator product; in other countries the price of generic drugs is somehow taken into account
 - Limited role attributed to pharmacists (see further)
 - Savings for the health insurance and patients might be larger by setting the reference price with respect to the price of all low cost drugs within a cluster (including generic products as well as original brands that lowered their price).

Belgian policy and generics

- Evaluation of reference pricing: findings (2)
 - No systematic differences in the use of low cost drugs were identified
 - In terms of overall equity the results are encouraging since the use of low cost alternatives is higher among more disadvantaged groups. Nevertheless 10 % of the co-payments for reimbursed medicines are so-called reference supplements. Since 1.4.2010 a security margin was introduced.
 - Perceptions of generic drugs among GP are increasingly positive. Reasons for not prescribing are varied (price, originator asked by patients, reticence on quality, specific therapeutic indications)

Belgian policy and generics

- New remuneration system for pharmacists: goals
 - Introducing remuneration for delivering medicines and dispensing pharmaceutical care;
 - Disconnecting partially the profit margin from the retail price;
 - Creating transparency for patients (invoice, copayments based on ex factory price).

Belgian policy and generics

- New remuneration system for pharmacists concrete
- 3 elements:
 - A fixed fee (3,88 €) per delivery, remunerating standard pharmaceutical care
 - A variable fee as a percentage of the ex-factory price (≤ 60 €: 6,04 %; >60 €: 3,62 € + 2 %; ex factory price – 60 €)
 - A complementary fee for specific pharmaceutical care (payment for first delivery, for delivery in INN in reference price system, for delivery medicines subjected on a priori approval)

Belgian policy and generics

- Targets for low cost prescriptions
 - Introduction in 2005 of minimum percentages for low cost prescriptions (generics and originator with price equivalent to generic).

Belgian policy and generics

- Targets for low cost prescriptions
 - Introduction in 2005 of minimum percentages for low cost prescriptions. In September 2006 96,7 % of GP and 85,5 % of specialists reached target. The global percentage of low cost medication increased from 27 % 2005 to 44 % in 2010
 - Commitment in national convention 2009-2010 between physicians and sickness funds to start the treatment in at least 8 of 10 patients with one of the "least costly" molecules. The target was not attained for some groups of molecules (e.g. statines)
 - In preparation: as from 2011 introduction of higher targets

Challenges for the future

- **Create headroom for innovation** through the promotion of **cost-aware** and **cost-efficient** management of scarce health care resources with all stakeholders
- To enhance the **dynamics of competition** especially in domains, not covered by actual policy, i.e. biosimilars and hospitals
- Particular attention for good use and compliance of medicines to avoid overmedicalisation of vulnerable patients, i.e. elderly in chronic care