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THE FACES OF REGULATION

PROFIT AND PRICE REGULATION OF THE UK PHARMACEUTICAL INDUSTRY AFTER THE 1998 COMPETITION ACT

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Contents

This Briefing discusses, inter alia, the role of the Office of Fair Trading (OFT) in competition cases affecting the pharmaceutical industry. It does so in the context of a discussion of "ex ante" versus "ex post" approaches to regulation. This refers to the balance of reliance in a market on competition, sector specific regulation, and general competition law to deliver efficient outcomes. It was written prior to the OFT decision announced 30 September 2005 to carry out a market study of the Pharmaceutical Price Regulation Scheme (PPRS) as part of its review of government procurement arrangements in key sectors of the economy. The OFT market study can be thought of as looking at the effectiveness of one element of regulation – the ex ante sector specific regulation undertaken by the Government – rather than at the balance of regulation between the Department of Health as buyer and of the OFT in its role as the agent of general competition law. The paper does not address the OFT market study of the PPRS. As with all OHE publications it was peer reviewed by its Editorial Board and by other experts in the field and is intended to be a contribution to research and to public policy making. It does not represent the views of the OHE or of its funding body the ABPI.

1 INTRODUCTION

The introduction of the 1998 Competition Act ('the 1998 Act') has made a significant impact on UK markets in all sectors of the economy. The 1998 Act is the most important recent piece of competition law in the UK, and is intended to bring UK's competition policy much more in line with European law.

The 1998 Act sets general standards of behaviour and allows for the first time in the UK the possibility of imposing financial penalties for anti-competitive practices. The 1998 Act in particular, and competition law in general, illustrate one face of regulation, namely ex post methods of regulation. Under ex post regulation any corrective action takes place after an anti-competitive event has happened. There are no strict rules set in advance and it is up to individuals and/or companies to complain about potentially anti-competitive practices. Once a complaint is initiated, it is then up to the relevant competition authorities (the Office of Fair Trading (OFT) in the UK) to decide whether or not the practices under investigation are indeed anti-competitive and, if so, whether or not a financial penalty needs to be imposed.

At the other end of the spectrum we have ex ante regulation, which sets strict rules of behaviour up front. The classic example of ex ante regulation is direct price control, i.e. the price a company charges for its product may not exceed a certain amount. Ex ante methods of regulation are usually sector specific, applying only to those companies that operate in a particular market.

All markets are regulated by some form of competition law i.e. by ex post measures. In addition, there are some sectors that face ex ante methods of regulation specific to their industry. In the UK ex ante regulation has been applied to the previously publicly-owned utilities (telecoms, electricity and gas supply, water companies and airports) and to the pharmaceutical market. The exact form of competition law is the same for the entire economy in any one country but can vary across countries. Sectoral regulation can vary between sectors within a country as well as between countries. In the UK we can observe a divergence between how utilities and pharmaceutical markets have been or are being regulated.

In the UK the ex ante elements of regulation are being eliminated in some utilities and reliance placed on competition law alone. This is partly due to the 1998 Act and partly to the development of greater competition in these markets. The introduction of the 1998 Act is a key milestone in the process of deregulating these markets[1].

The trends we are observing in the methods of economic regulation in the pharmaceutical industry are different from those in the utilities. All around the world, with the exception of the US, the economic regulation enforced in pharmaceutical markets is basically ex ante – measures include direct and indirect price controls and profit controls. This may partly be explained by the fact that pharmaceuticals are usually regulated in the context of a procurement arrangement. Governments are buying medicines or have political responsibility for those who are.

In the UK the large majority of the prescribed medicines market (about 80% by value) is regulated by the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS, being a profit control, is usually seen as a unique method of regulating pharmaceutical markets, given that more direct forms of price control are the norm in most other developed countries.

There is reluctance to base pharmaceutical regulatory mechanisms in the UK (and indeed in other countries with the exception of the US) on ex post principles, even though the 1998 Act represents a major strengthening of general competition policy. Two cases involving pharmaceutical companies, who were subject to the PPRS and were satisfying the terms of that Scheme, have been brought to date (i.e. by September 2005) under the 1998 Act. In the light of them, this Briefing explores the implications of the introduction of the 1998 Competition Act for the economic regulation of the UK pharmaceutical industry.

The Briefing is organised as follows. Section 2 reviews the principles of economic regulation while Section 3 describes the main characteristics of the 1998 Act. Section 4 explains the PPRS. Section 5 discusses in some detail the two pharmaceutical cases brought so far under the 1998 Act, focusing on the implications of these two cases for the UK pharmaceutical market. The last section, Section 6, offers some concluding observations.

2 ECONOMICS OF REGULATION

This section gives a brief introduction to the topic of regulation, discussing the general principles of why and when there is a need for it, and the range of approaches to economic regulation that are available. Section 2.3 explains how the pharmaceutical market in particular is regulated in terms of prices and profits.

2.1 Why regulate

A general presumption is that markets should be left to operate freely unless there are particular reasons to regulate. In other words, regulation is only justified if unregulated markets would otherwise fail to produce the most socially desirable outcome – i.e. a market failure exists – and regulation can improve the outcome. The most common market failures come under the headings of public goods, externalities, informational asymmetries, market power and natural monopolies (where natural monopolies are an extreme case of market power).

A need to address social inequities could be another reason not to rely on unfettered markets. Governments often intervene in markets to ensure that all citizens have access to the product or service in question. Furthermore, regulation is sometimes in place not only to ensure universal coverage for a particular good or service, but also to make it affordable to all consumers. In some of these cases

[1] Throughout this Briefing we use the term 'deregulation' to mean the elimination of ex ante methods of regulation and reliance solely on competition law, rather than elimination of all forms of economic regulation altogether.

Governments become buyers on behalf of the public and regulation becomes part of public procurement arrangements.

The outcome under an unregulated market with "perfect information" available to all participants and "perfect competition" between providers of goods and services is referred to as the best or efficient solution[2]. Perfect information is when everything is known, or rather, when the agents know the details affecting their current choices, and all agents involved in the process have this same information. Perfect competition results when there are large numbers of sellers and buyers, with no agent having market power to affect the outcome. Both firms and consumers are then 'price-takers'; i.e. they observe the market price, they decide what to do, but their unilateral decision does not affect this market price. The outcome under this situation equates the price that the consumer is willing to pay for an extra unit of that good or service (which equals the consumer's marginal utility gained from that extra unit) with the cost of producing this extra unit (its marginal cost).

This outcome has both allocative and productive efficiency properties. Allocative efficiency implies getting the right mix of goods and services in the economy as a whole. Productive efficiency means producing a certain quantity of the good or service at the lowest possible cost. Hence, if a market is competitive enough, and agents have enough information, it should be both allocatively and productively efficient and the starting presumption (other things being equal) would be that no regulation is then required.

We use perfect competition as a benchmark to illustrate the 'textbook' approach to regulation, although no markets in real life are perfectly competitive and some markets do not even get close to meeting the requirements of perfect competition. In that case, the unregulated outcome just described is either unachievable or would not be optimal from society's perspective. Hence there would be a rationale to regulate the market. In practice, and as discussed below, all markets are regulated to some degree, although the exact extent and method of regulation varies.

So far in this section, we have described a "public interest" approach to regulation, as developed in standard economics textbooks. However, there are alternative 'economics' views regarding regulation. For instance, regulation may in some cases be seen as a means of stopping markets from working, as in the 'capture theory' introduced by George Stigler (Stigler, 1971). Under this theory, governments regulate at the behest of producers who "capture" the regulatory agency and use regulation to prevent competition – for example, there may be unnecessary restrictions on new entry.

In addition, the aim of some forms of economic regulation can be to create the 'rules of the game' allowing competition to develop, rather than to correct specific market failures. This alternative view is particularly relevant for the sectoral regulation used in previously publicly-owned utilities. In a way, these 'rules of the game' are the by-laws for particular sectors that supplement general competition law. This does not make the traditional economic analysis of market failure redundant – the rules of the game are influenced by the same factors (externalities, information conditions, market power, and so on) – but it changes the emphasis.

2.2 Methods of regulation

There is a wide spectrum of possible regulatory tools available. "Ex ante" approaches are at one end: regulation that defines strict rules of behaviour in detail and in advance. Price control is one example of ex ante regulation, others include rules governing the quality of service to be provided, or the level and type of investment to be undertaken. By contrast, the "ex post" approach to regulation does not set specific rules in advance; rather it sets general standards of behaviour, such as 'not to abuse a dominant position' or 'avoid any agreement that prevents, restricts or distorts competition'.

All markets are subject to some form of ex post economic regulation, in the form of general competition law. In addition, some specific industries such as network utilities – telecoms, gas, electricity and water – and pharmaceuticals are, or have been, subject to more stringent, ex ante, regulation.

Ex ante regulation requires regulators to be forward looking and anticipate market outcomes, encouraging socially desirable outcomes and blocking undesirable ones. With ex post regulation, the authorities take a backward looking approach. It is only when a company has been accused of misconduct that these authorities are called into play. Or when the authority itself has reason to be concerned. The analysis is case by case. Hence, ex post regulation can also be referred to as a harm-based or an effects-based approach, since intervention will only occur if appreciable harm appears to have been done or is thought likely to arise as a result of the actions of one or more

[2] In economic jargon it is called the 'first best' solution.

companies[3]. In between these two end points lies a variety of different policy mixes.

Ex ante regulation is usually applied to markets where the initial degree of competition or consumer knowledge is not expected to be strong enough to enable normal market processes to protect consumers' interests. Here the presumption is that there would be many anticompetitive cases should the market be left unregulated. Ex ante regulation is then used to try and prevent this happening.

Ex post regulation is used in markets where competition is thought to be well established with reasonably well informed buyers and hence consumers are well protected most of the time. The expectation in these markets is that cases requiring intervention will be few. As a result the costs to consumers arising in such cases will be low as compared to gains in efficiency benefits from light regulation. (As we discuss, regulation imposes costs by distorting normal market processes as well as bringing benefits.)

Hence some privatised industries in the UK were first regulated using an ex ante approach and then, after some time as markets became more competitive, ex ante regulators looked to switch to ex post regulation. For example, in the case of Oftel (then the UK telecommunications industry regulator):

> *"…Oftel will therefore regulate [the telecoms market] only where competition is not yet effective or where competition alone does not sufficiently protect consumers' interests…" (Oftel, 2000).*

In a 2001 Consultation Document the Director General of Oftel argued that:

> *"…the overall picture at this stage is one in which competition is increasing and this is shown by prices increasingly moving towards costs, and consumers' views and behaviour. However, it is Oftel's view that competition may not be fully effective at present (and) retail price controls on BT should be extended for the period 1 August 2001 to 31 July 2002" (Oftel, 2001).*

This implies that the lower the degree of competition in a market, the greater the need for reliance on additional regulatory mechanisms, i.e. both ex ante and ex post regulation. With a low degree of competition, the positive effects of ex ante regulation (that arise by avoiding in the first instance anticompetitive practices that could potentially take place if no controls were in place) would outweigh any negative distortions (efficiency losses and disincentives created by the ex ante rules that could, for instance, discourage potentially valuable investments) arising from this form of regulation.

Thus, ex ante and ex post regulation are characterised by two major differences: how the rules of the game are defined (detailed specification of actions versus general standards of behaviour, respectively); and the (presupposed) extent of competition in the market in question (less versus more, respectively)[4].

Ex ante regulation is sector specific while ex post is more general. In the ex ante approach the parameters of the regulatory scheme are defined for each particular industry or sector. Ex post regulation relies on defining the broad guidelines of conduct for all industries. Then, should the regulator intervene, these general guidelines are applied to the particular relevant market.

2.3 Pharmaceutical economic regulation in practice

The focus of this Briefing is on the economic regulation of medicines' markets. By this is meant economic regulation dealing with the final product market, for example the extent to which prices are capped. Regulation that relates to granting authorisation to sell a medicine (i.e. product approval regulation) is outside the scope of this Briefing.

Economic regulation in the pharmaceutical market can be generally classified as ex ante. Rules are strictly defined and firms usually have few degrees of freedom. Probably the only exception to this is the US. In Europe, with the exception of the UK and Germany, individual prices are directly regulated.

And there are indirect price controls in the UK and Germany – profit regulation and reference prices respectively.

[3] The European Commission, as well as the OFT, usually uses market shares as a first step to decide whether or not any agreement can have an appreciable effect on competition. For instance, when the combined market share of the undertakings involved in the agreement is not higher than 10% of the relevant market, where the agreement is made between competing undertakings, then the agreement will be deemed not to have an appreciable effect. However, where the parties' combined market share exceeds these thresholds, regulatory authorities may still find that the effect on competition is not appreciable, as other factors will also be considered in determining whether the agreement has an appreciable effect.

[4] Directive 2002/21/EC of the European Parliament and of the Council, which reviews the regulation of the telecommunications sector in the EU with the objective of creating a common regulatory framework for electronic communications networks and services, makes clear that ex ante regulation should only be imposed where there is not effective competition. As discussed in more detail in Stumpf et al. (2003), there are generally three criteria considered that influence whether markets are susceptible to ex ante regulation: first, whether a market is subject to high and non-transitory entry barriers; second, whether a market has characteristics such that it will tend over time towards effective competition without the need for ex ante regulatory intervention; and third, whether competition law is sufficient by itself (without ex ante regulation) to redress the market failure.

Regulatory interventions in the pharmaceutical market can be directed at either the suppliers of medicines (manufacturers, wholesalers, retailers) or those who demand them (doctors, other prescribers and patients). The regulation is undertaken by or on behalf of third party payers – governments or insurers – and so is part of the payers' procurement arrangements. These regulatory interventions fall into four general categories:

1. price controls;
2. volume controls;
3. expenditure controls;
4. controls affecting licensed medicines' access to the market or reimbursement by third party payers – governments or insurers – such as economic evaluations.

Figure 1 provides a framework of economic regulatory interventions and incentive schemes faced by the different agents involved in the market for prescription medicines. The figure illustrates two key issues related to the pharmaceutical market. First, there are different agents involved who all face different incentives: prescribers, patients and firms, as well as the third party payers – governments and insurers – who are seeking to regulate the market as buyers. Second, there are numerous controls available. As a consequence, in most countries reliance is usually not placed on a single regulatory tool but on a package of measures.

Before going into the details of Figure 1, notice that some mechanisms are included in more than one category of intervention. This is because some of these measures can help payers achieve the various objectives of controlling prices, volumes and overall expenditure at the same time.

The first set of columns, under the heading 'price controls', include measures aiming to control the unit prices of pharmaceuticals. There is an important difference between the actual price of the medicine and its reimbursed price. The reimbursed price is that paid for a medicine by a third party payer; the actual price is the total price of the medicine, part of which may be paid by the patient.

Generally speaking, controls that aim to constrain the actual price level can do so either directly or indirectly. They range from setting individual prices based on the cost of each product to free pricing combined with a restriction on the rate of return earned by firms or with limits to the price reimbursed by the payer. Indirect controls allow companies to set actual prices freely, at least in theory. In practice, however, companies face other measures that impose restrictions on what prices to set. Such measures include those with the aim of controlling reimbursed prices. This is why reference prices, international reference pricing and copayments appear in Figure 1 both under the column headed 'reimbursement' and also under the heading 'indirect price controls'. Rate of return regulation allows some pricing freedom for companies, under an overall cap on the rate of profit earned, and although it does not control prices directly, it can restrain them as prices drive profits. Thus, the regulator, by controlling companies' profitability, might control the overall public expenditure on medicines, without worrying too much about individual medicines' prices. This is why rate of return regulation appears under the two headings.

The second group of columns in Figure 1 shows the measures that exist to control the availability of products in the market. These aim to control the volume sold by pharmaceutical firms of any particular product or basket of products, or to control the number of medicines available at any time in a country. Such mechanisms include:

- volume controls and economic evaluations, in combination with a cost-effectiveness threshold, that aim to ensure that medicines available and financed by third party payers are limited to those considered by those payers to be cost effective;
- formularies, positive lists and negative lists, which aim to influence the prescribing behaviour of physicians and the number of medicines that third party payers will reimburse. Positive lists specify those medicines that a third party payer will reimburse, while negative lists specify those they will not;
- measures affecting prescribers' and dispensers' behaviour. These measures include encouraging generic prescribing and facilitating substitution by dispensers of generic medicines for more expensive branded products.

Expenditure controls, shown in the third group of columns in Figure 1, aim to control overall spending rather than either prices or quantities specifically. Expenditure controls target firms, prescribers and/or patients.

While Figure 1 illustrates the general framework of pharmaceutical economic regulation, Figure 2 shows how major markets around the world are

regulated in practice. It highlights that in any one country there will be a whole package of measures in place, and that the make-up of the package varies from country to country.

We have noted that regulation is undertaken by or on behalf of third party payers – governments or insurers – and so is part of the payers' procurement arrangements. Public procurement and / or provision is a major factor in many health systems (which includes the market for pharmaceuticals). This is especially so in Europe, although it is also important in the US. This implies that public money is at stake, so the public sector cannot help but have an interest, not only in prices of the inputs needed to deliver health care (and medicines are an input in this process), but also in overall expenditure. Hence, we can presuppose that even in a competitive market without price controls, and even if there were no 'market failures', public bodies would be negotiating with pharmaceutical companies over prices and maybe over volumes too.

Figure 1 Market interventions and incentives aiming to affect price, quantity and overall expenditure in the market for prescription medicines

Price Controls			**Product Controls**			**Expenditure Controls**		
Price		*Reimbursement*	*Firm's volume*	*Products allowed onto market and / or reimbursed*	*Prescribers / dispensers*	*Firms*	*Prescribers*	*Patients*
Direct	Indirect							
Price controls	Reference prices	Reference prices	Marketing spend limits	Positive / negative lists	Generic substitution	Revenue controls	Physician drug budgets	Patient budgets
Price cuts / freezes	International reference pricing	International reference pricing	Product volume caps	Formularies	Generic prescribing	Price-volume agreements	Physician health care budgets	Copayments
	Copayments	Copayments		Economic evaluations		Rate of return regulation		Reference prices
	Rate of return regulation	Single EU price plus rebates						
	Economic evaluations							
Hold down unit prices			Limit prescribing, and / or steer prescribing towards more cost-effective drugs			Control overall spending, with some freedom in system		

Figure 2 Summary of controls in the pharmaceutical industry, eight largest markets countries (as of December 2004)

	Price Controls					Product Controls					Expenditure Controls				
	Price / Reimbursement					*Products allowed onto market and / or reimbursed*				*Prescribers / dispensers*	*Firms*		*Prescribers*		*Patients*
	Direct		Indirect			+ list	- list	Formularies	Economic evaluation	Generic substitution at pharmacy	Revenue controls	Price-volume agreements	Drug budgets	Health care budgets	Copays (F/P)
	PC	PF	RP	IRP	RoR										
Canada	✓		2	✓				✓*				✓			F/P
France	✓	✓	1	✓		✓				✓		✓			P
Germany		✓	1-3				✓			✓			✓		F/P
Italy	✓	✓	2	✓		✓	✓		✓	✓	✓				F/P
Japan	✓			✓		✓						✓			P
Spain	✓	✓	1	✓	✓	✓	✓			✓	✓				P
UK		✓			✓		✓		✓					✓	F
US								✓*	✓**	✓					F

Key:

PC: direct price controls; PF: price freezes / price cuts; RP: reference prices; IRP: international reference prices; RoR: rate of return regulation; + list: positive list; - list: negative list.

Reference price groups: Group 1: chemically equivalent medicines; Group 2: pharmacologically / therapeutically equivalent; Group 3: compounds with comparable therapeutic effects, especially combinations (for a more detailed discussion on reference pricing, see Mestre-Ferrandiz, 2003).

Copayments: F: fixed copayment unrelated to price of medicine; P: percentage of medicine's price.

* Formularies (for different regions in Canada and for private insurers in the US respectively).

** Applies to the private market.

3 THE 1998 COMPETITION ACT

The ex post regulatory tool currently in use in the UK is the 1998 Competition Act, which came into force on 1 March 2000. The 1998 Act sets general standards of behaviour for undertakings in all industries that operate in the UK. Its main objective is to ensure that markets are competitive. The 1998 Act brings UK competition policy more into line with EU legislation[5], being based on Articles 81 and 82 of the EU Treaty (which govern trade between Member States, but not within them).

There are two main prohibitions under the 1998 Act:

- Chapter 1 prohibits agreements between undertakings that have the object or effect of preventing, restricting or distorting competition in the UK. For it to be considered an infringement, an agreement needs to have an appreciable effect. The wording is identical to that of Article 81(1) of the EU Treaty;

- Chapter 2 prohibits abuse of a dominant position in a market in the UK. Chapter 2 prohibitions involve a two-stage test. The first step requires assessing whether or not an undertaking has a dominant position in the relevant market. If this is so, the second step analyses whether or not the firm is abusing that dominant position. Holding a dominant position is not in itself deemed to be an anti-competitive practice. The OFT has suggested that an undertaking with a market share of less than 25% will not normally be considered dominant; where as one with a market share of over 40% may well be dominant (OFT, 1999). However, these figures must not be treated as conclusive and there might be Chapter 1 and 2 prohibitions at lower market shares than those stated.

Financial penalties of up to 10% of up to three years of the firm's cumulative UK turnover may be imposed. (EU practice involves a penalty cap of up to 10% of worldwide turnover.) Moreover, for the first time in the UK, third parties that may have suffered losses as a result of the illegal action have, under the 1998 Act, the basis for a claim for damages in the courts.

The introduction of the 1998 Act is an event of major importance. It is the first time in UK competition law that a harm-based approach has been underpinned by substantial financial penalties. The 1998 Act gives the OFT considerable new powers to tackle anti-competitive behaviour. Moreover, the financial penalties are much heavier than was possible before the 1998 Act (Parker, 2000). Taken together, the new measures should deal with many of the weaknesses identified in previous UK policy: weak penalties and investigative powers; inability of third parties to sue; and the lack of power for early intervention to prevent potential harm to competitors or customers (Utton, 2000).

The 2002 Enterprise Act reinforces the importance of the 1998 Act. The main provisions of the 2002 Act relevant to this Briefing include the possibility of criminal sanctions for individuals who engage in cartelistic agreements, and giving the OFT a new power to apply for the court to disqualify directors involved in breaches of competition law. In addition, the Enterprise Act allows the OFT to conduct market studies, in order to identify whether perceived problems in particular markets should be addressed through the OFT's other functions[6] . The Enterprise Act makes a number of significant reforms to competition law and consumer law enforcement in the UK. The new provisions will work alongside the 1998 Act.

The 1998 Act aims to bring the UK's competition law closer to EU law, while allowing businesses the same degrees of freedom to compete and innovate as before, at least in principle. Moreover, one of the objectives of the 1998 Act is to increase the certainty for businesses as to what conduct is or is not permitted, and as to what could be deemed anti-competitive. The 1998 Act, however, only sets standards of behaviour. It is up to the OFT to apply the Act consistently so that firms have enough information as to how to interpret the OFT's decisions, and so understand what actions are likely to be regarded as being inside or outside of these standards of behaviour.

Hence, it could be argued that the best-case scenario after the introduction of the 1998 Act would be that businesses' degrees of freedom have not been reduced but the degree of uncertainty about what is allowed has been reduced. The introduction of the 1998 Act does not imply that regulation in the market place in general has become more lenient; in fact, it has become tougher, especially because of the possibility of financial and criminal penalties should the OFT consider any business practice to be in breach of Chapter 1 or 2 prohibitions.

[5] Some important distinctions still remain, particularly relating to structural issues. For more on this, see Parker (2000).

[6] In September 2005, the OFT launched a market study into the Pharmaceutical Price Regulation Scheme (PPRS). At the time of finalising this Briefing, no results have yet been published and we do not discuss this study further.

Although outside the scope of this Briefing, it is important to mention that the recent modernisation of the European competition regime is going to put a lot more cases in the hands of national courts. This 'decentralisation' of competition law increases the role of national competition authorities, including that of the OFT in the UK.

4 ECONOMIC REGULATION IN THE UK PHARMACEUTICAL MARKET

The UK pharmaceutical industry is subject to the Pharmaceutical Price Regulation Scheme (PPRS) for sales of branded medicines to the National Health Service (NHS). The current PPRS covers the period from 1 January 2005 to 31 December 2009. It is a voluntary agreement between the Department of Health (Department of Health), acting on behalf of the health departments of all four UK countries (England, Northern Ireland, Scotland and Wales), and the Association of the British Pharmaceutical Industry (ABPI) acting on behalf of all companies who sell branded medicines to the NHS, whether members of the ABPI or not. Any company that elects not to be part of the PPRS agreement, or breaches its terms, will be subject to statutory price control under the Health Act 1999[7].

Unbranded generic medicines are regulated separately from branded medicines in the UK. Since June 2005, Schemes M and W for manufacturers and wholesalers of generic medicines respectively have replaced the Maximum Price Scheme that was introduced in August 2000. Prior to the 2000 Maximum Price Scheme, prices for unbranded generic medicines were unregulated. As described in more detail below, there is aggressive purchasing of unbranded generics, in part because of the Discount Clawback mechanism which effectively imposed a form of yardstick competition on dispensing pharmacists.

4.1 The branded sector

The PPRS indirectly controls the prices which companies may charge to the NHS by regulating the profits earned from the total of a company's NHS sales of branded medicines. These medicines account for roughly 80% by value of total pharmaceutical sales to the NHS. Companies are free to set launch prices for new products, within the overall limits that are allowed on the rate of return they may earn from the totality of their branded sales to the NHS. After launch, approval for any price increase must be obtained from the Department of Health. For a price rise to be granted the overall profitability of the company must be below a certain threshold. Or the price rise must be linked to price reductions on other products supplied by the company as part of a "modulation" package which is cost neutral for the NHS. The PPRS can be classified as an ex ante method of regulation, both because it sets clear rules up-front and because it is sector specific.

In addition to the overall regulatory framework established by the PPRS, the UK government has imposed price cuts at the commencement of each of the last three PPRS agreements (in 1993, 1999 and 2005 respectively). The introduction of the latest PPRS, on 1 January 2005, imposed a 7% price cut on branded medicine sales to the NHS[8].

Box 1 summarises the elements of the 2005 PPRS. Unbranded generic products are not included. Prices of medicines sold other than to the NHS, e.g. to fill private prescriptions, are not regulated.

[7] Sections 33 to 38 of the Health Act 1999 empower the Secretary of State to: prohibit any manufacturer or supplier from increasing prices without the Secretary of State's approval; limit the price charged for medicines by any manufacturer or supplier; and limit prices or profits of manufacturers or suppliers of health service medicines. Additionally, Sections 33 to 38 also require manufacturers to pay a sum representing the amount of any excess if they do not comply.

[8] The nominal cuts have been increasing, but this may in part reflect the fall in inflation. To achieve a given real cut in prices requires a larger nominal cut in price.

Box 1
The 2005 PPRS

Objectives

1. Secure the provision of safe and effective medicines for the NHS at reasonable prices
2. Promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines
3. Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries

Term

1 January 2005 - 31 December 2009, unless terminated by either party; subject to mid-term review

Entry

Voluntary; non-members subject to Department of Health statutory powers

Scope

All branded licensed NHS medicines, except 'standard' branded generics, which will be subject to a public consultation on future pricing and reimbursement arrangements

Price Reduction

7% by 1 January 2005 (for companies with branded sales to the NHS of over £1m in 2004); modulation allowed (i.e. different price cuts permitted for different individual medicines, as long as the overall effect is equivalent to a 7% across-the-board cut in the prices of all of a firm's branded medicines sold to the NHS)

Return on Capital (ROC) / Return on Sales (ROS) Target

ROC target of 21%; ROS target of 6%

Margin of Tolerance (MOT)

Upper and Lower MOT at +40% and –60% of ROC target, i.e. if a firm's ROC for branded medicine sales to the NHS is in the range 8.4% to 29.4% then no price increases will be allowed nor price cuts imposed, respectively

R&D Allowance

20% (15%) of total NHS sales for assessing profits (for assessing price increases) plus further 0.25% allowances for each in-patent molecule with NHS sales of £300,000 or more, up to a maximum of 20 such molecules
1% of NHS home sales for each product with a marketing authorisation that includes a paediatric indication, up to three products a year

Marketing Allowance

For assessing profits (for price increases): Fixed element of £1m (£0.5m), plus 4% (2%) of NHS sales, plus an additional product servicing allowance for each molecule

Information Allowance

4% (2%) of home sales for assessing profits (price increases)

Annual Financial Return (AFR) Submission

Companies with NHS sales above £25m must submit an AFR to the Department of Health
Companies with NHS sales of £5m to £25m must submit audited accounts
Companies with NHS sales of less than £5m exempt from supplying financial information, unless requested by Department of Health

Source: Department of Health (2004c).

4.2 The generic sector

The off-patent NHS medicines sector is important for this discussion not only due to its market share (55% by volume of all NHS prescriptions dispensed in England outside hospitals[9]), but also because of the regulatory changes introduced in this market over the period 2000-2005.

The prices of unbranded generic medicines sold to the NHS are not regulated under the PPRS. In June 2005, the Department of Health announced the details of the new long-term arrangement for reimbursement of NHS generic medicines: Schemes M and W for manufacturers and wholesalers of generic medicines respectively. This arrangement replaced the Maximum Price Scheme introduced in August 2000, which is described later in this section, and applies to all generic licensed NHS medicines dispensed in the community in England that previously qualified to fall within category A of the Drug Tariff (see below).

In summary, under the new arrangement, which is voluntary, there are two schemes, one for manufacturers of generic medicines and one for wholesalers. One of the most important characteristics of the new scheme is that manufacturers and wholesalers are required to submit quarterly data to the Department of Health on, among other things, net sales values and net acquisition costs, on a product by product basis. One important change with respect to the previous system is that the information provided to the Department of Health on price levels now includes all discounts and rebates that are allocated to specific products. Previously, the information submitted only included prices before discount. The purpose of providing data on a quarterly basis is to enable the Department of Health to monitor regularly any changes in market characteristics[10].

The reimbursed price (the Drug Tariff price) is the volume-weighted average price charged by manufacturers. This reimbursed price will be recalculated as new products come into the market. Changes in reimbursement prices will be determined from the data submitted by manufacturers (or from that submitted by wholesalers if the data are not supplied by manufacturers). The new arrangements allow for price freedom for new generic products, subject to a maximum, which is set as the price of the originating brand product.

The Department of Health has stated that "where there is effective competition in respect of any given generic medicine then the Department will not interfere in the operation of that market for that medicine" (Department of Health, 2005). However, the Department also adds that they may intervene if the "normal market mechanisms have failed" to ensure that the "NHS pays a fair price for the medicine(s) concerned" (Department of Health, 2005).

Before August 2000, the NHS reimbursed (Drug Tariff Category A) price had been an average of the list prices of a number of major products, i.e. an average market price designed to follow the results of competition in the market between rival producers. In addition, pharmacists and dispensing doctors were (and still are) assumed to obtain discounts from medicine suppliers, so that the NHS reimbursement price is reduced by a predetermined 'clawback' percentage. The percentage clawback is graded according to the value of monthly NHS dispensing by a pharmacist (or dispensing doctor), being a higher percentage the greater the value of prescriptions dispensed per month, given that greater discounts are usually available for larger scale purchasers. As mentioned before, from June 2005 the new reimbursement prices take these discounts explicitly into account, i.e. they are incorporated into the reimbursement prices themselves.

Before August 2000 there were no direct controls on the prices at which generic medicines could be sold to community pharmacies and dispensing doctors. This was left to competition. However, aggressive purchasing was encouraged, as community pharmacists and dispensing doctors were, and still are, encouraged to buy their supplies of medicines at prices below the reimbursed price, as they are able to keep the difference between the reimbursed price and what they actually pay for a medicine.

Also before August 2000, whenever a generic medicine was in short supply at the Drug Tariff price, it was placed in Category D, which allowed reimbursement at the list price of the endorsed supplier. This meant that when pharmacists bought products in this category, they would be reimbursed the price they actually paid (minus the standard claw-back), no matter how high.

During 1999, there were supply problems across a range of generic preparations so there were no longer competing suppliers for many drugs. These drugs then moved from Category A (driven by competition) to Category D (reimbursement at the list price of the endorsed supplier). This process was associated with very large price increases. The overall level of prices paid by the NHS for generics

[9] 2003 figure, source: Department of Health (2004a).

[10] Note that the Department of Health may request monthly data for new products for the first two quarters following launch.

increased by around 45% (Department of Health, 2001a). The Department of Health initiated a complaint to the OFT as a result of these price rises to analyse whether there was evidence of anti-competitive practice. The OFT found that the price increases were the result of two supply shocks. The first was the temporary closure by the Medicines Control Agency of Regent GM in December 1998, which removed at a stroke a substantial part of the manufacturing capacity for some generics. Regent specialised in producing high-volume, low-cost generic drugs, including antibiotics.

The second supply shock identified by the OFT was the move, required by law, from bulk packaging of medicines to original (patient) pack dispensing. This move led to higher prices partly because the Drug Tariff did not include patient packs, so that pharmacies were not reimbursed specifically for dispensing these patient packs. Hence, manufacturers' patient packs were not being purchased, while the shortages of the bulk drugs as a result of manufacturers switching their production to patient packs pushed the bulk packs into Category D[11]. Patient-pack dispensing may have led to large price increases due to shortage problems, and generics being moved onto Category D.

An additional supply shock was the relocation overseas of manufacturing facilities by Norton and APS, the former with a market share among generic manufacturers of 39% and the latter of 11%. Probably, either of these relocations individually would have had small effects, but the problem was that they coincided with the closure of Regent (OXERA, 2001).

Following this turbulence in the generics market, the Government put in place in August 2000 a statutory Maximum Price Scheme covering the main generic medicines used in the community (i.e. dispensed outside hospitals). This Scheme, although announced as temporary when introduced, remained in force until the new M and W schemes were implemented in June 2005. Under the 2000-2005 Maximum Price Scheme, prices could be set freely, as long as they did not exceed the maximum price cap. The cap was set primarily by reference to the average prices that existed in the Drug Tariff for the period November 1998 to January 1999 – i.e. the three months prior to the start of the market turbulence which resulted in large percentage price rises – with certain adjustments made in the light of consultation with interested parties (Department of Health, 2001b). Thus generic prices were constrained to be at or below their 1998/1999 levels.

[11] The manufacturers have also claimed that patient packs cost more to produce as they require additional containers and patient information, and it is likely that this cost will be reflected in the price (OXERA, 2001).

Alongside this, from September 2000 Category D of the Drug Tariff was abolished. OXERA, in its review of the supply and distribution of generic medicines, commissioned by the Department of Health, concluded that Category D did not function satisfactorily (OXERA, 2001). The main advantages of placing medicines in Category D were to ensure that pharmacists were reimbursed fairly and to signal to manufacturers that there were shortages of those particular medicines. However, disadvantages of Category D included removing incentives for pharmacists to search for the lowest price, and encouraging speculative behaviour by suppliers (OXERA, 2001). The Department of Health considered that the supply problems of 1999 were partly due to exploitation of the Category D arrangement (Department of Health, 2001a). As a result, Category D was abolished and instead prescriptions for medicines that formerly would have been placed in this category were reimbursed at the level of the brand price where this had to be dispensed against a generic prescription on account of a shortage of the generic alternative.

In addition, four important (in value terms) generic medicine markets[12] where the original brand had come off-patent since the introduction of the Maximum Price Scheme in August 2000 had compulsory price cuts on the grounds that pharmacists were buying these generics significantly cheaper than the prices at which they were being reimbursed (Department of Health, 2004b).

In the opinion of the Government, the Maximum Price Scheme for generics was successful in meeting its objectives of avoiding further price increases while it was enforced. Before Schemes M and W were introduced, reimbursement prices for generics were close to their levels of before the 1999 price increases and, in the Department of Health's view, supply of these drugs had been stable since August 2000.

Investigations have been carried out in parallel with these regulatory changes regarding alleged cartel activities (price fixing) in the UK generic market. Investigations by the NHS Counter-Fraud and Security Management Service (CFSMS)[13] have focused on three active ingredients: warfarin (anticoagulant), penicillin-based antibiotics (the 'cillins') and ranitidine (anti-ulcer). Ten generic manufacturers in total have been investigated

[12] The four generic compounds are doxazosin, lisinopril, omeprazole and simvastatin.

[13] The CFSMS is a Special Health Authority created on 1 January 2003 with the responsibility for all policy and operational matters relating to the prevention, detection and investigation of fraud and corruption and the management of security in the NHS. It replaced the NHS Counter Fraud Service which was established in 1998.

(Eaton, 2004). This shows that in addition to actions under competition law, there is the possibility of criminal action against any company which is alleged to carry out anti-competitive, fraudulent, actions. This anti-fraud criminal law can also be considered as another form of ex post regulation, given it is harm-based with the possibility of financial penalties.

The UK generic medicines market, which prior to 1999 was considered to be competitive, moved in 2000 towards stringent ex ante regulation. From 2000, generic products that were already available before the 1999 price shock had their prices frozen at "pre-shock" levels; for post-1999 generic products, individual price regulation, including reimbursed price cuts, was the norm. These price controls on generics represented more direct regulation than is applied to the UK branded sector. Now, with the June 2005 arrangements, greater reliance is once more being placed on competition to control prices, although the generics market is more closely monitored than ever before, given the need for both manufacturers and wholesalers to submit quarterly data to the Department of Health on individual products. This may reflect the Department of Health's concern to ensure that it has the information to satisfy itself that price competition is working. While the Department of Health is now once more leaving the market unregulated when competition is effective, the option to intervene should it feel a need to do so remains. Thus the regulatory methods used in the generic segment have until recently had more interventionist elements of ex ante regulation than in the branded sector. Taking into consideration the basis for imposing ex ante methods of regulation (cf. Section 2), this might be seen as surprising if we consider that the generic segment is usually more competitive, as by definition patents have expired. However, given the "shock" of 45% average price increases over a short period of time, a temporary increase in ex ante regulation whilst underlying supply conditions are examined was understandable. If the generic market continues to work satisfactorily from the Department of Health's perspective, it might be expected that the level of ex ante regulation, including information requirements may diminish over time.

5 THE IMPACT OF THE 1998 COMPETITION ACT IN THE UK PHARMACEUTICAL MARKET

Both the PPRS and the 1998 Act acknowledge the importance of competitive pressures to obtain the desired outcomes: better products at affordable prices. But while the PPRS allows little flexibility for price changes, the 1998 Act does not include any explicit restrictions on price. Both recognise that price is only one element of competition and give importance to the development of new products.

The PPRS and the 1998 Act both identify the goal of avoiding excessive prices. One of the aims of the PPRS is to ensure "fair and reasonable prices" (Department of Health, 2004c), while the 1998 Act in effect prohibits excessive prices that result from abusive conduct. The PPRS does not concern itself with the possibility of firms abusing a dominant position in an individual market as long as they do not earn excessive profits overall from sales of medicines to the NHS. We will see later that this distinction between individual therapy markets and the overall NHS market can be important.

As we have noted, the introduction of the 1998 Act is an event of major importance for the UK economy, not merely pharmaceuticals. But it has proven to be particularly important for the pharmaceutical market because two of the early cases brought under the 1998 Act involved pharmaceutical companies. Moreover, in both cases the companies concerned have been fined for anti-competitive practices. Given that these companies are subject to the PPRS and were satisfying the terms of that Scheme, two issues need to be addressed:

- how and why they have been investigated and penalised under the 1998 Act; and
- whether or not there are any implications for the regulation of the UK pharmaceutical market.

5.1 Pharmaceutical cases under the 1998 Competition Act

5.1.1 Napp

The case of Napp Pharmaceutical Holdings Ltd. (Napp) was the first brought under the 1998 Act. The OFT penalised this company for supplying sustained release morphine (MST) tablets to UK patients in the community (i.e. outside hospital) at what it deemed to be excessively high prices, while supplying hospitals at a discounted level that in its view impeded competition from rival companies in that market. That is, Napp was deemed to be using predatory pricing to capture the hospital market, in the knowledge that doing so would enable it to win a major advantage in the out-of-hospital, community market. It should be noted, however, that the OFT did not use the actual words of 'predatory pricing'. However, given both the arguments used by the OFT ("…its (Napp's) prices in hospitals were below direct cost" (OFT, 2001b, pp. 67)) and a standard definition of predatory pricing (see, for instance, Martin (1993), where predation is defined as "cutting prices below rivals' average cost... to drive rivals from the market"), there seems to be a resemblance between both.

The OFT considered that "Napp has a strong and persistent first mover advantage (and) this is a barrier to entry to the community segment". The OFT also argued that "Napp's first mover advantage is accentuated by particular features of demand in the community segment of the market" (OFT, 2001a). General medical practitioners (GPs) prescribing in the community often follow the prescribing choices made for their patients by consultants (specialists) in hospitals.

Napp contended that the PPRS was the primary constraint on its pricing decisions, but the OFT replied that "the PPRS does not prevent Napp from holding a dominant position on the market for sustained release morphine in the UK". Napp also argued that the OFT decision did not take into account the nature of competition in pharmaceutical markets and that the OFT solutions would affect its ability to compete with rivals.

The fine imposed by the OFT on Napp was, after appeal, reduced from an initial £3.2m to £2.2m, which is approximately 4% of Napp's UK turnover in 2001 (£52m)[14]. In addition to the penalty, Napp had to reduce the price of its tablets to the community by at least 15% and limit the extent to which discounts could be offered to hospitals – the price of MST tablets sold to hospitals may not be less than 20% of the NHS (community) list price.

[14] From Napp's webpage: www.napp.co.uk (assessed 18 November 2002).

Napp is a member of the PPRS, and was not in breach of that Scheme. So, in the light of the PPRS, Napp had been behaving acceptably, while in the view of the OFT it was abusing a dominant position.

The first step in any investigation of abuse of a dominant position is to define the market. The principles and procedures for market definition are usually based on demand and supply substitution. A product would be considered a demand substitute, and hence included in the market, if consumers would be likely to switch to this product in the short term, and at a negligible cost, in response to a hypothetical small (5%-10%) but permanent relative price increase (from the competitive price) in the product under consideration[15]. Similarly, supply-side substitutability arises when suppliers are able to switch production or other resources to the relevant products and market in the short term without incurring significant additional costs or risks in response to a small but permanent increase in the relative price of a product (Stumpf et al., 2003).

In medicines, defining the relevant market is not an easy task. It has been recognised that the starting point for defining the market in the case of pharmaceutical products is the Anatomical Therapeutic Classification (ATC) system recognised and used by the World Health Organisation (WHO), and in particular the third level of aggregation (ATC level 3). This allows medicines to be grouped in terms of their therapeutic indications. In the Napp case this was indeed the starting point, but the market was subsequently defined more narrowly. Without going into the details of the process for defining markets, what needs to be taken into account is that markets for medicines do not work in the same way as markets for final consumer goods, where this test of demand- and supply-side substitution may work better and can be applied more easily.

Supply-side substitution is often limited in the pharmaceutical market, given the time taken to develop a new medicine. Hence, demand substitution will be the driving element when defining a market for a medicine. But applying demand-side substitution to the pharmaceutical market might also be problematic given that price is not the only, or even the main, factor affecting the prescribing and consumption decision. This implies that the degree of demand substitution may be difficult to assess. Indeed if pricing data are used to analyse whether two products are close competitors, that may prove inconclusive given that the price controls existing in the UK under the PPRS permit few price changes to take place. Moreover, different groups of patients

[15] This is the so-called "hypothetical monopoly test", otherwise referred to as the "SSNIP" test (small but significant non-transitory increase in price).

respond differently to the same medicines, and this needs to be taken into account when using the demand-substitution methodology.

In the Napp decision, a narrower definition of the market than ATC level 3 was used and Napp's high market share on this basis made its position a dominant one. One important issue is that nothing was said in the OFT decision or in the Competition Commission Appeal Tribunal (CCAT) judgement (CCAT, 2002) that suggested if the approach to be followed in the case of patented products (MST was already off-patent) would be different[16]. The implication could be that markets for medicines are defined narrowly by the OFT, implying that findings of dominance are more likely.

Let us consider now the issue of predatory pricing in the hospital segment. As stated in paragraph 188 of the OFT's decision (OFT 2001a), "The European Court has held that prices below average variable costs by means of which a dominant undertaking seeks to eliminate a competitor must be regarded as abusive" (p. 51). Napp argued that discounting prices to hospitals did not have the effect of hindering competition given that it is common practice as a result of the workings of the pharmaceutical market and the interlinkages between the hospital and community segments. Indeed, Napp contended that there is an objective justification for pricing below average variable cost in the hospital segment owing to the compensation margins earned through follow-on sales in the community segment. These linkages are acknowledged in the OFT decision. However, the OFT did not accept Napp's point, arguing that these linkages and the follow-on effects are not mechanistic but unpredictable, both in magnitude and timing.

There is an economic literature addressing this question in the context of foremarkets and aftermarkets. The foremarket-aftermarket model relates to those markets where consumers are locked in to an installed product A, say 'hardware', at period t and then have to buy monopolised product B, say 'software', at time t+1. The standard features of these sorts of markets are that products in the foremarket (in our analysis, the hospital market) are priced very low, and products in the aftermarket (the community segment) are priced relatively high. This characterisation can be applied to markets such as mobile phones and video games, where handsets and consoles are usually sold cheaply to stimulate demand for calls and games respectively that are priced above marginal and average cost.

[16] The Genzyme case, discussed later, applies to patented products, and shows that the methodology for market definition is the same irrespectively of the patent situation.

Thus if a lower bound is imposed on a medicine's price in the hospital market equal to the average variable cost, then it will prove to be a binding constraint and the price in this market will rise. The restriction will be binding because in its absence it is optimal from the perspective of a firm to charge a price below average variable cost. Other, (actual or potential) rival producers of the same generic medicine will also be affected by the imposition by the OFT of a lower bound on one firm's price. If they were to try to undercut the regulated firm's price, the OFT could apply the same methodology as in the Napp case, if the competitor had a dominant position (which it could easily achieve if it was pricing below the regulated firm's price), and decide that it is an abuse of a dominant position.

In the longer term, the impact of the OFT decision in the Napp case may be to reduce more generally the discounts offered in the hospital segment of the medicines market on a range of medicines, as companies seek to ensure they are not offering discounts that could be regarded as an abuse of a dominant position, and hence to result (in this respect) in a higher medicines bill for the NHS. A joint 2002 Department of Health/ABPI study on a variety of aspects of the UK pharmaceutical market found, inter alia, that in the hospital market "companies were beginning to reduce the discounts they were offering" (Department of Health/ABPI, 2002, pp. 226), although it is unclear whether this was due to the Napp case.

Focusing on the community market, the OFT accepts that price premiums may exist over competitors' prices even in the presence of effective price competition. However, the OFT does not accept that the premium over competing brands' prices should be as high as 40%, especially after patent expiry. The OFT argued in the Napp case that "while firms originating a new pharmaceutical product may retain high prices following patent expiry, it is not a feature of normal competition for the premium priced pioneer product to retain such a large share of sales volume" (OFT, 2001a, p.57). The OFT calculated a gross profit margin for Napp on its MST products sold to the community segment that was in "excess of 10 percentage points" above that of its nearest competitor, and concluded that "there seems to be little or no justification for such high margins".

Since there was no precedent for excessive charging in the UK under general competition law because that offence effectively only existed when the 1998 Act was enforced, the problem for other firms is how to interpret the Napp judgement to determine what will be deemed an acceptable price for any individual medicine (not too low in the hospital market and not too high in the community market) in

a situation where a company may, under some definitions of the relevant market, be thought to have a dominant position.

What is then the relationship between the PPRS and the Napp decision (and by implication, the 1998 Act)? The OFT did not carry out an analysis of the return on capital that Napp was making overall on its sales to the NHS and the contribution that MST sales were making towards this, which is the approach used in the PPRS. Napp was not in breach of the PPRS. The PPRS applies to a company's whole portfolio of branded products taken together, while the 1998 Act focuses on individual product markets. This is because the Department of Health is more concerned with the overall NHS medicines bill, than with the price of any individual product. This is understandable, because, as we have noted above, the PPRS is part of the public procurement arrangements for NHS medicines. This difference of perspective was highlighted in the CCAT decision: "The PPRS is not directed to the question whether or not the price of an *individual product* sold in a market where there is dominance is above the competitive level, which is the essential question in the present case. In our view, the fact that a pharmaceutical company is subject to the PPRS does not, of itself, give that company any kind of exemption from the Chapter II prohibition in general, as regards the prices of *individual products*" (p.107).

5.1.2 Genzyme

The second case involving a pharmaceutical company brought under the 1998 Act concerns Genzyme Limited. Genzyme was, and still is, covered by the PPRS. Like Napp, Genzyme was not in breach of the scheme. Genzyme was initially fined £6.8 million by the OFT for exclusionary pricing behaviour in breach of the Chapter 2 prohibition of the 1998 Act[17] for the supply of Cerezyme – a medicine for the treatment of Gaucher disease. On appeal, the fine was reduced to £3m.

There are two issues specific to Cerezyme. First, it is very expensive – around £100,000 per patient per annum – with a very small market – Gaucher disease affects about 180 patients in the UK. Second, this medicine is usually delivered direct to the patient's home, sometimes by a visiting nurse. One of the main issues in the competition case is whether or not the price paid by the NHS for Cerezyme included or excluded this homecare service.

In 1998, Genzyme appointed Healthcare at Home (HH) to provide the homecare element of the service, but in 2001 decided to terminate its contract with this provider in order to deliver homecare itself. HH still sought supplies of Cerezyme, but Genzyme demanded a price that HH considered to be unfair. HH argued that Genzyme was selling Cerezyme at a price that included the cost of providing the homecare services, and complained to the OFT on this basis under the 1998 Act. The OFT concluded that Genzyme had abused its dominant position.

The OFT argued in its decision there were two abuses of a dominant position by Genzyme for the supply of Cerezyme:

- "bundling abuse": charging the NHS a price for Cerezyme which includes not only the supply of the product but the price of home delivery of Cerezyme and provision of homecare services[18];
- "margin squeeze abuse": precluding viable competition by charging independent third party homecare service providers for Cerezyme at the NHS list price, a price that allows them no possible margins given that it includes the cost of supplying homecare services (OFT, 2003a).

The OFT argued that the bundling abuse excluded anyone other than Genzyme (or an agent under contract to Genzyme) from supplying the associated homecare services. In addition, the OFT contended that both abuses raised the barriers to entry in the market of drugs for the treatment of Gaucher disease, by making it more difficult for potential competitors of Genzyme to obtain access to Gaucher patients.

A major point of disagreement in this case concerned the definition of "NHS list price", and specifically whether or not this price includes the cost of delivering the drug to the patient's home. Genzyme argued that the cost of delivering Cerezyme to a patient's home is included in the NHS list price and the cost of providing homecare services is borne by Genzyme, as such services are supplied to the NHS free of charge. The OFT rejected Genzyme's argument that the NHS list price did in fact include this cost, and took the view that the NHS list price is "intended to cover the cost of the manufacturer of producing the drug and the cost of wholesale delivery of the drug to the pharmacy (plus a reasonable profit on these activities) and not intended to cover the cost of delivering the drug from the pharmacy to a patient's home" (OFT, 2003b).

[17] This initial fine was more than 12% of the firm's £54 million UK turnover in 2001 and shows the seriousness with which the OFT viewed this case.

[18] These services include dispensing, home delivery, an emergency help line, the supply of accessories, waste disposal and nursing at home, among others.

The OFT's decision was that Genzyme should offer Cerezyme to the NHS at a stand-alone price for the drug only, exclusive of any home delivery of Cerezyme and homecare services that may be provided, and should supply Cerezyme to third parties at a price no higher than the stand-alone price agreed between Genzyme and the Department of Health.

In its decision the OFT distinguished two markets: upstream and downstream. The upstream market refers to the supply of medicines for Gaucher disease. The downstream market is for the provision of additional services required for the patient to consume the medicine (i.e. homecare services). The OFT found that Genzyme had a dominant position in the upstream market, but not in the downstream one. However, the OFT argued that given that the list price for Cerezyme includes the provision of home care services, Genzyme was abusing its dominant position in the upstream market with the effect of foreclosing the related downstream market where it was more vulnerable to competition, i.e. this was exclusionary behaviour, as defined in Box 2. (The information contained in Box 2 relies heavily on Mota and de Streel (2003) and Evans and Padilla (2005).)

Box 2
What is excessive pricing?

- Article 82 and Chapter 2 prohibition both include provision for a condemnation of 'imposing unfair purchase or selling prices'. Excessive prices are an example of such unfair practices. However, excessive prices can reflect two concepts:
  - *Exploitative abuse:* direct exploitation of market power, including charging a high price to the dominant firm's customers. This abuse directly harms consumers.
  - *Exclusionary abuse:* putting rivals at a disadvantage by strengthening or maintaining the market power of a dominant firm, which includes a dominant firm charging an excessive price for an input to a downstream rival (i.e. a firm that requires this input to produce/sell the final good or service). This abuse may harm consumers indirectly.
- The number of excessive pricing cases in the EU has been relatively modest, partly due to the conceptual and practical difficulties of detecting excessive prices. However, a few recent cases (including Napp in the UK), the 'deregulation' of previously publicly-owned utilities, and the recent 'decentralisation' of competition law from the European Commission towards national competition authorities, might all suggest an increase in interest in this type of antitrust action. The reason is twofold. First, 'deregulation' opens to antitrust intervention sectors of the economy where prices used to be regulated and where dominant positions are prevalent. Second, the enhanced role of national courts can increase private actions, and cases of unfair pricing are potentially good candidates for unhappy customers.

'Exploitative' prices

- A price is excessive when it is significantly above the effective competitive level, where the price level has no reasonable relation to the economic value of the product.
- The European Commission defines the competitive price level as the minimum average cost.
- Excessive prices are measured by comparing the price under review with different indicators:
  - Cost measures of dominant firm;
  - Other prices of the dominant firm; or
  - Prices of other firms offering similar products to the one in question.

'Exclusionary' prices

The dominant firm is vertically integrated and the upstream affiliate produces an input that is used by its downstream affiliate as well as downstream independent firms for the production of a final good. If the price for the input is excessive, the competitor in the downstream market would suffer a competitive disadvantage. This is called a 'price squeeze'.

It has been argued that the OFT took a simple ex post approach in defining the relevant market (RBB Economics, 2003). The OFT considered clear medical preference for this medicine and the absence of actual competing products as decisive. Taking this approach implies very high market shares for Cerezyme, in excess of 90%. This, coupled with the view on the R&D needed to launch a new medicine and Genzyme's patent protection, underlined the OFT's conclusion of dominance.

Genzyme saw the fine reduced to £3m after appeal. The Competition Appeal Tribunal (CAT) reduced the fine on the grounds that the bundling abuse was not proved by the OFT (according to the CAT, this practice did not have a sufficient adverse effect on competition) and that the principal distortion was due to the margin squeeze abuse (although the CAT also acknowledged that this abuse was facilitated by the bundling of the price of Cerezyme). The CAT was very explicit about the importance of the Genzyme case more generally: "In this case we recognise the need to take into account a factor for deterrence, particularly given the size of Genzyme Corporation, and to dissuade other undertakings that may be contemplating similar practices" (CAT, 2004, p.210).

Similarly to the Napp case, the view taken by the CAT in the Genzyme case was that the PPRS does nothing to prevent an abuse of a dominant position. These two cases show that the PPRS will not exempt pharmaceutical companies from investigation by the OFT under the terms of the 1998 Competition Act even though both PPRS and Act appear to deal with the issues of pricing and profitability.

The PPRS applies to a company's portfolio of branded medicines sold to the NHS. Thus it gives a greater degree of pricing freedom in relation to individual pharmaceutical products than in many other major (non-US) pharmaceutical markets internationally. Indeed, this freedom is among the factors usually seen as attracting pharmaceutical industry activity to the UK. Freedom of pricing at market launch is one of the 12 key competitiveness indicators highlighted by the joint Department of Health/ABPI Pharmaceutical Industry Competitiveness Task Force (Department of Health and ABPI, 2004). However, the application of the 1998 Act imposes its own constraint on the pricing of medicines in the UK.

6 SUMMARY AND CONCLUSIONS

It is generally presumed that markets should be left unregulated unless there are particular reasons to regulate them, namely if significant market failures exist. In practice, however, all markets are subject to some form of economic regulation. But some industries are subject to more stringent regulation than others.

The focus of this paper has been on economic regulation, i.e. regulation primarily affecting prices and profits. Different forms of such economic regulation can be grouped under two main headings: ex ante and ex post regulation. Ex ante regulation defines in detail and in advance strict rules of behaviour to be met and is usually applied to specific, defined markets. Ex post regulation sets general standards of behaviour and punishments after the event if breaches are detected. All markets are covered by some form of ex post regulation in the shape of competition law. The additional regulation faced by some specific industries, such as utilities and pharmaceuticals, is ex ante. In the case of pharmaceuticals, regulation takes place in the context of a third party payer procurement arrangement.

The effectiveness of ex post regulation depends on how well competition law is defined (companies have to understand whether specific actions fall inside or outside of acceptable behaviour) and applied (companies have to believe there is a reasonable likelihood they will be held to account) and on the severity of the penalties that may be imposed on miscreants.

The 1998 Competition Act came into force in March 2000. It sets general standards of behaviour for undertakings that operate in the UK. Its main objective is to ensure that markets are competitive and it brings UK competition policy more into line with EU legislation governing trade between member states. The 2002 Enterprise Act reinforces and increases the powers given to the OFT by the 1998 Act. These Acts together represent ex post regulation in the UK currently. From the evidence of the Napp and Genzyme cases, this ex post regulation has the potential to have a major impact on pharmaceutical companies, as well as on companies in other sectors of the economy.

Regardless of ex post regulation, ex ante regulation of pharmaceutical prices (within the context of third party payer procurement arrangements) remains the norm internationally. The exact form of regulation varies widely and in any one country changes over time as governments continue to try new variants.

Ex ante regulation in the UK pharmaceutical market is represented by the PPRS for branded medicines and Schemes M and W for unbranded generics. The PPRS regulates pharmaceutical company profitability on the basis of return on capital, and hence indirectly controls prices that firms may charge for their branded sales to the NHS. Companies are free to set the launch prices for new products, within the overall limits that are allowed on the rate of return they may earn from the totality of their branded NHS sales. After launch, approval for any price increase must be obtained from the Department of Health.

The PPRS is a voluntary agreement between the Government health departments of England, Northern Ireland, Scotland and Wales on the one hand and the pharmaceutical industry on the other. Variants of it have been in place for nearly 50 years and regulation of the UK pharmaceutical market has thus been relatively stable as compared with other European pharmaceutical markets[19].

The generic segment of the UK medicines market has experienced important regulatory changes in recent years. More stringent ex ante regulation was introduced by the Department of Health in August 2000 as a result of sudden, large, price increases for some generic products the previous year. Direct price controls and fraud investigations were brought to bear on the generic sector. What is less clear is whether these price jumps were a result of a market failure or of defects in the previous regulatory regime for generic medicines – the Drug Tariff – or a combination of both. Since June 2005, the new M and W schemes offer more price flexibility in exchange for a requirement on companies to submit detailed information on revenues and costs of individual generic medicines on a regular basis.

The introduction of the 1998 Act has been an event of major importance. It marked the first time that a harm-based approach to competition policy has been underpinned by potentially large financial penalties. Moreover, for the first time, third parties who may have suffered losses as a result of illegal action will have the basis for a claim for damages in the courts. The 1998 Act gave the OFT considerable new powers to tackle anti-competitive behaviour and the financial penalties are proving to be much heavier than was possible before the 1998 Act. Taken together, the new measures can deal with many of the weaknesses identified in earlier UK policy: weak penalties and investigative powers; inability of third parties to sue; and the need for early intervention to prevent potential harm to competitors or customers.

The first abuse of a dominant market position found under the 1998 Competition Act involved a pharmaceutical firm, Napp. The OFT fined Napp for supplying sustained release morphine tablets in the community at what it considered to be excessively high prices ('exploitative' behaviour), while supplying hospitals at such a discounted level as to impede competition from rival companies.

The second case brought under the 1998 Act involving a pharmaceutical company was the Genzyme case. Genzyme was also found guilty of abusing its dominant position, albeit in a different way from Napp. After appeal, this company was found guilty of carrying out a 'margin squeeze' practice – effectively precluding competition in the market for homecare services for Gaucher disease patients through its pricing strategy for Cerezyme.

Important issues arising from the Napp and Genzyme cases have been addressed in this paper:

- The first concerns the relationship between the PPRS and the 1998 Act. The OFT has made clear that in its view the PPRS does not prevent a company from holding and abusing a dominant position. The scopes of the two regulatory mechanisms are different: the PPRS controls the overall portfolios of pharmaceutical companies supplying branded medicines to the NHS, while the 1998 Act impacts on businesses' pricing strategies for individual products;

- The second issue refers to the methodology used in the first stage of assessing whether there has been any abuse of dominance: defining the relevant market. The market for sustained release morphine in the Napp case was narrowly defined. A similarly narrow market definition was used in the Genzyme case. This implies that findings of dominance are also quite likely in future cases involving medicines;

- Thirdly, the judgement of predatory pricing in the hospital segment in the Napp case implies that other companies supplying medicines to hospitals have to

[19] Voluntary agreements between the Department of Health and the branded pharmaceutical industry have been the norm in the UK since 1957 to control branded medicine prices and profits, each lasting around five years, although the details of these agreements have evolved over time.

be extremely cautious with their pricing strategies. Firms with potentially significant market power will have to weigh up the benefits of undercutting rivals' price offers against the possible costs of being investigated by the OFT for such practices. One result may be that hospital discounting, a practice extensively used across the UK, is likely to be curtailed somewhat.

A final point deserves mentioning on the relationship between the PPRS and the 1998 Act, and refers back to the ways of defining 'excessive' prices, as described in Box 2. The Napp and Genzyme decisions both seem to fall into this category, i.e. predation and exploitation of captive customers in the case of Napp, and a price squeeze in the case of Genzyme. Thus, the 1998 Act is being used by the competition authorities to prevent potential abuses of types that the PPRS is not designed to stop. From this perspective, the PPRS and the 1998 Act complement each other quite well.

The Napp case may also set an important precedent as to how to define excessive pricing as an abuse of dominant position, not only for pharmaceutical companies, but also for UK industry as a whole. Price premiums of 40% over competitors' prices and gross profit margins in excess of 10 percentage points above Napp's nearest competitors were taken by the OFT to indicate excessive pricing and excessive profits. There was no analysis of the overall return on investment that Napp was earning and the contribution that sustained release morphine was making towards this. Given the importance of R&D costs in the pharmaceutical industry, it is difficult to measure the true profitability of a product by reference to current price-cost margins alone. The Napp case precedent may have added an additional layer of uncertainty as to how firms can determine what will be considered an acceptable price for a product.

As at June 2005, 74 cases brought under the 1998 Act, including the two pharmaceutical cases referred to in this Briefing, had been decided[20]. In 18 of these, one or more infringements of the 1998 Act were found to have occurred and most of the infringing firms have been fined, including Napp and Genzyme. The implementation to date of the 1998 Competition Act has almost certainly made the UK's pharmaceutical industry a tougher place in which to compete.

[20] From the OFT's webpage (www.oft.gov.uk/Business/Competition+Act/Decisions/index.htm). Accessed 23 June, 2005.

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