

For personal use only. Not to be reproduced without permission of the publisher (editorial@gabi-journal.net).

Analysis of European policy towards generic medicines

Pieter Dylst, PharmD; Professor Arnold Vulto, PharmD, PhD; Professor Steven Simoens, MSc, PhD

In this paper, we provide an overview of a PhD project we undertook on European policy on generic medicines. In the course of our research, we identified various causes for delayed market access of generic medicines and the need for policies to accelerate market access. These should work in conjunction with policies designed to influence demand, as these can significantly affect use of generic medicines. Ideally, demand-side policies should focus on promoting the use of generic medicines to physicians, pharmacists and patients, with or without financial incentives. Lastly, we present our recommendations for increasing the use of generic medicines.

Keywords: Demand-side policies, Europe, European policy, generic medicines, supply-side policies

Generic drugs are cheaper than originator drugs but of comparable quality to their branded counterparts, and can therefore yield substantial savings. We conducted a comparative analysis of policies on generic medicines in retail markets in Europe, and proposed tools to continue developing them. Here we provide an overview of our research.

European governments have implemented a variety of generic medicine policies, encompassing supply-side policies, i.e. market access, pricing and reimbursement; and demand-side policies, i.e. incentives for physicians, pharmacists and patients. On the supply-side, we analysed market access to generic medicines [1], and identified factors that might delay entry. These included defensive patenting strategies, patent litigations, patent linkage, third-party interventions during the process of obtaining marketing authorization, pricing and reimbursement decisions, and backlogs in national approval systems.

First, we examined the status and effect of generic medicine pricing policies in Europe [2]. Competition from Indian generic medicine manufacturers, European variation in generic medicine prices, and competition between generic medicine manufacturers by discount indicated that the potential savings from generic medicines to healthcare payers and patients were not fully realized in Europe. The European experience also suggests a fragmented approach towards developing generic medicine pricing policies in Europe. We identified a relationship between the market share of generic medicines and the change of their price level [3]. The average price level of generic medicines decreased more in countries with a high generics market share than in those with a low generics market share. In addition, we assessed the experience of tendering programmes for outpatient prescription pharmaceuticals in Europe [4]. Only seven countries had applied this policy for pharmaceuticals in ambulatory care in 2011. Tendering led to drastic reductions of the price level of medicines and generated significant short-term savings in some countries. Several negative long-term consequences were associated with this policy, including drug shortages, closure of domestic manufacturing plants, and closure of pharmacies.

We also analysed reference pricing systems in Europe [5, 6]. We found that reference pricing reduced medicines prices, usually only to the level of the reference price, and increased the use of medicines priced at or below the reference price. No negative effects on health outcomes of patients were reported in the literature. The effect on pharmaceutical expenditures was limited, as no, or only marginal, savings were attained, which also tended to be short term. Reference pricing, however, caused a once only setback of expenditure, whereupon the growth rate returned to its former levels. Although long-term growth of pharmaceutical expenditures was not affected, the setback of expenditures created headroom to finance innovative, expensive medicines.

On the demand side, we conducted a literature review of policies implemented by European governments to encourage the use of generic medicines [7]. We found that positive knowledge and perceptions of generic medicines by all stakeholders are necessary prerequisites to increasing the use of generic medicines. Therefore, governments must initiate appropriate policies to achieve this, e.g. independent academic detailing programmes, continuous medical education events for healthcare professionals, and information campaigns for all stakeholders. These policies should be combined with those designed to facilitate prescribing and dispensing of generic medicines and to increase all stakeholders' financial responsibility within the healthcare system.

We then analysed the effect of prescribing quota for cheap medicines in Belgium [8]. A cheap medicine was defined in this case as a generic medicine, an original medicine whose price has dropped to the reference price level, or a prescription by International Nonproprietary Name (INN). The policy was successful, as most groups of physicians reached their minimum annual percentages between 2006 and 2009. The percentage of cheap medicines (in defined daily doses) increased from 22.9% in January 2005 to 44.2% of all prescribed medicines in ambulatory care in December 2009. The percentage of generic medicines increased from 12.10% in 2004 to 24.03% of all prescribed medicines in ambulatory care in 2008. Despite the success of this policy, it could be even more successful. The definition of cheap medicines in Belgium currently

Author for correspondence: Pieter Dylst, PharmD, PhD, Department of Pharmaceutical and Pharmacological Sciences, KU Leuven, Onderwijs en Navorsing 2, PO Box 521, 49 Herestraat, BE-3000 Leuven, Belgium

Submitted: 29 October 2013; Revised: 13 November 2013; Accepted: 14 November 2013; Published online first: 27 November 2013

also includes any prescription by INN, whether or not this actually leads to the dispensing of a lower priced medicine.

We investigated pharmacist remuneration systems, as it is important that pharmacists are not financially penalized for dispensing generic medicines, which has been the case in some European countries [9]. Pharmacist remuneration should move towards a fee-for-performance model instead of a price-dependent model; the latter has been the model of choice in many European countries.

We also reviewed the Spanish generic medicines market, and identified hurdles that impede its development. We found that the market share of generic medicines varied among autonomous communities, demonstrating the importance of demand-side policies. Limited use of generic medicines, drastic reductions of the price level of both innovator and generic medicines, and the erosion of price differences between originator and generic medicines have undermined the economic viability of the Spanish generic medicines market. We make recommendations for increasing the sustainability of the Spanish generic medicines market and the efficiency of the pharmaceutical use within the healthcare system. These include accelerating market entrance of generic medicines, creating a price difference between originator and generic medicines, differentiating between patient co-payment rates between originator and generic medicines, improving physicians' and patients' trust in generic medicines, increasing prescribing by INN, deploying electronic prescribing systems, making physicians financially responsible for their prescribing behaviour, and making pharmacists' remuneration independent of the prices of medicines.

On the basis of our research, we propose recommendations to enhance market access of generic medicines in the European Union. These include establishing a unitary EU patent and a unified and specialized litigation system at European level; faster approval of pricing and reimbursement decisions upon marketing authorization; and a reduction of backlogs in national approval systems.

We make recommendations for governments so that they can continue developing their generic medicine retail markets. These proposed policies have been shown to increase the use of generic medicines effectively, independent of any country-specific characteristics. The recommendations concentrate mainly on demand-side issues, such as increasing prescribing by INN, improving physicians' training and education in drug selection, implementing electronic prescribing systems for physicians, introducing fee-for-performance systems for pharmacists, and improving patients' perception of generic medicines. The effect of hospital policies on generic medicines is discussed, as this may affect future medication schemes in ambulatory care.

We conclude by forecasting the future of the generic medicines industry. The industrial landscape for pharmaceutical companies is changing, with a tendency for pharmaceutical companies to combine both originator and generics divisions, and the

development of biopharmaceuticals and biosimilars [10]. Future research should focus on the development of generic medicines in emerging markets and country-specific analyses of other European countries with limited use of generic medicines.

Competing interests: Professor Steven Simoens holds the EGA Chair 'European policy towards generic medicines'. The authors have no conflicts of interest that are directly relevant to the content of this manuscript. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Provenance and peer review: Commissioned; internally peer reviewed.

Co-authors

Professor Arnold G Vulto, PharmD, PhD, Deputy Head Hospital Pharmacy, Professor of Hospital Pharmacy and Practical Therapeutics, Erasmus University Medical Center, PO Box 2040, 230 Gravendijkwal, NL-3015 CE Rotterdam, The Netherlands.

Professor Steven Simoens, MSc, PhD, Department of Pharmaceutical and Pharmacological Sciences, KU Leuven, Onderwijs en Navorsing 2, PO Box 521, 49 Herestraat, BE-3000 Leuven, Belgium.

References

1. Dylst P, Vulto A, Simoens S. Overcoming challenges in market access of generic medicines in the European Union. *J Generic Med.* 2012;9(1):21-8.
2. Dylst P, Simoens S. Generic medicine pricing policies in Europe: current status and impact. *Pharmaceuticals.* 2010;3(3):471-81.
3. Dylst P, Simoens S. Does the market share of generic medicines influence the price level?: a European analysis. *Pharmacoeconomics.* 2011;29(10):875-82.
4. Dylst P, Vulto A, Simoens S. Tendering for outpatient prescription pharmaceuticals: what can be learned from current practices in Europe? *Health Policy.* 2011;101(2):146-52.
5. Dylst P, Vulto A, Simoens S. The impact of reference-pricing systems in Europe: a literature review and case studies. *Expert Rev Pharmacoecon Outcomes Res.* 2011;11(6):729-37.
6. Dylst P, Vulto A, Simoens S. Reference pricing systems in Europe: characteristics and consequences. *Generics and Biosimilars Initiative Journal (GaBi Journal).* 2012;1(3-4):127-31. doi:10.5639/gabij.2012.0103-4.028
7. Dylst P, Vulto A, Simoens S. Demand-side policies to encourage the use of generic medicines: an overview. *Expert Rev Pharmacoecon Outcomes Res.* 2013;13(1):59-72.
8. Dylst P, Vulto A, Simoens S. Where a cheap medicine is not the same as a generic medicine: the Belgian case. *Journal of Pharmaceutical Health Services Research.* 2011;2:185-89.
9. Dylst P, Vulto A, Simoens S. How can pharmacist remuneration systems in Europe contribute to generic medicine dispensing? *Pharmacy Pract.* 2012;10(1):3-8.
10. Dylst P, Vulto A, Godman B, Simoens S. Generic medicines: solutions for a sustainable drug market? *Applied Health Economics and Health Policy* 2013; doi:10.1007/s40258-013-0043-z

DOI: 10.5639/gabij.2014.0301.011

Copyright © 2014 Pro Pharma Communications International