

Introduction

Fears have been expressed that therapeutic reference pricing, similar to Germany's 'jumbo groups', could spread in Italy as several regions there begin to experiment with the concept.

Since 2001, the regions have been accountable for 40% of healthcare deficits they incur, with drug costs capped at 13% of total National Health Service expenses in the ambulatory sector and at 3% in the hospital sector.

In accordance with the 2007 Finance Act (Law 296/06), those regions that have not already taken steps to recoup the budgetary overspends for 2005 and 2006 are empowered to introduce supplementary measures as alternatives to introducing a €10 hospital inpatient charge, which would undoubtedly upset patients. In addition the regions have been told they must clear healthcare deficits by 2009. As a result several of the regions have been looking at ways to reduce their drug expenditure.

As well as stepping-up the use of existing cost-containment tools brought in at regional level under Law 450/01 – e.g. limitations on prescribing by GPs, levying small prescription fees (€1-2 per item) on patients and allowing hospitals to dispense drugs to outpatients – regions can fix new reference prices for so-called "homogenous categories" of products grouped at ATC level IV. Reimbursement is capped at the cost of the DDD of the cheapest off-patent drug included in the group; the patient pays for any excess above this.

Impact on PPIs

Puglia in the south-east of the country and the central region of Abruzzo have implemented therapeutic reference pricing with one category, proton pump inhibitors (PPIs).

The reference price is based on the cost of the only off-patent drug in the group¹, lansoprazole, with the early impact on shares in the class being dramatic (Table 1).

Omeprazole and esomeprazole respectively were the second and third best-selling drugs in Italy in the first nine months of 2006, with pantoprazole in tenth place.

¹ While omeprazole has long gone generic elsewhere in Europe, the drug benefits from an extended Italian supplementary protection certificate (CCP) until 2010. Any CCP granted before January 1993 (when the EU SPC Regulation entered into force) remains valid according to national provisions, i.e. up to 18 years from the expiry of the patent. Of 400 CCPs granted by the end of 1992, 190 remain in force today.

Table 1: Evolution of PPI market share (%) by value

Region	month/year	9/06	10/06	11/06	1/07
Abruzzo	esomeprazole	22.9	13.0	5.6	5.4
	lansoprazole	37.2	54.4	65.2	65.0
	omeprazole	13.6	10.1	6.9	6.8
	pantoprazole	14.4	13.6	14.8	14.8
	rabeprazole	11.5	8.6	7.2	7.7
Puglia	esomeprazole	22.8	23.2	23.1	6.5
	lansoprazole	28.4	28.7	29.2	76.9
	omeprazole	22.5	21.7	21.2	6.0
	pantoprazole	19.6	19.8	20.0	7.9
	rabeprazole	6.4	6.4	6.3	2.5

Source: IMS Health (data cited by S Garattini)

The shares of some PPIs have clearly plummeted, while those of lansoprazole have markedly increased.

The northern region of Liguria, where patients have traditionally shown a greater willingness to access the private market, has gone further and set homogenous groups for four therapeutic categories (PPIs, statins, SSRIs and treatments for benign prostatic hypertrophy).

The prescription fee can also be waived if doctors in some regions choose to prescribe products whose DDD cost is the class minimum, e.g.

- in Abruzzo with PPIs;
- in Puglia for statins & SSRIs;
- in Tuscany for PPIs, statins & SSRIs;
- in Sardinia for PPIs

Other Regional Developments

The regional governments can incentivise use of low cost alternatives in other ways.

Prescribing targets may be set for the minimum share of a low-cost drug/drug class and/or the maximum share of a high-cost drug/drug class within a particular indication.

This impacts use of sartans in Abruzzo and four categories (PPIs, sartans, SSRIs, treatments for benign prostatic hypertrophy) in Tuscany, for example.

Physicians practising in Emilia Romagna and in Campania are now mandated to prescribe using the international non-proprietary name (INN). This could increase generic dispensing, which in Italy is among the lowest in Europe.

Instead of the 5% general price reduction imposed last September companies had the option to reimburse the regions directly for this amount allowing them to roll back prices to September 2006 levels from March 1st 2007.

National Changes - Online Price 'Negotiation' with AIFA

From May 2nd all applications to the Italian Medicines Agency AIFA for a new reimbursement price as well as any data missing from a previous application have been required to be made online. Parallel paper submissions are still needed though.

The change, which had a very brief run-in period (April 18th -27th), has four aims, according to AIFA:

- to allow companies to send in electronic format with password protection the necessary documentation for negotiation of P&R (i.e. letter of application, dossier, proposed price and reimbursement status, any CIPE decision, product SmPC and EPAR);
- to monitor in real time the progress of the application;
- to allow AIFA to update its records; and
- to monitor and analyse the assessment process, and provide an overview.

No actual negotiation takes place online and no shorter timelines for completing the process are promised (though Italy is already quite fast for a price-controlled market by European standards). The new scheme seems mainly to benefit AIFA by passing on to industry the administrative burden of keeping product files up-to-date. After the price is set, companies are required to record the AIFA decision, the date of its publication in the Official Journal and the start of commercialisation.

The user IDs and passwords are company specific and the same as introduced last year for use in regulatory affairs. Different application forms can be downloaded from the AIFA website (www.agenziafarmaco.it) for products with regulatory approval through the national, centralised and mutual recognition routes. The online registration procedure applies to Category A, H and C products alike.

Implications for Strategy Development

Long seen as offering one of the more unstable P&R environments in Europe, the emerging patchwork of regional cost-cutting measures only adds to Italy's complexity. The cost containment measures are likely to increase because the regions are being made to be responsible to clear their healthcare deficits, with drug prices and drug expenditure an obvious target.

However, Italy is an important market, the fourth-largest in Europe. Italian prices also affect 10 other countries, according to the R&D industry association Farindustria, namely: Bulgaria, Czech Republic, Greece, Hungary, Portugal, Romania, Slovakia, Slovenia, South Korea and Turkey. Other markets in Europe and beyond either formally or informally keep a watch on Italian prices.

The regions are increasingly driving the cost-containment agenda in Italy, not just locally but nationally too. Three of the five members of the AIFA Board are elected by the regions.

Companies need to develop their regional lobbying efforts to counter 'no go' areas like therapeutic reference pricing and mandatory INN prescribing before they become trends.

Companies should develop their pricing strategies to take account of the increasingly hostile environment, with contingencies built in to deal with the cost containment policies such as these in Italy.

This requires in depth knowledge of the markets and experience of what counter measures can be practically applied. The successful companies will be those which plan ahead.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has specific expertise on a wide range of policy matters and detailed knowledge of P&R rules in all major markets worldwide.

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