

Original Research

The Portuguese generic medicines market: a policy analysis

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Received (first version): 1-Oct-2008

Accepted: 15-Mar-2009

ABSTRACT*

Objectives: This study aims to conduct a descriptive analysis of the policy environment surrounding the generic medicines retail market in Portugal. The policy analysis focuses on supply-side measures (i.e. market access, pricing, reference-pricing and reimbursement of generic medicines) and demand-side measures (i.e. incentives for physicians to prescribe, for pharmacists to dispense and for patients to use generic medicines).

Methods: The policy analysis was based on an international literature review. Also, a simulation exercise was carried out to compute potential savings from substituting generic for originator medicines in Portugal using IMS Health data.

Results: Portugal has developed a successful generic medicines market by increasing reimbursement of generic medicines (until October 2005), by introducing a reference-pricing system, by encouraging physicians to prescribe by international non-proprietary name (INN), and by allowing generic substitution by pharmacists. However, the development of the generic medicines market has been hindered by the existence of copies, pricing regulation, certain features of the reference-pricing system, weak incentives for physicians to prescribe generic medicines and a financial disincentive for pharmacists to dispense generic medicines. Increased generic substitution would be expected to reduce public expenditure on originator medicines by 45%.

Conclusions: The development of the Portuguese generic medicines market has mainly been fuelled by supply-side measures. To support the further expansion of the market, policy makers need to strengthen demand-side measures inciting physicians to prescribe, pharmacists to dispense and patients to use generic medicines.

Keywords: Drugs, Generic. Reimbursement, Incentive. Drug Costs. Portugal.

EL MERCADO PORTUGUÉS DE MEDICAMENTOS GENÉRICOS: ANÁLISIS POLÍTICO

RESUMEN

Objetivos: Este estudio intenta realizar un análisis descriptivo del ambiente político que rodea el mercado minorista de genéricos en Portugal. El análisis político se centra en las medidas de la oferta (p.e. acceso al mercado, precio, precios de referencia, y reembolso de medicamentos genéricos) y medidas de la demanda (p.e. incentivos a médicos para prescripción, a farmacéuticos para dispensación, y a pacientes para el uso de medicamentos genéricos).

Métodos: El análisis político se basó en una revisión a la literatura internacional. También se realizó una simulación para calcular los ahorros potenciales de la sustitución de medicamentos genéricos en Portugal utilizando los datos de IMS Health.

Resultados: Portugal ha desarrollado un exitoso mercado de medicamentos genéricos aumentando el reembolso de genéricos (hasta octubre 2005), introduciendo un sistema de precios de referencia, animando a los médicos a prescribir por denominación común internacional (DCI), y permitiendo la sustitución genérica por los farmacéuticos. Sin embargo, el desarrollo del mercado de genéricos ha estado dificultado por la existencia de copias, regulación de precios, ciertos hechos del sistema de precios de referencia, pobres incentivos a los médicos para prescribir genéricos y un desincentivo financiero a los farmacéuticos para dispensar genéricos. Sería de esperar un aumento de la sustitución genérica para reducir el gasto público en medicamentos un 45%.

Conclusiones: El desarrollo del mercado portugués de medicamentos genéricos se ha alimentado de medidas del lado de la oferta. Para apoyar la expansión futura del mercado, los políticos necesitan reforzar las medidas del lado de la demanda, incitando a los médicos a prescribir genéricos, a los farmacéuticos a dispensarlos, y a los pacientes a utilizar medicamentos genéricos.

Palabras clave: Medicamentos genéricos. Incentivos de reembolso. Costes de medicamentos. Portugal.

INTRODUCTION

Pharmaceutical expenditure in Portugal is high as compared to other countries of the Organisation for Economic Co-operation and Development (OECD).¹ Total pharmaceutical expenditure per capita amounted to US\$ 445 (using purchasing power

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parity conversion rate) in 2005, and grew at an annual rate in real terms of 3.7% between 1995 and 2005. Furthermore, pharmaceutical expenditure made up 21.9% of total health expenditure in 2005. Pressure to control pharmaceutical expenditure and price competition among pharmaceutical companies has fuelled the development of a generic medicines market in Portugal.

A generic medicine is a product that is launched with no intellectual property or other protection after the protection expires on the originator medicine. A generic medicine has the same qualitative and quantitative composition in active substances, the same pharmaceutical form, and the same bio-availability as the originator medicine.² If two medicines have the same bio-availability, a similar therapeutic effect can be assumed.³ Generic medicines tend to be 20% to 90% cheaper than originator medicines because generic medicines companies incur lower costs of research and development than originator medicines companies. Competition from generic medicines may also bring down prices of 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.⁴

The aim of this paper is to carry out a descriptive analysis of the policy environment surrounding the generic medicines retail market in Portugal. The policy analysis focuses on supply-side measures (i.e. market access, pricing, reference-pricing and reimbursement of generic medicines) and demand-side measures (i.e. incentives for physicians to prescribe, for pharmacists to dispense and for patients to use generic medicines). Finally, a number of avenues are proposed that policy makers can follow to continue developing the Portuguese generic medicines market.

METHODS

A review of the international literature was carried out by searching the following electronic databases up to December 2008: PubMed, EMBASE, Bath Information and Data Services, Cochrane Library, EconLit, and Social Science and Citation Index. Search terms included 'pharmaceutical policy', 'generic medicines', 'off-patent market', 'pricing', 'reimbursement', 'reference pricing', 'incentives', 'prescribing', 'physician budgets', 'international non-proprietary name (INN)', 'dispensing', 'generic substitution', 'patient co-payment' alone and in combination with each other. Additionally, the bibliography of included studies was checked for other relevant studies. The review focused on studies published in English. The policy description and analysis was validated by a panel of experts working for the Portuguese Association of the Generic Medicines Industry, individual generic medicines companies in Portugal, and INFARMED (the National Authority of Medicines and Health Products).

A simulation exercise was conducted to compute potential savings to the National Health Service

from substituting generic for originator medicines in Portugal using IMS Health data.⁵ This illustrative exercise was limited to the best-selling active substances that had the highest public expenditure of originator medicines in 2004. For each active substance, average price levels weighted by volume of sales of the various medicines belonging to the group of originator medicines and to the group of generic medicines were calculated. Annual savings were obtained by multiplying the price difference between generic and originator medicines by the volume of originator medicines to be substituted. In the United States, actual generic substitution rates have attained 80% in specific medicine classes,⁶ and some analysts have set generic substitution target rates at 95%.⁷ Our analysis considered 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, this exercise calculated the potential savings from 'increased' rather than 'full' generic substitution.

RESULTS

Portuguese generic medicines market

Figure 1 presents data on market shares and policy measures relating to the Portuguese generic medicines market from 2000 to 2007.⁸ The introduction of a series of policy measures promoting generic medicines since the early 2000s has driven the development of the Portuguese generic medicines market. The generic medicines market share by value (i.e. total expenditure on generic medicines divided by total pharmaceutical expenditure) increased from 0.13% in 2000 to 17.85% in 2007. Market share of generic medicines by volume (as measured by the number of packages) amounted to 11.67% in 2007. The Portuguese market share of generic medicines is relatively low as compared with European countries with mature generic medicines markets: the market share by volume amounted to 5.09% in Portugal in 2004 as compared with 86.5% in Poland, 65% in Denmark, 49.3% in the United Kingdom and 41.1% in Germany.⁹ The Portuguese policy measures relating to generic medicines (see Figure 1) are analysed in the following sections.

Market access

Patent

The development of the Portuguese generic medicines market has been restrained by the presence of a market for copies which existed alongside the market for generic medicines. If copies of an originator medicine exist, companies are less likely to develop generic versions of that originator medicine. These copies have developed 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 voluntary programme was launched to convert copies of off-patent medicines into generic medicines by

demonstrating their bio-equivalence with the originator medicine.

Registration

Conform to European legislation, Portugal has in place a simplified registration procedure that facilitates market entry for generic medicines.² If the application relates to an active principle that has been registered for at least eight years in one of the European Union countries and if the generic medicine is essentially similar to the reference medicine, the generic medicines company does not need to provide pre-clinical and clinical documentation, but can refer to the documentation of the reference medicine. This implies that pharmaceutical companies can submit an abridged application for a generic medicine after the first ten years of the patent on the original medicine have passed.

Pricing and reimbursement approval

Generic medicines enter the market following determination of pricing and reimbursement status by Portuguese authorities. The Transparency Directive 89/105/EEC specifies a 90-day limit for adopting a pricing decision and a 90-day limit for reimbursement for all European Union Member States.¹⁰ In Portugal, pricing and reimbursement applications for a generic medicine need to be made consecutively (rather than simultaneously). A market review undertaken by the European Generic Medicines Association found that it takes an average of 21 and 90 days for a generic medicine in Portugal to obtain pricing approval and reimbursement approval, respectively.¹¹ As in other European Union Member States¹⁰, pricing and reimbursement procedures in Portugal delay market entry of generic medicines and appear to be unnecessarily long in the case of a generic medicine that has demonstrated the same quality, safety and therapeutic efficacy as the originator medicine.

Pricing

Pricing regulation established a minimum price difference between generic and originator medicines. Since 2001, the public price of generic medicines must be at least 35% lower than the price of the originator medicine with an equivalent dosage and pharmaceutical form. This pricing regulation deterred generic medicines companies from entering active substance submarkets that had lower prices.¹² This is because the potential profit margin for a generic medicine is lower in a submarket where the generic medicine has to be at least 35% cheaper than a low-priced originator medicine. Conversely, the regulation encouraged companies to focus on launching generic medicines for more expensive active substances or those with higher market shares. To facilitate generic medicines entry for less expensive active substances, the minimum price difference between generic and originator medicines needs to be at least 20% of the price of the originator medicine if the wholesale price of the originator medicine is less than 10 € as of 2007. To the best of the author's knowledge, the impact of this measure on

promoting generic medicines use has not been investigated to date.

Prices of all marketed medicines were reduced by 6% in 2006 and in 2007. However, the price reduction for a generic medicine depended on its market share. The price reduction was set at 5% for generic medicines with a market share between 50% and 60%; 4% for generic medicines with a market share between 60% and 70%; and 3% for generic medicines with a market share exceeding 70%. This measure was designed to stimulate generic medicines competition given that generic medicines with a larger market share benefit from a lower price reduction.¹²

A price reduction of generic medicines by 30% was introduced in October 2008 for those generic medicines that had been approved prior to April 2008. The impact of this measure may be mixed. On the one hand, such price reductions are likely to contribute to containing public pharmaceutical expenditure and to stimulating patient demand for generic medicines. On the other hand, price reductions reduce the economic viability of the generic medicines market and may restrict market entry of generic medicines.

Portuguese pricing regulation imposing successive price reductions on both originator and generic medicines over time and creating a minimum price difference between generic and originator medicines adversely affects the profitability of generic medicines and hinders the development of the Portuguese generic medicines market. Indeed, the European experience indicates that penetration of generic medicines is higher in countries that permit (relatively) free pricing of medicines than in countries that have pricing regulation.⁴

Reference-pricing

A reference-pricing system was launched in 2003. Such a system establishes a reimbursement level or reference price for a group of interchangeable medicines. The Portuguese reference-pricing system groups medicines on the basis of active substance, dosage, pharmaceutical form and package. Each group contains at least a generic medicine and an originator medicine. The reference price is set at the level of the most expensive generic medicine marketed in a specific reference group. The reference price is based on the price per dose unit and updated when the price of the most expensive generic medicine changes. If a medicine is priced above the reference price, the patient pays the difference between the price of the medicine and the reference price. However, a number of features of the Portuguese reference-pricing system may inhibit price competition and demand for generic medicines.

The establishment of the reference price at the level of the most expensive generic medicine and the fact that generic medicines need to be at least 35% cheaper than originator medicines 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 reference price.

In response to this, the Government implemented a price reduction of generic medicines by 30% in October 2008. This measure further increases the price difference between generic and originator medicines.

A reference-pricing system promotes generic medicines use by imposing a co-payment on originator medicines priced above the level of the reference price. However, if the reference-pricing system is accompanied by price reductions of originator medicines to the level of the reference price, there is no difference in co-payment between originator and generic medicines, and the system 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 reference-pricing system has been found for Portugal.¹³

The Portuguese reference-pricing system applies to medicines for which generic medicines are on the market, but excludes originator medicines under patent protection. This implies that physicians can prescribe a patented medicine with a similar therapeutic indication as the generic medicine that does not fall under the reference-pricing system (so-called 're-allocation of demand').¹⁴ The European experience shows that re-allocation of demand has happened to some extent in, for instance, France and Italy.⁴

Reimbursement

Medicines can fall under five different reimbursement regimes with rates of 100% for medicines classified as life-saving products, 95% in category A, 69% in category B, 37% in category C, and 15% 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%. This measure was abolished in 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 in 2006, the cost of generic medicines to patients increased.

Incentives for physicians

Overall, physicians face weak incentives to prescribe generic medicines. Physicians need to prescribe medicines for which generic equivalents exist by their INN since 2002, even though they are free to add a brand name or a marketing authorisation holder name. Physicians and pharmacists need 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, but have not yet been fully implemented. Physicians can also consult a 'generic medicines guide' booklet, published every quarter by INFARMED. Also, INFARMED has developed databases

enabling physicians to compare medicine prices. Finally, physicians still question the quality of generic medicines and influence a patient's perspective on this issue.¹⁴

Incentives for pharmacists

Generic substitution by community pharmacists is allowed since 2002. 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 an INN prescription 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. However, generic substitution is not in the financial interests of pharmacists because pharmacist margins amount to a flat rate of 18.25% since September 2005. This implies that pharmacists earn a higher margin in absolute terms on an expensive originator medicine than on a cheaper generic medicine.

A study eliciting the views of Portuguese physicians and pharmacists about generic medicines indicated that the majority of physicians and pharmacists had a favourable opinion about the introduction of generic medicines on the market and showed confidence in generic medicines as compared with originator medicines. Furthermore, generic substitution by the pharmacist was allowed in all cases by 30% of physicians or frequently by 36% of physicians.¹⁵

Incentives for patients

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.¹⁶ A recent study has shown that Portuguese patients tend to agree with the prescription of a generic medicine, although the level of endorsement of generic medicines was significantly lower for illnesses that were perceived to be more serious.¹⁷ However, it should be noted that, even if a patient would prefer the prescription of a generic medicine, the physician decides which medicine to prescribe and whether to allow or forbid generic substitution.

Potential savings from generic substitution

Table 1 presents public expenditure on best-selling originator medicines in Portugal in 2004 and savings from increased generic substitution pertaining to the National Health Service. Increased substitution of generic for originator medicines could yield considerable savings, amounting to an estimated total of around 110 million €. The size of potential savings varies widely between active substances, ranging from 3.5 million € for ramipril to 40 million € for ethinylestradiol.

Table 1. Potential savings from increased generic substitution in Portugal, 2004

Active substance	Public expenditure on originator medicines	Savings from generic substitution
Ethinylestradiol	47,817,774 €	40,705,211 € (85%)
Nimesulide	30,030,728 €	19,016,350 € (63%)
Lisinopril	26,747,517 €	9,446,755 € (35%)
Trimetazidine	25,518,526 €	8,540,041 € (33%)
Pravastatin	23,891,425 €	10,132,428 € (42%)
Diclofenac	23,483,241 €	6,858,129 € (29%)
Ramipril	22,675,143 €	3,584,040 € (15%)
Sertraline	21,653,772 €	7,916,845 € (36%)
Amoxicillin	21,145,870 €	3,909,730 € (18%)
Total	242,963,996 €	110,109,529 (45%)

Note: Savings from generic substitution are expressed in absolute terms and as a percentage of public expenditure on originator medicines.

The policy and regulatory environment surrounding generic medicines appears to influence savings to be gained from generic substitution. The minimum price difference between originator and generic medicines of 35% in Portugal seems to be the main factor behind our estimated reduction in public expenditure on originator medicines of 45% as a result of increased generic substitution.

DISCUSSION

This study has carried out a descriptive analysis of policy towards generic medicines with a view to proposing avenues to support the further development of the Portuguese generic medicines market. The Portuguese generic medicines market has grown substantially over time as the result of a series of policy measures (see Figure 1), although no formal evaluation of the impact of any single policy measure on the generic medicines market share was identified in the literature.

Portugal has attempted to develop its generic medicines market mainly by adopting supply-side measures relating to pricing, reference-pricing and reimbursement of generic medicines. It is recommended that regulation imposing a minimum price difference between generic and originator medicines is abandoned. Free generic medicine pricing would stimulate companies to introduce generic medicines for less expensive active substances.⁴ Also, setting the reference price 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. 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 and reducing pharmaceutical expenditure.

A comparative analysis of generic medicines policies in 11 European Union countries indicated

that 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.⁴ This high volume is dependent on demand-side policies inciting physicians to prescribe, pharmacists to dispense and patients to use generic medicines.

In Portugal, demand for generic medicines has been driven by policy measures encouraging physicians to prescribe by INN and by requiring pharmacists to dispense the cheapest generic medicine when physicians prescribe by INN. This can be supported further by making medical students aware of INN prescribing during their undergraduate education as is the case in the United Kingdom.⁴ Alternatively, the recommendation could be made that physicians prescribe low-cost generic medicines, unless a more expensive, originator medicine is required for therapeutic reasons. In other words, physicians would need to provide a therapeutic rationale for forbidding generic substitution.

Mandatory INN prescription could be introduced in Portugal. However, the European experience shows that INN prescribing does not necessarily lead to generic medicines use.⁴ 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. Therefore, mandatory INN prescription would raise the generic medicines market share in Portugal only if INN dispensing regulation and remuneration of pharmacists favours the dispensing of generic medicines.

Pharmacists need to receive a remuneration that does not financially penalise them for dispensing generic medicines. Therefore, Portugal needs to move away from distribution margins that are set as a fixed percentage of the public price of medicines. Instead, Portugal needs to consider introducing a pharmacist remuneration system that is neutral or that favours the delivery of generic medicines from a financial perspective. In France, for example, pharmacists are entitled to higher discounts on generic medicines than on originator medicines.¹⁸

Portugal needs to incite patients to demand generic medicines. The Government needs to envisage extending the financial incentive that increased the reimbursement rate of generic medicines by 10%. There is a remaining need to convince patients that generic medicines have the same safety, quality and efficacy as originator medicines, and to inform them of the cost-saving potential of generic medicines.

This paper has demonstrated that substantial savings could be gained from increased substitution of generic for originator medicines by Portuguese pharmacists. Caution needs to be exercised when using these estimates. The reader should note that this exercise was carried out for illustrative purposes and that the findings give an idea of the order of magnitude of savings from generic

substitution, but do not represent exact data. Also, generic medicines markets evolve rapidly with new generic medicines being introduced over time. Therefore, our data relating to 2004 may no longer reflect the current market situation. One additional limitation of the simulation exercise 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.

Our study was of a descriptive nature by necessity due to the lack of studies that have evaluated the impact of policy measures on the Portuguese generic medicines market. The analysis may be biased by focusing on studies published in English, but this is usual practice in literature reviews. In the absence of policy evaluations, this study mainly analysed policy measures in terms of the incentives that they put in place for different stakeholders, such as industry, physicians, pharmacists and patients. There is a need for decision makers and researchers to make sure that the introduction of new measures governing generic medicines is accompanied by an evaluation of their impact on the multiple goals that the Portuguese health care system aims to attain.

CONCLUSIONS

Portugal has developed a successful generic medicines market by increasing reimbursement of generic medicines (until October 2005), by introducing a reference-pricing system, by encouraging physicians to prescribe by INN, and by allowing generic substitution by pharmacists. However, the development of the generic medicines market has been hindered by the existence of copies, pricing regulation, certain features of the reference-pricing system, weak incentives for physicians to prescribe generic medicines and a financial disincentive for pharmacists to dispense generic medicines. A number of avenues were proposed to support the further development of the Portuguese generic medicines market.

ACKNOWLEDGEMENTS

I am indebted to INFARMED for providing information about the Portuguese generic medicines market.

CONFLICT OF INTEREST

The author has no conflicts of interest that are directly relevant to the content of this manuscript. No financial support was received for this study.

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Figure 1. Market share and policy measures relating to Portuguese generic medicines retail market

