Pharma to boycott UK?

From being one of the least regulated markets in Europe, the new agreement will move the UK to one of the most heavily regulated, Andrew Monro, a partner at consultancy KPMG in London, points out. He says big biotech and pharma companies particularly resent the fact that the government refuses to allow them to market their entire product portfolio in the UK—and now it wants explicit price control for the limited portfolio it does allow.

"Those restrictions feed through into companies' perceptions of how attractive the UK market really is," says Monro. "Companies will come to the UK later and later in their launch programs." He points out that the UK is a big employer of R&D scientists, with Pfizer (Sandwich), AstraZeneca (Charnwood), GlaxoSmithKline (Brentford) and Merck (Hoddesdon) all running substantial R&D facilities here. "If you restrict their profits you may force these companies to do research in other countries such as China, Japan and the US."

The drug industry is wary of making explicit threats to this effect, but it is dropping heavy hints. As Nigel Brooksby, head of the UK operation of Sanofi-Aventis in Guildford, UK, puts it: "The PPRS [Pharmaceutical Price Regulation Scheme] has been responsible for a lot of investment in the UK, and some people in the industry are saying that they won't invest here until the current black clouds are lifted." *PM*

role in medicines reimbursement, says Nick Scott-Ram, an industry consultant who represented the biotech industry in the recent negotiations. The industry now expects concessions in the detailed appraisal process: drug evaluations should take into account some of the wider socioeconomic issues, such as the cost of personal caregivers, which NICE doesn't count at the moment.

Various other 'flexible measures' are also being proposed that might blunt NICE's claws. For example, when NICE uses early, incomplete data to assess a product as not cost effective, the sponsor could be told what extra data would be needed to prove cost effectiveness, and given time to collect and submit it, rather than having the product rejected out of hand. And NICE will be pushed to accelerate its assessment work. A Department of Health report published in late June promises that "improvements to the topic selection and appraisal process…will mean that NICE can issue the majority of its appraisal guidance within a few months of a new drug's launch," instead of the two years' delay common today. "These are all encouraging words for the larger biotech companies, particularly those trying to launch innovative medicines focusing on niche indications, and first-in-class molecules," says BIA's Burnand.

Significantly, though, the concept that was supposed to be at the root of the renegotiation—that is, a move to pricing medicines according to their therapeutic value—seems to have been kicked into the long grass. Almost no progress has been made on moving the idea forward, says Scott-Ram. One key obstacle to value-based pricing is that value means different things to different parties—to the government as payer, to patients and to clinicians. "The challenge is to find a definition of value that is acceptable to all," says Scott-Ram.

Another, almost insoluble, problem is the choice of reference products. When a new drug is introduced, which existing product should it be compared against for pricing? "Developing a new drug is very expensive, even if it is only a minor improvement on existing products, but if NICE compares its price with an earlier drug in the class it will often come out uneconomic," says Scott-Ram. "It's even worse if the first-in-class product has become generic and thus much cheaper." So if NICE is too ruthless in calculating the cost-effectiveness of incremental innovations, he says, it will end up throwing the baby out with the bathwater.

"It was unrealistic to expect that we would come up with a new mechanism overnight," says Burnand. "Whatever is meant by value for money will have to be decided in the future. If it is going to be done it needs to be done properly, and it can't be done on the back of an envelope." Moreover, she says, other European countries are closely observing the UK's progress toward rational medicines pricing. "Their governments are wrestling with the same issues of cost effectiveness and early access to medicines as we are," she says. "Many of them see the UK as setting a price benchmark that they can follow."

Ultimately, the UK and other European governments that run their own health services are all facing the same dilemma. Namely, they need to restrain the future medicines bill, while satisfying the expectations of their electorates and encouraging industry to innovate. It could be a reach too far.

Peter Mitchell *London*

IN brief

EC/FDA joint inspections

The European Commission (EC) and the US Food and Drug Administration (FDA) will collaborate to conduct inspections of pharmaceutical manufacturing sites globally. On June 17, the Transatlantic Economic Council, a bilateral body created to foster economic cooperation between the EU and US, laid out 15 projects designed to boost cooperation and 2 to attain more good manufacturing practices (GMP) inspection coverage while cutting the administrative burden. The action plan was drafted by the EC in collaboration with the European Medicines Agency (EMEA) and the FDA based on presentations made by industry during a workshop held in Brussels in late 2007. EU commissioner Matus Ferech says the pilot programs are intended to explore the feasibility of joint inspection teams investigating manufacturing sites in both the EU and US, and in third countries, for example, Asia. The pilot phase will also help advance procedural cooperation to come up with a common format for reporting inspected facilities for EU and the US. To widen GMP inspection coverage abroad and better identify manufacturing sites producing active pharmaceutical ingredients the action plan calls for sharing inspection schedules, results and information on inspected sites. "There is a genuine feeling that there are so many overseas facilities that it would be impossible to inspect them all," says Ferech. Transatlantic cooperation between the EMEA and FDA resulted, in June, in the joint validation of seven biomarkers for drug-induced renal toxicity. *–Barbara Nasto*

Supply size matters

Invitrogen and Applied Biosystems will merge to create a major biotech tool provider. Invitrogen is paying $6.7 billion in cash and stock to buy Foster City, California–based Applied Biosystems. The new company will retain the Applied Biosystems name but have its headquarters at the Invitrogen site in Carlsbad, California. The combined company will provide consumers with a range of biotech tools, estimating $3.5 billion in annual sales of reagents and systems for genetic analysis, cell biology and proteomics. William Quirk, senior analyst at Piper Jaffray, says the acquisition will bring together Applied Biosystems' systems business with Invitrogen's portfolio of consumables, allowing customers to benefit from economies of scale and a wider range of products and services. Market observers point to a trend for suppliers to grow in size to offer biotech customers the ease of a 'one-stop shop' rather than just reagents. Applied Biosystems makes instruments such as mass spectrometers and DNA sequencers whereas Invitrogen has 35,000 products and services including cell lines, culture media and fluorescent markers. The new company is expected to generate more than 70% of its revenue from consumables and own more than 3,600 patents and licenses. It will join other giant suppliers like Waltham, Massachusetts–based Thermo Fisher Scientific (which recently acquired RNA interference company Open Systems) and Sigma Aldrich. *–Susan Aldridge*