
Papers

The European generic pharmaceutical market in review: 2006 and beyond

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Abstract Dramatic changes in pharmaceutical markets make it imperative for generic medicines producers to seek out, and work with governments to create the best conditions for developing, manufacturing and marketing their products. Similar to its involvement in the G10 Medicines process, the European Generic Medicines Association (EGA) is now actively engaged in the European Commission's follow-up initiative, the Pharmaceutical Forum. To bring substance to this debate, the EGA has recently completed two important studies of European generics markets and the governmental policies across Europe that effect them. These studies aim to determine the progress of initiatives to promote generic medicines by examining market shares and go on to suggest ways of increasing the up-take of these affordable medicines. The traditional instruments employed by governments to promote generics — reference-pricing systems, prescribing budgets, generic substitution, patient co-payments, information campaigns — can indeed be effective in stimulating generic up-take, but they must also stimulate competition on the markets. Pricing systems must encourage price competition and more affordable quality healthcare for patients. They must also be managed to guarantee the long-term sustainability of the European Union (EU)-based generic medicines industry so that it can compete effectively on EU and global markets and continue contributing to affordable healthcare in Europe.

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Introduction

European generic pharmaceuticals markets have experienced dramatic changes in recent years. The business environment has become significantly more complex, and generic pharmaceutical companies are becoming

increasingly international. To excel, companies must seek out the best conditions for developing, manufacturing and marketing their products. And they must work with governments to create this environment.

The final report adopted by the G10 High-level Medicines Group¹ includes a recommendation for action at the European and national levels urging Member States to 'secure the development of a competitive generic market in Europe'.² The European Commission is now engaged in the

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Pharmaceutical Forum as follow-up to the G10 High-level Group. This reflection initiative represents the central feature of the Commission's new industrial policy for the European pharmaceutical sector and is designed to generate the momentum and political mandate for further developments in the sector and to provide a high-level platform for discussions on competitiveness and related public health issues.³

The Pharmaceutical Forum will focus on three areas identified by the G10 High-level Group as requiring additional reflection before implementation:

- Information to patients
- Pricing and reimbursement
- Relative effectiveness

Given the importance of generic medicines in the European healthcare equation and, consequently, to these discussions, it is ever more important to have a firm understanding of the various European pricing and reimbursement systems and the ways in which these systems can be improved to develop a viable and competitive generic medicines industry in Europe. It is equally important to establish the progress of national governments and generic pharmaceutical companies in achieving their goal of promoting the manufacture and use of generics in Europe.

Generics market shares across a broad selection of European countries can serve as an indicator of this progress. Establishing consistent figures for each market, however, is extremely difficult as evidenced in Figure 1a and b, given the diversity of the markets and the definition of the products in question.

The data in Figure 1a, for example, are derived directly from the IMS Health MIDAS database; the data in Figure 1b were collected directly from European Generic Medicines Association (EGA) members during the 2005 EGA internal survey of European generics markets.⁴ The EGA has been working with IMS over the past two years to develop a new, more accurate definition of generic

medicines (eg, branded generics, unbranded generics, etc) to include in their statistics.⁵ As the data in Figure 1a were compiled from IMS statistics based on the 'old definition', the generic market shares illustrated in it differ dramatically in some markets from the EGA figures. In Germany, for example, generic medicines are generally recognised as having attained approximately 41 per cent market penetration by volume and 22 per cent by value, nearly double the IMS figures. The figures for Poland and other countries also deserve careful attention. Once IMS has fully implemented the 'new definition', employing a standardised criteria for generics across Europe, the figures are expected to correspond more accurately to the actual reality of generic markets.

In the meantime, regardless of the source, the market data concur in highlighting the broad variations in levels of generic penetration from one country to the next. These disparities respond not only to differing historical and economic backgrounds, but also to the policies employed by national authorities that reflect a government's choice between a more or a less interventionist approach to creating a robust environment for promoting generics. Countries are generally clustered in three groups according to their market shares:

- Less than 10 per cent market share by value: Austria, Belgium, Finland, France, Ireland, Italy, Portugal, Spain;
- Between 10 and 40 per cent market share by value: Denmark, Estonia, Netherlands, Slovak Republic, Slovenia, Sweden, Turkey, the United Kingdom;
- Greater than 40 per cent market share by value: Croatia, Czech Republic, Germany, Latvia, Lithuania, Hungary, Poland.

A range of factors can affect generics markets within Europe. Businesses, for example, in an effort to simplify the market, are seeking to harmonise pharmaceutical registration processes as well as product packaging, marketing strategies and branding.

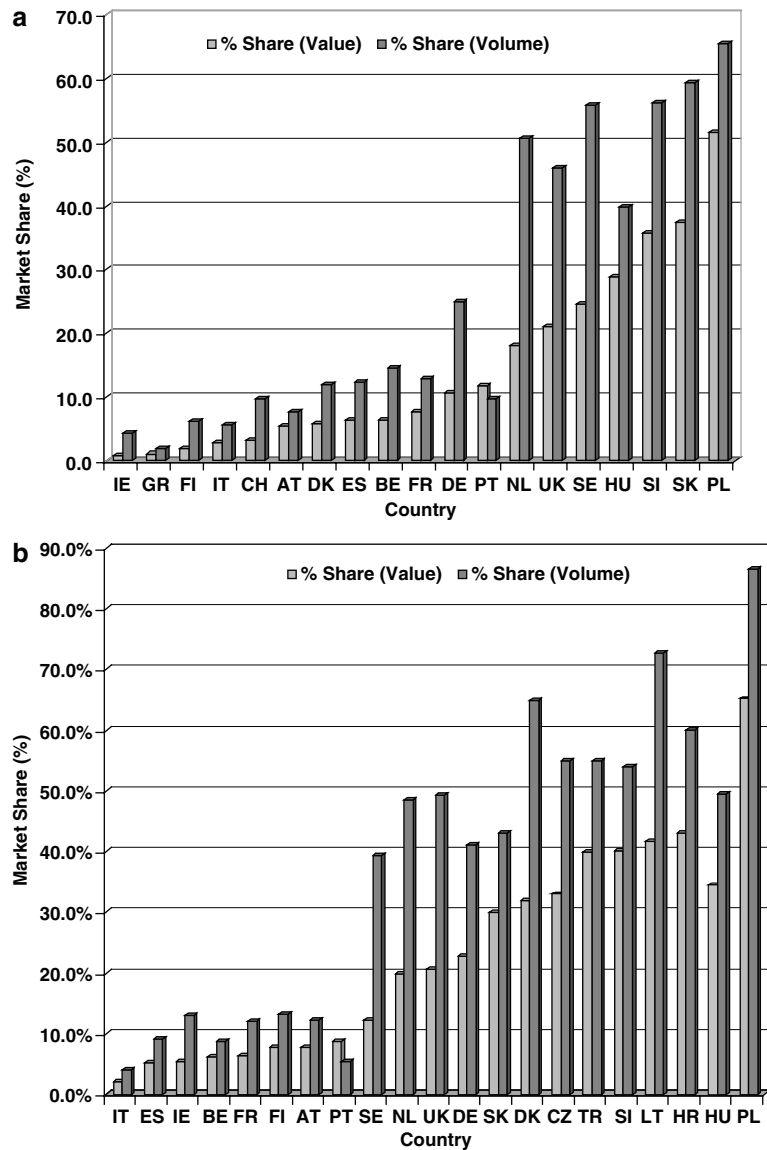


Figure I: (a) Generic market shares in Europe in 2005

Source: IMS Health.

(b) Generic market Shares in Europe in 2004

Source: EGA internal survey

Governments, concerned with the rising cost of pharmaceuticals within their national healthcare budgets, are striving to promote the use of generics over high-priced originator products. Reference-based pricing regimes are increasingly being implemented that benchmark not only products, but also countries.

Indeed, the European pricing and reimbursement map is very complex. Each

Member State deploys its own regime, adapted to its own economic and healthcare needs. Governments worldwide continue to search for the ideal system, elusive as it may be. In the meantime, pricing and reimbursement agreements play an important role in regulating supply and demand in healthcare systems. Their objective is to achieve the savings that generics can provide

relative to the costs of originator products, while ensuring a fair rate of return to manufacturers and others in the supply chain. It is ultimately a question of creating an economically sustainable healthcare system and ensuring access to affordable medicines to all patients.

For a full understanding of the pricing and reimbursement mechanisms in place, therefore, it is, important to look beyond market penetration figures to investigate the following key points:

- How pricing for generic medicines is established;
- How reimbursement systems for generic medicines are established and managed;
- The role of patient co-payment in healthcare systems;
- The public's general attitude towards the use of generic medicines;
- The prescribing behaviour of physicians with regard to generics medicines, and how they are assisted in their generic prescribing;
- The regulations governing the dispensing of generic medicines, and how pharmacists are remunerated;
- The delays to market caused by post-market authorisation procedures for establishing price and reimbursement status.

GENERIC PRICING AND REIMBURSEMENT

European pharmaceutical pricing systems are either (1) a generic free-pricing system or (2) a generic price-regulated system. Countries with a price-regulated system typically deploy a reference pricing system based on criteria that differs from market to market.

In countries boasting price-regulated systems, prices are regulated and established according to: (a) an average of selected European Union (EU) countries, (b) a percentage below the originator price, (c) a maximum price (price index), (d) a negotiable price (price/volume) or (e) some other measure.

The second internal EGA survey of European generics markets⁶ found that, in terms of pricing and reimbursement systems in Europe, 82 per cent of the countries surveyed have implemented price-regulated systems. In 36 per cent of these countries, price levels are set at a predetermined percentage below the originator price, whereas in 21 per cent price levels are based on the average price of pharmaceuticals in a selection of countries (Figure 2).

These reference pricing systems were introduced in 71 per cent of European countries as a tool to reduce pharmaceutical

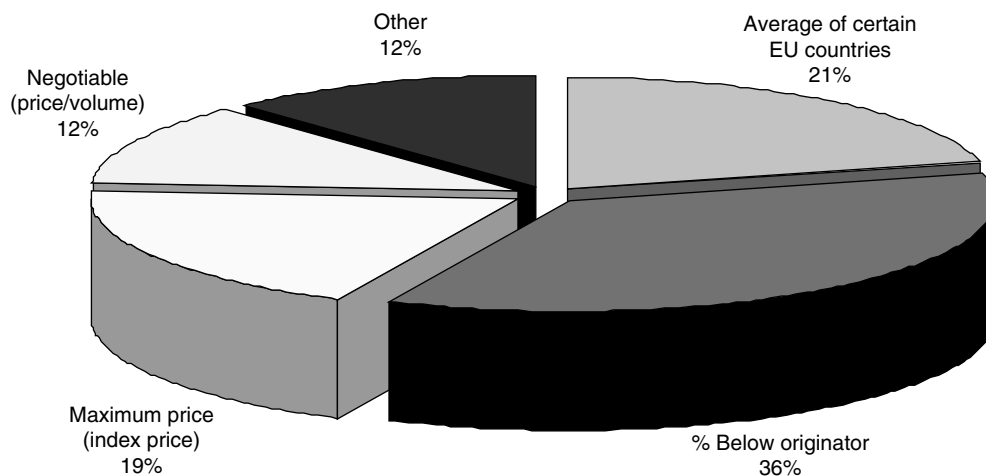


Figure 2: Setting price levels
Source: EGA internal survey 2006

expenditure. Reference pricing systems are, therefore, a significant aspect of healthcare systems — and cost containment efforts — across Europe.

In a reference pricing system, medicines are categorised into groups with identical or similar active ingredients, the so-called ‘reference groups’. Three ways of classifying similarity between medicines are used by national health authorities: (1) chemical, (2) pharmacological and (3) therapeutic equivalence. The authorities will then determine a maximum reimbursement price (reference price) for each reference group. This year’s internal EGA survey verified that the majority of European countries (63 per cent), which use a reference pricing system, establish their reference prices based on the active substance (Figure 3).

National health authorities also take into account the prices of existing medicines in the relevant reference group when determining the reference price. Thirty-two per cent of the European countries surveyed currently base their reference price on the lowest-priced medicine; 16 per cent of countries base their reference price on the lowest-priced generic (Figure 4).

PATIENT CO-PAYMENT

In publicly funded healthcare systems, it is important to highlight the role of patient

co-payment in financing a country’s healthcare system as it can strongly influence the patient’s ultimate decision on the medicine he or she will take. Patient co-payment is common practice in all European countries with the exception of Ireland and Malta. Even so a great deal of variation exists in how these regimes are actually implemented.

In most EU countries, the patient’s role in contributing towards the total cost of medicines (co-payment) is very limited. Patients are generally concerned with the outcome of the therapy prescribed and their participation in the cost. Patients may become more involved as their contribution increases. Patient co-payments are typically charged according to one of the following four mechanisms:

- Fixed fee per prescription (per item, per prescription, or according to pack size);
- A percentage of cost of the medicines prescribed (partially reimbursed);
- The difference above the reference price (reference price is equal to the maximum reimbursed price);
- A combination of the above, usually comprised of a fixed fee and a percentage of the cost of medicines prescribed.

This year’s EGA survey has found that the majority of countries in Europe calculate

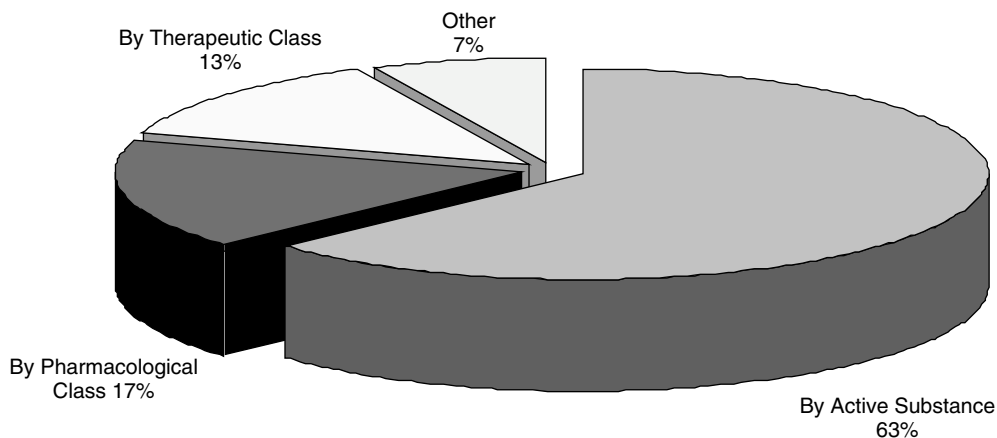


Figure 3: Establishing the reference price using medicines classification
Source: EGA internal survey 2006

patient co-payment either as a percentage of the cost of the medicine (36 per cent), or as the difference above the reference price (34 per cent), as illustrated in Figure 5.

GENERIC PRESCRIBING

The prescription process is an essential source of efficiency in healthcare systems. This is particularly true when prescribing generic medicines as a means to reduce costs to payers. Therefore, it is important to understand (1) what factors influence doctors to prescribe generic medicines; (2) what

format doctors use to prescribe generics and (3) under what conditions they prescribe generics. According to this year's EGA survey, doctors are encouraged to prescribe generics in only 50 per cent of the countries reviewed, and generic prescribing is compulsory in only 7 per cent (Figure 6).

Doctors prescribe medicines according to both a patient's therapeutic needs and the financial implications. There are few restrictions on the prescribing of medicines, but not all medicines are reimbursed.

Consequently, national governments develop

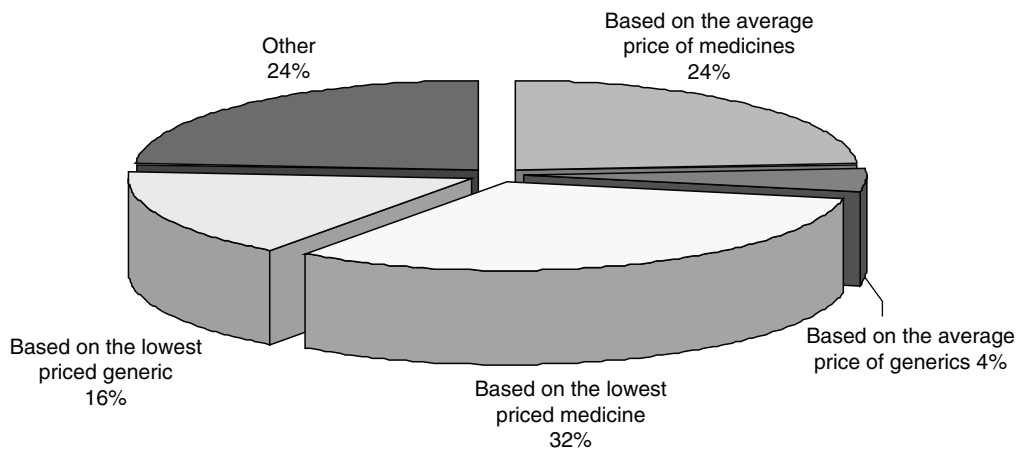


Figure 4: Establishing the reference price using price measures
Source: EGA internal survey 2006

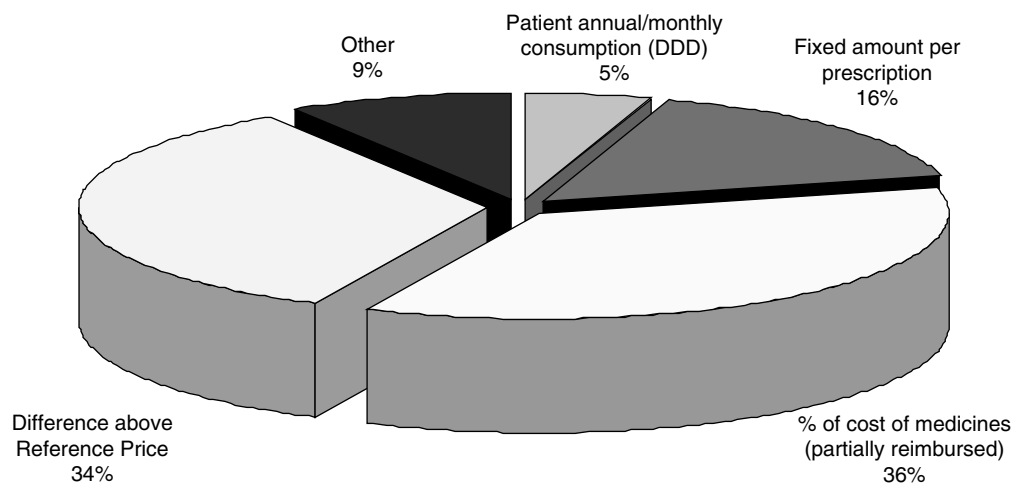


Figure 5: Calculation of patient co-payment
Source: EGA internal survey 2006

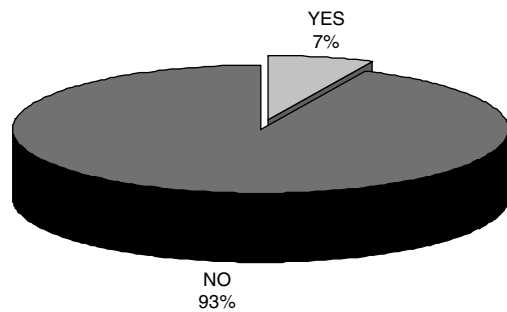


Figure 6: INN Prescribing
Source: EGA internal survey 2006

guidelines to inform and aid doctors in their prescribing. In general, Guidelines exist on therapeutic considerations, available budgets and cost efficiency, as well on as how to write prescriptions to allow more efficient dispensing.

A significant factor affecting the way medicines are dispensed and/or substituted is the format the doctor uses in the prescription, that is, whether it is prescribed using a brand name or the International Non-proprietary Name (INN).

Figure 6 would indicate that most prescriptions in Europe are written using a brand name, with doctors rarely prescribing by INN. Usually doctors only prescribe by INN if they are trained to do so. In the UK, medical students are taught to prescribe using INN, although it is not compulsory by law, and pharmacists are obliged to dispense exactly as written on the prescription. In countries where INN prescribing is compulsory, only in Portugal are physicians obliged to do so for all medicines when a generic product is available, and in Lithuania doctors must use the INN only for those products that are reimbursed.

GENERIC SUBSTITUTION

Where generic substitution is allowed, a doctor prescribes a specific product and the pharmacist is either free or is obliged to substitute it with a less expensive generic product. Generic substitution is used as a means to promote cost-effective prescription

and rational dispensing in healthcare systems. Ultimately, generic substitution is a key issue for all generic pharmaceutical manufacturers as it can provide an effective boost to the dispensing of generic medicines, consequently providing room for growth in the generics market. Substitution of course is not always a necessity if doctors are prescribing generic medicines adequately. The UK, for example, has high generic volume but no need for substitution because of the general prescribing practice. But for national governments where generic prescribing is insufficient, generic substitution translates into cost-savings in pharmaceutical expenditure and into access to quality affordable medicines for patients. Generic substitution has been adopted in 71 per cent of the European countries in this year's survey. However, rules governing generic substitution in markets where it is allowed often vary from country to country and according to the different circumstances surrounding the actual act of dispensing in the pharmacy.

MARKETING AUTHORISATION

Lastly, one of the key issues addressed in this year's survey concerns the specific conditions of market access following the granting of a marketing authorisation (MA) for generic medicines. Europe is still a complex market in terms of transparency, hence making it difficult to assess how long it will take for generic manufacturers to obtain their price and reimbursement status after receiving MA. Although delays for price approval have improved — in part due to the European Commission's recommendations and the EU Price Transparency Directive⁷ — the time delays for reimbursement status remain an obstacle to a competitive generic medicines industry in Europe.

Market access conditions for generics constitutes a core issue for generic medicines manufacturers as these tend to differ from country to country in Europe. The variables affecting market access generally include:

- (a) the need for the MA holder to apply for

price, (b) the delay between the MA grant and price approval, (c) prevention of generic MA due to Supplementary Patent Certificate (SPC) period, (d) naming of the generic product, (e) delays in approving the generic reimbursement and/or substitution status, (f) conditions for a generic medicine to be determined therapeutically interchangeable and thus apt for substitution.

Despite the European Commission's G10 Medicines Recommendations,⁸ the time required to receive pricing approval still varies considerably across Europe. This situation can, and often does, create difficulties for the generic industry in assessing the time needed to launch a generic product onto a particular market. Figure 7 illustrates the discrepancies between countries in time delays for price approval after the MA is granted to a generic product.

Figure 7 only includes those countries where price approval is required. This statistic does not apply to Germany, Malta, the UK and Poland, as their pharmaceutical prices

are either set freely or are approved together with the MA grant. Similarly, additional time delays exist for obtaining reimbursement status; these also vary considerably across Europe (Figure 8).

GENERIC AND SUSTAINABLE HEALTHCARE: NEXT STEPS

Constructive initiatives in the past such as the European Commission's G10 process have developed important recommendations for improving the competitiveness of the industry while meeting vital social objectives. And as the data presented above indicate, the challenge of benefiting fully from the savings potential offered by generic medicines has yet to be met. Striving to do so requires constant analysis of the environment in the individual markets, followed by the identification of the specific measures best suited to stimulating generic up-take, which in turn must be evaluated in terms of their financial implications for Europe's healthcare budgets.

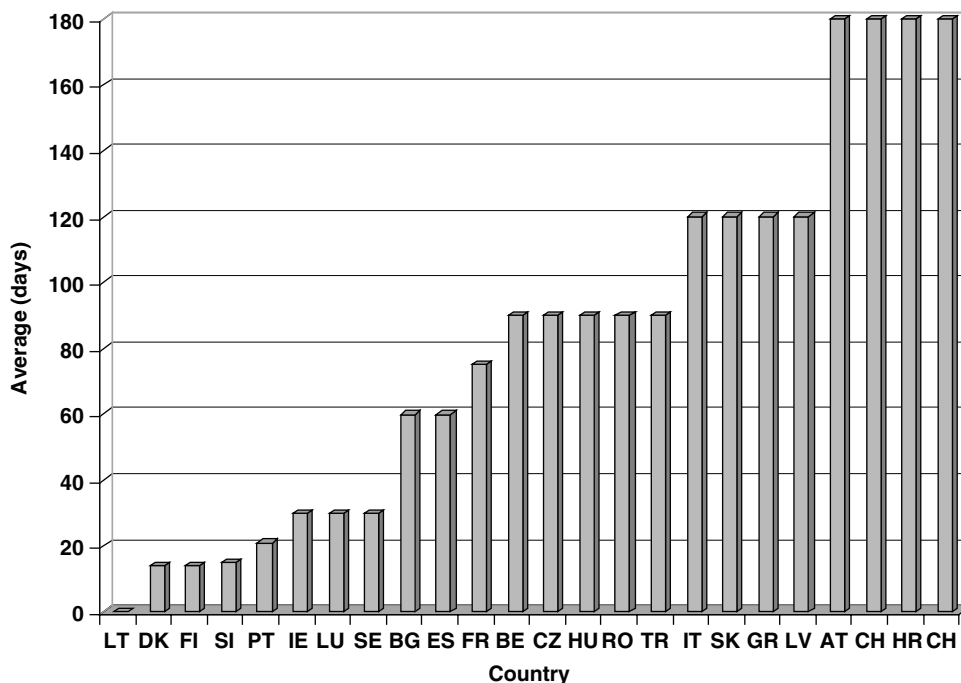


Figure 7: Time delay for price approval after granting of marketing autorisation (MA)
Source: EGA internal survey 2006

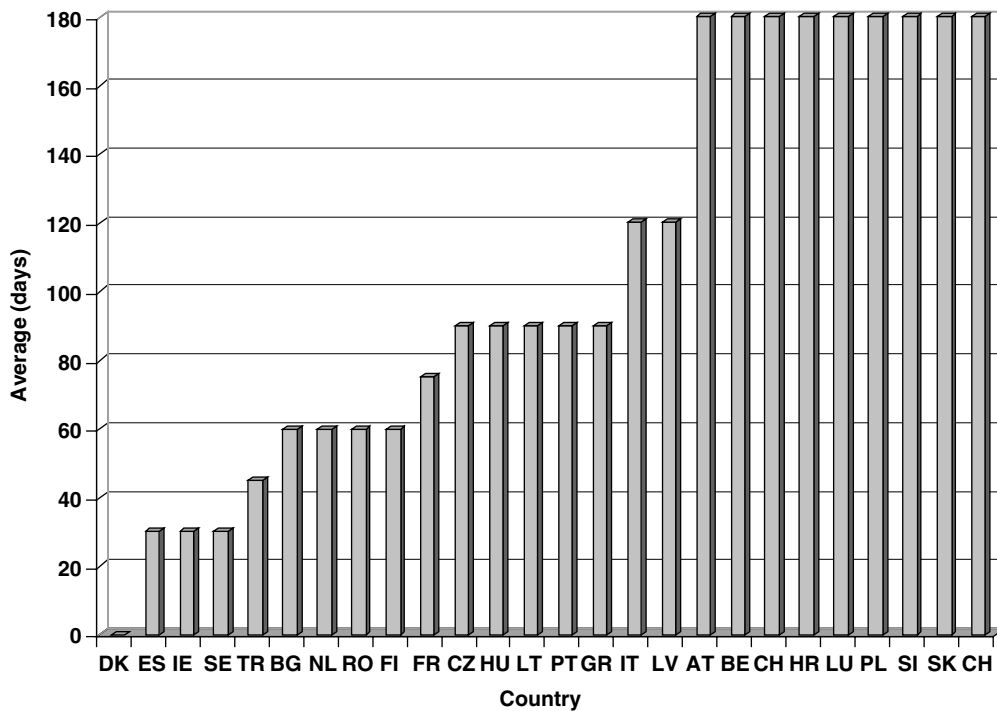


Figure 8: Time delay for reimbursement status after granting of MA
 Source: EGA internal survey 2006

To this end, the EGA recently commissioned a study from the Research Centre for Pharmaceutical Care and Pharmaco-economics at the Catholic University of Leuven to compliment our own internal statistics. The resulting report, authored by Professor Steven Simoens, was published in April 2006 under the title, *Sustaining Generic Medicines Markets in Europe*.⁹

Working with the data from a variety of sources (including the data collected in the 2005 and 2006 internal EGA surveys),¹⁰ the study 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 products by generic equivalents for just ten active substances would reduce public pharmaceutical expenditure by 27–48 per cent 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 UK. It urges greater freedom in setting prices for generic medicines and encourages price competition.

In the sections above, we have briefly examined some of the more important policy instruments used by governments to promote the use of generic medicines. The Leuven study concludes that these traditional instruments — reference-pricing systems, prescribing budgets, generic substitution, patient co-payments, information campaigns — can indeed be effective in stimulating generic up-take, but that they must be designed to stimulate competition. The report goes on to say 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.¹¹

The study clearly identifies the importance of a high-volume share of the market for generic medicines in order for the EU generic medicines industry to compete effectively:

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.¹²

The report proposes seven policy recommendations, urging governments to:

- Introduce a coherent generic medicines policy;
- Encourage price differentiation / competition within existing regulatory frameworks;
- Disseminate pricing information to all actors in the healthcare equation;
- Increase confidence of actors in generic medicines;
- Provide incentives for physicians to prescribe generic medicines;
- Remove financial disincentives for pharmacists to dispense generic medicines;
- Provide incentives for patients to demand generic medicines.

Undoubtedly a need still exists for a less complex and more cohesive European market for generics. The industry continues to strive toward a more transparent and sustainable environment to reach its full healthcare potential. Consequently, and armed with the results of the two studies discussed above, the EGA will maintain an active presence within the Pharmaceutical Forum. Within the Forum, the EGA will be striving to achieve a greater commitment on the part of governments to introduce measures that increase patient access to generic medicines, particularly by reducing the time delays for access to markets and by dealing with market distortions caused by

certain regulatory & patent issues. The EGA will push for real rewards for real innovation and the ensuing generic competition in European pricing and reimbursement systems. Similarly, the EGA will strive to ensure headroom for competition and the sustainability of the EU generic medicines industry, while working with governments to improve information on the quality, safety, efficacy and economic advantages of generic and biosimilar medicines for European patients.

Indeed, the challenge is ever more pressing. At present, the European generic industry is facing strong competition from India and China, which benefit from low labour and production costs, weaker environmental and patent protection laws, and a growing high-tech scientific base. European generics must also compete with much better-positioned American generics companies which benefit from a large, unified market fortified by a strong legal and commercial environment designed to favour generic medicines competition. In contrast, the EU generic medicines industry must operate within the constraints and additional costs of solid social, environmental and intellectual property protection, coupled with those generated by a lack of a genuine Single Market for pharmaceuticals in Europe.

In some respects, this situation mirrors certain problems also faced by the originator sector of the industry. The fact that the EU generic industry must struggle to compete successfully by both gaining high volume and selling at competitive prices makes it more vulnerable to these conditions, especially as an industry that operates with lower margins and higher cost-sensitivity.

The challenge is obviously far from over. While it is necessary to ensure that pricing systems encourage price competition and more affordable quality healthcare for patients, it is equally important that pricing systems are managed with the objective of guaranteeing the long-term sustainability of the EU based generic medicines industry so that it can

compete effectively in the EU and global markets. Only then can it continue to deliver the affordable medicines so necessary to the sustainability of European public healthcare.

It is now up to governments to face the generics challenge head on. They can do this by implementing pro-generics policy measures — particularly in the area of pricing and reimbursement — while better informing doctors, pharmacists and patients about the benefits of generic medicines.

Acknowledgments

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