



Making Medicines Affordable

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

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## A. THE CONTRIBUTION OF GENERIC MEDICINES TO HEALTHCARE DELIVERY AND EU COMPETITIVENESS

### 1. Generic Medicines: Patient Access and Budget Control

Increasing patient access to pharmaceutical healthcare and reducing budget costs by increasing the use of generic medicines has been a key aspect of many European governments' healthcare policies for some time.

However, the ageing population in Europe and the higher healthcare expectations of patients reinforce the need for the greater availability of affordable generic medicines to ensure a sustainable healthcare provision for EU countries. The simple fact is that, without the increased use of generic medicines, EU countries will not be able to meet the increased costs that an ageing population creates.

Pricing and reimbursement agreements are important in setting the conditions for regulating supply and demand in healthcare systems. Governments worldwide are still searching for the ideal system that best suits their needs. The goal is to achieve the savings that generics can provide relative to the costs of the originator products, whilst ensuring a fair rate of return to manufacturers and others in the supply chain, and to create sustainable healthcare systems.

### 2. Generic Medicines and Innovation

Promoting competition through increased access to generic medicines also acts as a significant stimulant to pharmaceutical innovation. The expiry of a product's patent and Supplementary Protection Certificate (SPC) creates major incentives for originator companies to develop truly innovative medicines.

Moreover, savings made by the use of generic medicines can also be used to reimburse more expensive breakthrough innovations - a mechanism known as "budgetary headroom for innovation."

***"The promotion of generics can have important impact in reducing costs and creates headroom to help pay for new innovative products"***

**(EU Council of Ministers June 2000)**

This symbiotic relationship between pharmaceutical innovation and generic competition was emphasised by the G10 High Level Group on Innovation and Provision of Medicines. Recommendation 4 of the G10 final report specifically encourages greater use of generic medicines.



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***“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)***

### **3. Generic Medicines Improving EU Competitiveness**

From the standpoint of improving EU competitiveness and meeting the goals of the Lisbon Agenda, the European generic medicines industry also has an important role to play. In recent years, Europe has witnessed dramatic changes in the generic pharmaceutical markets. The environment in which business is conducted has changed significantly and generic pharmaceutical companies are becoming increasingly international. To excel, companies are seeking out the best conditions in which to develop, manufacture and market their products.

EU enlargement has also substantially increased the importance of the generic medicines industry in the EU, both as an industrial base and as a supplier of medicines. Enlargement has brought a large number of companies into the EU pharmaceutical family and created a strong grouping of exporters to the remaining region of Eastern Europe and Russia.

Opportunities to improve the EU generic medicines industry’s global competitiveness should also be stimulated by the Bolar provision of the new EU pharmaceutical law (Article 10.6 Directive 2004/27). This provision has created the opportunity for EU companies to research and develop products in advance of patent expiry, creating more of a level playing field with the generic medicines industry from others regions in the world.

### **4. Biosimilars - New Opportunities for EU Healthcare and Competitiveness**

The creation of a regulatory pathway for biosimilar medicines and the adoption of the Bolar provision in the EU pharmaceutical law now place the EU in the position to be the world leader in the research, development and production of biosimilar products.

Biosimilar medicines 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).***

The recent European Commission approval of the first two biosimilar medicines therefore marks a breakthrough opportunity for the European Union.



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## B. EUROPEAN GENERIC MEDICINES INDUSTRY'S PRIORITIES FOR PRICING & REIMBURSEMENT IN THE PHARMACEUTICAL FORUM

### 1. Greater Commitment to Measures Increasing Patient Access to Generic Medicines

Generic medicines are essential to reducing costs, increasing access, stimulating innovation and creating the necessary headroom to help finance new, innovative drugs. Therefore, it is essential to stimulate generic medicines use in all EU Member States. However, there are major differences between the EU Member States' use of generic medicines and generic medicines policy measures.

In order to assess the status of generic medicines in the EU, it was necessary to identify which are the most appropriate measures to stimulate generic uptake and assess the implications for healthcare budgets. For this purpose, the EGA commissioned a study from the Research Centre for Pharmaceutical Care and Pharmaco-economics from the Catholic University of Leuven.

The study - *Sustaining Generic Medicines Markets in Europe* (Simoens S. April 2006)- analyses public policy toward generic medicines in 11 EU Member States and their respective levels of generic market penetration. It demonstrates that increased substitution of originator product by generic equivalents for just 10 active substances would reduce public pharmaceutical expenditure by 27% - 48% in countries like Belgium, Denmark, France, Italy, the Netherlands, Portugal and Spain. It also determined that the promotion of generic medicines is more successful in countries with relatively free pricing policies for medicines, as in Germany, the Netherlands and the United Kingdom. It urges greater freedom in setting generic medicines pricing and the encouragement of price competition.

The study further points out that the traditional instruments used to promote generics – such as reference-pricing systems, prescribing budgets, generic substitution, patient co-payments, information campaigns – can be effective, but must act to stimulate competition.

Furthermore, the study emphasises that:

***“To develop a generic medicines market, supply-side measures need to be supplemented by demand-side policies, creating incentives for physicians, pharmacists and patients to use generic medicines. Indeed this report demonstrates that demand-side policies are critical to a sustainable generic medicines market”***

Concerning the ability of the EU generic medicines industry to compete effectively the report clearly identifies the importance of a high-volume share of the market for generic medicines.

***“The ability of the generic medicines industry to deliver competitive prices can only be achieved and sustained if it is assured a high volume of the pharmaceutical market. The high volume is dependent on demand-side policies”***



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The study urges Member States to adopt the following seven policy recommendations:

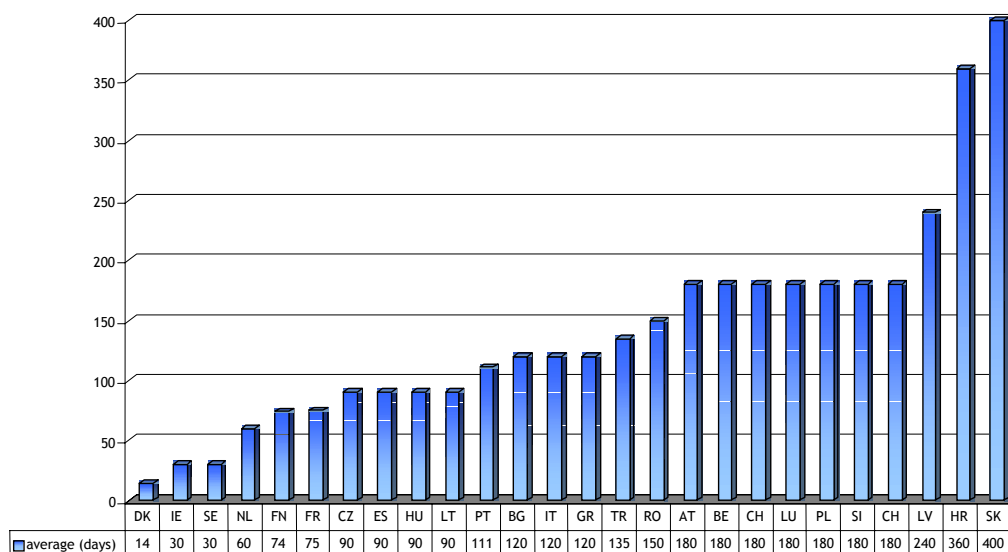
1. Introduce a coherent generic medicines policy
2. Encourage price differentiation / competition within existing regulatory frameworks
3. Disseminate pricing information to actors
4. Increase confidence of actors in generic medicines
5. Provide incentives for physicians to prescribe generic medicines
6. Remove financial disincentives for pharmacists to dispense generic medicines
7. Provide incentives for patients to demand generic medicines.

This study delivers valuable information about the differences in healthcare policies used and their effects on the generic medicines policy. For this reason, the EGA has distributed the study *Sustaining Generic Medicines Markets in Europe* to the Pharmaceutical Forum Pricing Working Group participants. (The study is also available on [www.egagenerics.com/doc/simoens-report](http://www.egagenerics.com/doc/simoens-report))

## 2. Reducing Time Delays for Market Access of Generic Medicines

At present, following marketing authorisation (MA), generic medicines invariably face time delays in obtaining pricing and reimbursement approvals and substitution status. The use of well-known and proven-quality generic medicines is, in many cases, the first choice in effective and safe pharmacotherapy. Therefore, it is a priority to minimise delays in pricing and reimbursement approvals of generic medicines, to enable equitable patient access to affordable high quality medicines.

- 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.)



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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. Generic medicines seek to compete on price with the off-patent originator product. Consequently, generic products, which have been granted a Marketing Authorisation (MA), should be given automatic pricing and reimbursement approvals and substitution status. EU Member States should carry out the necessary changes to allow automatic price and reimbursement approvals and substitution status. However, if this is not forthcoming, it may be necessary for the Price Transparency Directive to be amended to ensure this.

### **3. Rewarding Real Innovation and Generic Competition in the European Pricing & Reimbursement Systems**

The EGA fully endorses pharmaceutical innovation and recognises the existence of incremental as well as breakthrough innovation. However, the generic medicines industry is concerned that certain product changes, which claim to bring innovation in fact offer little added benefit to patients. Such products are rather designed to prolong the life cycle of the originator product and to stop competition from generic alternatives. Part of this problem lies with the patent system, which may not be strong enough in the assessment of patent applications. Patents are not always real measures of innovation.

In the case of pricing and reimbursement systems, clearly there is major role to be played in the assessment of product changes and incremental innovation. It should be clear that only products that bring real added benefits to patients and which are truly cost-effective compared to established pharmacotherapies should be reimbursed.

### **4. Dealing with Market Distortions Caused by Certain Regulatory & Patent Issues**

A misuse of certain regulatory mechanisms and patent issues, specific to generic medicines, have a direct negative impact on the access of generic medicines to European markets. EU pricing and reimbursement agencies need to address the following issues in particular:

#### **a) Differences in SmPCs / patient information leaflet (PIL) between originator and generic products**

These differences generally occur between older originator products, which have been approved by national procedures (having national SmPCs/ PILs), and recently approved generic equivalents of these originator products, which have been approved by the Mutual Recognition Procedure (MRP) or the Decentralised Procedure (and which must have a single harmonised SMPC/ PILs). Moreover, differences can also exist where originators have usage patents on certain indications, which would prevent the generic company from including the indication on its patient information leaflet.

In these cases, the product information of the generic medicine will differ from that of the originator product. As a result, in certain countries these differences make generic substitution impossible. This practice against generic substitution, which effectively reduces patient access to more affordable quality generic products, must be addressed.



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### **b) Patent linkage**

In certain countries, there are also attempts to prevent generic medicines from seeking or being granted pricing and reimbursement approvals or substitution status during the duration of a patent, even when no intention to market the product before patent expiry is envisaged by the generic company. The European Commission has already indicated that similar actions in the regulatory area, which seek to prevent the submission of a generic medicine application during the patent period, are against EU law. The same approach should be taken by EU Member States in the area of pricing and reimbursement. If such restrictions are allowed then the generic medicine will have to wait for patent expiry in order to proceed with all the administrative requirements to obtain pricing and reimbursement approvals and substitution status. This will clearly delay market access for generic medicines.

### **c) Naming of Generic Medicines and Restrictions on Multiple Applications**

The existence of different national naming requirements for generic medicines, specific national requirements for special generic logos, and national differences in prescribing and generic substitution laws make it extremely difficult and expensive for generic companies to operate on the EU market. Moreover, these national differences combined with the EU requirement for one single name make it impossible to operate in certain countries. The problem is intensified by the prevention of multiple applications by companies, which would otherwise enable companies to tailor their products to the national requirements for generic medicines. These problems are clearly related to pricing, reimbursement and substitution issues and there is an urgent need to resolve them if EU patients and healthcare systems are to have full access to generic medicines. For example, ending the restriction on multiple applications would go a long way to solving this problem.

## **5. Ensuring Headroom for Competition and Sustainability of the EU Generic Medicines Industry**

At present, the European generic industry faces strong competition from mainly from:

- a) India and China, which benefit from low labour and production costs, weaker environmental and patent protection laws, and a growing high-technology scientific base, and
- b) Better-positioned USA generic pharmaceutical companies, which benefit from a single market and a strong legal and market environment favouring generic medicines competition.

Additionally, the EU generic medicines industry is operating within the constraints and additional costs created by a lack of a genuine single market for pharmaceuticals in Europe.



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In some respects, this mirrors certain problems also faced by the originator sector of the industry. However, the fact that the EU generic industry must compete successfully on gaining high volume and selling at competitive prices makes it more susceptible to these issues. This is especially the case with a model that operates with lower margins and faces higher cost-sensitivity.

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.***