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REVIEW ARTICLE

European payer initiatives to reduce prescribing costs through use of generics

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Introduction: Pharmaceutical expenditure is increasingly scrutinised by payers of health care in view of its rapid growth resulting in a variety of reforms to help moderate future growth. This includes measures across Europe to enhance the utilisation of generics at low prices.
Methods: A narrative review of the extensive number of publications and associated references from the co-authors was conducted, supplemented with known internal health authority or web-based articles.
Results: Each European country has instigated different approaches to generic pricing, which can be categorised into three groups, with market forces in Sweden and UK lowering the prices of generics to between 3–13% of pre-patent loss originator prices. Payers have also instigated measures to enhance the utilisation of generics versus originators and patent-protected products in a class or related class. These can be categorised under the 4Es: education, engineering, economics and enforcement, with the measures appearing additive. The combination of low prices for generics coupled with measures to enhance their utilisation has resulted in appreciable cost savings in some European countries with expenditure stable or decreasing alongside increased utilisation of products in a class.
Conclusion: Reforms will increase as resource pressures continue to grow with the pace of implementation being likely to accelerate. Care though with the introduction of prescribing restrictions to maximise savings as outcomes may be different from expectations.

Keywords: Demand measures, generics, pharmaceuticals, pricing

Introduction

Pharmaceutical expenditure is increasingly scrutinised by payers in view of its rapid growth, outstripping growth in other components of health care [1-7]. This growth has resulted in pharmaceutical expenditure in ambulatory care becoming the largest, or equal to the largest, cost component in this sector [1, 3-9], with expenditure on drugs in ambulatory care typically appreciably greater than inpatient drug costs, particularly in Europe. This growth in pharmaceutical expenditure has been driven by well-known factors including changing demographics, rising patient expectations, strict clinical outcome targets, and the continued launch of new and expensive drugs [1, 3, 5, 6, 10].

As a consequence, third-party payers have introduced multiple reforms and initiatives in recent years to optimise the managed entry of new drugs and, in addition, to help control expenditure on existing drugs through encouraging the increased prescribing of generics at low prices [1, 2, 6, 7, 11-13]. The various measures to increase the prescribing of generics among existing molecules and classes, as well as their potential impact, will be appraised in this review article. A list of potential, additional measures that third-party payers could introduce as they seek further measures to help control their rising prescribing costs is also provided.

This review will be divided into two sections: firstly, the measures that have been instigated to lower the prices of generics; secondly, measures to enhance their utilisation. However, we acknowledge that there will be overlap between these two sections. The principal focus will be on Europe.

Pricing policies to help lower the price of generics in Europe

Each European country has introduced different measures to lower the price of generics. However, the variety of measures can be categorised into three distinct approaches [1, 3, 4, 8, 11, 14-17]:

- *Prescriptive pricing policies*: mandated price reductions for reimbursement, e.g. under the 'stepped price' model in Norway, there is an automatic 30% price reduction for the first generic versus the originator pre-patent loss prices, which increases to 55% or 75% reduction six months later depending on overall expenditure. There is a maximum 85% reduction for high expenditure generics after a further 12 months. In France, generics currently have to be 55% below pre-patent loss originator prices to be reimbursed, with further price reductions in subsequent years.
- *Market forces*: market forces are used in a number of European countries to lower the price of generics. This is achieved by introducing a variety of demand-side measures that encourage the prescribing and dispensing of generics versus originator molecules, as well as lowering their prices. Market forces can be categorised by the 4Es: namely education, engineering, economics and enforcement. Table 1 gives the definition of each category alongside examples, with Table 2 documenting examples of initiatives to enhance the prescribing and dispensing of generics versus originators among European countries with different methods of financing health care, geographies, and epidemiology.
- *Mixed approach*: a combination of prescriptive pricing for the first generic(s) with market forces after that, e.g. in Austria the

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Table 1: Definition and examples of the 4Es

Measure (4Es)	Explanation and initiatives
Education	• Activities range from simple distribution of printed material to more intensive strategies including academic detailing and monitoring of prescribing habits coupled with feedback • Examples include: ⇨Education of trainee doctors in medical schools to prescribe by INN, e.g. UK ⇨Information and other campaigns among patients to address any fears about the effectiveness and/or safety of generics including speaking with patients to address any fears, e.g. France ⇨Physicians and pharmacists developing a list of potentially non-substitutable products where there are concerns with bioequivalence as well as the therapeutic equivalence of generics, e.g. Sweden and UK
Engineering	• This refers to organisational or managerial interventions • Examples include substitution targets for certain drugs in community pharmacies if physicians are still prescribing the originator, e.g. France, and prescribing targets for generics versus originators or patent protected products in a class or related class, e.g. France, Spain, Sweden and UK
Economics	This includes financial incentives for physicians, patients and pharmacists, for example: • Higher co-payments for patients if they wish to receive a more expensive product than the current referenced price molecule, e.g. Finland, France and Sweden • Devolution of drug budgets to physicians with sanctions for over-budget situations, e.g. Germany, Sweden and UK
Enforcement	This includes regulations by law such as mandatory INN prescribing or mandatory generic substitution at pharmacies apart from a limited number of agreed situations, e.g. Lithuania, Finland and Sweden.

Based on references [1-3, 7, 8, 16-19]; INN: international non-proprietary name.

first generic must be priced 48% below pre-patent loss originator prices to be reimbursed, second generic 15% below the first generic and the third generic 10% below the second (overall 60% below pre-patent loss prices). Market forces to further lower prices from the fourth generic onwards, with each new generic necessarily priced lower than the last one for reimbursement and physicians financially incentivised to prescribe the cheapest branded generic(s). In Finland, the price of the first generic must be 40% lower than the pre-patent originator price to be reimbursed. Prices of subsequent generics must not be higher than the first generic for reimbursement with market forces, including the need for additional co-payment for more expensive products than the reference priced molecule, helping to reduce prices.

These are in addition to compulsory price cuts for both originators and generics instigated among some European countries as they struggle to contain rising pharmaceutical expenditure [1, 3, 5, 8, 9].

The different approaches to the pricing of generics has led to an appreciable variation in reimbursed prices for generics across countries, with prices varying up to 36-fold depending on the molecule [3, 20].

However, the general trend is for countries to introduce additional measures to lower their generics prices to maximise savings with countries continuing to learn from each other [3, 5, 8], introducing initiatives highlighted in Table 1. For instance, high volume generics in Sweden and UK are priced at between 3–13% of pre-patent loss prices through a variety of market force measures, some of which are highlighted in Table 2 [3, 7, 14, 21]. This is driven by global sales of products likely to lose their patents between 2008 and 2013 estimated at US$50 – US$100 billion (Euros 35 – Euros 70 billion) per year [22, 23], with global sales of pharmaceuticals estimated at US$820 billion (Euros 579 billion) in 2009 [24].

Demand-side measures to enhance the prescribing of generics

Currently, there is also an appreciable variation in the utilisation of generics across Europe. This includes the prescribing and dispensing of generics versus originators, as well as the prescribing of generics versus patent-protected products in a class or related classes. Table 2 contains examples of ongoing demand-side measures across Europe to enhance the prescribing and dispensing of generics versus originators, which resulted in high utilisation rates for generic omeprazole versus the originator and generic simvastatin versus the originator in 2007 in a recent cross-national study, see Table 3; full details of the measures undertaken to increase the utilisation of generics in individual European countries can be found in references 3 and 5.

European countries have also introduced a variety of different measures to encourage the prescribing of generics within a class. The objective is again to take advantage of the availability of lower priced generics in a class. As a result, these measures help fund increased drug volumes and new drugs without having to raise taxes or health insurance premiums. However, recent research has shown that among the proton pump inhibitors (PPIs), 3-hydroxy-3-methil-gluteryl-CoA reductase inhibitors (statins) and renin-angiotensin products, there is considerable variation in the prescribing of generics within a class or related classes once generics become available in a class [5, 8, 15, 26, 27]. Consequently, there are appreciable opportunities for countries to further enhance their prescribing of generics and lower their prescribing costs through learning from each other.

Examples of ongoing initiatives to increase the prescribing of generic products in a class, again broken down by the 4Es building on Tables 1 and 2, include [1, 4-8, 14-17, 27-29]:

- *Educational activities*: local, regional and national formularies coupled with monitoring of prescribing patterns and

Table 2: Examples of market forces across Europe to enhance the prescribing and dispensing of generics collated under the 4Es

Country	4Es	Approach
Estonia	Enforcement	• Physicians obliged to prescribe by INN, and only using originator names where medically necessary and justified • Prescriptions are monitored to reduce inappropriate prescribing behaviour
Finland	Economics Enforcement	• Generic substitution in the pharmacy with a cheaper product, patients required to pay the difference themselves for a more expensive product • Substitution mandatory unless forbidden by the physician or patient although patients can accept higher co-payments for more expensive products than the reference priced molecule
France	Economics Engineering	• Recent introduction of reference pricing for some products, with patients having to pay a higher co-payment for a more expensive molecule than the current reference priced molecule • Patients have to wait to be reimbursed the costs of their prescription (from the Social Insurance) if they do not wish to be dispensed the generic. Otherwise no personal cost, with the pharmacist dealing directly with Social Insurance • Nationally agreed substitution targets for pharmacists—national level of 80%; less for some drugs, e.g. 75% for clopidogrel and 65% for tramadol
Germany	Economics	• Patient co-payments are abolished if the reimbursed price of the dispensed generic is at least 30% below the current reference price • Alongside this, prescribing costs for physicians are regularly benchmarked by the Sickness Funds against colleagues with financial sanctions for continued high prescribing costs enhancing the prescribing of generics
Lithuania	Economics Enforcement	• Mandatory INN prescribing unless a biological drug is prescribed or physicians receive prior approval from the Hospital or Polyclinic Therapeutic Committee • Pharmacists obliged to stock the cheapest generics with financial penalties if they do not comply
Spain	Economics Enforcement	• Mandatory substitution in pharmacies with the cheapest molecule once multiple sources are available when prescribed by INN • No opportunity for patients to cover the additional costs themselves for a more expensive molecule than the current referenced price molecule, with the cheapest molecule establishing the reference price
Sweden	Enforcement	• Mandatory generic substitution in pharmacies apart from a minority of situations
UK	Education Engineering Economics	• INN prescribing encouraged through education and follow up activities, over 82% across all products and up to 99.5% once drugs lose their patent, e.g. generic simvastatin • Measures to increase the transparency in the pricing of generics as well as the extent of rebates currently being offered by manufacturers to wholesalers and community pharmacists to increase the dispensing of their generic

Based on references [1-8, 14, 17-19, 25]; INN: international non-proprietary name.

academic detailing. One example is the 'Wise Drug' list in Stockholm County Council, which contains approximately 200 drugs covering conditions typically encountered in ambulatory care. Prescribing suggestions typically include older well-established and well-documented drugs, which are generally available as generics, rather than newly marketed drugs. Physician-prescribing patterns are continually benchmarked against the list and their colleagues to enhance adherence to the guidance, with the instigation of educational activities if needed.

- *Engineering activities*: a number of European countries have instigated prescribing targets. These typically include the percentage of generic drugs within a class such as the percentage of generic PPIs versus all PPIs, percentage of generic statins versus all statins and percentage of angiotensin-converting enzyme inhibitors (ACEIs) versus all renin-angiotensin drugs.
- *Economic interventions*: financial incentives to physicians for achieving agreed prescribing targets in a class, as well as devolution of drug budgets to local general practitioner groups combined with regular monitoring of prescribing behaviour.
- *Enforcement*: prescribing restrictions such as restricting the prescribing of patent-protected statins to second-line in Austria, Finland, Norway, and Sweden as well as restricting the prescribing of angiotensin receptor blockers (ARBs) to second-line in Austria and Croatia.

However, in countries with less intensive demand-side measures to combat industry and other pressures to prescribe patent-protected drugs, there is typically an increased prescribing of patent-protected products once multiple sources are available. Examples include increased prescribing of esomeprazole with decreased prescribing of omeprazole as a % of total PPI utilisation, which has been seen in France, Ireland, and Portugal [5, 8]. The reverse was seen in countries that have instigated multiple and intensive demand-side measures such as Spain (Catalonia), Sweden, and UK. A similar situation was seen with the statins, with increased utilisation of atorvastatin and rosuvastatin and decreased utilisation of simvastatin in countries with less intensive demand-side measures, with the exception of Portugal where the utilisation of all three statins increased following the availability of generic simvastatin [5, 8].

Table 3: Percentage utilisation of generics: two examples

Country	Omeprazole	Simvastatin
Austria	89	95
England	97	97
France	88	87
Germany	100	99
Norway	66	88
Portugal	94	93
Scotland	98	97
Spain (Catalonia)	85	82
Sweden	98	98

This table shows the percentage utilisation of generic omeprazole versus all omeprazole, and generic simvastatin versus all simvastatin on a defined daily dose basis in 2007 [5].

The differences in price that can be obtained for generics in countries, coupled with measures to enhance their prescribing versus originators as well as patent protected products in a class, can have a profound impact on overall prescribing costs. Table 4 documents changes in reimbursed expenditure between 2001 and 2007 among western European countries for both PPIs and statins alongside changes in their utilisation [5, 8]. The introduction of reference pricing for both PPIs and statins in Germany appreciably increased the utilisation of omeprazole and simvastatin at the expense of esomeprazole and atorvastatin [5, 19, 25]. However, higher expenditure/defined daily doses for generic omeprazole and generic simvastatin compared with Sweden and UK limited efficiency gains in practice [30, 31].

The different patterns seen in Table 4 resulted in appreciable differences in overall expenditure for the PPIs and statins among European countries in 2007 when adjusted for population sizes, see Table 5.

The quality of care does not appear to be compromised through initiatives to enhance the utilisation of generics. This demonstrates the potential of releasing considerable resources through the increased use of generics, see Table 5, without negatively affecting outcomes. This is further illustrated by health authorities and health insurance agencies typically viewing all PPIs as having similar effectiveness based on available data [5-8, 14, 19, 25]. They also generally believe generic statins can be used as first-line to treat patients with coronary heart disease and hypercholesterolaemia adequately, with patent-protected atorvastatin and rosuvastatin reserved for patients failing to achieve target lipid levels with, e.g. generic simvastatin [5-8, 11, 14, 15, 17, 19, 25]. These beliefs are endorsed by a recent ecological study, which showed that outcomes, in terms of the subsequent impact of drug treatment on lipid levels, were similar whether patients were prescribed formulary drugs (including generic simvastatin) versus non-formulary drugs, which included patent-protected statins [32]. Published studies have also shown that patients can be successfully switched from atorvastatin to simvastatin without compromising care [33], and physicians in UK extensively prescribe generic simvastatin to achieve agreed target lipid levels in the quality and outcomes framework to help maximise their income [14, 21, 34, 35]. Alongside this, pharmaceutical companies have failed to provide reimbursement agencies with any published studies documenting increased effectiveness of ARBs versus ACEIs to support premium prices for ARBs [26, 27]. In addition, only 2–3% of patients in the ACEI clinical trials actually discontinued ACEIs due to coughing [36, 37], and a recent ecological study again showed that outcomes, in terms of the subsequent impact of drug treatment on blood pressure, were similar whether patients were prescribed formulary drugs (including generic ACEIs) versus non-formulary drugs, which included patent-protected ARBs [32]. As a result, generic ACEIs can be prescribed first line with patent-protected ARBs reserved for patients where there are concerns with side effects without compromising outcomes.

Finally, care may be needed when considering the introduction of prescribing restrictions (enforcement). This is because their nature and follow-up appear to influence subsequent utilisation patterns appreciably [4, 15, 17, 26]. For instance, the prescribing restrictions for patent-protected statins, atorvastatin and rosuvastatin, had less influence on increasing the utilisation of generic statins, e.g. simvastatin, in Norway versus Austria and Finland. This was the result of having no prior authorisation scheme in Norway, unlike Austria, or no close scrutiny over prescriptions as seen in Finland [4, 15, 17]. In Austria, atorvastatin and rosuvastatin can only be reimbursed if physicians obtain agreement from the Chief Medical Officer of the patient's Social Health Insurance Fund [4]. The Norwegian authorities also recently introduced prescribing restrictions for esomeprazole. However, hospital specialists in Norway have to verify the diagnosis and recommend therapy before PPIs are reimbursed, and they are not subject to the same restrictions [15]. This reduced the influence of the prescribing restriction in practice, with physicians generally reluctant to deviate from the initially prescribed drug or the advice for the prescription if this was for esomeprazole [15].

Conclusion

The differences between the extent and intensity of supply- and demand-side measures encouraging the prescribing of generics at low prices led to over tenfold difference in reimbursed expenditure for the PPIs and statins in 2007 between European countries when adjusted for populations, see Table 5. However, there was greater morbidity among the Irish population studied [5, 8]. Consequently, there are considerable opportunities for

Table 4: Differences in utilisation and reimbursed expenditure for proton pump inhibitors and statins

	Utilisation increasing but expenditure decreasing or remaining stable	Both utilisation and expenditure increasing
Proton pump inhibitors	Spain (Catalonia), Sweden, and UK	Austria, France, Germany, Ireland, and Portugal
Statins	Austria, Germany, Norway, Spain (Catalonia), Sweden, and UK	France, Ireland, and Portugal

Based on defined daily doses between 2001–7 [5, 8].

Table 5: Reimbursed expenditure in 2007 for proton pump inhibitors and statins

Class	Euros per 1,000 inhabitants per year in 2007
Proton pump inhibitors	Ireland – over Euros 60,000* Austria – Euros 19,299** France – Euros 15,194 Portugal – Euros 15,197 Germany – Euros 13,864** Spain (Catalonia) – Euros 12,796 England – Euros 6,186 Sweden – Euros 5,832
Statins	Ireland – over Euros 60,000* France – Euros 14,896 Spain (Catalonia) – Euros 14,174 England – Euros 13,439*** Portugal – Euros 10,031 Germany – Euros 6,833** Sweden – Euros 5,192

These data are for the selected European countries found in Table 4 [5, 8, 14]; *Population in the Republic of Ireland with subsidised health care with greater morbidity than the total population; **Total expenditure; ***Physicians in England are incentivised to reach target lipid levels which appreciably increased statin utilisation versus other European countries.

countries to learn from each other to reduce their prescribing costs, especially with the influence of demand-side measures appearing additive.

Both supply- and demand-side measures are thought to be important to limit costs, with countries limiting the extent of any potential efficiency gain if they principally concentrate on one set of measures. For example, in Germany, the reimbursed prices for generics are appreciably higher than seen in UK, which limited potential savings in reality [38]. The limited number of demand-side measures in Portugal also reduced their efficiency gains from recent initiatives to lower generic prices [3, 5, 8]. This is changing with recent reforms. However, payers are urged to consider the nature of any prescribing restrictions they may seek to introduce, and their follow-up, when they forecast the possible influence of these measures, as there could be appreciable differences from expectations [15, 26, 27].

We are already seeing countries learning from each other to identify new initiatives to enhance their prescribing efficiency, i.e. increased drug utilisation at similar or lower costs. Examples include greater transparency in the pricing of generics, prescribing targets, physicians financial incentives, compulsory prescribing with the international non-proprietary name, and prescribing restrictions [1, 3, 5, 6, 8, 18]. It is likely that the pace of implementation of what has been learned will accelerate to maintain the European ideals of universal, affordable, and comprehensive health care, especially given the current financial concerns coupled with ongoing pressures. This will need to be reviewed in future publications.

For patients

The costs of health care are rising across Europe through ageing populations resulting in greater prevalence of patients with chronic diseases, stricter clinical targets for managing patients with long term (chronic) diseases, the continued launch of new and more expensive drugs as well as rising patient expectations. The provision of generics (multiple sourced products once the original product loses its patent) at considerably lower prices than the price of the originator just before it lost its patent, and with similar effectiveness and safety to the originator through strict licensing regulations, allows European governments to continue to provide comprehensive and equitable health care without prohibitive increases in either taxes or health insurance premiums. This paper discusses a number of measures introduced by health authorities or health insurance companies in recent years to increase the prescribing and dispensing of generics, with countries continuing to learn from each other as cost pressures continue growing.

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The majority of the authors are employed directly by health authorities or health insurance agencies or are advisers to these organisations. No author has any other relevant affiliation or financial involvement with any organisation or entity with a financial interest, in or financial conflict with, the subject matter or materials discussed in the manuscript.

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