



CRA Insights: Life Sciences

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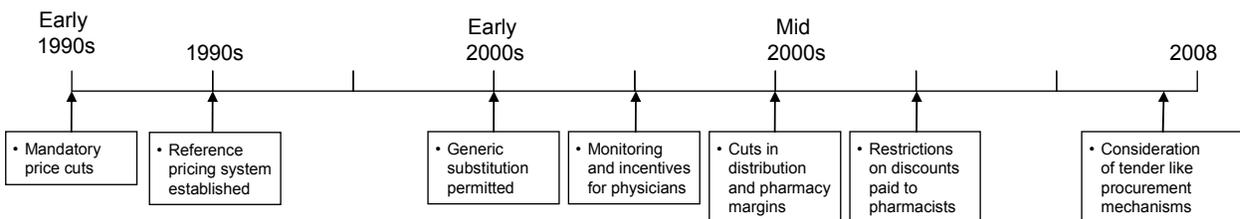
Lessons from the Sector Inquiry

One of the many lessons drawn from 2009's European DG Competition Sector Inquiry into the pharmaceutical industry was the difficulty created by the speed at which the policy environment is changing. Appropriate policy conclusions can only be reached after developing an understanding of the market's structure, the system of regulation, and the impact that regulations have on how pharmaceutical products are prescribed and purchased. As we discuss below, this is equally important for commercial strategy considerations and economic litigation issues.

Tracking the policy environment

In most European markets, the rules and regulations affecting the pharmaceutical market, specifically the pricing and reimbursement regime, change on an annual basis. Over a ten-year period, fundamental changes can occur, and as a result, aggregating data together across the period or comparing case studies from different periods can be quite misleading. In the research undertaken by Charles River Associates on behalf of the innovative pharmaceutical industry,¹ we depict the evolution of off-patent regulation in different European markets. A number of new policy instruments were introduced over the last ten years. By plotting the changes in different regimes, we observe a common pattern, as illustrated in Figure 1. For example, many European countries introduced generic reference pricing (i.e., when the reimbursement of an off-patent molecule is determined based on existing prices in the market) in the 1990s; then they introduced generic substitution by pharmacists, new methods to encourage appropriate physician prescribing practices (i.e., through targets or financial penalties), and changes to the compensation and reward mechanisms for pharmacists; and they are now considering alternative mechanisms to pay for off-patent medicines.

Figure 1: Illustrative timeline



Source: CRA analysis

¹ "Factors affecting Generic Entry in Europe", CRA International, submitted to the DG Competition Sector Inquiry.

By comparing experiences across different national markets, a number of lessons can be drawn:

- All markets (including those that have appeared to be working effectively for a long time) have seen fundamental policy initiatives over the last ten years.
- “Fads and fashions” exist in policy development—the same policies are introduced across different markets during a period of time.
- New policy initiatives are commonly layered on top of one another; reductions in regulatory burden are significantly less common than increases.
- Even if markets use similar policy tools, the combination of policy instruments is often unique.

Implications for policy assessments

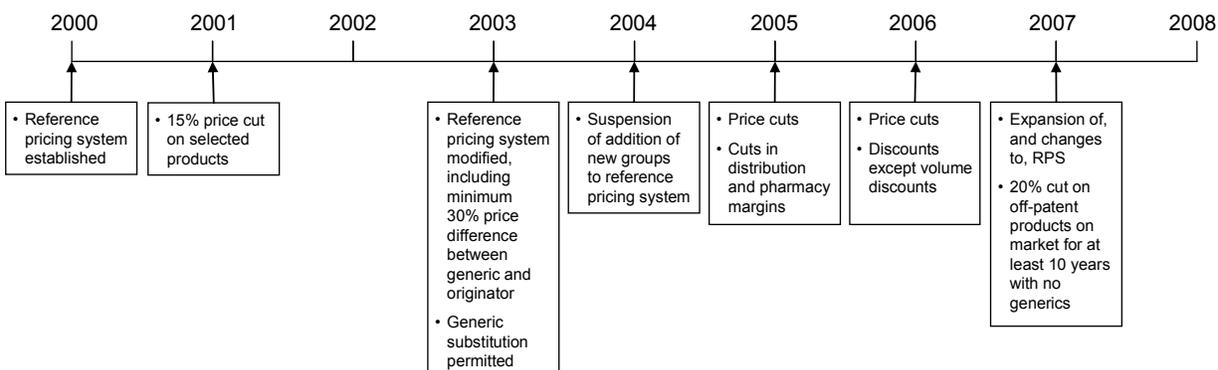
The implications for policy analysis are very significant.

First, assessments of how well different markets are working need to be undertaken with considerable care. An analysis based on long time periods can result in misleading interpretations. As the final sector inquiry report illustrated, the utilization of data from the earlier part of the decade to assess the speed and impact of generic entry is misleading if you are concerned with how the market works today.² The more recent data shows generics entering more quickly and for a greater proportion of the medicines that lose market exclusivity—as we might expect given the amount of policy change that has taken place. Only by examining the changes over time is it possible to establish a link between the way the market functions and the different policy tools.

Second, assessments of the effectiveness of particular policy instruments need to take into account the context of the regulatory environment at the time and allow time for the market to react to changes in the regime. For example, the impact of rules allowing pharmacists to substitute generic versions of a medicine depends on the incentives that pharmacists face (these are often determined through the fixed margin system, but they can also be influenced by any formal or informal discounts being offered in the market). The impact also will depend on rules concerning the ownership of pharmacies and whether they can be vertically integrated with wholesalers. This impact on pharmacy behavior then would be expected to influence concentration in the provision of generic medicines and the basis on which generics compete with the manufacturers of the off-patent branded products. It should therefore not be surprising that we can observe a range of different outcomes from the introduction of rules allowing pharmacists to substitute generic medicines. For instance, to understand the impact of generic substitution in Spain, as described in Figure 2, it is important to understand the subsequent changes to pharmacy remuneration.

² “Pharmaceutical Sector Inquiry Final Report”, 8 July 2009. Available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

Figure 2: Timeline of regulatory changes in Spain



Source: CRA analysis

The above does not mean that anticipation of the impact of policy changes (e.g., the recent policy proposals to allow generic substitution in the UK³) cannot benefit from examining past experience. However, it requires careful selection of the most comparable markets to be used as analogues and appropriate incorporation of idiosyncrasies.

Wider implications for litigation and strategy

The impact of changes in the policy environment has clear ramifications for investigations that might follow the sector inquiry. Concerns regarding apparent delays in the entry of generic competitors need to be analysed in the policy context at the time, taking into account the regulatory rules, the incentives they created, and the consequent market structure. Reviewing past behavior in the context of how markets are working today will lead to incorrect conclusions.

Equally, there are important lessons that feed into strategic considerations for the pharmaceutical industry—companies often attempt to anticipate the impact of losing market exclusivity based on how markets have behaved in the past. Significant effort is exhausted in attempts to find comparable products with similar characteristics (i.e., in terms of distribution channel, commercial value, clinical attributes that affect patient switching); however, less effort seems to be invested in ensuring that the analogue products experienced similar regulatory conditions (or in accounting for differences in the impact of subsequent regulatory changes between the analogue and the original product). Without considering the impact of changes in the policy environment, strategies and tactics that rely heavily on the “lessons” from analogues will be more likely to fail.

Conclusions

There is a lot to be learned by properly examining the market reaction to policy changes. These lessons are important considerations for assessing the effectiveness of different policy initiatives and anticipating the impact of current policy proposals. Equally, an understanding of the many changes to pricing and reimbursement systems over the last ten years is an important component of market investigations and strategic analysis.

³ “The proposals to implement ‘generic substitution’ in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009. Consultation document.” Published 5th January 2010.

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