Working with the authorities

As the incidence of type 2 diabetes continues to soar, Jean-Michel Peny and Marie-Paule Serre look at how pharma is working with the French health authorities to ensure maximum take-up of their treatments

In the past, pharma companies have generally regarded health authorities as a barrier to the development of their business. In the EU in particular, the industry has become familiar with measures to control the cost of healthcare such as price and volume controls, reference pricing, and the removal of drugs from reimbursement lists.

In some circumstances, however, health authorities can become valuable allies. This possibility arises from the significant role they often play in public healthcare initiatives. By launching programmes in focused therapeutic areas, such as the fast-growing demand for type 2 diabetes treatments, they can contribute to the development of specific pharmaceutical market segments.

In our view, such public healthcare initiatives are a major opportunity that must be seized by the industry. Furthermore, to gain a real competitive advantage, pharma should not merely consider such initiatives as external events that may or may not impact a particular market. Rather, companies should integrate them into their strategic thinking about individual products, and draw up a specific and detailed action plan to leverage the growth opportunity they offer.

Rising numbers of diabetics

The market for drugs used to treat type 2 diabetes is a particularly good illustration of such an opportunity. Health authorities throughout the world are concerned about this disease owing to its increasing prevalence and economic impact. Globally, it affects more than 150 million people, a figure predicted by the World Health Organization to grow to 215 million by 2008. This represents an average increase of 4.6% year on year, and is primarily linked to the growing prevalence of obesity, a result of sedentary lifestyles and the increasing number of people in the high-risk age group of over 65 years.

Health authorities in major countries are also worried about the economic impact of the long-term complications of type 2 diabetes, such as retinopathy, neuropathy and nephropathy. In France, diabetes represented 4.7% of National Health Funds (CNAMTS) expenditure in 1982. Of the €4.9 billion spent on diabetes, 45% was for hospital care. Annual healthcare costs for a diabetic patient are estimated at €3,680, 1.7 times those for a non-diabetic patient.

These economic considerations underscore the need for health authorities to promote prevention and screening. Pharma companies have a potentially strong marketing weapon if they can argue successfully that the increased spend on drugs which comes from early diagnosis will be more than offset by the saving in treatments for the complications of the disease that necessitate hospitalisation. They must also be ready to take advantage of the public healthcare programmes that are likely to expand over the coming years in various countries.

Most of the programmes sponsored by public healthcare funds for diabetes focus on increasing physician and patient awareness, with the aim of encouraging greater diagnosis and educating physicians to comply with clinical and therapeutic guidelines.

The most widely used guidelines for diagnosing and treating type 2 diabetes are those of the American Diabetes Association (ADA). In 1997, the ADA lowered its threshold criteria for diagnosing diabetes, with the World Health Organization falling into line the following year. Tight glycaemic control became the watchword of medical practice. However, in countries like Italy, Japan and the UK, fewer than half the physicians follow official guidelines; instead, they have developed their own clinical habits.

Similarly, the proportion of the population screened for diabetes varies from 10% in the UK to 40% in Japan. These major differences are the result of variations in the quality of national healthcare systems and the degree of priority devoted to type 2 diabetes in national public healthcare initiatives. It is estimated that although approximately 60% of type 2 diabetic patients are diagnosed, only 50% are actually treated.

Type 2 diabetes is often asymptomatic and is only detected on average seven to ten years after its biological onset – a situation favouring the development of complications. Consequently, 10% of type 2 diabetics already have clinical and biological complications when they are diagnosed. Several studies have established that diabetics have double the mortality of non-diabetics of similar age: 40% of the excess risk is attributable to ischaemic heart disease, while cerebrovascular and other cardiovascular diseases account for a further 25% of deaths. Diabetes is also the leading cause of blindness and amputations in the major western countries.

Improved screening

Improved screening can be expected to increase the type 2 diabetes patient population by reducing the number of undiagnosed cases and by increasing life expectancy as patients begin treatment earlier. With the exception of Italy, most type 2 diabetics in major countries are diagnosed by general practitioners. Consequently, educational and awareness campaigns intended to increase screening must be targeted at this group. Bear in mind, though, that these potential benefits of improved screening may not be seen in the short term. Analysis of the growth in sales of type 2 diabetes drugs in France between 1982 and 2000 does not show any significant change that could be related to CNAMTS' public healthcare programme.

In November 2001, the French Ministry of Health announced the launch of a programme to prevent and better manage type 2 diabetes. It is planned to run from 2002 to 2005 and includes national awareness campaigns targeted at physicians, other healthcare professionals and the general public. It focuses on the need for a more systematic screening of at-risk populations (such as patients with obesity, hypertension or dyslipidaemia), earlier diagnosis and treatment of diabetes to prevent or retard complications, and better adherence to clinical and therapeutic guidelines that are to be drawn up by the National Agency for Accreditation and Health Evaluation (ANAES) and the French Association of Diabetologists (ALFEDIAM).

There are at least four ways in which these measures could favour the growth of the type 2 antidiabetic market. They should have the effect of increasing the number of type 2 diabetics being treated and the number who are treated with drugs as opposed to exercise and diet alone. They should

also boost the number receiving combination therapy, and increase the level of patient compliance with treatment.

According to our estimates, the French public awareness campaign could potentially generate growth in the oral antidiabetic market of 46% between 2001 and 2005, which corresponds to an average annual growth of 10%. The actual level of success will largely depend on how the health authorities implement the programme and the extent to which the general population and heathcare professionals become involved.

Depending on their competitive position, not all antidiabetic products will derive the same benefit from this programme. National awareness campaigns that promote screening and early diagnosis usually benefit leading brands the most. That should be the case for the four leading oral antidiabetics on the French market: Servier's Diamicron (gliclazide), Lipha's Glucophage (metformin), Aventis' Amarel (glimepiride) and Bayer's Glucor (acarbose). Between them, these companies accounted for 67% of the market in 2001.

As such they could consider proactively supporting and reinforcing the health authorities' initiative using their sales force, which last year made approximately 400,000 calls to 43,000 prescribers. Thus, while calling on physicians, they can emphasise the importance of screening the at-risk population and of initiating drug treatment as soon as diet and exercise recommendations have failed. This naturally leads on to a discussion of the company's product. Alternatively, or in addition, they could organise medical meetings, including sponsorship of Continuous Medical Education (CME) programmes. These meetings are particularly appropriate for conveying the importance of following clinical and therapeutic guidelines.

All companies benefit

Furthermore, maintaining tight control of blood glucose levels requires the earlier prescription of drugs, increased dosage and earlier switch to combination therapy. Consequently, the programme will also benefit companies other than the market leaders: a recent entrant like Novo Nordisk's Novonorm (repaglinide) may have more opportunity to be prescribed at higher average dosages and in combination. Thiazolidinediones or 'glitazones' such as Takedas' Actos (pioglitazone) and Venvia (rosiglitazone) from GlaxoSmithKline, which are expected to enter the French market by the end of 2002, should also capitalise on an earlier switch to combination therapy. On the other hand, concerns about potential liver toxicity may mean that these new entrants will be labeled as second-line treatments, to be prescribed in combination therapy only.

The most appropriate means to leverage this opportunity is probably to carry out either a Phase IV study or an epidemiological survey. The former is more appropriate for new products like the thiazolidinediones, while the latter is recommended for established products. Such studies could be advocated to physicians within the context of health authorities' screening programmes.

Irrespective of their competitive position, all pharmaceutical companies have a great incentive to develop tools and educational materials for physicians and patients that will foster treatment compliance over the long term. For example, home diabetes testing kits, which are used by only an estimated 50% of type 2 diabetics in France, could form part of a compliance plan involving both physicians and patients. Considering that the average type 2 diabetes patient complies with the prescribed treatment for 240 out of 365 days each year (ie, only 66% of the time), the room for progress, and consequently sales growth, is significant.

If such an initiative is to increase drug consumption it is important that the French Drug Pricing Committee (CEPS) should not impose any extra tax burden on pharma companies. In practice, the French authorities are unlikely to exempt them completely, but they could at least restrict any increase in the level of taxation.

Political lobbyists and scientific experts, along with pharmacoeconomists and health economists, could provide valuable support in convincing governments to invest in public healthcare programmes. Market leaders may go even further and propose that health authorities co-promote or even co-finance public health programmes that could simultaneously serve public health issues and favour the development of their major products. Before investing in such programmes, a detailed analysis of the corresponding return on investment must be performed and compared with conventional medico-marketing investment. SM

•Jean-Michel Peny is president of the Paris-based strategy and management consulting firm, Smart Pharma Consulting. Marie-Paule Serre is a consultant specialising in government and regulatory affairs.