KATHOLIEKE UNIVERSITEIT
LEUVEN

Sustaining Generic Medicines Markets in Europe

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Research Centre for Pharmaceutical Care
and Pharmaco-economics

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The authors

Research Centre for Pharmaceutical Care and Pharmaco-economics

Since the early 1990s, the Research Centre for Pharmaceutical Care and Pharmaco-economics at the Katholieke Universiteit Leuven has made a scientific contribution to the efficient, effective and safe use of medicines, medical devices and related products. In addition to research into the key areas of pharmaco-economics, pharmaco-therapeutics and pharmaceutical care, the Centre is committed to transferring scientific knowledge in these areas to health care professionals, policy makers, pharmaceutical industry, and patients.

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Steven is a Professor at the Research Centre for Pharmaceutical Care and Pharmaco-economics. He is a health economist and leads the Centre's research into the economics of medicines, medical devices and related products. His research interests focus on issues surrounding competition and regulation of the pharmaceutical industry, and economic evaluation of medicines and medical devices. Previously, Steven worked at the Organization for Economic Co-operation and Development and at the University of Aberdeen. He holds a degree in commercial engineering from the Katholieke Universiteit Leuven, a MSc in Health Economics from the University of York and a PhD in Economics from the University of Aberdeen.

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Executive summary

Background

In an era of ageing populations and rising health care costs, generic medicines allow patients to access safe, effective, high-quality medicines at 20%-80% of the price of branded originator medicines. In this way, generic medicines support the sustainability of health care provision and contribute to controlling pharmaceutical expenditure. Competition from generic medicines also incites originator companies to develop innovative medicines and to reduce prices on off-patent originator medicines, thus generating additional savings to patients. Savings on the pharmaceutical budget, in turn, enable Governments to reimburse newer, more expensive medicines. Generic medicines markets have not developed to the same degree in European countries. This variation owes, amongst other things, to differences in generic medicines policy.

Study objectives

This report analyses the policy environment surrounding the generic medicines retail market in selected European countries since 1990. The analysis of the policy environment focuses on pricing and reimbursement systems, and other incentives for physicians to prescribe, for pharmacists to dispense and for patients to use generic medicines. A sample of countries with mature generic medicines markets (Denmark, Germany, Netherlands, Poland, United Kingdom) is compared with countries that have developing markets (Austria, Belgium, France, Italy, Portugal and Spain).

European experience with generic medicines policy

The experience of European countries shows that there is no single approach towards developing a generic medicines market. For instance, demand for generic medicines in mature markets is driven by generic substitution by pharmacists in Denmark and the Netherlands, a favourable attitude of physicians towards generic medicines in Poland, physician budgets in Germany and the United Kingdom. Also, the development of a generic medicines market needs to be actively sustained by a generic medicines policy. Consequently, countries that have promoted generic medicines for 10-15 years naturally have a more mature generic medicines market than countries that have only recently implemented measures to stimulate generic medicines use.

Countries have drawn on supply-side policies relating to pricing and reimbursement to develop their generic medicines market. Limiting policy to supply-side measures only, as is the case in Austria, is insufficient in realising the full potential of a generic medicines market. To develop a generic medicines market, supply-side measures need to be supplemented by demand-side policies, creating incentives for physicians, pharmacists and patients to use generic medicines. Indeed, this report demonstrates that demand-side policies are critical to a sustainable generic medicines market.

The ability of the generic medicines industry to deliver competitive prices can only be achieved and sustained if it is ensured a high volume of the pharmaceutical market. This high volume is dependent on demand-side policies. On the one hand, countries with mature generic medicines markets have in place incentives for physicians, pharmacists and/or patients to demand generic medicines. On the other hand, there are few incentives to stimulate generic medicines consumption in countries with developing generic medicines markets. In Italy and Spain, the limited volume of generic medicines consumption in combination with low medicine prices due to certain supply-side measures has undermined the economic viability of the generic medicines market.

Supply-side policies

Variation in delays for pricing and reimbursement approval obstructs the creation of a level playing field for market entry across EU countries and hinders the development of a competitive European generic medicines industry.

Penetration of generic medicines is more successful in countries that permit (relatively) free pricing of medicines (e.g. Germany, Netherlands, United Kingdom) than in countries that have pricing regulation (e.g. Austria, Belgium, France, Italy, Portugal, Spain). This is because countries that adhere to free market pricing generally have higher medicine prices, thereby facilitating market entry of generic medicines, and a higher price difference between originator and generic medicines.

Reference-pricing systems appear to have aided the development of national generic medicines markets by imposing a patient co-payment on originator medicines priced above the level of the reference price. However, the primary objective of a reference-pricing system is to contain public pharmaceutical expenditure, not to stimulate generic medicines use. In France, where the introduction of the reference-pricing system was accompanied by price reductions of many originator medicines to the level of the reference price, the contribution of the reference-pricing system to the development of the generic medicines market was limited.

Demand-side policies

Physician budgets created a stimulus to prescribe generic medicines in Germany and the United Kingdom, but rewards and sanctions for budget surpluses and deficits, respectively, are a necessary condition for making budgets effective. Initiatives to promote INN prescribing provide impetus for generic medicines use only if regulation specifying which medicine pharmacists need to dispense and the system of pharmacist remuneration favour the delivery of generic medicines.

Generic substitution aids generic medicines use if it is financially attractive to pharmacists to substitute generic for originator medicines. However, the remuneration system of pharmacists in the majority of selected countries provides a financial disincentive to dispense generic medicines. Belgian and French remuneration systems that guarantee the same absolute margin on originator and generic medicines provide a neutral financial incentive to pharmacists, but increase the price of generic medicines relative to originator medicines. Few countries have in place systems that financially reward pharmacists for substituting generic for originator medicines. In countries where companies compete by offering discounts to pharmacists, health care payers and patients do not capture the potential savings from generic medicines use.

Patient co-payment seems to play a role in stimulating demand for generic medicines in Poland and Portugal. This incentive does not exist in France where co-payments tend to be covered by private insurance. Many countries have launched advertising campaigns to inform patients of generic medicines, but the effectiveness of such campaigns has not been evaluated.

Savings from generic medicines use

An illustrative exercise showed that increased substitution of generic for originator medicines can yield substantial savings. For the top 10 active substances by expenditure of originator medicines, generic substitution would reduce public expenditure on the originator medicines containing these active substances by 21%-48% in selected countries, with a proportional reduction of 27% in Austria, 42% in Belgium, 48% in Denmark, 35% in France, 47% in Germany, 31% in Italy, 41% in the Netherlands, 21% in Poland, 42% in Portugal, 33% in Spain, and 33% in the United Kingdom.

Recommendations to sustain European generic medicines markets

To sustain the development of a competitive generic medicines market, the following recommendations are proposed:

1. *Introduce a coherent generic medicines policy*

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.

Supply-side policies

2. *Encourage price differentiation / competition within existing regulatory frameworks*

With respect to pricing, countries can opt for one of two options or a combination of both. Countries can establish a system of fixed minimum price differences between generic and originator medicines within the context of existing reference-pricing systems. Alternatively, countries can establish a free pricing system within the context of existing reference-pricing systems. In countries with mature generic medicines markets, the reference price could be set at the average price level of generic medicines in the reference group or at a lower price level. This must be combined with incentives to stimulate demand for generic medicines aimed at physicians, pharmacists and patients. Generic medicine companies would have an incentive to compete in order to boost their market share by driving down (reference) prices of medicines. In countries with developing generic medicines markets, setting the RP at a higher level to encourage market entry could be considered as a temporary measure to stimulate the generic medicines market until it reaches a more mature level of development. Additionally, competition through discounts to pharmacists is not transparent. Countries should consider moving away from competition by discount to competition by price.

3. *Disseminate pricing information to actors*

Information about the price difference between originator and generic medicines needs to be communicated to relevant actors, thus creating an incentive for physicians to prescribe, pharmacists to dispense, and patients to ask for generic medicines.

4. *Increase confidence of actors in generic medicines*

National medicine agencies need to play a more active role in communicating the availability and bio-equivalence of generic and originator medicines to physicians, pharmacists and patients.

Demand-side policies

5. *Provide incentives for physicians to prescribe generic medicines*

Countries need to recommend that physicians prescribe low-cost medicines, unless a more expensive, originator medicine is required for therapeutic reasons. Generic medicine prescribing can be encouraged by making medical students aware of prescribing by International Non-

Proprietary Name during their undergraduate education; by demonstrating to physicians the amount of savings that can be made from generic medicines use; by supporting physician prescribing with electronic prescribing systems, medicine databases, audit of and feedback on prescribing data, prescribing guidelines and formularies, substitution lists, and local pharmaco-therapeutic discussions between physicians and pharmacists. These policy tools need to be accompanied by rewards/sanctions for physicians who do/do not adhere to them, respectively.

6. *Remove financial disincentives for pharmacists to dispense generic medicines*

Pharmacists need to receive a remuneration that does not financially penalise them for dispensing generic medicines. Countries need to move away from distribution margins that are set as a fixed percentage of the public price of medicines or margins that, even though they are regressive, still favour the delivery of originator medicines. Instead, countries need to consider introducing pharmacist remuneration systems that are neutral or favour the delivery of generic medicines from a financial perspective.

7. *Provide incentives for patients to demand generic medicines*

Countries need to incite patients to demand generic medicines. This may take the form of financial incentives that reduce co-payment on generic medicines or impose higher co-payment on originator medicines.

1 Introduction

Over the past decades, medicines have made a major contribution to improving the health status of patients. At the same time, pharmaceutical expenditure has increased rapidly, with spending on medicines outpacing economic growth in many European countries (OECD, 2005). As a result, Governments seek to implement effective pharmaceutical policies that support further health improvements by accommodating the introduction of new and more effective medicines, whilst containing pharmaceutical expenditure.

In the face of these pressures, a growing number of European countries pursue the development of their domestic generic medicines market. A generic medicine is a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bio-equivalence with the reference medicinal product has been demonstrated by appropriate bio-availability studies (Directive 2004/27/EC).

A favourable environment for generic medicines is likely to aid Governments in sustaining health care provision and controlling pharmaceutical expenditure because generic medicines have the same quality, safety and therapeutic efficacy as the originator medicine, but are less expensive than originator medicines. Their lower cost derives from the fact that companies of generic medicines do not incur the development costs of innovative medicines. Competition from generic medicines also incites originator companies to develop innovative medicines and to reduce prices on off-patent originator medicines, thus generating additional savings to patients (European Commission, 2004). Savings on the pharmaceutical budget, in turn, enable Governments to reimburse newer, more expensive medicines.

The size of generic medicines retail markets varies widely between European countries. Two groups of countries can be distinguished in terms of the market share of generic medicines by volume in 2004 (IMS Health, 2004). Countries with a mature generic medicines market exhibited a generic market share exceeding 40% (e.g. Denmark, Germany, Netherlands, Poland, United Kingdom). In countries with developing generic medicines markets, market share of generic medicines did not surpass 20% (e.g. Austria, Belgium, France, Italy, Portugal, Spain). Variation in the development of national generic medicines retail markets owes, amongst other things, to differences in the policy and regulatory environment surrounding generic medicines.

This study aims to analyse the policy environment surrounding the generic medicines retail market in selected European countries since 1990. A sample of countries with mature generic

medicines markets as well as countries with developing markets was included. Analysis of the policy environment focuses on pricing and reimbursement systems, and other incentives for physicians to prescribe, for pharmacists to dispense and for patients to use generic medicines. In light of Directive 2004/27/EC which harmonizes data exclusivity provisions and marketing authorisation procedures across EU countries, such issues are not discussed in this report, except for when they had a clear impact on the development of a domestic generic medicines market over the last 15 years.

The material presented in this report was derived from a review of the international peer-reviewed literature and relevant legal texts. This was supplemented by information collected by the 2005 and 2006 EGA surveys of pricing and reimbursement systems governing generic medicines markets (EGA, 2005 and 2006). Information derived from these sources was validated by representatives of the EGA Healthcare Economics Committee, national generic medicines associations, Ministries of Health and National Medicines Agencies.

The study is structured as follows. For each of the selected countries, an overview is presented of generic medicines policy during the last 15 years. Incentives created by policy measures are analysed and key factors aiding and hindering the development of the domestic generic medicines market are identified. This is followed by a comparative analysis of the policy tools that countries have used to strengthen their generic medicines market and of their experience with them. A set of general and country-specific recommendations is developed that can aid policy makers in sustaining their domestic generic medicines market. Finally, the potential savings that could be realized from increased substitution of generic for originator medicines are illustrated.

The analysis is exemplified by data from IMS Health. Differences were noted between the IMS Health classification of originator and generic medicines, and EGA definitions. Therefore, data were presented only for those countries where a close match could be obtained between IMS Health and EGA definitions. Further work is undertaken by IMS Health and EGA to resolve remaining data issues.

The report hopes to aid policy makers in gaining a better understanding of how pharmaceutical companies, physicians, pharmacists and patients react to incentives created by generic medicines policy, and to propose tools that policy makers can use to continue developing domestic generic medicines retail markets.

PART I

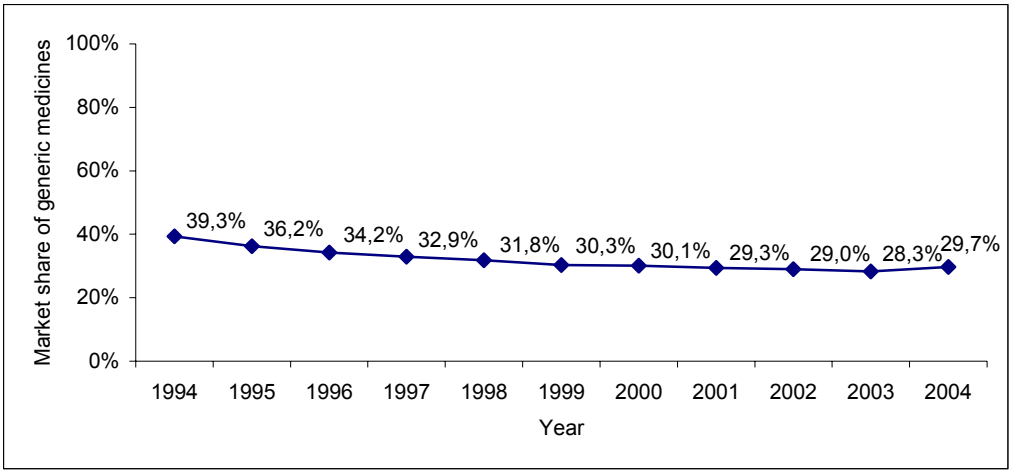
GENERIC MEDICINES POLICY IN COUNTRIES WITH MATURE MARKETS

2 Denmark

2.1 Generic medicines market

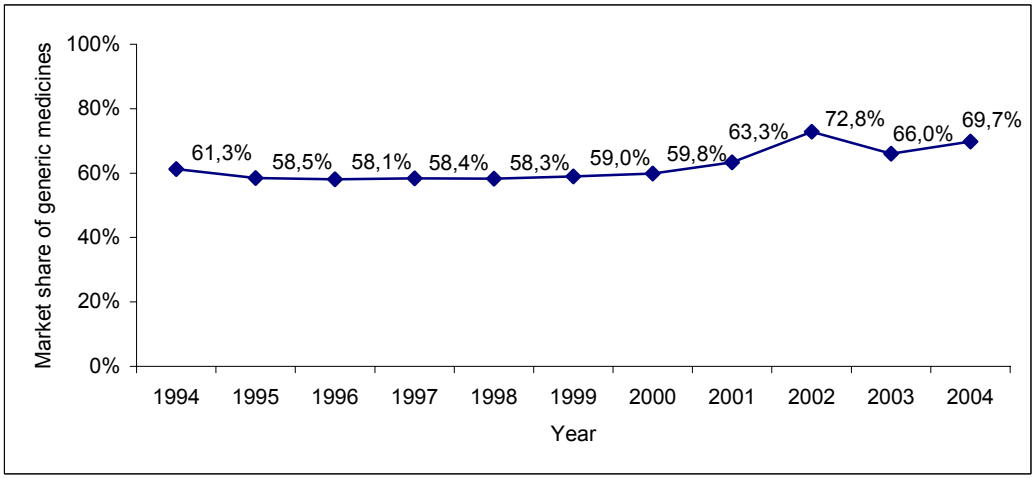
Danish generic medicines policy has created conditions fostering a low-price, high-volume generic medicines market. Market shares of generic medicines in terms of value of consumption have decreased from 39.3% in 1994 to 29.7% in 2004 as a result of falling prices of generic medicines. This has been accompanied by increased volume of consumption of generic medicines, with market shares rising from 61.3% in 1994 to 69.7% in 2004.

Figure 1. Market share of generic medicines by value in Denmark, 1994-2004



Note: Data relate to both hospital and retail pharmacy.

Figure 2. Market share of generic medicines by volume in Denmark, 1994-2004



Note: Data relate to both hospital and retail pharmacy.

2.2 Generic medicines policy

2.2.1 Pricing

In Denmark, pharmaceutical companies are essentially free to set medicine prices. For reimbursement purposes, generic medicines generally need to be priced below the price level of originator medicines.

2.2.2 Reference pricing

A RPS by active substance was launched in 1993. Physicians can exempt patients from the RPS on specific medical grounds. Originally, the RP was set at the average price per dosage unit of the two lowest-priced medicines in the homogeneous group. Since 2001, the price of the cheapest medicine in the group has been used to determine the RP. The level of RPs tends to change every two weeks.

2.2.3 Incentives for physicians

The Danish Medicines Agency has introduced the 'Medicine Profile', a database that GPs and patients can access to check their individual medicine use and to compare the price of the prescribed medicine with that of equivalent medicines. The Agency also publishes a monthly newsletter targeted at physicians giving them advice on cost-effective prescribing.

Decentralised initiatives exist in all counties that stimulate generic prescribing through the use of databases which report only the cheapest medicine, through medical audit and dissemination of prescribing data, and through visits to GPs to discuss their prescribing behaviour. These initiatives have contributed to reducing the proportion of prescriptions where physicians forbid generic substitution.

The Danish College of General Practice and the Medical Colleges of the various specialties have compiled practice guidelines, but no incentives or sanctions have been attached to physician (lack of) adherence to these guidelines. Physicians are neither legally required nor encouraged to prescribe medicines by INN.

2.2.4 Incentives for pharmacists

In 1991, generic substitution by pharmacists was introduced. If the price of the prescribed medicine is less than 100 DKK, the pharmacist must substitute with the least expensive (generic

or originator) medicine that is at least 5 DKK cheaper than the prescribed medicine. For medicines priced between 100 and 400 DKK, substitution with the cheapest medicine is mandatory if it is at least 5% cheaper than the prescribed medicine. If the price of the prescribed medicine exceeds 400 DKK, the pharmacist must dispense the cheapest medicine that is at least 20 DKK below the price of the prescribed medicine.

Physicians can write on the prescription form that generic substitution is forbidden. In the third quarter of 2005, generic substitution was not allowed on 6.1% of prescriptions (Danish Medicines Agency, 2006). The responsibility of informing patients of the availability of generic medicines lies with the pharmacist. Patients have the right to refuse substitution, but incur a higher patient co-payment if they do so.

Generic substitution is reinforced by dispensing budgets for pharmacists, which provide an incentive to dispense cheap generic medicines. Pharmacists have no personal financial interest in dispensing generic medicines as their remuneration is made up of a fee per prescription item and a percentage margin, the regressive nature of which is limited.

2.2.5 Incentives for patients

Since 2005, patients incur the full costs of medicines up to 520 DKK per year. Once expenditure surpasses that level, patient co-payment as a percentage of medicine costs decreases as expenditure crosses specific thresholds: 50% co-payment from 520 to 1,260 DKK; 25% from 1,260 to 2,950 DKK; and 15% from 2,950 DKK onwards. Reimbursement is calculated on the basis of the price of the cheapest medicine among the different products with the same active substance and effect. No campaigns to raise patient awareness of generic medicines have been conducted.

2.3 Policy analysis

The Danish generic medicines market is a low-price, high-volume market. This is because the RPS and generic substitution by pharmacists create a set of conditions that reward generic medicines companies that have competitive prices for an active substance with high sales. For most active substances, the market consists of around ten companies that compete on price. Low prices also stimulate patient demand for generic medicines. This approach ensures the economic viability of the generic medicines market.

Demand for generic medicines is supported by generic substitution by pharmacists. Generic substitution rules require pharmacists to dispense the cheapest medicine. Also, generic substitution by pharmacists is not inhibited by physician opposition. Financial incentives for pharmacists tend to be neutral or in favour of dispensing generic medicines. Finally, generic prescribing is promoted by non-financial incentives facing physicians.

The Danish generic medicines market is a competitive market where RPs change regularly and some companies specialise in offering a limited number of generic medicines at the lowest cost. Price competition and low prices could endanger the long-term sustainability of the generic medicines industry, particularly those companies that offer a broad range of medicines.

Key factors aiding the development of the generic medicines market:

- The RPS and generic substitution by pharmacists reward generic medicines companies that set competitive prices for an active substance with high sales
- Physicians tend to have a favourable attitude towards generic substitution by pharmacists and face non-financial incentives to prescribe generic medicines

Key factors hindering the development of the generic medicines market:

- Strong price competition and low prices could endanger the long-term sustainability of the generic medicines industry

3 Germany

3.1 Generic medicines market

Data on the market share of generic medicines are not reported due to incompatibility of IMS Health and EGA definitions of generic medicines.

3.2 Generic medicines policy

3.2.1 Pricing

In Germany, free medicine pricing prevails in that ex-factory prices of medicines are set independently by pharmaceutical companies. Medicine prices in Germany tend to be higher than those in other EU countries (Mrazek, 2002).

An illustrative analysis focusing on five active substances revealed that generic medicines in Germany were priced at an average level as compared with prices in France, Italy, Spain and the United Kingdom in 2005 (Accenture, 2005).

3.2.2 Reference pricing

A RPS was launched in 1989 and gradually introduced in the early 1990s. Physicians have the legal obligation to inform patients of the surcharge when prescribing a medicine priced above the RP. RPs were set for homogeneous groups of medicines, which were defined at three levels. Level 1, implemented in 1989, related to off-patent medicines with the same active substance. As of 1991, level 2 applied to medicines with pharmacologically and therapeutically comparable active substances. Level 3 was introduced in 1992 and grouped medicines with a comparable therapeutic effect without restrictions on chemical similarity. Initially, levels 2 and 3 of the RPS covered patented medicines from the moment that the first patent for an active substance in the group had expired. Subsequently, newly-patented medicines were exempted from the RPS after 1996. The RP is calculated as a function of ex-factory prices, medicine dosage and package size, and the number of generic competitors. In 1998, an additional condition was imposed, specifying that the RP could not surpass the highest price in the bottom third of the price range for the homogeneous group.

3.2.3 Incentives for physicians

During the 1990s, Germany has experimented with different models of budgets at regional level and budgets at physician level. In 1993, regional budgets were introduced, the level of which was

determined by law from 1993 to 1995 and negotiated between regional sickness funds and physician associations thereafter. Although legislation called for any deficit on medicine budgets to be paid by physician associations, such collective sanctions were never executed. Despite an initial drop in medicine prescriptions in 1993, costs started to rise in 1994 and exceeded the medicine budget in a number of regions from 1995 onwards (Ess et al., 2003). There is also some evidence pointing to physicians increasing the number of referrals and hospital admissions following the introduction of budgets (Schoffski, 1996; von der Schulenburg, 1997).

In the late 1990s, regional budgets met with legal challenges. They were abolished in 1998, re-introduced in 1999 and discontinued again in 2001. From 1998 onwards, in practice, regional budgets were replaced by physician budgets based on practice-specific prescription targets. Physicians surpassing their individual target by more than 15% received written notice informing them to reconsider their prescribing practices. Physicians exceeding 125% of the medicine budget were required to refund the difference between the actual budget and 115% of the target budget in the absence of a justification for the budget deficit. Although this recourse procedure generally took years, it was successfully carried out in a number of regions (Schreyogg et al., 2004).

Physician budgets based on prescription targets were supported by feedback on prescribing behaviour. From 2000 onwards, data on regional prescribing practices were sent to each physician. Additionally, physicians received information about a three-monthly volume of prescriptions of their specialty group in the region and their individual prescription volume since 2003. Physicians can also draw on computerised prescribing to inform their prescribing behaviour. However, physicians are neither legally required nor stimulated to issue prescriptions by INN.

Both the RPS and physician budgets appear to have boosted the German generic medicines market during the 1990s: actual generic prescriptions as a percentage of potential generic prescriptions increased from 60% in 1992 to 75% in 2003 (Busse and Riesberg, 2004). However, no studies have been able to assess the separate effect of RPS and physician budgets on generic medicines prescription rates as these policy measures were introduced concomitantly.

Additionally, physicians and their patients accept and have confidence in generic medicines due to well-known company branding of generic medicines.

3.2.4 Incentives for pharmacists

Rules governing generic substitution by pharmacists have changed over time. Until 2001, physicians had to indicate on the prescription form that they allowed substitution. Since 2002, pharmacists were required to substitute and dispense lower-cost, equivalent medicines, unless the physician forbids it. In the case of a prescription by INN, the pharmacist must dispense one of the three cheapest medicines. If the physician issues a prescription for a specific medicine without excluding substitution, the pharmacist must dispense the prescribed medicine or one of the three cheapest alternatives provided that they have an identical dosage and package size, an interchangeable pharmaceutical form and same range of indications.

From 1980 to 2003, pharmacists were paid by regressive margins. However, as the regressive effect was restricted and the absolute size of the margin still increased with medicine prices, the delivery of generic medicines was penalised. Margins of pharmacists were reduced in 2002. From 2004 onwards, pharmacists are paid a fixed margin of 3% in addition to a flat-rate payment of 8.10 €. This remuneration system implies that pharmacists financially benefit from dispensing an originator medicine.

3.2.5 Incentives for patients

Patient co-payments are currently set as a percentage of the public price of medicines. No Government initiatives have been undertaken to inform patients of generic medicines.

3.3 Policy analysis

High medicine prices assist market entry of generic medicines. Regulation governing the establishment of RPs stimulates the German generic medicines market by facilitating market entry of generic medicines (higher prices are awarded in groups with fewer generic competitors). Furthermore, price competition is stimulated in established markets, but not to the extent that it becomes economically unviable for generic medicines companies to remain on the market.

Germany has incentives for physicians (physician budgets in combination with prescription targets and feedback on prescribing behaviour) that, as they are primarily geared towards containing costs, promote generic prescribing by physicians. The experience with regional budgets seems to suggest that rewards or sanctions are a necessary condition for making budgets effective. It also indicates that budgets may have unintended side effects. Budgets may provide an incentive for physicians to refer costly patients to hospital or may encourage the

selection of less risky patients if they do not take into account patient profiles or do not cover a comprehensive range of health care services. Significantly, there is a high rate of confidence and acceptance of generic medicines among both physicians and patients mainly due to well-known company branding of generic medicines.

Demand for generic medicines is supported by generic substitution by pharmacists. Furthermore, conditions governing substitution have been losened from physicians having to allow substitution to physicians opposed to substitution having to forbid it. The former incentive not to substitute has thereby been removed. However, pharmacists are financially penalised for dispensing generic medicines.

Key factors aiding the development of the generic medicines market:

- Market entry of generic medicines benefits from a RPS that sets higher RPs in medicine groups with fewer generic competitors and that stimulates price competition, but still makes it possible for generic medicines companies to earn profits
- Demand for generic medicines is driven by generic substitution by pharmacists and by physician budgets in combination with prescription targets and feedback on prescribing behaviour

Key factors hindering the development of the generic medicines market:

- Pharmacists are financially penalised for dispensing generic medicines

4 Netherlands

4.1 Generic medicines market

The Dutch generic medicines market has grown rapidly over time, with public expenditure increasing from 185 million € in 1994 (market share by value of 8.5%) to 830 million € in 2004 (market share of 17.7%). The fall in market share of generic medicines by value between 2003 and 2004 is likely to originate from a 2004 policy that substantially reduced prices of generic medicines. Market share of generic medicines by volume has more than doubled from 19.9% in 1994 to 44.3% in 2004.

Figure 3. Market share of generic medicines by value in the Netherlands, 1994-2004

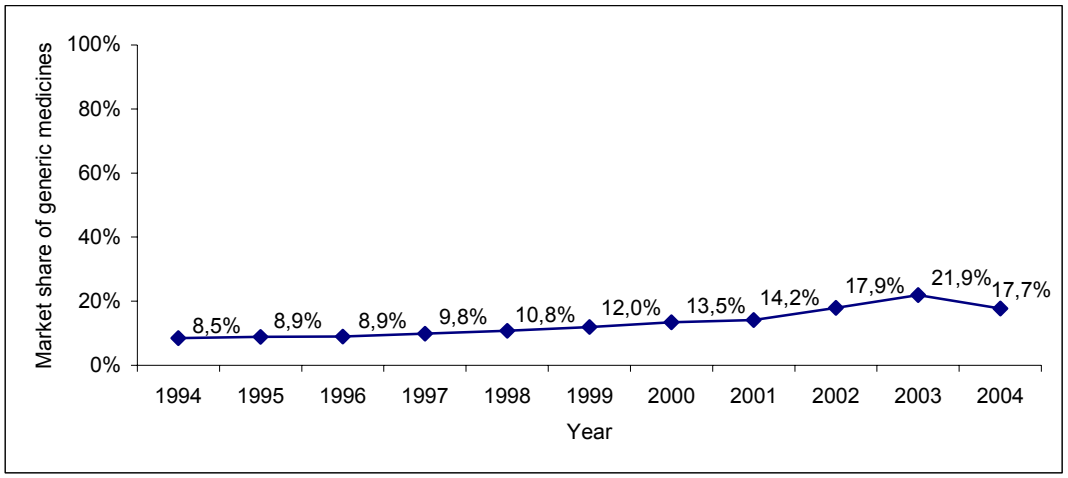
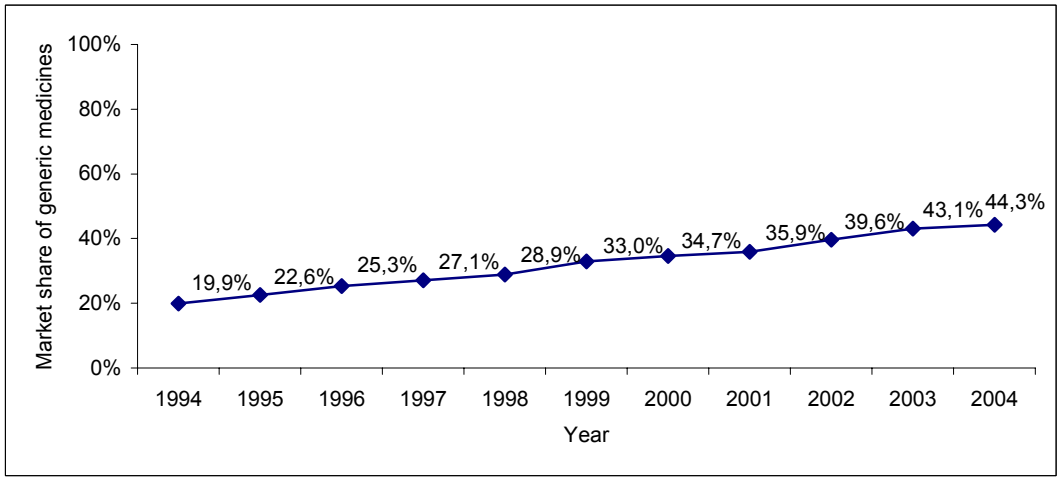


Figure 4. Market share of generic medicines by volume in the Netherlands, 1994-2004



4.2 Generic medicines policy

4.2.1 Pricing

The Netherlands enforced pricing regulation setting maximum prices of medicines in 1996. Companies that set prices above the maximum level are liable for criminal injunction. The maximum price is based on the average price of both originator and generic medicines having the same active substance, strength and dosage form in Belgium, France, Germany and the United Kingdom. In general, this led to a 15% fall in medicine prices (Danzon and Ketcham, 2003). However, the level of medicine prices still tended to be higher in the Netherlands as compared to other EU countries in the early 2000s (Koopmanschap and Rutten, 2003). Health insurance funds, pharmacists, generic medicines companies, and the Government agreed to reduce prices of generic medicines by 40% (including claw-back) on average in 2004. Medicine prices were at the average level of EU prices in 2005.

4.2.2 Reference pricing

In 1991, a RPS by therapeutic class was introduced. Irrespective of patent status, medicines with a comparable therapeutic effect were grouped if they had the same mechanism of action, a similar route of administration for treating the same indication in the same age group and a comparable clinical effect. For each active substance in a homogeneous group, the average price per defined daily dose of all originator and generic medicines with that active substance is calculated. The RP is then set as the median of the distribution across all active substances in the group.

The 1996 pricing regulation introduced maximum prices for many medicines below the level of RPs (Danzon and Ketcham, 2003). In 1999, RP levels were recalculated taking into account actual prices.

4.2.3 Incentives for physicians

Since 1995, the Dutch Government has stimulated physicians to prescribe by INN. This has been supported by the introduction of an electronic prescription system, although this system is not yet widely used.

The Netherlands has a tradition of developing and implementing prescribing guidelines and treatment protocols that promote the efficient use of medicines. Local pharmaco-therapeutic discussions take place periodically between GPs and community pharmacists to evaluate

medicine prescribing and dispensing, and formularies have been developed to rationalise prescribing practices. Information campaigns have urged physicians to use generic names rather than brand names. There are no sanctions for physicians who do not respond to these incentives.

A recent initiative by one health insurance fund is the introduction of a financial stimulus for the doctor if (s)he uses generic medicines more frequently. This initiative has been legally challenged by the originator medicine industry.

4.2.4 Incentives for pharmacists

Generic substitution by pharmacists is allowed if physicians and patients agree with it. Physicians can indicate on the prescription form that generic substitution is not permitted for medical reasons. When the physician prescribes a branded originator medicine that is out of patent and generic substitution is allowed, the pharmacist can dispense any generic medicine without reference to the physician. If the prescription is issued by INN, the pharmacist may dispense any originator or generic medicine. Health insurance funds have also agreed a target rate of generic substitution with pharmacists.

Pharmacists receive a fixed dispensing fee per prescription. This implies that the delivery of a generic or originator medicine is neutral from a financial perspective. As a consequence, it is in the interests of pharmacists to dispense the medicine with the highest profit margin. Two policy measures were introduced in the early 1990s that have a financial impact on pharmacist dispensing practices. First, if the pharmacist issues a medicine that is priced below the level of the RP, the pharmacist can retain one third of the price difference between the price of the medicine and the RP. Second, pharmacists can keep any discounts awarded by pharmaceutical companies since 1991. Pharmacists are thus able to retain 100% of discounts offered by wholesalers, but only 33% of the difference between the medicine price and the RP. This led to competition between companies through discounts to pharmacists rather than lower medicine prices. In fact, prices of several generic medicines were raised to the level of the RP (Brouwer and Rutten, 2002). Therefore, since 1998, a claw-back system imposed a mandatory reduction in pharmacists' reimbursement of 6.82% of medicine acquisition costs. This claw-back mechanism does not intend to fully recover discounts as discounts are seen by the Government as an instrument to remunerate pharmacists, obviating the need to increase the fixed dispensing fee.

4.2.5 Incentives for patients

In the Netherlands, patients don't have a financial incentive to buy generic medicines because there are no patient co-payments, except for the difference between the price of the medicine and the RP if the patient buys a medicine priced above the level of the RP. A specific policy measure targets three active substances (omeprazole, pravastatin and simvastatin). For these active substances, reimbursement is granted on the basis of the medicine with the lowest pharmacy acquisition cost plus a pharmacist margin. No campaigns to raise patient awareness of generic medicines have been run.

4.3 Policy analysis

The main driver of generic medicines use in the Netherlands is the financial attractiveness of generic substitution to pharmacists. A financial incentive and discounts awarded by pharmaceutical companies has encouraged pharmacists to dispense generic medicines. However, competition in the form of discounts to pharmacists rather than by price implies that health insurance funds do not fully benefit from the cost-saving potential of generic medicines. In response to this, a claw-back mechanism was introduced. This type of government intervention is unlikely to be as efficient as a market mechanism where pharmaceutical companies compete on the basis of prices rather than discounts to pharmacists.

Additionally, the Dutch generic medicines market is supported by the lower prices of generic medicines. The Government has provided a range of financial and non-financial incentives for physicians to prescribe generic medicines, but adherence to these incentives is voluntary. Health insurance funds have set generic substitution target rates in consultation with pharmacists.

Key factors aiding the development of the generic medicines market:

- The financial attractiveness of generic substitution by pharmacists sustains generic medicines use
- The generic medicines market is driven by the lower prices of generic medicines
- A range of financial and non-financial incentives for physicians support generic prescribing
- Health insurance funds have agreed generic substitution target rates in consultation with pharmacists

Key factors hindering the development of the generic medicines market:

- Patients have few incentives to buy generic medicines

5 Poland

5.1 Generic medicines market

Poland has a mature generic medicines market. Irrespective of expressing shares by value or by volume, market shares of generic medicines have fallen in the 1990s, but stabilized in the early 2000s. In 2004, market shares of generic medicines attained 60% by value and 85% by volume.

Figure 5. Market share of generic medicines by value in Poland, 1994-2004

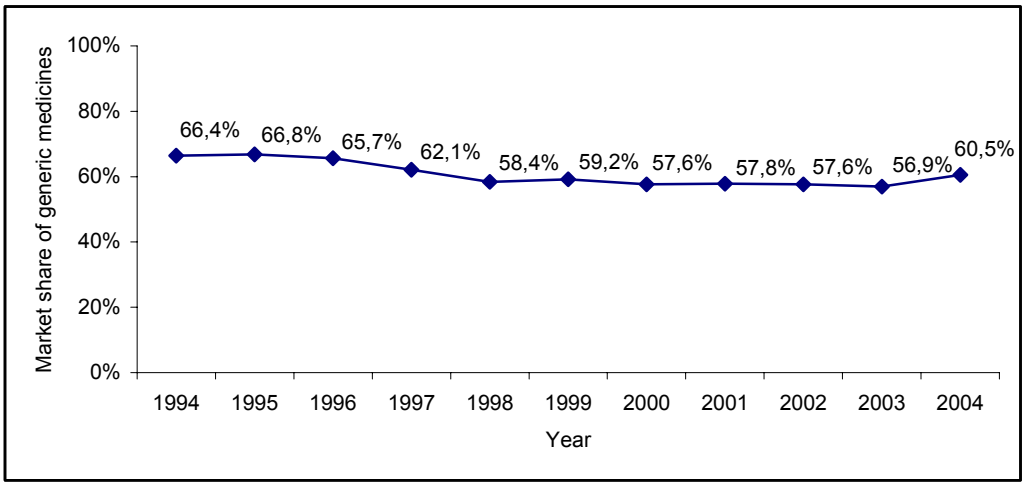
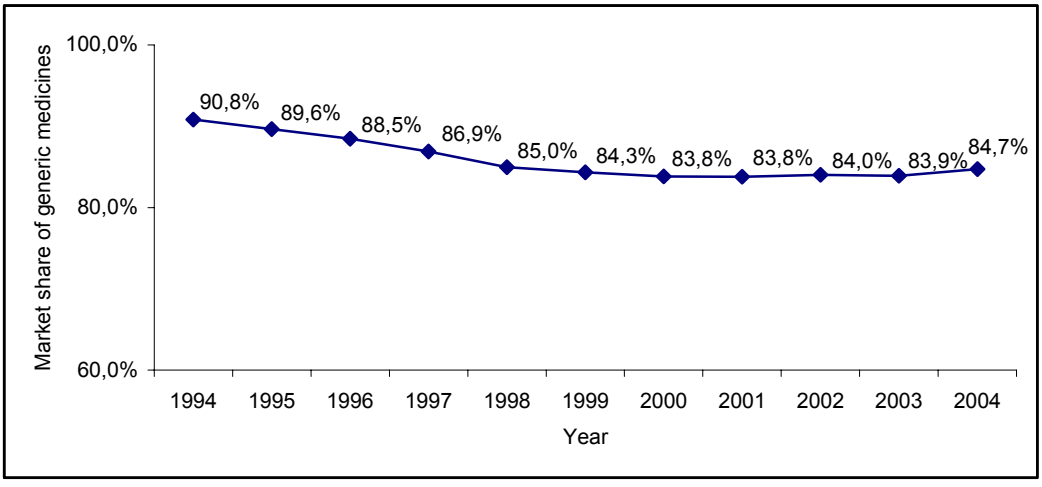


Figure 6. Market share of generic medicines by volume in Poland, 1994-2004



5.2 Generic medicines policy

5.2.1 Intellectual property rights

As in many Central and Eastern European countries, prescription of generic medicines is common practice due to the limited availability of originator medicines in ambulatory care prior to the end of communism in 1989 and due to the absence of product patents until the early 1990s. The Polish generic medicines market benefited from regulation imposing a three-year data exclusivity period until EU accession of Poland. During the data exclusivity period, the application for marketing authorisation for a generic medicine cannot refer to the pre-clinical and clinical documentation of the originator medicine. As the Polish data exclusivity period was shorter than the 6-10 years of data exclusivity granted in the EU at that time, this served to speed up entry of generic medicines into the Polish market.

In recent years, there has been a significant increase in the market share of imported originator medicines (Krumschmidt, 2006). Furthermore, the introduction of Supplementary Protection Certificates for all patented medicines registered in Poland since 2000 can be expected to reduce generic medicines market shares in future years.

5.2.2 Pricing

Polish medicine prices tend to be lower than those in other EU countries (Pharmacos, 2005). Poland operates a price-regulated system for medicines that wish to be entered on the reimbursement list.

5.2.3 Reference pricing

Poland runs two RPS in parallel, one by active substance and the other by pharmacological class. The RP is set below or equal to the price of the cheapest generic medicine.

5.2.4 Incentives for physicians

Prescribing of branded and unbranded generic medicines is common because physicians have long-term, positive experience with generic medicines and because they are conscious of the limited ability of patients to meet co-payments. Physicians are not encouraged to prescribe by INN and they are not assisted in generic prescribing.

5.2.5 Incentives for pharmacists

Generic substitution by pharmacists is allowed. In the case of the prescription of a branded generic medicine, the pharmacist can dispense any generic medicine. If the physician prescribes by INN, the pharmacist may deliver any originator or generic medicine. Pharmacists are required to inform patients of the availability of cheaper generic medicines and of generic substitution. Generic substitution by pharmacists is conditional on physicians not forbidding substitution.

Until the mid-1990s, pharmacists earned a margin of 33% on local medicines and 25% on imported medicines irrespective of whether this concerned originator or generic medicines. Since 1995, pharmacist margins are regressive, but this did not completely remove the financial incentive to dispense originator medicines. Discounts awarded by pharmaceutical companies encourage pharmacists to dispense generic medicines.

5.2.6 Incentives for patients

Four rates of patient co-payment apply depending on therapeutic class and patient characteristics. Patient co-payment consists of a fixed amount per prescription for essential medicines (list 1). Supplementary medicines are subject to a patient co-payment of 30% (list 2) or 50% (list 3). Other prescription medicines that are not included in the reimbursement lists as well as over-the-counter medicines are fully paid for by the patient. Initiatives to inform patients of generic medicines have not been undertaken.

5.3 Policy analysis

The development of the Polish generic medicines market has benefited from the limited availability of originator medicines and a short data exclusivity period. Setting the RP at the price of the cheapest generic medicine in combination with the low level of medicine prices in Poland would be expected to keep down profitability of generic medicines. However, the economic viability of the Polish generic medicines market derives from the fact that it is a high-volume market as a result of the positive attitude of physicians towards generic medicines and the high level of patient co-payments.

The absence of incentives for physicians to prescribe generic medicines inhibits the further development of the market. Pharmacists are financially penalised for dispensing generic medicines, except for discounts awarded by pharmaceutical companies.

Key factors aiding the development of the generic medicines market:

- The economic viability of the generic medicines market originates from low prices and high volume of consumption
- Setting the RP at the level of the cheapest generic medicine has led to low prices of generic medicines
- The high volume of consumption derives from the positive experience of physicians with generic medicines and the high level of patient co-payments

Key factors hindering the development of the generic medicines market:

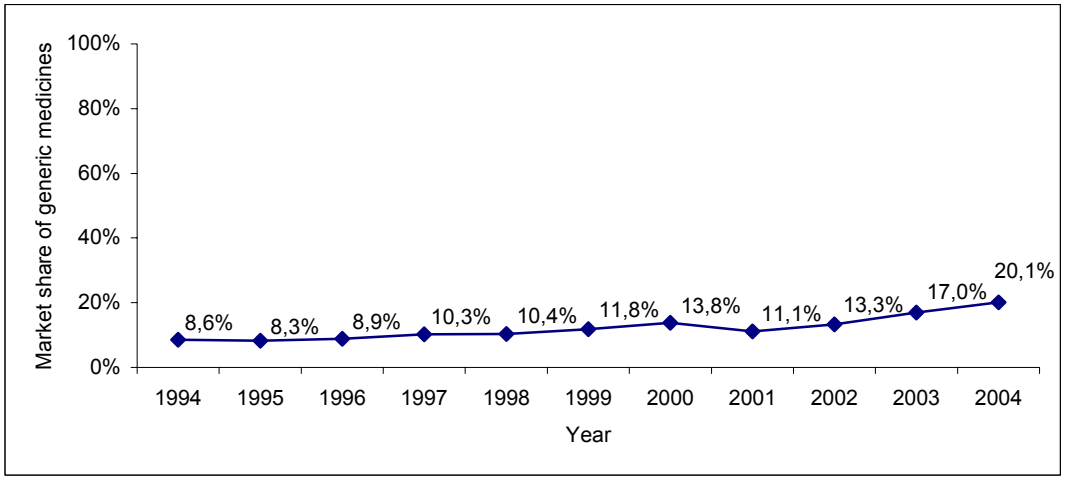
- Physicians have no incentives to prescribe generic medicines
- Pharmacists are financially penalised for dispensing generic medicines

6 United Kingdom

6.1 Generic medicines market

The market share of generic medicines has more than doubled over a decade in the United Kingdom. Public expenditure on generic medicines rose from 655 million € in 1994 (market share by value of 8.6%) to 3,625 million € in 2004 (market share of 20.1%).

Figure 7. Market share of generic medicines by value in the United Kingdom, 1994-2004



Data on generic medicines market share by volume are not reported due to incompatibility of IMS Health and EGA definitions of generic medicines.

6.2 Generic medicines policy

6.2.1 Pricing

Regulation of originator medicine prices is governed by the Pharmaceutical Price Regulation Scheme. This voluntary scheme between the British Pharmaceutical Industry and the Department of Health does not control prices directly. Instead, pharmaceutical companies strike an agreement enabling them to gain a specific return on capital which is set equal to profits from sales to the NHS minus allowable costs. Companies are free to set launch prices of new medicines as long as they do not systematically exceed the target rate of return on capital. This system has led to medicine prices in the United Kingdom being higher than in other EU countries (Burstall, 1997).

The Pharmaceutical Price Regulation Scheme does not apply to generic medicines and companies are free to set prices of generic medicines. This system led to price competition between generic medicines and falling prices for those medicines supplied by multiple companies

in the late 1990s. For drugs in short supply, price increases were observed in 1999 (Kay and Baines, 2000). In response to this, the Government introduced a statutory price ceiling for the main generic medicines in 2000.

A new pricing system for Category M generic medicines came into effect in 2005 which allows freedom of pricing. It also incorporates an additional measure to stimulate price competition between generic medicines by enabling the Department of Health to intervene in the marketplace if trends in medicine expenditure suggest that market mechanisms have failed to create price competition. To date, the Department of Health has not availed itself of this measure.

6.2.2 Reference pricing

The United Kingdom does not have a RPS.

6.2.3 Incentives for physicians

A principal factor in stimulating generic medicines use has been the fact that medical students are taught to prescribe by INN in British medical schools. In 2004, 79% of all prescription items were prescribed by INN in England (Health and Social Care Information Centre, 2005).

The United Kingdom has used medicine budgets to control pharmaceutical expenditure and to incite generic prescribing by GPs. Initially, medicine budgets were set at the level of the general practice under the fundholding scheme which ran from 1991 to 1997. Although budgets for GPs who did not become fundholders were indicative only, prescribing behaviour was controlled by peer pressure and the threat of sanctions for GPs who overspent. Fundholding practices held an actual budget not only for medicines, but also for outpatient care, diagnostic testing, elective surgery and community care. Savings on the budget could be reinvested in patient care or could be used to upgrade premises and practice-based facilities. Reviewing the fundholding experience, Gosden and Torgerson (1997) concluded that medicine costs of fundholding practices had increased at a lower rate as a consequence of increased generic prescribing than those of non-fundholders. However, as fundholding practices had different characteristics than non-fundholders, this effect may have stemmed from selection bias rather than from fundholding.

Budgets have also been set for groups of general practices as for example in the case of GP and locality commissioning groups, total purchasing pilots and, more recently, primary care trusts. A review of the first three years of operation of a sample of primary care trusts showed that many trusts had set generic prescribing targets supported by incentive schemes, prescribing guidelines

and formularies, and guidance issued through the National Institute of Clinical Excellence, the Royal Colleges and National Service Frameworks (Wilkin et al., 1999, 2001 and 2002).

Generic prescribing by GPs has been supported by computer programmes such as PRODIGY (PRescribing ratiOnally with Decision support In General practice studY) which indicates generic alternatives to the GP. Preliminary findings pointed to a 3.2% increase in generic prescribing following the introduction of PRODIGY (Purves, 1996).

6.2.4 Incentives for pharmacists

Generic substitution by pharmacists is not permitted. Pharmacists earn a fixed fee per prescription item for a minority of medicines and the difference between NHS reimbursement (so-called 'Drug Tariff') and the purchase price. In the case of an INN prescription, the reimbursement level is listed in Part VIII of the Drug Tariff and depends on the category in which a medicine is placed. Category A consists of generic medicines that are readily available. The corresponding Drug tariff is calculated as the average price charged by two major wholesalers and three companies. Drug Tariff reimbursement levels tend to be well below the price level of originator medicines. Therefore, pharmacists generally fill INN prescriptions with generic medicines and increase their income by dispensing generic medicines that offer discounts.

In response to this, companies of originator medicines compiled a 'brand equalisation formulary', a list consisting of originator medicines that may be substituted for INN prescriptions. This enables companies to sell originator medicines at Drug Tariff level that otherwise would have led to the dispensing of a generic medicine. In addition, pharmacists receive a discount, which appears to be attractive enough to pharmacists to not dispense a generic medicine.

As competition in the generic medicines market takes the form of discounts to pharmacists and the NHS does not fully benefit from the cost-saving potential of generic medicines, a claw-back system was introduced that aims to recover the discounts that pharmacists receive. However, a study of the United Kingdom generic medicines market estimated that a significant portion of discounts is not recouped by the NHS (Senior et al., 2000). To reduce NHS reimbursement, a new category M of generic medicines was added to Part VIII of the Drug Tariff in 2005 which includes some medicines previously in Category A. The reimbursement level for Category M medicines is set at a volume-weighted, average price charged by pharmaceutical companies net of discounts.

6.2.5 Incentives for patients

Patient co-payment consists of a fixed fee per prescription item for a minority of medicines. The Government has attempted to inform patients of generic medicines through leaflets.

6.3 Policy analysis

Regulation governing profits rather than prices of medicines has led to high medicine prices and stimulated market entry of generic medicines.

The economic viability of the generic medicines market derives from low prices and high volume of generic medicines use. The United Kingdom has moved away from a reimbursement system that rewarded pharmacists for seeking discounts to a system that determines reimbursement in relation to market prices. This creates the conditions for a competitive generic medicines market that has low prices, is transparent, rewards companies that attain efficiency gains, and enables the NHS to capture the cost-saving potential of generic medicines.

The high volume of generic medicines sales originates from strong incentives for physicians to prescribe generic medicines. INN prescribing is common practice, even for patented medicines. Budgetary incentives at the level of individual general practices and groups of practices have encouraged generic prescribing by GPs. Generic prescribing is further supported by the installation of software packages in general practice. However, demand is inhibited by the lack of incentives for patients to buy generic medicines.

Key factors aiding the development of the generic medicines market:

- Generic medicines companies compete with each other on price, enabling the NHS to capture the cost-saving potential of generic medicines
- Medical students are taught to prescribe by INN and INN prescribing by physicians is common practice
- Generic prescribing has been stimulated by setting physician budgets in combination with generic medicines prescribing targets, incentive schemes, and prescribing guidelines

Key factors hindering the development of the generic medicines market:

- Patients have no incentives to buy generic medicines

PART II

GENERIC MEDICINES POLICY IN COUNTRIES WITH DEVELOPING MARKETS

7 Austria

7.1 Generic medicines market

In the context of a generic medicines policy that consists of some supply-side measures, but no demand-side measures, the Austrian generic medicines market has developed slowly over the years. Market share of generic medicines has grown from 5.5% in 1994 to 8.8% in 2004 in terms of value of consumption and from 9.2% in 1994 to 15.8% in 2004 in terms of volume of consumption.

Figure 8. Market share of generic medicines by value in Austria, 1994-2004

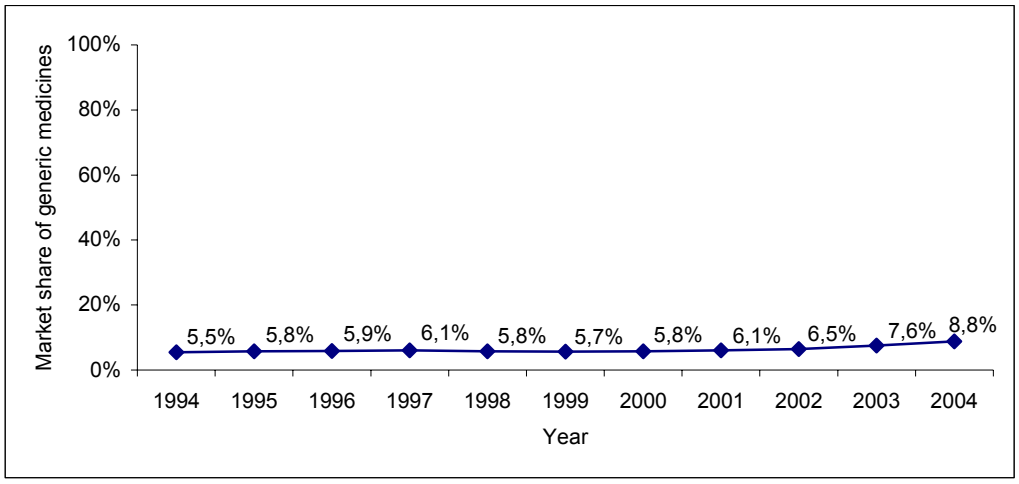
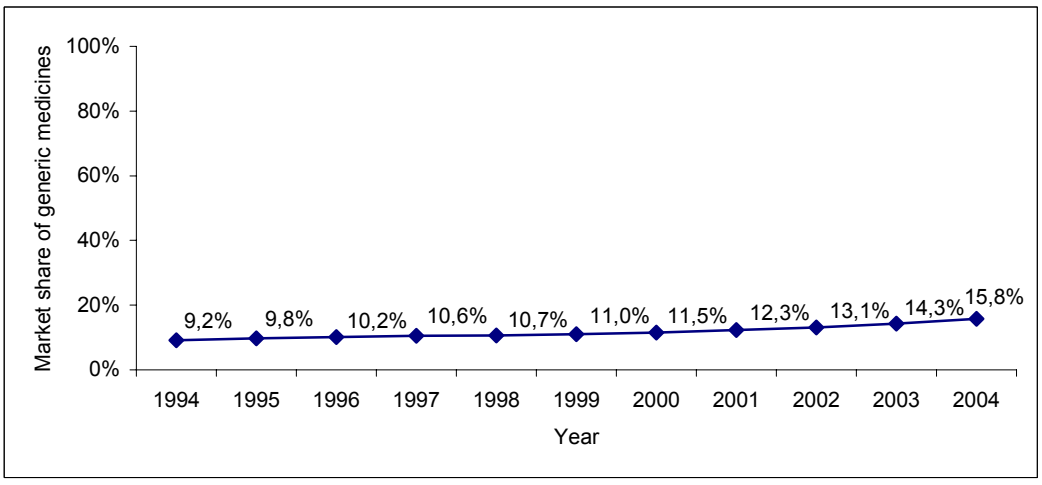


Figure 9. Market share of generic medicines by volume in Austria, 1994-2004



7.2 Generic medicines policy

7.2.1 Pricing

The Austrian medicine market is characterised by low prices (Pharmig, 2002). In the 1990s, generic medicines were included in the social insurance fund's approved list of reimbursed medicines if they were priced at least 30% lower than the originator medicine. This was followed by a demand to reduce the price of the originator medicine by 23%. This means that generic medicines tended to be around 7%-10% cheaper than originator medicines.

In 2004, a new pharmaceutical pricing policy came into force, with medicine prices based on average prices of some EU countries. Furthermore, prices of generic medicines and originator medicines that are off-patent were regulated as follows. The first generic medicine is priced 44% in 2004, 46% in 2005, and 48% from 2006 onwards below the price level of the originator medicine. The price of the originator medicine needs to decrease by 30% three months after entry of the first generic medicine. The price of the second generic medicine is 15% below the price level of the first generic and the third generic medicine is priced 10% below the level of the second generic medicine. Additionally, the prices of the originator, first and second generic medicines need to go down to the price level of the third generic medicine not later than three months following the market entry of the third generic medicine. The fourth and any subsequent generic medicine needs to be at least 0.10 € cheaper than the least expensive generic medicine.

7.2.2 Reference pricing

Austria does not have a RPS.

7.2.3 Incentives for physicians

Physicians who have a contract with a social insurance fund need to observe guidelines on the cost-effective prescribing of medicines. Adherence to guidelines is monitored by social insurance funds by comparing prescription rates among peers. Failure to comply with guidelines may result in a reprimand, obligation to refund the social insurance fund or loss of contract with the fund. Physician generic prescribing targets have been successfully implemented in Vienna, but have not been extended to other provinces. There is no legal obligation or encouragement for physicians to prescribe by INN. However, the hospital discharge letter points out that physicians can prescribe a generic medicine. Physicians are assisted in their prescribing by computerised prescribing and a medicine database.

7.2.4 Incentives for pharmacists

Generic substitution by pharmacists is not permitted by law. In practice, the pharmacist can substitute a branded originator medicine that is out of patent or a branded generic medicine by any generic medicine with reference to the physician.

Austria has in place a system of regressive pharmacist margins, with pharmacy margins for medicines purchased by insured patients ranging from 27% for pharmacy purchase prices less than 10 € to 3.8% for prices above 357.08 € from 2004 onwards. However, pharmacists still earn a lower margin on generic medicines in absolute terms than on originator medicines.

7.2.5 Incentives for patients

Patients usually have to pay a fixed fee per prescription (4.6 €) for each prescribed medicine included in the reimbursement list. In some cases, two packs can be prescribed for a single fee. For medicines not included in the reimbursement list, patients have to pay the full price, unless the prescription is permitted by a senior consultant of the social insurance fund. Exemption from co-payment is also granted to patients in need of social protection and patients whose income does not surpass a specific level.

7.3 Policy analysis

In the 1990s, pricing regulation has restricted demand for generic medicines by reducing prices of originator medicines, leading to a small price differential between generic and originator medicines. Added to that, low price levels of medicines in Austria limited market entry for generic medicines.

The 2004 pharmaceutical pricing policy is designed to contain public pharmaceutical expenditure by reducing prices of originator and generic medicines. Incentives embodied by the pricing policy for generic medicines are mixed. On the one hand, this policy stimulates market entry of generic medicines by enforcing a substantial price difference between the originator medicine and the first three generic medicines for a limited period of time. On the other hand, the policy imposes price reductions on successive generic medicines entering the market, thereby reducing their profitability. Furthermore, price differences between originator and generic medicines are non-existent or limited in established markets with three or more generic medicines, respectively. This is likely to inhibit patient demand for generic medicines.

The role that several stakeholders can play in developing the Austrian generic medicines market has been ignored to date. Few incentives exist for physicians to prescribe generic medicines. Generic substitution by pharmacists is not allowed and pharmacists are financially penalised for dispensing generic medicines. There are no incentives for patients to demand generic medicines.

Key factors hindering the development of the generic medicines market:

- In the 1990s, the Austrian generic medicines market suffered from the low level of medicine prices, reductions in the price level of originator medicines, and limited price differences between originator and generic medicines
- Few incentives exist for physicians to prescribe generic medicines
- Pharmacists are financially penalised for dispensing generic medicines

Key factors aiding the development of the generic medicines market:

- Since 2004, substantial price differences between originator and generic medicines in developing markets stimulate market entry

8 Belgium

8.1 Generic medicines market

Belgium had a small generic medicines market during the second half of the 1990s. Its development was boosted by the introduction of a generic medicines policy in 2001. Public expenditure on generic medicines rose from 18 million € in 1994 (market share by value of 0.8%) to 213 million € in 2004 (market share of 4.8%). Market share of generic medicines by volume nearly quadrupled from 2.2% in 1994 to 8.0% in 2004.

Figure 10. Market share of generic medicines by value in Belgium, 1994-2004

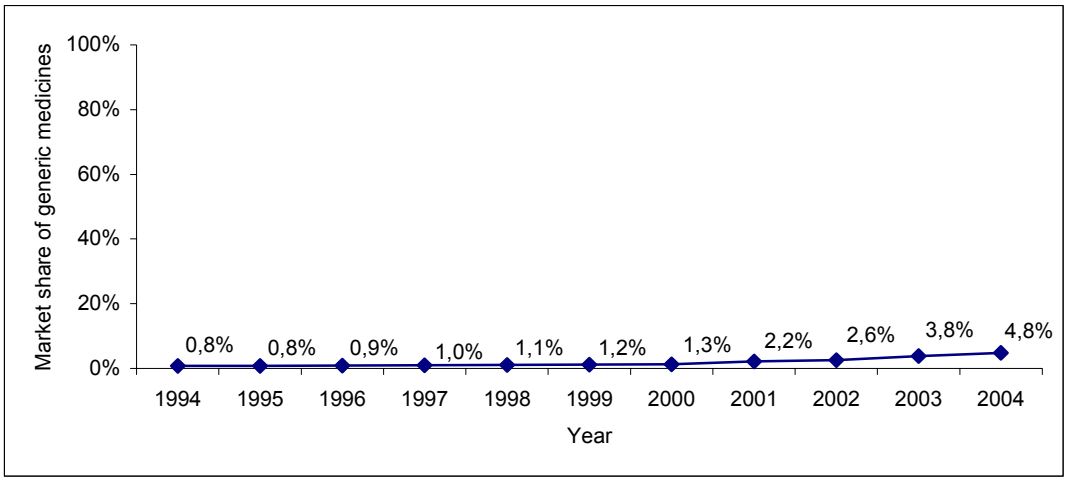
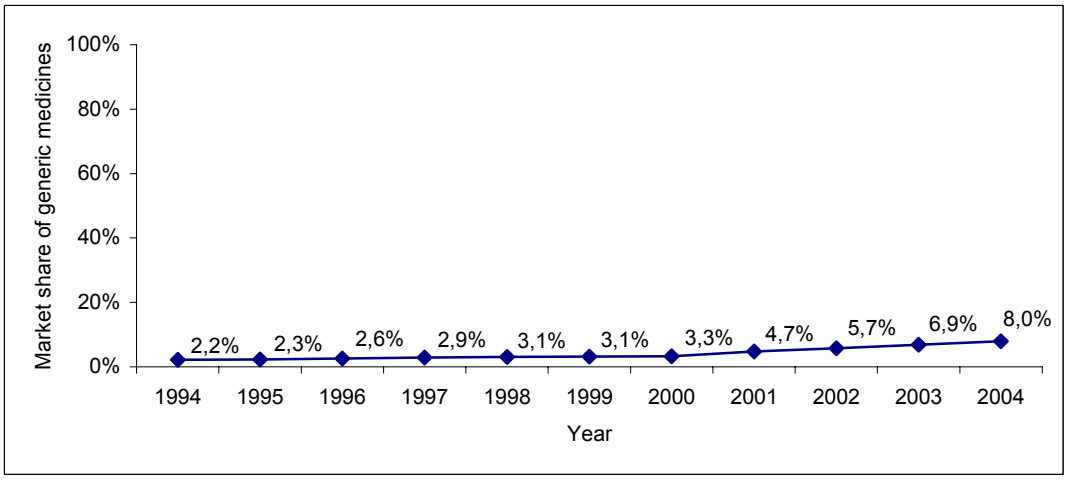


Figure 11. Market share of generic medicines by volume in Belgium, 1994-2004



8.2 Generic medicines policy

8.2.1 Pricing

Generic medicines need to be priced at or below the level of the RP in order to qualify for reimbursement.

In 2006, a policy measure reduces turnover of pharmaceutical companies by 2%. This reduction can be accomplished by a 2% price decrease of medicines. Alternatively, companies can choose to reduce the price of specific medicines by a minimum of 4% in order to achieve a total fall in turnover of 2%.

8.2.2 Reference pricing

A RPS by active substance was implemented in June 2001. Over time, the Belgian Government has progressively reduced the RP from 84% (until July 2002), 80% (until January 2003) to 74% of the price of the originator medicine (until July 2005). The current level stands at 70% of the price of the originator medicine. The RPS was associated with an increased market share of generic medicines (Simoens et al., 2005). The RPS was enlarged in 2005 to include all pharmaceutical forms and dosages of the same active substance. Additionally, the law offers the possibility to set a RP for a class of medicines with a similar therapeutic indication. If prices of originator medicines fall under the 2006 pricing policy, the corresponding RPs decreases as well.

8.2.3 Incentives for physicians

Physicians face some incentives that aim to promote generic prescribing. Prescribing guidelines exist that provide comparative information about, amongst other things, costs of medicines in a number of therapeutic classes. There are no incentives for physicians to prescribe the most efficient medicine and physicians do not have to adhere to these guidelines.

Pharmanet is an information system that was created in 1996 and that collects data on prescriptions for reimbursed medicines in ambulatory care. From late 1998 onwards, each individual GP received periodic updates of his/her individual medicine prescription profile from Pharmanet. This tool purported to improve prescribing behaviour through peer pressure. Prescription profiles were discussed and compared in local peer review groups, with physician accreditation depending on their participation in such groups. Although penalties were attached for physicians who do not prescribe appropriately, such penalties have never been imposed in practice.

In 2005, a regulatory framework governing INN prescribing was introduced. This makes it possible, but not compulsory, for physicians to prescribe by INN.

In 2006, quotas for prescribing low-cost medicines – generic medicines or originator medicines that have reduced their price – are assigned to physicians. Pharmanet data are used to check whether physicians comply with quotas. If physicians prescribe expensive medicines inappropriately, they are monitored by the Ministry of Health for at least six months and receive information and training in low-cost prescribing.

8.2.4 Incentives for pharmacists

A law permitting generic substitution by pharmacists conditional on getting approval from the prescribing physician and patient was passed in 1993. However, as the royal decree necessary to put this legislation into practice has not been passed to date, generic substitution by pharmacists is not allowed.

If the physician prescribes by INN, the pharmacist can dispense an originator medicine or any generic medicine priced at or below the level of the RP in consultation with the patient. If this option does not exist, the pharmacist can dispense an originator medicine priced above the level of the RP. Failing this second option, the pharmacist can deliver an originator medicine not included in the RPS. The choice of medicine by the pharmacist is inspired in the first instance, by the therapeutic interests and continuity of care of the patient; and in the second instance, by the price of the medicine.

Pharmacist margins in Belgium are set at a specific percentage of the public price of medicines (a maximum of 31%, with a limit on the absolute amount of 7.44 €). This system did not favour generic medicines as pharmacists received less in absolute terms when delivering a generic medicine. To make sure that pharmacists were not financially penalised for delivering generic medicines, pharmacists' profits on generic medicines were set equal to their profits on originator medicines in absolute terms in 2001. The delivery of generic medicines is therefore neutral to pharmacists from a financial perspective. Even though discounts to pharmacists and other commercial practices do not violate pharmaceutical legislation, questions remain over the legality of discounting in Belgium.

8.2.5 Incentives for patients

Patient co-payments range from 0% to 80% of the medicine price depending on the type of patient and medicine. Belgian policy attempts to foster demand for generic medicines by increasing patient co-payment for specific medicine classes. Maximum patient co-payment on a range of not-life-saving medicines for which the ATC4 class contains a generic medicine increased at the end of 2005.

In 2004, the Government launched an information campaign to increase patient awareness of generic medicines. However, the campaign was short-lived and had limited exposure, so that its impact is likely to have been limited.

8.3 Policy analysis

Although the introduction of the RPS was accompanied by an increase in generic market share, regulation governing the establishment of the RP appears to be guided by a concern to contain pharmaceutical expenditure, ignoring the negative impact of successive reductions in the level of RPs on the economic viability of generic medicines to enter and remain on the market.

The 2006 pricing policy may produce a negative pricing spiral where original medicines reduce their prices and corresponding RPs fall as well. As generic medicines need to be priced at or below the level of the RP, the prices of generic medicines need to fall as well. Hypothetically, companies could choose a few market segments where they reduce the price of originator medicines by a substantial proportion in order to attain the 2% reduction in turnover. Generic medicines, which need to be at least 30% cheaper than the reduced price of the originator medicine, could be priced out of the market.

Physicians face few incentives to prescribe generic medicines and incentives tend to be weak. Furthermore, some features of the INN prescribing policy are likely to restrict its impact on sustaining generic medicines use. First, physicians do not tend to be in favour of INN prescribing as this allows pharmacists to decide which medicine to dispense. Second, pharmacists can continue to dispense the originator medicine if this is considered to be in the therapeutic interests of the patient. Third, the patient needs to agree with a switch from an originator to a generic medicine.

Belgian policy makers have removed the financial disincentive for pharmacists to dispense generic medicines. Dispensing an originator or generic medicine is now neutral to pharmacists

from a financial perspective. However, generic substitution by pharmacists is not allowed in practice. Furthermore, the impact of the guarantee of pharmacists' absolute margins on the development of the generic medicines market needs to be analysed in conjunction with the RPS. On the one hand, the reduction in RPs over time translates into decreased public prices of generic medicines. On the other hand, pharmacist margins on generic medicines are guaranteed in absolute terms. This puts pressure on pharmaceutical companies to reduce ex-factory price levels and may jeopardise entry and survival of generic medicines.

Key factors hindering the development of the generic medicines market:

- Successive reductions of the RP and the guarantee of absolute pharmacist margins threaten the economic viability of the generic medicines market
- Physicians have few incentives to prescribe generic medicines
- There are no incentives for pharmacists to dispense generic medicines

Key factors aiding the development of the generic medicines market:

- Generic medicines use has been stimulated by the introduction of a RPS

9 France

9.1 Generic medicines market

France had an undeveloped generic medicines market during the second half of the 1990s. This changed with the introduction of incentives for physicians and pharmacists in the early 2000s. Market share of generic medicines has grown from 0.9% in 1994 to 6.6% in 2004 in terms of value of consumption and from 1.8% in 1994 to 10.4% in 2004 in terms of volume of consumption.

Figure 12. Market share of generic medicines by value in France, 1994-2004

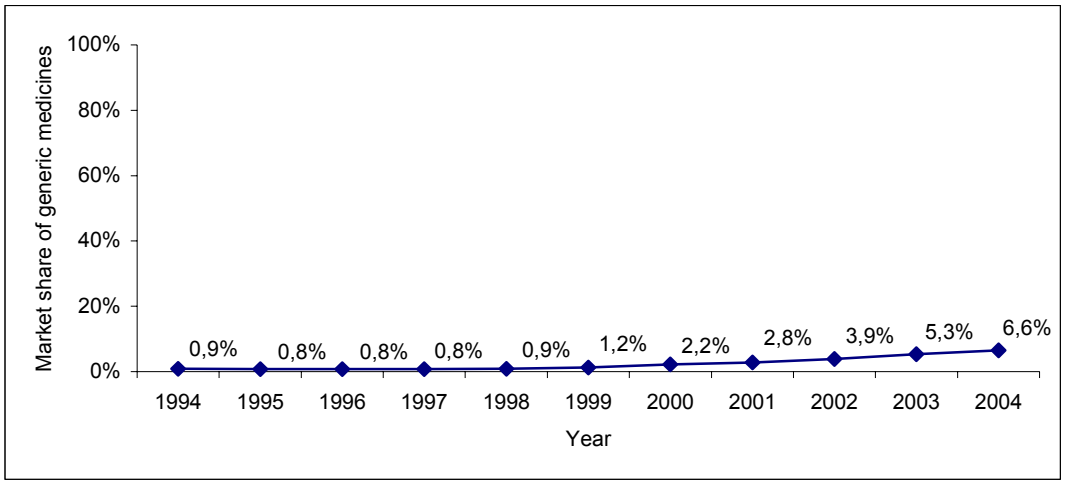
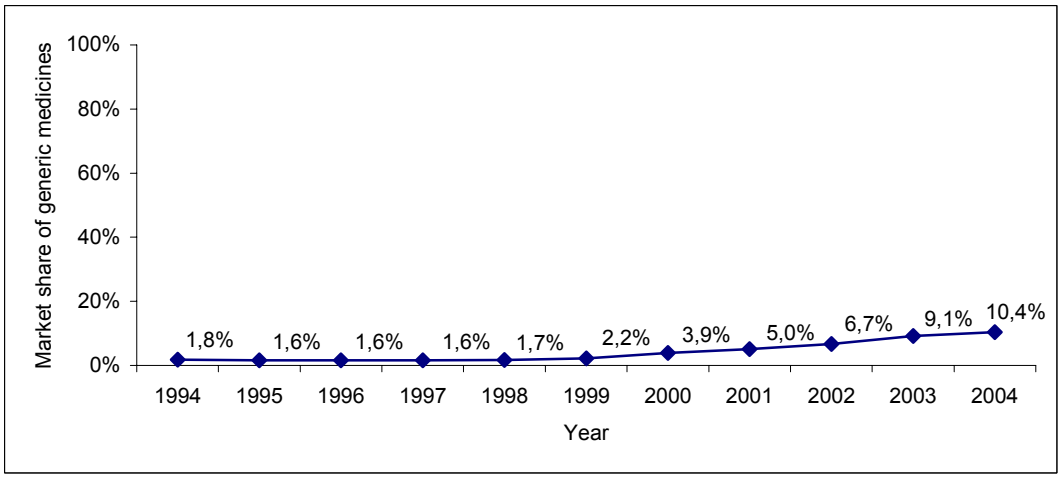


Figure 13. Market share of generic medicines by volume in France, 1994-2004



9.2 Generic medicines policy

9.2.1 Intellectual property rights

To compensate for the delay between the date of filing the patent application and the date of marketing authorisation of the medicine, patent protection could be extended by up to seven years. This legislation was introduced in France in 1990, three years before the implementation of the EU Supplementary Protection Certificate for a maximum period of five years in 1993. The concept of a 'generic medicine' has only been defined as recently as 1997.

9.2.2 Pricing

Medicine prices in France tend to be lower than in other EU countries (Le Pen, 2003). Generic medicines need to be at least 30% cheaper than the originator medicine. In 2005, the Government imposed an additional price cut of 10% on existing generic medicines and the price of new generic medicines was set at 40% below the price level of the originator medicine. The minimum price difference between originator and generic medicines increases to 50% in 2006. Additionally, prices of off-patent medicines are reduced by 15%-19% in 2006.

9.2.3 Reference pricing

A RPS by active substance was launched for those active substances with generic medicine substitution rates of less than 45% in 2003. The average price of generic medicines determines the RP. Following the implementation of the RPS, the price of 65% of originator medicines dropped to the level of the RP (Peny, 2005). Furthermore, as reference groups are organized by active substance, re-allocation of demand away from a RPS group to patented medicines with a similar therapeutic indication seems to have occurred (Le Pen, 2005).

9.2.4 Incentives for physicians

In France, physicians have tended to be reluctant to prescribe generic medicines because they value their prescribing freedom, are visited by originator medicine companies, and are used to prescribing brand-name medicines (Blachier and Kanavos, 2005).

Physicians face some incentives to prescribe generic medicines:

- Clinical guidelines have been implemented, but no sanctions have been imposed on non-compliance with guidelines (Durieux et al., 2000).

- Physicians have been allowed to prescribe by INN since 2002. An agreement was struck with physicians' unions that raised physician fees for patient visits by 5 € in exchange for writing at least 25% of prescriptions by INN. No specific penalties for failure to adhere to this agreement were specified (Le Pen, 2003). INN prescribing has not been successful to date, with an INN prescription rate of around 7% in the year leading up to May 2005 (Mutualité Française, 2006).

- Patients have a financial incentive to register with a gatekeeping GP who determines access to specialist services. As they aim to provide efficient health care services, gatekeeping GPs may generate savings by prescribing generic medicines.

- Physicians are contacted by local authorities with a view to encouraging generic prescribing.

- Physicians are assisted in their prescribing behaviour by a quarterly medicine database published by the Social Security.

- Restrictions are placed on the number of visits that originator medicine companies can make to physicians for specific categories of brand-name medicines in 2006.

9.2.5 Incentives for pharmacists

In 1999, legislation was approved that allows pharmacists to substitute generic for originator medicines, unless the prescribing physician specifically prohibits substitution. In the case of substitution, the pharmacist is obliged to inform the patient who can refuse substitution. When the physician prescribes a branded originator medicine that is out of patent or a branded generic medicine, the pharmacist can dispense any generic medicine without reference to the physician. If the prescription is issued by INN, the pharmacist may dispense any generic medicine. In 2006, the Government has set an objective of attaining a generic substitution rate of 70%.

Until 1999, pharmacists were paid by means of a regressive margin on public prices of medicines, thereby restricting the development of the generic medicines market. Since 1999, pharmacist remuneration consists of a fixed sum of 0.53 € per prescription item and a sliding scale margin (26.1% of the amount of the ex-factory price excluding VAT below 23 € and 10% of the amount above 23 €).

To make the dispensing of generic medicines neutral from a financial perspective, pharmacists are guaranteed the same absolute margin in euros on generic and originator medicines if a 35% substitution rate between generic and originator medicines is attained. If this target rate is not achieved, pharmacists' compensation is supposed to be reduced, although this has never actually happened.

A financial incentive to dispense generic medicines has been created with pharmacists being entitled to receive discounts of up to 10.74% of the ex-factory price for generic medicines as compared with 2.5% for originator medicines. In practice, these discount ceilings were not adhered to. In 2004, estimates of discounts awarded to pharmacists amounted to 45% for generic medicines and 6% for originator medicines (Peny, 2005). Consequently, pharmacists are included in the Jacob law which regulates discounts awarded in the distribution chain to a maximum of 20% in 2006 and 15% in 2007.

9.2.6 Incentives for patients

Patient co-payment consists of a fixed amount per prescription and a proportion of the public price which varies according to the type of medicine. Patient co-payments are generally covered by an additional private insurance taken out by the patient.

In 2005, patients suffering from a chronic illness and who regularly take an originator medicine were contacted by the third-party payer to inform them of the existence of a generic equivalent. In a first instance, patients were sent a personalized letter. If consumption patterns did not change, patients received a telephone call in the second instance. This policy measure follows experiments indicating that nearly half of patients started using a generic medicine after they had been contacted (Medical Insurance, 2005).

9.3 Policy analysis

The growth of the French generic medicines market has been slowed down by the existence of legislation regulating medicine patent extension.

The fact that medicine prices in France tend to be lower than in other EU countries in combination with the requirement that generic medicines need to be at least 30% cheaper than the originator medicine inhibits generic medicine entry. Pressure on generic medicines prices increased as a result of the introduction of additional price cuts in 2005 and 2006.

The implementation of the RPS has been accompanied by price reductions of originator medicines, thereby removing the competitive price advantage of generic medicines. Also, there is some evidence of re-allocation of demand towards patented medicines with a similar therapeutic indication.

The development of the French generic medicines market has been inhibited by the lack of incentives facing physicians and patients to demand generic medicines. Physicians traditionally tend to prescribe brand-name, originator medicines and incentives to prescribe generic medicines are limited. Patients have no financial incentive to demand generic medicines as they have to pay nothing or a small percentage of already low-priced medicines.

The generic medicines market has been driven by generic substitution which is financially attractive to pharmacists as a result of discounts awarded by generic medicines companies. However, these discounts benefit pharmacists, but not patients. They also inhibit the development of a competitive French generic medicines market where companies compete on the basis of price. The Jacob law setting a maximum discount level reduces, but does not eliminate competition on the basis of discounts.

Key factors hindering the development of the generic medicines market:

- In the 1990s, the French generic medicines market was inhibited by legislation extending the period of patent protection, low medicine prices, the prescription of brand-name medicines by physicians, and a financial disincentive for pharmacists to dispense generic medicines
- Generic medicines have tended to lose their price advantage as compared with originator medicines as a result of the RPS
- Patients have no financial incentive to buy generic medicines

Key factors aiding the development of the generic medicines market:

- Some policy measures to encourage physicians to prescribe generic medicines have been taken in recent years
- Substitution of generic for originator medicines is financially attractive to pharmacists

10 Italy

10.1 Generic medicines market

The Italian generic medicines market tends to be small in comparison to the medicine market as a whole. Policy measures to stimulate the generic medicines market in the early 2000s appear to have had little impact on generic medicines market share. Market share of generic medicines grew from 0.9% in 1994 to 2.5% in 2004 in terms of value of consumption and from 1.4% in 1994 to 4.5% in 2004 in terms of volume of consumption.

Figure 14. Market share of generic medicines by value in Italy, 1994-2004

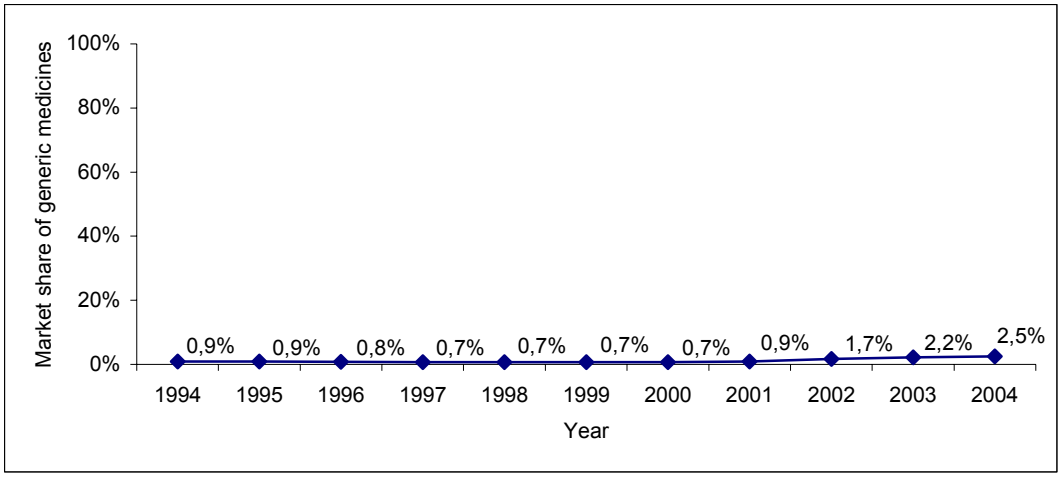
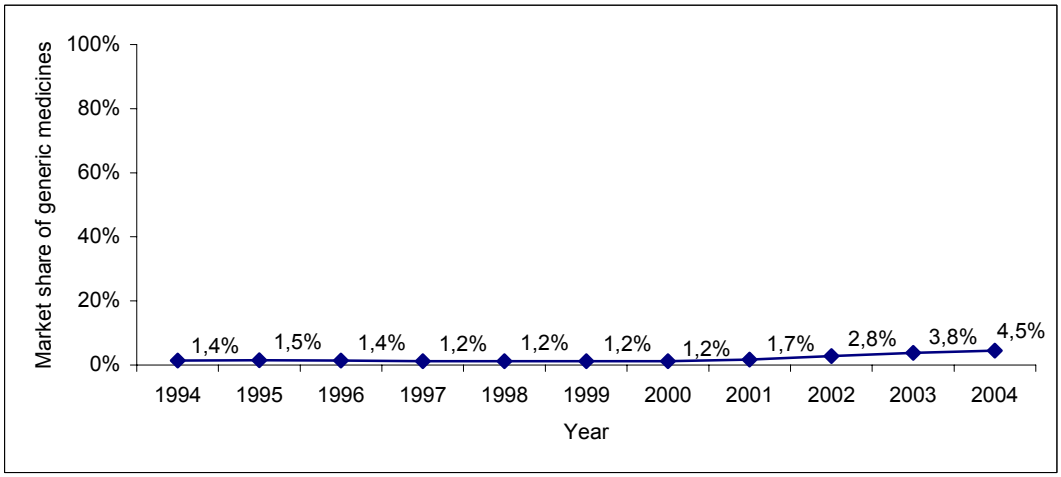


Figure 15. Market share of generic medicines by volume in Italy, 1994-2004



10.2 Generic medicines policy

10.2.1 Intellectual property rights

Copies have thrived in Italy (Ghislandi et al., 2005). This originates from the historical absence of patent protection offered to medicines, with protection being granted as late as 1978.

In addition to patent coverage for a period of 20 years, a Supplementary Certificate of Protection was introduced in 1991 which can extend patent protection for up to 18 years. The supplementary term of protection is calculated as the number of years that have elapsed from the date of filing the patent application to the date of the initial marketing authorisation. This prolongation of patent coverage was granted to around 400 active substances (Lucioni, 1995). In the long-term, the system of the Supplementary Certificate of Protection will be abolished. From 2003 onwards, the supplementary term of protection is being reduced every two years by one year.

The term ‘generic medicine’ was first defined in legislation in 1996. A generic medicine is to be marketed under the INN followed by the name of the company. The definition of ‘generic medicine’ was extended in 2003 to cover all off-patent medicines, including copies.

10.2.2 Pricing

Generic medicines need to be at least 20% cheaper than the originator medicine if they wish to be listed in the same patient co-payment class as the originator medicine.

10.2.3 Reference pricing

A RPS by active substance was launched in 2001. The RP was originally calculated as the average price, weighted by volume of sales, of equivalent medicines where the price is inferior to that of the most expensive generic medicine. The RP was reduced at the end of 2001 and is now set at the level of the price of the cheapest medicine. Case studies pertaining to three active substances revealed that prices of originator medicines dropped following the implementation of the 2001 rules governing the establishment of RPs (Ghislandi et al., 2005).

There is some evidence that the RPS induced pharmaceutical companies to shift demand away from medicines covered by the RPS to medicines not covered by the RPS (so-called ‘re-allocation of demand’). The Ministry of Health estimated that reallocation of demand was responsible for an increase of 3.1% of public pharmaceutical expenditure in 2003 (OsMed, 2003). The case of ranitidine shows that the falling market share of ranitidine following the advent of

generic medicines was offset by increasing sales of patented medicines with the same therapeutic indication (e.g. omeprazole and its derivatives) (Ghislandi et al., 2005).

10.2.4 Incentives for physicians

Physicians face few incentives to prescribe generic medicines. They are obliged to inform patients of the existence of generic medicines if the prescription concerns off-patent medicines. The more efficient prescription of medicines by physicians at local level has been stimulated by initiatives that periodically report to GPs on their prescribing patterns; by local agreements with GPs on pharmaceutical expenditure; and by the implementation of clinical guidelines.

10.2.5 Incentives for pharmacists

From 2001 onwards, pharmacists were allowed to substitute the cheapest generic medicine for an originator medicine subject to patient agreement and absence of physician prohibition to substitute.

In Italy, the remuneration of pharmacists consists of a fixed mark-up on the public price (excluding VAT) of reimbursed medicines. Mandatory discounts on pharmacist margins for medicines covered by the NHS were initiated in 1997, with higher discount rates applying to higher price ranges (discounts ranged from 3.75% for prices less than 25.82 € to 19% for prices greater than 154.94 € in 2003). This system of regressive pharmacist margins contributed to, but did not completely succeed in, removing the financial disincentive to dispense the cheaper generic medicines. In 2003, NHS mandatory discounts on pharmacist margins on generic medicines priced below or at the level of the RP were abolished. Nevertheless, the regressive effect of this system remains limited. Pharmacists are still financially better off by dispensing the more expensive originator medicines. They can gain extra discounts from generic medicines companies, but the legality of this practice is arguable.

10.2.6 Incentives for patients

Medicine co-payments and charges were introduced in Italy in 1978, but abolished in 2001. To curb the subsequent increase in pharmaceutical expenditure, some regions have re-initiated patient co-payments in 2002. Information campaigns have been run in 2001 and 2005 to raise patient awareness of generic medicines.

10.3 Policy analysis

The marketing of copies during the period covered by the patent has presented an obstacle to generic medicines entry. Furthermore, the prolongation of patent coverage postponed the onset of generic competition.

Establishing the RP at the level of the price of the cheapest medicine and the absence of incentives for physicians and pharmacists to demand generic medicines has led to a low-price, low-volume market. This inhibits the economic viability of generic medicines entering and remaining on the market. In the absence of generic medicines, there is no incentive for originator off-patent medicines to reduce prices and the RPS has little impact. Furthermore, the implementation of the RPS seems to have been accompanied by some re-allocation of demand towards medicines not covered by the RPS.

Physicians face few incentives to prescribe generic medicines and existing incentives are weak. The impact of initiatives promoting generic medicines use is likely to be limited. Initiatives are voluntary and there is substantial variation in the extent to which local health enterprises have implemented them. Moreover, the absence of effective sanctions if physicians fail to adhere to these initiatives is likely to restrict their effectiveness. There are few incentives for pharmacists to promote generic medicines use as generic substitution is voluntary and not in the financial interests of pharmacists.

Key factors hindering the development of the generic medicines market:

- The existence of a market of copies and the extension of patent coverage posed barriers to the development of the Italian generic medicines market
- Setting the RP at the level of the cheapest generic medicine inhibits generic medicines entry, especially when considered in combination with the low volume of generic medicines consumption
- Physicians face few incentives to prescribe generic medicines
- Pharmacists are financially penalised for dispensing generic medicines

11 Portugal

11.1 Generic medicines market

Market shares of generic medicines did not exceed 1% in the second half of the 1990s. The introduction of a generic medicines policy in the early 2000s has driven the development of the Portuguese generic medicines market. Public expenditure on generic medicines increased from 6 million € in 1994 (market share by value of 0.5%) to 253 million € in 2004 (market share of 8.6%). Market share of generic medicines by volume rose from 0.8% in 1994 to 7.2% in 2004.

Figure 16. Market share of generic medicines by value in Portugal, 1994-2004

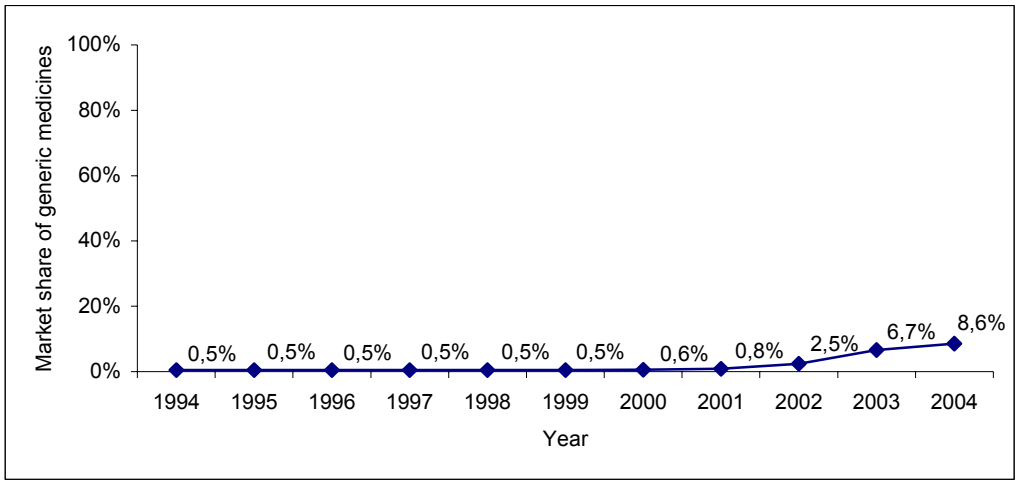
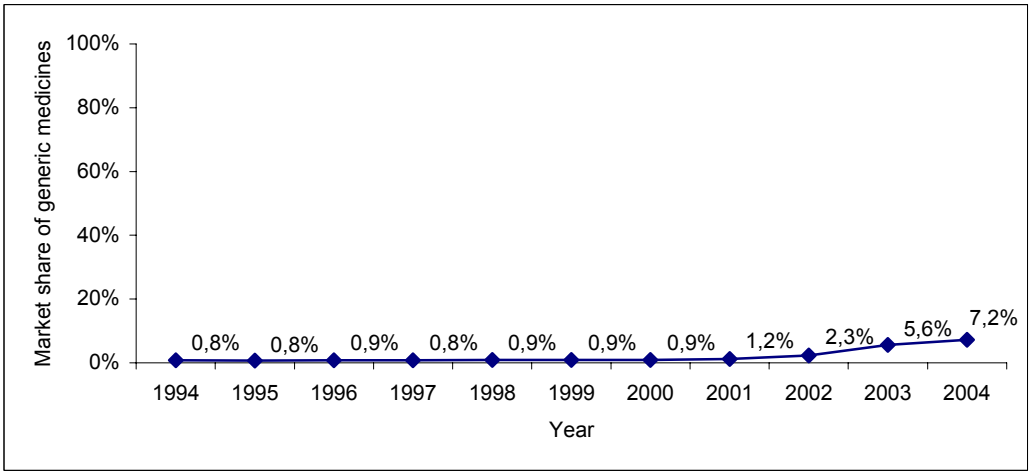


Figure 17. Market share of generic medicines by volume in Portugal, 1994-2004



11.2 Generic medicines policy

11.2.1 Intellectual property rights

Historically, Portugal has a developed market for copies as a result of process patent legislation. Legislation was amended in 1995 to regulate product patents for medicines, although companies were allowed to continue marketing copies if these were initially authorized prior to 1995. In 2003, a programme was launched to convert copies of off-patent medicines into generic medicines.

11.2.2 Pricing

Since 2001, the minimum price difference between generic and originator medicines needs to be 35% of the price of the originator medicine.

In 2005, a decree came into effect reducing prices of all marketed medicines by 6%, with 4.17% of the reduction being borne by pharmaceutical companies and the remainder by wholesalers and pharmacists.

11.2.3 Reference pricing

A RPS by active substance was launched in 2003. The RP is established at the level of the most expensive generic medicine.

11.2.4 Incentives for physicians

In 2002, a law stipulated that physicians need to prescribe medicines for which generic equivalents exist by their INN, even though they are free to add a brand name or a marketing authorisation holder name. Moreover, physicians and pharmacists were forced to inform patients about the range of available generic medicines and their costs at the time of prescribing and dispensing a medicine. Although guidelines regarding appropriate prescribing behaviour were issued to physicians, compliance with such guidelines is not rewarded or sanctioned. To inform generic prescribing by physicians, a medicines database and computerised prescribing have been pilot tested since 2004, but have not yet been fully implemented. Physicians can also consult a ‘generic medicines guide’ booklet, published every quarter by INFARMED, the National Institute of Pharmaceuticals and Medicines, or on the website of INFARMED.

11.2.5 Incentives for pharmacists

Generic substitution by pharmacists is allowed since 2003. The physician can indicate on the prescription form whether (s)he permits or forbids substitution. If the physician prescribes by INN, the pharmacist must dispense the cheapest generic medicine available. If the physician issues a prescription by INN followed by a brand name, the pharmacist may substitute with a generic medicine if the physician allows substitution. If the physician ticks neither box permitting/forbidding substitution, substitution with a generic medicine by the pharmacist is allowed.

Pharmacists have no financial incentive to dispense generic medicines as pharmacist margins amount to a flat rate of 19.15% since September 2005. Discounts of 3%-5% are offered by generic medicines companies to pharmacists.

11.2.6 Incentives for patients

Medicines can fall under five different reimbursement regimes with rates of 100% for medicines classified as life-saving products, 95% in category A, 70% in category B, 40% in category C, and 20% in category D. Patients with low incomes receive an additional reimbursement of 15%. In 2000, patient demand for generic medicines was stimulated by an increase in the reimbursement rate of generic medicines by 10% (until October 2005).

Taking together the impact of the withdrawal of the 10% additional reimbursement for generic medicines and the price reduction of 6% of all marketed medicines, generic medicines cost 4% more to patients since October 2005.

The Government has conducted pro-generic-medicine media campaigns, targeted at patients in addition to physicians and pharmacists. These media campaigns appear to have contributed to raising demand for generic medicines (INFARMED, 2006), although no formal evaluation of the impact of campaigns exist.

11.3 Policy analysis

The development of the Portuguese generic medicines market has been restrained by the existence of a market for copies. Pricing regulation establishing a minimum price differential between generic and originator medicines encouraged companies to focus on launching generic medicines for more expensive active substances or those with higher market shares. The 2005

price reductions are likely to contribute to containing public pharmaceutical expenditure, but adversely affect the profitability of generic medicines and hinder the development of the generic medicines market.

Regulation establishing a minimum price difference between generic and originator medicines and setting the RP at the level of the most expensive generic medicine stimulates generic medicines companies to concentrate prices around the maximum level that is allowed. It does not incite companies to compete on price and reduce prices below the level of the RP.

The Portuguese generic medicines market has been sustained by inciting physicians to prescribe by INN, by permitting generic substitution by pharmacists, and by a temporary increase in reimbursement of generic medicines. However, physicians face few incentives that influence their decision to permit or forbid generic substitution. Furthermore, generic substitution is not in the financial interests of pharmacists.

Key factors hindering the development of the generic medicines market:

- Regulation requiring that generic medicines are at least 35% cheaper than originator medicines and setting the RP at the level of the most expensive generic medicine stimulates companies to launch generic medicines for expensive active substances and limits price competition between generic medicines companies
- Physicians face few incentives that influence their decision to permit or forbid generic substitution
- Pharmacists are financially penalised for dispensing generic medicines

Key factors aiding the development of the generic medicines market:

- Portugal developed a successful generic medicines policy by increasing reimbursement of generic medicines (until October 2005), by encouraging physicians to prescribe by INN, and by allowing generic substitution by pharmacists

12 Spain

12.1 Generic medicines market

Market shares of generic medicines were small in the second half of the 1990s, hovering around 1.5% in terms of value of consumption and 2% in terms of volume of consumption. The 2000 and 2003 generic medicine policies appear to have had a limited impact on the development of the Spanish generic medicines market. With respect to value of consumption, market shares of generic medicines grew from 1.7% in 1994 to 5.0% in 2004. With respect to volume of consumption, market shares of generic medicines increased from 2.0% in 1994 to 8.1% in 2004.

Figure 18. Market share of generic medicines by value in Spain, 1994-2004

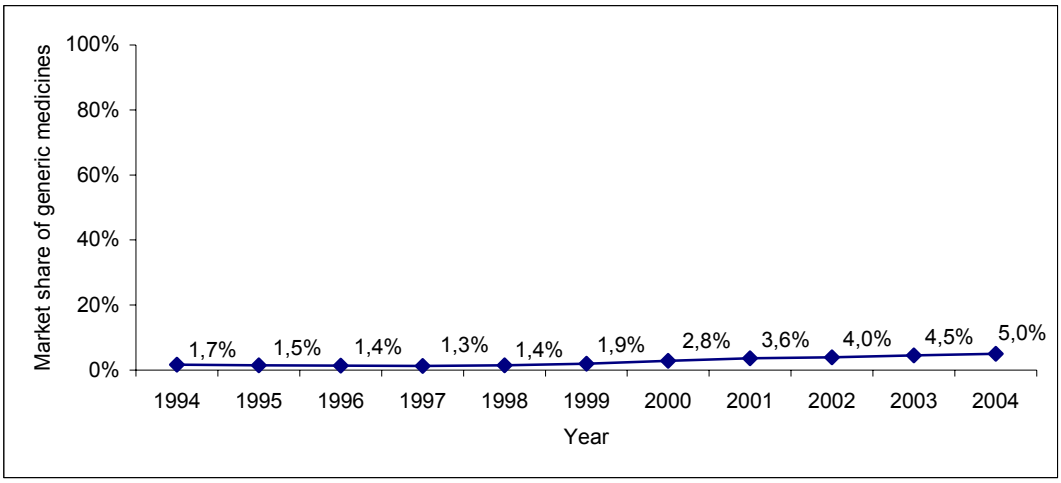
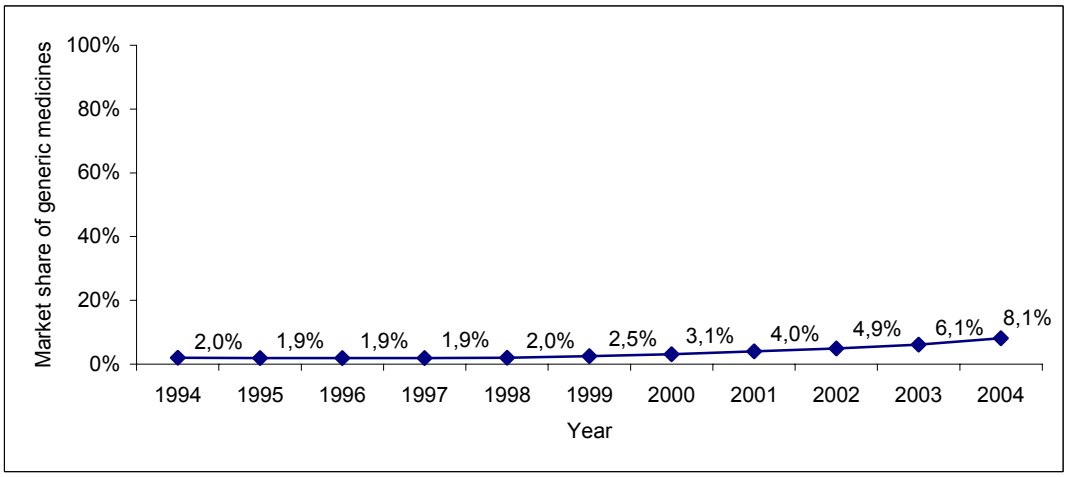


Figure 19. Market share of generic medicines by volume in Spain, 1994-2004



12.2 Generic medicines policy

12.2.1 Intellectual property rights

The nature of the Spanish patent system until 1992 has contributed to the success of the market of copies. This system allows to patent processes to prepare medicines rather than medicines themselves. In 1992, new legislation was introduced recognising product patents.

In legislation passed in 1996, the term 'generic medicine' was outlined and the requisites for registration of a generic medicine were specified. This legislation clearly distinguished generic medicines from copies, clearing up previous confusion surrounding these concepts (Rovira and Albarracin, 2001).

12.2.2 Pricing

In the 1990s, medicine prices in Spain tended to be lower than in other countries (Rovira and Darba, 2001). Furthermore, Spain took a number of measures to reduce medicine prices and encourage price competition. The introduction of the 2000 RPS was accompanied by mandatory price reductions of copies to the level of the RP in 2000 and a 15% decrease in the price of active substances if their price exceeded the average price of the three cheapest medicines in the homogeneous group by more than 15% in 2001. Direct pricing regulation made marketing authorisation of new generic medicines conditional on setting their price below the level of the lowest-priced medicine in the homogeneous group.

In 2003, pricing regulation established the price of the first generic medicine at least 30% below the price level of the originator medicine. Moreover, the price of a generic medicine cannot exceed the RP.

12.2.3 Reference pricing

A RPS by active substance was implemented in 2000, and is annually updated and progressively expanded to cover most off-patent medicines. The RP is calculated with respect to the average, weighted by volume of sales, of the lowest-priced medicines that make up at least 20% of sales. If the difference between this average price and that of the highest-priced medicine in the group does not surpass 15%, the RP is set at 90% of the highest price. If the difference exceeds 50%, the RP is established at 50% of the highest price. The RP cannot be inferior to that of the lowest-priced generic medicine.

The RPS initially applied to a small proportion of the pharmaceutical market: 114 homogeneous groups containing 590 medicines, accounting for 10% of public pharmaceutical expenditure (Antonanzas, 2003). Since then, the scope of the RPS has been enlarged to cover, for example, 200 groups of medicines in 2002.

In 2003, some features of the RPS were changed. The breadth of homogeneous groups was enlarged to include all presentations and pharmaceutical forms (except for retard and paediatric forms) of the same active substance. The RP was calculated as the average of the three lowest costs per daily defined dose for each pharmaceutical form of an active substance. In 2004, the addition of new active substances to the RPS was suspended.

12.2.4 Incentives for physicians

The prescribing behaviour of physicians is assisted by computerised prescribing and a medicine database. In most Spanish regions, primary care physicians can earn additional annual lump sums if they meet targets relating to, for example, generic medicines prescription rates. The impact of such measures is likely to be limited as these incentive payments make up approximately 2% of the physician's gross salary (Antonanzas, 2003). On the other hand, physicians are not obliged or stimulated to prescribe by INN.

12.2.5 Incentives for pharmacists

The implementation of the 2000 RPS was supported by the ability of pharmacists to substitute generic for originator medicines (unless the patient specifically demands the originator medicine). Generic substitution by pharmacists encountered physician resistance (Rovira and Albarracin, 2001), although no evidence of its effect on substitution rates has been discovered.

A new system of regressive pharmacist margins was introduced in 2000. For medicines with an ex-factory price at or below 78.34 €, pharmacist margins were set at 33% for generic medicines as compared with 27.9% for non-generic medicines. For medicines priced above 78.34 €, pharmacist margins were fixed at 33.54 €. Currently, pharmacists receive a margin of 27.9%, irrespective of whether it concerns an originator or generic medicine.

In 2003, explicit rules governing generic substitution by pharmacists were specified. Generic substitution of brand-name (originator or generic) medicines depends on the price of the medicine. If the medicine price is inferior or equal to the RP, the pharmacist has to dispense the brand-name medicine. If the medicine price surpasses the RP and the medicine class contains

generic medicines, the pharmacist is required to dispense the cheapest generic medicine. This, in effect, means that medicines priced above the RP are excluded from public reimbursement. If the medicine price is superior to the RP, but generic medicines in the class are not available or, being available, are not included in the list of medicines reimbursed by the NHS, then the pharmacist has to dispense the brand-name medicine, but at the level of the RP. If the physician prescribes by INN, the pharmacist must dispense the cheapest generic medicine in the medicine class or the brand-name medicine at the RP level in the absence of a generic medicine.

12.2.6 Incentives for patients

Spain operates a system of patient co-payments for medicines prescribed by NHS physicians, which range from 0% to 40% depending on the type of patient and medicine. The Government has launched an advertising campaign to inform patients of generic medicines.

12.3 Policy analysis

The 2000 generic medicines policy consisting of pricing regulation, a RPS and generic substitution by pharmacists did little to boost the Spanish generic medicines market for a number of reasons. First, pricing regulation in combination with historically low medicine prices created less room for generic medicines to enter the market. Second, the impact of the RPS was inhibited by the fact that the RPS initially applied to a small proportion of the pharmaceutical market. Third, the system of pharmacist margins did not promote generic substitution as the high prices of originator medicines compensated for the lower pharmacist margins on them. Furthermore, increased margins for generic medicines encouraged pharmacists to dispense the highest-priced generic medicines. The limited price difference between originator medicines and the highest-priced generic medicines did not provide incentives for patients to buy generic medicines. Fourth, incentives for pharmacists in the form of generic substitution and higher pharmacist margins for generic medicines, in combination with rules governing the level of the RP appear to have led to price competition, not in the form of lower medicine prices, but in the form of lower acquisition costs for pharmacists. The benefits of price competition therefore did not accrue to patients, inhibiting demand for generic medicines.

The 2003 generic medicines policy contained a number of measures exerting pressure on prices of generic medicines. First, pricing rules established a minimum price difference between generic and originator medicines. Second, the RP was set close to the level of marginal costs. Third, regulation governing generic substitution by pharmacists provided strong incentives for originator medicines to reduce their prices to the level of the RP, eroding the price advantage of generic

medicines. The generic medicines policy failed to support generic medicines consumption, apart from regulation governing generic substitution by pharmacists, which tends to favour the consumption of generic medicines. Pharmacists are now financially penalised for dispensing generic medicines. Few incentives for physicians to prescribe generic medicines have been implemented. As a result, the Spanish generic medicines market tends to be a low-price, low-volume market, thus hindering the economic viability of generic medicines to enter and remain on the market.

Key factors hindering the development of the generic medicines market:

- Historically, the Spanish generic medicines market has been small due to the existence of a developed market of copies and low medicine prices
- Competition created by the 2000 generic medicines policy benefited pharmacists rather than patients, thus inhibiting demand for generic medicines
- The 2003 generic medicines policy incited companies to reduce prices of originator medicines to RPs that are set close to marginal costs, thus limiting the profitability of and demand for generic medicines
- Few incentives exist for physicians to prescribe generic medicines
- Pharmacists are financially penalised for dispensing generic medicines

PART III

COMPARATIVE ANALYSIS OF GENERIC MEDICINES POLICIES

13 Experience with generic medicines policy

There is no single approach towards developing a generic medicines market. For instance, demand for generic medicines in mature markets is driven by generic substitution by pharmacists in Denmark and the Netherlands, a favourable attitude of physicians towards generic medicines in Poland, physician budgets in Germany and the United Kingdom. Furthermore, generic medicines policy has grown incrementally in countries over time and reflects demographic, cultural, economic and institutional constraints. Therefore, there is no reference set of policy measures that countries can adopt to promote their generic medicines market.

Countries that have promoted generic medicines for 10-15 years (e.g. Denmark, Germany, the Netherlands) naturally have a more mature generic medicines market than countries that have only recently implemented measures to stimulate generic medicines use (e.g. Austria, Belgium, Portugal). This suggests that the development of a generic medicines market needs to be actively sustained by a generic medicines policy.

Countries have drawn on supply-side policies relating to pricing and reimbursement to provide impetus to the development of the generic medicines market. However, limiting policy to supply-side measures only, as is the case in Austria, is insufficient to realise the full potential of a generic medicines market. Therefore, countries tend to complement supply-side policies with demand-side policies, creating incentives for physicians to prescribe, pharmacists to dispense, and patients to demand generic medicines. Demand-side policies are critical to a sustainable generic medicines market.

The ability of the generic medicines industry to deliver competitive prices can only be achieved and sustained if it is ensured a high volume of the pharmaceutical market. This high volume is dependent on demand-side policies. On the one hand, countries with mature generic medicines markets have in place incentives for physicians, pharmacists and/or patients to demand generic medicines. On the other hand, there are few incentives to stimulate generic medicines consumption in countries with developing generic medicines markets. In Italy and Spain, the limited volume of generic medicines consumption in combination with low medicine prices has undermined the economic viability of the generic medicines market.

The remainder of this part of the report contrasts the specific policy tools that countries have used to strengthen their generic medicines market and their experience with them. Table 1 outlines the strengths and weaknesses of policy instruments.

13.1 Market entry

Having a marketing authorisation does not tend to suffice for a generic medicine to enter the market. Generic medicines enter the market following determination of price and reimbursement status by authorities. Each EU country has national responsibility over pricing and reimbursement decisions. Procedures for determining pricing and reimbursement delay market entry of generic medicines and appear to be unnecessarily long in the case of generic medicines that have demonstrated the same quality, safety and therapeutic efficacy as the originator medicine. There does not seem to be a case for delaying market access to generic medicines once all intellectual property and data exclusivity periods are exhausted.

The Transparency Directive 89/105/EEC specifies a 90-day limit for adopting a decision on price and a 90-day limit for reimbursement. Several studies have shown that, in practice, delays in obtaining pricing and reimbursement approval have exceeded these time limits (Europe Economics, 1998; Cambridge Pharma Consultancy, 2002). An EGA survey revealed that the time delay for price approval in January 2005 surpassed 90 days in Austria and Italy, equalled 90 days in Belgium and Portugal, was shorter than 90 days in France, the Netherlands and Spain (EGA, 2005). There is no formal pricing approval process in Denmark. In Germany and the United Kingdom, generic medicines can be put on the market following marketing authorisation. Further delays are experienced as a result of reimbursement and substitution policies.

Variation in delays for pricing and reimbursement approval obstructs the creation of a level playing field for market entry across EU countries and hinders the development of a competitive European generic medicines industry.

13.2 Pricing

Penetration of generic medicines is more successful in countries that permit (relatively) free pricing of medicines (e.g. Germany, the Netherlands, United Kingdom) than in countries that have pricing regulation (e.g. Austria, Belgium, France, Italy, Portugal, Spain).

Countries that adhere to free market pricing generally have higher medicine prices. Average medicine prices in Germany, the Netherlands and the United Kingdom surpassed those in France, Italy and Spain in 2001 (Schulz, 2004). Higher medicine prices stimulate generic medicines companies to enter the market. This contrasts with regulated markets, where pricing regulation drives down the originator price over the life cycle of the medicine. This lowers the potential profit margin for a generic medicine company and discourages market entry.

Table 1. Country experiences with policy tools to promote generic medicines use

Type of policy	Country of policy	Policy strengths	Policy weaknesses
Market entry			
- Pricing and reimbursement approval process	Austria, Belgium, Denmark, France, Italy, Netherlands, Poland, Portugal, Spain	Mechanism to check justification for price and reimbursement status	Delays market entry of generic medicines and prevents level playing field across countries.
Pricing			
- Free pricing of medicines	Germany, Netherlands, United Kingdom	High medicine prices create attractive conditions for market entry by generic medicines. Large price differences between originator and generic medicines stimulate patient demand for generic medicines.	Strong price competition could endanger the long-term sustainability of the generic medicines industry.
- Pricing regulation	Austria, Belgium, France, Italy, Portugal, Spain	Mechanism to contain public pharmaceutical expenditure.	Lower medicine prices discourage market entry of generic medicines. Smaller price differences between originator and generic medicines restrict patient demand for generic medicines.
Reference pricing			
- Reference-pricing system	Belgium, Denmark, France, Germany, Italy, Netherlands, Poland, Portugal, Spain	Financial incentive for patients to demand generic medicines priced below reference price.	Does not stimulate generic medicines use if originator medicines reduce their price below level of reference price.
° Low reference price	Denmark, Italy, Poland	Establishes clear price differential between originator and generic medicines.	Forces companies to price generic medicines close to marginal costs and threatens economic viability.
° High reference price	Portugal	Facilitates market entry of generic medicines.	Small price difference between originator and generic medicines restricts patient demand for generic medicines.
° Narrow reference groups	Denmark, France, Italy, Portugal	Homogeneous groups of medicines.	Re-allocation of demand between groups or between group and patented medicines not covered by RPS.
° Broad reference groups	Germany, Netherlands	Stimulates competition among medicines that target the same illness. Reduces potential for re-allocation of demand.	Heterogeneous groups of medicines with potential of prescription of less effective medicine in order to avoid co-payment.

Table 1 (cont). Country experiences with policy tools to promote generic medicines use

Type of policy	Country of policy	Policy strengths	Policy weaknesses
Incentives for physicians			
- Budgets	Germany, United Kingdom	Increases generic prescription rates.	Only effective in combination with sanctions for budget overruns. May encourage referral or admission to hospital.
- INN prescribing	Denmark, Netherlands, Portugal, United Kingdom	Creates potential for delivery of generic medicines by pharmacists.	Depends on attitude of physicians, dispensing regulation and remuneration of pharmacists.
- Non-financial incentives	Austria, Belgium, Denmark, France, Netherlands, Italy, Portugal	Tools that support low-cost prescribing by physicians.	Voluntary nature of schemes with unproven effect on generic prescription rates.
Incentives for pharmacists			
- Absolute pharmacist margins on medicines	Belgium, France	Pharmacists gain same margin on originator and generic medicines.	Increases price of generic medicines relative to originator medicines.
Incentives for patients			
- Patient co-payment	Belgium, Denmark, France, Germany, Italy, Netherlands, Poland, Portugal, Spain	Higher co-payment on originator medicines stimulates demand for generic medicines.	Stimulus weakened if physicians are not cost-conscious or co-payment covered by additional insurance.
- Information campaign	Belgium, Italy, Portugal, Spain, United Kingdom	Increases patient awareness of and demand for generic medicines.	Small effect if campaign is short-lived and has limited exposure.

In countries with free pricing, the price difference between originator and generic medicines tends to be higher than in countries with pricing regulation. International comparisons indicate that the price differential for blockbuster medicines of 80% in Germany, the United Kingdom and the United States (de Joncheere et al., 2002; King and Kanavos, 2002) exceeded the minimum price difference of 10% in Austria, 20% in Italy, 30% in France, and 35% in Portugal at the end of the 1990s / early 2000s.

13.3 Reference pricing

The majority of countries included in this report have introduced a RPS. The objective of a RPS is to contain public pharmaceutical expenditure by controlling the reimbursement level of medicines. A RPS may aid generic market penetration because originator medicines priced above the level of the RP are likely to lose market share as a result of an additional patient co-payment. Conversely, if the RPS is accompanied by price reductions of originator medicines to the level of the RP, the RPS does not aid the development of the generic medicines market. Evidence of such a pricing strategy of originator medicine companies in the context of a RPS was found for France and Italy. A RPS tends to be more successful in markets characterised by a developed

generic medicines segment, substantial price differences between medicines within a group, and a high level of medicine prices (Lopez-Casasnovas and Puig-Junoy, 2000).

13.3.1 Level of reference price

The RP is generally calculated as a function of market prices of medicines, with differences between countries as to which medicines are taken into account. A low reimbursement level is chosen in Denmark, Italy and Poland where the RP equals the price of the cheapest (generic) medicine. A higher reimbursement level applies in the Netherlands, where the RP is set as the median price of all medicines in the group, or in Portugal, where the highest price of available generic medicines makes up the RP. These differences in the level of the RP influence the economic viability of generic medicines companies to enter the market and the competitive price advantage of generic versus originator medicines. By calculating the RP as a function of prices and the level of generic competition as for example in Germany, a RPS can stimulate the development of the generic medicines market, while containing public pharmaceutical expenditure.

13.3.2 Breadth of reference groups

As equivalence criteria for selecting a group of interchangeable medicines are broadened from active substance to pharmacological class and, ultimately, to therapeutic class, heterogeneity of medicines within the same group increases. A RPS by therapeutic class may lead to the prescription of a less effective medicine within the group if it allows the patient to avoid a co-payment. Therefore, countries tend to define more narrow groups of medicines by active substance or pharmacological class. However, the experience of France and Italy shows that such systems may suffer from re-allocation of demand away from a RPS group to patented medicines with a similar therapeutic indication that do not fall under the RPS.

13.4 Incentives for physicians

In their capacity of prescribing medicines, physicians play a key role in the development of a generic medicines market. Therefore, countries have introduced a variety of financial and non-financial incentives to encourage generic prescribing.

Some countries have experimented with budgets at regional level (e.g. Germany) or budgets at the level of an individual physician (e.g. United Kingdom). The experience of these countries with budgets suggests that rewards or sanctions are a necessary condition for making budgets

effective. Budgetary schemes may require careful monitoring and regulation because financial incentives which in fact reward cost containment may reward selection of less risky patients, stimulate referrals and hospital admissions, and jeopardise quality of care and health outcomes. Additional remuneration if physicians attain specific generic medicines prescription rates appear to have had little impact in France and Spain.

Some countries have attempted to stimulate generic medicines use through INN prescribing. Successful INN prescribing policies have been implemented in Denmark and the United Kingdom, where students are taught to prescribe by INN in medical school; in the Netherlands, where physicians are stimulated to engage in INN prescribing; and in Portugal, where physicians are required to prescribe reimbursed medicines for which generic equivalents exist by INN. The attitude of physicians towards INN prescribing is a crucial determinant of the success of such policies. INN prescribing has been limited in countries such as Belgium and France in light of opposition by physicians who value their prescribing freedom and their tradition to prescribe brand-name medicines.

INN prescribing does not necessarily lead to generic medicines use. The success of INN prescribing policies in stimulating generic medicines use depends on regulation governing which medicine the pharmacist needs to dispense. The decision of which medicine to dispense is also influenced by the financial remuneration of pharmacists. Only if INN dispensing regulation and remuneration of pharmacists favours generic medicines, then INN prescribing can be expected to raise generic medicines use.

Countries have initiated various non-financial incentives to stimulate generic medicines use. Generic prescribing by physicians has been supported by electronic prescribing systems, medicine databases, audit of and feedback on prescribing data, prescribing guidelines and formularies, and local pharmaco-therapeutic discussions between physicians and pharmacists. Such policy measures generally are voluntary and the absence of sanctions if physicians do not adhere to these initiatives is likely to restrict their effectiveness. The impact of non-financial incentives on promoting generic medicines use has rarely been investigated.

13.5 Incentives for pharmacists

Generic substitution may aid generic medicines use if it is financially neutral or attractive to pharmacists to substitute generic for originator medicines.

The remuneration system of pharmacists in some countries provides a financial disincentive to dispense generic medicines. Setting pharmacists' remuneration as a fixed percentage of the public price of medicines as in Portugal and Spain rewards the delivery of originator medicines. Countries such as Italy and Poland have adopted sliding scales where the percentage remuneration decreases as prices rise. However, the regressive effect of such scales is not sufficient to remove the financial incentive to dispense originator medicines.

Other remuneration systems have been used that make the delivery of a generic or original medicine neutral to pharmacists from a financial perspective. Pharmacists earn the same margin in absolute terms on originator and generic medicines in Belgium and France. However, a system of absolute margins increases prices of generic medicines relative to originator medicines, thereby inhibiting generic medicines use. Alternatively, pharmacists can be paid by means of a fixed fee per prescription (item). This provides a neutral financial incentive for pharmacists to dispense a generic or originator medicine.

Few countries have in place systems that financially reward pharmacists for substituting generic for originator medicines. In the Netherlands, pharmacists are encouraged to dispense medicines that are priced below the RP by being able to retain a percentage of the difference between the medicine price and the RP. In France, pharmacists are entitled to higher discounts on generic medicines than on originator medicines. In Spain, higher percentage margins for generic medicines than for originator medicines stimulate pharmacists to dispense the most expensive generic medicines. Pharmacist remuneration in these countries attenuates the incentive for companies to compete with each other on price and reduce prices of generic medicines below the level of the RP. Instead, companies compete through offering discounts to pharmacists. Such a system may financially benefit pharmacists, but is not sustainable in the long run as health care payers and patients do not capture the potential savings from a generic medicines market where companies compete on price.

13.6 Incentives for patients

Countries have not fully recognised the role that patients play in generic medicines consumption. Generally, few policy measures are in place that either incite patients to demand generic medicines or penalise patients for not demanding generic medicines.

The extent to which patients contribute to the cost of drugs is likely to play a role in the use of generic medicines. A RPS may promote generic medicines use by imposing a co-payment on originator medicines priced above the level of the RP. Also, a lower percentage co-payment on

generic medicines appears to have stimulated the Portuguese generic medicines market. The Polish experience indicates that the impact of patient co-payments depends on the extent to which physicians are conscious of the level of patient co-payments and take it into account in their prescribing decisions. Furthermore, the stimulus to prescribe generic medicines is likely to disappear if co-payments are covered by the private insurance of patients such as in France.

Several countries including Belgium, Italy, Portugal, Spain and the United Kingdom have launched advertising campaigns to inform patients of generic medicines. In Belgium, the campaign was short-lived and had limited exposure. In Portugal, pro-generic-medicine media campaigns aimed at physicians and pharmacists in addition to patients appear to have contributed to raising demand for generic medicines. No formal evaluations of the impact of advertising campaigns on generic medicines consumption exist.

PART IV

RECOMMENDATIONS TO STRENGTHEN GENERIC MEDICINES MARKETS

14 Strengthening generic medicines markets

Based on the experience of developing generic medicines markets in selected countries, this part of the report proposes a number of recommendations to strengthen generic medicines markets. The guiding principle used here is recommendation 4 of the report prepared by the G10 High Level Group on Innovation and Provision of Medicines in the European Union in 2002:

"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."

General recommendations for the group of selected countries as well as recommendations for each individual country are suggested.

14.1 General recommendations

1. Introduce a coherent generic medicines policy

Policy intervention is required to develop a competitive generic medicines market. A generic medicines policy requires both supply-side measures (pricing and reimbursement) and demand-side measures (incentives for physicians, pharmacists, patients). Attention needs to be paid to interactions between policy measures. Different policy measures need to reinforce each other and be part of a coherent generic medicines policy.

2. Encourage price differentiation / competition within existing regulatory frameworks

All countries studied have introduced pricing regulation to some extent. This has taken the form of direct fixed price controls, profit controls or reference pricing. Countries can establish a system of fixed minimum price differences between generic and originator medicines in the context of existing RPS. This approach has the benefit of guaranteeing savings to health insurance funds, although it is not clear at what level maximum prices need to be set. Health insurance funds will lose out if they have established prices at a higher level than would have been observed in a competitive market.

An alternative approach is to establish a free pricing system within the context of existing RPS. The RP can be set at the average price level of generic medicines in the reference group or at a

lower price level, once the generic medicines market has reached a minimum level of development. This minimum level could, for instance, be set at a generic market share by volume of 40%. In combination with incentives to stimulate demand for generic medicines, generic medicine companies would have an incentive to compete, thereby driving down (reference) prices of medicines. In countries with developing generic medicines markets, setting the RP at a higher level to encourage market entry can be introduced as a temporary measure to boost the generic medicines market until it reaches a more mature level of development.

Information about prices needs to be transparent. This may not be the case in countries where generic medicines companies compete with each other through offering discounts to pharmacists. The practice of discounting is not clear to market actors and is not fair as pharmacists are not rewarded for services rendered, but for their ability to negotiate discounts on artificial prices. Therefore, countries need to consider moving away from competition by discount to competition by price. Such a system would be transparent and easy for all market actors to understand, and would ensure that prices paid by health insurance funds reflect best value for money.

3. Disseminate pricing information to actors

Information about the price difference between originator and generic medicines needs to be communicated to relevant actors, thus creating an incentive for physicians to prescribe, pharmacists to dispense, and patients to ask for generic medicines. It is important to ensure that actors have access to information about medicine prices that is correct, comprehensive, and up-to-date. The collection and dissemination of pricing information may be carried out by national medicine agencies through the regular publication of a medicine pricing guide. Additionally, pricing information can be included in medicine databases, electronic prescription systems, prescribing guidelines and treatment protocols.

4. Increase confidence of actors in generic medicines

More emphasis needs to be placed on convincing physicians, pharmacists and patients of the bio-equivalence of generic and originator medicines. This entails providing actors with information about the quality, safety and efficacy of generic medicines. National medicine agencies can play a role by periodically publishing lists of all active ingredients for which generic medicines have been approved by regulatory authorities.

5. Provide incentives for physicians to prescribe generic medicines

Prescribing decisions by physicians play a key role in the use of generic and originator medicines. Countries need to recommend to physicians to prescribe low-cost medicines, unless a more expensive, originator medicine is required for therapeutic reasons.

Countries need to initiate financial and non-financial incentives for physicians to prescribe generic medicines. Recommended policy tools include the following:

- Improve prescribing education at undergraduate level and make medical students aware of INN prescribing;
- Demonstrate to physicians the amount of savings to pharmaceutical and physician budgets that can be attained from prescribing generic medicines;
- Support physician prescribing by electronic prescribing systems, medicine databases, audit of and feedback on prescribing data, prescribing guidelines and formularies, substitution lists, and local pharmaco-therapeutic discussions between physicians and pharmacists.

These policy tools need to be accompanied by rewards/sanctions for physicians who do/do not adhere to them, respectively.

6. Remove financial disincentives for pharmacists to dispense generic medicines

Pharmacists need to receive a remuneration that does not financially penalise them for dispensing generic medicines. Countries need to move away from distribution margins that are set as a fixed percentage of the public price of medicines or margins that, even though they are regressive, still favour the delivery of originator medicines. Instead, countries need to consider introducing pharmacist remuneration systems that are neutral or favour the delivery of generic medicines from a financial perspective.

7. Provide incentives for patients to demand generic medicines

Countries need to incite patients to demand generic medicines or penalise patients who do not demand generic medicines. This may take the form of financial incentives that reduce co-payment on generic medicines or impose higher co-payment on originator medicines. Furthermore, countries can raise patient awareness of generic medicines by means of advertising campaigns. Initiatives that attempt to influence consumption patterns by personally contacting patients can also be envisaged.

14.2 Country-specific recommendations

For each country, recommendations are proposed that build on the key factors aiding / hindering the development of the national generic medicines market as set out in the first two parts of the report.

14.2.1 Austria

Austria has adopted a rigid pharmaceutical pricing policy that regulates the price level of originator and generic medicines. This policy has not stimulated market entry of generic medicines or supported the economic viability of the generic medicines market. The pricing system needs to be deregulated and market forces should determine the price difference between originator and generic medicines.

There are no policy measures in place that stimulate demand for generic medicines. Therefore, policy makers need to focus on creating incentives for physicians to prescribe, pharmacists to dispense, and patients to demand generic medicines. Incentives for physicians may take the form of national implementation of generic prescribing targets. Generic substitution by pharmacists needs to be allowed and the financial disincentive for pharmacists to dispense generic medicines needs to be removed.

14.2.2 Belgium

By setting the RP at a certain percentage below the price of the originator medicine, the RPS contributes to containing public pharmaceutical expenditure, but does not stimulate price competition between companies. It is proposed to abolish minimum price differences between generic and originator medicines, and establish the RP at the average price level of generic medicines in the reference group or at a lower price level. This would be expected to create price competition between companies as well as restrict public expenditure.

To ensure the economic viability of the Belgian generic medicines market, competitive prices would need to be accompanied by demand-side measures supporting the volume of generic medicines consumption.

Although Belgium has recently implemented initiatives that incite physicians to promote generic medicines use, these incentives tend to be weak and need to be reinforced. Allowing INN prescribing is likely to be insufficient in a climate of physician opposition to INN prescribing.

Therefore, medical students need to be taught and physicians need to be actively encouraged to prescribe by INN. Furthermore, generic prescribing by physicians needs to be supported by electronic prescribing systems, medicine databases, substitution lists, and local pharmaco-therapeutic discussions between physicians and pharmacists. Physician adherence to prescribing guidelines needs to be stimulated.

INN prescribing needs to be complemented by incentives for pharmacists. One option is to introduce a requirement that the pharmacist dispenses the cheapest medicine in the case of an INN prescription. An alternative option is to allow pharmacists to dispense an originator or generic medicine when the prescription is issued by INN. In addition to this, pharmacists would retain a percentage of the difference between the RP and the price of the medicine dispensed. This would encourage pharmacists not to seek discounts as this practice is questionable from a legal perspective, but to dispense the medicine with the lowest price. This proposed pharmacist remuneration system would replace the current system which drives up generic medicine prices and inhibits patient demand by guaranteeing the same absolute margin on generic and originator medicines.

14.2.3 Denmark

Denmark has a competitive generic medicines market where regulation governing the establishment of RPs and generic substitution by pharmacists creates low prices and a high volume of generic medicines consumption. However, the administrative burden of running the RPS is considerable. In a market where price competition is taking place as a result of generic substitution rules, there may not be a need for a RPS.

There may be scope to increase demand for generic medicines by creating incentives for physicians and patients. The Government may consider taking initiatives to inform and persuade physicians and patients of the substitutability of generic for originator medicines. This may reduce the (low) proportion of prescriptions where the physician has forbidden substitution and the proportion of patients who refuse substitution.

14.2.4 France

Low medicine prices and regulation imposing a substantial price difference between generic and originator medicines has hindered market entry of generic medicines. Abolishing minimum price differences between generic and originator medicines in combination with the existing RPS would be expected to support entry of generic medicines in market segments with few competitors and

incite price competition in market segments with many competitors. Price competition can also be strengthened by further reducing the level of discounts that companies are allowed to award to pharmacists.

There is a need for policy to boost demand for generic medicines. Although some incentives for physicians to prescribe generic medicines have been introduced in recent years, more effort needs to be put into promoting professional acceptance of generic medicines by physicians. In particular, INN prescribing needs to be actively stimulated by including it in the education of medical students or by rewarding physicians who reach specific INN prescribing target rates. This will stimulate demand for generic medicines as pharmacists may dispense any generic medicine in the case of an INN prescription. To reduce re-allocation of demand, the Government could collect data on the physician prescription profile of off-patent medicines and patented medicines with the same therapeutic indication, and set target prescription rates of off-patent medicines.

As co-payment tends to be covered by additional private insurance, patients do not have a financial incentive to demand generic medicines. Government or health insurance fund initiatives that inform patients of the existence of a generic equivalent need to be expanded as pilot projects have shown a positive influence on generic medicines use.

14.2.5 Germany

The RPS appears to have contributed to developing the German generic medicines market, but its operation represents a considerable administrative burden. In this mature generic medicines market characterised by price competition and generic medicines priced substantially below the level of originator medicines, there may not be a need for a RPS. If the RPS was to be abolished, incentives for generic substitution and dispensing by pharmacists would need to be reinforced. Regulation requiring pharmacists to substitute with the least expensive medicine if neither physician nor patient objects to such substitution and a dispensing budget for pharmacists are likely to sustain price competition and provide a stimulus for generic medicines use. The financial incentive for pharmacists to dispense originator medicines needs to be abolished.

The German generic medicines market is driven by physician prescribing of generic medicines. Financial and non-financial incentives for physicians appear to have supported generic medicines use, but their effectiveness can be strengthened by executing sanctions for physicians who do not adhere to them or by awarding a bonus to physicians who adhere.

14.2.6 Italy

The Italian generic medicines market is in the early stages of development and suffers from low prices and low volume of generic medicines consumption.

Setting the RP at the level of the least expensive medicine poses a barrier to market entry, especially when considered in combination with low demand for generic medicines. To facilitate market entry of generic medicines, the RP needs to be set at a higher level (for instance, price of most expensive generic medicine). This should be seen as a short-term measure to start off the Italian generic medicines market. Once it reaches a more mature level of development, the measure can be rescinded and the RP can be set at the average price level of generic medicines in the reference group or at a lower price level.

It is imperative that measures are taken to boost demand for generic medicines by physicians, pharmacists and patients. Policy needs to focus on physician prescribing attitudes and introduce financial and non-financial incentives for physicians to prescribe generic medicines. The current financial incentive for pharmacists to dispense originator medicines needs to be removed. Exemption from co-payment on generic medicines may be considered to augment patient demand.

14.2.7 Netherlands

Generic substitution and competition between generic medicines companies through discounts to pharmacists drive demand for generic medicines and are key features underlying the success of the Dutch generic medicines market. Discounts are seen by the Government as a way of remunerating pharmacists. To recoup the remainder of discounts, a claw-back mechanism was introduced. This system requires government intervention, incurs an administrative cost, and is unlikely to be as efficient as a system where pharmaceutical companies compete on the basis of prices.

In order to reinforce market transparency, the practice of discounting should be outlawed in favour of a system where generic medicines companies compete with each other on price. Such a system would create a competitive generic medicines market where prices paid by health insurance funds reflect best value for money from an efficiency perspective. Pharmacists would still have an incentive to dispense cheap medicines as they are able to retain one third of the price difference between the RP and the price of the medicine dispensed. In addition to this, the

fixed dispensing fee per prescription could be augmented to compensate pharmacists for the financial loss as a result of banning discounts.

14.2.8 Poland

The Polish generic medicines market is a mature market where the establishment of the RP at the level of the cheapest generic medicine promotes price competition between generic medicines companies. Even though price competition is occurring, there appears to be some scope for pharmaceutical companies to award discounts to pharmacists. Banning the practice of discounting would provide an added stimulus for price competition, increase market transparency, and stimulate patient demand for generic medicines.

Physicians face no incentives to prescribe generic medicines. To sustain demand for generic medicines, consideration could be given to introducing budgetary incentives for physicians and assistance in generic prescribing through electronic prescribing systems, medicine databases, audit of and feedback on prescribing data, prescribing guidelines and formularies, and substitution lists. The financial disincentive for pharmacists to dispense generic medicines needs to be removed.

14.2.9 Portugal

In Portugal, regulation imposing a minimum price difference between generic and originator medicines needs to be abandoned. Free generic medicine pricing would stimulate companies to introduce generic medicines for less expensive active substances. Also, setting the RP at the average price level of generic medicines in the reference group or at a lower price level, instead of the most expensive, generic medicine could be envisaged to increase price competition between generic medicines companies, raise demand for generic medicines, and reduce pharmaceutical expenditure.

Demand for generic medicines has been driven by policy measures encouraging INN prescribing by physicians and by requiring pharmacists to dispense the cheapest generic medicine when physicians prescribe by INN. INN prescribing can be supported by expanding a project piloting a medicines database and computerised prescribing. INFARMED could play a role in convincing physicians of the substitutability of generic and originator medicines, thereby influencing the rate of prescription items for which physicians permit or forbid substitution. The financial disincentive for pharmacists to dispense generic medicines needs to be removed.

14.2.10 Spain

Spanish generic medicines policy tends to be a pricing policy inciting companies of originator and generic medicines to reduce their prices to the level of the RP which is set close to marginal costs. In a context where generic and originator medicines have similar price levels, patients are likely to prefer originator medicines out of brand loyalty and demand for generic medicines is stifled.

The Spanish generic medicines market needs to be developed by boosting demand. There is a need to implement incentives that support physician and pharmacist demand for generic medicines. Medical students need to be taught to prescribe by INN and INN prescribing needs to be compulsory. If the prescription is by INN, pharmacists should be required to dispense the cheapest medicine. Such a system would support price competition between generic and originator medicine companies. The financial disincentive for pharmacists to dispense generic medicines needs to be abolished.

14.2.11 United Kingdom

The United Kingdom has implemented a coherent generic medicines policy that incites all relevant stakeholders to promote generic medicines use. Supply-side measures relating to pricing and reimbursement have created conditions for a generic medicines market where companies compete on price and the NHS maximises the cost-saving potential of generic medicines. Demand for generic medicines has been sustained by financial and non-financial incentives for physicians. The proportion of INN prescription items has steadily increased over time, although there appears to be scope to further raise this percentage by means of electronic prescribing systems, incentive schemes within primary care trusts, prescribing guidelines and formularies. Pharmacists have a financial incentive to dispense generic medicines when physicians prescribe by INN, although this incentive has been attenuated recently by the 2005 reimbursement scheme. Patients have no incentive to demand generic medicines. Initiatives could be launched that inform patients of the existence of a generic equivalent and aim to influence consumption patterns.

PART V

SAVINGS FROM GENERIC MEDICINES USE

15 Potential savings from generic substitution

To underline the need for developing generic medicines markets, an exercise was conducted quantifying the potential savings from increased substitution of generic for originator medicines in a number of countries for which data were available in 2004.

Focusing on the off-patent market, the top 10 active substances were selected by expenditure of originator medicines in 2004. As these active substances have the highest expenditure of originator medicines, they would be expected to generate the largest potential savings from generic substitution. This exercise calculates the savings that can be made if originator medicines for the top 10 active substances are replaced by generic medicines. There is no country that attains a 100% generic substitution rate in the off-patent market. Therefore, our analysis assumed that, following generic substitution, 5% of market volume for each active substance would be made up by originator medicines and 95% by generic medicines. Hence, the term “increased” generic substitution is used.

Annual savings from generic substitution were obtained by calculating the average price level for the group of originator medicines and for the group of generic medicines. The price difference between originator and generic medicines was then multiplied by the volume of originator medicines to be substituted. The following equation was used to calculate savings from generic substitution:

Annual savings = (average price of originator medicines – average price of generic medicines) x (volume of originator medicines – 0.05 x (volume of originator and generic medicines))

It is important to stress that this exercise is carried out for illustrative purposes and does not claim to generate an exact estimate of savings from generic substitution. Also, generic medicines markets evolve rapidly so that, even though the most recent data relating to 2004 were used, the data may no longer reflect the market situation. One additional limitation of the analysis needs to be noted. An active substance may contain medicines in different forms, strengths and package sizes. Our analysis did not account for differences in form, strength or package size between individual products, but substituted generic for originator medicines at aggregate level.

Figures 20 to 30 show the top 10 active substances for a country, public expenditure on originator medicines with that active substance, savings from increased generic substitution in absolute terms and as a proportion of expenditure on originator medicines. These Figures indicate that increased substitution of generic for originator medicines can yield substantial savings. For the

top 10 active substances by expenditure of originator medicines, generic substitution would reduce public expenditure on the originator medicines containing these active substances by at least 20% in selected countries, with the proportional reduction varying between 21% in Poland and 48% in Denmark.

15.1 Austria

Figure 20. Potential savings from increased generic substitution in Austria, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Lisinopril	33,545,548	7,973,247
2. Ramipril	26,715,264	11,717,770
3. Ciclosporin	22,456,438	3,545,505
4. Amlodipine	22,379,694	3,701,259
5. Metoprolol	22,017,335	9,580,570
6. Carvedilol	21,043,749	2,998,096
7. Pravastatin	19,565,709	5,364,850
8. Lamotrigine	17,006,227	5,539,110
9. Enalapril	16,588,539	2,183,517
10. Omeprazole	16,292,170	5,358,914
Total	217,610,673	57,962,838 (27%)

15.2 Belgium

Figure 21. Potential savings from increased generic substitution in Belgium, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Pravastatin	67,863,755	45,053,083
2. Simvastatin	64,440,658	22,766,941
3. Paroxetine	50,898,729	25,860,104
4. Amoxicillin	39,097,970	10,130,949
5. Bisoprolol	35,277,554	10,521,594
6. Fluconazole	29,793,234	9,688,854
7. Lisinopril	27,124,437	9,290,259
8. Hydrochlorothiazide	25,613,208	13,723,962
9. Tramadol	24,274,928	4,758,127
10. Domperidone	20,534,051	8,990,262
Total	384,918,524	160,784,134 (42%)

15.3 Denmark

Figure 22. Potential savings from increased generic substitution in Denmark, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Metoprolol	19,289,107	4,833,861
2. Ethinylestradiol	16,955,876	9,630,174
3. Citalopram	16,500,176	6,177,473
4. Fentanyl	15,974,500	13,323,841
5. Amlodipine	14,821,236	10,932,913
6. Mirtazapine	10,151,964	5,266,104
7. Interferon beta 1a	9,731,771	4,058,237
8. Sertraline	8,305,894	763,244
9. Ciprofloxacin	7,139,290	4,039,866
10. Gestodene	6,399,640	1,165,579
Total	125,269,454	60,191,292 (48%)

Note: Data relate to both hospital and retail pharmacy.

15.4 France

Figure 23. Potential savings from increased generic substitution in France, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Omeprazole	446,515,016	117,723,086
2. Paracetamol	145,522,610	23,838,883
3. Paroxetine	137,898,121	45,042,899
4. Ethinylestradiol	137,520,042	101,370,687
5. Bisoprolol	135,870,312	60,368,156
6. Hydrochlorothiazide	115,174,757	41,624,759
7. Citalopram	101,443,283	38,817,197
8. Trimetazidine	100,035,279	35,760,821
9. Fenofibrate	97,599,601	38,537,643
10. Gliclazide	92,798,116	22,206,603
Total	1,510,377,137	525,290,734 (35%)

15.5 Germany

Figure 24. Potential savings from increased generic substitution in Germany, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Hydrochlorothiazide	743,868,532	481,855,404
2. Fentanyl	357,910,602	231,209,670
3. Ramipril	209,363,878	78,004,998
4. Metoprolol	193,642,730	90,953,846
5. Ciclosporin	126,479,271	82,189
6. Pravastatin	111,223,448	32,111,332
7. Carvedilol	98,232,964	44,951,176
8. Formoterol	93,867,715	9,722,254
9. Mirtazapine	93,308,038	18,744,557
10. Budesonide	70,218,590	4,868,830
Total	2,098,115,768	992,504,255 (47%)

15.6 Italy

Figure 25. Potential savings from increased generic substitution in Italy, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Ceftriaxone	125,640,866	48,480,174
2. Citalopram	100,430,819	50,486,889
3. Lorazepam	98,028,700	38,695,638
4. Carvedilol	82,540,290	24,387,474
5. Alprazolam	79,877,958	23,171,157
6. Paroxetine	78,529,774	1,616,645
7. Nimesulide	76,111,366	29,513,768
8. Gentamicin	76,028,312	12,857,475
9. Bromazepam	65,943,659	14,886,738
10. Gabapentin	61,822,545	19,412,604
Total	844,954,289	263,508,563 (31%)

15.7 Netherlands

Figure 26. Potential savings from increased generic substitution in the Netherlands, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Pravastatin	67,314,038	29,605,918
2. Fluticasone	67,306,151	5,329,635
3. Omeprazole	56,793,271	28,253,150
4. Budesonide	38,842,590	24,000,806
5. Fentanyl	31,043,301	27,339,017
6. Paroxetine	21,299,697	5,544,048
7. Itraconazole	20,180,460	905,892
8. Mirtazapine	20,167,057	8,238,806
9. Gabapentin	19,244,761	8,265,270
10. Salbutamol	18,034,798	9,078,160
Total	360,226,124	146,560,702 (41%)

15.8 Poland

Figure 27. Potential savings from increased generic substitution in Poland, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Simvastatin	10,088,853	623,500
2. Gliclazide	8,145,560	304,841
3. Azithromycin	7,756,479	84,458
4. Amoxicillin	6,232,929	811,800
5. Donepezil	6,028,764	3,012,783
6. Budesonide	6,317,025	3,855,495
7. Atorvastatin	4,990,985	2,000,705
8. Cetirizine	4,646,962	484,645
Total	54,207,557	11,178,228 (21%)

15.9 Portugal

Figure 28. Potential savings from increased generic substitution in Portugal, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Ethinylestradiol	47,817,774	40,705,211
2. Hydrochlorothiazide	37,685,108	7,691,830
3. Nimesulide	30,030,728	19,016,350
4. Lisinopril	26,747,517	9,446,755
5. Trimetazidine	25,518,526	8,540,041
6. Pravastatin	23,891,425	10,132,428
7. Diclofenac	23,483,241	6,858,129
8. Ramipril	22,675,143	3,584,040
9. Sertraline	21,653,772	7,916,845
10. Amoxicillin	21,145,870	3,909,730
Total	280,649,104	117,801,359 (42%)

15.10 Spain

Figure 29. Potential savings from increased generic substitution in Spain, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Paroxetine	132,429,541	29,471,752
2. Sertraline	129,299,355	40,615,260
3. Lansoprazole	110,407,204	32,498,577
4. Amoxicillin	97,950,628	31,451,200
5. Gabapentin	82,137,404	31,228,269
6. Ibuprofen	76,860,517	27,478,084
7. Pravastatin	76,281,565	22,670,866
8. Doxazosin	74,941,029	33,637,217
9. Citalopram	72,419,900	14,683,572
10. Budesonide	64,183,290	38,005,375
Total	916,910,433	301,740,171 (33%)

15.11 United Kingdom

Figure 30. Potential savings from increased generic substitution in United Kingdom, 2004

Active substance	Public expenditure on originator medicines (€)	Savings from generic substitution (€)
1. Pravastatin	173,926,201	1,827,321
2. Doxazosin	167,861,096	120,582,878
3. Beclometasone	141,198,568	8,721,002
4. Simvastatin	130,721,082	36,535,810
5. Nifedipine	93,826,729	40,906,097
6. Budesonide	88,848,854	30,632,531
7. Omeprazole	79,995,288	28,369,791
8. Fentanyl	73,644,518	67,750,188
9. Gabapentin	60,788,304	1,526,222
10. Paroxetine	59,976,234	12,993,094
Total	1,070,786,874	349,844,935 (33%)

PART VI

ANNEXES

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17 Abbreviations

ATC	Anatomical Therapeutic Chemical classification system for drugs
EGA	European Generic Medicines Association
EU	European Union
GP	General Practitioner
INN	International Non-proprietary Name
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
RP	Reference Price
RPS	Reference-Pricing System

18 Glossary

Active substance: that component of a medicine that gives it its therapeutic effect.

ATC classification: a standard for classifying drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

Bio-availability: the amount of an active substance that is absorbed by the organism and the speed at which this occurs when introduced in a given dosage form.

Bio-equivalence: bio-equivalent medicines contain the same amount of active substance and have the same bio-availability when administered in equal doses under equal conditions.

Copy: an off-patent medicine that is neither an originator medicine, nor a licensed medicine, nor a generic medicine through the Abridged Procedure and has, for example, been approved through the Well-Established Use Procedure. For a copy, bio-equivalence with the originator medicine has not been approved.

Data exclusivity: the period of time during which the application for marketing authorisation of a generic medicine cannot refer to the pre-clinical and clinical documentation of the originator medicine.

Defined daily dose: the assumed average daily dose of a medicine needed to treat its main indication in an adult person weighing 70 kg.

Dosage: amount of a medicine that is administered to a patient.

Generic medicine: a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bio-equivalence with the reference medicinal product has been demonstrated by appropriate bio-availability studies (Directive 2004/27/EC). A generic medicine is approved through the Abridged Procedure and marketed by a company other than the originator medicine company.

Generic substitution: procedure by which a physician prescribes a specific medicine, but the pharmacist replaces it by a generic medicine that has the same active substance and bio-availability as the medicine that is prescribed.

International non-proprietary name: a single name awarded by the World Health Organization for each active substance that is marketed as a medicine. This name identifies the active substance rather than the final product which can be sold under different brand names.

Licensed medicine: medicine with the same active substance as the originator medicine that has an official licensing, distribution or co-marketing agreement with the originator medicine company.

Originator medicine: the first version of a medicine developed and patented by an originator pharmaceutical company which receives exclusive rights to marketing the medicine in the European Union for 15 years.

Patent: a document granting a company exclusive rights to exploit a new medicine for a given period of time. The patent prohibits others from selling this medicine without the permission of the company in the territory where the patent was issued.

Pharmaceutical form: the physical form in which a medicine is taken by patients as determined by its route of administration. Pharmaceutical forms include tablets, capsules, injectables and liquids.

Reference-pricing system: a system that establishes a reimbursement level or reference price for a group of interchangeable medicines. If a medicine is priced above the reference price, the patient pays the difference between the price of the medicine and the reference price. Equivalence between medicines can be defined at three levels: 1) by active substance, i.e. medicines with the same active substance; 2) by pharmacological class, i.e. medicines with chemically-related active substances that are pharmacologically equivalent; 3) by therapeutic class, i.e. medicines that have a comparable therapeutic effect.

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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.

This study shows that coordinated government policies are critically needed in many EU countries. Experience demonstrates that supply-side policies (such as pricing reductions) need to be supplemented by demand-side policies (such as incentives for physicians, pharmacists and patients to use generic medicines) to lead to a successful and sustainable generic medicines market.

The EU should now seek to foster and sustain its EU generic medicines industry, which plays an important role in the overall competitiveness of the EU pharmaceutical industry.

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