

Italy is turning the corner after reference-price cuts

Italian industry's refusal to bow to reference-price reductions has provided the spur for initiatives to raise volumes, local generics association Assogenerici told Aidan Fry.

For the head of an industry association whose members have just experienced reimbursement reductions of up to 40%, Assogenerici's chairman Giorgio Foresti is in remarkably high spirits. While those reference-price cuts threaten the sustainability of the industry – and in particular, the existence of smaller players in Italy's generics market – Foresti says the Italian authorities are starting to realise that they must raise generic volumes if they are to generate further savings. "We have reached a crucial, and positive, moment," Foresti told *Generics bulletin*. Authorities including the country's Ministry of Health and medicines regulatory agency AIFA were now openly discussing the need to increase generic usage and thereby improve access to low-cost medicines, he said. "This is really the first time this has happened," Foresti remarked.

When AIFA unveiled reference-price reductions of up to 40% from 15 April this year, Assogenerici warned that the move threatened to drive several local generics players out of business (*Generics bulletin*, 22 April 2011, page 1). The price cuts – which affected 4,188 off-patent products – would slash profit margins on certain products to the extent there would be no incentive to market them, Assogenerici cautioned.

In calculating the new prices, AIFA referenced Italian prices for off-patent medicines against those in "the pharmaceutical markets that most closely resemble that of Italy – France, Germany, Spain and the UK".

Most products faced reimbursement cuts of between 10% and 40%, although for around 1,700 products that were already priced in line with the average in France, Germany, Spain and the UK, the reduction was 8%. With the aim of protecting the "operating sustainability" of pharma firms, AIFA set the maximum reimbursement price cut at 40% and did not cut prices for drugs that already had reference prices of €2.00 (US\$2.93) or lower.

Assogenerici's Foresti said the unsustainable reference prices set for certain molecules meant that the association's members had adjusted their retail prices to the lower reference prices for only around 60% of the affected products. For the other two-fifths, industry

had refused to match the reference price, so patients were having to make up the difference through co-payments, typically of around €0.50 per pack.

"Industry's reaction was a shock to the system," Foresti maintained. By refusing to match many of the reduced reference prices, companies had stressed that the generics sector could not survive on meagre margins without a major rise in volume penetration.

"The authorities are now realising that they can't keep cutting generic prices without raising volumes substantially," Foresti observed, noting that Italy's antitrust watchdog had recently recognised the need to incentivise generic prescribing and dispensing.

Assogenerici is currently engaged in intensive discussions with Italy's healthcare authorities on developing models similar to those used elsewhere in Europe – such as in France – for setting targets for generic prescribing and dispensing. "Furthermore," Foresti remarked, "we are discussing implementing incentives for generic substitution."

According to Foresti, the reference-price reductions on 15 April largely overshadowed a development that, in the long term, could prove even more important. Just days earlier, three of Italy's most influential healthcare professional associations had taken the unprecedented step of calling for general practitioners to prescribe generics. "They no longer doubt the quality of generics," Foresti observed. Such calls are being backed up by consumer groups that are mindful of the public's need to spend wisely in a difficult economic environment.

Foresti and his Assogenerici colleagues have been at pains to stress the small size of any extra co-payments that consumers are having to make on generics that are priced above the new reference prices. And in any case, Foresti pointed out, Italians already paid almost €600 million extra each year to receive specific brands.

That €600 million in voluntary spending is equal to the amount that AIFA expects Italy's regional health authorities to save through the new reference prices.

Citing IMS Health data, Assogenerici said Italy's total generics market expanded by 16% last year to

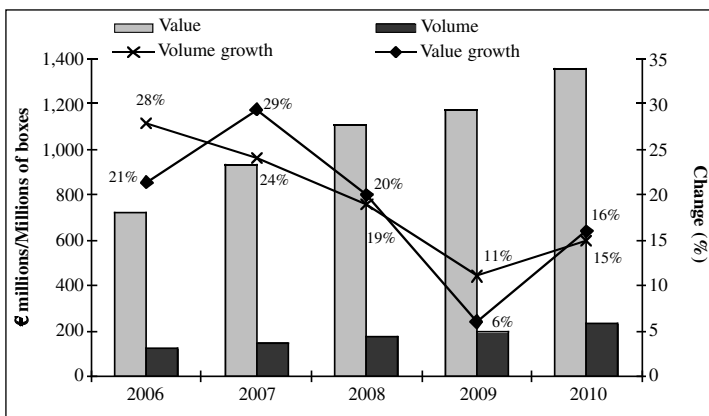


Figure 1: Retail sales of pure generic medicines in recent years, showing changes in both value and volume terms (Source – AssoGenerici/IMS Health)

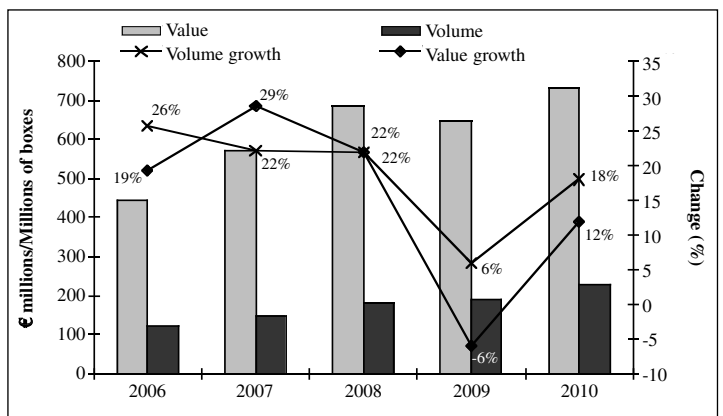


Figure 2: Ex-factory sales of pure generic medicines in recent years, showing changes in both value and volume terms (Source – AssoGenerici/IMS Health)

€1.35 billion at retail selling prices (see Figure 1). This growth was below historical levels, but marked a significant acceleration over a sluggish 2009 (**Generics bulletin**, 28 May 2010, page 24). However, when measured at ex-factory prices, 2010 generics market growth was a more modest 12% to €733 million (see Figure 2), although that was far better than the 6% reverse suffered in 2009. In volume terms, the advance – based on sell-in data – was 18% to 226 million packs.

If recent launches upon patent expiries were excluded, Foresti noted, the base generics value growth would have been just 3% to 4%. And with the owners of off-patent originals typically adjusting their prices to maintain a uniform gap to generic rivals, there was currently little incentive to increase generic usage.

Generics shares measured at retail selling prices, based on sales out of pharmacies, were 12.5% by volume and 6.8% by value respectively. Off-patent brands clung onto 46.2% of the overall market by volume, and more than a third by value (see Figure 3). Patent-protected brands accounted for just over two-fifths of the market by volume, but 57.6% by value.

“Volume sales remain largely in the hands of the originators,” Foresti observed, adding that structural changes were needed to break the cycle of consumers demanding specific brands from doctors and pharmacists.

Italian originators also have other tricks up their sleeves to ensure they continue to dominate the local market. They are persevering in their efforts to link patent status with regulatory or pricing and reimbursement status, even though their efforts to block generics through administrative courts have met with limited success and have triggered an investigation by Italy’s antitrust watchdog into whether Pfizer abused its dominant position with Xalatan (**Generics bulletin**, 12 November 2010, page 1). Furthermore, the impact of biosimilar launches is being muted by originator-sponsored drives to question their quality, safety and efficacy.

Formal proceedings over linkage

Earlier this year, the European Commission’s directorate-general for health and consumers opened formal infringement proceedings against Italy for linking marketing authorisations with patent status (**Generics bulletin**, 8 April 2011, page 1). The Commission’s action followed complaints submitted by Assogenerici and the European Generic medicines Association (EGA).

The infringement proceedings relate to a revision of Italy’s industrial-property code last year. The amended Article 68.1bis of the code states that a generic applicant can only start the registration procedure “one year before the expiry of the supplementary protection certificate (SPC) or – in the absence of the latter – one year before patent expiry of the active substance, also taking into account other extensions”. Acting under Article 258 of the Treaty on the Functioning of the European Union (EU), the Commission initiated proceedings by sending a request for information on whether Article 68 of Italy’s industrial-property code complied with EU law by linking the timing of generic filings with protections attached to the reference product. If the Commission is not satisfied with the answers provided by the Italian authorities, it may send a formal request or ‘reasoned opinion’ that calls on Italy to detail what measures it is taking to conform to EU law.

While the Commission investigated Article 68.1bis

of Italy’s intellectual-property code, Foresti said local brand industry association, Farmindustria, had adjusted its strategy to push for new linkage legislation through Italy’s Ministry of Economic Development. “The proposed bill aims to link generic authorisations with patent expiry data supplied by the brand industry,” Foresti objected, pledging that Assogenerici would oppose the legislation vigorously.

Meanwhile, Farmindustria has been denigrating the quality, safety and efficacy of biosimilars, whilst also enlisting key opinion leaders in areas such as rheumatology and oncology to question publicly the therapeutic equivalence of products such as erythropoietin, filgrastim and somatropin. Constant vigilance was needed to combat such misinformation, Foresti said, particularly as big pharma sought to exclude biosimilars from hospital tenders.

Assogenerici and its members have been doing their part to stress the quality, safety and efficacy of generics by running print advertisements in the national press as well as a television commercial that ran from February until late April on major channels. While the association continues to talk to the AIFA agency about following up the campaign’s messages, one of Italy’s leading consumer associations has approached Assogenerici about creating a joint campaign. “I am confident our members will spend some money to back this initiative,” Foresti stated.

Foresti also welcomed the outcome of recent research – both in Italy and in France (**Generics bulletin**, 8 April 2011, page 26) – that had refuted a long-held suspicion that Italian generics prices were among the highest in Europe. “Our prices are in the middle of the pack, but we still have the lowest volumes,” he stressed.

“Our industry is finally in a good place,” Foresti believed, pointing to the considerable wave of patent and SPC expiries that would occur over the next few months. This year’s budget for Italy’s statutory health insurance scheme, the SSN, includes €300 million of additional savings through recent patent or SPC expiries. The recent valsartan expiry in May, followed on 20 June by levofloxacin, are together expected to contribute about a third of the €300 million savings. Generic letrozole is set to arrive in July, with olanzapine coming off patent in September. Atorvastatin will follow in November this year. “If one assumes a price reduction of 60% for atorvastatin, that already implies annualised savings of around €300 million,” Foresti pointed out.

This wave of launch opportunities – coupled with a growing acceptance among Italian health authorities that they must drive up generic volumes to generate greater savings – is giving Assogenerici hope of an upturn in fortunes. “Italy is finally on its way to becoming a fully-developed generics market,” Foresti insisted. **G**

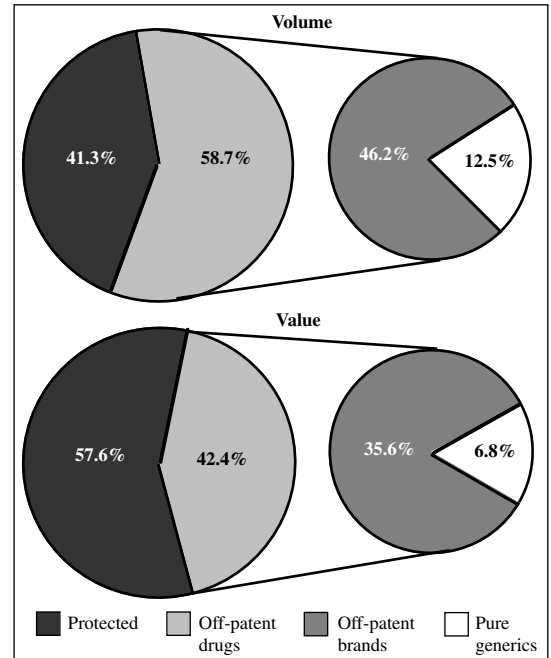


Figure 3: Italy's total retail market in 2010 at public prices showing sales out of pharmacies. Off-patent drugs include pure generics and equivalent off-patent branded drugs (Source – AssoGenerici/IMS Health)

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