

**The Centre for
International
Public Health Policy**



**Briefing on the specification of pharmaceutical product
defects**

08 January 2009

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We have been asked to contribute to the search for an analysis that might help the Court to determine whether or not a pharmaceutical product is defective. The Court's decision depends on an assessment of the legitimate expectation of safety of persons under the Consumer Protection Act 1987. That provision was derived from a preceding EC Directive (85/37/EEC) which referred to "the lack of safety which the public at large is entitled to expect."

We argue that the public's expectation of safety can be assessed properly only with reference to the responsibilities allocated by the UK's regulatory regime for drugs products. These provisions in one way or another serve to define, explicitly or implicitly, the duties of pharmaceutical companies with respect to drug safety. We show that price regulation is the key mechanism by which successive governments have sought to internalise the costs and risks of defects to the industry and that for the last fifty years pharmaceutical suppliers to the NHS have been paid substantially above cost in order that drug safety, among other things, shall be improved.

The Pharmaceutical Price Regulation Scheme (PPRS)

In 1957, the Treasury, the Ministry of Health, and the industry agreed a voluntary price regulation scheme based on a price control formula developed by the Association of the British Pharmaceutical Industry (ABPI). In 1969 a profit control formula was substituted for direct price control. This arrangement continued until a little over a year ago when product price regulation was reintroduced as an interim measure. In June 2007 the PPRS was ruled by the High Court to be a contract (see below).

The PPRS has three objectives. These are to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices;
- 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;
- Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.¹

The PPRS allows companies to set the price of new medicines and requires them to seek Department of Health agreement for price increases. Companies with NHS sales of more than £25 million a year are required "to submit annual data on sales, costs, assets and profitability and to repay the excess where profits exceed the agreed return on capital threshold."²

The PPRS arose in response to concerns about industry profits first expressed in 1951 by a parliamentary committee.³ Attempts to control profits were strongly opposed by the industry. The industry body, the ABPI, argued, and the government ultimately accepted that the profits from proprietary medicines subsidized standard drugs, funded export marketing and supported R&D.⁴ The arguments for voluntary controls and high profit margins remain virtually unchanged today⁵ and have for many years provided the basic rationale for the PPRS. Indeed, by 2005 the Health

¹ Pharmaceutical Price Regulation Scheme (2006) *Report to Parliament*. London: Department of Health.

² *Ibid.*

³ Webster, C (1988) *The health services since the war. Vol.1, Problems of health care: the National Health Service before 1957*. London: HMSO, p224.

⁴ Webster, *op cit*, p225.

⁵ Office of Fair Trading (2007) *The Pharmaceutical Price Regulation Scheme*.

Committee would describe the PPRS as a key mechanism for Government sponsorship⁶ of the pharmaceutical industry:

By determining company profit margins allowed against the sale of medicines to the NHS, and by incorporating into these margins allowances for R&D, innovation, drug promotion and the provision of information, the PPRS provides a key mechanism by which the Department can act as the UK-based industry's sponsor.⁷

No major changes to the terms of the profits scheme are reported after 1969 other than adjustments to the profit control formula and reporting standards. Allowable rates of return have increased substantially since the scheme was first introduced and now stand at 28% of NHS sales (on a profit to sales ratio).

We have not been able to examine the evolution of PPRS objectives but there is evidence to suggest that they have changed little since the inception of the scheme in the 1950s. The industry asked for protection for R&D at least as early as 1956⁸ and the objective was firmly established by 1996, when the first parliamentary report was published. The objectives have certainly remained unchanged since 1999⁹ and the only change since 1994 involves the addition of the third export-related objective.

PPRS is periodically renegotiated. However, the 2005 scheme, which had been intended to run for five years, had to be renegotiated prematurely following criticism from the Office of Fair Trading¹⁰, conflicts with a new efficiency drive from the Treasury, and inconsistency with a June 2007 High Court judgment which ruled that the PPRS was a contract.¹¹ Special stop-gap arrangements were put in place during negotiations with the industry according to which price controls were agreed with firms on a product-by-product basis. Epilim and Orlept are both covered under these arrangements.¹²

London: OFT.

⁶ Sponsorship mechanisms have been augmented since the Health Committee's report with the creation of the UK Clinical Research Collaboration and the Department of Health's new R&D strategy, *Best research for best health*.

⁷ House of Commons Health Committee (2005) *The influence of the pharmaceutical industry*. London: The Stationery Office, p35.

⁸ Webster, *op cit*, p224.

⁹ Pharmaceutical Price Regulation Scheme, *op cit*.

¹⁰ OFT, *op cit*.

¹¹ 2008 memo. We have not sought further details of this case. The following account is taken from the internet: On the 21st June 2007, the High Court gave judgment on the legal effect and interpretation of the 1999 Pharmaceutical Price Regulation Scheme (PPRS), a voluntary scheme which like its successor (the 2005 PPRS) governs sales of branded medicines to the NHS. Ruling on an appeal by GlaxoSmithKline against a finding of the PPRS arbitration panel, Mr Justice Cooke held that the 1999 PPRS, and the arbitration provisions under it, took effect as a binding contract between the Department of Health and GlaxoSmithKline. In consequence, he found that (contrary to the Department of Health's submissions) the High Court did have jurisdiction, under the Arbitration Act 1996, to hear appeals from awards of the PPRS Panel.

http://www.brickcourt.co.uk/detailnews.asp?news_id=158

¹⁰The list referred to by the Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008.

<http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulation/scheme>

Estimating the value of the premium paid for improved safety

The scale of the subsidy paid to industry to improve drug safety is impossible to quantify because relevant data is not released to the public or, in some cases, to the responsible government agency.

Until the recent interim measures, the PPRS operated at the firm not the product level by regulating the profits that companies make on sales to the NHS. The formula involved placing a ceiling on the rate of return on capital employed. However, details of the profit agreements reached with individual firms are not released to the public.

There are also major concerns about the accuracy of data returned by the industry to the regulator. PPRS scheme members are required to submit annual financial returns (AFRs). In its 2006 report to parliament, the PPRS secretariat expressed concern about the quality of the returns: “there remain concerns about whether submitted AFRs meet the degree of transparency required by the scheme.” However, Department of Health staff do not have official powers to seize documents or compel the industry to answer questions about data. The data are not released by Department of Health for professional scrutiny.

Profits calculation, and therefore the true scale of the safety premium being paid, is in any event inherently imprecise because the industry has considerable latitude when accounting for profit. The lead author of the recent Office of Fair Trading inquiry into the PPRS identifies major practical difficulties for profit regulation arising from pharmaceutical companies’ increasingly global cost base. The global base allows ‘transfer pricing’ from affiliates abroad, which now covers about 70% of sales to the NHS. Higher prices on products transferred in count as cost increases not as higher profits. They therefore evade profits regulation.¹³

The PPRS is not the only subsidy system from which drug companies benefit. Tax credits are allowed in addition to the PPRS R&D incentive. Tax credits for pharmaceutical R&D are managed by specialist pharmaceutical units established by the tax authority. In 2006, total R&D tax credits were reported to be £1.5 billion.¹⁴ We have not examined the terms under which tax credits are granted.

PPRS and the Medicines and Healthcare Products Regulatory Agency (MHRA)

Whilst the government pays for improvements in drug safety through the PPRS, insufficient data on safety is released by the industry to the regulator.

The MHRA is the government agency responsible for ensuring the safety of medicines (in the post-marketing surveillance (Phase IV) stage through its Vigilance and Risk Management of Medicines division). Reports of adverse drug reactions (ADRs) are monitored and recorded after a licence has been issued and the medicine is on the market. Drug companies are required to report all suspected ADRs. The MHRA/CSM and others acknowledge considerable under-reporting of suspected ADRs by drug companies. Moreover, R&D prioritization remains a private industry responsibility. We have been unable to establish what links exist between the PPRS and the MRHA.

Conclusion

Responsibility for safety improvement is transferred to the pharmaceutical industry via a price regulation scheme that has run for more than fifty years.

¹³ Thornton S (2007) Drug price reform in the UK: debunking the myths. *Health Econ.* 16: 981–992.

¹⁴ HM Revenue and Customs, *Tax bulletin 85*. <http://www.hmrc.gov.uk/bulletins/tb85.htm>