Potential savings from increased substitution of generic for originator medicines in Europe

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Abstract This study aims to estimate annual savings from increased generic substitution in the retail market of 11 European countries in 2004. Savings from generic substitution were calculated for the top ten active substances by public expenditure on originator medicines in each country. For each active substance, average price levels weighted by volume of sales of medicines belonging to the group of originator medicines and to the group of generic medicines were calculated. The price difference between originator and generic medicines was multiplied by the volume of originator medicines to be substituted. The analysis considered that, following generic substitution, 5 per cent of market volume for each active substance would be made up by originator medicines and 95 per cent by generic medicines. Increased generic substitution for the top ten active substances generated total potential savings of around €3bn, with country savings ranging from €11m in Poland to €1bn in Germany. Increased generic substitution would be expected to reduce public expenditure on originator medicines containing these active substances by at least 20 per cent in each country. Countries that pursue the development of their domestic generic medicines market, therefore, can expect to gain substantial savings from increased generic substitution.

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INTRODUCTION

The size of generic medicines retail markets varies widely between European countries. The proportion of the pharmaceutical retail market made up by generic medicines in volume (number of packs) exceeded 40 per cent in Denmark, Germany, Netherlands, Poland, United Kingdom, but did not surpass 20 per cent in Austria, Belgium, France, Italy, Portugal and Spain in 2004.¹ This variation in

the development of generic medicines markets suggests that not all countries are realising the full potential of generic medicines. The aim of this study is to quantify the potential savings from increased substitution of generic for originator medicines in Europe. This study was part of a wider project commissioned by the European Generic Medicines Association that analysed the European experience with developing generic medicine retail markets and proposed recommendations to further sustain generic medicines markets.²

METHODOLOGY

Focusing on the off-patent retail market, this exercise computed potential savings from substituting generic for originator medicines. The analysis was limited to the 10 active substances in each country that had the highest public expenditure of originator medicines in 2004. For each active substance in the top ten, 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 per cent in specific medicine classes,³ and some analysts have set generic substitution target rates at 95 per cent.⁴ Our analysis considered that, following generic substitution, 5 per cent of market volume for each active substance would be made up by originator medicines and 95 per cent by generic medicines. Hence, this exercise calculated the potential savings from 'increased' rather than 'full' generic substitution.

RESULTS

Table 1 presents public expenditure on originator medicines for the top 10 of active substances in each country and savings from

Table 1: Potential savings from increased generic substitution for the top 10 of active substances in selected countries, 2004

Country	Public expenditure on originator medicines	Savings from generic substitution
Germany	€2,098,115,768	€992,504,255 (47%)
France	€1,510,377,137	€525,290,734 (35%)
United Kingdom	€1,070,786,874	€349,844,935 (33%)
Spain	€916,910,433	€301,740,171 (33%)
Italy	€844,954,289	€263,508,563 (31%)
Belgium	€384,918,524	€160,784,134 (42%)
Netherlands	€360,226,124	€146,560,702 (41%)
Portugal	€280,649,104	€117,801,359 (42%)
Denmark	€125,269,454	€60,191,292 (48%)
Austria	€217,610,673	€57,962,838 (27%)
Poland	€54,207,557	€11,178,228 (21%)
Total		€2,987,367,211

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

increased generic substitution in absolute terms. Increased substitution of generic for originator medicines could yield considerable savings, amounting to an estimated total of around €3bn for the 11 countries studied. The size of potential savings varies widely between countries, ranging from €11m in Poland to €1bn in Germany.

Table 1 also indicates that public expenditure on originator medicines can be substantially reduced as a result of increased generic substitution. For the top ten active substances in 2004, generic substitution would be expected to reduce public expenditure on originator medicines containing these active substances by at least 20 per cent in selected countries. At one end of the spectrum, a potential proportional reduction of 21 per cent could be attained in Poland. At the other end, public expenditure on originator medicines could nearly be halved by means of increased generic substitution in Denmark and Germany.

DISCUSSION

Few studies have been published that calculate possible savings from increased generic substitution and these studies related to individual countries.^{3,5-7} This paper has

highlighted the variation in potential savings from higher generic medicines utilisation among European countries. This exercise was carried out for illustrative purposes and does not claim to generate an exact estimate of savings from increased generic substitution. Generic medicines markets evolve rapidly so that, even though the most recent data relating to 2004 were used, the data may no longer reflect the market situation.

The policy and regulatory environment surrounding generic medicines influences the savings to be gained from generic substitution. For instance, a minimum price difference between originator and generic medicines has been imposed in several countries, amounting to 30 per cent in France and Spain, and 35 per cent in Portugal in 2004. This appears to be the main factor behind our estimated reduction in public expenditure on originator medicines of 35 per cent in France, 33 per cent in Spain and 42 per cent in Portugal as a result of increased generic substitution.

How can savings from increased generic substitution be attained? In countries with a high rate of generic medicines use, savings appear to have originated from the substantial price differential between generic and originator medicines, and increases in the consumption of generic medicines.^{2,8} This suggests that countries need to supplement supply-side policies, such as pricing reductions, by demand-side policies that create incentives for physicians, pharmacists and patients to use generic medicines. When developing generic medicines policies, issues relating to bio-equivalence between generic and originator medicines, quality assurance of generic medicines, and the impact of generic substitution on treatment compliance also need to be considered.

CONCLUSION

The G10 High Level Group on Innovation and Provision of Medicines in the European Union recommended in 2002 that member states promote generic penetration in

domestic markets.⁹ Our findings suggest that the market share of generic medicines in several European countries is limited and that substantial savings could be gained from increased substitution of generic for originator medicines.

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