Generic medicines from a societal perspective: Savings for health care systems?

Elizabeth Seeley, Panos Kanavos

**Summary:** Despite the emphasis placed on generic policies, as a means of creating savings to health insurance budgets, there seems to be a lack of robust evidence on their effectiveness. By studying generic policies in seven OECD countries (USA, UK, Germany, France, Italy, Spain, Canada) and for a number of drugs, we find that generic penetration varies significantly among them and could be enhanced further, particularly in France and Italy, but also Spain and Canada. We also find that generic price decline post patent expiry is variable and that countries regulating generic prices, e.g. through price capping or reference pricing, display significantly lower price declines over time compared with countries that do not. As generic savings are influenced by the combined effect of genericisation and price reduction post-patent expiry, we conclude that significant additional savings to health insurance can be realised – up to 43% of current generic sales – if generic purchasing and genericisation improve further.

**Keywords:** Generic medicines, pharmaceutical policy, competition, efficiency

**Background and conventional thinking**

Given the intense debate surrounding health care cost containment and efficiency in health care resource allocation, it is not surprising that generic policy has received much attention in Organisation of Economic Co-operation and Development (OECD) countries. Generic medicines are both chemically equivalent and bioequivalent to their branded equivalents, but can be significantly cheaper since they do not have to recoup large R&D costs and are protected by a patent. In general, originator drug prices may not decline significantly after patent expiry, but rather pursue a market harvesting strategy that focuses on the brand loyal, price insensitive portion of the market, leaving their lower priced generic equivalents to compete for the more price sensitive consumers.1,2 As a result, health insurers, both public and private, have been eager to promote generic drug use, with a view to reducing off-patent drug costs. Failure to do so implies that health insurance will continue to pay premium prices for products whose patents have expired.

There are significant differences in regulatory frameworks for generic medicines across OECD countries and North America. In France, Italy and Spain, for instance, regulators have implemented reference pricing for generics as well as generic substitution, in addition to promoting generic prescribing. In other countries, generic prescribing and dispensing have been key features of pharmaceutical policy for decades (for example, the USA and the UK). Table 1 provides an overview of supply and demand side generic policies across the EU-G5 (UK, Germany, France, Italy, Spain), the USA and Canada. These policies may help to improve generic substitution as well as spur generic price competition. To the extent that generic savings are achieved, policy makers may then have more resources to invest in new treatments, creating headroom for innovation.

Despite the emphasis on generic policies,3 there is a lack of robust evidence on their actual effectiveness in different environments, whether they indeed result in high rates of generic penetration, and whether they encourage sustainable price reductions. In this article we briefly address three questions:

- How does generic penetration compare across countries?
- Are generic prices influenced downwards by the entry of new competitors?
- How do price regulation and market structure affect generic competition and savings to health insurance?

**Generic penetration and price competition in off-patent markets**

We empirically examined aspects of competition in the market for relatively established drugs in seven OECD countries (USA, EU-G5 and Canada) and used a panel of twelve products (shown on
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Table 2) subjected to generic competition post-patent expiry, and accounting for 19% of the off-patent market by value in these countries.

We find that generic penetration varies significantly among countries and that it could be enhanced further in most countries, especially in France and Italy, which appear to have the lowest generic penetration. Spain and Canada exhibit average levels of generic penetration, while the US, Germany and the UK exhibit the highest levels of generic penetration for these products (Figure 1).

While generic penetration may be a necessary condition for the creation of savings to health care systems, it is not sufficient, as savings are greatly affected by price levels and in particular, the price differential between originator and generic drug, as well as the speed with which generic prices decline. It is therefore necessary to take a closer look at generic prices in order to better evaluate the degree of savings national generic policies are achieving. Our study shows that there is significant variability in generic prices which sometimes result in a fifteen-fold difference between countries for the same molecule. In addition to comparing prices at one point in time, the evolution of prices over time must also be compared across countries. Figure 2 shows that, in general, US and UK generic prices decline faster post-patent expiry than other countries, while French, Canadian and Italian generic prices are the most rigid downwards.

In looking at Figure 3, we see that prices range very little among generics in countries with reference pricing, (such as Germany, France and Italy) suggesting a lack of price competition in reference pricing countries. This is not surprising. Under a reference price scheme, patients are made to pay the difference between the reference price and the price of the product in the form of a co-payment. Moreover, reference prices are usually pegged to some of the lowest generic prices in the market. As a result, if companies were to price above the reference price, they would likely experience a collapse in market share, whereas if they were to price below the reference price, this would further drive down the reference price itself, forcing other companies to follow suit or health insurance to adjust reference prices downwards. The result is a clustering of prices around the reference price, rather
Figure 2: Generic price evolution over time (2000–2005)

Figure 3: Impact of reference pricing on generic prices and competition, 2005 (prices in Euros per pack)
than price reductions over time, as would be expected in a price competitive market. Generic prices seem to remain relatively stable in countries with reference pricing and decline slowly, whereas a significant reduction in prices is seen in countries without reference pricing, such as the USA and the UK.

Finally, it is important to understand the effect that the number of generic firms (i.e. generic entry) has on generic price competition. In a competitive market, price premiums should attract new competitors, which should, in turn, result in price competition that leads to lower prices. The analysis of competition patterns within the generic segment suggests that the number of generic entrants is not a predictor of lower generic prices in most study countries. For example, Table 2 shows that for many products, Germany and the USA have the largest number of generic competitors, despite Germany exhibiting slow price reduction and the USA relatively faster price reduction over time. Thus, the effect of the number of generic firms on price competition seems muted in Germany, as the reference price incentives discussed above would predict.

Meanwhile, the UK has relatively few generic competitors, despite showing signs of relatively fast price declines. This suggests that the off-patent market displays non-linearities such that the addition of a new firm to those already existing may not be linked directly to price reductions. For prices to be impacted by generic entry, there may need to be a significant increase in the number of generic entrants. It seems, therefore, that entry by generic producers is in itself a necessary but not sufficient condition for a sustainable reduction in generic drug prices for payers and that (generic) price regulation may have an adverse effect on generic price reduction irrespective of the number of players entering the market.

In summary, competition in the off-patent market seems to be variable and country-dependent. The countries showing little evidence of downward price trends within the generic segment following generic entry are France, Italy, Spain and Canada, whereas in Germany generic prices respond to generic entry weakly. Whilst the results were expected for France, Italy and Spain, three countries that have only in recent years introduced measures to promote generic drug use and have smaller generic penetration levels and high generics prices, they were not in Germany, given its overall market size (in monetary terms), the level of generic penetration (in terms of generic market share for patent expired molecules) and depth (in terms of the number of generic firms active on each product market). In short, current regulatory frameworks may encourage high prices for generics and limit potential savings for health insurers.

### Savings for Payers

As a result of the above it looks as though governments, particularly in Europe, may not be realising the full benefits of genericisation and are even wasting resources by overpaying for generic products. The potential savings to health care systems could improve significantly, provided generic penetration increases through improved generic prescribing and dispensing practices and provided generics are available at competitive prices. This requires greater competition in this segment. In total, we estimate potential savings to be in the vicinity of $3 billion, or 43% of current sales of generic medicines in our sample, as depicted in Figure 4. These foregone savings, if realised, could be invested in novel treatments that improve quality of life and offer significant health gains.

To achieve more efficient generic purchasing, countries need to revise some of their generic policies. For example, in order to reduce price rigidity where it exists and achieve greater price responsiveness to competitive forces, it may be necessary to introduce policy changes that would promote the latter; potential options could include the abolition of reference pricing as a factor that stifles price competition over time, or introducing ‘managed competition’ through gradual stepwise price reductions by payers once off-patent product markets mature further. In order to encourage

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### Table 2: Proliferation of generic firms in European Countries, 2004

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Germany</th>
<th>Italy</th>
<th>France</th>
<th>UK</th>
<th>Spain</th>
<th>Total EU-5</th>
<th>Canada</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>45</td>
<td>41</td>
<td>17</td>
<td>15</td>
<td>64</td>
<td>182</td>
<td>11</td>
<td>48</td>
</tr>
<tr>
<td>Clavulanic Acid</td>
<td>16</td>
<td>6</td>
<td>10</td>
<td>4</td>
<td>20</td>
<td>56</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Hydrochlorothiazine</td>
<td>60</td>
<td>6</td>
<td>8</td>
<td>9</td>
<td>28</td>
<td>111</td>
<td>15</td>
<td>80</td>
</tr>
<tr>
<td>Iron ferrous</td>
<td>126</td>
<td>34</td>
<td>31</td>
<td>30</td>
<td>22</td>
<td>243</td>
<td>48</td>
<td>144</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>24</td>
<td>1</td>
<td>7</td>
<td>3</td>
<td>13</td>
<td>48</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>Mesalazine</td>
<td>19</td>
<td>16</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>46</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Metformin</td>
<td>49</td>
<td>10</td>
<td>16</td>
<td>7</td>
<td>2</td>
<td>84</td>
<td>17</td>
<td>25</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>11</td>
<td>5</td>
<td>19</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>24</td>
<td>0</td>
<td>14</td>
<td>6</td>
<td>44</td>
<td>88</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Paroxetine</td>
<td>24</td>
<td>5</td>
<td>7</td>
<td>4</td>
<td>15</td>
<td>55</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Salbutamol</td>
<td>27</td>
<td>6</td>
<td>6</td>
<td>13</td>
<td>5</td>
<td>57</td>
<td>13</td>
<td>52</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>33</td>
<td>1</td>
<td>N/A</td>
<td>5</td>
<td>27</td>
<td>66</td>
<td>10</td>
<td>N/A</td>
</tr>
</tbody>
</table>
greater generic penetration, generic prescribing should be encouraged further through financial and non-financial incentives that target physicians, and cost sharing strategies that target patients, such as co-payments. Finally, in terms of further encouraging generic entry, regulatory hurdles such as price setting and capping should be eliminated, so that the generics market can acquire depth. Where eliminating regulations appears difficult for several reasons a system of ‘managed competition’ could help to achieve price reductions over time.

Figure 4: Total effect of efficient generic purchasing in EU-G5, Canada and USA

Does pharmaceutical parallel trade serve the objectives of cost control?

Panos Kanavos and Stacey Kowal

Summary: The extent to which pharmaceutical parallel trade can contain pharmaceutical costs has been debated intensely. Although parallel import penetration is significant in many EU countries, parallel trade generates at best moderate savings to health insurance, is not necessarily associated with sustainable long-term price competition and can lead to product shortages in exporting countries and, recently, a higher probability of counterfeiting. Parallel distributors emerge as the key beneficiaries from this practice. The high transaction costs associated with parallel trade, the lack of sustainable long-term price competition and the lack of tangible benefits to patients make this practice an inefficient means of containing costs.

Keywords: pharmaceutical parallel trade, efficiency, cost containment, single market

Background
Parallel trade refers to the “legal importation of a patented product from one country where it is legally marketed into a second country where the patent holder also markets that product but without authorisation of the patent holder”. Therefore, it constitutes a form of arbitrage, or the purchase and sale of identical products from different markets for the purpose of gaining a profit from unequal prices. While parallel trade is illegal in many parts of the world, it is legal within the European Union (EU) after the move to a single market for phar-