



Pricing of medicinal products and reimbursement systems in EU

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Malta
April 18th, 2008



Pricing of medicinal products and reimbursement systems in EU

Agenda

1. Transparency Directive 89/105/EEC



Directorate General Enterprise & Industry

Transparency Directive 89/105/EEC:

**Transparency of measures relating to pricing
and reimbursement of medicinal products**

Agenda

1. Transparency Directive 89/105/EEC
2. Price-setting schemes in EU member states

Table 1 Examples of international price comparisons in price setting schemes in EU member states, 2003

- **Country** **Price comparison**
- **Belgium** Ex-manufacturer's price in France, Germany, Luxembourg and the Netherlands
- **Denmark** Average European ex-manufacturer's price excluding Greece, Portugal, Spain and Luxembourg, but including Liechtenstein
- **Finland** Average EU wholesale price
- **Ireland** Average wholesale price of Denmark, France, Germany, the Netherlands and the UK
- **Italy** Weighted average ex-manufacturer's prices in EU (excluding Luxembourg and Denmark)
- **Netherlands** Average ex-manufacturer's price of Belgium, France, Germany and the UK
- **Portugal** Minimum ex-manufacturer's price of identical products in France, Italy and Spain

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1. Transparency Directive 89/105/EEC
2. Price-setting schemes in EU member states
3. Summary of approaches in EU member states

Table 2 Summary of approaches in the regulation of pharmaceutical prices in EU member states, 2003

	Market segment	Free pricing	Direct price controls	Use Intern. price compar.	Profit controls	Ref. pricing
Austria	In-patent Off-patent		✓ ✓	✓ ✓		
Belgium	In-patent Off-patent		✓	✓ ✓		✓
Denmark	In-patent Off-patent			✓ ✓		✓
Finland	In-patent Off-patent		✓ ✓	✓ ✓		

Table 3 Summary of approaches in the regulation of pharmaceutical prices in EU member states, 2003

	Market segment	Free pricing	Direct price controls	Use Intern. price compar.	Profit controls	Ref. pricing
France	In-patent Off-patent		✓	✓		✓
Germany	In-patent Off-patent	✓				✓
Greece	In-patent Off-patent		✓ ✓	✓ ✓		
Italy	In-patent Off-patent		✓	✓		✓

Table 4 Summary of approaches in the regulation of pharmaceutical prices in EU member states, 2003

	Market segment	Free pricing	Direct price controls	Use Intern. price compar.	Profit controls	Ref. pricing
Netherl.	In-patent		✓	✓		✓
	Off-patent		✓	✓		✓
Spain	In-patent		✓	✓		
	Off-patent			✓		✓
Sweden	In-patent		✓	✓		
	Off-patent		✓	✓		
UK	In-patent	✓			✓	
	Off-patent		✓			

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1. Transparency Directive 89/105/EEC
2. Price-setting schemes in EU member states
3. Summary of approaches in EU member states
4. External reference prices in EU - Policies on generic drugs

Policies on generic drugs

	<i>Generic promotion</i>	<i>Generic prescribing (1)</i>	<i>Generic substitutio (2)</i>	<i>Incentive (1) or and (2)</i>	<i>Public/prescriber view on generics</i>	<i>Generic market share (%)</i>	<i>Value (US\$ million)</i>
Austria	no			☐	neut-neg	5-6	88
Denmark	strongly	☐	☐	☐	pos	22-40	197-359
Netherl.	yes	☐	☐	☐	pos	12	276
Germany	strongly	☐	☐	☐	pos	41	4,600
UK	strongly	☐	☐	☐	pos	22	1,435
Ireland	yes	☐		☐	pos	na	na
Finland	no	☐	☐		na	na	na
Switzerl.	no	☐			na	3	84
Norway	no			☐	na	na	na
Sweden	strongly	☐	☐	☐	pos	39	1,061
Belgium	no				neg	6	360
France	no	☐	☐	☐	neg	3-4	365-545
Italy	no		☐		na	1	88
Greece	no				na	na	na
Portugal	no			☐	na	1	8
Spain	yes	☐		☐	neg	1	51

Pricing of medicinal products and reimbursement systems in EU

Few examples for “new” EU countries

1. Czech Republic



2. Poland



3. Hungary



1. Czech Republic - Pricing



Before marketing:

- Obtain max market price* (M.o.Finance)
- Reimbursement price (M.o.Health)

* A list with max prices is published in July each year

Different price-setting systems are used for domestic and imported products:

- Domestic drug prices: production costs + 30% gross margin for the manufacturer
- Imported drug prices: max prices are set on the basis of comparator countries (Spain, Italy, France)

Pricing of medicinal products and reimbursement systems in EU

1. Czech Republic – Reimbursement



Products fall into four categories:

- Fully reimbursed medicines
- Medicines reimbursed for hospital use
- Reimbursement restricted to prescriptions written by named specialists
- Reimbursement restricted to specific indications

“ The ATC system provides the basis for the reimbursement list”

1. Czech Republic – Reimbursement



- Full reimbursement is based on the reference price –usually the cheapest- in each therapeutic group
- The patient having to pay the difference between the reference price and higher-priced products in the group
- As price comparisons are therapeutically based, patented original products compete with generics in the same class
- In addition, ATC classifications means that a reference price may be set for a category in which drugs are used in different conditions

1. Czech Republic – Reimbursement



- When a new generic enters a therapeutic group, it can trigger reimbursement cuts for all products in that group
- Example: when the first generic “sartan” entered the market, the government reduced the price of all “sartans” by 60%

Patented “sartans” collectively lost 70% of the market to generics within six months

- Similar trend for other patented products like, statins, ACE-inhibitors, antipsychotics and PPI’s

2. Poland



Pharmaceutical prices are set at maximum retail price according to the Pricing Law 2001.

Products requiring reimbursement are then subjected to a further price review and most fall into the reference pricing system



2. Poland – Pricing

- Three ministries – health, public finance and economy – are involved in pricing and reimbursement decisions.
- There is a considerable lack of transparency over how maximum retail prices and reimbursement prices are determined.
- The new government has indicated that the introduction of transparent principles for pricing and reimbursement is one of its key priorities



2. Poland – Pricing

- A number of factors are thought to be taken into consideration when determining prices for new molecules including, the price of the drug in other EU countries with a similar GDP (including Czech Rep., Slovakia, Hungary, Greece and Portugal).

2. Poland – Pricing



- Factors:
 - the price competitiveness of the drug relative to existing treatments
 - historical and forecast volume sales
 - cost of production
 - proven efficacy
 - cost-effectiveness
 - potential role in controlling epidemics or treating public health diseases
 - daily treatment costs
 - average cost of standard therapy and potential impact on the drugs budgets



2. Poland – Reference Price

Poland operates a reference pricing system:

- In theory, it should only apply to reimbursed drugs with generic equivalents but, in practice, it also includes patented products
- Reference prices are set at the level of the cheapest generic version of a drug within a group of products so as more generics are launched into a group at lower prices, the reference price decreases
- The criteria for grouping products for reference price purposes are not very transparent
- Groups can include drugs with different active ingredients and different modes of action and tend to be based around therapeutic classes



2. Poland – Reference Price

- In practice, the reference pricing system has triggered strong price competition amongst generics in a class
- Some companies are slashing the price of existing products by as much as 50%, so that they can become the reference product
- This strategy is increasing price erosion in the market



2. Poland – Reimbursement

- The reimbursement system in Poland is based on positive lists and reference pricing
- Reimbursed drugs fall into one of two categories :

- ❖ essential medicines

- ❖ supplementary medicines



2. Poland – Reimbursement

❖ essential medicines:

- Essential medicines are fully reimbursed at the relevant reference price
- Patient pay the basic prescription charge (flat rate fee) of Zloty 3,20 (1 Zloty = Euro 0.286833), plus any difference between the reference price and the price of the drug they receive.



2. Poland – Reimbursement

❖ supplementary medicines (two groups):

- those that are reimbursed at a rate of 70%
- those that are reimbursed at a rate of 50%

- Patients pay the 30% or 50% difference (based on the reference price) in the form of a co-payment plus any price differential between the reference price and the price of the product they receive.

- *Disabled war veterans receive prescriptions medicines free of charge*

3. Hungary



- The more positive environment for pricing and reimbursement following implementation of the EU Transparency Directive
- Non-reimbursed drugs can now enjoy complete pricing freedom and manufacturers can launch new products
- More frequent price revisions to reimbursed categories will seek to reduce generic prices in those groups where competition is weak

3. Hungary – Pricing



- Pharmaceutical products not seeking reimbursement are no longer subject to the restrictions previously imposed
- While non-reimbursed products have enjoyed pricing freedom, their market introduction was permitted only on a quarterly basis and pricing data had to be published in both the MoH's and Pharmacists gazettes
- From Nov. 2005 manufacturers have freedom to launch non-reimbursed products whenever they choose and are free to set and revise their own prices

3. Hungary – Pricing



- Manufacturers seeking reimbursement are required to apply to the OEP (Hungarian National Health Insurance Fund Administration - Országos Egészségbiztosítási Pénztár)
- Reimbursement assessments are carried out by the Institute for Technology Evaluation which acts as an advisory body to the OEP
- The reimbursed price proposed by the manufacturer is either rejected or accepted by the OEP

3. Hungary – Pricing



- Reimbursed prices are calculated on the basis of an international reference pricing system
- Using prices of a basket of 15 countries including 14 EU members and the US
- Prices in four of the cheaper EU markets – France, Greece, Portugal and Spain – tend to play a more prominent role
- Volume market shares in the reference countries are also taken into account by the OEO
- For products where the same active ingredient is already available in Hungary, prices are compared with local products

3. Hungary – Reference Price



- Two types of reference pricing are used in Hungary
 1. Under the fixed reimbursement scheme, where there are four or five equivalent actives on the market, the cheapest drug based on DDD that accounted for at least 3% of the market in the preceding year is typically used as the reference product.
- If none of the products meets the reference criteria, the average price of medicines with a 1% market segment share is used as reference price
- Higher priced drugs are reimbursed only at the level of the reference price.

3. Hungary – Reference Price



2. Therapeutic reference pricing is used for specific therapeutic groups in which a fixed reimbursement rate is set according to the lowest DDD of different active ingredients within the therapeutic group.

- Both generics and patented original brands are included in the calculation

3. Hungary – Pharmacoeconomics



- In the decision-making process, OEP takes into consideration the recommendations of ESKI (Technology Institute) which evaluate the cost-effectiveness of drugs
- Cost effectiveness evaluation is undertaken for innovative drugs or those attracting high reimbursement
- Multinationals can use foreign data adapted to the local market to support their pharmacoeconomic assessment

3. Hungary – Reimbursement



- Reimbursement assessments are based:
 - ⊕ on clinical efficacy
 - ⊕ affordability
 - ⊕ accountability and predictability
 - ⊕ public interest
 - ⊕ pharmacoeconomic studies (where required)
- In line with the EU directive reimbursement decisions must be made within 90 or 180 days, depending on the type of procedure

3. Hungary – Reimbursement



- Drugs assigned to the “normative” reimbursement category are reimbursed at 90%, 70% or 50% and are prescribed by GP’s without special conditions.
- Drugs in this category account 25% of the OEP’s drug reimbursement budget and include antibiotics, NSAID’s, minor tranquillisers, sleeping pills and mucolytics

3. Hungary – Reimbursement



- The system also includes the EU90 and EU100 categories which are drugs that can be prescribed only by specialists and are reimbursed 90% and 100%.
- Drugs for Cancer, diabetes, Multiple sclerosis and depression are fully reimbursed
- Drugs for treat epilepsy, ulcers, rheumatoid arthritis and asthma are reimbursed at 90%

This categories represent 40% of reimbursed expenditure

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5. Why are drug costs rising ?

Why are drug costs rising ?

Higher volumes and higher prices

➤ Ageing population

Why are drug costs rising ?

Higher volumes and higher prices

- Ageing population
- More chronic illnesses
- Shift to new chemical entities-new medicines
- "Life-style drugs"
- New drugs for diseases that could not be treated e.g. AIDS
- Increased number of prescriptions per patient
- Increased overall volume of prescriptions
- Hospital - primary care shifts

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6. Financial and Managerial measures on containing costs

Financial measures on containing costs

- Fixed and indicative budgets for prescribers
- Budgeting for regions, PHC groups with pay-back mechanisms
- Price regulations and reference prices
- Patient co-payment
- Financial incentives to pharmacies for better dispensing
- Differential reimbursement rates
- Promote generics

Managerial measures on containing costs

- Positive and negative lists
- Disease management
- Restrict distribution and prescription
- Prescribing support systems
- Regulate marketing, approved indications and commercial information
- Practice guidelines

Table 7

Examples of government–industry agreements in EU member states

<u>Country</u>	<u>Type of government–industry agreements</u>
Austria	Agreement on drug expenditure targets for the Social Insurance Institution; growth to be slowed through price reductions
Denmark	Agreement on reduction in overall price level such that overall expenditure on subsidized pharmaceuticals is kept constant
France	Sector-based agreements on issues including exchange of information, promotion of compliance with national objectives, rational drug use, development of a generic drug market and others
Ireland	Agreement on supply terms, conditions and prices of medicines for the health service
Portugal	Agreement with industry to cap NHS drug expenditures and repay excess
Spain	Multiple agreements covering price cuts, expenditure targets and company repayment if spending targets are exceeded
UK	Pharmaceutical Price Regulation Scheme

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7. Future Trends for Europe

Future Trends for Europe

- Demographic data
- (Local) epidemiology of disease
- (Local) clinical practice variations
- (Local) perceptions of disease and unmet needs
- Impact on (local) economy

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7. Future Trends for Europe
8. Conclusions

Conclusions

- **Many governments** are using the systems to price and reimburse pharmaceuticals as a core component of their strategy to reduce healthcare expenditure.
- **Getting the message to all levels**, that P & R is a core function and that pharmaceutical pricing should now form an integral part of the marketing mix.
- **Pharmaceutical drug pricing** would need to be justified to all stakeholders, for which a value-based pricing approach is necessary

Conclusions

- **Any price negotiation** will need as much supportive data as possible, including Pharmacoeconomic's
- **More resources** in understanding regional environments