EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE BRANDED MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) AMENDMENT REGULATIONS 2009

2009 No. 3030

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 262(1), 263(1), 266(1) and 272(7) of the Act and they will apply to any company which is not 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

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 2010 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 2010, the maximum price which may be charged for medicines within scope of these regulations is 5.8% less than the price of that medicine on 1st December 2008. The requirement to reduce prices by 5.8% mirrors the arrangements in the voluntary scheme, which also requires a reduction in the prices of branded medicines of 5.8% to take effect from 1st January 2010.

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 2010.

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

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment for the Continuation of a Statutory Scheme to Control the Prices of Branded Medicines in the NHS**	
Stage: Final	**Version:** 1.0	**Date: October 2009**
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 was implemented from 1st January 2009, including, amongst other things, provision for a second cut in the price of branded medicines from 1st January 2010. 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 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, sustainability and predictability.

The Government proposes to continue statutory measures to control the prices of branded medicines, with an additional price cut from the 1st January 2010. 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 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. Continue statutory measures to control the prices of branded medicines, with a price cut from 1st January 2010 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.

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 January 2011.

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:

Mike O'Brien..... Date: ***12th November 2009***

Summary: Analysis & Evidence

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

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	Shareholders in the global pharmaceutical industry lose part of their UK profits due to price cut. This loss is estimated as £87mn.
£	
Average Annual Cost (excluding one-off)	
£87mn	**Total Cost** (PV)

Other **key non-monetised costs** 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.

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	Reduced spend by the NHS on the primary care drugs bill, leading to greater spending on health services and benefits for NHS consumers. Estimated as savings for the NHS of £94mn for 2010.
£	
Average Annual Benefit (excluding one-off)	
£ 94mn	**Total Benefit** (PV)

Other **key non-monetised benefits** 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 £2.40.

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 2009	Time Period 1 Year	**Net Benefit Range** (NPV) £	**NET BENEFIT** (NPV Best estimate) **£7mn**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				1st January 2010	
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 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, to be followed by a 1.9% cut in January 2010. For further details on this scheme, see www.dh.gov.uk/pprs.

Purpose and intended effect

Objective

The Department proposes to continue the statutory measures already in place, and impose a price cut of 1.9% from 1st January 2010. This is 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 and a further price cut of 1.9 per cent to 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 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 requires a 1.9% statutory price cut in January 2010, 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 cut of 1.9% (in line with the price cut in the voluntary scheme) is applied to branded pharmaceuticals from the 1st January 2010. 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: 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 cut of 1.9%, 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[1].

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

[1] 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 1.9% 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 be members of 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 benefit 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 incur an equivalent loss of revenue, 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[2] and NERA[3], 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[4].

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

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

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

Benefits: Savings 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[5]. 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[6]. 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.

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 £94mn (UK) in primary care[7] in 2010. As stated previously, this saving due to the statutory price cut is a maximum estimate, since the majority of firms are expected to participate in the PPRS.

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

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

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

[7] 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.

Costs: Negative impact on profits in the pharmaceutical industry

Overview of Costs

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[8]. 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[9].

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 from current sales volumes are expected to reduce, as described above. However the costs of

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

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

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 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)[10].

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 £87mn in 2010. Once again, this is a maximum estimate of costs to the pharmaceutical industry, since the majority of firms are expected to join the PPRS.

Net benefit

The net benefit of the price cut is calculated as +£7m per year[11]. 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.

[10] 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.

[11] 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 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.

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 cut of 1.9% in January 2010.

Implementation and Delivery Plan

Staff in Medicines Pharmacy and Industry Group will be responsible for the implementation and enforcement of the price cut of 1.9%.

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[12].

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.

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.

[12] 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.

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 £90m 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, as part of the consultation in 2008. A copy is attached in appendix A.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

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

Appendix A – 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