

SUSTAINABLE PROVISION OF GENERIC MEDICINES IN EUROPE

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Executive summary

Generic medicines offer the same quality, safety and efficacy as originator medicines, but at a more affordable price. Therefore, generic medicines play a crucial role in sustaining patient access to health care. Given that generic medicine market shares vary between countries, there is unequal access to generic medicines and thus to health care in Europe.

Recommendation 1:

Educate and inform health care professionals and patients about quality, safety and efficacy of generic medicines and about interchangeability of generic and originator medicines.

Market access of generic medicines in Europe is inhibited by issues surrounding intellectual property protection (e.g. evergreening tactics, patent linkage), pricing and reimbursement delays. Procedures governing marketing authorization, pricing and reimbursement should not consider intellectual property protection issues. Also, there is a case to be made for speeding up pricing and reimbursement approval for generic medicines.

Recommendation 2:

Prohibit the linkage of intellectual property protection with marketing authorization, pricing and reimbursement procedures.

Recommendation 3:

Adopt faster or immediate pricing and reimbursement procedures for generic medicines following marketing authorization.

Ad hoc measures implemented in the context of the financial and economic crisis, external price referencing, price linkage, and the introduction of tendering systems for medicines in ambulatory care put pressure on generic medicine prices. This negative price spiral endangers the sustainable provision of generic medicines in Europe. Countries can increase medicine utilization (with expenditure increasing at a lower rate or even decreasing) if measures to lower generic medicine prices are also supported by strong demand-side policies aimed at increasing the use of generic medicines.

In the context of a reference pricing system, setting low reference prices can support sustainable price competition if there are strong incentives to support generic medicine use. Shifts in prescribing patterns and the homogeneity of medicines within the reference group are important considerations when defining reference groups. Reference pricing systems reduce medicine prices, may increase generic medicine use, and yield short-term savings without a negative impact on health outcomes.

The development of a generic medicine market needs to be supported by demand-side policies inciting physicians to prescribe, pharmacists to dispense and/or patients to use generic medicines. Which specific policies are implemented depends on local demographic, cultural, economic and institutional constraints. Since 2006, countries with a mature generic medicine market have further increased the volume of generic medicines but at substantially lower prices, thus undermining the sustainable provision of generic medicines, such as in Germany and the United Kingdom. Some countries with a developing generic medicine market have been successful in increasing the generic medicine market share by volume, such as France and Portugal. This is because they have implemented key generic medicine policies during the last couple of years. However, much more remains to be done in order to bring the generic medicine market share in these countries to the levels observed in countries with a mature generic medicine market.

Recommendation 4:

Introduce demand-side policies to maximize savings for health care payers and to support the competitive, but sustainable provision of generic medicines in an era of stringent price cuts across Europe.

With respect to demand-side policies for physicians, pharmaceutical prescription budgets and prescription quota reduce pharmaceutical expenditure and prescription volume, and increase generic medicine prescribing. The implementation of pharmaceutical budgets has been accompanied by measures to support generic medicine prescribing such as computerized prescribing systems. Other prescribing tools such as guidelines, substitution lists or prescribing by international non-proprietary name can be integrated in computerized prescribing systems. The impact of prescribing by international non-proprietary name on generic medicine use depends on pharmacist dispensing regulations and pharmacist remuneration systems.

Recommendation 5:

Support generic medicine prescribing by introducing computerized prescribing systems. Integrate other prescribing tools such as guidelines, substitution lists or prescribing by international non-proprietary name in computerized prescribing systems.

Recommendation 6:

Support prescribing by international non-proprietary name by coherent dispensing regulation or a pharmacist remuneration system that does not penalize generic medicines.

The main demand-side policy for generic medicines targeting pharmacists in Europe is generic substitution. The impact of generic substitution depends on the pharmacist remuneration. There is a trend in Europe to move away from a percentage of the medicine price (which favours originator medicines) to a fee per prescription and/or medicine (which provides a neutral financial incentive to engage in generic substitution) or to a combination of these two systems.

Recommendation 7:

Move pharmacist remuneration away from a percentage of the medicine price to a fee per prescription and/or medicine or to a combination of these two systems.

Patient demand for generic medicines is influenced by financial incentives, by information campaigns and by communication between health care professionals and patients regarding generic medicines.

Recommendation 8:

Introduce financial incentives for patients to use generic medicines such as lower co-payments.

Recommendation 9:

Launch information campaigns and promote communication between health care professionals and patients to support demand for generic medicines.

Countries

	Austria		Latvia
	Belgium		Lithuania
	Bulgaria		Luxembourg
	Croatia		Netherlands
	Czech Republic		Norway
	Denmark		Poland
	Estonia		Portugal
	Finland		Romania
	France		Slovakia
	Germany		Spain
	Greece		Sweden
	Hungary		Switzerland
	Ireland		Turkey
	Italy		United Kingdom

1. GENERIC MEDICINES: QUID?

Generic medicines offer the same quality, safety and efficacy as originator medicines, but at a more affordable price. Therefore, generic medicines play a crucial role in sustaining patient access to health care.

A generic medicine is a medicinal product which has the same qualitative and quantitative composition in active substances, has the same strength, pharmaceutical form and administration route as the originator medicine, and whose bio-equivalence with the originator medicine has been demonstrated by appropriate bio-availability studies ¹. A generic medicine has the same quality, safety and efficacy as the originator medicine and, therefore, generic and originator medicines are interchangeable. However, questions remain over the interchangeability of generic and originator medicines with a narrow therapeutic index (e.g. anti-epileptic medicines, immunosuppressants), where a small difference in concentration can have a substantial impact on safety and efficacy ². There is a need to educate and inform health care professionals and patients about the interchangeability of generic and originator medicines.

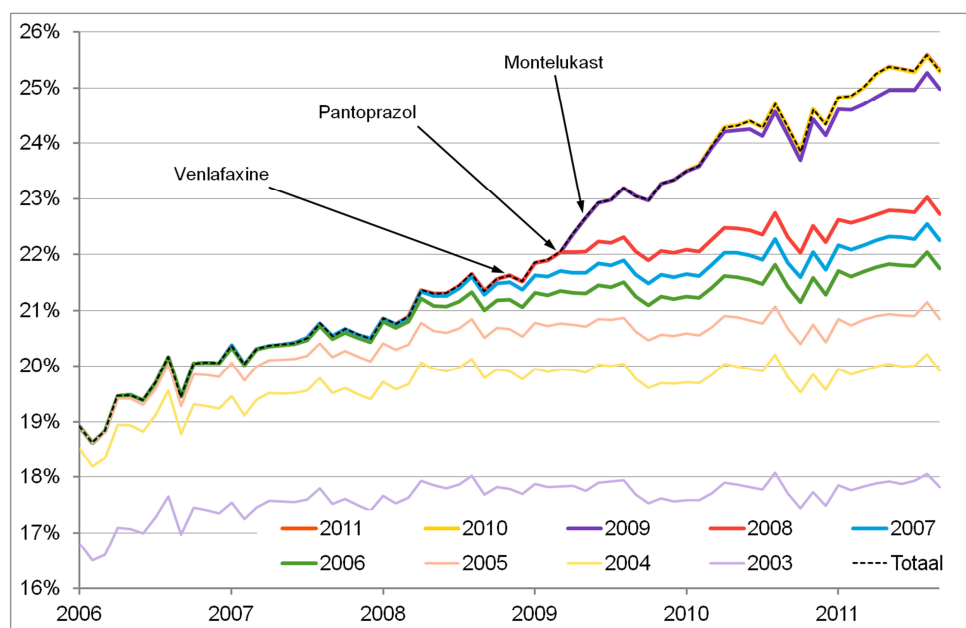
Given that generic medicines contain well-known, safe and effective active substances that have been on the European market for at least ten years, generic medicine companies do not need to replicate pre-clinical tests and clinical trials ³. The lower costs of research and development explain why generic medicines are more affordable than originator medicines. As a result of their more affordable prices, the availability of generic medicines is expected to improve the cost-effectiveness of pharmacotherapy. Numerous studies have also highlighted the savings associated with generic medicine use for health care payers ⁴. Therefore, generic medicines play a crucial role in sustaining patient access to health care.

Over the coming years, fewer new generic medicines are likely to be introduced in the market. This results from the falling productivity in research and development of originator medicines, implying that fewer new active substances reach the market for which generic

medicines can be developed in due course ^{5,6}. For instance, only 39 new active substances were approved by the US Food and Drug Administration in 2012 ⁷.

The importance of market entry of new generic medicines for the development of a generic medicine market is illustrated in Figure 1. For each year, this Figure presents generic medicine market shares by volume of the group of active substances for which generic medicines were available in that year. For instance, Figure 1 shows that the increasing market share of generic medicines in Belgium mainly originated from the introduction of new generic medicines of venlafaxine in 2008, pantoprazol and montelukast in 2009.

Figure 1. Market shares of generic medicines in Belgium ⁸



Note: Figure 1 is an updated version of a Figure previously published in PharmacoEconomics ⁹.

2. MARKET ACCESS OF GENERIC MEDICINES

Market access of generic medicines in Europe is inhibited by issues surrounding intellectual property protection (e.g. evergreening tactics, patent linkage), pricing and reimbursement delays. Procedures governing marketing authorization, pricing and reimbursement should not consider intellectual property protection issues. Also, there is a case to be made for speeding up pricing and reimbursement approval for generic medicines.

Originator medicines benefit from intellectual property protection provided by patents and supplementary protection certificates. Furthermore, data exclusivity and marketing exclusivity apply. Data exclusivity refers to the period of time during which the application for marketing authorization of a generic medicine cannot draw on the pre-clinical and clinical documentation of the originator medicine. Marketing exclusivity relates to the period of time following data exclusivity during which a generic medicine cannot enter the market. A generic medicine can enter the market after all protection on the originator medicine has ended and after it gains marketing authorization, pricing and reimbursement approval ¹⁰.

Although intellectual property protection serves to promote innovation and to aid the dissemination of knowledge ¹¹, intellectual property protection may also inhibit market access of generic medicines in some cases. For instance, disputes about patent status between originator and generic medicine companies are a barrier to the development of the generic medicines market in countries such as Portugal and Spain ¹².











A particular concern is that originator medicine companies attempt to extend the period of intellectual property protection by developing new medicines based on changes in patented non-essential features of the original medicine (e.g. isolation of the active enantiomer in the new medicine) ¹³. These so-called ‘evergreening’ practices have been shown to delay market access of generic medicines and have led to litigation due to dubious secondary patents ¹².

Another example of evergreening tactics is patent linkage, i.e. the attempt by a third party to link the patent status of an originator medicine to the award of marketing authorization, pricing and reimbursement to the generic medicine ¹⁴. This practice has delayed market access of generic medicines in for example Italy and Portugal due to the time needed by regulatory agencies to consider claims of patent infringement. However, European legislation forbids patent linkage and confirms that marketing authorization, pricing and reimbursement agencies may not take account of patent issues ^{10;15}.

The Pharmaceutical Sector Inquiry investigated patent settlement agreements between originator and generic medicine companies in Europe between 2000 and 2008 ¹². In around 50% of settlements, the ability of the generic medicine company to market the product was restricted, although this was sometimes accompanied by a value transfer from the originator to the generic medicine company (by means of for example direct payment, license or distribution deal). Also, many agreements pertaining to the sale of generic medicines were concluded between originator and generic medicine companies, some of which were initiated prior to the loss of the originator medicine's exclusivity.

In the past, not all European countries respected the obligation ¹⁶ to adopt a pricing decision for a (generic) medicine within 90 days from the day of application and a reimbursement decision within 90 days ¹⁷. Table 1 shows that several countries were still not meeting these timeline requirements in 2011.

Table 1. Pricing and reimbursement timelines for generic medicines in 2011 ¹⁸

<i>Pricing</i>		<i>Reimbursement</i>	
<i>Countries meeting timeline (≤ 90 days)</i>	<i>Countries not meeting timeline (> 90 days)</i>	<i>Countries meeting timeline (≤ 90 days)</i>	<i>Countries not meeting timeline (> 90 days)</i>
  	 	  	 

Given that generic and originator medicines are interchangeable (see chapter 1), it is recommended that pricing and reimbursement approval for generic medicines is immediate or rapid once all protection on the originator medicine is exhausted. Furthermore, pricing and reimbursement procedures should not take into account intellectual property protection, or evaluate data (for instance, bio-equivalence data) that have already been considered in the marketing authorization procedure ¹⁰.

3. GENERIC MEDICINE PRICING

Ad hoc measures implemented in the context of the financial and economic crisis, external price referencing, price linkage, and the introduction of tendering systems for medicines in ambulatory care put pressure on generic medicine prices. This negative price spiral endangers the sustainable provision of generic medicines in Europe.

Over the last couple of years, several trends exist in European countries that produce a negative price spiral for generic medicines.

Numerous European countries have introduced ad hoc measures in response to the financial and economic crisis that (in)directly reduce generic medicine prices. Such ad hoc measures include: cuts in generic medicine prices (e.g. Turkey), increase of price difference between generic and originator medicines (e.g. Switzerland), restriction of reimbursement to cheapest generic medicines (e.g. Italy), expansion of the reference pricing system to more generic medicines (e.g. France), reduction of reimbursement levels in the reference pricing system and price reductions imposed on generic medicines to qualify for exemption from patient co-payments (e.g. Germany), selection of countries with lower price levels in the generic medicine external price referencing system (e.g. Portugal), expansion of tendering systems to include more medicines (e.g. the Netherlands), and the reduction of wholesale and pharmacy remuneration (e.g. Ireland).

Some European countries (such as Bulgaria, Croatia, Czech Republic, Latvia)¹⁸ set the price of a generic medicine based on average prices in selected other countries (i.e. external price referencing). As has been observed for originator medicines¹⁹, external price referencing can be expected to lower generic medicine prices in Europe. External price referencing is based on the assumption that pharmaceutical markets in European countries are comparable. However, European countries differ substantially not only in their economic and financial structure, but also in their health care systems. Specifically, they differ in their pharmaceutical markets because of distinct market penetration of generic and originator medicine volume, linked also with different national price regulations. Therefore, a report published in the

context of the World Health Organisation and Health Action International project on medicine prices and availability recommended that countries need to consider all approaches to set efficient medicine prices, including not only external price referencing, but also price competition and other pricing approaches ²⁰.

An alternative approach to setting generic medicine prices is price linkage, i.e. the price of a generic medicine is set at a particular percentage below the price of the originator medicine. A system of price linkage implies that the price of a generic medicine is determined by a competitor, the originator medicine company ²¹. As a result, price linkage produces an incentive for originator medicine companies to lower the prices of their products in an attempt to drive generic medicines out of the market. For instance, the price linkage system in Switzerland implied that the maximum price of generic medicines was set at 60% of the originator medicine price in 2008. Additional price cuts by originator medicines forced generic medicine companies to reduce prices further, so that generic medicines at market entry were priced in practice at 42% of the originator medicine price rather than 60% ²².

An increasing number of European countries have implemented or are considering to implement a tendering system for medicines in ambulatory care. A tender is a mechanism whereby a purchaser (e.g. health insurance fund) buys medicines based on a competitive bidding process ²³. Significant pharmaceutical budget savings can be attained from tenders in the short term, but the long-term results are uncertain ²⁴. More specifically, companies that do not win the tender may close production lines and withdraw from the market, thereby reducing competition when the next tender is awarded. For instance, the number of companies that participate in tenders in Germany has decreased over time, with a few large companies winning the majority of contracts ²⁵.

Market entry and uptake of new generic medicines is likely to be influenced by the price level at which generic medicines enter the market and by the extent and speed of price erosion following market entry. In this respect, a case can be made against organising tenders during the first couple of years, and in favour of policies that attract multiple players to the market and let competition reduce prices ²⁶.

The negative price spiral endangers the sustainable provision of generic medicines in Europe. This is evidenced in particular when companies start to withdraw from the market. In this

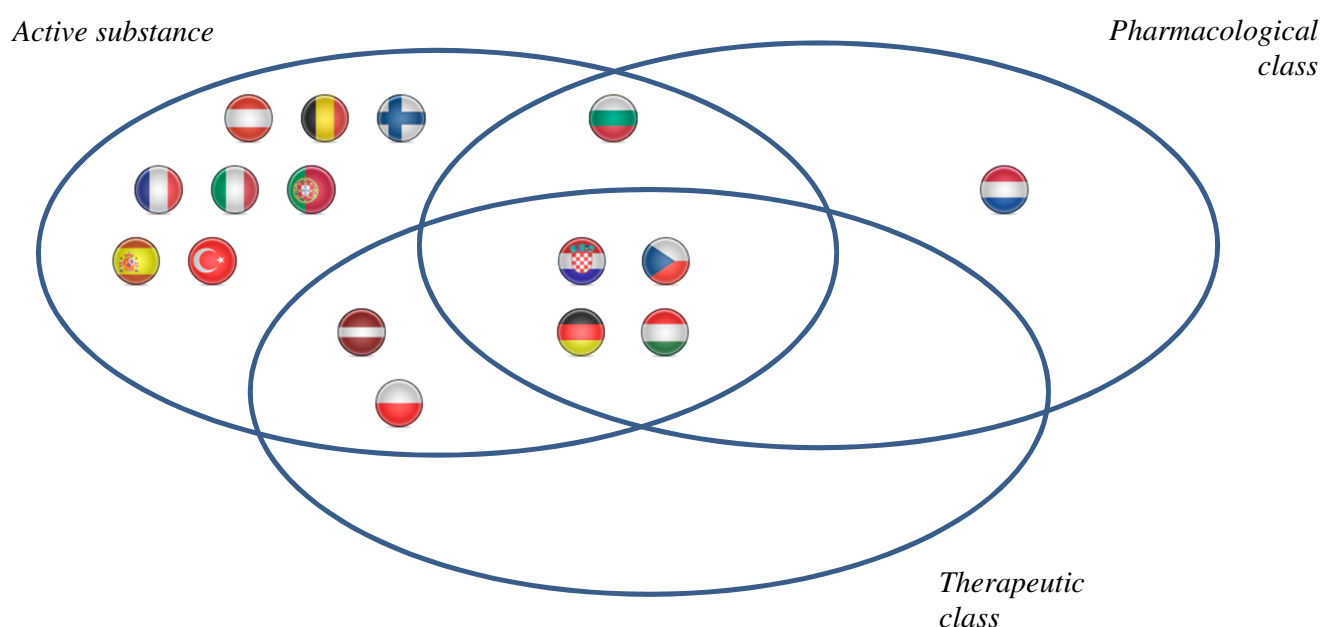
respect, it should be noted that a price-volume relationship is likely to apply to medicine markets: a recent study showed that medicine prices decreased to a greater extent over time in European countries that had a larger generic medicine market share than in countries with a smaller generic medicine market share ²⁷. Therefore, it seems that European countries can increase medicine utilization (with expenditure increasing at a lower rate or even decreasing) if measures to lower generic medicine prices are supported by demand-side policies aimed at increasing the use of generic medicines ^{28;29}. For instance, France has coupled generic medicine price cuts with a measure that grants immediate reimbursement to patients in the community pharmacy if a generic medicine is dispensed.

4. REFERENCE PRICING

Setting low reference prices can support sustainable price competition if there are strong incentives to support generic medicine use. Shifts in prescribing patterns and the homogeneity of medicines within the reference group are important considerations when defining reference groups. Reference pricing systems reduce medicine prices, may increase generic medicine use, and yield short-term savings without a negative impact on health outcomes.

A reference pricing system sets a common reimbursement level (the reference price) for a group of interchangeable medicines (the reference group). Thus, a reference pricing system is an example of a policy instrument relating to reimbursement. Reimbursement is determined in relation to the reference price and patients are required to pay the difference between the price of the medicine and the reference price for medicines that are priced above the reference price. Reference groups can be defined by active substance, by pharmacological class, by therapeutic class or by a combination of these (see Figure 2).

Figure 2. Methods for establishing reference groups in 2011¹⁸



Reference pricing systems have been shown to sustain demand for medicines priced at or below the reference price (e.g. generic medicines) ³⁰. However, generic medicine use may not be supported by a reference pricing system if originator medicine prices drop to the reference price ³¹. Also, in reference pricing systems by active substance, physicians may shift their prescribing patterns away from generic medicines in the reference pricing system towards patented originator medicines with a similar therapeutic indication outside the reference pricing system ¹⁷, a practice which has been observed for some active substances in Italy, the Netherlands and Spain ³⁰. The implementation of substitution lists and therapeutic guidelines may avoid such a prescription shift. A prescription shift does not occur when reference groups are set by therapeutic class, although then the heterogeneity of medicines included in the same reference group increases ¹⁷.

In Europe, there seems to be a trend to set the reference price at the level of the lowest priced medicine (e.g. Bulgaria, Czech Republic, Finland, Hungary, Italy, Latvia, Poland, Spain and Turkey) or the lowest priced generic medicine (e.g. Austria, Bulgaria, France and Latvia) ¹⁸. Such an approach may help to exploit savings to health care payers and promote price competition between companies if there are sufficient incentives to support generic medicine use (e.g. Poland). However, there is a risk that companies enter the market that focus on providing a few products for a limited period of time at the lowest price, thereby undermining the sustainability of health care provision and of the generic medicine industry in the long run (e.g. Denmark and Spain) ²⁴.

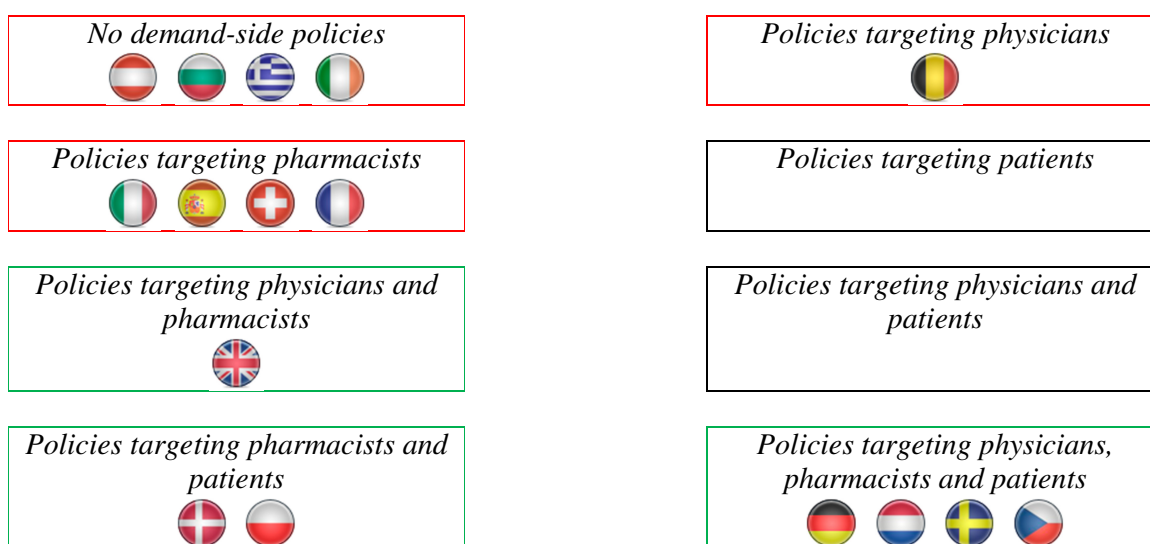
Finally, a literature review found that reference pricing systems reduce medicine prices and thus generate savings for health care payers without a negative impact on health outcomes. However, prices do not necessarily fall below the reference price and savings may be short-lived ³⁰.

5. DEMAND-SIDE POLICIES FOR GENERIC MEDICINES

The development of a generic medicine market needs to be supported by demand-side policies inciting physicians to prescribe, pharmacists to dispense and/or patients to use generic medicines. Which specific policies are implemented depends on local demographic, cultural, economic and institutional constraints.

The key difference between mature generic medicine markets and developing generic medicine markets is the presence/absence of demand-side policies inciting physicians to prescribe, pharmacists to dispense and/or patients to use generic medicines ²⁶. This is illustrated in Figure 3 where demand-side policies in the mature generic medicine markets of the Czech Republic, Denmark, Germany, Netherlands, Poland, Sweden and the United Kingdom are contrasted with those in the developing generic medicine markets of Austria, Bulgaria, Belgium, France, Greece, Ireland, Italy, Spain and Switzerland.

Figure 3. Demand-side policies for generic medicines in 2011 ¹⁸



Which demand-side policy does a country need to introduce to develop its generic medicine market? A country needs to choose a key policy driver that fits with local demographic, cultural, economic and institutional constraints. Therefore, this key policy driver is likely to vary from country to country. Additionally, the key policy driver needs to be reinforced by other demand-side policies to ensure that policies targeting physicians, pharmacists and patients are aligned with a view to promote generic medicine use ²⁶.

For instance, since 2011, the key policy driver of the Portuguese generic medicine market is mandatory electronic prescribing by international non-proprietary name. This is complemented by measures targeting pharmacists, i.e. the obligation for pharmacists to dispense one of the three cheapest medicines of the prescribed active substance and a change in the pharmacist remuneration system (which now consists of a fee in addition to a percentage of the medicine price). Also, multiple information campaigns have been launched for health care professionals and patients ³².

6. POLICIES TARGETING PHYSICIANS

Pharmaceutical prescription budgets and prescription quota for physicians reduce pharmaceutical expenditure and prescription volume, and increase generic medicine prescribing.

The implementation of pharmaceutical budgets has been accompanied by measures to support generic medicine prescribing such as computerized prescribing systems.

Other prescribing tools such as guidelines, substitution lists or prescribing by international non-proprietary name can be integrated in computerized prescribing systems.

The impact of prescribing by international non-proprietary name on generic medicine use depends on pharmacist dispensing regulations and pharmacist remuneration systems.

A literature review found that physicians in general have a neutral or slightly supportive attitude towards the use of generic medicines, but still question the quality, safety and efficacy of generic medicines³³, especially in those countries with a developing generic medicine market. Thus, a workshop bringing together national medicine agencies from Austria, Belgium, Germany, Ireland, Norway, Portugal, Spain and Sweden recommended in 2011 that national medicine agencies play a role in:

- highlighting equivalent quality, safety and efficacy between generic and originator medicines;
- supporting communication campaigns about generic medicines;
- exploring the development of generic substitution lists and therapeutic guidelines in collaboration with scientific societies³⁴.

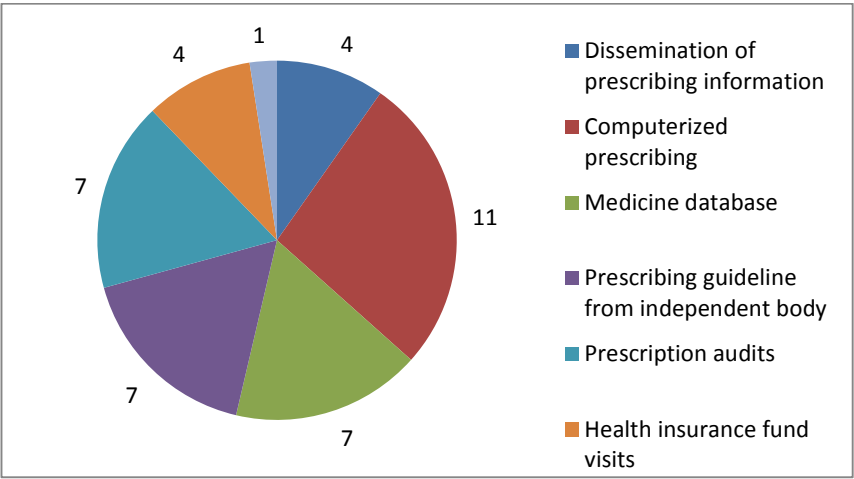
In general, European countries have implemented three main categories of demand-side policies targeting physicians: pharmaceutical prescription budgets and prescription quota, instruments to assist generic medicine prescribing, and prescribing by international non-proprietary name.

From a theoretical perspective, physicians can more easily meet pharmaceutical budgets when they prescribe less expensive medicines such as generic medicines. Although the available

evidence is limited and suffers from methodological shortcomings, the experience with pharmaceutical budgets shows that budgets reduce pharmaceutical expenditure and prescription volume, and increase generic medicine prescribing³⁵.

The implementation of pharmaceutical budgets has been accompanied by measures to support generic medicine prescribing. In 2011, approximately 70% of European countries had in place a range of instruments to assist generic medicine prescribing¹⁸. Figure 4 shows that generic medicine prescribing was sustained by computerized prescribing in 11 countries, by a medicine database in seven countries, by a prescribing guideline from an independent body in seven countries, and by prescription audits in seven countries. In particular, policy tools such as guidelines, substitution lists or prescribing by international non-proprietary name can be integrated in computerized prescribing systems with a view to promoting generic medicine use³⁵. Finally, research has demonstrated that other tools such as feedback on prescribing practices (alone or in comparison with other physicians), matrix models, peer-review meetings and quality circles incite physicians to prescribe generic medicines³⁶⁻⁴⁰.

Figure 4. Number of countries that had instruments to assist generic medicine prescribing in 2011¹⁸



A third type of demand-side policies targeting physicians is prescribing by international non-proprietary name (rather than by the brand name of the medicine). Table 2 indicates that several countries imposed or encouraged prescribing by international non-proprietary name in 2011. The impact of this policy measure on generic medicine use depends on pharmacist dispensing regulations and pharmacist remuneration systems (see chapter 7)¹⁷.

Table 2. Prescribing by international non-proprietary name in 2011 ¹⁸

	<i>Country</i>
Is compulsory	   
Is encouraged	   

7. POLICIES TARGETING PHARMACISTS

The main demand-side policy for generic medicines targeting pharmacists in Europe is generic substitution. The impact of generic substitution depends on the pharmacist remuneration. There is a trend in Europe to move away from a percentage of the medicine price (which favours originator medicines) to a fee per prescription and/or medicine (which provides a neutral financial incentive to engage in generic substitution) or to a combination of these two systems.

The main demand-side policy for generic medicines targeting pharmacists in Europe is generic substitution. This refers to the procedure by which the pharmacist dispenses a generic medicine that has the same active substance and is bio-equivalent when the physician has prescribed an originator medicine. Generic substitution is allowed (or compulsory) in many European countries (see Table 3), although in general physicians retain the right to prohibit substitution. Also, pharmacists need to inform patients of generic substitution and patients can refuse substitution.

Table 3. Generic substitution by pharmacists in 2011 ¹⁸

	Country
Is compulsory	     
Is allowed	        

The majority of physicians, pharmacists and patients seem to have a positive attitude towards generic substitution and believe that this is a suitable demand-side policy for health care payers to save money ^{35;41-43}. However, physicians tend to have a less favourable attitude towards generic substitution due to fears to lose control over the specific medicine that the patient receives, concerns over the interchangeability of originator and generic medicines, and questions about the pharmacist's ability to engage in safe generic substitution ⁴². Furthermore, a significant minority of patients is not comfortable with generic substitution because: a) they feel that lower prices translate into lower quality of generic medicines; b) differences in physical attributes between originator and generic medicines (e.g. different shape or colour)

cause confusion; and c) they prefer to receive the specific medicine that is prescribed by the physician ⁴¹. With respect to the latter factor, a Norwegian study indicated that patients are more willing to accept generic substitution when properly informed by their physician or pharmacist ⁴³. This highlights the need to involve the physician and pharmacist in the generic substitution decision and to provide information to patients ⁴¹.

Generic substitution has been shown to produce savings in pharmaceutical expenditure ³⁵. The experience of Finland, the Netherlands, Norway and Sweden demonstrates that savings in pharmaceutical expenditure arise from two sources: a) substitution of less expensive generic medicines for more expensive originator medicines, and b) increased price competition between originator and generic medicine companies ⁴⁴⁻⁴⁷.

The impact of generic substitution depends on the pharmacist remuneration, i.e. whether the pharmacist has a financial (dis)incentive to engage in generic substitution. In this respect, it should be noted that European countries are moving away from a percentage of the medicine price, which makes it financially more attractive for pharmacists to dispense a more expensive originator medicine than a less expensive generic medicine; to a fee per prescription and/or medicine, which provides a neutral financial incentive for pharmacists to dispense a generic or originator medicine; or to a combination of these systems ⁴⁸. A Swiss study suggested that physician prescribing behavior and their beliefs about generic substitution are the most important determinants of generic substitution. Also, generic substitution rates were higher when there are more generic products on the market and when the price difference between originator and generic medicines is greater ⁴⁹.

Another form of medicine substitution takes the form of switches between originator and generic medicines when patients transition between the ambulatory care and hospital settings. A Belgian study indicated that medicine substitution associated with a hospital stay is limited: a generic medicine was replaced by an originator medicine in 2% of cases and an originator medicine was replaced by a generic medicine in 2% of cases ⁵⁰. Also, schemes have been put in place to promote seamless care between health care settings focusing on medicine substitution. For instance, the Safe Therapeutic Economic Pharmaceutical Selection (STEPS) method in Northern Ireland reached agreement between specialist physicians, general practitioners, hospital pharmacists, community pharmacists and prescribing advisers to align prescribing and dispensing practices with a focus on using generic medicines ⁵¹.

8. POLICIES TARGETING PATIENTS

Patient demand for generic medicines is influenced by financial incentives, by information campaigns and by communication between health care professionals and patients regarding generic medicines.

A literature review has identified three major drivers of generic medicine use by patients: financial incentives, information campaigns, and communication between health care professionals and patients regarding generic medicines ⁵².

With respect to financial incentives, the extent to which patients need to contribute to the cost of medicines plays a role in the use of generic medicines. Patients are more likely to demand generic medicines when the difference in co-payment between originator and generic medicines is larger ⁵³. In this respect, reference pricing systems tend to provide financial incentives for patients to use generic medicines (see chapter 4). Also, a lower co-payment for generic medicines than for originator medicines has been shown to promote generic medicine use. This can be illustrated with the growth of the generic medicine market in Switzerland as a result of the introduction of a 10% lower co-payment for generic medicines in 2006 ²².

Many European countries have launched information campaigns targeting patients to inform them about generic medicines ¹⁸. For instance, Table 4 gives an overview of information campaigns in Portugal. Although no formal evaluations exist of the impact of information campaigns on generic medicine use, evidence from Portugal indicates that generic medicine use increased during the period that information campaigns ran, but this impact was not sustained in the long term ⁵⁴.

Table 4. Information campaigns about generic medicines in Portugal ³²

<i>Information campaign</i>	<i>Target</i>	<i>Materials</i>	<i>Year</i>
Generic medicines, find the differences	Patients	TV and point-of-sale material	2001
Generic medicines, people deserve it	Patients	Point-of-sale material	2002-03
Generics, equal quality different price	Patients	TV, radio, press, point-of-sale material	2004
Quality, safety and efficacy. Generics. You can trust.	Patients	TV, radio, outdoors and point-of-sale material	2007-08
Don't you think that being ill already costs enough	Patients / health care professionals	Internet, point-of-sale material	2009
You save, we all save	Patients	TV and radio	2010

Finally, communication between physicians and/or pharmacists on the one hand and patients on the other hand is likely to support patient demand for generic medicines. Although this has not been investigated in Europe, US evidence clearly shows that patients who communicate with health care professionals about generic medicines and who are comfortable with generic substitution are more likely to use generic medicines ^{55,56}.

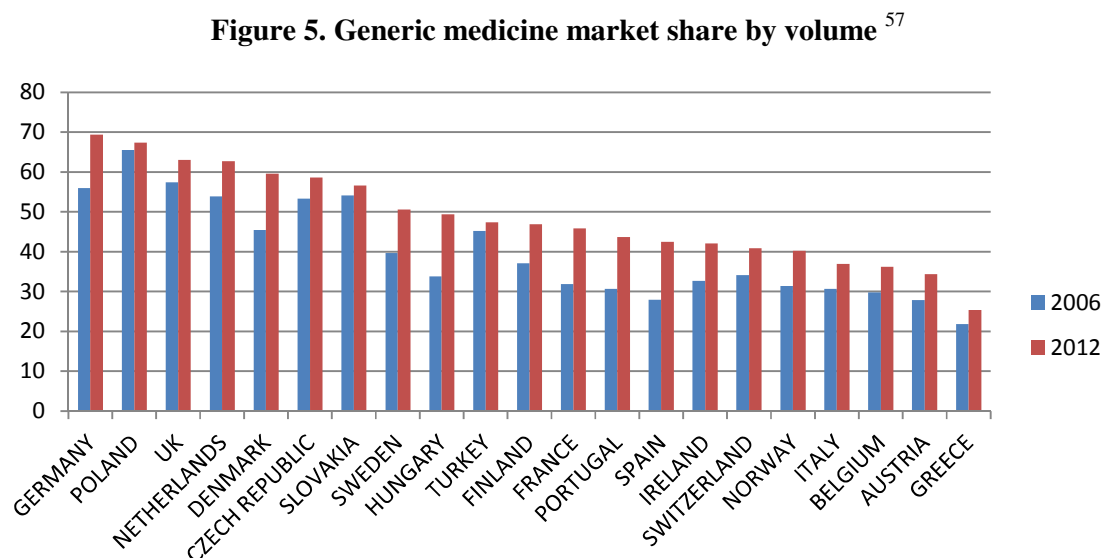
9. GENERIC MEDICINE MARKETS: EVOLUTION

Since 2006, countries with a mature generic medicine market have further increased the volume of generic medicines but at substantially lower prices, thus undermining the sustainable provision of generic medicines.

Some countries with a developing generic medicine market have been successful in increasing the generic medicine market share by volume. This is because they have implemented key generic medicine policies during the last couple of years.

A previous report established an overview of generic medicine markets in European countries in 2006 and proposed a number of key recommendations to develop generic medicine markets¹⁷. How have generic medicine markets in European countries evolved between 2006 and 2012, and how can we explain this evolution?

Figure 5 contrasts the generic medicine market share by volume (expressed in standard units) in European countries in 2006 with the market share in 2012.

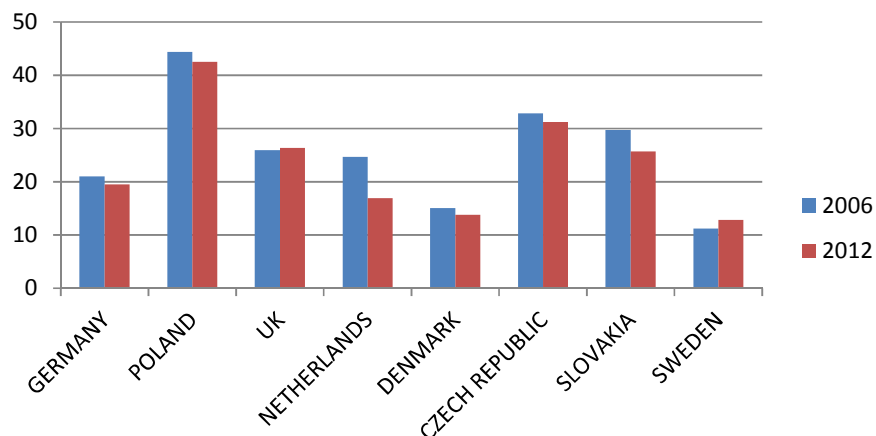


Note: Data for the Netherlands related to 2007 instead of 2006.

Whereas countries with a mature generic medicine market (i.e. Germany, Poland, United Kingdom, the Netherlands, Denmark, Czech Republic, Slovakia and Sweden) had a market share exceeding 40% in 2006, this market share has further increased to 50% or more in 2012.

However, this volume growth has come at a cost: the generic medicine market share by value (expressed at ex-manufacturer prices) has actually fallen or stayed relatively constant in countries with a mature generic medicine market between 2006 and 2012 (see Figure 6). This suggests that health care payers in these countries benefit from increased volume and price reductions of generic medicines, but the evolution in the market share by value threatens the sustainable provision of generic medicines.

Figure 6. Generic medicine market share by value in mature markets ⁵⁷



Note: Data for the Netherlands related to 2007 instead of 2006.

In countries with a developing generic medicine market (see Figure 5), a distinction can be made between countries such as Spain, Hungary, France and Portugal where generic medicine market share by volume has increased substantially between 2006 and 2012; and countries such as Austria, Belgium, Italy, Switzerland and Greece where generic medicine market share by volume has risen at a slower pace. This can be explained by the observation that during the last couple of years the former countries have implemented most, if not all, of the key recommendations to develop their generic medicine market as proposed in the 2006 report ¹⁷, whereas the latter countries have not (yet) introduced these key recommendations (see Table 5). However, much more remains to be done in order to bring the generic medicine market

share in these countries to the levels observed in countries with a mature generic medicine market.

**Table 5. Implementation of key recommendations to develop a generic medicine market
(as of 2012)**

Recommendation:	Spain	Hungary	France	Portugal	Austria	Belgium	Italy	Switzerland	Greece
1. Introduce a coherent generic medicines policy	+	+	+	+	-	+/-	-	-	-
2. Encourage price differentiation / competition within regulatory frameworks	+/-	+	+	+	+	-	+	-	-
3. Disseminate pricing information to actors	-	+	+	+	-	-	-	-	-
4. Increase confidence of actors in generic medicines	+	+	+/-	+	-	-	+	-	-
5. Provide incentives for physicians to prescribe generic medicines	+	+	+	+	+/-	+/-	+/-	-	-
6. Remove financial disincentives for pharmacists to dispense generic medicines	+	-	+	+	-	+	-	+	-
7. Provide incentives for patients to demand generic medicines	+	+	+	+	-	+/-	-	+	-

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