

ABSTRACTED SCIENTIFIC CONTENT

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Measuring performance in off-patent drug markets

Generic medicines can play a role in curbing rising pharmaceutical costs, and therefore the cornerstone of key policies within Organisation for Economic Co-operation and Development (OECD) countries has been to promote the wider use of generics after patent expiry, or loss of market exclusivity of originator drugs. At patent expiry, however, prices and market share of different generics in different countries vary significantly [1, 2] compared with branded originator drugs. Studies examining the effect of generics entry on originator prices and market share have produced contradictory results [3, 4].

In an attempt to address the key concerns of decision-makers about the performance of generics policies, Kanavos [5] has developed a methodological framework comprising five indicators (independent of policy mix) that can be used as a benchmark for evaluating generics policy in non-tendering settings once originators lose exclusivity. These indicators are: (1) generic drug availability after patent expiry; (2) delay in time to generics entry; (3) number of generics competitors; (4) price development of originators and generics after loss of exclusivity; and (5) evolution of generics volume market share.

Kanavos [5] proposes a number of metrics to assess the performance of each of the indicators over time. For generic drug availability, the metrics include: (1) the share of total molecules studied in each country, with generic entry within the first 12 and 24 months after patent expiry; (2) the proportion of total sales facing generics entry within the same time-frame; and (3) the proportion of sales facing generics entry in the top and bottom decile of each market by sales, 12 and 24 months after patent expiry.

Intercontinental Medical Statistics data (last quarter of 1998 to last quarter of 2010) for 101 molecules that had lost patent protection in 12 European Union countries were analysed to test and measure the performance of the indicators. Countries were divided into three tiers according to perceived strength of their generic policies. The aim was to understand the drivers behind generic entry and competition in each country, and to identify any associated changes in prices, sales and market share over time after the originator patent had expired.

The empirical analysis carried out by Kanavos [5] confirms the hypothesis that different regulatory policies produce diverse outcomes. Some general predictions were confirmed, and the expected effects of individual policies were questioned.

Tier 1 countries (Denmark, Germany, The Netherlands and the UK), for example, had high levels of generics prescribing and substitution, consistently less time delay to generics entry, higher numbers of generics competitors, faster price declines and higher generics volume shares compared with Tier III countries (Greece, Italy and Portugal), which showed opposite trends; these countries implemented price capping on generics and had fewer incentives for generics prescribing. Tier II countries (Austria, Finland, France, Spain and Sweden) had moderate levels of generics prescribing and used price reduction strategies.

Price reductions in some countries implementing supply-side measures, such as price capping or linking generic price to

the originator price as done in France, Greece and Italy, were significantly slower over time than seen in countries that did not have these controls, such as Denmark, Germany, The Netherlands and the UK; countries with no such controls had the shortest delay in time to generic entry and the highest rate of generic penetration.

Kanavos [5] questions the extent to which reference pricing facilitates faster and more extensive generic competition after patent expiry. In Sweden and the UK, which do not have international reference pricing (IRP), delays to generics entry are shorter compared with countries that have IRP. The UK's open-market pricing system for post-patent drugs allows price competition to be achieved quickly after patent expiry, and the decreases in the price of both generic and originator drugs 12 and 24 months after patent expiry are relatively large. Other reasons accounting for the speed of competition in the UK include implementation of attempts to teach medical students the cost-saving benefits of generic drug products, and implementation of mandatory International Nonproprietary Names (INN) prescribing.

Germany, in contrast, has an established IRP system but a more competitive market compared with the UK. An association, however, was identified between the use of reference pricing and a pattern of high prices for originator drugs and continually decreasing prices for originator drugs after patent expiry. The volume share for generics 24 months after originator patent expiry is large in Germany. Greece is an outlier; although it has implemented a reference pricing system, this has not been reinforced with INN prescribing or mandatory generics substitution that could increase generics uptake.

Another question addressed by Kanavos [5] is the effect of the introduction of generic drugs on the prices of originators whose patents have expired. In most cases, prices of originator drugs were found to decline in response to generics entry. Paradoxically, in Germany and Denmark, prices of originator drugs in fact increased. The opposite has been observed in Greece, where prices of off-patent originators that do not face generics entry generally decreased although in some cases they increased. This suggests that generics competition and availability of generics are important determinants of price reductions of off-patent originator brands, since in their absence the price of these products can increase.

Countries that have strong demand-side policies, e.g. mandatory or strongly encouraged INN prescribing, have a higher degree of generics penetration after patent expiry and lower time delays to generics entry compared with countries that do not encourage these policies. The effect of generics pricing and substitution, however, may be related to the specific components of the policies, i.e. whether physicians or patients are permitted to overrule generics substitution and whether pharmacists are offered incentives or disincentives to dispense generic over branded drug products, as well as the price difference between originator brand and generic drug.

Although the author acknowledges some limitations to the study, he suggests that the broad conclusions and specific findings have important policy implications. He believes that further

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research is needed to identify the most effective policy mix that will maximize generic entry and penetrations and lead to greater expenditure optimization by health insurers.

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