Regulating the price of the UK's drugs: second thoughts after the government's first report

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Few industries in the UK are directly subject to profit regulation by central government. One such industry is the pharmaceutical industry supplying drugs to the NHS, which has had its profits regulated since 1969. Yet only in May 1996 did the government produce its first annual report on the regulatory scheme, and even then the report fails to cast much light on the scheme. In particular, there are seven major problems with the regulations and the way they are negotiated: they lack robust reasoning, a theoretical basis, an empirical basis, transparency, accountability, due process, and an analysis of their impact. Moreover, patients and health professionals are excluded from the bargaining process. All these problems could be resolved if the political will to debate them emerges.

Introduction

Since 1957 the UK government and the pharmaceutical industry have cooperated to control the rewards to drug manufacture.¹⁻⁵ Until 1969 the main focus was on drug prices: since 1969 it has been on profits on sales to the NHS. From April 1978 the system has misleadingly been called the pharmaceutical price regulation scheme.³⁻⁵ Yet for an agreement covering a major industry and its relationship with one of the key components of the welfare state, remarkably little is known about it.

The agreement represented by the pharmaceutical price regulation scheme is a voluntary one made in private between the Department of Health and the Association of the British Pharmaceutical Industry and covering all companies supplying drugs to the NHS.¹⁻⁵ New drugs, generic prescriptions, private prescriptions, and non-prescription medicines are exempt from the scheme.

The stated objectives of the current pharmaceutical price regulation agreement (set to run from 1993 to 1998) are:

- (1) To secure the provision of safe and effective medicines for the NHS at reasonable prices.
- (2) To promote a strong and profitable pharmaceutical industry in the United Kingdom capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines.
- (3) To encourage in the United Kingdom the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

One part of the scheme regulates the amount of profit—measured as rate of return on capital employed—that drug companies can keep on their sales to the NHS (the band is 17-21%). A second part regulates price rises, a third the amount of advertising expenditure that can be considered as a cost of supplying drugs to the NHS, and the fourth the amount of research and development expenditure the companies can set against sales to the NHS. Generally it is thought that about 20% of research and development expenditure is allowed as a cost of supplying to the NHS, although the current agreement gives no data to confirm this.

Though the scheme has existed in some form since 1969 and the current agreement started in 1993, we have had to wait until 1996 for the first report on the scheme. This report² came about as the government's response⁶ to the House of Commons select committee on health's recommendation that the price and profit regulations between government and the drugs industry should be made more transparent, "in particular by means of publishing an annual report on the pharmaceutical price regulation scheme."⁷ Though a welcome sign of more open government, there are seven major problems with the report² and with the regulatory system as a whole.

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A Whitehall fix? The regulatory agreement is made between the Department of Health (left, at 79 Whitehall) and the Association of the British Pharmaceutical Industry (right, at 12 Whitehall)

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What is wrong with the scheme?

No robust reason for the regulations
No theoretical basis
No empirical basis
No transparency
No accountability
No due process
No impact analysis

Why should prices and profits be regulated?

No robust reason is given for regulating profits in either the current agreement or the report. Under the section entitled “The need for regulation” the report claims, “It has been government policy since the inception of the NHS that patients should receive all the medicines for which they have a real medical need, and that doctors should have available to them the full range of medicines necessary to meet this requirement.” This does not sit easily with all the other various strands of government policies on delisting drugs from NHS reimbursement, switching drugs from prescription to non-prescription status, and the continuing rise in the NHS prescription charge. And it is not a robust reason for profit regulation.^{3 4 8-11}

The report also argues that the pharmaceutical price regulation scheme is legal, as if this was justification enough for continuing with the regulations. In fact the legality of the scheme has never actually been tested in a UK or European court.³⁻⁵ The report also says that governments in nearly every other country directly regulate the incentives and rewards in drugs markets. The fact that everyone else is regulating is not, however, a sound reason for regulating in the UK.⁸⁻¹¹

The report also justifies the regulations because many drugs are protected by patents, which “limit the scope for effective price competition.” Even if true—and no evidence was given—it is certainly not a robust reason for the existence of the UK’s profit regulations as any anticompetitive practice caused by patents can be dealt with by UK competition laws and European Union legislation.^{4 9 10}

Despite the importance of drugs to everyday life, there is no robust reason why the pharmaceutical price regulation scheme exists

No theoretical basis

The second problem is that the pharmaceutical price regulation scheme lacks a theoretical basis—for three main reasons. Firstly, neither the government nor the drugs industry has requested any such basis in their bargaining. Secondly, the existing theoretical models of regulating rates of return are not yet well developed to match the reality of the pharmaceutical price regulation scheme. Thirdly, the pharmaceutical price regulation scheme is one of the least studied regulations in the UK. This is surprising not just because of the importance of drugs to everyday life but also because the scheme has been in place for many years.^{1 3 5}

No empirical basis

The third problem is the lack of an empirical basis for the regulations—that is, the dataset on which the government and the drug companies strike their bargains is unknown to other parties, as are the data on which the profit allowances are calculated.

Data from Scrip’s *Pharmaceutical Company League Tables* show that in 1994, 47 drug companies worldwide had an operating profit to sales margin above 21% and 66 had a margin above 17%, with the highest margin being 99.7% profit on sales.¹² On average drug companies worldwide made an 11.3% margin; when the two companies that made over 90% return are excluded the average margin for drug companies worldwide was 9.5%. Alternatively, when the UK drug industry is compared with other UK industries there is also a wide difference between what other industries earn and what the drug companies are allowed to earn. Hence the question arises: what is the empirical basis on which the UK government allows a return on capital employed of 17-21%?^{1 7 10 12}

Lack of transparency

The fourth problem is the lack of transparency. From the recent report on the scheme we now know for the first time that three teams at the Department of Health’s pharmaceutical industry branch each deal with groups of drug companies.² However, it is still not clear what data, information, skills, experiences, negotiation qualities, and specific objectives the parties have when they are striking their bargains or how the bargains actually unfold or even where they are struck. Thus the main concerns lie in the lack of transparency of the data, the process, and the outcomes of each bargain.¹⁰

The lack of transparency makes it impossible to determine whether the agreements that are made concur with the regulatory system: anecdotal evidence suggests that the regulatory teams use discretion. Discretion may allow the government to bargain outside the agreement. Although the government denies that this happens in the pharmaceutical price regulation scheme, it presents no evidence to support its claim. The lack of transparency in the scheme also makes it impossible to assess the regulations from a welfare perspective. Furthermore, there is a law against opaqueness in price and profit regulation: the European Union’s transparency directive.¹³ The pharmaceutical price regulation scheme has not yet been

tested against the directive. A related legal point is that the report says that the UK government is “a sponsor” of the drugs industry (para 1.6). This raises a question as to the legality of government’s behaviour: public sponsorship of private enterprise is a serious matter for European Union law.^{4 10}

The lack of transparency in regulations also means that drug companies have no knowledge whether they are being treated equitably by the government. Some companies think they are not treated equitably. More generally the wider public is not clear about the efficacy or equity of the bargains being struck.

Lack of accountability

The fifth problem is the lack of accountability.^{1-5 9 10 14 15} The chain of accountability between the teams in the pharmaceutical industry branch of the Department of Health and the Secretary of State for Health (who is formally accountable to parliament and hence to the public) is long, the scheme is complicated, and effective accountability is lacking. For example, when Dr Brian MaWhinney was minister of health he told the House of Commons Select Committee on Health that “the PPRS is inordinately complicated and I make it clear to the committee that I would never take it as my question on *Mastermind*.” The wider government and the public have even less understanding of the scheme.

The pharmaceutical industry branch could be held to account—but in fact never has been—by the Department of Health and indeed the Treasury, the Department of Trade and Industry, the National Audit Office, and the House of Commons Public Accounts Committee for the deals it does with drug companies.

Lack of due process

The sixth problem is the lack of due process: the regulators explaining what they decided and why.¹⁰ Regulatory systems in other countries, such as the United States, insist on due process, as a part of transparency and fairness. The Department of Health does not have to provide full detail or full reasoning of any bargains struck to anyone outside the bargain. Drug companies can, it now seems, appeal to the head of the pharmaceutical industry branch for a review of a bargain struck and if still unhappy can seek a higher administrative review in the department, or even a judicial review. The government has produced no evidence of such reviews ever having taken place.

Furthermore, all the other stakeholders in health care (patients, health professionals, taxpayers) are devoid of the detail, decision, or reasons for the bargains struck. Acting on the 1994 government’s code of practice on access to government information will prove all but worthless for anyone investigating the pharmaceutical price regulation scheme and due process.

No impact analysis

The seventh problem is the lack of impact analysis.^{1-5 16} Given that the scheme does have explicit objectives, it should be possible to determine whether the regulation has met these objectives. There are problems—firstly, of identifying the relation between

The pharmaceutical industry is one of Britain’s most successful industries, but it might be even more successful without the price regulation scheme...

regulation and outcomes, and, secondly, of distinguishing the effects of the scheme from those of all the other policies and pressures affecting the healthcare environment.⁸ Nevertheless, it should not be impossible to establish the impact of the pharmaceutical price regulation scheme under close analysis.

The 1996 report claims that the UK has “reasonable” drug prices. Whether or not prices are reasonable remains a matter of unsettled debate going back the Sainsbury committee report of 1967¹⁶ (which incidentally argued against government controls of drug profits), the Guillebaud report of 1956,¹⁷ and the Cohen report of 1949.¹⁸ UK prices may in fact not owe much to the pharmaceutical price regulation scheme at all but be more influenced by other factors in the healthcare market such as other companies’ pricing decisions.^{2 3 19 20}

The report actually claims that there were savings of £89.8m in 1994 alone due to a 2.5% price reduction in drugs. This price cut, from September 1993 for three years, was not, however, part of the regulation scheme agreement at all. It is also not clear how the savings were calculated or to what use they were put.

Who wants transparency and debate?

These problems with the pharmaceutical price regulation system are important. But do either the drug companies or the government want any of the problems resolved? Some companies would rather not have any annual report at all, never mind a wider debate that would address the seven deficits I have identified. Others, however, want all these issues discussed in the next report and would also like “open meetings” between government and industry which anyone could attend. Still other companies want the whole scheme abolished: four major companies say they would rather see a variation on the Australian “value for money” regulations. Since January 1993 the Australian government has not paid for a drug unless it has proved itself to be good value for money.²¹

Does the government want to improve policy and debate? This is unclear, but the government’s hand

... And drugs might be better value

may be forced by developments in the European Union, in particular in the transparency directive.¹³ Having its hand forced could actually help the government: if it suddenly opened the process to outside scrutiny of its own accord this might damage its relationship with the drug companies: if the transparency directive forces it to open up the process then the government can always blame the European Union.

A further issue is what other stakeholders want. Healthcare professionals and taxpayers are in effect disenfranchised from the bargains of the pharmaceutical price regulation scheme. One way to determine what these stakeholders want is to ask them, but this seems never to have been done.³⁻⁵

Although the drugs industry is one of the most successful industries in the UK—for example, recording the highest trade surplus of all industries in 1995—we do not know how much of this is due to government regulation and sponsorship (legal or not). Indeed, the UK drugs industry might possibly have been even more successful if the pharmaceutical price regulation scheme had not existed. Similarly, UK patients, doctors,

and healthcare financiers might have been better off without the scheme.

There is an increasing need to open up the debate about the merits and legality of the UK pharmaceutical regulations. In this paper I have identified crucial messages and points for debate for government and the drug companies to think about. Other stakeholders need to become involved in the debate; indeed, the European Commission and some union lawyers are contemplating a legal scrutiny of the pharmaceutical price regulation scheme.

Thus although the first annual report on the pharmaceutical price regulation scheme is a welcome development, there is substantial room for improvement in the next report and indeed in the pharmaceutical price regulation scheme itself. But the starting points in any regulatory debate should be to consider the following questions:

Why regulate?

Who should regulate?

What should be regulated?

What tools should be used?

What are the costs, outcomes, and effects?

Will central government regulations aggravate, stimulate, or ignore local freedoms, preferences, and efficiencies of healthcare professionals?^{23-5 8-11 21}

Key points

- To a degree profits are a stimulus for companies to produce new and better products
- Drug profits on sales to the NHS have been regulated by central government since 1969
- In May 1996 the government produced its first annual report on the profit regulations
- Most patients and healthcare professionals are disenfranchised from the regulatory bargains
- There are additional problems with the regulations and report: a lack of robust reasoning for the regulations; a lack of theoretical basis; a lack of empirical basis; a lack of transparency; a lack of accountability; a lack of due process and a lack of impact analysis
- These problems can be resolved but only if the political will exists

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