

Introduction

Individually and collectively through groupings like EFPIA (the European Federation of Pharmaceutical Industries Associations), the pharmaceutical industry devotes considerable time, effort and resources to lobbying policy makers at the European level. Without doubt it has made considerable gains in key areas like regulatory affairs and intellectual property rights, but achievements in Brussels on P&R that penetrate down to national level are much more difficult to highlight.

Take two recent examples in countries nearly at opposite ends of Europe, both geographically and economically.

Norway

Norway has one of the highest per capita GDP in OECD countries, \$40,000 PPP in 2004. Having the ability to pay should mean greater willingness to pay premium prices for innovative therapies, but Norway aims for 'medicine prices as low as possible', a Norwegian Medicines Agency spokesman told a recent London P&R conference.

In the latest international price comparison of a product basket conducted by the local R&D industry association, the LMI, Norway was second to last, coming only before Greece. Maximum prices are officially set as a mean of the three lowest market prices in nine north European countries (Austria, Belgium, Denmark, Finland, Germany, Ireland, Netherlands, Sweden & the UK). Prices for more than 300 of the best-selling medicines (90% of the market) are then recalculated annually by this formula.

Price intervention does not stop here. Allegedly as an alternative to therapeutic reference pricing, Norway introduced its 'preferred medicine' scheme in mid-2005. In three therapeutic classes (statins, antihistamines and PPIs), with more to come, doctors are obliged to prescribe the first choice product unless there are medical reasons for not doing so.

Low prices for new brands are accompanied by high prices for generics. The latter is a direct result of a failed attempt to improve competitiveness by liberalising pharmacy ownership in 2001. Three vertically integrated, foreign-owned chains now control 96% of the private pharmacy market with few procurement discounts passed on to the payer. The government's response to this market failure of its own making was to create a complex 'step price system' for patent-expired molecules. Introduced at the beginning of 2005, the scheme has already been revised once.

Bulgaria

Bulgaria, one of the two new member states that joined the EU at the beginning of 2007, published on April 13 a

new Act on Medicinal Products for Human Use designed to transpose European rules, including the price transparency Directive (89/105/EC), into the country's legislative system.

One surprise, strongly but unsuccessfully objected to by local industry bodies, was that non-reimbursed prescription drugs would continue to face price regulation by the state. 'We opposed this provision in parliament and advocated free pricing for all non-reimbursed medicines as recommended by the G10 report from 2002, but the majority party decided to keep the status quo for "social reasons" as it was described in the press', Rossen Kazakov, Executive Director of the Association of Bulgarian Pharmaceutical Manufacturers (ABPhM) explained to *PriceSpective*. Only OTC product prices would be free.

The May 2002 report of the High Level Group on Innovation and Provision of Medicines, better known as the G10 Medicines Group, certainly called on the Commission and Member States to 'secure the principle that a member state's authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the state' (Recommendation 6). But it was not the first or the last EU initiative to seek this objective. Price deregulation of non-reimbursed products was a prime target of one of the working groups of the 'Pharmaceutical Forum' created out of the first 'round table' convened by Commissioner Martin Bangemann in 1996. Price deregulation remains high on the industry's agenda.

Pharmaceutical Forum

Two of the three working groups at the Pharmaceutical Forum are dealing with pricing policy and relative effectiveness. The pricing group has three objectives - cost control, access to medicines and reward for innovation - with industry sensing a bias favouring the first of these. Progress on defining innovation is reportedly slow, with agreement on clinical outcomes only.

The European Commission is pressing ahead with the aim of having some interim recommendations to present at the upcoming meeting of the Council of EU Health Ministers. These will take the form of a short (2-3 page) statement of principles and a 'toolbox' of good P&R practices. The latter was developed out of the six P&R techniques reviewed in a study for the Commission by the Andalucian School of Public Health. Member states are also sharing access to their price databases, after a pilot price transparency exercise covering 15 medicines co-ordinated by consultants Gesundheit Österreich. Formerly known as ÖBIG, this group hosted the first Pharmaceutical Pricing & Reimbursement Information conference in Vienna on June 29.

A major challenge facing the Forum is how to arrive at consensus among 27 EU member states (plus representatives from the EFTA countries). This is double the number Commissioner Bangemann had to deal with when he attempted to update EU policy in this area in 1996-98.

There are many different bodies that represent the pharmaceutical industry and this partly explains why it seems to speak with many contrasting voices. EFPIA might be the umbrella organisation but it represents 30 disparate national associations (e.g. the ABPI – Association of the British Pharmaceutical Industry - with 75 company members), 45 individual company members, European vaccine manufacturers (8 members) and European Biopharmaceutical Enterprises (65 members). There are other industry groupings present too - EuropaBio (24 association and 80 company members), the European Generic Medicines Association (47 association and company members), and the Association of the European Self-Medication Industries (25 association members) – plus representatives of the European Parliament and stakeholder groups (doctors, wholesalers, pharmacists and mutual health insurers).

The news that, as a separate exercise, the Commission plans to issue before the end of 2007 yet another Communication 'on the future of the single market in the pharmaceutical sector' as been greeted with little enthusiasm.

Some readers may recall that under Article 9 of the price transparency Directive, the Commission was obliged to submit to the Council 'a proposal containing appropriate measures leading towards the abolition of any remaining barriers to, or distortions of, the free movement of proprietary medicinal products, so as to bring this sector closer into line with the normal conditions of the internal market'. The original deadline for submission of this proposal was the end of 1991.

PhRMA's Price Policy

Perhaps another part of the problem with the slow process to price liberalisation is that industry has too many 'red lines' when it comes to techniques used by payers for constraining the growth in the drugs bill. In 2001, the US industry association, PhRMA, published 'Health System Reform Principles', reviewing 18 common cost containment methods. It found fault with all but one – requiring the patient to pay directly for a part or all of the cost of medicines.

More recently, as part of the Pharmaceutical Forum, PhRMA developed 'a cost containment policy platform', listing measures from "worse" to those seen as "most acceptable" to industry (see table). It also developed, for internal industry use, a series of recommended positions ('soft landings when measures will be imposed') for use when discussing with government officials the different policy approaches they seek to take.

Implications for Strategy Development

Pharmaceutical pricing strategists have no alternative other than working in the policy framework in which they find themselves. Where this framework is found wanting strategists should become involved in ensuring that attempts are made to put it right, but also aware of

where battles can be won and where they can't. The industry must try to influence member states as well as the central bodies in order to bring about improvements in the European P&R environment.

The Bangemann round tables (1996-1998), the G10 Group meetings (2001-2002) and now the Pharmaceutical Forum (2006-2008) were all convened with the best intentions, but have so far failed to deliver.

These initiatives should be seen more as keeping the political dialogue open at European level between industry and governments/payers rather than leading directly towards tangible results. National associations and individual companies have to work to achieve these at national level. As the Bulgarian and Norwegian examples described show, this is challenge enough in itself.

Above all, perhaps the industry has to accept that payers do not have bottomless pockets, that some spending constraints are required. Meeting policy makers' part of the way may allow a worthwhile exchange of ideas.

Table: PhRMA's cost containment policy platform

<p>Worse</p> <ul style="list-style-type: none"> • Global budget/capped growth for pharmaceuticals • Illegal parallel importation • Contracts by sickfunds in developed countries establishing single product therapeutic categories • Therapeutic clustering and substitution • Medical needs clauses/mandatory cost-benefits/fourth hurdle • Reference prices, phases II and III • Restrictive prescribing guidelines/formularies • Drug budgets/limitations of physician prescribing practices with individual penalties for overruns • Restrictive access/prior authorization • Weakened patent rights (e.g. compulsory licensing) • New product pricing controls • Rebates • Tying new product prices to int'l comparisons • Delisting of specific products from reimbursement
<p>Tolerable, but not desirable</p> <ul style="list-style-type: none"> • Across-the-board price cuts • Profit controls • Capitation/flat fees • Volume linkages • Incentives to physicians/pharmacists to prescribe cheaper products (generics/parallel imports) • Generic substitution • Price control on in-market products • Quantitative controls and taxes of promotional expenses • Price freezes • Reference price, phase I
<p>Acceptable</p> <ul style="list-style-type: none"> • Generic competition • De-listing of categories from reimbursement • Graduated reimbursement scales • Providing pricing information to physicians • Peer review mechanisms/flexible prescribing guidelines • Changes in value-added tax • Reduction of wholesalers'/pharmacists' margins • Increased patient contribution on a % basis • Hospital cost containment measures such as homecare, out-patient services • More utilization of private healthcare insurance • Utilization of wellness/preventative programs

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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