EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE BRANDED MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) (NO. 2) REGULATIONS 2008

2008 No. 3258

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These regulations control the maximum price of prescription only, branded medicines supplied to the National Health Service and require manufacturers and suppliers of branded pharmaceutical companies to provide the Department of Health with information on sales income and discounts. These requirements do not apply to any company that is a member of a voluntary scheme to control the prices of branded health service medicines.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 Sections 260 to 266 of the National Health Service Act 2006 make provision for the Secretary of State powers to control maximum prices of health service medicines and medical supplies. They also make provision for powers of the Secretary of State relating to voluntary schemes limiting the prices of NHS medicines and the profits of the manufacturer and suppliers of such medicines.

4.2 There is in existence a voluntary scheme, the Pharmaceutical Price Regulation Scheme (PPRS), made by the Department of Health and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI), to control NHS expenditure on branded medicines. The PPRS applies to those manufacturers and suppliers of branded medicines who elect to be scheme members. The latest agreement reached between the Department and the industry is due to start in January 2009.

4.3 These regulations are made under sections 261(7), 262(1), 263 to 266 and 272 of the Act and will apply on expiry of the current PPRS to any companies who do not sign up to the PPRS that is due to start in January 2009.

4.4 These regulations replace the Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008, which provided that, subject to certain exceptions, no price increases were permitted from 1st September 2008 so that maximum prices were in effect frozen.

4.5 The Regulations comply with the requirements of Council Directive 89/105/EEC of 21st December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national insurance systems.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The National Health Service (NHS) spends about £9 billion a year on branded prescription medicines in the UK. The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism, which the Department of Health (on behalf of the UK Health Departments) uses to control the prices of these medicines by regulating the profits that companies can make on these sales. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI). The PPRS seeks to achieve a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry to enable it to research, develop and market new and improved medicines for the benefit of NHS patients.

7.2 The PPRS covers all licensed, branded, prescription medicines sold to the NHS. It does not cover products without a brand name (generics) nor branded products available without prescription (over the counter (OTC) medicines) except when prescribed. It is a UK wide scheme and covers around 80 percent by value (some £9 billion) of the medicines used in the NHS in both primary and secondary care.

7.3 The scheme, which has existed in various forms since 1957, is generally renegotiated every five or six years. The latest scheme agreed by the Department and the industry is due to start in January 2009 and to last for a period of 5 years.[1]

7.4 The Department is introducing these regulations to control the price of prescription only branded NHS medicines from 1st February 2009 to safeguard the financial position of the NHS by ensuring that a statutory fall-back for the PPRS is in place for any companies which choose not to become members of the voluntary scheme. These statutory measures would apply to those companies who chose not to sign up to any new voluntary scheme. Statutory measures would not apply to any company that was a member of a voluntary scheme.

7.5 These Regulations protect NHS expenditure by providing that, subject to the exceptions set out below, from 1st February 2009, the maximum price which may be charged for medicines within scope of these regulations is 3.9% less than the price of that medicine on 1st December 2008. The requirement to reduce prices by 3.9% mirrors the arrangements in the voluntary scheme, which also requires a reduction in the prices of branded medicines of 3.9% to take effect from 1st February 2009.

7.6 There is an exemption from the requirement to reduce the price by 3.9% compared to the price on 1st December 2008 for low cost presentations. Low cost presentations are presentations which cost the NHS not more than £450 000 in a calendar year, or which have a reimbursement price of less than £2.00.

7.7 Products may also be exempted from the effect of regulation either on the election of the Secretary of State or in response to an application from the relevant manufacturer or supplier on the grounds that the supply of that medicine may be jeopardised. Similarly, the Secretary of State can provide for a price increase for products by means of a direction. The Regulations set out criteria to be taken into account in reaching this decision.

[1] Further details on the voluntary scheme are available at www.dh.gov.uk/pprs.

7.8 The Regulations include information requirements to monitor the proposed price controls and their impact. The information required is based on that required in the Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007, which are amended by these Regulations, although additionally sales in respect of each pack size and strength of a branded product are required. Companies with NHS sales of less than £25m are exempt from the information provisions. Amongst other things, this information will allow the Government to determine whether the benefit of the price reduction to the NHS is eroded by a reduction in discounts, which would otherwise have to be compensated under the new pharmacy contract.

7.9 As well as controlling the maximum price of existing products, the Regulations include controls on the maximum price of new products. This power will be exercised to give new products that are new active substances freedom of pricing on entering the market. However, the Secretary of State will be able to set the maximum price of products that are not new active substances by issuing a direction, having taken factors defined in the Regulations into account.

7.10 The Regulations give manufacturers the right of appeal against any decision made by the Secretary of State and any enforcement decision made under these price controls.

7.11 The Regulations include enforcement provisions, which provide for the recovery of any payments in excess of maximum prices permitted under the regulations, with an additional premium of 5% of the excess payment for the first contravention. The additional premium rises for each subsequent contravention to a maximum of 50% for the fifth or subsequent contraventions. Interest (at 2.5% above the Bank of England base rate) will be charged for late payment.

7.12 There will be limited interest in these Regulations outside the branded pharmaceutical industry.

8. Consultation outcome

8.1 The Department consulted with the ABPI as the appropriate body under the National Health Service Act 2006 and at the same time carried out a public consultation on its proposal to cap the maximum prices chargeable for branded health service medicines.

8.2 The consultation was in two parts. The first part started on 18th June and terminated on 15th July 2008 and related to matters covered by the Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008. Ministers agreed a short consultation period in order to maximise the opportunity for both the Department and the industry to conclude negotiations on a new voluntary scheme. The second part of the consultation related to the price cut (which is introduced by these regulations) and reductions in the price of out of patent branded medicines. The second part of the consultation started on 18th June and terminated no 25th September 2008.

8.3 The consultation document was sent to relevant trade and representative bodies associations, including the Association of the British Pharmaceutical Industry (ABPI), PPRS scheme members, and NHS organisations. A summary of the responses to the consultation is attached to this explanatory memorandum.

9. Guidance

9.1 The Department prepared guidance on the implementation of the Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008, which it will revise to take account of the changes introduced by these regulations.

10. Impact

10.1 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business. Companies with NHS sales of less than £25m are exempt from the information provisions

12. Monitoring & review

12.1 The Regulations will be reviewed annually, so as to ensure compliance with Council Directive 89/105/EEC, Article 4 of which requires that any price freeze be reviewed at least once a year.

13. Contact

Luisa Stewart at the Department of Health Tel: 020 79725374 or e-mail: luisa.stewart@dh.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment of the Introduction of a Statutory Scheme to Control the Prices of Branded NHS Medicines**	
Stage: Final	**Version:** 1.0	**Date: 25 November 2008**
Related Publications: Consultation on a Statutory Scheme to Control the Prices of Branded Medicines		

Available to view or download at:

http://www. dh.gov.uk/consultations

Contact for enquiries: Danny Palnoch **Telephone:** 0207 9722844

What is the problem under consideration? Why is government intervention necessary?

The NHS in the UK spends approximately £9 billion a year on branded prescription medicines. The Pharmaceutical Price Regulation Scheme (PPRS) controls their prices by regulating the profits that companies can make on these sales. It is not a conventional market with a single purchaser (the government) and manufacturers, which hold patents that provide temporary monopolies over supply of their products. A new PPRS will be implemented from 1st January 2009, which will include, amongst other things, provision for a cut in the price of branded medicines from 1st February 2009, with further price adjustments in each January of subsequent years. In the absence of statutory fall-back measures, companies could avoid that price cut by choosing not to join the voluntary scheme.

What are the policy objectives and the intended effects?

The Government has agreed a new voluntary, non-contractual scheme which is expected to deliver value for money; encourage and reward innovation; assist the uptake of new medicines; and provide stability, sustainability and predictability.

The Government proposes to introduce statutory measures to control the prices of branded medicines from 1 February 2009 in place of the current PPRS in order to safeguard the financial position of the NHS. This would apply to companies who were not members of a voluntary scheme.

What policy options have been considered? Please justify any preferred option.

The Government has considered the following two options:

i. No intervention - which would leave the NHS exposed to the financial risk of companies choosing not to join the voluntary scheme and thereby avoiding the price cut

ii. Introduce statutory measures to control the prices of branded medicines, including a price cut from 1 February 2009 in order to safeguard the financial position of the NHS. These would apply to those companies who chose not to sign up to a new voluntary scheme. This is the preferred option.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The statutory measures will be reviewed annually - no later than February 2010.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Dawn Primarolo ..... Date: ***17th December 2008***

Summary: Analysis & Evidence

Policy Option: Statutory measures	Description: A Statutory Scheme to control the prices of Branded NHS Medicines

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	Cost saving to the NHS from the primary care drugs bill, leading to greater spending on health services and benefits for NHS consumers.
£	
Average Annual Cost (excluding one-off)	
£ -£245m	**Total Cost** (PV) **-£245m**

Other **key non-monetised costs** by 'main affected groups'

Effect on parallel imports – drugs purchased abroad – which would be shielded from the price cut.

Reduction in hospital drug costs is uncertain, and has not been monetised.

No adjustment has been made to reflect the additional returns to society of healthcare purchased in the NHS – where £1 of spending is usually estimated to generate benefits valued at £2.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	Shareholders in the global pharmaceutical industry lose part of their UK profits due to price cut.
£	
Average Annual Benefit (excluding one-off)	
£ -£225m	**Total Benefit** (PV) **-£225m**

Other **key non-monetised benefits** by 'main affected groups'

Reduction in spending on Sales & Marketing, which will partially offset loss of revenue.

Reduction in sales to hospitals is difficult to forecast, and has not been monetised.

Key Assumptions/Sensitivities/Risks

Valuation measures impact if applied to all pharmaceutical sales – though most companies are expected to join the voluntary scheme.

Price Base Year 2008	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£ 20m**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				1 February 2009	
Which organisation(s) will enforce the policy?				Department of Health	
What is the total annual cost of enforcement for these organisations?				£ 0	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N/A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	N/A	N/A	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £nil Decrease of £ nil **Net Impact** **£** nil

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

Introduction

The NHS spends about £9 billion a year on branded prescription medicines in the UK. The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism which the Department of Health (on behalf of the UK Health Departments) uses to control the prices of these medicines, by regulating the profits that companies can make on these sales. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI). The PPRS seeks to achieve a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry to enable it to research, develop and market new and improved medicines for the benefit of NHS patients. It complements Government action on other fronts aimed at ensuring that clinically and cost-effective medicines are available and used by the NHS for the benefit of its patients.

The Department of Health and the ABPI have reached agreement on a new PPRS that will start on the 1st January 2009. This new scheme provides for a number of measures, including a cut of 3.9 per cent price cut in the cost of branded drugs sold to the NHS from February 2009. For further details on this scheme, see www.dh.gov.uk/pprs.

Purpose and intended effect

Objective

The Department proposes to introduce statutory measures from 1 February 2009 to introduce a price cut of 3.9% and control the prices of branded medicines in order to safeguard the financial position of the NHS. These would apply to those companies who chose not to sign up to a new voluntary scheme or in the event of failure to reach agreement.

Background

On 19th November 2008, the Department of Health and the ABPI reached agreement on a new PPRS that will start on the 1st January 2009. This new scheme provides for a number of measures, including:

- a cut in the cost of drugs sold to the NHS: a 3.9 per cent price cut will be introduced starting in February 2009 and a further price cut of 1.9 per cent will be introduced in January 2010;
- subject to discussion with affected parties, the Department of Health will also introduce generic substitution from January 2010. There would be further price adjustments on January of each year aimed as the proportion of savings from generic substitution varies with time;
- action to support innovation so patients have faster access to new medicines that are clinically and cost-effective;
- a new non-contractual voluntary scheme providing stability and predictability in Pharmaceutical Pricing for the next 5 years;

- new and more flexible pricing arrangements that will enable drug companies to supply drugs to the NHS at lower initial prices, with the option of higher prices if value is proven at a later date; and

- the more systematic use of patient access schemes by drug companies to allow access to medicines which have not initially been assessed as cost or clinically effective by NICE

For further details on this scheme, see www.dh.gov.uk/pprs.

Although the Department expects that the majority of companies will choose to join the voluntary scheme, the Department also needs to safeguard the financial position of the NHS. It therefore intends to ensure that a fall-back statutory scheme is in place for those companies who choose not to sign up to the new voluntary scheme. The Department therefore intends to introduce statutory measures as a fall-back to the 2009 PPRS from 1st February 2009. These statutory measures would apply to those companies who chose not to sign up to the new voluntary scheme and statutory measures cannot apply to any company who is a member of a voluntary scheme.

The Department is of the view that the further measures outlined in the 2009 PPRS – and explained above – are not necessary for inclusion in a statutory scheme.

Following consultation, it is therefore proposed that a price cut of 3.9% (in line with the price cut in the voluntary scheme) is applied to branded pharmaceuticals. The cut is to be implemented on 1st February 2009. The proposals include exemptions for products with low total cost.

Consultation

Since September 2007, the Department has been meeting with the ABPI as the appropriate representative industry body under section 261(7) of the National Health Service Act 2006 to negotiate a new voluntary scheme.

The Department of Health has consulted on the proposed statutory measures set out in this impact assessment. The consultation document is available at http://www.dh.gov.uk/consultations. The Department has also held meetings with the ABPI to discuss the statutory scheme.

Options

The Department has identified two options:

Option 1: No change - which would leave the NHS exposed to the financial risk of companies choosing not to join the voluntary scheme and thereby avoiding the price cut

Option 2: Introduce statutory measures to control the prices of branded medicines in order to safeguard the financial position of the NHS. These would apply to those companies who chose not to sign up to a new voluntary scheme. The measures include a price cut of 3.9%, with exemptions for products that have a reimbursement price less than £2.00, or a relevant annual cost to the health service in England of not more than £450,000[2].

There is no additional administrative burden from these proposals compared to the current PPRS.

[2] The "relevant cost" is the cost of a presentation for the twelve calendar months ending on 30th June in the preceding calendar year where that cost does not include any dispensing costs or fees, any adjustments for discounts or income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a pre-payment certificate as determined by the Prescription Pricing Division the NHS Business Services Authority.

Analysis of Costs and Benefits

This section identifies the major expected impacts of the intended 3.9% cut in the price of branded pharmaceuticals, with exemptions for products that have a reimbursement price less than £2.00, or a relevant annual cost to the health service in England of not more than £450,000

The impacts are described and evaluated by comparison with a counter-factual situation in which prices remain at current levels, as a result of the statutory price freeze already in place.

Under EU law (Transparency Directive), the government is required to review these proposals after 12 months. This analysis therefore only considers the impacts over one year.

The analysis below calculates the impact expected if the proposal were applied to all companies. However, as described above, it is expected that the majority of companies will choose to join the voluntary PPRS scheme. The actual impacts will therefore be commensurately reduced.

Summary of Costs and Benefits

Reducing the prices of branded pharmaceuticals should lead to a direct cost saving in the NHS – with no loss of health benefits – as less expenditure is incurred in providing the medicines currently purchased.

Pharmaceutical companies are expected to suffer an equivalent loss of revenues, and a corresponding loss of profits. However, this loss may be partially offset by two factors:

i) the NHS is expected to spend some of its savings on more medicines, replacing some of companies' lost revenues

ii) companies are expected to incur lower sales and marketing costs after the price cut, partially offsetting the loss in profits

These offsetting effects mean that the gains of the NHS will outweigh the profit losses of industry, implying a net beneficial impact.

To the extent that pharmaceutical companies lose profits, there will be a redistribution between shareholders in these companies and patients in the NHS.

The price cut only applies to current medicines. The possibility of an indirect effect on R&D via future prices has been considered, but it is thought unlikely to be significant, because:

- it is unclear whether companies' expectations of future prices will actually change;
- prices of products launched in the future will not be directly linked to the prices of existing products affected by the current proposal
- the UK only represents a small proportion of the global market for pharmaceuticals.

The Office of Fair Trading[3] and NERA[4], conclude that pricing has little or no impact on UK R&D investment. That said, NERA found that firms often have a number of alternative locations for investment assets that are broadly equal in other dimensions, and in these situations market conditions can be an influence on the ultimate choice[5].

[3] http://www.oft.gov.uk/advice_and_resources/resource_base/market-studies/price-regulation

[4] http://www.nera.com/Publication.asp?p_ID=3277

[5] However, it should be noted that OFT were sceptical of this view.

Costs: Cost savings in the NHS[6]

Annual spending on branded pharmaceuticals

The NHS in the UK is expected to have spent over £9bn in 2008 on branded pharmaceuticals[7]. However, the price cuts will not be effective on all of this spending, as explained below.

Price cuts are not effective on spending accounted for by the distribution margin

Generally manufacturers allow the supply chain a 12.5% discount from the list price of branded pharmaceuticals[8]. This enables wholesalers to cover their costs for distributing medicines. Some of this discount is passed on to pharmacies who in turn have an amount deducted through the discount clawback scale.

Cost savings

The price cut is only effective on the set of currently approved branded medicines. In time, these products will lose patent protection, after which generics are expected to take the bulk of market share, and generic prices are determined by other arrangements, which will not be affected by the price cut. Therefore, the impact of the price cut will diminish as the current product set loses patent protection.

After adjusting for low-cost product exemptions, the savings from the price cut are estimated to be in the region of £245m (UK) in primary care[9] in 2009/10.

Savings from the hospital sector are difficult to forecast, but they are expected to be less significant and they have not been monetised.

[6] By convention, impacts affecting government spending are reckoned as costs. In this case, the impact is a cost saving to the NHS – i.e. a negative cost.

[7] PCA (Net Ingredient Cost) and Pharmex data, 2007, projected to 2008.

[8] Although recent developments in the supply of medicines means that this may be changing

[9] Normally benefits (and costs) would be valued over a longer time frame and expressed in Net Present Value terms. As these arrangements are intended as an interim measure subject to review, a net present value over, say, ten years, would not be very meaningful.

Benefits: Negative impact on profits in the pharmaceutical industry[10]

Overview of benefits

It is assumed that the price cut, with exemptions for low cost products, will not result in companies selling at below production costs so pharmaceutical companies will continue to supply products after the price cut. This means that there is no loss of health benefits to patients in the NHS due to withdrawal of medicines currently supplied.

The major benefit of the price cut is, in fact, a net *negative* effect on the profits of pharmaceutical companies, as they receive less revenue for the medicines they supply.

The loss in revenue to the pharmaceutical industry may be partially offset by two factors: increased spending on medicines (using the cash released from the price reductions); and lower sales and marketing costs.

Impact on supply of pharmaceuticals

In patent medicine prices will remain significantly greater than the cost of their manufacturing and distribution, it is therefore assumed that pharmaceutical companies will continue to supply products following the price cut. This means there will be no resulting loss of health benefits for the NHS.

While this assumption is likely to hold true for the great majority of pharmaceuticals, it is possible that the price cut will make supply uneconomical in the case of some niche products,. It is therefore proposed that the price cut shall not apply to products that have a reimbursement price less than £2.00, or a relevant annual cost to the health service in England of not more than £450,000.

Direct reduction in company revenues due to price cut

Companies will lose sales revenues equal to the savings in the NHS – after taking account of the pharmacy distribution margin.

Extra sales due to NHS spending savings from the drugs bill

It is assumed that the NHS reallocates the savings it makes on its drugs bill in the same way it allocates its current budget – that is, a proportion will be spent on additional prescriptions of branded pharmaceuticals, at the new price level.

It may be that these additional sales will be more profitable, on average, than current sales. This is because any additional drugs purchased by PCTs are likely to be new branded products – such as those for which NICE guidance has been issued. However, this calculation makes the conservative assumption that the additional sales will generate average levels of profit.

After accounting for the distribution margin, the NHS spent 8% of its budget in 2007 on branded pharmaceuticals[11]. It may therefore be estimated that 8% of savings resulting from the proposed price cuts will be spent on pharmaceuticals. This factor is adjusted downwards to 7% to allow for the costs of manufacturing this additional volume of products[12].

Reduced sales and marketing costs

Companies have the objective of maximising the profits they are able to return to shareholders. Profit is the difference between revenues and costs. Pharmaceutical company revenues are

[10] By convention, all impacts beyond effects on government spending are reckoned as benefits – in the case of the impact on the industry these are negative benefits.

[11] Chief Executive's report 2007; PCA data.

[12] This implies marginal manufacturing costs of 12.5% of sale price

expected to reduce, as described above. However firms are expected to manufacture and supply the same volumes of product as before the price cut. The costs of production and distribution for existing sales should therefore not be affected. As described above, R&D costs are also not expected to be affected. However, there is one type of cost that is expected to change – sales and marketing.

Pharmaceutical companies spend significant proportions of their income on sales and marketing, in order to make prescribers aware of their product, and grow market share. If the market value of pharmaceutical sales is reduced with a price cut, it is reasonable to suppose that companies will have less incentive to spend on sales and marketing (in particular in supporting out of patent brands: if the value of sales is less, there must be lower returns to sales and marketing expenditure)[13].

This reduction in spending on sales and marketing would reduce company costs, and partially offset the loss of revenue after the price cut.

The magnitude of this effect has not been calculated. It is therefore currently included as a "non-monetised" impact.

On the basis of the savings figure estimated above, The loss to the pharmaceutical industry in lost profits is therefore estimated to be £225m per year.

Net benefit

The net benefit of the price cut is calculated as +£20m per year[14]. This net benefit represents a mixture of consumer and producer surplus from the purchase by the NHS of an increased volume of branded drugs.

Redistributive effects

In addition to reporting the calculated net benefit, it is important that any economic evaluation identifies any significant redistributive effects of a policy. For example, if redistribution is not considered, the net benefit will effectively treat £1 gained by a rich individual as being equally valuable to £1 gained by a poor individual.

This policy will lead to some redistribution of wealth from shareholders to the NHS (and ultimately either patients or taxpayers). However it is difficult to quantify such an effect as we would require equity weights that relate to the gainers and losers, and the latter will be represented by UK and foreign shareholders, making such a calculation difficult.

[13] To see why this is true, consider the extreme case where the price of a product is reduced to the cost of production. Now any spending on sales and marketing would cause the company to make a loss on the product – therefore spending on marketing would cease, even if that meant that there were no sales of the product.

[14] Because the NHS is reckoned to generate benefits worth £2 for every £1 of additional spending, costs accruing to the NHS are usually doubled before calculating the net benefit, in order to take account of the true cost of the benefits foregone. However, to maintain consistency with previous analyses, this doubling has not been effected here.

Enforcement sanctions and monitoring

Option 2 would be enforced under sections 263 to 266 and 272 of the National Health Service Act 2006. Companies would have a right of appeal in accordance with regulations under section 265(5) of the National Health Service Act 2006.

The statutory measures to control the prices of branded medicines from 1 February 2009 would apply to those companies who chose not to sign up to a new voluntary scheme or in the event of failure to reach agreement.

Implementation and Delivery Plan

Staff in Medicines Pharmacy and Industry Group will be responsible for the implementation and enforcement of the price cut of 3.9% per cent.

Competition Assessment

Overview

This section provides analysis of the potential impact of the proposed price cut on competition in the market for branded pharmaceuticals.

First, the structure of the branded pharmaceutical market is described. It is argued that an important basis of competition in this market is spending on sales and marketing – rather than price, or quality, both of which cannot be changed in the short term. This means that conventional assessments of competition may not be applicable.

To determine whether the price cut is likely to influence competition, an OFT filter identifying likely competition impacts is used. It is shown that a socially undesirable effect is unlikely.

Competitive structure of the branded pharmaceuticals market

The total market for branded pharmaceuticals is divided into many sub-markets, based around disease states. Within an individual disease market there may be many additional sub-markets reflecting different stages of disease progression, variations in characteristics of patients and other factors.

Manufacturers of branded pharmaceuticals hold patents, which prevent competitors from supplying the same product. Nevertheless, for many disease markets there are substitute products available. This means that competition is heterogeneous: some markets may be served by many substitutable brands, while other markets may be dominated by a single product, if it is the only treatment available.

Competition among in patent pharmaceutical products is based more around sales & marketing, rather than price

In the long run, competition on quality provides incentives for investment in R&D and new product development. Companies compete to bring to market new innovative medicines that can provide health improvement relative to existing medicines and generate returns, and to be first to market where a number of companies may be carrying out R&D in similar areas.

Therefore, there are strong incentives, largely driven by the intellectual property regime, to compete in the R&D process.

Prices in this market are subject to arrangements under the Pharmaceutical Price Regulation Scheme. Firms are able to influence the price of their product, particularly at launch, but the final level is set within the scheme. Moreover, purchasers of branded pharmaceuticals – usually prescribing physicians – are not very aware of relative prices of products (except to the extent that they are generally aware that generics are usually considerably cheaper than brands).

These characteristics of the pharmaceutical market mean that pricing is generally not competitive – in the traditional sense. Consistent with this notion it is observed, and generally accepted, that prices far exceed marginal production costs for virtually all branded pharmaceuticals.

Without price competition, consumer choice in markets for branded pharmaceuticals is largely determined by two factors:

i) the performance or quality of the product

ii) sales and marketing

In the long run, competition on quality provides incentives for investment in R&D and new product development. But in the short term, firms are unable to substantially change the quality of existing products. This means that the most important basis of competition for existing products is sales and marketing.

The social impacts of sales and marketing are complex. While initial spending on sales and marketing is likely to have a socially beneficial effect, as consumers/purchasers gain information to help them make choices, excessive levels of sales and marketing can have a social cost, as companies gain market share by exploiting asymmetry of information. In pharmaceutical markets, it is likely that competitive spending at the margin on sales and marketing has a negative social impact[15].

Assessment of price cut using OFT criteria for identifying potential competition issues

The OFT has developed a filter to determine whether a regulatory proposal is expected to have an impact on competition. It consists of the following questions:

Would the proposal

a) Directly impact the number or range of suppliers?

b) Indirectly impact the number or range of suppliers?

c) Limit the ability of suppliers to compete?

d) Reduce suppliers' incentives to compete vigorously?

Impact on the number or range of suppliers

Manufacturers of branded pharmaceuticals are multi-national companies operating in global markets. The number and range of suppliers is determined by revenue streams and production economics on a global scale. The UK comprises approximately 3.5% of this market, and any change in UK pricing will have a negligible effect on the viability of these global businesses.

Moreover, the present price cut is directly targeted at existing products, whose marginal cost of production will still be far exceeded by their price. As described above, it is not expected that the price cut will have a significant effect on companies' expectations for profits from future products. This means there will be no significant effect on decisions to employ capital in the pharmaceutical industry.

[15] Gonul et al., 2001. "Promotion of prescription drugs and its impact on physicians' behaviour choice." *J Marketing* 65:79-90. References therein describe results of other studies.

For these reasons, it is considered highly unlikely that the number or range of suppliers will be affected, directly or indirectly, by this price cut.

Impact on the ability of suppliers to compete

As described above, a major basis of competition in branded pharmaceuticals is sales and marketing. A price cut will reduce the profits available from spending on sales and marketing. It may therefore reduce the ability and incentives of suppliers to compete vigorously, inasmuch as it constrains their spending on competitive sales and marketing. However, this would very likely be a beneficial effect, as sales and marketing is likely, at the margin, to have a negative social impact.

Overall, the price cut is not expected to have any socially detrimental effect through an impact on competition.

Other Specific Impact tests

Small Firms Impact Test

The proposed price cut is not expected to impose additional regulatory burdens on companies – so there is not expected to be a differential negative effect on small firms. In fact, the exemption of low-cost products might be expected to result in a slightly more favourable impact on small firms, overall.

It should be noted that companies with sales of less than £25m continue to enjoy exemption from information provisions under this scheme.

Legal Aid

The proposals will not introduce new criminal sanctions or civil penalties.

Sustainable Development

The Department does not envisage any impact on sustainable development from the proposals.

Carbon Assessment

The Department does not envisage any change in emission of Greenhouse Gases resulting from the proposals.

Other Environment

The Department does not envisage any other adverse environmental impacts from the proposals.

Health Impact Assessment

The proposals are expected to have an overwhelmingly positive impact on health, as the savings from current pharmaceutical expenditure are used to fund additional treatments and services. As over £200m per year will be released for the health service to spend on additional health interventions, this will result in increased health for the UK population.

Human Rights

The Department does not envisage any adverse impacts on human rights.

Rural Proofing

The Department does not envisage any different impact on rural areas.

Equality Impact Assessment

The Department has also carried out a DH Equality Impact Assessment, which is annexed to the consultation document.

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	No
Disability Equality	No	No
Gender Equality	No	No
Human Rights	No	No
Rural Proofing	No	No

Summary of Responses to the Department of Health's Consultation on a Statutory Scheme to Control the Prices of Branded NHS Medicines

December 2008

Introduction

The National Health Service (NHS) spends about £9 billion a year on branded prescription medicines in the UK. The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism, which the Department of Health (on behalf of the UK Health Departments) uses to control the prices of these branded medicines, by regulating the profits that companies can make on their sales. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry, which is represented by the Association of the British Pharmaceutical Industry (ABPI). The PPRS seeks to achieve a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry to enable it to research, develop and market new and improved medicines for the benefit of NHS patients. It has existed in various forms in the UK for over 50 years but has been renegotiated every five years or so and the terms of the scheme have changed over time to reflect developments in the NHS and the pharmaceutical industry.

At the beginning of August 2007, the Government announced its intention to renegotiate the PPRS. As well as renegotiating the PPRS, the Government planned to implement a statutory scheme that would apply to any company that chose not to join the new voluntary scheme or that would apply to all companies in the event of failure to reach agreement on a new scheme.

The Department of Health and the Association of the British Pharmaceutical Industry announced on 19 November 2008 that they had reached agreement on a new PPRS that would apply from January 2009 (the 2009 PPRS).

The consultation

On 18 June 2008, the Government published the *Consultation on a Statutory Scheme to Control the Prices of Branded NHS Medicines*. It sought views on the Government's use of statutory powers to introduce a statutory scheme to
Control the prices of NHS branded medicines. The statutory scheme would apply to any company that did not sign up to a voluntary PPRS or to all companies in the event of failure to reach an agreement on a new scheme. The consultation was in two stages:-

- a consultation on the introduction of statutory controls on the prices of branded medicines, including a temporary price freeze (this part of the consultation ended on 15 July 2008), and
- a consultation on the introduction of a price cut that would be implemented in January 2009 (this part of the consultation ended on 25 September 2008).

A total of 66 responses were received for both stages of the consultation. 12 of the respondents responded separately to each stage of the consultation. Some of the respondents responded only once, and used a single response to cover both stages of the consultation, while some responded to only one stage of the consultation. Annex B lists the respondents.

Some stakeholders further discussed the issues consulted on at meetings with the Department.

Statutory scheme

After completion of the first stage of the consultation, on 21 July 2008 the Government laid regulations *The Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008, S.I. 2008/1938* which came into effect on 1 September 2008. These regulations provided that, subject to certain exceptions, no price increases were permitted from 1st September 2008 so that maximum prices were in effect frozen. They also included other provisions, such as requirements to provide information and enforcement provisions. The regulations are available at:
http://www.opsi.gov.uk/si/si2008/uksi_20081938_en_1

Revised Regulations are being introduced in the light of responses received during the second stage of the consultation.

This report

This report summarises the themes arising in the written responses to the consultation, and the Government's responses to them.

The key themes emerging from the consultation responses were:

- Widespread support for exemptions proposed for small companies.
- Widespread support for retention of freedom of pricing for new active substances.
- Many thought that the 1 January implementation date for the price cut should be delayed.
- Many said that there was no need for the Government to set discount levels for medicines.
- Many said the price control should apply to list prices.
- Many perceived the information requirement proposed as unnecessarily burdensome.
- Though there were varied comments on the penalties proposed, a significant number of respondents thought they were punitive.

Annex A summarises developments on the new PPRS that will begin on 1 January 2009 and the statutory scheme the Government plans to bring into effect from February 2009.

Summary of key responses to the consultation questions and the Government's responses to them

Price cut

***Question 1*: We asked, "Views are invited on the proposed level of price cut and the date from which it would apply. Should the level of price cut be equivalent to 5 per cent? Should it apply from 1st January 2009?"**

More than a third of respondents commented on this question. Many did not comment on the level of price cut, though a few said there was no need for a price cut.

A lot of the respondents thought that 1st January was not a good date for implementation as the Christmas period is the busiest time of the year for both prescribing and dispensing, which could lead to problems in the supply of medicines. Some went further to say that wholesalers would aim to reduce stock prior to the price cut and that could compound supply problems.

Government's response
After due consideration, the Government decided to implement a price cut of 3.9 per cent on 1st February 2009. This mirrors the price cut that is due to be implemented in the voluntary scheme (the 2009 PPRS) that has been agreed between the Government and the pharmaceutical industry. There will be a subsequent price cut of 1.9 per cent in January 2010, which will also mirror provisions in the 2009 PPRS.

***Question 2:* We asked, "Should the prices of out of patent branded medicines be set at a price that is 1.5 times the reimbursement price of the equivalent generic price? If not, should the level of the price cut be adjusted to compensate for loss of savings?"**

Some respondents expressed the view that the consultation document was not clear as to whether the 1.5 times premium was optional or fixed. Therefore, varying arguments emerged on this question:

Some thought that the premium should be fixed while others thought it should be optional.

Some felt the proposal was unnecessary and that market forces should determine prices.

Others supported the proposal as stated

Some said off-patent medicines should be priced at Drug Tariff prices

A few said that the proposal did not take account of all the full regulatory protections

Government's response

The proposal to limit the prices of out of patent branded medicines to 1.5 times the reimbursement price of the equivalent generic medicine had at one stage formed part of the agreement on the voluntary scheme. This was later replaced by a proposal to implement generic substitution. The proposal to limit the prices of out of patent branded medicines to 1.5 times the reimbursement price of the equivalent generic will therefore not be part of the statutory scheme that will come into force in February 2009. Generic substitution will be implemented separately and will not form part of the statutory scheme.

Exemptions

***Question 3:* We asked, "Should any exemptions from the price cut and freeze apply in given circumstances:**

- **Should there be an exemption from the price cut or freeze on the grounds that the supply of that medicine may be jeopardised? If so, what should the criteria be?**
- **Should there be a mechanism for exempting medicines during the life of the scheme on other grounds? If so, what should the criteria be?**

• Should GSL (general-sales-list), and P (pharmacy) medicines be excluded from the price freeze or the price reduction? That is to say, should the price cut and freeze be limited to prescription-only medicines (POM)?
• Should inexpensive medicines, say less than a defined cost per packet, be exempt from the price cut and freeze? If so, what should this defined cost be?
• Should small companies or medicines on which the NHS spends comparatively little be exempt from the price cut and/or freeze? If so, what annual expenditure should define exemption? For companies with sales of £25 million or less, should the first £5 million of sales be exempt?
• Should the overall percentage price reduction be increased to compensate for any exemptions?"

About a third of respondents commented on this question.

Many did not think that the exemptions proposed for some categories of medicines were necessary for the price freeze nor the price cut. However, some respondents felt that the exemptions should be applied by the Government where there were potential supply problems.

There was a lot of support for the exemptions proposed for small companies, with some saying that they should go further.

A lot of respondents did not think that the level of price cut should be increased to compensate for any exemptions.

Government's response

Products may be exempt from price control regulations for a period of time, either on the election of the Government or in response to an application from the relevant manufacturer or supplier on grounds that the supply of that medicine may be jeopardised. In addition, low cost presentations of prescription only medicines (POMs) will not be subject to the price reduction measures. A "low cost presentation" refers to a presentation that (i) has a relevant cost to the health service in England of not more than £450,000, or; (ii) has a reimbursement price less than £2.00.

Price Increases

Question 4: **We asked, "What should the mechanism be for price increases? What considerations should the Secretary of State take into account in deciding whether to grant an increase?"**

Not many respondents commented on this question, but those who did broadly said that the new PPRS should allow price increases in some circumstances for economic reasons.

A few also said that price increase arrangements should be equitable under both statutory and voluntary schemes.

Government's response

We have considered the comments. The Regulations make provision for the Secretary of State (either on his own motion or on application from a manufacturer or supplier) to assess and make a decision on a price increase.

Discounts

Question 5: **We asked, "Views are also sought on the following questions:**
• Should the price control apply to the list price or the factory gate price?
• What should be done in cases where the NHS procures medicines outside the traditional wholesaler route such as through tenders or contracts?

• Should a minimum discount be set? Alternatively, should the revised prices take account of discounts and further reduce the price?
• Given that discounts offered by manufacturers affect the cost of acquisition for the NHS, what further information should be collected on levels of discount and how often?"

About a quarter of respondents commented on whether list or factory-gate prices should be used, and they said that list prices should be used because factory-gate prices are not transparent.

Most, if not all of those who commented on the second aspect, said that existing arrangements for NHS medicines procured outside the traditional wholesale route need not be changed.

Most of those who commented on whether minimum discounts should be set by the Government said that there was no need for the Government to do that. A few added a caution that there may be competition law aspects to consider were the Government to set discount levels.

The few that felt that discount levels should be set by the Government supported their views with the arguments that it would allow wholesalers to compete for customers and it would be prudent to set discount levels in the statutory scheme.

Government's response

The price control will apply to NHS list prices only. Although the Government will not set a minimum discount level, it will seek transparency on the levels within the supply chain to ensure that the NHS obtains value for money and that the price controls are not eroded through changes to discounts.

Information

In the consultation, the Government proposed to seek information to monitor proposed price controls and their impact. The information required was based on that required in the Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007 although additionally sales in respect of each pack size and strength of a branded product was required, and the Government proposed that such information be submitted monthly. Amongst other things, the information was to allow the Government to determine whether the benefit of the price reduction to the NHS is eroded by a reduction in discounts, which would otherwise have to be compensated under the new pharmacy contract.

Question 6: **We asked, "What information is required to monitor the price reduction and freeze?"**

A little over a third of respondents commented on this question. Most of them felt that there was no need for DH to request additional information to the information it already had.

Some described the information request proposed in the consultation as being burdensome.

Government's response

At the end of the first stage of the consultation, the Government considered comments from respondents and introduced the information requirements proposed in the consultation document. The Government considered that monthly reporting was appropriate for a scheme that was expected to last four months. In the light of subsequent comments received in the second stage of the consultation, the Government is amending the Regulations so that the returns are required quarterly instead of monthly. Companies with NHS sales of less than £25m will be exempted from the information provisions.

Pricing of new products

As well as freezing the prices of existing products, the Government proposed in the consultation that there should be controls on the maximum price of new products. The consultation document said, "New products that are new active substances would have freedom of pricing on entering the market. However,

the Secretary of State will be able to set the maximum price of products that are not new active substances by issuing a direction. In deciding the maximum price, he would take the following factors into account:
• the expected level of sales of the new product to the NHS,
• the cost of therapeutically similar medicines,
• the cost of the new product in other markets if it is available elsewhere in the world,
• the cost of manufacture of the new product,
• the cost of research and development of the new product,
• whether any need on reasonable terms for the product will be met at the maximum price.
Any decision of the Secretary of State may be subject to appeal."

Question 7: **We asked, "This consultation invites views on the proposed criteria for setting the prices of new products introduced during the price cut and freeze. Should major new products i.e. new active substances retain freedom of pricing?"**

About a third of respondents commented on this question. Many of them supported the Government's proposal to retain freedom of pricing, though a few felt that the proposal should go further to reward non-new active substances that have demonstrated some innovation that would enhance patients' care.

Government's response

The Regulations include provision for the Government to issue a direction setting the maximum price of new active substances. The Secretary of State will consider factors outlined in the Regulations before setting the maximum price. This provision will be applied in a way that gives new active substances freedom of pricing.

Penalties

Question 8**: We asked, "What penalties should be imposed for failure to meet the requirements of the new regulations? Should they be related to turnover?"**

Comments on the penalties proposed were varied. Key messages were that they:

- Were unnecessary
- Were punitive
- Could put some companies at risk of viability
- Should be based on the scale of the breach
- Should be based on the company's turnover
- Should be based on the company's NHS sales

Government's response
After due consideration of the comments received, the Government concluded that it was necessary to protect the NHS and ensure that appropriate sanctions were in place. The penalties introduced were as consulted upon and were based on the precedent set in *The Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000*. The same penalties will continue in the new regulations in 2009.

Impact Assessment and Equality Impact Assessment

Question 9**: We said, "Comments are welcome on the Impact Assessment, in particular the analysis of costs and benefits. Comments are also invited on the Equality Impact Assessment attached to the consultation."**

Not many of the respondents commented on the impact assessment, but the comments broadly said that it did not accurately represent the potential impact on the pharmaceutical industry. Examples were that:

- It made no reference to impact on UK job losses

- It did not accurately represent the implications for smaller companies
- It did not assess the potential impact of some parts of the proposals on the generics market
- It misleadingly implied that only sales and marketing spend would be used to offset loss in revenue caused by a price cut

Government's response

Appropriate amendments, where relevant, have been made to the Impact Assessment. A copy of the final impact assessment is available from the Department of Health website (www.dh.gov.uk).

Additional comments on issues not specifically consulted on

Price freeze issues

A few said that there was no need for the price freeze.

Some respondents expressed the view that it was not easy to separate arguments and comments on the statutory price freeze from issues concerning the 2009 statutory scheme.

Price cut and 2009 PPRS issues

A few of respondents suggested that the Department should explore generic substitution.

Some said there was lack of clarity or confusion about whether the proposal to price off-patent medicines at 1.5 the price of the equivalent generic was optional or fixed.

Many of the manufacturers of NHS branded medicines expressed a view that over or under delivery of savings to the NHS, as a result of the 7 per cent price cut under the 2005 PPRS should be allowed to be carried forward into the new 2009 scheme.

Conclusion

We are grateful for all the responses that we received for both stages of the consultation. They have all informed development of both of the Regulations.

Two important issues that emerged from the consultation that we did not specifically consult on are:

- The Government should explore generic substitution.
- The handling of over or under delivery of savings to the NHS as a result of the 7 per cent price cut under the 2005 PPRS.

We have considered these points, and on 19 November, the Government announced that it will introduce generic substitution as part of the voluntary scheme, but not before January 2010. A copy of the announcement is available at:
http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=384674&NewsAreaID=2&NavigatedFromDepartment=False

A copy of the text of the 2009 PPRS is available from http://www.dh.gov.uk/pprs.

The 2009 PPRS addresses the issue of over or under deliveries of the 7 per cent price cut under the 2005 PPRS.

General comments about the consultation itself will be taken into account in future consultations.

Developments

On 19 November the Department together with the ABPI issued a letter to members and prospective members of the PPRS updating them on agreement made for the new scheme as a result of the consultation and the negotiation discussions. Key components of the new scheme are:

- The scheme will run for a minimum of five years and will be non-contractual and voluntary.

- The Department and the industry have committed to a number of specific initiatives aimed at encouraging and rewarding innovation and assisting the uptake of cost-effective new medicines.

- Two new provisions, flexible pricing and patient access schemes will ensure there is a pricing system that better reflects the value of medicines to patients.

- The new PPRS will preserve companies' ability to set the prices of new active substances.

On 11th December 2008, the Department of Health sent copies of the 2009 PPRS to scheme and prospective scheme members. The new voluntary PPRS starting on 1 January 2009 will introduce 3.9 per cent price cut with effect from 1 February 2009. A further 1.9 per cent price cut will be introduced January 2010.

Subject to discussions with affected parties, the Government will introduce generic substitution from January 2010 with price adjustments in January each year as the proportion of targeted savings from generic substitution varies each year.

In the light of the responses received from the second stage of the consultation, new regulations are being introduced to amend some parts of the statutory scheme that came into force on 1 September 2008. The new Regulations revoke the *Health Service Branded Medicines (Control of Prices and Supply of Information) Regulations 2008, S.I. 2008/1938*. They will apply to those companies that choose not to join the new voluntary PPRS which starts in January 2009.

Annex B

List of respondents to the consultation (some responded to both stages of the consultation, while others responded to only one part)

1. Actavis UK Ltd
2. Archimedes Pharma UK Ltd
3. Dermal Laboratories
4. GlaxoSmithKline
5. Merck Sharp & Dohme
6. Octapharma Limited
7. Schering Plough Ltd
8. Natural Health Pharmacy
9. Somerset Primary Care Trust
10. Sigma Pharmaceuticals
11. Association of British Pharmaceutical Industry
12. Bioindustry Association
13. British Association of Pharmaceutical Wholesalers
14. Pharmaceutical Services Negotiating Committee
15. Devon Local Pharmaceutical Committee
16. Discovery
17. Beacon
18. Grunenthal Ltd
19. Janssen-Cilag
20. Roche
21. Merck Sharp & Dohme
22. BMS
23. Ovation Pharm
24. Wyeth
25. Cambridge Lab
26. NHS Borders
27. Cancer Research UK
28. Alliance Pharmaceuticals Ltd
29. AstraZeneca
30. Eli Lilly & Company Limited
31. Lincoln Medical Limited
32. Nycomed UK Limited
33. Pfizer
34. Teva UK Ltd
35. Avicenna plc
36. Sunderland Local Pharmaceutical Committee
37. Ethical Medicines Industry Group
38. National Pharmaceutical Supplies
39. British Generic Manufacturers Association
40. Community Pharmacy Scotland
41. Royal College of General Practitioners
42. Stragen UK
43. Astellas
44. ALK Abello
45. Alcon
46. Covidien
47. Amgen
48. Prescription Pricing Division
49. Bristol-Myers Squibb
50. Janssen-Cilag
51. Novartis
52. Norgine
53. Sanofi-aventis
54. Board of Community Health Councils in Wales