Life Sciences case study

Market reform in Italy

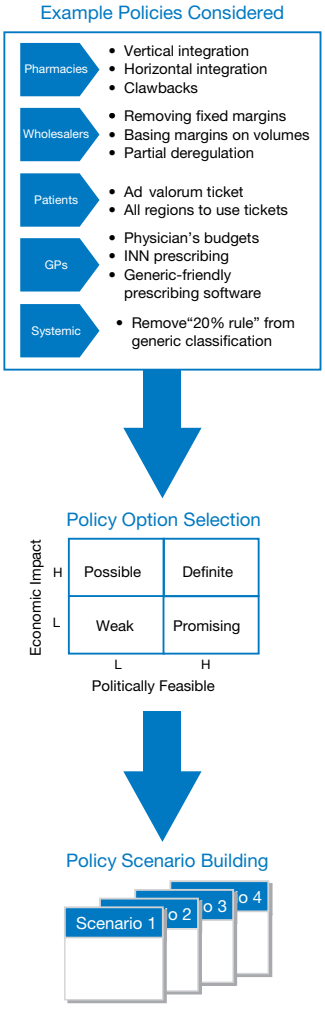
Background to the assignment

The US pharmaceutical trade association (PhRMA) asked CRA to identify concrete evidence-based proposals on market reforms aimed at creating a more competitive 'off-patent' sector in order to generate savings for the Italian National Health Services (SSN).

Value added

Working with industry participants, we assessed the potential policy alternatives based on an assessment of the economic and the political realities of the Italian market. This resulted in five potential policy options ranging from tougher enforcement of current generic policy to reforming the incentives for different distribution.

Methodology employed



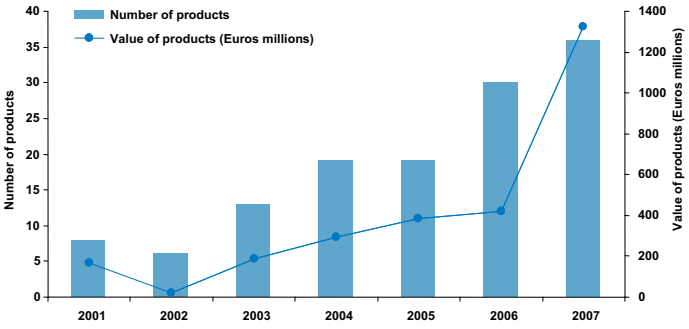
Source: CRA analysis

To identify the potential for policy reform in any market, it is necessary to examine evidence regarding the current efficiency of the system and to understand the impact of existing policy – both to take into account policy changes already working through the system but also to learn from previous experience.

Understanding the way the market is evolving

Over the last few years, we have seen significant change in the performance of the Italian off-patent market. There has been a substantial increase in the number and value of products losing market exclusivity as a result, the generic market is also growing quickly, and we commonly observe immediate generic entry following the loss of market exclusivity. When generics enter the market there are substantial price reductions of the order of 40%, the generic reference pricing system results in both generic and originator product price declining. However, it can be characterised as exhibiting static competition with little subsequent price changes.

The number and the value of products losing exclusivity in 2000-2007



Source: CRA International and IMS Data

The potential for additional cost savings

Based on the available evidence, the efficiency of the off-patent market could still be improved:

- The generic reference price system removes the competitive advantage that generic companies have and does not stimulate competition post generic entry so there is only static competition.
- The incentive of pharmacists are seemingly perverse with the result that there is little competition on the list price and competition occurs instead on the discounted price.
- Even though competition at launch has intensified, generic companies continue to offer pharmacists significant discounts indicating significant cost saving remain in the system.

Continued

These cost savings could be used to reward innovative products that bring benefits to Italian patients. The current regulatory system in Italy encourages a situation where (i) generics offer a price discount at launch; (ii) originators, priced at a small premium, retain a share in the market; and (iii) pharmacists are rewarded through discounts when consumers choose to use a generic. Although in the short term this may represent an equilibrium satisfactory to all sides, this leaves substantial cost savings on the table, which will continue to attract government attention.

Conclusions to the study

By using data on how the market works today and simulating the impact of different policy scenarios, we can model the potential impact on the market in terms of how competition works and the cost savings that would be generated for the SSN. We find that:

- *Enforcing current policy* generates minimal savings for the health services because the incentives for pharmacists to substitute for generics are already in place due to the discounts offered by the manufacturers.
- *Capturing current discounts* could generate savings up to €200 million if the government sets up a system that could clawback a certain percentage of the discounts currently benefiting only the pharmacists.
- On a stand alone basis, *legalising discounts across all segments in the Class A off-patent market* may not generate savings for the national health services as it would lead to competition only on discounts, benefiting once again the pharmacists. In order for it to be beneficial for the national health services, it is necessary for the government to establish, as in the previous scenario, a clawback mechanism. In that case the saving could be between €300 million and €900 million.
- If the *current pharmacy remuneration system is restructured* into a fixed dispensing fee system similar to that in the UK, then the cost saving for national health services could be approximately €1.2 billion.
- Establishing *unregulated and transparent distribution margins* based on regional levels would generate the highest cost saving for the national health services. However, using the cost of direct distribution is an upper bound on the cost saving this could achieve. Assuming that this system is applied across all the pharmaceutical market, it could produce approximately €1.6 billion in saving to the current system.

From the scenarios investigated, significant cost savings result from clawback of discounts from pharmacists, changing pharmacy remuneration to a fee for service model and allowing regional flexibility over distribution.

Impact of scenarios

Scenario	Impact on competition	Potential cost savings (as a % of SSN expenditure on pharmaceuticals)
Enforcement of current policy	Competition remains focused on discounts with little change	Minimal
Clawback of savings from pharmacist	Exploit commercial interest of pharmacists but large monitoring and compliance costs	0.5%– 2%
Liberalising discount of originators	Could encourage competition on discounts between generics and originators	3%– 7%
Fee for service	Reduced revenue to pharmacists; Incentive still depends on discounts	10%
Regional pharmacy	Benchmark competition	14%

Source: CRA analysis

About CRA's Life Sciences Practice

We provide life sciences companies, law firms and regulatory agencies across the globe with the industry experience and analytical expertise needed to address the industry's toughest issues. Our reputation is for rigorous and innovative analysis, careful attention to detail and the ability to work effectively as part of a wider team of advisers. CRA has offices throughout the world including European offices in London, Brussels, Hamburg and Amsterdam; United States offices in Boston, New York and Washington DC; and offices in Toronto, Bahrain and Hong Kong.

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