



Making Medicines Affordable

# CONTRIBUTION BY THE EGA TO THE PHARMACEUTICAL FORUM PRICING WORKING GROUP

(7 NOVEMBER 2006)

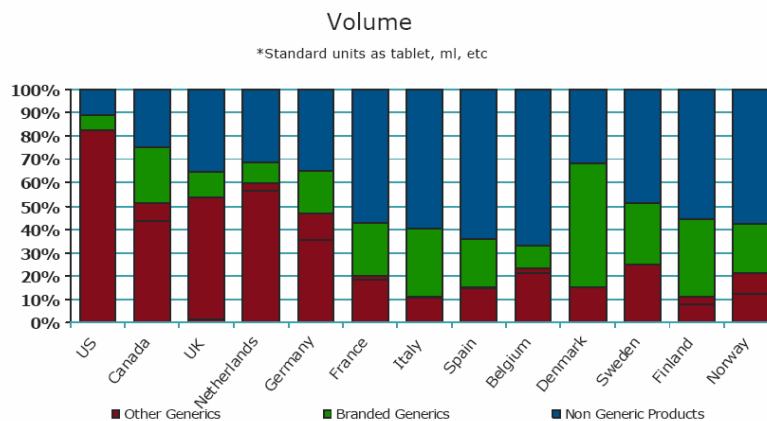
## 1. Europe's Savings Leakage

### a) The Generic Potential

Generic medicines can provide major savings to patients and healthcare budgets in Europe. Competitive markets are the most efficient way of allocating resources and achieving such savings. However, the potential for savings through generic competition is not being maximised. Generic medicines can still provide over 40% more savings to healthcare budgets in Europe.

Table 1

Europe has a potential for a lot more generic erosion



Source: IMS Health, 22 September 2006 (IMS Health MIDAS MAT/1Q06 Ethical Market only (Nordics-PREVIEW (MKTSG4))

For the full potential of savings and headroom for innovation to be realised, it is essential to develop and maintain a strong European generic industry. To achieve this, EU Member States and the European Commission should implement G10 Recommendation 4.

*“To secure the development of a competitive generic market, Member States - facilitated by the Commission - should explore ways of increasing generic penetration in individual markets (including generic prescribing and dispensing). Particular attention should be given to improved market mechanisms in full respect of public health considerations.”* (Recommendation 4: G10 Report June 2002)

The Pharmaceutical Forum endorsed the importance of the G10 Recommendation 4 and the need to provide incentives to competition, as well as valuable innovation, on



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29 September 2006.

*“Identifying, assessing and recommending ways to ensure incentives for competition (including on price) and valuable innovation, in particular in line with the relevant G-10 recommendations on pricing (Recommendations 3, 4, 5 & 6)”.*

(Pharmaceutical Forum Progress Report 29 September 2006)

## b) Prescription Switching Loss

The current level of switching varies between molecule and between EU Member State. Switching is affected by both the intensity and type of government measures to promote generic medicines.

For example, certain EU countries only encourage price competition between generic alternatives as opposed to between the originator and generic medicines in general. Again certain EU countries only allow substitution where an INN is prescribed. Equally, there is often no reward for prescribers to make a rational choice.

The level of switching, and the subsequent savings leakage, is also affected by the existence of so-called “new” variations of the originator product, which are introduced to mitigate generic competition.

Table 2

### Level of switching varies by molecule and by country

*Share of original/licensed brand in total molecule value, Q4 2005*

	AMLODIPINE Norvasc	CITALOPRAM Cipramil	OMEPRAZOLE Losec	PRAVASTATIN Pravachol	RAMIPRIL Triatec	SIMVASTATIN Zocor
Austria	43	43	32	54	71	14
Belgium	70	40	11	88	97	43
Denmark	30	48	31	22	16	7
Finland	85	61	35	40	69	27
France	N/A	60	62	0	N/A	43
Germany	43	28	4	32	41	26
Greece	94	100	41	100	97	25
Ireland	91	80	73	90	92	84
Italy	100	73	100	100	84	92
Latvia	80	35	3	N/A	N/A	5
Netherlands	9	5	34	10	15	16
Norway	39	34	62	31	98	26
Poland	5	24	6	N/A	87	18
Portugal	56	N/A	3	47	66	23
Spain	87	72	18	41	91	35
Sweden	99	71	28	100	69	36
UK	42	27	16	40	11	11

Mainly brand >75%  
50-75%  
25-49%  
Mainly generic 0-24%

Source: IMS Health, 22 September 2006 (IMS Health MIDAS MAT/1Q06 Ethical Market only (Nordics-PREVIEW (MKTSG4))

Many systems regulate prices of generic medicines, but few regulate reimbursement according to the pharmacotherapeutic relevance of a product. An efficient management of healthcare budgets will ensure that the best choice is made in reimbursement according to the clinical relevance and pharmacotherapeutic value of one product over another.



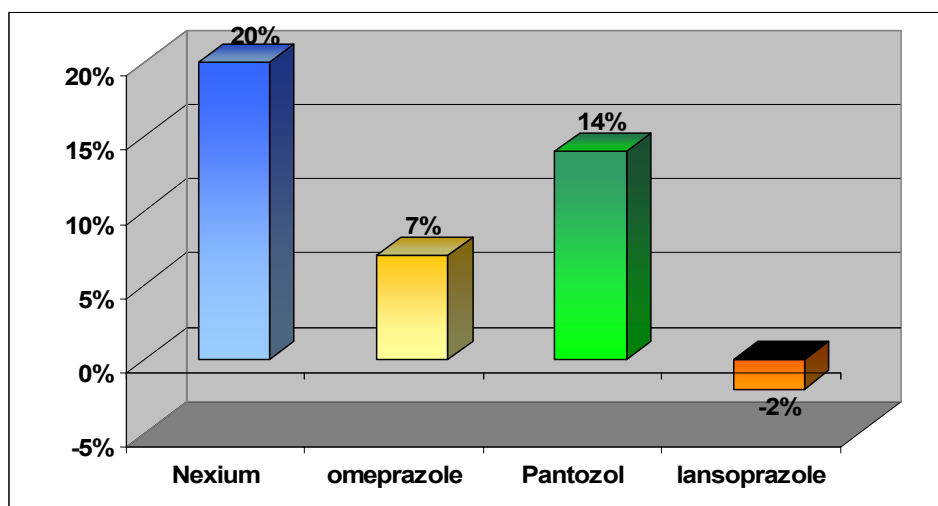
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The introduction of these so-called “new products”, which are no more than chemical variations of the original reference product and provide no significant therapeutic advancement for the patient can offset the impact of generic competition.

Failure by reimbursement systems to discourage such pseudo-innovations creates an unnecessary savings leakage for Europe’s healthcare systems by switching prescribing and dispensing away from lower-priced generic medicines.

Table 3

Example: Comparative Percentage Increase in the Dispensing of Antacid Medicines in the Netherlands (July 2006). Patented Products Outgrowing Generics.



### c) Time Lost

Substantial savings are lost for healthcare systems, insurers and patients as a result of unnecessary pricing and reimbursement procedures applied to generic medicines. Although there may be justification in the need to review the application for price and level of reimbursement of a new originator product to assess its cost-benefit advantages, no such procedure is needed for generic medicines, which have well-known properties and profiles.

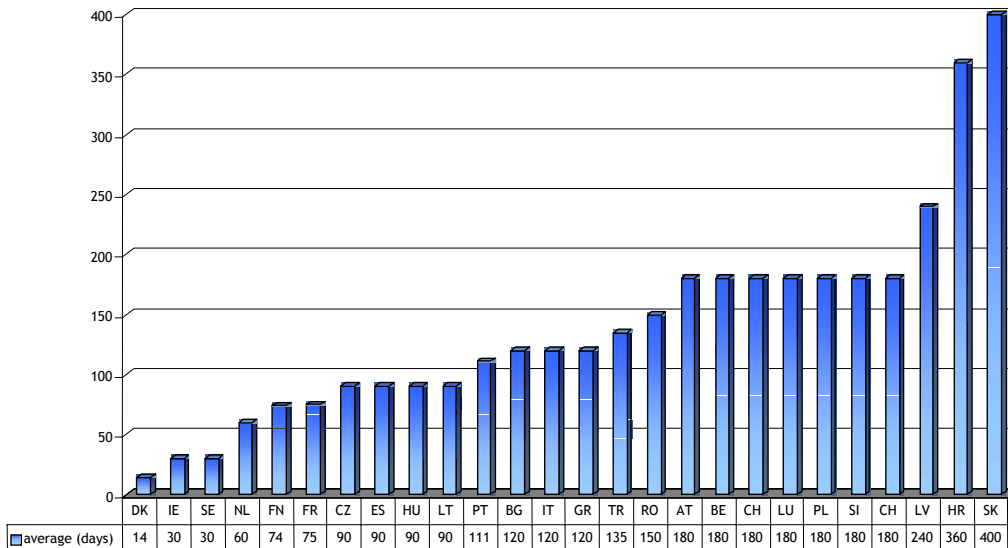
Consequently, generic products, which have been granted a Marketing Authorisation (MA), should be given automatic pricing and reimbursement approval and a substitution status. EU Member States should carry out the necessary changes to allow automatic pricing and reimbursement approvals and substitution status in cases where the price request is lower than the comparable originator product. However, if this is not forthcoming, it may be necessary for the Price Transparency Directive to be amended to ensure this.



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Table 4

- Time delay for generic price & reimbursement approval after granting of MA



Source: EGA members: No delays recorded in the case of Germany, Malta, and the UK as prices are set freely or price approval is automatically delivered at the time of the MA grant.

## 2. Biosimilar Budget Opportunities

Biosimilars also create a major opportunity for widening patient access to quality healthcare delivery and for reducing healthcare costs.

*“Biosimilar medicines offer new opportunities both for the growth of our generic industry and for the control of national healthcare expenditure.”*

(Günter Verheugen, Vice President and Commissioner for Enterprise and Industry)

Biologicals include 7 of the top 10 injectable treatments (Insulin/EPO). Treatment costs for biopharmaceuticals are between 5,000-30,000 Euros a year. Biosimilars can bring 20-30% savings on these therapies and increase patient access to suitable healthcare. For example, Omnitrope was launched in Australia at 25% discount.

Another good example of the social and budgetary importance of biosimilars is Poland.

- Gensulin was launched by Biotin in 2001 resulting in a 28% price decline that year;
- The Polish healthcare system saved 90 million Euros in four years and is now saving 65 million Euros per year.

## 3. EU Generic Competitiveness Compromised by Market Hurdles

Currently, the EU generic medicines industry operates in a highly complex environment in Europe. The industry is faced with several hurdles that are not existent in other parts of the world such as the USA, which has the most favourable environment for generic competition.



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**Table 5**

	EU	US
Fragmented market	✓	
Registration fees	✓	(Fee waivers)
Harmonisation of Summary of Product Characteristics (SmPC) of originator reference product		✓
Pricing & Reimbursement time delays	✓	
Delayed entry from data exclusivity periods	6-10 years (8+2+1 years)	5 years
Legal incentive and mechanism to challenge patents		✓
API's GMP undertakings by individual companies	✓	(Carried out by FDA at no expense to industry)

#### 4. Europe's "A La Carte" Approach To Generic Medicines

Additionally, there is still a lack of national measures to encourage the uptake of generic medicines.

**Table 6**

Overall lack of generic prescribing	Only 50% of European countries encourage generic prescribing
Lack of incentives for generic dispensing	71% of European countries' pharmacists are allowed to substitute but in 90% of these countries this can be prevented by the doctor. Moreover, the method of pharmacist remuneration limits generic dispensing e.g. only 3 countries actually reward for generic substitution.
Lack of generic info campaigns	Only 32% of European governments have run information campaigns on generic medicines. Very few EU agencies have websites with information on generics; one major exception is Portugal. This compares with the USA which runs major campaigns on generics and has a dedicated website and generics office



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#### Threat of Patent Linkage

Slovakia is the clearest case of patent linkage where no generic application is allowed until the patent expires. However, some other EU countries create limitations on receiving market authorisation or pricing status whilst a patent remains in place.

### 5. Key Actions For Generic Competition

Consequently, the EU generic medicines companies are struggling to meet both the objectives of competitive prices and the sustainability of the European generic medicines industry in the long term. The EGA recommends that EU Member States adopt the following 6 policy recommendations.

Table 7

1. Introduce a coherent generic medicines policy
2. Provide automatic pricing and reimbursement approvals and substitution status for generic medicines once they have obtained a market authorisation (MA) in cases where the price request is lower than the comparable originator product.
3. Structure reimbursement according to the clinical relevance and pharmacotherapeutic value of a product over another and ensure that there is no switching to non-added value higher priced patented products away from lower-priced generic medicines.
4. Provide incentives for physicians to prescribe generic medicines and encourage peer reviews of prescribing practices
5. Remove financial disincentives for pharmacists to dispense generic medicines
6. Provide information and incentives to patients to demand generic medicines

Whilst it is necessary to ensure that pricing systems encourage price competition and more affordable quality healthcare to patients, it is equally important that pricing systems are managed with the objective of ensuring the long-term sustainability of the EU based generic medicines industry so that it can compete effectively in the EU and global markets.

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The EGA is the official representative body of the European generic pharmaceutical and biosimilar medicines industry. The EGA is at the forefront of providing high quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector. The EGA consists of members from generic medicine companies and national associations, representing the industry in 34 European countries.