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Generic policies: rhetoric vs. reality

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Payers in Europe and North America have embraced generic medicines because of their perceived cost advantages in relation to branded products and the savings they create to health insurance. A robust body of evidence exists to date pointing at savings achieved through genericization. All stakeholders accept that realizing these savings is desirable as health systems face continuous cost pressures and demands to invest in new technologies.

However, the questions that arise are whether savings from genericization are robust across different policy settings and whether regulation of (generic) pharmaceutical markets has any bearing on their magnitude. This article explores these questions alongside summarizing some of the key generic policies as they prevail in seven key OECD countries.

Policies encouraging use of generic medicines

The policy environment has become particularly favourable for the use of generic medicines in many OECD countries, precisely because of their perceived cost advantages in relation to branded originator drugs. Stimulating generic competition intuitively leads to price reduction, which, in turn, should lead to greater savings to health insurers. Consequently, both supply- and demand-side policies have been introduced aiming to fulfill this policy objective. Table 1 summarizes these policies as they apply in key pharmaceutical markets.

Early entry legislation

Generic policies include the improvement of generic medicine availability, through 'early entry' legislation. Bolar provisions, a practice where generic manufacturers are allowed to complete their regulatory requirements prior to the expiry of the originator molecule's patent, have been common practice in Europe and North America for several years. Moreover, in certain environments, the speed of making generics available on the market is rewarded by protecting the first generic by a market exclusivity period; in the US, the first generic post-patent expiry has a six-month market exclusivity, which is meant to encourage generic manufacturers to enter the market quickly.

Prescribing incentives

There is a series of incentives for physicians to prescribe generically and pharmacies to dispense or substitute for a generic. Incentive structures relate primarily to targeting the prescribing behaviour of physicians, the dispensing patterns of pharmacists and consumer behaviour.

Physicians responsible for generating demand for medicines through prescribing may respond positively to the entry of generic drugs, but they are not always sensitive to price. As a result, influencing the way they prescribe can significantly influence overall generic prescribing, and can be achieved by providing them with financial or/and non-financial incentives. Financial incen-

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Table 1: Generic pharmaceutical policies in seven OECD countries, 2000–2006

Measure	UK	Germany	France	Italy	Spain	US	Canada
Supply-side policies							
Bolar-type regulation	√	√	√	√	√	√	√
Price cap	√		√	√	√		
Reference pricing		√	√	√	√		√
Proxy demand-side policies							
Promoting generic prescribing		√	√		√	√	√
Compulsory generic prescribing	√						
Prescribing monitoring & audit	√	√	√	√	√	√	√
Generic substitution		√	√	√	√	√	√
Flat fee combined with regressive margin		√	√	√	√		
Flat fee per script	√					√	√
Discounting allowed	√		√			√	√
Clawback	√						
Demand-side policies							
Differential co-payments						√	
Co-insurance or flat fee	√	√	√	√	√		√

Source: Kanavos, Costa-Font and Seeley (2008).[5]

tives include prescribing budgets and provide an explicit incentive to contain costs, which, in turn, encourages generic prescribing. The incentives may be structured to reward physicians who underspend, or penalize those who overspend, or both. The international experience suggests that unless budgets are fixed and linked to clear and enforceable rules, they are unlikely to work.

Non-financial incentives affecting physician prescribing include promotion of generic prescribing, prescription monitoring, audit, and the use of clinical guidance and IT to influence prescribing decisions. It is unclear what effect non-financial incentives and measures have in practice, but it is thought that unless they are vigorously implemented and monitored by health insurance, their effectiveness is likely to be poor.[1]

For policies encouraging the use of generics to be successful there needs to be an integrated pharmacy policy in place. Conceptually, it is important that pharmacists (a) are reimbursed in such a way as to not discourage them from dispensing the least expensive product and (b) are able to substitute for a cheaper (generic) product if a physician has prescribed a branded medicine, so long as a generic is available.

In terms of margins, fixed fees per prescription or regressive margins either leave pharmacists indifferent (fixed fees) or do, in principle, provide an incentive to dispense a generic (regressive margins), other things being equal. Moreover, an effective policy on pharmacy margins would be incomplete without generic substitution.

Generic substitution is allowed in some form in Canada, Germany, and the US, and has been introduced in France, Italy, and Spain since the late 1990s, but is disallowed in the UK (in outpatient settings, but is allowed in in-patient settings). Typically, however, physicians may often

be given some control to prevent substitution where a particular situation warrants this; for example, if they believe that prescribing a branded originator medicine is required on medical grounds.

Finally, pharmacists may also receive discounts or/and rebates from wholesalers and/or manufacturers. Such practices typically provide incentives to dispense the drug offering the highest discount. The treatment of discounts differs depending on the policy setting. They are widely allowed (US, Canada, UK), are allowed up to a limit for generic medicines (France), may be disallowed altogether by law (Germany), or may operate with the knowledge of health insurance, but without any explicit policies regulating or disallowing them (Italy, Spain). In the UK payers manage to retain a proportion of the total discount through a clawback* policy.

Price caps and reference price schemes

Payers have imposed price caps on generic medicines in many countries, often linked to the price of originator drugs, or have introduced maximum reimbursement ceilings through reference pricing.

Countries with well-established generic pharmaceutical markets may or may not impose price caps on generic medicines. The US, Germany and the UK do not impose such price caps, although the UK has introduced a statutory maximum price scheme for a number of generic medicines, whose supply was short a while ago and, as a result, experienced significant price hikes.[2] In France the price ceiling regulation stipulates that prices of generics should be at least 30% lower than the equivalent branded product. Comparable provisions exist in Austria, where there is an upper price ceiling for the first generic entrant and lower ceilings for subsequent entrants.

In contrast with price caps, reference pricing schemes operate on the basis of health insurance setting a maximum reimbursement price per product (or per product class), irrespective of the price variation that exists on the market. This is done by grouping together similar molecules and defining a maximum reimbursement price. This means that prices above the reference level will not be reimbursed and, should patients prefer medicines whose prices are above the reference level, they will bear the additional cost out-of-pocket. In this case, health insurance transfers the risk of additional expenditure to the insuree.

The degree to which reference pricing encourages generic medicines is dependent on how this policy tool is implemented and the extent to which it covers the entire off-patent segment, or parts thereof. Evidence on the performance of reference pricing from Germany suggests that the prices of drugs included in reference pricing groups declined, but branded drug manufacturers compensated for this by increasing the prices of non-reference-priced drugs.[3]

An earlier study on Germany found that the savings brought about by reference pricing were equal to 9% of pharmaceutical expenditure.[4] Smaller savings were found in the case of the Canadian province of British Columbia which introduced a reference-based system in 1994 in its programmes for seniors.[5]

Patient incentives

Finally, the uptake of generics can be influenced by their acceptance by patients, the structure of co-payments facing them and reference pricing.

Typically, co-payments comprise flat fees per prescription, a percentage of the prescription cost or deductibles. A flat fee would not, in principle, promote generic use among patients, unless there is a tiered flat co-payment structure in place; in other words, patients would pay less for a generic and more for a branded drug, as is frequently practised in the US.

The percentage co-payment can also promote generic use, as, *ceteris paribus*, consumers pay a proportion of the cost of the drug dispensed. Often, however, percentage co-payments (co-insurance) are too modest and subject to significant exemptions to actively influence drug consumption by patients (for example, in France and Spain). Reference pricing also leaves the choice of final drug selection with the patient. Patients who wish to purchase the more expensive branded drug will have to cover the difference between the reference price and their drug of choice.

What is the outcome of generic policies?

While significant attention has been paid over the past two decades to encouraging the use of generic medicines through a combination of supply- and demand-side measures, it is also important to determine whether such measures have had an effect on the fast uptake of generic medicines and whether (generic) prices decline quickly in the post-patent expiry period; and, if so, whether regulation of generic markets has any bearing on price developments.

(i) Is there 'sufficient' generic entry?

Conceptually, rising numbers of competitors in homogeneous markets, such as generics, should have an impact on the degree of price competition, forcing prices to decline further and faster. Therefore, a sufficient number of generic competitors on the market post-patent expiry should, in principle, lead to intensified price competition between them.

Recent evidence[6] taking into account generic entry after patent expiry in 12 products across five key EU countries (UK, Germany, France, Italy, Spain) and comparing it with the US and Canada, suggests that in most European countries there is a proliferation of generic entrants (Table 2). In the majority of products studied there are far more generic competitors in Germany and Spain than there are in the US. France and Italy are also following suit, although the number of competitors per molecule in these two countries is, on average, lower than it is in Germany or Spain. In the UK there appear to be fewer competitors altogether, but, then again, the UK market is

* A policy tool whereby health insurance is aware of discounting practices taking place at pharmacy level and retain a proportion of that discount.

Table 2: Number of generic entrants in seven countries and for 12 products, 2004

Molecule	Germany	Italy	France	UK	Spain	Total EU-5	Canada	US
1. Amoxicillin	45	41	17	15	64	182	11	48
2. Clavulanic acid	16	6	10	4	20	56	3	7
3. Hydrochloro-thiazine	60	6	8	9	28	111	15	80
4. Levonorgestrel	38	4	6	5	4	57	4	6
5. Lisinopril	24	1	7	3	13	48	1	16
6. Mesalazine	19	16	3	5	3	46	5	6
7. Metformin	49	10	16	7	2	84	17	25
8. Methylphenidate	4	0	1	4	2	11	5	19
9. Omeprazole	24	0	14	6	44	88	1	6
10.Paroxetine	24	5	7	4	15	55	8	7
11. Salbutamol	27	6	6	13	5	57	13	52
12. Simvastatin	33	1	N/A[a]	5	27	66	10	N/A[a]

Note: [a] data not available, as the patent of simvastatin had not expired in the US and France in 2004.

Source: Author's compilation from IMS.

dominated by unbranded generics, whose source cannot be identified. Overall, it appears that the presence of generic competitors in the five EU countries is very strong and, often more so than in the US or Canada. Other things being equal, the large number of competitors could be a predictor of intense price competition.

(ii) Do generic prices decline fast enough?

Having established that generic competition, in principle, should be fairly intense based on the number of generic competitors, one very concrete question is the extent of generic price reduction post patent expiry.

Intuitively, the introduction of several generic alternatives competing in a homogeneous market should result in price competition and a concurrent decline in prices. Indeed, two studies conducted in the US confirm the inverse relationship between the price of a generic drug and the number of competing firms.[7,8]

Further empirical evidence suggests that even though residual loyalty remains to the brand after patent expiry, this does not completely deter generic competition.[9] Within one year of entry, generic products captured a large share of prescriptions dispensed (44%) and market sales (50%) in the US.[7,10] Evidence on generic prices indicates that they fall to a fraction of the originator drug price, although this reflects the situation in the US, where prices are not regulated and significant price competition exists, particularly after patent expiry. In the US, at the time of generic launch, the average generic price was 25% lower than the originator brand price and as more generics entered the market, the price fell to about one-fifth of the initial average generic price.

Despite the US evidence, a closer examination of generic prices and the rate at which they decline in a number of European countries indicates that fast price falls do not always occur.

Having examined average price declines across the generic alternatives of 12 high-selling molecules in the five European countries, a different picture emerges. As Table 3, (2nd column) suggests, the largest price decline is registered in the UK, where generic prices may decline to a fraction of the originator drug price. In Germany and France the decline is significantly smaller and can reach 40%, whereas smaller overall price declines are observed in Italy (20%) and Spain (<30%). Overall, significant generic entry in some key European countries seems to be associated only with moderate price declines of generic medicines and these

Table 3: Pricing and penetration of generics in five selected European countries

Country	Average difference between branded price and generic price up to 3 years after first entry (%)	Average generic penetration up to 3 years after first entry (%) (potential maximum generic market share, by sales)
UK	80%	55% (95%)
Germany	25–40%	45% (85%)
France	30–40%	10–20% (30%)
Italy	20%	10–18% (25%)
Spain	<30%	10–25% (60%)

Source: Author's compilations based on a sample of 12 products.

declines take a long time to materialize as opposed to occurring within a year post-patent expiry.

(iii) Is generic penetration occurring sufficiently fast?

The extent of generic penetration varies significantly by country. Table 3 shows that the average generic penetration across the 12 molecules by sales reached 55% in the UK, but was significantly lower in other countries (45% in Germany and only 10–25% in France, Italy and Spain). If there is price parity between branded originator drugs and generics, this should not be an issue, but, if not, it means that generic medicines can still capture significant market share, which, combined with lower prices, should increase savings to health insurers even further.

(iv) What is the impact of regulation?

The significant differences in generic price declines across the five EU countries examined raises questions about the additional factors that may influence price behaviour.

It is highly likely that pricing and reimbursement regulation may be limiting the extent of price competition post patent expiry, rather than increasing it. Interestingly, of the five countries shown in Table 3, only the UK has a liberal pricing regime for generic medicines. All other countries either apply price capping (France, Italy) and/or reimbursement regulation, particularly reference pricing (Germany, France, Italy, Spain).

A recent quantitative examination of the impact of regulation on generic price competition has shown that regulation, in the form of reference pricing, has a dampening effect on generic price competition post-patent expiry.[6] Although this is not immediately compelling, it is intuitively easy to understand: reference prices are set by payers based on observation of (generic) market prices. The behaviour of payers will thus be determined by market dynamics. If market prices stay the same or decline modestly, the reaction of payers will mirror these movements. Unless payers pro-actively indicate what they are prepared to pay post generic entry, it is unlikely that prices of generic medicines will "race to the bottom".

It appears, therefore, that although reference pricing encourages entry into the generic market and contributes to price declines, the effect of these price declines can be smaller than when the off-patent market is left to operate without market intervention.

(v) What other factors may influence diffusion of generics?

In addition to the way reimbursement regulation works, there may be further reasons why prices are sluggish downwards. Policy-makers need to be aware that generic diffusion also may be affected by further parameters reflecting market dynamics. One of them is product differentiation.

Product differentiation in generic product markets may include:

(a) altering some of the product characteristics (dose, pack size, mode of administration);

(b) focusing only on some aspects of a product market (for example, launching generic versions in some rather than all dosage forms or pack sizes);

(c) exiting and potentially re-entering the market with a slightly differentiated product and price; or

(d) offering price and/or volume discounts to the distribution chain in order for the latter to dispense the product more frequently to patients.

These strategies seem to advocate attempts to build elements of brand awareness among generics and reinforce a perception of better quality. In this way, generic producers are able to depart from the link with the price of the originator brand and create market niches in an otherwise mature and homogeneous product market. New presentations may also affect reference price levels, as insurers take all prices on the market in order to set a reference price at a point in time.

Unless such attributes offer therapeutic advantages over existing generic presentations, they should be treated as perfect substitutes to existing presentations and

be subject to price competition.

Conclusions and policy implications

The wide range of supply- and demand-side policies shown in Table 1 is often used in combination to enable greater use of generic medicines.

Systems that either facilitate early market entry of generic pharmaceuticals or put in place financial incentives for their use, are, in principle, better able to achieve the dual aims of increasing generic consumption and creating a competitive market in which substantial differences in prices exist between generics and branded originator medicines.

However, the implementation and continuous monitoring of generic policies on the supply- and demand-side requires rigour and persistence, hitherto seen in very few cases internationally.

Whereas physicians and pharmacists are key in prescribing and dispensing generic medicines respectively, the effectiveness of policies targeting prescribing and dispensing behaviour is contestable. Although generic prescribing by physicians, in principle, is promoted in most countries, the extent to which this is happening in practice varies significantly as do monitoring and prescribing audit by health insurance.

In the majority of cases, compulsion is missing on the part of health insurance. In the case of generic prescribing, from a broader European perspective, it is mandatory only in the UK where it is supported by the relevant information technology structure and software for each prescribing physician.

Generic substitution policies could offer significant benefits, but much depends on their enforcement and the availability of cheaper alternatives at the pharmacy when a prescription is dispensed.

Similarly, while patient co-payments could contribute to higher generic use by differentiating between co-payments for generic versus branded medicines, this tool has not been leveraged enough in Europe, due to extensive exemptions related to age or type of illness.

It seems that the only policies that have been implemented vigorously in most policy settings are related to the supply-side and have to do with price ceilings on reimbursement through variation of reference pricing. It appears that such measures are easier to implement than having to target and monitor physician prescribing patterns or making patients responsible for a greater part of their prescription costs. Overall, the uptake of generics and the benefits to health insurance are different. In order for financial benefits from genericization to be maximized, it is important that a switch to lower priced generics occurs early on and that the price gap between branded and generic is maximized as fast as possible.

The 2008 study by Kanavos, Costa-Font and Seeley[6] found that with regard to the relationship between originator and generic drug prices, regulation in the form of reference pricing does not have a sizeable impact on originator drug prices and may be dependent on the presence of other elements of pharmaceutical market regulation, such as price capping. These results are broadly consistent with the generics paradox (see article in this issue). Furthermore, reference pricing may actually inhibit price competition and delay price reduction in the off-patent sector. As a result, the strategy of payers should be to switch to generic alternatives as soon as possible after the originator patent expires. Failure to do so or delays in this taking place implies that health insurance will continue to pay premium prices for products whose patents have expired.

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Generic policies and the 'Generics Paradox'

Sotirios Vandoros

A key objective of genericization and generic entry post patent expiry is the reduction in the cost of the patent-expired drug. Generic entry and competition should in principle lead to price reduction in this market segment over time. However, while these two factors primarily affect the prices of generic medicines, this may not be the case for their originator equivalents. In fact, in some countries despite the presence of cheaper generic alternatives, the prices of originator medicines have been shown to carry on increasing, a phenomenon called the "generics paradox". This is a surprizing outcome, given that the advent of market entry by generics and the ensuing competition intuitively should lead to price decreases.

Empirical evidence based on 32 drugs with significant sales in the mid-1980s which had gone off-patent found that the introduction of generic products in the pharmaceutical market led to price increases in originator brand medicines rather than price decreases.[1] Further work also found that originator brand manufacturers do not decrease prices after generic market entry,[2] and that generic entry only leads to a slow-down in the increase of originator drug prices.[3] Empirical evidence also suggests that R&D-based drug manufacturers do not attempt to deter generic entry through their pricing strategies.[4] Rather, in most cases, these manufacturers continued to increase their prices at the same rate as prior to generic entry. All these studies used US data to demonstrate the existence of the generics paradox.

How can the Generics Paradox be explained?

The presence of the generics paradox can be explained in a number of ways. First, it could be attributed to physician prescribing habits; physicians may be 'used to' prescribing the originator product and do not change their behaviour post patent expiry, unless they are penalized for overspending, or are otherwise advised by health insurance. Second, the generics paradox may be due to brand loyalty, as some patients may perceive that the branded product is of better quality, despite generics being bioequivalent to the originator. If the insurer covers the drug, the originator manufacturer can use its brand name and relative market power to carry on increasing the branded drug's price, subject to insurers' bargaining power with drug manufacturers and the structure and extent of co-payments affecting patients.

Generics paradox and regulation

An important question is whether the generics paradox still holds in pharmaceutical markets that are regulated. While the US provides an unregulated policy environment, whereby manufacturers can change their prices relatively easily, little is known about how generic entry would affect originator drug prices in regulated policy environments, particularly those that apply direct and indirect price controls on generic medicines, such as fixed price ceilings or reference pricing. In order to demonstrate the effect of generic entry on the originator drug, the case study presented here (based on data over the 1997–2002 period) reports evidence from two recent studies. The first[5] uses four countries representing different regulatory regimes: the UK, where there are few controls on the prices of generic medicines, other than certain price caps on a number of molecules; France, which, at the time had a cap on generic prices set at a maximum of 70% of the originator price, and the Netherlands and Germany, both of which had reference pricing in place. Captopril, an ACE inhibitor,* was used as an example to demonstrate the effect on the originator drug price. Table 1 summarizes the results.

Between the expiry of the originator drug and the end of the study period, the effect on sales is clear across the four countries. Sales of originator captopril declined very significantly across all study countries (a decrease ranging between 51–97%). In all cases, the originator maintains a small to marginal market share and in some cases discontinues some of the product presentations (Table 1). The highest loss in originator drug sales and, in consequence, market share, is shown in the UK and Germany.

While originator sales declined significantly post-patent expiry, the impact on originator drug prices was, nevertheless, quite different. Originator captopril prices presented an effect similar to that found in the earlier US literature (ie. price rises for the originator drug) only in the UK and France. In Germany and the Netherlands, however, prices of the originator declined steeply, with a view to maintaining some of the market share they enjoyed prior to patent expiry. As both countries had a reference pricing system in place, it appears as though reference pricing, coupled with appropriate prescribing and dispensing policies, induced originator drug prices to decline in order to stay on the market. Therefore, it appears that although the generics paradox seems to hold in unregulated markets, in some regulated markets this may not be the case; the outcome is at least ambiguous and may depend on the nature and intensity of regulation and the therapeutic class which the product

* Used for the treatment of hypertension.

Table 1. Effect of patent expiry on the sales and prices of an originator branded drug (captopril) between time of patent expiry and end of 2002

	UK	Netherlands	France	Germany
Originator sales	-74% overall	-51% overall	-51% overall	-69% overall
	-86% for top selling presentations	-92% for top selling presentations	-90% for top selling presentations	-97% for top selling presentations
Originator prices	+30% for top selling presentations	-14% overall	+ 7% for top selling presentations	-61% overall
	2 presentations discontinued	-7% for top selling presentations		-48% for top selling presentations

Note: Effect shows the impact on branded captopril, an ACE inhibitor. Patent expiry varied by country, as follows: UK (February 1997), France (February 1998)., Germany (February 1995), the Netherlands (December 1997).

Source: Adapted from Kanavos and Srivastava, 2008.[5]

belongs to. This also suggests that there may be therapeutic class dynamics that affect price movements of originator drugs.

Another study,[6] researched the possibility that the generics paradox may also be present in regulated pharmaceutical markets, particularly countries with supply-side controls on prices or reimbursement ceilings of generic medicines. Twelve drugs drawn from four different therapeutic categories with significant generic availability (plain ACE inhibitors, atypical antipsychotics, Proton Pump Inhibitors and antidepressants) across six European countries (Denmark, Germany, Netherlands, Norway, Sweden and UK) were studied in a quantitative model over the period 1997–2002. When considering all countries together, strong evidence emerged that prices of originator products increased after generic entry and continued to increase as the market share of generics increased. When considering each country separately however, the generics paradox was found to be present only in the UK and Sweden. This was expected as both countries have relatively unregulated generic markets compared with the remaining countries in the sample. For the remaining countries (Germany, the Netherlands, Norway and Denmark), the results were unclear. While there was a decrease in the originator price, this was not found to be statistically significant. This could mean that that the generics paradox might also be present in these countries. Further analysis showed that there could be a therapeutic category bias in the results. For instance, in the Netherlands, prices of originators appeared to increase with generic entry for proton pump inhibitors, but decrease with generic entry and penetration for atypical antipsychotics.

Policy implications

The findings of studies on the generics paradox are important for policy makers as they provide evidence that generic entry does not necessarily lead to a decrease in the prices of originator products in environments where prices of medicines are not regulated. In unregulated environments, for generic policies to be successful a switch to generic alternatives must take place early on after patent expiry. In regulated pharmaceutical markets, it is possible that the generics paradox may be called into question and it is also possible that regulation may cause prices of originator drugs to decline, rather than increase, although this is dependent on market dynamics, the extent of regulation and the nature of competition within the product therapeutic class.

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Maximising the benefits from generic competition

Elizabeth Seeley

In recent years, one of the ways in which OECD countries have sought to address the increasing cost of health care is by increasing the use of generic medicines.

Early literature provided evidence of the lower cost of generics, compared to their original brand equivalents, which encouraged governments to introduce supply and demand-side regulations that promote generic substitution.[1,2] Such regulations ranged from allowing pharmacists to substitute generics, providing physicians with financial and non-financial generic prescribing incentives, and introducing patient cost-sharing.

As discussed this issue's overview article, these regulations have resulted in varying degrees of success in increasing the use of generics. Consequently, the ensuing savings to health insurance also have varied, leaving room for further savings in most cases. This case study quantifies the additional potential savings to health insurance from genericization, or in other words, the current savings foregone to health insurance.

The case study uses proprietary sales, retail price and volume data from Intercontinental Medical Statistics (IMS) for omeprazole, simvastatin, lisinopril, paroxetine and metformin in the UK, France, Germany, Italy, Spain, US and Canada, during the period 2000–2005.[3] All original brand drugs in this sample went off patent during this period, albeit in different years. Thus, the degree of generic diffusion, and hence potential savings, may partially reflect the differing timescales since generic entry across molecule and country markets, as well as countries' differing pharmaceutical regulations.

There are four dimensions of savings that contribute to the total savings foregone to health insurance.

Figure 1: Evolution of original brand and generic prices in comparison with total volume in the Lisinopril market in the United States

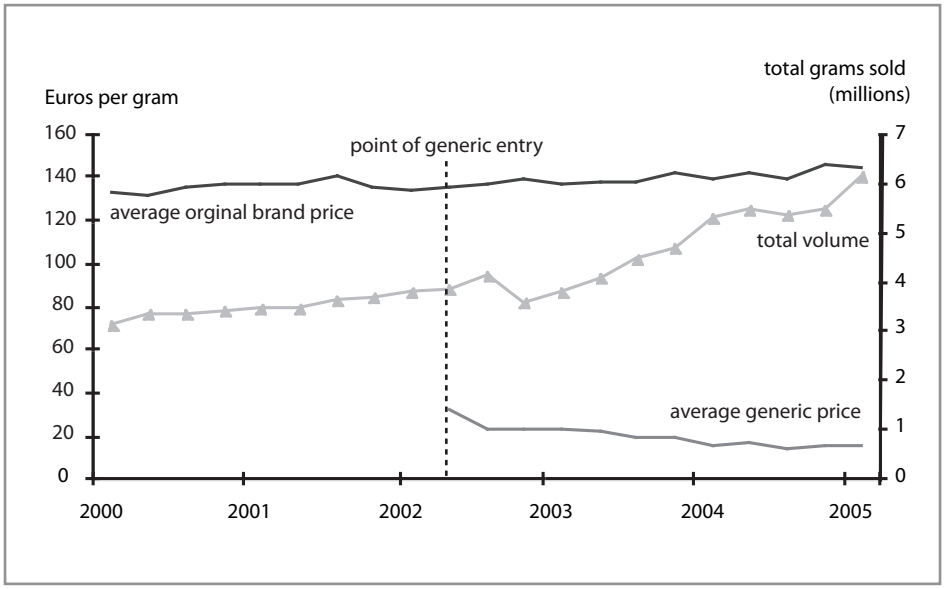

Figure 2: Evolution of original brand and generic prices in comparison with total volume in the Lisinopril market in Germany

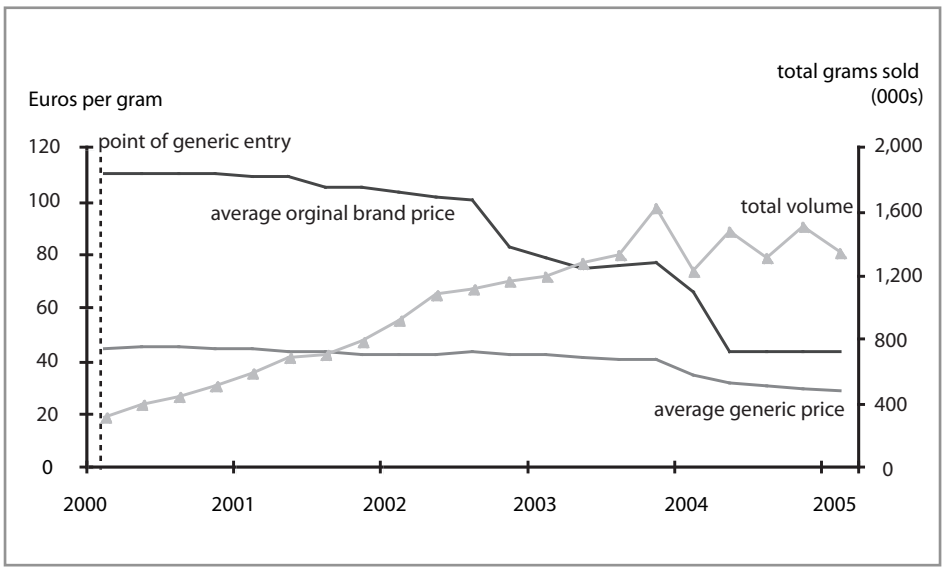

Table 1. Generic policies, savings foregone and impact on stakeholders, 2003–2004, seven countries* (based on five off-patent molecules)**

	2003 (US$ million)	2004 (US$ million)
Outlays for generic medicines by health insurance (based on actual generic sales)	6,467.40	6,899.20
Outlays through efficient purchasing and improved genericization	4,430.20	3,899.70
Efficiency loss (potential saving) to health insurance	2,218.60	3,024.90
Saving to health insurance as a percent of current sales	34.30%	43.80%
Impact (current gain) on generic manufacturers	1,258	1,724.20
Impact (current gain) on wholesalers	131.3	179
Impact (current gain) on pharmacies	718.8	980
Impact (current gain) on VAT or sales tax	110.3	150.4

Notes: * UK, Germany, France, Italy, Spain, Canada, US.

** Omeprazole, simvastatin, lisinopril, paroxetine and metformin. Simvastatin was under patent in the US in 2003 and 2004, therefore no additional savings can be calculated in this particular case.

Source: The author based on IMS data.

Generic penetration

The first and most obvious dimension reflects the level of generic penetration in a molecule market, post patent expiry. Generic penetration is a measure of the share of a molecule market that is purchased as generic. Differing strengths and package sizes have been adjusted for, in order to standardize volume across generic and original brand purchases. The total average volume-related generic penetration for the countries and products in the study are: UK: 76%, Germany: 66%, US: 65%, Canada: 51%, Spain: 50%, France: 33% and Italy: 19%. Thus, assuming there is a price difference between originator and generic, Italy and France could realize the largest savings by increasing their generic penetration, although there is significant room for improvement in all study countries for these molecules.

Originator – Generic price differences

The second dimension of savings that contributes to total foregone savings is the price difference between the originator drug and the generic equivalent. The larger the difference between the two and the smaller the generic penetration, the greater are the foregone savings to health insurance.

Figures 1 and 2 (on previous page) show two examples of where the price difference between the average originator brand price and the average generic price is relatively large, as in the case of Lisinopril* in the US, and relatively small (although still significant), as in the case of Lisinopril in Germany.

The figures are also an example of the significant price differences across countries; in this case, in the US the price of originator Lisinopril continued to rise mildly after the expiry of the product patent, whereas in Germany it declined sharply but took several years to do so. Whereas the originator brand price difference between US and Germany was approximately 20% in 2000, the steep decline in the price of the originator brand in Germany post-patent expiry made the product price more than three times higher in the US than in Germany. By contrast, the average price of generic Lisinopril was nearly twice as high in Germany as it was in the US in 2005.

In addition, the German generic price declined very slowly and over a much longer period of time, whereas in the US the decline in the average generic price was significantly steeper over a much shorter period of time. This could be explained by a lack of competition in Germany, but in terms of generic competitors on the market, the number of German generic competitors in this product market was 24 compared with 16 in the US. Consequently, factors other than the number of competitors may play a bigger role in explaining the generic price patterns observed in Germany.

Generic price differences

The third dimension that contributes to total foregone savings is the difference between the actual purchased generic price and the lowest generic price. This dimension reflects the degree of efficient purchasing in the generics market itself, independent of generic penetration and

* An ACE inhibitor used in the treatment of hypertension.

original brand prices. Often this dimension of savings is the most neglected by policymakers, despite the fact that in some cases, the generic price spread may exceed ten to one.

Discounts

Finally, the fourth dimension of potential savings to health insurance is a share of the discounts that generic manufacturers and wholesalers may offer to the retail sector in order to gain an edge over their competitors. It is widely known that such discounts exist, but their true extent is unknown in most markets. Recent published evidence on a number of generic medicines from the UK[4] and France[5] suggests that in France such discounts vary from 20–80% off the wholesale price, and in the UK they exceed 60% off the Drug Tariff price. While the UK has a policy tool in place to recoup part of these discounts (the clawback), its level is significantly below that of the actual discount. In France, no such measure exists, although a recent reform linked the discount pharmacies receive with their margins. Given that the volume of generics consumed is significant (over 70% in the UK and over 40% in France), the potential gains to health insurance from this source could be significant.

Cost savings

By estimating the effect of additional generic penetration that could occur and assuming that health insurers are in a position to procure more cost effectively to the lowest available price on the market, the additional savings to health insurance (or the savings that currently health insurance foregoes) can be calculated. Table 1 shows the total savings forgone for this case study's sample of products and countries. Based on the above model, improved genericization and more efficient purchasing would have saved health insurers over US$3 billion in 2004, amounting to a savings on current sales in the order of 43.8%. This saving excludes the effect of discounts which, as already mentioned, can be substantial. In looking at the current allocation of foregone savings across the distribution chain, manufacturers benefit the most, with pharmacies also experiencing significant gains.

Policy implications

The evidence presented in this case study indicates that despite the actual savings made on generic medicines, even where positive trends in genericization of branded medicines exist, there is still a significant opportunity to create savings from this process if generic penetration is greater, if purchasing occurs at a lower price and if some of the actual discounts given to the retail sector return to health insurance. It also suggests that health insurance may be overpaying for off-patent medicines and that governments may want to re-evaluate their policies in the interest of more efficient purchasing and promotion of greater generic competition.

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New Health Systems in Transition (HiT) profiles

Estonia has health outcomes that still lag behind the EU average and therefore faces important public health challenges. The Government has increased its efforts to strengthen integrated public health programmes as a response to the key risk factors causing ill health, and reform of Estonia's health system has been vigorous. Life expectancy and public satisfaction have increased steadily since the large-scale restructuring in the early 1990s that introduced mandatory social health insurance, a purchaser–provider split and health care centred on family medicine. Nevertheless, persistent inequity in health status and in access to health care remains a common concern to be tackled.

Available at http://www.euro.who.int/Document/E91372.pdf

Latvia's health care system has undergone major changes since the country achieved independence in 1991. These have included: adoption of a public health strategy (which aims to develop an integrated approach to prevention and treatment), reform of health care financing (e.g. payment for hospital services, introduction of a primary health care payment system based on capitation and fund holding, pooling and channeling of almost all funds through the centralized State Compulsory Health Insurance Agency), regulation of pharmaceutical pricing and the introduction of a centralized health management information system. However, quality of services, long waiting lists and access to specialized care are areas of concern for citizens.

Available at http://www.euro.who.int/Document/E91375.pdf

THE EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES IS A PARTNERSHIP BETWEEN

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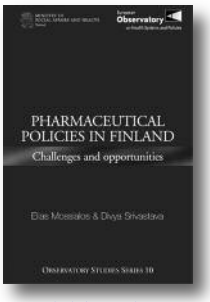
Pharmaceutical policies in Finland. Challenges and opportunities

Elias Mossialos and Divya Srivastava



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Health systems are under continuous pressure to meet the demands of their populations. In Finland, one area currently under review is that of pharmaceutical policy.

Following a request made by the Health Department, Ministry of Health and Social Affairs (MSAH) of Finland, this report provides a policy review of the country's regulatory system for pharmaceutical policies.

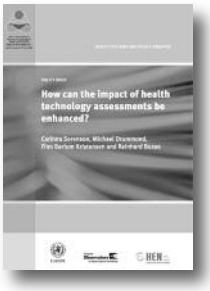
The assessment suggests that despite the challenges within a very developed system of pharmaceutical regulation, there are practical options to improve transparency and pricing policies, to strengthen the institutional environment and to improve the development of pharmacotherapy practices.

The purpose of this report is not to provide prescriptive solutions but to suggest a range of options for policy makers to reflect on. The report offers a range of views from an international perspective and aims to stimulate further debate on the continuing development of pharmaceutical policies.

Joint Policy Brief Series: WHO Health Evidence Network and European Observatory on Health Systems and Policies

How can the impact of health technology assessment be enhanced?

Corinna Sorenson, Michael Drummond, Finn Børlum Kristensen and Reinhard Busse



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Growth in the diffusion of new health technologies has led to remarkable improvements in health and quality of life. These benefits, however, also bring challenges in ensuring value for money and concerns over the willingness of third party payers and patients to pay for expensive treatments, devices and drugs. As policy-makers seek to obtain maximum benefit from limited resources, and do so in legitimate and transparent ways that reflect the values underpinning health systems, health technology assessment (HTA) is a tool increasingly used to support this aim and encourage the efficient use of health technologies.

This Policy Brief examines selected issues in the application and uptake of HTA in Europe, including the impact on HTA by the bodies and stakeholders involved in the assessment and appraisal process, the need to ground HTA in robust and transparent methods and processes based on clear and standardized guidelines, and the effective and timely application of HTA decision-making and subsequent implementation.

While providing strategies and recommendations to European governments to improve HTA implementation, the authors recognize that challenges remain. Some are specific to the HTA process itself, while others pertain to broader social and system-level considerations. The impact of HTA depends in large part on the quality and transparency of the assessment and decision-making process, in addition to the broader institutional, organizational, political and cultural dynamics of national health care systems.

As many countries increasingly gear their health systems towards policies that emphasize measurement, accountability, transparency and evidence-based practices, the challenges of HTA should be addressed in order to achieve concurrent health system goals and to support those services that offer greatest value for money and impact on health outcomes.

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