



*Making Medicines Affordable*

# How to Increase Patient Access to Generic Medicines in European Healthcare Systems

A Report by the  
EGA | Health Economics Committee



EUROPEAN GENERIC  
MEDICINES ASSOCIATION

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The EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, which 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 represents companies and their subsidiaries from throughout Europe which provide over 130,000 jobs. The EGA plays an important consultative role in European healthcare policy making. The EGA and its members work with European national governments and the EU institutions to develop affordable solutions for pharmaceutical care and to increase Europe’s competitive strength in the global pharmaceutical market.

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## I. EXECUTIVE SUMMARY

Generic medicines are widely believed to contribute significantly to maintaining the sustainability of healthcare delivery, a matter of increasing concern to European governments. The expenditure on pharmaceutical products is a significant component of total healthcare costs and the search for less expensive therapeutic alternatives has shown the importance of generic medicines in lowering these costs.

It can be argued that sustainable healthcare systems can only be achieved through the increased use of generic medicines. Generic medicines are well-known medicines with proven therapeutic value available at affordable prices which consequently translate into savings for both healthcare systems and patients. In addition, generic medicines stimulate market competition thus driving the development of new medicines for illnesses and conditions for which treatment may not yet be available.

The importance of generic competition and the need to stimulate generic access was clearly recognised by the G10 High level pharmaceutical working group:

**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."<sup>1</sup>

The lack of high-volume uptake of generic medicines in Europe and the unexploited savings from generics due to the lack of coherent pharmaceutical policies was highlighted by Simoens in 2006:

"The ability of the (European) generic medicines industry to deliver competitive prices can only be achieved and sustained if it is assured a high volume of the pharmaceutical market. High volume is dependent on demand side measures"<sup>2</sup>

"Generic medicines create major savings for healthcare providers and stimulate innovation. However, the EU is not maximizing its full potential in generic medicines. Added savings of 27%–48% could be attained if the appropriate measures were taken by EU countries."<sup>3</sup>

Kanavos reinforces the importance of generic medicines and how to incentivise a well-balanced generic market,

"Payers in Europe and North America have embraced generic medicines because of their perceived cost advantages in relation to branded products and the savings they create to health insurance."<sup>4</sup>

The High Level Pharmaceutical Forum also addressed the key importance of generic medicines to European healthcare systems, suggesting key actions to promote the correct environment for generic medicines uptake.

"Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines."<sup>5</sup>

Most recently the preliminary report of the European Commission sector inquiry into the pharmaceutical sector has indicated clear behavioural activities of originator companies aimed at blocking legitimate launches of generic medicines where loopholes in the patent system and regulatory system enable this to happen:

<sup>1</sup> European Commission–G10 High Level Group on Medicines, 2002

<sup>2</sup> Simoens, 2006

<sup>3</sup> Simoens, 2006

<sup>4</sup> Kanavos, 2008

<sup>5</sup> European Commission–Pharmaceutical Forum, Progress Report, 2007

"Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are being delayed, then we need to find out why and, if necessary, take action."<sup>6</sup>

Clearly it is widely understood that Europe is not fully benefiting from the potential savings of generic medicines competition. This report focuses on those pricing and reimbursement aspects at national level which contribute to delays in market access and more significantly to the causes of Europe's failure to embrace high-volume post-patent generic competition.

It is important to note this paper does not address patent issues, regulatory issues nor behavioural activities of originators, which also contribute to significant problems for generic competition, particularly in ensuring immediate post-patent product launch. The EGA's concerns in these areas are addressed in other publications and submissions (eg, EGA submission to the inquiry: *"Patients Must Have Immediate Access to Affordable Generic Medicines at Day One After Patent Expiry"*<sup>7</sup>; EGA Report: *"Patent-related Barriers to Market Entry for Generic Medicines for Generic Medicines in the European Union"*<sup>8</sup>; EGA submission to the Public Consultation Process Initiated by the European Commission on *"The Future of Pharmaceuticals for Human Use in Europe"*<sup>9</sup>).

Rather, this paper looks into certain aspects of the lack of promotion for competition from generic medicines in the European pharmaceutical sector, a sector which is heavily impacted by the different regulatory systems operating in the various European markets. Northern European markets, where generic medicines have the highest penetration rates, are also markets characterised by consistent long-term generic medicines policies and fewer obstacles to entry, such as pricing barriers or time delays for granting post-market approval of pricing and reimbursement status.

By eliminating the barriers to generic medicines, European governments will be creating more effective competition in the pharmaceutical sector and generating significant economic savings which governments can then reallocate to fund real pharmaceutical innovation. Removing the obstacles to the entry of generic medicines will benefit the pharmaceutical sector at large by generating greater competition and ensuring much needed savings on pharmaceutical expenditure.

As the generic medicines industry is essentially driven by volume, attaining substantial market share is crucial to the sustainability of the sector. Limiting its potential to enter specific markets by introducing local price distortions can prove to be very prohibitive to the introduction of affordable generic medicines for entire populations and the development of viable markets for generic medicines. ■

<sup>6</sup> Kroes, 2008

<sup>7</sup> For the submission see: [www.egagenerics.com/doc/ega\\_pharma-inq\\_response\\_20090130-exsumm.pdf](http://www.egagenerics.com/doc/ega_pharma-inq_response_20090130-exsumm.pdf)

<sup>8</sup> For the report see: [www.egagenerics.com/ega-barriers\\_rpt.htm](http://www.egagenerics.com/ega-barriers_rpt.htm)

<sup>9</sup> For the submission see: [www.egagenerics.com/doc/ega\\_FuturePharmaceuticals.pdf](http://www.egagenerics.com/doc/ega_FuturePharmaceuticals.pdf)

## II. KEY BARRIERS TO GENERIC MEDICINES WHEN ENTERING THE EUROPEAN MARKETS

- Failure of governments to create long-term generic medicines policies.
- Lack of transparency on prices and availability of generic medicines.
- Continued price linkage, after generic medicines market entry, to originator reference products.
- Delays to market caused by post-market authorisation procedures for establishing price and reimbursement status.
- Market entry delays originated by patent linkage in marketing authorisation and price and reimbursement approval of generic medicines.
- Reimbursement that delays competition rather than encouraging genuine innovation that brings higher therapeutic efficacy/safety.
- Evergreening of medicines.
- Lack of incentives for physicians to prescribe generic medicines.
- Economic disincentives for pharmacists to dispense generic medicines.
- Limited incentives for patients to request generic medicines.

## III. URGENT RECOMMENDATIONS TO GOVERNMENTS AND PRICE & REIMBURSEMENT AUTHORITIES

1. **Urgent implementation of successful long-term generic medicines policies with a special focus on the removal of potential barriers to the penetration of generic medicines, thus promoting the sustainability of the sector.**

Most European countries do not have a long-term policy on generic medicines combining demand and supply-side measures that are ultimately conducive to a more efficient market. Lack of such a policy has cost repercussions for healthcare systems and patients.

- 1.1 Ban linkage systems that cause delays, block market entry, or obstruct the development of competitive and sustainable market environments.**

Market competitiveness starts with ensuring a level playing field for the entire sector. **Patent linkage** is not conducive to a competitive market as it extends the period of market exclusivity enjoyed by originator companies, preventing or delaying entry of generic medicines onto the market. Originator companies often use these tactics to perpetuate a well-established market position. Governments need to look carefully into these actions to prevent undesirable obstructions to the market.

**Continued price linkage** after generic medicines market entry is a mechanism that skews the rules of fair competition toward the originator sector, creating a competitive disadvantage for generic medicines companies attempting to enter the market.

The generic medicines sector is clearly under threat when it is dependent upon its competitors to set its prices. It is difficult to imagine another sector where such conditions could prevail.

**1.2 Create a mechanism for granting automatic pricing and reimbursement status upon marketing authorisation, eliminating current time delays.**

The current time delays in approving price and reimbursement status after market authorisation are unreasonable given that a generic medicine has demonstrated its therapeutic equivalence to a well-known pharmaceutical product through the market authorisation process. These delays on pricing and reimbursement status cannot be justified.

**2. Application and enforcement of clear criteria for innovation, unambiguously defining innovation to be synonymous with added relative therapeutic efficacy/safety, thereby eliminating rewards for evergreening practices.**

2.1 Carefully assess and reward innovative medicines that bring added therapeutic value/safety rather than medicines that represent little more than cosmetic changes to existing products.

2.2 Cease to reward companies/products that take advantage of the system by introducing "innovative drugs" or new formulations of existing drugs that do not demonstrate clinically relevant additional therapeutic value.

2.3 Be aware of the fact that patents are not synonymous with innovation.

**3. Introduce mechanisms to influence the prescribing and dispensing behaviour of physicians and pharmacists in European countries in favour of generic medicines.**

3.1 Take steps to raise awareness amongst physicians of the benefits of generic medicines. Physicians need coherent and harmonised support throughout Europe in terms of greater availability of prescribing information, computerised prescribing, medicines databases, prescribing from an independent body, and prescription audits.

3.2 Reduce the discretion of doctors to disallow generic dispensing by introducing mechanisms to encourage physicians to prescribe generic medicines, thus promoting their use.

3.3 Establish systems throughout Europe that are based on budgetary incentives, allocating prescription budgets to physicians and granting them the discretion to use those savings to prescribe more expensive treatments where necessary.

3.4 Deploy mechanisms to guarantee that pharmacists are rewarded for dispensing generic medicines, particularly as it is currently not economically attractive for pharmacists to dispense generic medicines in some markets due to their lower price. A guaranteed absolute margin can be seen as a necessary step to eliminate the financial disincentives.

3.5 Ensure that pharmacists are aware of the benefits of dispensing generic medicines. An integrated approach encompassing all stakeholders is needed to create savings for patients and governments.

## IV. OVERVIEW OF BARRIERS TO GENERIC MEDICINES UPTAKE IN EUROPE

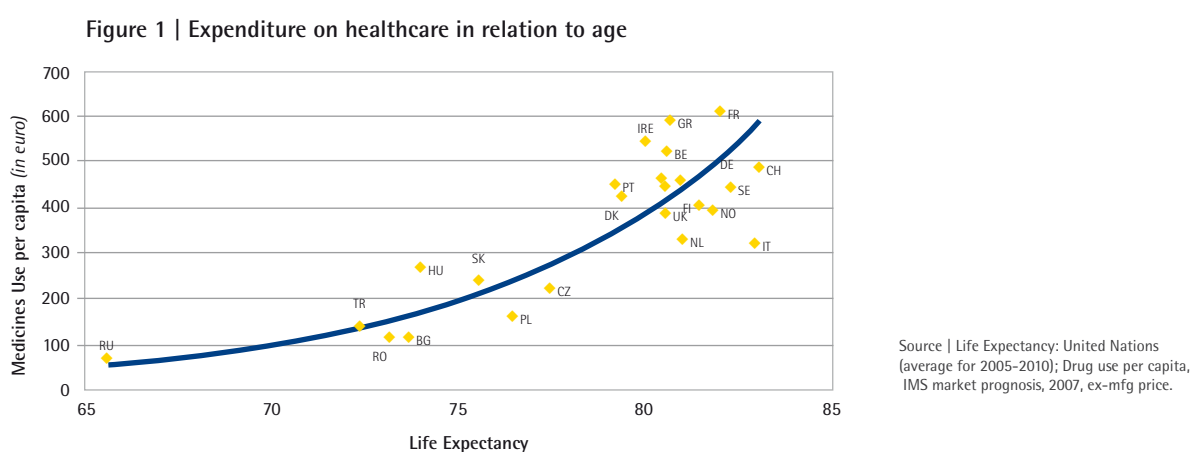
### 1. INTRODUCTION | The Role of Generic Medicines in Generating a Sustainable and Affordable European Healthcare System

The increasing concern of European governments with the rising costs of healthcare can be seen in the high level of political attention given to the issue of access to medicines and to the European pharmaceutical sector as a whole. European policy makers have undertaken numerous initiatives in this area in recent years, both at national and European levels:

- G10 High Level Group on Medicines;<sup>10</sup>
- High Level Pharmaceutical Forum<sup>11</sup> and consequently the Andalusia report<sup>12</sup> issued by the Working Group on Pricing and Reimbursement;
- The PPRI initiative that published a final report in May 2008;<sup>13</sup>
- The ongoing sector inquiry into the pharmaceutical market initiated by DG Competition.

These initiatives have also focused on the dynamics of the pharmaceutical sector in European countries and underscore the specific advantages of an efficient generic medicines market that facilitates access to essential medicines and creates financial headroom for innovative medicines in answer to the medical needs of Europe's population.

The rapidly ageing population in Europe, the increasing prevalence of certain age-related diseases and the consequent need for more specialised and individualised treatments in Europe will result in a considerable increase in pharmaceutical costs in the near future (Figure 1).



A report published by the research company Frost & Sullivan in July 2007 highlights what it identifies as the major challenge to European governments in the coming years—developing a sustainable healthcare model in which generic medicines play a key role:

<sup>10</sup> European Commission–G10 High Level Group on Medicines, 2002

<sup>11</sup> European Commission–Pharmaceutical Forum, “Final Conclusions and Recommendations 2005–2008”, 2008

<sup>12</sup> Rovira, 2007

<sup>13</sup> PPRI Report, 2008

"With expensive drugs increasing healthcare costs, generic medicines have a critical role in the European market. Generic medicines are widely regarded as the best method to allow access to safe, effective and high-quality drugs at affordable prices to a vast majority of patients. They also play a vital role in the development of sustainable healthcare models by imposing a direct influence on pharmaceutical spending."<sup>14</sup>

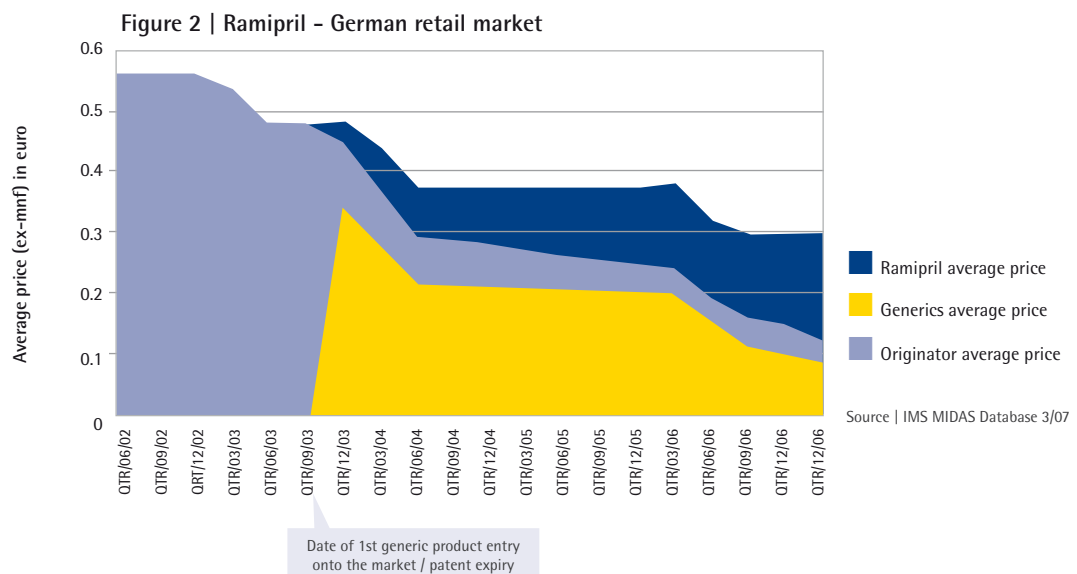
The search by governments and health insurers for less expensive therapeutic alternatives has shown the importance of generic medicines—which are acquiring greater relevance—as generic medicines signify clear long-term savings to national healthcare budgets (Mossialos et al, 2002). In this context, generic medicines are an essential part of the equation for the sustainability of European healthcare systems.

Sustainable healthcare systems are achieved through implementing well balanced policies that allow the increased usage of generic medicines. This is true not only because of their affordable prices, which consequently translate into savings for both healthcare systems and patients, but also because the generic medicines sector provides a continuous source of cost effective medicinal treatment while generating yearly savings of more than €25 billion for European healthcare systems and patients.

In addition, the highly competitive market they create drives pharmaceutical prices down, thus contributing to cost containment and stimulating the innovation needed to provide new added value products<sup>15</sup>, as confirmed by Murray Aitken, from IMS and in the European Commission's Pharmaceutical Sector Inquiry.

[In relation to the generic medicines market in 2008] "...we are seeing the first significant decline in sales growth as manufacturers increasingly compete in fierce price battles within most of the world's major markets."<sup>16</sup>

As stated in the European Commission's Pharmaceutical Sector Inquiry<sup>17</sup>, "average prices [in markets with generic medicines] dropped by almost 20% after the first year following loss of exclusivity and about 25% after two years", though in certain cases the decrease can go further than that, such as in the RAMIPRIL molecule case in the German market where the average price decreased 74% in the five years after patent expiry (Figure 2).



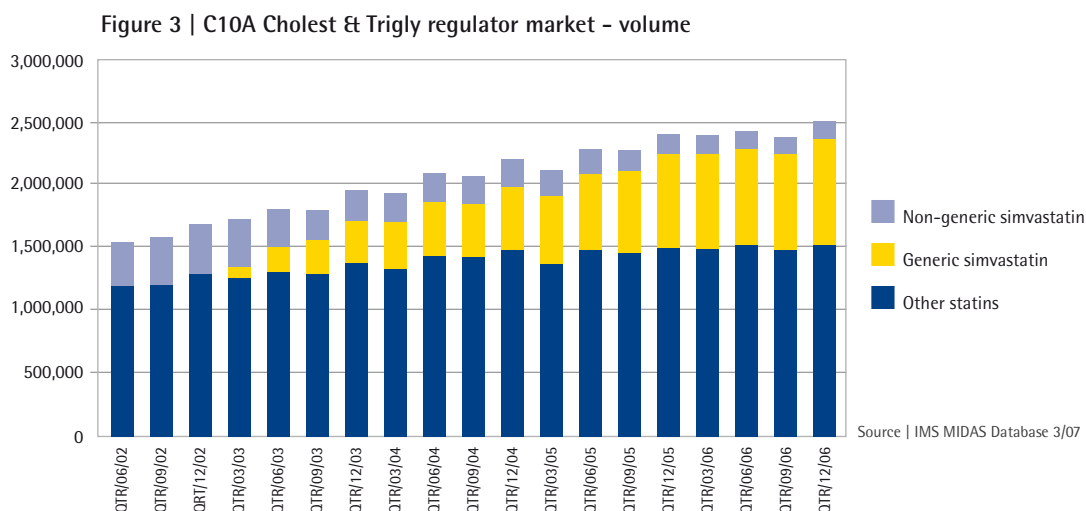
<sup>14</sup> Frost & Sullivan, 2007

<sup>15</sup> EGA Contribution to the Public Consultation Process Initiated by the European Commission on The Future of Pharmaceuticals for Human Use in Europe, 2007

<sup>16</sup> Aitken, 2009

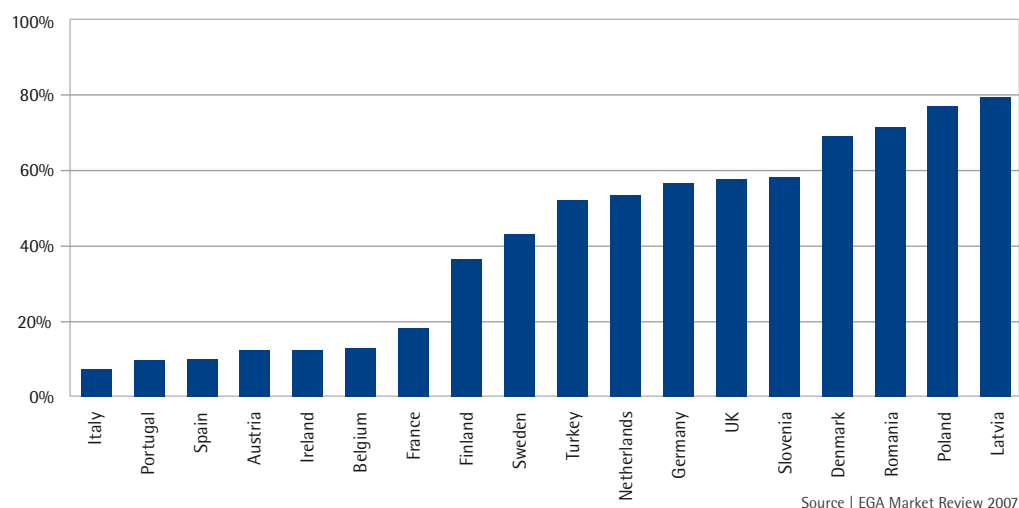
<sup>17</sup> European Commission-Pharmaceutical Sector Inquiry Preliminary Report, 2008

Furthermore, generic medicines also increase patient access to affordable treatments, as seen, for example, with the molecule SIMVASTATIN where the statins market increased 67% within four years of the generic version's entry (Figure 3).



The European generic medicines industry today is a well-established essential partner in European healthcare, providing more than 130,000 jobs<sup>18</sup> in Europe in such diverse areas as research and development, production, and sales. Representing nearly half of the volume of medicines dispensed to European citizens, generics correspond to only 18% of the value of the total pharmaceutical market.<sup>19</sup>

**Figure 4 | Generic medicines market share volume 2007 (total market)**

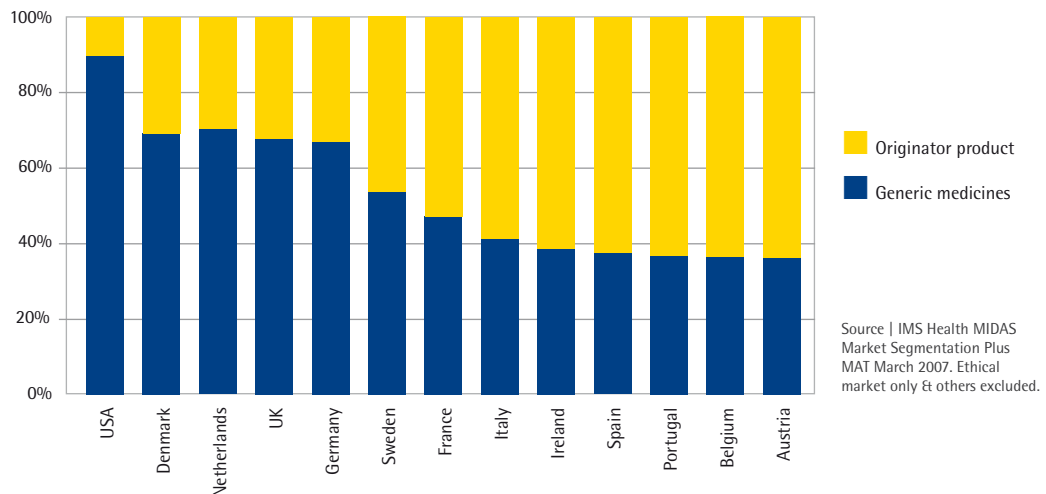


However, volume share changes at country level, as seen within the mature markets of Denmark, United Kingdom, Germany, the Netherlands and Sweden with volume market shares above 40%, and in developing markets such as France, Belgium, Austria, Spain and Italy, all with volume market shares below 20% (Figures 4 and 5).

<sup>18</sup> EGA Contribution to the Public Consultation Process Initiated by the European Commission on The Future of Pharmaceuticals for Human Use in Europe, 2007

<sup>19</sup> EGA Internal Survey, 2007

Figure 5 | Generic medicines market share volume 2007 (unprotected market)



The main reason for such discrepancies in relation to market shares is the varying effectiveness of differing healthcare policies in enhancing generic medicines penetration. The European generic medicines industry is consequently under great pressure due to this lack of adequate generic medicines policies and, more recently, the use of short-term pricing strategies such as tendering in some mature markets.

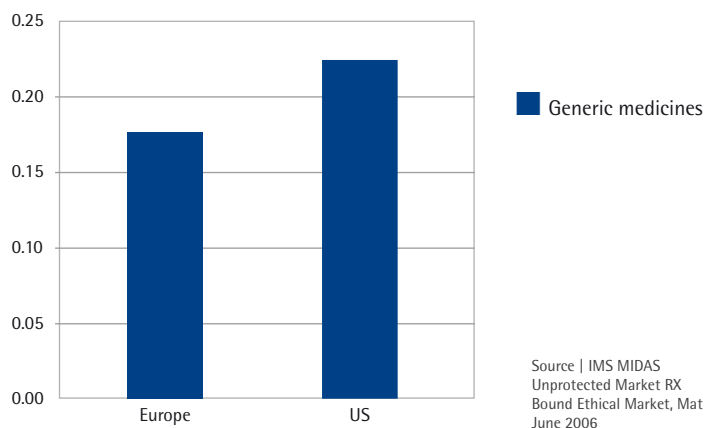
In developing markets such as France, Spain and Italy, where volume market shares are lower despite generic medicines companies providing affordable treatment to patients, savings can only be achieved if government supply policy initiatives are designed to increase the competitiveness of generic medicines whilst creating the proper conditions for higher generic penetration (Simoens et al, 2006).

In some developed markets, such as Germany and the Netherlands, new short-term pricing procurement strategies such as tenders and similar pricing systems have been introduced into the retail off-patent market where fierce competition already exists (as seen earlier, average prices in some cases can fall as much as 74% in the unprotected market).

The European generic medicines industry recognises the efforts policy makers make to guarantee well-functioning generic medicines markets aimed at growing the use of generic medicines throughout Europe. It also points out that a number of unnecessary barriers still exist which hinder the entrance of generic medicines onto markets, raising obstacles to the development of a sufficient volume of generic medicines to realise their full potential for savings.

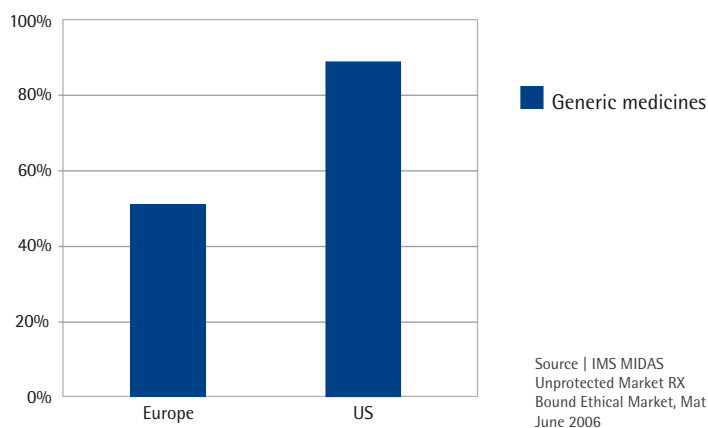
The capacity of generic medicines companies to offer affordable medicines prices is highly dependent on the volume of the market made up of generic medicines. The lack of significant volumes on the pharmaceutical market endangers the generic medicines industry's ability to contribute fully to safeguarding healthcare budgets and ensuring patient access to lower-priced medicines.

Figure 6 | Europe vs US: average ex-mfg prices (euro/\$)



It is significant to note that average ex-factory prices of generic medicines are lower in Europe than in the United States of America (Figure 6).

Figure 7 | Europe vs US: average volume SU (unprotected market)



This situation exists despite a lower volume market share in Europe as compared to the unprotected US market, where the volume share has reached 89%<sup>20</sup> (Figure 7). Consequently, generic medicines companies operating on European markets are struggling in a highly competitive price market without the necessary volume conditions that guarantee long-term sustainability.

Consequently, this report aims to present a summary of the barriers that have been identified as obstacles to the sustainable development of the generic medicines sector in Europe and to recommend a number of actions to be undertaken by governments and the responsible authorities.

<sup>20</sup> IMS Midas Unprotected Market RX Bound Ethical Market, Mat June 2006, "New dispensing and distribution trends in Europe", February 2006

## 2. European and National Regulation Influencing the Price and Reimbursement Status of Generic Medicines

Medicines provide a cost-effective means for treating diseases, but still represent a substantial expense to European citizens, and national healthcare and health insurance budgets. Generic medicines have the potential to generate important savings.

The 27 EU Member States and other European countries regulate—each through their own unique system—the reimbursement price and status of pharmaceuticals sold on their territory. These price and reimbursement systems clearly distinguish between patented medicines (marketed by the originator companies), and off-patent pharmaceuticals, including generic medicines.

The patented pharmaceutical market is a monopolistic market where originator medicines are launched with the aim of responding to the medicinal needs of society and individual patients. This clinical innovation must be stimulated and rewarded, while governments control prices in order to restrain pharmaceutical expenditure.

However, once a patent has expired a number of alternative generic products are allowed to enter the market, creating price competition. This competition between reference (originator) products and generic medicines constitutes an effective tool for containing costs. As stated in the Andalusian report<sup>21</sup> on pricing and reimbursement mentioned above:

"A successful generic policy also requires competition on the supply side: ...regulated pricing would not attain the desired results."<sup>22</sup>

European governments therefore need a clear strategy for developing the role of generic medicines for cost containment. Rather than rely on unnecessary regulation, national strategies should include the use of effective price and reimbursement systems designed to stimulate the immediate market entry for generic medicines and to promote their broader uptake. Such an approach would contribute greatly to optimising the use of healthcare funds.

### 2.1 Types of pricing systems that foster generic competition

European governments are under increasing pressure to implement measures that lead to greater savings on pharmaceutical spending. With the rising cost of healthcare, longer life expectancies, and an ageing population, governments are being pushed to devise more sustainable healthcare systems. Therefore, in the words of a report from the Centre for the New Europe:

"...any reduction [in medicines prices] is likely to be welcomed by politicians and managers who are trying to squeeze as much as they can out of increasingly inelastic budgets."<sup>23</sup>

Government pricing systems that pay proper attention to generic medicines can play an important role in these solutions. Indeed, as reported in an article in *Pharmaceutical Technology Europe*:

"Pricing and reimbursement are critical for the generic medicines market as it has a direct bearing on limiting healthcare costs. However, the major challenge facing several European countries is to establish a sustainable healthcare model where generics can provide a fair rate of return to manufacturers, making medicines affordable to all."<sup>24</sup>

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<sup>21</sup> Rovira, 2007

<sup>22</sup> Rovira, 2007

<sup>23</sup> Gabb, 2004

<sup>24</sup> Pharmaceutical Technology Europe, 2007

All European countries employ some type of price and reimbursement scheme in their attempts to maximise savings wherever possible. While these systems may vary in detail, they also contain many similarities. As Anna Merino Castelló (2003) concludes in her doctoral thesis:

"The European markets for generic drugs fall broadly into two main categories: free markets, such as the United Kingdom and Germany—the two largest markets in Europe in terms of absolute value—and price-regulated markets, including France, Spain, Belgium and Italy"<sup>25</sup>.

This division into categories is upheld by the *Pharmaceutical Price and Reimbursement Information Report*, which divides the pharmaceutical markets into similar categories, proposing the following definitions of the two modalities:

"Free pricing: In this pricing system pharmaceutical prices may be freely set by the manufacturers. Price control: Here pharmaceutical prices are determined by the authorities."<sup>26</sup>

Before entering into the detail of the mechanisms used by the authorities to set medicines prices, we will first determine which countries fall into each of the two main categories. As presented in Table 1, 77% of the European countries reviewed in the 2007 EGA Market Review (updated in 2008) have a regulated pricing system in place.

Table 1 | Comparative analysis - Generic medicines pricing systems across Europe

	Austria	Belgium	Bulgaria	Croatia	Czech Rep	Denmark	Estonia	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Turkey	UK
no Free pricing system?	no	no	no	no	no	yes	no	no	yes	no	no	no	no	yes	no	no	yes	no	no	no	no	no	no	no	yes	no	yes
Price-regulated system?	yes	yes	yes	yes	yes	no	yes	yes	no	yes	yes	yes	yes	no	yes	yes	no	yes	yes	yes	yes	yes	yes	yes	no	yes	no

Source | EGA Market Review 2007

In their search for sustainable healthcare systems, some governments try to increase their savings by promoting systems that include free pricing market competition, such as the United Kingdom or Sweden. In other cases medicine prices are regulated, as in France or Italy, where the price of generic medicines is generally determined as a certain percentage below the price of the reference product. Other measures are also employed to establish prices, such as using the average price of a product from a selection of EU Countries; using a percentage below the originator's price; and employing a maximum price (index price) or a negotiable price (price/ volume). Which countries use which mechanism is presented in Table 2.

Table 2 | Comparative analysis - Mechanisms used in regulated pricing systems

	Austria	Belgium	Bulgaria	Croatia	Czech Rep	Estonia	France	Greece	Hungary	Ireland	Italy	Luxembourg	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Turkey
Average of some EU countries	yes	no	yes	yes	yes	no	no	no	no	no	no	no	yes	no	no	yes	yes	yes	no	no
% Below originator	yes	yes	no	yes	no	no	yes	yes	yes	yes	yes	no	no	no	yes	no	yes	yes	yes	yes
Maximum price (index price)	no	yes	yes	no	yes	yes	no	no	no	no	no	no	yes	yes	no	no	no	yes	no	yes
Negotiable (price/volume)	no	no	no	yes	yes	yes	no	no	no	no	yes	no	no	no	no	no	no	yes	no	no
Other	no	no	no	no	no	no	yes	no	no	no	no	yes	no	yes	no	no	no	yes	no	no

Source | EGA Market Review 2007

<sup>25</sup> Castelló, 2003

<sup>26</sup> PPRI Report, 2008

In addition, the percentage below the reference product that is applied may vary from country to country, with governments attempting through such measures to obtain automatic discounts on medicines prices. This issue will be discussed in the next chapter.

## 2.2 Continued price linkage | Artificial barrier to generic medicines after market entry

As seen in the previous section, regulated pricing systems are employed in one form or another in a number of European countries to restrain the prices of pharmaceuticals and to reduce health-care expenditure. These systems produce automatic discounts by regulating the price of generic medicines through one or more mechanisms, most commonly by pegging the price of the generic medicine to a set percentage below the price of the originator product, or to an average of prices from a selection of EU countries.

Continued price linkage after generic market entry represents a significant barrier to the market penetration of generic medicines because of the disharmonised and irregular manner of application throughout Europe. And it creates a competitive disadvantage for generic medicines companies if the price continues being linked to the originator reference price after market entry.

Governments must therefore seriously consider the negative consequences of continued price linkage measures after market entry and adjust their policies accordingly. Market competition starts with ensuring a level playing field for all players in the sector. Artificial price barriers create distortions that lead to market inefficiency. By forcing generic medicines companies to price their products at a set percentage below the price of the originator product, governments increase the commercial pressure on generic medicines companies from their competitors.

Indeed, generic medicines manufacturers are often forced to accommodate substantially and increasingly reduced profit margins in order to maintain their product's price at the authorised level with regard to the falling price of an originator product. If, for example, a generic medicine is priced at 55% below the price of an originator equivalent throughout its entire lifecycle (as is the case for example in France), then originator companies can attempt to lower prices drastically with the sole intention of driving generic competitors out of the market. Such price differentials, enforced through price linkage mechanisms, allow big players the price discretion to force new entrants off the market by eliminating profit margins. Large originator pharmaceutical companies can often live with reduced margins on a major product, while this is seldom the case for generic medicines companies, especially for small and medium-sized enterprises (SMEs) with limited resources.

In the long term the number of new off-patent products on the market may decline as generic medicines companies are faced with difficult market conditions, unfair competition rules, and unsustainable profit margins. As companies find it difficult to attain optimal shares of profitable markets, the sustainability of the generic medicines sector is called into question.

For instance, in virtually all sectors the incumbent player benefits from all the advantages of having an established presence on the market. These advantages include the experience curve and market knowledge in all its variants. All of these, under similar market conditions, constitute a solid base for a strong competitive advantage. This is also true of the pharmaceutical sector, for which the application of continued price linkage after market entry provides an additional immediate advantage to the incumbent and an often dissuasive disincentive to most new entrants.

As a result, national healthcare systems will also have fewer options for offering more affordable medicines to their citizens and the increasing financial pressure on overstretched healthcare budgets will be accentuated as the potential savings from fostering a stronger, more competitive generic medicines sector will fail to materialise. The issue, however, is not entirely about price. If allowed to operate freely under fair and competitive pricing conditions, the generic medicines sector can ultimately become an important contributor to the overall sustainability of the healthcare sector, as less expensive generic medicines will allow patients better access to more affordable medicines.

**Key Points:**

- Continued price linkage after generic medicines market entry constitutes an artificial barrier to entry for generic medicines.
- Continued price linkage after generic medicines market entry has potentially negative effects on the sustainability of the generic medicines sector and the availability of future new generic medicines in the off-patent market.

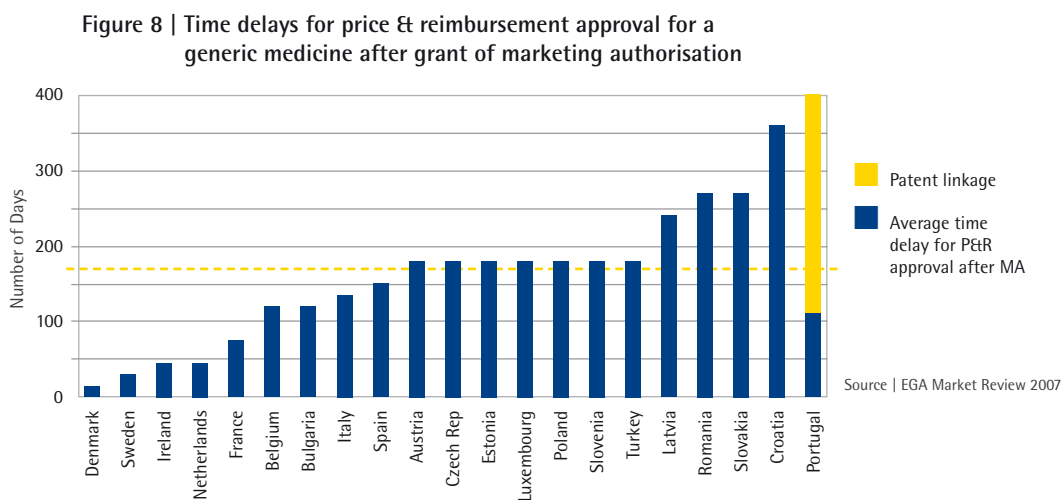
### 2.3 Time delays of pricing and reimbursement status after Marketing Authorisation (MA)

In its final report in May 2002, the G10 High Level Group on Medicines recommended that,

**Recommendation 3** | "Respecting national competence, Member States should examine the scope for improving time taken between the granting of a marketing authorisation and pricing and reimbursement decisions in full consistency with Community legislation. They should do this with a view to securing greater uniformity and transparency between markets and rapid access of patients to medicines"<sup>27</sup>

Once a marketing authorisation has been granted, generic medicines companies must obtain price and reimbursement approval for their product. Although the systems in place seem to be aligned and working well, the bureaucratic nature of these approval systems and the concession of market authorisations creates a time gap with significant negative consequences for governments, payers, patients and the generic medicines industry.

The time delays of pricing and reimbursement approval systems vary significantly in Europe, which generates hurdles to establishing a truly competitive European pharmaceutical market. On average a generic medicines company must wait 153 days after the grant of a marketing authorisation to receive price and reimbursement approval (Figure 8).



Although approved for marketing, generic medicines cannot enter the market while awaiting price and reimbursement status; in the meantime, patients miss out on access to these more affordable treatments and, where no other competitive pressures exist, originator companies continue to provide unnecessarily high priced medicines to payers.

Although marketing authorisation (MA) is required in all European markets, this process does not always coincide with the price and reimbursement processes, which vary widely from country to country. Where these two processes are not simultaneous, increased time delays result. In the case of Portugal for example, different health and economics authorities are called upon to grant these approvals which results in even further bureaucratic inefficiency and unreasonable delays of up to 400 days (Figure 8).

In other countries, such as the United Kingdom and Germany, generic medicines obtain their price and reimbursement approval automatically upon grant of market approval, eliminating

<sup>27</sup> European Commission-G10 High Level Group on Medicines, 2002

burdensome delays and enhancing generic competition. Similarly, Denmark and Sweden have substantially shorter time delays for obtaining price and reimbursement status after market authorisation than many countries. They also represent countries where generic medicines companies have successfully gained significant market shares for their products (Table 3).

In contrast, countries such as Austria or Spain have time delays that are above the European average and as a consequence generic medicines enter the market more than 153 days after receiving marketing authorisation.

Overall, countries where there are no, or only minimal, time delays, show a solid rate of uptake for generic medicines after their introduction onto the market (Table 3).

Table 3 | Comparative analysis - Time delays by country for price & reimbursement approval

	Austria	Belgium	Bulgaria	Croatia	Czech Rep	Denmark	Estonia	France	Ireland	Italy	Latvia	Luxembourg	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Turkey
Average time delay for price approval	80	90	90	180	90	14	90	75	45	135	120	30	-	180	21	90	120	15	75	30	60
Average time delay for reimbursement approval	180	120	30	180	90	14	90	75	45	135	120	180	45	180	90	180	150	180	75	30	120
Are P&TR applications for generic medicines simultaneous?	yes	yes	no	no	yes	yes	no	yes	yes	yes	no	yes	yes	yes	no	no	no	yes	no	yes	no
Average time delay for P&TR approval after MA	180	120	120	360	180	14	180	75	45	135	240	180	45	180	111	270	270	180	150	30	180

Source | EGA Market Review 2007

By now a well-established fact, generic medicines contain the same well-known active ingredients as their equivalent originator pharmaceutical that has been on the market for a number of years and whose safety and efficacy have been scientifically assessed and verified through use over a long period. Time delays can therefore not be justified on these grounds. Indeed, given this reality, governments can safely create fast-track registration systems and/or lower registration fees—as is the case in the Netherlands, France and Sweden<sup>28</sup>—to expedite price and reimbursement decisions.

If a reference product exists on a European market for a given generic product, then the granting of price and reimbursement status should be a rapid and straightforward process. Where prices are set at a percentage below that of the reference product, the price status for the equivalent generic medicine should be immediate. It is unreasonable for health authorities to delay the granting of pricing and reimbursement status for generic medicines once it has been established that the generic medicine is priced appropriately to the equivalent reference product.

These time delays clearly constitute artificial barriers to the entry of generic medicines onto European markets. They are often the result of needless—and sometimes heedless—bureaucracy, a critical lack of resources for certain agencies, and stubborn bottlenecks in processing the growing number of generic applications each year. Altogether, this has created a situation that was unambiguously described in Scrip pharmaceutical newsletter:

<sup>28</sup> Rovira, 2007

"The gap between the information required by regulatory authorities and payers is causing industry problems as increasingly more time and money are needed to bring a drug to market..."<sup>29</sup>

Generic medicines companies operate under permanent time pressure to get onto the market as quickly as possible before price linkage enables the originator companies to lower their prices to levels where generic medicines companies can no longer remain on the market. The time delays to market for generic medicines companies can seriously jeopardise their return on investment.

Indeed, according to research conducted by Frost & Sullivan:

"... time to market is the key to generate significant returns in today's competitive generic drug market. If a new product is delayed in entering the market, the return is likely to be significantly lower."<sup>30</sup>

The time delays caused by the inexistence of automatic price and reimbursement approval can also lead to unforeseen consequences to the healthcare system, such as a reduced number of treatments in the long term. Generic medicines companies may find it economically untenable for them to provide the best prices in such adverse conditions, forcing them to decide against marketing their products.

#### Key Points:

- In a number of European markets generic medicines manufacturers face unacceptable delays in obtaining price and reimbursement status after receiving marketing authorisation
- Automatic price approval for generic medicines should be granted in order to contribute to a more competitive market, reduce time delays, and allow for less expensive alternatives on the market more rapidly.
- Time delays for P&R are responsible for lost savings to healthcare systems.

<sup>29</sup> Scrip, "Gap between economic assessments and regulatory approval requirements causes problems", 2008

<sup>30</sup> Frost & Sullivan, 2007

## 2.4 Market entry delays originated by patent linkage in MA and P&R approval of generic medicines

Patent linkage is another mechanism that delays the entry of generic medicines into the market. From an economic perspective, patent linkage is also considered a barrier to generic medicines competition:

"The economic effect of such a decision [suspension of the MA or price & reimbursement by responsible authorities or by following legal action by originator companies] for a generic medicines company is the same as a refusal to grant marketing authorisation: generic products cannot be put on the market"<sup>31</sup>

Kristof Roox, Attorney at the Belgian Bar, has defined patent linkage as *"... the practice of linking market approval, the pricing and reimbursement status or any regulatory approval for a generic medicine to the patent status of the originator reference product."*<sup>32</sup>

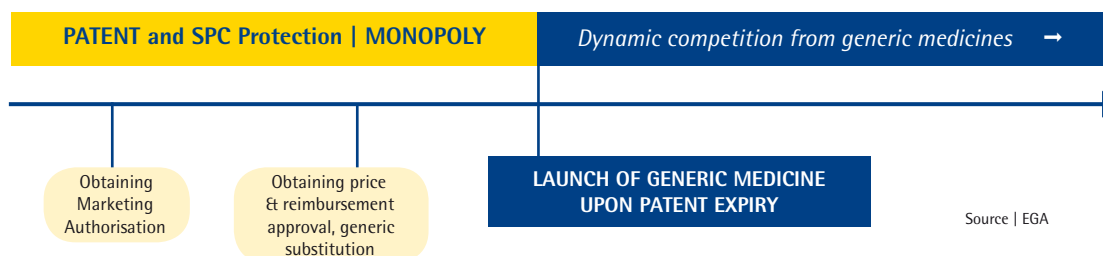
The most common practices of patent linkage involve notifying the patent holder of a generic medicine application, requiring declarations of non-patent infringement to the regulatory authorities, not allowing an application or granting an authorisation during the patent period, and the submission of patent status to pricing and reimbursement authorities for a decision.

Patent linkage is an egregious abuse of the European Union regulatory framework for pharmaceuticals, as EU pharmaceutical legislation explicitly provides for the development, application, and registration of generic medicines during the patent period.<sup>33</sup>

The Slovakian case is an example of patent linkage in the regulatory system, as under its original implementation of the EU pharmaceutical legislation the regulatory authorities could even reject outright the application for the registration of a generic medicine if the reference product or active substance used in the reference product was protected by a patent/SPC. This provision has been challenged and was dropped following intervention by the European Commission. However, the law still contains patent linkage in that the market authorisation given to a generic medicine will be suspended until patent expiry.

When the provisions of the EU regulatory system are fully respected, generic medicines can be ready to enter the market without delay upon patent expiry (Figure 9).

Figure 9 | Launch of a generic medicine onto the market without patent linkage



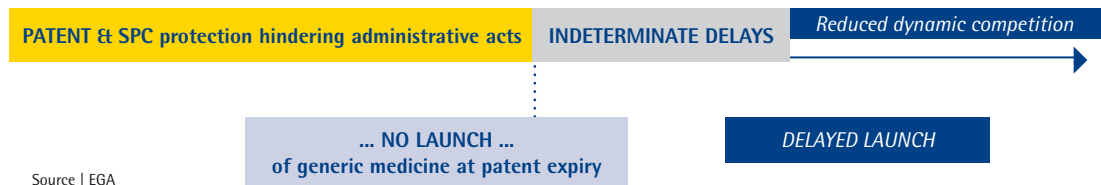
<sup>31</sup> European Commission-Pharmaceutical Sector Inquiry Preliminary Report, 2008

<sup>32</sup> Roox, 2008

<sup>33</sup> "Bolar" provision (article 10.6. of the Directive 2001/83/EC as amended in 2004)

The application of patent linkage, however, alters the situation dramatically, and generic medicines are either blocked or delayed in their access to the market (Figure 10).

Figure 10 | Delay in launch of a generic medicine onto the market due to patent linkage



The indeterminate delays suffered by generic medicines when entering the market due to patent linkage form a significant barrier to generic medicines competition, as well as a major negative impact for the sustainability of European healthcare and availability of affordable treatments for patients. This is emphasised in the European Commission Sector Inquiry Preliminary Report,

"Apart from the impact on the business of generic companies, the delays can have significant consequences for public health budgets and ultimately consumers as the lower prices could only be introduced later than expected."<sup>34</sup>

In the same report, some cases are presented of how much pharmaceutical companies extended or prolonged their sales at premium prices for products which were already out of the patent protection period, causing delays in the market entry of generic medicines by delaying the marketing authorisation or pricing & reimbursement status.

If generic medicines entry had not been delayed, significant savings could have been made for patients and healthcare providers from day one of patent expiry.

Other important entities such as the World Health Organisation (WHO) are also conscious of the negative outcome of such mechanisms for generic medicines companies and access to medicines, advising the rejection of any case of patent linkage:

"Medicines fall under two separate legal and regulatory systems. These systems have different objectives, are administered separately and function independently. Efforts to integrate these two systems via...linkage or other means are likely to have negative implications for access to medicines. Thus developing countries would be well advised to keep these systems separate and to reject any and all efforts to make connections between them"<sup>35</sup>

Several different cases of patent linkage can be found in various countries, such as Portugal, Sweden, Austria, Slovakia, France, Belgium and other European countries, as was referenced in the European Commission's Sector Inquiry Report. In this chapter special attention will be given to the cases of Portugal and Sweden.

"Clusters of cases involving patent linkage were observed in Portugal during the sector inquiry. Originator companies pursue deliberate actions, including litigation, creating administrative difficulties for generic companies which might result in delays in generic entry. The flowchart below illustrates such actions by originator companies, usually coinciding with the price application by a generic company to the authorities responsible for marketing authorisation and pricing and reimbursement.

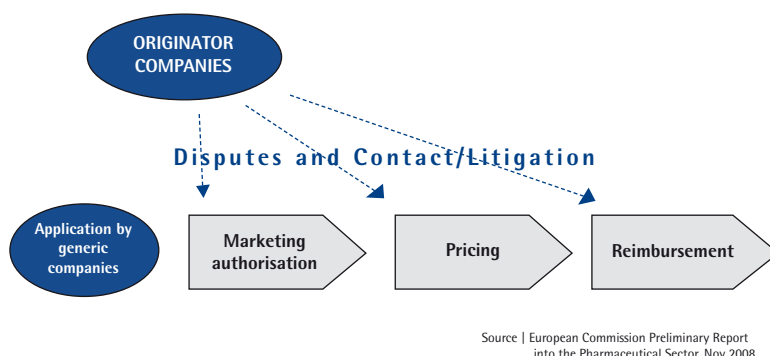
A number of marketing authorisations issued by the Portuguese Medicines Agency (INFARMED) for generic medicinal products have been challenged in the administrative courts by originator companies, on the grounds that the reference products are still protected by a patent. These legal actions

<sup>34</sup> European Commission-Pharmaceutical Sector Inquiry Preliminary Report, 2008

<sup>35</sup> WHO Report, 2006

have affected the pricing process for the generic products concerned. Indeed, the Direcção-Geral das Actividades Económicas (DGAE) in the Ministry of Economic Affairs and Innovation reportedly suspends the price approval process for generic medicines when originator companies launch legal proceedings based on an alleged patent violation.

Figure 11 | Illustration of patent linkage in Portugal resulting from originator company activity



Source | European Commission Preliminary Report into the Pharmaceutical Sector, Nov 2008

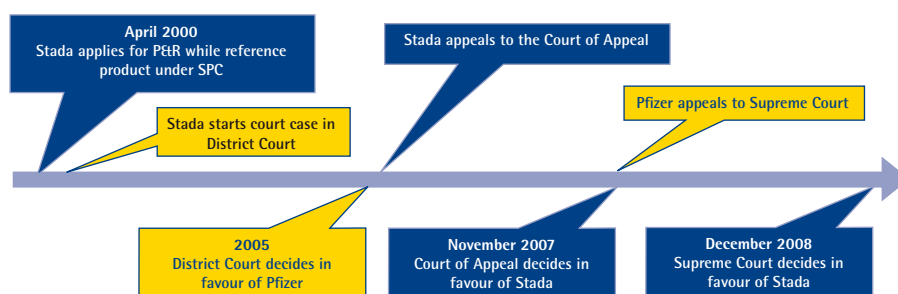
Several requests for approval of prices for generic medicines were suspended in 2007 and 2008, pending the judgments of the administrative courts to which the cases had been referred. Altogether, more than 70 court cases are currently pending. The court proceedings take a long time. In one case, price approval has been delayed for almost 18 months. Furthermore, in several cases the administrative courts decided to suspend the marketing authorisations granted to generics until the patents expired or until the patent litigation was resolved by the commercial courts.<sup>36</sup>

Reference can also be made to the 2005 decision of the Swedish Medical Products Agency in which it was decided that the generic pharmaceutical risperidone was interchangeable with the patented pharmaceutical Risperdal®. In appeal it was argued that the Medical Products Agency did not have the right to decide on the interchangeability of pharmaceuticals that were still protected by patent. It was even argued that the decision of the Medical Products Agency constituted contributory patent infringement.

In its judgment delivered in February 2007, the County Administrative Court rejected the appeal. It was, inter alia, decided that the Medical Products Agency cannot take a position on issues regarding intellectual property rights, but can only decide whether or not the medical demands for interchangeability have been met.

This is the case in the Stada vs Pfizer case (figure 12).

Figure 12 | Stada vs Pfizer: sertraline case



Source | EGA

<sup>36</sup> European Commission Pharmaceutical Sector Inquiry Preliminary Report, 2008

In December 2008 the Supreme Court's final decision against Patent Linkage was as follows:

"The submission of an application for reimbursement status and price to the responsible authority, and the potential contacts between the authority and the applicant in connection with the application, cannot as such be deemed to have been carried out with the purpose of causing the authority to acquire any right to a product, neither for the authority's own account nor on account of anyone else. Hence, the contested action does not constitute an offer in the sense of Section 3, first paragraph, of the Patent Act."<sup>37</sup>

In summary, patent linkage is inconsistent with the concept of the application of patent rights. Neither the granting of a market authorisation nor obtaining price or reimbursement status can be seen as the actual marketing of the product. These are simply administrative procedures required for placing the product on the market once the patent has expired.

#### Key Points:

- Practices of patent linkage are increasing in Europe and there is a clear need for regulators to take action against it.
- By blocking the entry of generic medicines into the market, governments and payers are not able to retain savings from generic medicines.
- Patent linkage is clearly damaging the competitiveness of the sector, and is initiated by monopolist companies trying to protect their market position.
- Patent linkage prevents patients from having immediate access to affordable generic medicines.

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<sup>37</sup> For the report see [www.egagenerics.com/ega-barriers\\_rpt.htm](http://www.egagenerics.com/ega-barriers_rpt.htm)

### 3. Government Measures Impacting the Entry of Generic Medicines onto European Markets

In their 2007 "Study on Pharmaceutical Policy Practices", Rovira and Espin concluded that:

"Generic policies face in many countries strong obstacles and opposition derived from lack of information, prejudices (both justified and unjustified) and vested interests from all parties involved, patients, prescribers and pharmacists, as well as from the innovative multinational corporations..."<sup>38</sup>

In a similar vein, Frost & Sullivan's research on the European generic medicines market (2007) provides excellent insights into the importance of coherent pricing and reimbursement policies for generic medicines as determinant factors in establishing a more competitive market and introducing an affordable national healthcare system:

"Pricing and reimbursement are critical in the context of generic medicines as it has a direct bearing on limiting healthcare costs. However, the major challenge facing several European countries is to establish a sustainable healthcare model where generics can provide a fair rate of return to manufacturers, making medicines affordable to all."<sup>39</sup>

This challenge is obviously not met when European governments try to implement unsuccessful benchmark measures that create pressure on the generic medicines sector instead of promoting higher generic medicines volumes and stronger competition. Table 4 presents a comparative analysis of European government policies on generic medicines and how these measures impact the penetration of generic medicines in the market.

Table 4 | Comparative Analysis – The perspective of national generic medicines associations on the generic medicines policies of European governments

	Austria	Belgium	Portugal	Spain	Italy	France	Poland	Netherlands	Denmark	Germany	UK	Sweden
I. Countries with a coherent generic medicines policy	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✓	✓
II. Generic medicines competition within existing regulatory frameworks	✗	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓
III. Countries with incentives for physicians to prescribe generic medicines	✗	✗	✗	✗	✗	✓	✗	✗	✗	✓	✓	✓
IV. Countries with incentives for pharmacists to dispense generic medicines	✗	✗	✗	✗	✓	✓	✓	✓	✓	✗	✓	✓
V. Countries with incentives for patients to demand generic medicines	✗	✗	✗	✗	✓	✓	✓	✗	✓	✓	✗	✓

Source | EGA Market Review 2007

#### I. Countries with a coherent generic medicines policy

Research conducted by Izmirlieva (2003) concludes that generic medicines comprise the most promising cost-containment strategy available to governments. The author points out the impact of regulation on both the supply-side and the demand-side in this market.<sup>40</sup>

<sup>38</sup> Rovira, 2007

<sup>39</sup> Frost & Sullivan, 2007

<sup>40</sup> Izmirlieva, 2003

Government policies have been analysed here in this context and compared against the definition of a successful generic medicines policy as laid out in the report by Simoens, "Sustaining Generic Medicines Markets in Europe":

"A generic medicines policy requires both supply-side measures relating to pricing and reimbursement, and demand-side incentives for physicians, pharmacists and patients. Different policy measures need to reinforce each other and be part of a coherent generic medicines policy."<sup>41</sup>

Certain conclusions may be drawn from the data in Table 4: approximately 67% of the countries surveyed do not have a long-term generic medicines policy in place, and most governments have failed to implement a set of measures that create the conditions to guarantee the long-term sustainability of the generic medicines industry.

This current lack of a coherent medicines policy in most European countries is, with few exceptions, also accompanied by a lower penetration of generic medicines on their markets.

Although Poland, however, does not have a clear generic medicines policy in place, there is a strong tradition of generic medicine usage in the country, and the principal stakeholders—such as physicians, pharmacists and patients—are clearly favourable to generic medicines. Difficult economic conditions and limited government funds have increased patient co-payments resulting in a collective responsibility to ask for the most affordable, cost-effective medicines for treating a given condition or illness.

A history of local production has also played a role in greater market shares in the region. According to a report from the PPRI:

"The new Member states in Central and Eastern Europe have a tradition for local production of generic medicines... As a result, the market shares of generics have always been relatively high (around 50% and more in volume) in these countries."<sup>42</sup>

The PPRI report further points out that the diversity of healthcare regulatory systems found in Europe allows governments to "cherry pick" *ad-hoc* measures from other countries with parallel systems. This type of action is dangerous, and while positive results have been reached in one country, others have shown negative results under similar policy measures:

"A lesson learned from the PPRI (Pharmaceutical Pricing and Reimbursement Information) analysis is that "formulas for success" cannot simply be copied one-to-one from one country to the other; in order to be effective, policies have to be adapted to the country specific environment."<sup>43</sup>

The generic medicines sector needs consistent long-term policies with measures that create dynamic pricing systems and the promotion of generic medicines to physicians, pharmacists and patients. This will provide a secure pathway towards sustainable volume penetration of affordable generic medicines.

## II. Generic medicines competition within existing regulatory frameworks

When setting the arena for a competitive market, it is crucial to eliminate barriers to market entry for generic medicines. The fact that the regulatory frameworks in 50% of the countries surveyed here do not allow fair competition represents the most important barrier for generic medicines. The countries falling into this category are Austria, Belgium, Portugal, Spain, and Italy (Table 4).

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<sup>41</sup> Simoens, 2006

<sup>42</sup> PPRI, 2008

<sup>43</sup> PPRI, 2008

Inefficient and short-term pricing and reimbursement policies, such as those in Germany or the Netherlands, in effect obstruct the savings potential of generic medicines and their contribution toward a long term sustainable healthcare system with benefits for insurers and patients alike. Such systems and their downsides can be avoided. For example, although the Swedish pricing system can be described as regulated, generic medicines are not price-linked in this market and generic medicines companies are not under constant threat of being pushed out of the market.

Additionally, regulatory frameworks should aim for pricing and reimbursement measures that promote sustainability and competition in the market from the supply side while providing incentives on the demand side. This combination of measures will generate the necessary penetration of generic medicines to ensure a sustainable industry and a continued supply of more affordable medicines.

### III. Countries with incentive policies for physicians to prescribe generic medicines

In only 33% of the countries studied here do doctors have an incentive to prescribe generic medicines. Countries like Germany, the UK and Sweden even employ concrete economic measures to promote the prescribing of generic medicines (Table 4).

Although Belgium has implemented a system where doctors are required to prescribe 27% of medicines within the class of "cheap medicines" (including both originator and generic medicines), targets are understood to have been set too low as some physicians had already achieved levels beyond the 27% target. This measure could have achieved substantially higher benefits.

Emilien (1997) suggests that *"by encouraging doctors to prescribe and customers to use generic medicines, competition is enhanced... More emphasis is being laid by government in educating customers to cost-awareness and cost-benefit ratios with regard to pharmaceuticals."*<sup>44</sup>

In countries such as Austria, Spain and Portugal physicians are not encouraged to prescribe generic medicines. Whilst there is little question today that physicians are aware of generic medicines in terms of their therapeutic equivalence to products emanating from the originator industry, this by no means guarantees that physicians are predisposed to prescribing them.

### IV. Countries with policies providing incentives to pharmacists to dispense generic medicines

Governments also need to understand the economic structure of the pharmaceutical industry and to choose the most favourable policy formulations to withdraw the financial disincentives for pharmacists to dispense generic medicines.

Government measures here should recognise that the consumption of generic medicines will only increase if it is at least economically neutral when pharmacists dispense generic medicines versus originator products. This is certainly not the case in certain markets today as originator products, being more expensive, generally offer greater margins for pharmacists.

Pharmacists must have a structure of remuneration that in the final analysis makes it economically sensible—or even feasible—for them to dispense generic medicines. If the current regulatory framework does not require them to substitute generic medicines, margin equalisation can be adopted as one way of dealing with the situation.

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<sup>44</sup> Emilien, 1997

The advantages of generic medicines need to be explained more fully and with greater emphasis to pharmacists, while simultaneously implementing measures to promote the dispensing of generic medicines. Training and educational campaigns should directly focus on rational dispensing and making information more widely available and should be included in the package of policy incentives aimed at pharmacists.

There is a great deal of room to improve in this policy area in Europe. Fully 42% of the countries surveyed in Table 4 have not yet implemented a sound programme of incentives to promote the dispensing of generic medicines. This is typically the case in countries with low volume market shares for generic medicines, such as Austria, Belgium or Spain.

#### V. Countries with incentives for patients to request generic medicines

Generic medicines have been proven to deliver substantial savings to national health systems and to increase access to more affordable treatments for patients. Yet only very limited effort is expended to promote patients' acceptance and use of generic medicines in countries with low market shares. 50% of the countries with high volume market share in Table 5 have concrete mechanisms in place to encourage patients to request or accept affordable generic medicines.

Although every country has some form of a co-payment system, co-payments are limited in Germany, Sweden and the UK. In Germany co-payment is limited to a certain percentage of the patient's income, up to a maximum out-of pocket limit per prescription and combined with co-payment exemptions as a further incentive to reducing the cost. Similarly, in Sweden patients have a maximum payable out-of pocket value stipulated by a ceiling for a given time period. The patient must make a co-payment for a higher-priced generic version or the originator product.

In Denmark, patients that refuse the officially reimbursed medicine are asked to co-pay the price difference between the officially reimbursed medicine and the product chosen. In England, there is a fixed co-payment (or "prescription charge"), from which approximately half of the population is exempt. As a result, 88.6% of prescription items attracted no charge in England in 2007.

Similarly, governments and healthcare authorities may also need to face the irrational reluctance of key stakeholder groups to adopt generic medicines. Certain psychological barriers on the part of physicians and patients need to be overcome through effective communications and education directed at these crucial groups.

Created market conditions also play an important role in this area. According to Porter (1985), the five forces that most impact company strategy are new entrants, buyer bargaining power, supplier bargaining power, substitute services or products, and competitor rivalry. When analysing the pharmaceutical sector in the light of Porter's five-force framework, we can infer that there are large obstacles to a dynamic and competitive environment in this sector. It is in fact difficult to find other sectors with such a high level of artificial market regulations and barriers.

Entry barriers are high and substitute products cannot be found for a particular molecule while it remains on patent. The sector is also characterised by a strong brand identity and brand loyalty amongst critical decision-makers, ie, pharmacists, physicians and patients. Brand loyalty, whether to corporate images or product brands, is often very resistant to change and, indeed, represents one of the strongest behavioural barriers to generic medicines.

Unfortunately, scientific evidence and the demonstrated bioequivalence of generic medicines do not always translate into competitive parity between generic medicines and their reference products. Other aspects, such as long-term monopolistic positions on the market and strong,

well-funded marketing campaigns influence the competitive balance between generic and originator medicines.

A well balanced market position for generic medicines can only be achieved by developing the trust of key interested parties over years of satisfactory presence on a market. Moreover, the bargaining power of patients is also low in the pharmaceutical sector as patients often accept what the physician prescribes without question. Sometimes patients are faced with little choice other than the patented brands for a particular molecule. Pharmacists can play a key role in creating a truly competitive market for generic medicines by helping to inform patients of the cost-effective choices available to them, and still fulfil their role of dispensing quality medicines. First, however, more must be done by governments to incentivise pharmacists to dispense generic medicines.

In other countries, particularly in Southern European markets such as Italy, Spain and Portugal where market penetration of generic medicines is lower than in the North of Europe, physicians are the key drivers of pharmaceutical penetration. Doctors and their prescribing habits and preferences are therefore key for anyone who wants to successfully enter the market.

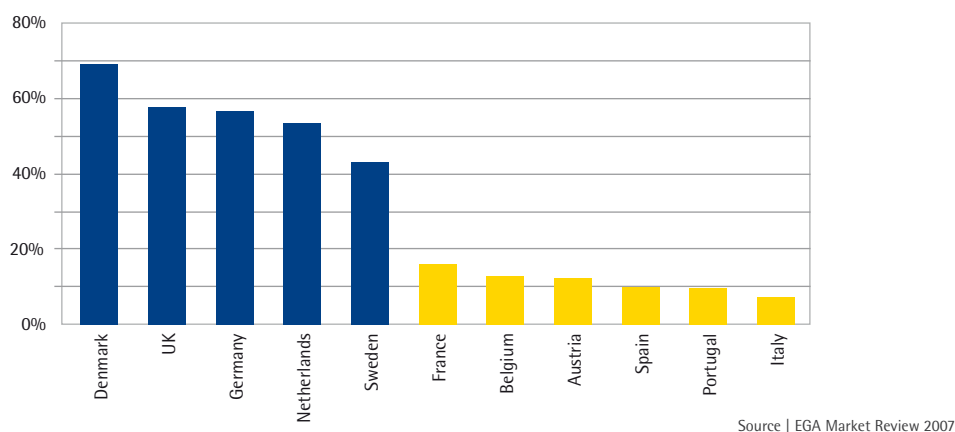
In 2007 only Portugal and Italy, from the countries with low volume market share, initiated national campaigns by the health authorities involving all players, aimed at promoting generic medicines, informing patients about the bioequivalence of generic medicines, and raising the awareness on the importance of using generic medicines when available. As a result, in Italy:

“...surveys conducted during 2007, highlighted an increasing confidence in generics by the general public at the pharmacy level. It is imperative for the generic medicines sector that patients are aware of the benefits of generic medicines and are encouraged to request generic medicines.”<sup>45</sup>

## Conclusion

The impact that less efficient regulatory frameworks with little or no incentives exert on the penetration of generic medicines by volume in the different countries surveyed is remarkable.

Figure 13 | Generic medicines volume market share



Countries that do not have a long-term, consistent generic medicines policy and that do not attempt to increase awareness of the economic benefits of generic medicines are precisely those countries with the lowest volume market shares. These systems offer the least potential for savings to governments and the least affordable prices to patients (Figure 13).

<sup>45</sup> Assogenerici, 2007

**Key Points:**

- There is an obvious and urgent need for long-term generic medicines policies. Of the countries surveyed, only 33% present such long-term measures to promote the use of generic medicines.
- *Ad-hoc* government measures create inefficiencies in price and reimbursement systems.
- Countries where governments do not implement long-term generic medicines policies—and where there are little or no incentives to physicians, pharmacists and patients—are also countries with lower volume generic medicines market shares.

### 3.1 Measures that influence prescribing and dispensing of generic medicines

This chapter will analyse the measures that have been implemented in certain countries to create the correct conditions to encourage physicians to prescribe and pharmacists to dispense generic medicines. These behaviours will lead to an increased use of generic medicines, resulting in greater savings to governments and to patients.

Although the behaviour of patients is not specifically addressed in this chapter, patients are of course crucial stakeholders on the demand-side of the equation. In this context, mechanisms referred to in the previous chapter should be implemented by governments and national agencies to increase awareness amongst patients of the availability of cost-effective generic medicines and to promote their optimal usage.

In our attempt to better understand prescribing and dispensing behaviours in Europe, we will begin by asking the question, "Who is the DRIVER in the market?" Our goal is to identify the markets that are driven by either physicians, pharmacists, health insurance funds or other stakeholders, and to establish the best practices employed in those countries to incentivise the driver of demand.

Figure 14 | Drivers of EU pharmaceutical markets

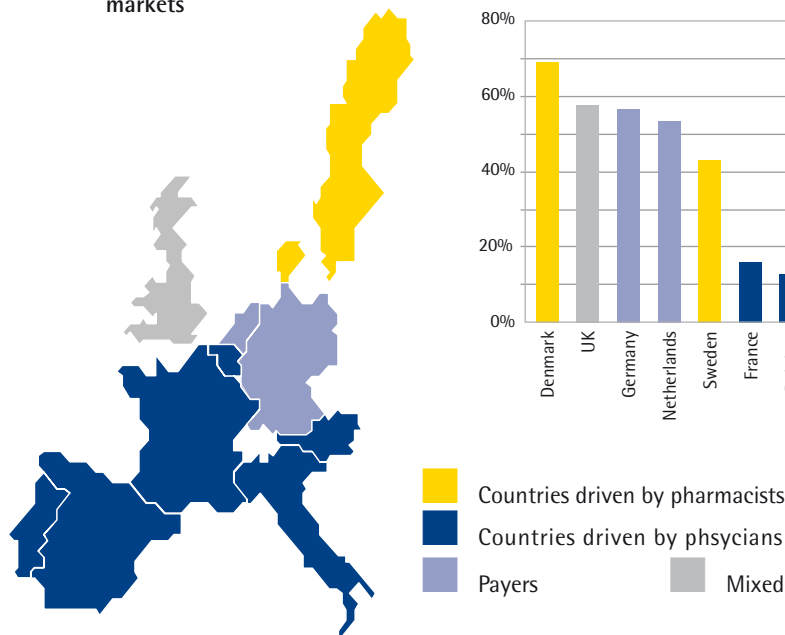
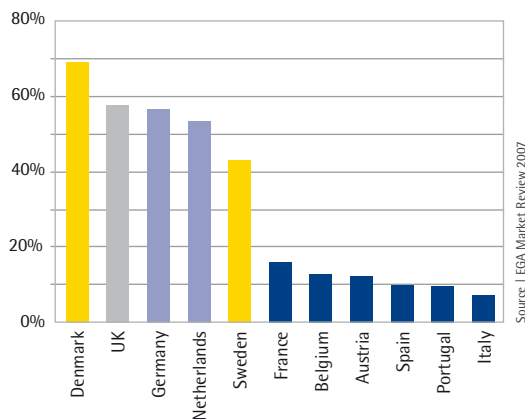


Figure 15 | Generic medicines volume market share



The data presented in Figures 14 and 15 show a clearly discernible correlation between the recognised driver in the market and the level of generic medicines market penetration by volume. This relationship deserves further examination.

In Figure 14 markets that are driven by physicians are presented in dark blue, while pharmacist-driven markets are coloured in yellow. Payers drive the market in countries presented in light blue (Germany and the Netherlands), and finally countries in grey (the UK) have mixed medicines markets that are driven by both physicians and pharmacists.

In the UK, physicians are encouraged to prescribe by INN—82.6% of all prescriptions, irrespective of patent status, are written by INN. Where this is the case, and a generic is available, pharmacists

are reimbursed at the generic rate. So there is a significant incentive for pharmacists to dispense the generic unless, as is sometimes the case, the originator effectively sells the equivalent brand at the generic price (so-called "brand equalisation"). Furthermore, the UK Government sets the generic reimbursement price at a level such that pharmacists make a profit of £500m nationally on dispensing generics (the so-called "purchase profit").

Under the new dynamics at work in the pharmaceutical market in Germany, the individual physician is still responsible for the prescribing of medicines, but the influence exercised by health insurance funds and pharmacists over the final choice of product is gaining ground. Legislative changes have introduced new threats by establishing so-called tendering rebate contracts for contractual cooperation between the pharmaceutical industry and the health insurance schemes (rebate contracts in accordance with section 130a Article 8 of the Social Security Code [SGB] V) and this is shifting the balance of the German generic medicines market. The leading health insurance schemes, led by the market leader AOK with 40% market share, are now taking tendering rebate contracts. Similarly, the pharmacist is legally obliged by the "aut-idem-rule" to dispense a discounted medicine if one is available. With discounted medicines, the physician's professional sovereignty is limited to the choice of substance.

### 3.2 Lack of incentives to physicians to prescribing generic medicines

The advantages of generic medicines need to be explained more fully and forcefully to physicians while simultaneously implementing measures to promote the prescribing of generic medicines.

The incentives that influence physicians to prescribe generic medicines vary amongst the two categories of countries described above. Although, there is no concrete and well-defined policy to encourage physicians, in some countries a pattern of measures exists to influence physicians toward generic prescribing. Such measures include budgetary restrictions, budgetary incentives and prescription monitoring, and are frequently found in countries with a higher market penetration of generic medicines (Table 5).

Table 5 | Comparative analysis - Incentives for physicians to prescribe generic medicines

	Austria	Belgium	France	Italy	Portugal	Spain	Poland	Denmark	Germany	Netherlands	Sweden	UK	Total Yes	Total No	Total
By budgetary restrictions	x	x	x	x	x	x	x	x	✓	x	✓	✓	3	9	12
By budgetary incentives	x	x	✓	x	x	✓	x	x	✓	x	x	✓	4	8	12
Prescription monitoring	✓	✓	✓	✓	x	✓	x	✓	✓	x	✓	✓	9	3	12
Compulsory prescription guidelines	x	x	✓	x	x	x	x	✓	✓	x	x	x	3	9	12

Source | EGA Market Review 2007

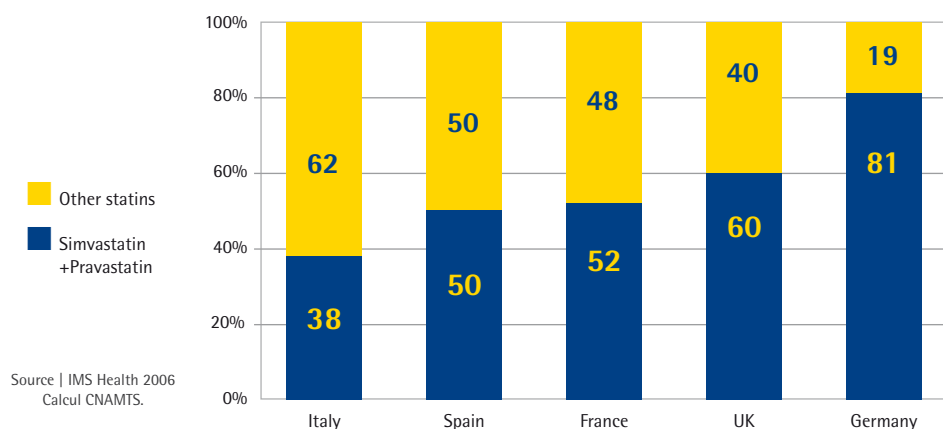
Schwermann *et al* (2003), on the matter of measures that lead physicians to prescribe generic medicines, addressed the effects of pharmaceutical budgets and price and reimbursement regulations in Germany. In their findings, until 2001 Germany's pharmaceutical budget was

centrally controlled. Since then it has moved rapidly to a system of regional budgets with budget restrictions per physician based on historical data and currently moves to a morbidity based doctor's fee budget. This measure has promoted greater economic awareness on the part of physicians and has fostered more restrictive prescribing habits.

In other countries physicians are also encouraged to prescribe generic medicines through budget incentives. For example, in the United Kingdom, physicians were given indicative budgets as a goal, and savings beyond the budget could be used by doctors for other purposes such as training. France has deployed several different incentives to encourage physicians to prescribe generic medicines. These range from compulsory prescription guidelines, to visits from representatives of the social security system to explain the advantages of prescribing generic medicines. In Italy prescribing is monitored by the local authorities in an effort to encourage physicians to prescribe first level generic medicines or the least expensive product available.

The results of incentivising physicians to prescribe generic medicines are clear in the charts below: the greater the incentives for doctors to prescribe generic medicines, the greater their uptake. This correlation is readily apparent in Figure 16, which shows the prescribing practices of physicians in different European countries for the class of medicines known as statins. In countries like the UK and Germany, where doctors receive greater incentives or have generic prescribing quotas, generic molecules are logically prescribed more frequently.

Figure 16 | Prescription patterns for statins in Europe



Inversely, physicians in countries like France, Spain or Italy, where incentives are not present, continue to prescribe originator medicines despite the availability of less expensive equivalent generic formulations of such molecules as simvastatin and pravastatin. Although not represented in the graphic, Belgium is also highly representative of this situation:

"Several Belgian newspapers reported that the general practitioners have started prescribing more brand medicinal products again. Brand products maintain a high market share without there being any significant therapeutic differences, according to the "Mutualités Chrétiennes". Lipitor for instance, the most sold medicinal product in 2007, is used for treatment in patients with hypercholesterolemia, is not very different from Zocor (simvastatin) and its generic counterparts. According to the Mutualités, this is mainly due to the marketing power of the brand manufacturers."<sup>46</sup>

<sup>46</sup> De Standaard, 2008

Although physicians are incentivised through budgetary systems or prescription guidelines, generic medicines prescribing needs to be promoted through a broader dissemination of information in the form of computerised prescribing, medicines databases, and the extensive use of reference literature and other means of communication that help to keep physicians fully informed (Table 6).

Table 6 | Comparative analysis – Incentives for physicians to prescribe generic medicines

	Austria	Belgium	France	Italy	Portugal	Spain	Poland	Denmark	Germany	Netherlands	Sweden	UK	Total Yes	Total No	Total
By dissemination of prescribing information	✓	✓	✓	✗	✓	✗	✗	✗	✓	✗	✗	✓	6	6	12
By computerised prescribing	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	10	2	12
By a medicines database	✗	✗	✓	✓	✓	✓	✗	✗	✓	✗	✗	✓	6	6	12

Source | EGA Market Review 2007

Most countries have in place a computerised system to assist physicians in prescribing, but in only six countries is the dissemination of prescribing information used as a method to encourage physicians to prescribe generic medicines.

In effect, in most countries physicians are normally able to determine exactly which medicinal product the patient will ultimately receive. It is therefore essential to educate physicians about the imperatives of rational and cost-contained prescribing. Failing this, there are no reasons to believe that physicians will modify their behaviour—and this can represent a significant barrier to entry for generic medicines in European markets.

### 3.3 Pharmacists dispensing generic medicines

The role of pharmacists in dispensing medicines is crucial when analysing the competitive arena of medicines, and presents great potential for inefficiencies in the system. Ultimately pharmacists should, where the prescription allows, dispense a pharmaceutical product that for each transaction signifies the most economical solution for healthcare systems and represents the greatest savings to patients while respecting their individual healthcare. The overriding principle should be one of cost efficiency. This is obviously not the case in many countries.

In most countries mechanisms to incentivise pharmacists to dispense generic medicines do not exist. Table 7 indicates that 25% of the European countries that were scrutinised for the purposes of the report do not legally allow substitution.

Table 7 | Comparative analysis – Generic medicines substitution

	Austria	Belgium	France	Italy	Portugal	Spain	Poland	Denmark	Germany	Netherlands	Sweden	UK	Total Yes	Total No	Total
Is generic substitution legally allowed?	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	9	3	12

Source: EGA Market Review 2007

In Portugal and Spain, where pharmacists are allowed to dispense generic medicines in place of originator products, there are no real incentives for pharmacists to do so. In Germany, pharmacists are obliged to substitute the prescribed product with the discounted product for which the patient's health insurance has a rebate contract or, where no rebate contract exists, with one of the three least expensive generic medicines available if this is not ruled out by the prescribing physician. The doctor's authorisation to substitute is not required. Pharmacies in Sweden are state owned and substitution for a less expensive generic medicine is common practice. Denmark and Sweden are all countries where physicians are encouraged to prescribe generic medicines.

Dispensing rules differ from country to country, and in markets where the dispensing of generic medicines is not compulsory, it is crucial to have persuasive mechanisms in place to incentivise the pharmacist to dispense generic medicines. These normally must be economic in nature, but some countries present evidence of alternative ways to deal with this issue.

Indeed, an interesting example of the role of the pharmacist can be found in France. Pharmacists obtained the right of substitution in 1999 and have since been encouraged to dispense generic medicines through a list called the "*Répertoire*". This list consists of a number of generic molecules that pharmacists should dispense when the originator product is prescribed by physicians.

In order to incentivise pharmacists to substitute an original product with the equivalent generic medicine, the French Health authorities used the *Répertoire* to create specific incentives, such as margin equalisation, and allowed commercial cooperation between generics manufacturers and pharmacists (maximum discounts are now fixed by law). This is considered to be the main driver of generic medicine market development in France. In addition to this, a measure called "1/3 co-pay versus generics" put the pressure on patients who refused substitution. Under this advance cash system, when a patient refuses to accept a generic medicine, he must pay the pharmacist directly for the originator product and later request reimbursement from the social security system instead of receiving the prescription at no charge.

The penetration of generic medicines within the *Répertoire* is considerably high, representing 70% of the total by volume and 62% by value in 2007.<sup>47</sup> However, despite its proven role as an effective driver for the French pharmaceutical market, only a limited number of generic medicines are included in it. Extending the *Répertoire* and similar substitution lists in other countries to include a greater number of generic medicines would foster a greater volume uptake of these more affordable products and would increase the savings to governments and patients.

Given the important role of pharmacists in product choice, efforts to increase generic dispensing practices should be encouraged. Training pharmacists to take advantage of opportunities to increase substitution can reduce costs.<sup>48</sup>

Perhaps an alternative approach to assessing the role of pharmacists in dispensing pharmaceutical products and their impact on the competitiveness of the sector should focus on the financial compensation of pharmacists. Such an approach would contribute to eliciting a greater understanding of where and how pharmacists derive economic benefit from the current system.

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<sup>47</sup> Gemme, 2008

<sup>48</sup> Bhosle et al, 2003

Table 8 | Comparative analysis – Pharmacists remuneration with regard to generic medicines

	Austria	Belgium	France	Italy	Portugal	Spain	Poland	Denmark	Germany	Netherlands	Sweden	UK	Total Yes	Total No	Total
Regressive margins	✓	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗	2	10	12
Guarantee of absolute margin	✗	✓	✓	✗	✓	✓	✗	✓	✓	✗	✗	✓	7	5	12
Other	✗	✗	✓	✓	✗	✗	✗	✗	✗	✓	✓	✓	5	7	12

Source | EGA Market Review 2007

On incentives to pharmacists, Schwermann et al (2003) conclude that pharmacists need to receive a remuneration that does not penalise them for dispensing generic medicines. The study suggests that countries should move away from distribution margins that are set as a fixed percentage of the public price of medicines to consider introducing pharmacist remuneration systems that are neutral or which favour the delivery of generic medicines by taking economic criteria into account.<sup>49</sup>

Different types of pharmacist remuneration schemes for generic medicines exist in Europe (Table 8), although regressive margins or guarantees of an absolute margin are the ones most commonly used. More than half of the countries studied here employ alternative systems.

In this context, pharmacists should not be penalised for dispensing generic medicines. They should never be forced to receive lower margins for dispensing more cost effective generic medicines. Of the countries surveyed, 58% use absolute guaranteed margins. A wider use of guaranteed absolute margins is one possible means of removing the financial disincentives for pharmacists to dispense generic medicines more willingly.

## Conclusion

In both Northern and Southern European countries mechanisms are in place that encourage the physician or the pharmacist to prescribe or dispense generic medicines. Countries such as Denmark and Sweden have more, and perhaps more effective, incentives to promote the use of generic medicines than countries such as Belgium or Spain. In countries that have implemented less encouraging actions on the driver of demand, the uptake of generic medicines is correspondingly low.

It is fundamental that responsible authorities implement long-term generic medicines policies that include measures that support and encourage physicians and pharmacists in economically rational prescribing and dispensing practices. As expressed by Izmirlieva, *“These measures will help to shape the behaviour of physicians and pharmacists when prescribing and dispensing.”*<sup>50</sup>

<sup>49</sup> Schwermann et al, 2003

<sup>50</sup> Izmirlieva, 2003

**Key Points** (*physicians prescribing generic medicines*):

- Prescribing attitudes toward generic medicines are considerably different between European countries. Physicians need to be exposed to a higher quality of information from the responsible authorities, leading to improved rational prescribing.
- There are various ways to incentivise physicians to prescribe generic medicines, ranging from budgetary incentives to budgetary restrictions. Countries with budgetary incentives show higher market shares of generic medicines.
- More encouragement to physicians by governments is necessary. There is clearly room for increased incentives for generic medicines prescribing.

**Key Points** (*pharmacists dispensing generic medicines*):

- Pharmacists need to be encouraged to maintain a rational cost-containment approach when dispensing a medicine.
- Generic substitution will only be effective if governments and health authorities incentivise pharmacists to dispense generic medicines.
- Ultimately pharmacists must not be penalised for dispensing a generic medicine. Guarantees of equal remuneration levels for dispensing a generic or an originator medicine are required.

#### 4. Evergreening of Medicines and Reimbursement that Delay Competition Rather than Encourage Genuine Innovation

Evergreening includes the practice whereby an originator obtains follow-on patents covering non-essential features of an active substance that is already on the market and facing the end of its patent protection.<sup>51</sup> The purpose of evergreening is to prolong the period of patent protection by introducing a new (patented) formulation that may offer no significant additional clinical benefit to the patient. In some cases the original formulation is withdrawn from the market.

Often these non-essential features are presented as innovative, but actually represent no more than a new formulation (eg, in solution or in solid form), a different concentration in the dosage, changes in the isometric form of the drug, or an additional salt of the active substance. Unless some relevant clinical advantage is demonstrated—in which case, of course, what is happening is genuine innovation and not evergreening—these “new” formulations do not offer better patient outcomes, but do allow the company to prolong the protected period of the molecule. The patentability of such “new” formulations is not directly related to additional clinical benefits as is clearly demonstrated in *“Patent-related Barriers to Market Entry for Generic Medicines in the European Union”*, a report published in summer 2008 by the EGA.

Generic medicines manufacturers are contesting the nature of many so-called innovations being introduced onto the market by originators, arguing that they do not constitute clear and unambiguous improvements in efficacy.

Price and Reimbursement authorities must be more rigorous when assessing the value of innovation, and must not allow purely cosmetic changes to incumbent products to come onto the market with premium price and reimbursement status. The authorisation criteria should include added therapeutic efficacy/safety relative to the existing product. In the words of Jean Marimbert, director general of the French medicines agency, *afssaps*, this would imply:

“...increased selectivity of healthcare systems for reimbursement, based on therapeutic added value and cost-efficiency.”<sup>52</sup>

The lack of rigorous assessment by the price and reimbursement authorities that leads to reimbursement status being granted to products that involve minor changes without offering greater therapeutic benefits also acts as a disincentive to real innovation, prevents generic competition and, as a result, restricts patient access to more cost-effective treatments. Evergreening is clearly anti-competitive, results in higher expenditure for Europe’s financially burdened healthcare systems, and drives up patient co-payments.

Time pressures, misinterpretation of documentation in the assessment process, and the presentation of “solutions” to artificial problems are common features of the patent system for pharmaceutical products. Such “solutions” are often no more than new particle sizes, solvent forms, or different pharmaceutical composition forms such as dissolution rates or formulation stability.

Other common forms of evergreening include the patenting of alternative methods of treatment covering amended dosage regimes that claim to treat different medical conditions. The practice is described succinctly in a study from Deakin University in Victoria, Australia:

“A company manufactures a product for which it secures a patent. Shortly before the expiration of that patent, the company will file a new patent which revises or extends the original. When the original patent expires, a new patent is in effect, which prevents the manufacture of generic versions of the product.”<sup>53</sup>

<sup>51</sup> Roox, 2008

<sup>52</sup> Marimbert, 2008

<sup>53</sup> Barraclough et al, 2007

Where evergreening is used by a dominant company to block the entry of a generic medicine and maintain its own dominance, it is clearly anticompetitive. Such behaviour imposes substantial and unjustified cost on healthcare systems and patients. A system that rewards patents regardless of real innovation is one that will ultimately lead to economic inefficiency and divert financial resources away from genuinely innovative medicines for patients.

It is difficult to understand why the practice of evergreening appears to be tolerated with little regard for the impact it has on patients. It represents a clear barrier to market access for generic medicines and is a major obstacle to dynamic competition in the sector.

According to *Chain Drug Review*, cost savings from generic medicines have enabled governments to reimburse originator pharmaceutical companies for their development costs, a positive feature that a strong generic medicines sector enables. A stronger generic medicines market means greater savings and more resources to reimburse the development costs of the originator sector.<sup>54</sup>

In contrast, Kesselheim points out that, *"Some pharmaceutical patents push the statutory bounds of the Patent Act and earn products undeserved market exclusivity. Patent-protected products such as esomeprazole can increase health care costs."*<sup>55</sup>

The pricing and reimbursement authorities reimburse new formulations that offer no added therapeutic value at higher levels than the molecules already on the market, encouraging physicians to engage in less cost-effective prescription behaviour and causing patients to pay premium prices unnecessarily.

Ciparalex<sup>®</sup> is an excellent example. Ciparalex<sup>®</sup> is a follow-on product to citalopram. Citalopram is a selective serotonin reuptake inhibitor, approved for symptomatic relief of major depressive disorder. Chemically, citalopram is a racemic mixture. Ciparalex<sup>®</sup> (escitalopram oxalate) contains only the S-enantiomer from the racemic mixture.

When Ciparalex<sup>®</sup> was assessed by the Canadian Expert Drug Advisory Committee (CEDAC) on its clinical value and price, its conclusions were as follows:

"...CEDAC reported that the price of generic citalopram is \$0.88 per day and this price is lower than the price submitted to the CDR for Ciparalex. In CEDAC's view, there was insufficient evidence that Ciparalex provides clinically important advantages to justify the higher price."<sup>56</sup>

Another case of high costs for the healthcare systems is clearly shown in a study cited by Kesselheim from Health Affairs:

"... 3 brand name pharmaceutical products whose market exclusivity was extended through patent evergreening efforts. These efforts included lawsuits aimed at exploiting federal statutory loopholes and attempts to patent peripheral aspects of products. Our analysis identified \$1.5 billion in revenue that the Medicaid system could have saved if generic alternatives to these 3 medications had been available."<sup>57</sup>

The generic medicines sector is also affected. Authorising reimbursement and giving premium price approval to products containing evergreened molecules means that generic medicines are prescribed less frequently by physicians (due to the impact of marketing by originator companies). This leads to a reduction in generic competition and sales, which in turn increases pressure on the sustainability of the generic medicines industry generally and on its capacity to provide affordable generic medicines. Again quoting Kesselheim:

<sup>54</sup> Chain Drug Review, 2007

<sup>55</sup> Kesselheim, 2007

<sup>56</sup> Critchley, W, 2007

<sup>57</sup> Kesselheim, 2006

"For example, AstraZeneca developed the proton pump inhibitor omeprazole (Prilosec<sup>®</sup>) and later received a patent on its purified *s*-isomer (esomeprazole, Nexium<sup>®</sup>). The latter can be considered an obvious subsequent development step. Despite the similar efficacy of these two molecules, the company used its marketing resources to promote the more expensive *s*-isomer when omeprazole, the original product, faced loss of its patent protection."<sup>58</sup>

#### 4.1 Evergreening practices

Evergreening practices are increasingly being documented and brought to public attention by the media. The recent example of Gaviscon<sup>®</sup> in Britain is a good illustration. The BBC's Newsnight programme was given access to internal documents that showed that the pharmaceuticals manufacturer Reckitt Bentsler had deliberately blocked generic equivalents to Gaviscon<sup>®</sup>, a product available in several formulations, all of which are based on sodium alginate. These practices alone may have cost the NHS up to £40 million since 1999 for this one product.

Another well-known case of evergreening concerns AstraZeneca's heartburn product Nexium<sup>®</sup> mentioned above. Nexium<sup>®</sup> was introduced to replace the blockbuster product Prilosec<sup>®</sup> which was due to come off patent protection. Nexium<sup>®</sup> is no more than a mixture of two isomers of the omeprazole molecule, yet apparent legal loopholes in the system were exploited by the originator company to obtain a patent on the "new" product.

Clinical studies have demonstrated that Nexium<sup>®</sup> represents no improvement on Prilosec<sup>®</sup>, yet it is alleged that AstraZeneca promoted the product as being therapeutically superior. As a result, a legal complaint has been introduced in the courts by PAL against AstraZeneca over the product:

"Nexium costs much more than Prilosec, which is now available in both a generic and over-the-counter form. Pal's lawsuit claims Astrazeneca misled consumers into thinking the drug was an improvement over Prilosec, even though clinical studies showed that Nexium is no more effective than Prilosec."<sup>59</sup>

Kesselheim has also weighed in on the subject, saying that "*Some pharmaceutical patents push the statutory bounds of the Patent Act and earn products undeserved market exclusivity. Patent-protected products such as esomeprazole can increase health care costs.*"<sup>60</sup>

Other well-known cases also exist, including Plavix<sup>®</sup> (Sanofi-Aventis) and Lexapro<sup>®</sup> (Lundbeck/Forest Labs, the purified stereoisomer of Celexa<sup>®</sup>), where similar strategies have been used to extend patent protection in relation to products having active and inactive stereoisomers.<sup>61</sup>

More recently, the pharmaceutical firm Servier was accused by the Danish generics industry (IGL) association of using the practice of evergreening in Denmark to extend the life-cycle of their product Coversyl<sup>®</sup>, an antihypertensive product, by introducing onto the market a "therapeutically identical" product of Coversyl<sup>®</sup>, called Coversyl Novum<sup>®</sup>. As reported in the industry press:

"By promoting Coversyl Novum—which contains perindopril arginine rather than the original tert-butylamine salt—at different strengths to the original, Servier is attempting to protect its monopoly on the ACE-inhibitor...."<sup>62</sup>

The costs of Coversyl Novum<sup>®</sup> to the Danish healthcare system in 2007 was €10.7 million. According to the IGL, the use of the generic formulation could potentially have saved the authorities €8.1 million.

<sup>58</sup> Kesselheim, 2007

<sup>59</sup> Pal Director Alex Sugerman-Brozan interviews Jerry Avorn, MD (2004) author of "Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs"

<sup>60</sup> Kesselheim, 2006

<sup>61</sup> Noonan, 2006

<sup>62</sup> Generics Bulletin, 2008

**Key Points:**

- **Evergreening:** products approaching patent expiration are often changed slightly and a new patent is obtained for what is in reality the same active substance delivering the same therapeutic result.
- Evergreening of medicines should not be rewarded by price and reimbursement authorities with premium prices and reimbursement status.
- A patent is not a synonym for innovation for pricing and reimbursement status. All products, including new formulations of existing products, should be rigorously evaluated on clear relevant clinical parameters.
- Evergreening of medicines by originator companies is a very costly practice for healthcare systems and for patients.

## 5. Recommendations to Increase the Uptake of Generic Medicines in Europe

An audit of the pharmaceutical industry across Europe is required to pinpoint the inefficiencies in policy that are creating barriers or not allowing for a higher presence of generic medicines in individual countries. The European Commission's initiative in launching a sector inquiry on the pharmaceutical sector shows good progress and provides sound insights into what needs to be done to create a sustainable and competitive pharmaceutical market.

The recommendations presented in this chapter are intended to contribute to the elimination of existing barriers to the entry of generic medicines into European markets.

### 1. Urgent implementation of successful long-term generic medicines policies with a special focus on the removal of potential barriers to the penetration of generic medicines, thus promoting the sustainability of the sector.

Most European countries do not have a long-term policy on generic medicines combining demand and supply-side measures that are ultimately conducive to a more efficient market. Lack of such a policy has cost repercussions for healthcare systems and patients.

#### 1.1 Ban linkage systems that cause delays, block market entry, or obstruct the development of competitive and sustainable market environments.

Market competitiveness starts with ensuring a level playing field for the entire sector. **Patent linkage** is not conducive to a competitive market as it extends the period of market exclusivity enjoyed by originator companies, preventing or delaying entry of generic medicines onto the market. Originator companies often use these tactics to perpetuate a well-established market position. Governments need to look carefully into these actions to prevent undesirable obstructions to the market.

**Continued price linkage** after generic medicines market entry is a mechanism that skews the rules of fair competition toward the originator sector, creating a competitive disadvantage for generic medicines companies attempting to enter the market.

The generic medicines sector is clearly under threat when it is dependent upon its competitors to set its prices. It is difficult to imagine another sector where such conditions could prevail.

#### 1.2 Create a mechanism for granting automatic pricing and reimbursement status upon marketing authorisation, eliminating current time delays.

The current time delays in approving price and reimbursement status after market authorisation are unreasonable given that a generic medicine has demonstrated its therapeutic equivalence to a well-known pharmaceutical through the market authorisation process. These delays on pricing and reimbursement status cannot be justified.

### 2. Application and enforcement of clear criteria for innovation, unambiguously defining innovation to be synonymous with added relative therapeutic efficacy/safety, thereby eliminating rewards for evergreening practices.

#### 2.1 Carefully assess and reward innovative medicines that bring added therapeutic value/safety rather than medicines that represent little more than cosmetic changes to existing products.

- 2.2 Cease to reward companies/products that take advantage of the system by introducing "innovative drugs" or new formulations of existing drugs that do not demonstrate clinically relevant additional therapeutic value.
- 2.3 Be aware of the fact that patents are not synonymous with innovation.
- 3. Introduce mechanisms to influence the prescribing and dispensing behaviour of physicians and pharmacists in European countries in favour of generic medicines.**
  - 3.1 Take steps to raise awareness amongst physicians of the benefits of generic medicines. Physicians need coherent and harmonised support throughout Europe in terms of greater availability of prescribing information, computerised prescribing, medicines databases, prescribing from an independent body, and prescription audits.
  - 3.2 Reduce the discretion of doctors to disallow generic dispensing by introducing mechanisms to encourage physicians to prescribe generic medicines, thus promoting their use.
  - 3.3 Establish systems throughout Europe that are based on budgetary incentives, allocating prescription budgets to physicians and granting them the discretion to use those savings to prescribe more expensive treatments where necessary.
  - 3.4 Deploy mechanisms to guarantee that pharmacists are rewarded for dispensing generic medicines, particularly as it is currently not economically attractive for pharmacists to dispense generic medicines in some markets due to their lower price. A guaranteed absolute margin can be seen as a necessary step to eliminate the financial disincentives.
  - 3.5 Ensure that pharmacists are aware of the benefits of dispensing generic medicines. An integrated approach encompassing all stakeholders is needed to create savings for patients and governments.

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**G**eneric medicines are widely believed to contribute significantly to maintaining the sustainability of healthcare delivery, a matter of increasing concern to European governments. Expenditure on pharmaceutical products is a major component of total healthcare costs and the search for less expensive therapeutic alternatives has shown the importance of generic medicines in lowering them.

Indeed, it can be argued that sustainable healthcare systems can only be achieved through the increased use of generic medicines. Generic medicines are well-known medicines with proven therapeutic value available at affordable prices which consequently translate into savings for both healthcare systems and patients. In addition, generic medicines stimulate market competition, thus driving the development of new medicines for illnesses and conditions for which treatment may not yet be available.

Even so, it is widely understood that Europe is not fully benefiting from the potential savings of generic medicines competition. This report focuses on those aspects of pricing and reimbursement policy at national level which contribute to delays in market access and to the causes of Europe's failure to fully embrace high-volume post-patent generic competition.