EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE BRANDED MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) AMENDMENT REGULATIONS 2010

2010 No. 2798

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 change the maximum prices of prescription-only, branded medicines supplied to the National Health Service. These regulations 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 enable the Secretary of State to control maximum prices of health service medicines and medical supplies. They also provide for 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, the 2009 PPRS, started 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 or to any company not being a member of the 2009 PPRS.

4.4 These regulations amend the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008, which provided that, subject to certain exceptions, that prices of medicines should be reduced by 3.9% from 1st February 2008.

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

- ***What is being done and why***

7.1 The National Health Service (NHS) spends about £9 billion a year on branded prescription medicines in the UK. The 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 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 so years. The latest scheme agreed by the Department and the industry started in January 2009 and is intended to last for five years.

7.4 The Department is introducing these amending regulations to control the prices of prescription-only branded NHS medicines from 1st January 2011 at levels which mirror those in the 2009 PPRS and to safeguard the financial position of the NHS by ensuring that there is a statutory fall-back for the PPRS to cover any companies choosing not to be members of the voluntary scheme. These statutory measures do not apply to any company whilst it is 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 January 2011, the maximum price which may be charged for medicines within scope of these regulations is 5.7% less than the price of that medicine on 1st December 2008. The requirement to reduce prices by 5.7% mirrors the arrangements in the voluntary scheme, which also requires a reduction in the prices of branded medicines of 5.7% to take effect from 1st January 2011.

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.

7.8 The information requirements to monitor the proposed price controls and their impact contained in the regulations which this instrument amends remain unchanged, as do the controls on the maximum price of new products and the rights of appeal against any enforcement decisions made by the Secretary of State.

7.9 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. The ABPI were content with the proposed amendments to mirror the effect of the 2009 PPRS from 1st January 2011.

9. Guidance

9.1 The Department has issued guidance on the implementation of these regulations directly to those companies affected and has made that guidance available to the ABPI.

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

13.1 Katy Peters at the Department of Health who may be reached by telephone on 020 79725374 or by e-mail at Katy.Peters@dh.gsi.gov.uk.

Title:	Impact Assessment (IA)
Impact Assessment for the Continuation of a Statutory Scheme to Control the Prices of Branded Medicines in the NHS	**IA No:** 5043
Lead department or agency: DH	**Date: 31/10/2010**
Other departments or agencies:	**Stage:** Final
	Source of intervention: Domestic
	Type of measure: Primary legislation
	Contact for enquiries: Danny Palnoch

Summary: Intervention and Options

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 was implemented from 1st January 2009, including, amongst other things, provision for cuts in the price of branded medicines in 2009 and 2010 and price adjustments in subsequent years. In the absence of statutory fall-back measures, companies could avoid price controls by choosing not to join the voluntary scheme.

What are the policy objectives and the intended effects?

The Government has agreed the PPRS, a 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 and predictability. The 2009 agreement included a pricing package comprising price cuts of 3.9% in 2009, and a further 1.9% in 2010, together estimated to save the NHS £350m per year from 2010. The agreement also permits price increases of 0.1%, 0.2% and 0.2% in 2011, 2012 and 2013 respectively. As part of this package, the Government proposes to continue statutory measures to control the prices of branded medicines, with a price increase from the 1st January 2011. This would match the provisions in the PPRS and apply to companies who were not members of a voluntary scheme.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

The Government has considered the following options:

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

Option1: continue statutory measures to control the prices of branded medicines, with a price increase from 1st January 2011 in order to safeguard the financial position of the NHS. These would apply to those companies who chose not to be members of the voluntary scheme. This is the preferred option.

Will the policy be reviewed? It will/will not be reviewed **What is the basis for this review? duty to review**	**If applicable, set review date 01/2012** **If applicable, set sunset clause date**
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: ***Earl Howe***..... Date: ***18th November 2010***

Summary: Analysis and Evidence

Policy Option 1

Description:

Continuation of the Statutory Scheme to control the prices of Branded Medicines in the NHS

Price Base Year 2010	PV Base Year n/a	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: -0.4**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate			4.9	**4.9**

Description and scale of key monetised costs by 'main affected groups'

Increased spend by the NHS on the primary care drugs bill, leading to less spending on other health services and losses for NHS consumers. Estimated as costs for the NHS of £4.9mn for 2011.

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

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

Rise 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 £2.40.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate			4.6	**4.6**

Description and scale of key monetised benefits by 'main affected groups'

Shareholders in the global pharmaceutical industry gain additional UK profits due to price rise. This gain is estimated as £4.6mn.

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

Growth in spending on Sales & Marketing will partially offset gain of revenue.

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

Key assumptions/sensitivities/risks **Discount rate (%)** n/a

Evaluation for one year only, so no discounting applied.

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

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure classified as
Costs:	**Benefits:** 4.6	**Net:** 4.6	**Yes**	**OUT**

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			01/01/2011		
Which organisation(s) will enforce the policy?			DH		
What is the annual change in enforcement cost (£m)?			£0		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** n/a	**Non-traded:** n/a	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** 100	**Benefits:** 100	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	16
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	13
Small firms Small Firms Impact Test guidance	No	15
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	15
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	15
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	15
Human rights Human Rights Impact Test guidance	No	15
Justice system Justice Impact Test guidance	No	15
Rural proofing Rural Proofing Impact Test guidance	No	15
Sustainable development Sustainable Development Impact Test guidance	No	15

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	PPRS policy website: http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/DH_494
2	
3	
4	

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Total Transition costs										
Total Annual recurring cost										
Total annual costs	4.9									
Total Transition benefits										
Total Annual recurring benefits										
Total annual benefits	4.6									
Business transition costs										
Business annual recurring costs										
Business annual costs										
Business transition benefits										
Business annual recurring benefits										
Business total annual benefits	4.6									

* For non-monetised benefits please see summary pages and main evidence base section

One In One Out

The proposal will result in increased revenues to business of £4.6m in 2011.

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 reached agreement and the new PPRS began on 1st January 2009. This new scheme provides for a number of measures, and imposed an initial cut of 3.9 per cent price cut in the cost of branded drugs sold to the NHS from February 2009, followed by a 1.9% cut in January 2010. The present assessment relates to a scheduled rise of 0.1% in January 2011. For further details on this scheme, see www.dh.gov.uk/pprs.

Purpose and intended effect

Objective

Branded drug prices are controlled by the PPRS - a voluntary agreement between the Department of Health and the Association of British Pharmaceutical Industries - which aims to achieve a balance between reasonable prices for the NHS and a fair return for the industry to enable it to research, develop and market new and improved medicines.

The 2009 agreement included a pricing package comprising price cuts of 3.9% in 2009, and a further 1.9% in 2010, together estimated to save the NHS £350m per year from 2010. The agreement also permits price increases of 0.1%, 0.2% and 0.2% in 2011, 2012 and 2013 respectively.

As part of this overall package,the Department proposes to continue the statutory measures already in place, and allow a price rise of 0.1% from 1st January 2011. This is part of an overall policy to control the prices of branded medicines in order to safeguard the financial position of the NHS. This would continue to apply to those companies who choose not to be members of the voluntary scheme.

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 introduced in February 2009, a further price cut of 1.9 per cent in January 2010 and price increases of 0.1 per cent in January 2011, 0.2 per cent in January 2012 and 0.2 per cent in January 2013;

- 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. Following a full public consultation the Department of Health decided not to progress with proposals to implement the substitution by dispensers of branded drugs for generic versions when dispensing a prescription in primary care. The further use of generic medicines may still provide valuable savings. The Department of Health is instead looking at other ways of supporting the use of generic medicines where it is appropriate and safe.

- 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 has seen the majority of companies choosing to join the voluntary scheme, the Department needs to safeguard the financial position of the NHS. It therefore intends to ensure that the fall-back statutory scheme remains in place for those companies who have chosen not to be members of the voluntary scheme. The Department therefore intends to continue statutory measures as introduced in February 2009, as a fall-back to the 2009 PPRS. Continuing these measures implies a 0.1% statutory price rise in January 2011, to match the PPRS agreement. These statutory measures would apply to those companies who have chosen not to be members of the voluntary scheme. Statutory measures cannot apply to any company who is a member of the 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 rise of 0.1% (in line with the price rise in the voluntary scheme) is applied to branded pharmaceuticals from the 1st January 2011. 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 the following alternatives:

No change - which would leave the NHS exposed to the financial risk of companies choosing not to join the voluntary scheme. Note that prices of branded medicines would remain constant in nominal terms under this option.

Option 1: Continue 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 be members of the voluntary scheme. The measures include a price rise of 0.1%, 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. This 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 0.1% rise 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 be members of the voluntary PPRS scheme. The actual impacts will therefore be commensurately reduced.

Summary of Costs and Benefits

Raising the prices of branded pharmaceuticals will lead to a direct cost increase for the NHS, as more expenditure is incurred in providing the medicines currently purchased.

Pharmaceutical companies are expected to benefit from an equivalent rise in revenue, and a corresponding gain of profits. However, this benefit may be partially offset by two factors:

i) the NHS is expected to fund part of the increased payments by reduced spending on other medicines, reducing the net gain in revenues and profits

ii) companies are expected to incur higher sales and marketing costs after the price rise, partially offsetting the rise in profits

The value of losses to the NHS is expected to exceed the gains to companies.

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

The price rise 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: increased spending on pharmaceuticals in the NHS

Annual spending on branded pharmaceuticals

The NHS in the UK is expected to have spent over £9bn in 2008 on branded pharmaceuticals[6]. However, the price rise will not be effective on all of this spending, as explained below.

The price rise is 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[7]. 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.

Increased costs

The price rise 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 rise. Therefore, the impact of the price rise will diminish as the current product set loses patent protection.

After adjusting for low-cost product exemptions, the additional costs arising from the price rise are estimated to be in the region of **£4.9mn** (UK) in primary care[8] in **2011**. As stated previously, this increase due to the statutory price rise is a maximum estimate, since the majority of firms are expected to participate in the PPRS.

Additional expenditure in the hospital sector is difficult to forecast, but it is expected to be less significant and has not been monetised.

[6] PCA (Net Ingredient Cost) and Pharmex data, 2007, projected to 2008.
[7] Although recent developments in the supply of medicines means that this may be changing
[8] 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: positive impact on profits in the pharmaceutical industry

Overview of Benefits

The major benefit of the price rise is a net positive effect on the profits of pharmaceutical companies, as they receive more revenue for the medicines they supply.

The gain in revenue to the pharmaceutical industry may be partially offset by two factors: reduced NHS spending on medicines (as cash is required to fund the price rise); and greater sales and marketing costs.

Direct reduction in company revenues due to price rise

Companies will gain sales revenues equal to the additional costs for the NHS – after taking account of the pharmacy distribution margin.

Reduced sales due to NHS savings from the drugs bill

It is assumed that the NHS generates the additional funds required for the price increase evenly across current spending areas – that is, a proportion will be derived from reduced prescriptions of branded pharmaceuticals, at the new price level.

After accounting for the distribution margin, the NHS spent 8% of its budget in 2007 on branded pharmaceuticals[9]. It may therefore be estimated that 8% of the price rise is funded by withdrawal of spending that would otherwise have been made on other pharmaceuticals. This factor is adjusted downwards to 7% to allow for the costs of manufacturing these products[10].

Increased 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 from current sales volumes are expected to increase, as described above. However the costs of production and distribution for existing sales should 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 increased with a price rise, it is reasonable to suppose that companies will have more incentive to spend on sales and marketing (in particular in supporting out of patent brands: if the value of sales is greater, there must be higher returns to sales and marketing expenditure)[11].

This growth in spending on sales and marketing would increase company costs, and partially offset the gain of revenue after the price rise.

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 gain to the pharmaceutical industry in additional profits is therefore estimated to be **£4.6mn** in **2011**. Once again, this is a maximum estimate of benefits to the pharmaceutical industry, since the majority of firms are expected to join the PPRS.

[9] Chief Executive's report 2007; PCA data.
[10] This implies marginal manufacturing costs of 12.5% of sale price
[11] 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.

Net benefit

The net impact of the price rise is calculated as a loss of **£0.4m** per year[12].

Redistributive effects

In addition to reporting the calculated net loss, 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 patients in the NHS to shareholders. However it is difficult to quantify such an effect as we would require equity weights that relate to the gainers and losers, and the former will be represented by UK and foreign shareholders, making such a calculation difficult.

[12] Because the NHS is reckoned to generate benefits worth £2.40 for every £1 of additional spending, costs accruing to the NHS are usually increased 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 increase has not been effected here.

Enforcement sanctions and monitoring

Option 1 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.

Companies who chose not to be members of the voluntary scheme.would be subject to the continuing statutory measures to control the prices of branded medicines, and the price rise of 0.1% in January 2011.

Specific Impact Tests

Competition Assessment

Overview

This section provides analysis of the potential impact of the proposed price rise 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 rise 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[13].

Assessment of price rise 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 rise is directly targeted at existing products, whose marginal cost of production will be far exceeded by their price. As described above, it is not expected that the price rise 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.

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

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 rise will increase the profits available from spending on sales and marketing. It may therefore increase the ability and incentives of suppliers to compete vigorously, inasmuch as it constrains their spending on competitive sales and marketing.

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

Other Specific Impact tests

[13] 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.

Small Firms Impact Test

The proposed price rise 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

As the proposals will not introduce new criminal sanctions or civil penalties, a specific Legal Aid impact test has not been carried out.

Sustainable Development, Carbon Assessment and Other Environmental Impacts

The Department does not expect the proposals to have any impact on sustainable development, as they do not increase the quantities of supply or consumption of pharmaceutical products or any other products or services.

Health Impact Assessment

The proposals are expected to have an slight negative impact on health, as the growth in pharmaceutical expenditure is funded by withdrawal of treatments and services elsewhere in the NHS. This effect is quantified and analysed in the main evaluation of Costs and Benefits.

Human Rights

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

Rural Proofing

The Department is not aware of any reason why a 0.1% change in the price of pharmaceuticals should have a differential negative impact on rural areas.

Copy of the Equality Impact Assessment from the 2008 Consultation:

Equality Impact Assessment

Equality Impact Assessment: Introduction of a Statutory Scheme to Control the Prices of Branded NHS Medicines

Summary of the purpose and aim

The NHS spends about £9 billion a year on branded prescription medicines. Prices are controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The Government is currently renegotiating the PPRS with the pharmaceutical industry with the aim of reaching agreement on a new voluntary scheme. The current PPRS expires at the end of August 2008. The Government would prefer to reach agreement on a new voluntary scheme, but if agreement has not been reached by that date, the Government intends to introduce statutory measures to replace the current PPRS from 1st September 2008 in order to safeguard the financial position of the NHS.

Assessment

The proposed policy is not thought likely to impact differently on people on grounds of their race, disability, gender, transgender, age, religion or belief, and sexual orientation. The reasons are that the costs of branded medicines dispensed on a NHS prescription are paid for by the Government. Neither the prescriber nor patient pays the cost of their prescription medicine and the amount paid as a prescription charge, where applicable, is not related to the cost of the medicine. A reduction in the price will have an impact on the profits of pharmaceutical companies supplying branded medicines to the NHS. The Government is consulting on proposals for exemptions from the price reduction to ensure that there is continuity of supply of medicines for NHS patients. The proposals are thought likely to have a positive impact on health as savings from current pharmaceutical expenditure are used to fund additional treatments and services.

Signed by the relevant Director: Mike Brownlee

Name: Mike Brownlee

Directorate: Medical Directorate

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review]; The PPRS provides for annual review and modulation of prices, as described above. In 2014, the PPRS will be replaced by a new policy of Value-Based Pricing. Development of this policy - and the accompanying Impact Assessments - will include a detailed review of pharmaceutical pricing and reimbursement in the NHS. No additional arrangements for review are considered necessary.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]
Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]