

THE PHARMACEUTICAL PRICE REGULATION SCHEME



A response by the American Pharmaceutical Group to the discussion paper on the Pharmaceutical Price Regulation Scheme issued by the Department of Health, September 2003.

31 October 2003

THE SUCCESS OF UK INDUSTRIAL POLICY

The record of the pharmaceutical sector over the last 50 years is one of the UK's rare industrial success stories, producing a world-class business. The renegotiation of the Pharmaceutical Price Regulation Scheme (PPRS) provides an opportunity for policymakers to work to enhance this position.

The industry's strength is very evident in Research and Development (R&D). The Department of Trade and Industry's 2003 R&D Scoreboard shows that the highest proportion of R&D in the UK (40%) is in pharmaceuticals and biotechnology. This is more than any other sector and means that the pharmaceutical industry is the UK leader in R&D.

This level of research in British laboratories has led to the discovery and development of nearly a quarter of the world's top one hundred medicines. More were discovered and developed in Britain than any other country with the exception of the US.

In addition to this, the pharmaceutical industry:

- has grown by 6.6% a year over the ten years to 2001
- produced a trade surplus of £2.8 billion in 2002
- employs around 70,000 people, many of them highly skilled
- generates another 250,000 jobs in related industries.

The APG member companies hold a major position in the British sector, accounting for 35% of the UK-based industry and employing over 15,000 people.

Against this background, it is understandable that a stated objective of the Pharmaceutical Price Regulation Scheme (PPRS) agreed by the Government is to:

“promote a strong and profitable pharmaceutical industry capable of such sustained research and development as should lead to the future availability of new and improved medicines.”

Any tightening of the regulatory approach would put these benefits at risk. Clearly it would be contradictory for the pharmaceutical industry, key to a successful industrial strategy, to be undermined through a more restrictive PPRS.

More innovation and productivity could be achieved by less regulation.

The pharmaceutical industry is one of the most important elements of UK manufacturing. This matters. The manufacturing industry as a whole creates a fifth of UK national output, employs four million people and produces the majority of the country's exports. As the Secretary for Trade and Industry rightly stated:

“The success of United Kingdom manufacturing is therefore crucial to our country's prosperity, now and in the future.” (The Government's Manufacturing Strategy, August 2002)

The Government's industrial strategy and the above PPRS objective can be run in tandem, with the one supporting the other.

THE CHALLENGE TO THE UK PHARMACEUTICAL INDUSTRY

Despite the relative success of UK industrial policy in the pharmaceutical sector, there is no room for complacency. The biggest rival to the UK is no longer found in the continent but across the Atlantic. The last decade has seen a significant shift in the pharmaceutical industry away from Europe and in favour of the US.

The US has overtaken Europe in a number of key areas:

- Europe was responsible for discovering 97 new molecular entities between 1988-92 but, by 1998-2002, this had fallen to 68. Over the same periods the US numbers rose from 52 to 77, overtaking Europe (source: July 2003 G10 Medicines Conference).
- Between 1990 and 2002 pharmaceutical spending in Europe on R&D rose from €7,941m to €19,800m; but over the same period spending in the US rose from the €5,342m to an enormous €27,890m, far above the level of Europe (source: *ibid*).
- Europe accounted for 37.8% of the world pharmaceutical market in 1990, falling to 25.4% in 2002. By contrast, the percentage for the US and Canada rose from 31.1% to 50.9% over these years (IMS World Review 2003 and IMS Consulting).

The G10 Medicines Group was set up in the European Union in 2001 to review the situation and has suggested proposals to help remedy the position.

Unfortunately, Europe's worsening position will not be helped by measures being taken by Germany, where a 16% pharmaceutical price cut set for January 2004 will further reduce its attractiveness as a place for pharmaceutical investment.

By contrast, there is an opportunity for the UK to respond positively, so the UK could become very clearly the leading pharmaceutical country in the EU. The choice is in its own hands.

The American Pharmaceutical Group (APG) endorses a co-operative approach by the Government which focuses on making markets work better.

SPECIFIC ISSUES

The setting up of the Pharmaceutical Industry Competitiveness Task Force by the Government, with the involvement of the industry, has been an excellent example of co-operation which has produced tangible benefits for the industry, government and patients.

However there are certain specific areas where further action is needed to create an improved environment. These are practical issues relevant to the implementation of the Government's industrial strategy, and against which the role of the PPRS should be considered. They include:

- **Low utilisation of new medicines:** The average utilisation of new medicines in the UK five years after launch is only 62% of the average in twelve other comparator countries, which disadvantages patients and puts longer-term burdens on the economy. This analysis coupled with recommendations is in a report commissioned by the American Pharmaceutical Group (“Headroom for Innovation in Primary Care”, OHE Consulting, September 2003).
- **NICE:** Further discouragement of the uptake of new, cost-effective effective medicines is caused by the patchy implementation of NICE guidance. This is particularly noticeable in certain cancer and mental health treatments, and the Government’s commitment to abolish postcode prescribing needs to be strengthened.
- **Taxes and the labour market:** The introduction of new taxes, particularly the increase in employer National Insurance levels; the higher costs of pension provision; and the extra bureaucratic restrictions imposed on industry are acting as disincentives for UK-based companies seeking new inward investment.
- **Support of R&D:** R&D is central to the future of the UK pharmaceutical industry. The Chancellor identified greater investment in science and technology as a key issue at the 2003 Labour Party Conference. The R&D allowances allowed in the PPRS should be strengthened to support this policy
- **Information to patients:** The Chancellor has also drawn attention to the lack of information for patients, pointing out that a patient may be: *“poorly informed of available treatment, reliant on others to understand the diagnosis, uncertain about the effectiveness of different medical interventions and thus is not sovereign”* (Speech to SMF, 3 February 2003). This lack of information limits the freedom of choice in healthcare to which the Government is rightly committed and to which the Health Secretary is personally committed. Provisions within the PPRS to allow greater educational information would match this direction of official policy.
- **Clinical trials:** A number of companies are concerned that the new EU Clinical Trials Directive to be implemented in 2004 will negatively affect European competitiveness in clinical research.
- **Parallel trade:** The rising tide of parallel trade affects some 20% of the UK-based prescription market, costing UK companies some £1.3 billion in UK sales in 2002 (IMS data 2003) with no compensating contribution to healthcare delivery by the parallel importing companies. This means that, in addition to suffering serious financial losses, some manufacturing plant is running below capacity.

DEREGULATION

General

Deregulation or progressive deregulation is an option in the PPRS Discussion Paper.

The link between deregulation and a competitive innovative environment is well documented. In its 1998 White Paper, *Our Competitive Future*, the Department of Trade and Industry acknowledged that regulatory intervention should focus on making markets work better rather than on direct market controls. Academic thinking supports this view. Less regulation implies more innovation and productivity growth.

The privatisation programme begun some twenty years ago heralded a sea change in the official approach to industry, and has been accompanied by greatly reduced controls over business. The benefits to customers, efficiency and the economic standing of the country are clear, therefore the programme has been continued.

The sole exception has been the pharmaceutical industry. The system of pharmaceutical industry financial controls, originally bought in during the 1950s, is based on the post-war era. In the modern world, financial restrictions and limitations should be replaced where possible by encouragement and reward.

In the biotechnology sector in particular, the limits defined within the PPRS could lead to the unintended consequence of dampening innovation and investment. Greater deregulation would allow for appropriate incentives to be put in place to encourage this increasingly important and high value sector of the pharmaceutical market.

What could deregulation look like?

Any renegotiation of the PPRS would provide a chance to explore opportunities for deregulation in the pharmaceutical market.

The 1999 PPRS was a step towards deregulation. The introduction of different target rates of returns (for profit assessment and for applications for price increases) has more closely mimicked market conditions, with good performance rewarded and less support for poor performance.

Regulation brings costs of its own and introduces market distortions. Supply-side regulations such as the PPRS distort decision-making on pricing and investment planning and limit the scope for competitive market forces to come to the fore. These effects extend beyond the domestic market and impact globally.

The number of demand-side controls (encouraging appropriate prescribing with due recognition of cost) has grown in recent years and this calls into question the need to continue to control the supply-side of the market (specifically pricing).

A lower level of supply-side regulation could help stimulate innovation and the domestic research-based infrastructure as evidenced by the location of industry R&D activity, the national origins of new chemical entities, the location of phase three trials, and early launch markets. The result would be cost benefits for the NHS and taxpayer by providing patients with early access to innovative medicines that reduce or eliminate the need for more costly invasive and in-patient treatment.

ABOUT THE AMERICAN PHARMACEUTICAL GROUP

The American Pharmaceutical Group (APG) was set up in 1985 to improve understanding of the industry, and the health care contribution of the American companies in particular, among Government, Parliament and interested stakeholders. The APG works closely with the industry's trade body, the Association of the British Pharmaceutical Industry, but with the US being the most competitive market for medicines in the world and accounting for over half of the developed world's R&D, the APG is able to add a special perspective.

The aims of the American Pharmaceutical Group are to:

- Ensure an overriding commitment to better patient care and information.
- Maintain a reputation and standing as a high quality, responsible and well-informed Group, making a constructive contribution to health care policy and debate.
- Provide information from, and direct access to, its parent companies.
- Advise how the UK can attract inward investment from the US, especially as APG members account for more inward investment than any other national pharmaceutical group.
- Take a lead role on policy issues affecting health care and pharmaceuticals, such as patient empowerment and competition.
- Input APG views to national organisations like the Association of the British Pharmaceutical Industry and the Ministerial Industry Strategy Group.

The Group is strongly committed to Corporate Social Responsibility through accountability, responsibility and the building of trust.

In its community activities, companies are involved in local works, support of charities and assistance for developing countries.

Details of the industry's work across the globe to fight disease and improve public health in the developing world rivals that of the World Health Organisation, and involves widespread collaboration with national governments, voluntary bodies and community-based organisation, improving access to medicines. Details are set out in "Global Partnerships" produced by the Pharmaceutical Research and Manufacturers of America in March 2003.