EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE BRANDED MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) REGULATIONS 2008

2008 No. 1938

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

2. Description

2.1 These regulations limit 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 Background

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.

4.3 The Department is in the process of renegotiating the current PPRS with the industry and gave six months notice of termination on the current scheme on 29th February 2008.

4.4 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 a new scheme, or in the event of failure to reach agreement on a new scheme with the industry.

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

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 current PPRS provides for the scheme to operate for five years from 1st January 2005 subject to six months' notice of termination of the scheme by either party (which could not take effect before 1st July 2007).

7.4 At the beginning of August 2007, the Department announced its intention to renegotiate the PPRS[1]. The three reasons for the Department concluding that it is necessary to renegotiate the PPRS are:

- an Office of Fair Trading (OFT) published a report on the PPRS[2], which recommended that the scheme should be reformed

- The NHS will be required to make significant efficiency savings[3] over the next three years as part of the Comprehensive Spending Review (CSR).

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[1] http://www.gnn.gov.uk/environment/fullDetail.asp?ReleaseID=304805&NewsAreaID=2

[2] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft885.pdf

- In June 2007, a High Court ruling undermined crucial parts of the PPRS and put in jeopardy the effective operation of the scheme and the delivery of savings from the 7 percent price cut agreed in 2005.

7.5 The Department published its interim response to the OFT report on 2nd August 2007[4] at the same time as announcing its intention to renegotiate the PPRS. This set out the principles, which Department would take into account in discussing proposals with the industry and making further proposals as part of the renegotiation of the PPRS:

- Delivering value for money
- Encouraging and rewarding innovation
- Assisting the uptake of new medicines
- Providing stability, sustainability and predictability

7.6 The Department would prefer to reach agreement on a new voluntary scheme with the industry and the Department and the ABPI have reached agreement on key components of the scheme, though further discussions are required before agreement is finalised and a new voluntary scheme can be implemented.

7.7 On 29th February, the Department of Health gave six months' notice to the ABPI and to scheme members in accordance with paragraph 5.1 of the scheme to terminate the current agreement. Giving six months notice was necessary as a result of the court case, which ruled that the PPRS was a contract. Previously it had been possible to terminate PPRS agreements by mutual consent when agreement on a new scheme had been reached (on the assumption that it was a non-contractual scheme). This means that the 2005 PPRS will terminate on 31st August 2008.

7.8 The Department is introducing these regulations to control the price of branded NHS medicines from 1st September 2008 to safeguard the financial position of the NHS by ensuring that a statutory fall-back for the current PPRS is in place when the current scheme ceases. Whilst the Department expects there will be a new voluntary scheme in place from that date, these statutory measures would apply to those companies who chose not to sign up to any new voluntary scheme or in the event of failure to reach agreement. Statutory measures would not apply to any company that was a member of a voluntary scheme.

7.9 These Regulations protect NHS expenditure by providing that, subject to the exceptions set out below, no price increases will be permitted from 1st September 2008 and maximum prices will in effect be frozen at the reference price. The reference price is the NHS list price used for the purpose of pricing prescriptions by the NHS Business Services Authority on 29th February 2008, the day that the Department gave six months' notice of the termination of the 2005 PPRS. For medicines placed on the market after 29th February, the reference price is the NHS list price on 31st August 2008.

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[3] Value for money reforms realising annual net cash-releasing savings of at least £8.2 billion by 2010-11. Source: 2007 Pre-Budget Report and Comprehensive Spending Review Para D2.6 http://www.hm-treasury.gov.uk/media/4/7/pbr_csr07_annexd2_197.pdf

[4] http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=304783&NewsAreaID=2

7.10 Products may 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.

7.11 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.

7.12 As well as capping 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.

7.13 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.

7.14 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.

7.15 The Regulations will expire after one year, 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.

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

7.17 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. The consultation started on 18th June and terminated on 15th July 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.

7.18 A four week consultation was carried out starting 18th June 2008. Ministers agreed that a consultation period of less than 12 weeks was appropriate in order to

maximise the opportunity for both the industry and the Department to conclude negotiations on a new voluntary scheme. Implementation of these measures cannot be delayed later than 1st September 2008 as that is when the current scheme expires.

7.19 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. 28 responses were received, though 7 responses did not relate to a statutory cap on maximum prices and only 21 responses related to the proposals for a cap on maximum prices.

7.20 The responses showed there was broad consensus in some areas, including:

(i) that the scheme should make provision for price increases (as does the current voluntary scheme)

(ii) that price controls should apply to list prices, not to the factory gate price

(iii) that there should be freedom of pricing for all new active substances.

The Regulations either give effect, or will be applied to give effect, to these areas on which there was broad consensus.

7.21 Views differed in other areas, including:

(i) Whether there should be exemptions and on what basis they should apply.

(ii) Whether the information provisions were appropriate: a number of responses raised concerns that the information provisions could be burdensome.

(iii) The enforcement provisions and whether they should extend beyond repayment of sums owed.

7.22 The Department will make arrangements to ensure that the Regulations are drawn to the attention of existing PPRS scheme members and will prepare guidance on the impact of the regulations.

8. Impact

8.1 An Impact Assessment is attached to this memorandum.

8.2 There is no impact on the public sector.

9. 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 proposal	**Version:** 2.0	**Date:** 18 July 2008
Related Publications: Consultation on a Statutory Scheme to Control the Prices of Branded NHS Medicines		

Available to view or download at:
http://www. dh.gov.uk/publications

Contact for enquiries: Luisa Stewart **Telephone:** 0207 972 5374

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. The current scheme will expire on 31st August 2008 after the Government gave six months' notice to the industry.
The Government is seeking to agree a new voluntary, non-contractual scheme to replace the PPRS. However, if agreement to such a scheme is not reached, branded pharmaceutical manufacturers will be free to raise prices. The NHS will be effectively forced to pay these higher prices, resulting in greater costs of medicines, and a reduction in provision of other treatments to NHS patients.

What are the policy objectives and the intended effects?

The objective of this policy is to safeguard the financial position of the NHS in the event that companies do not sign up to the new voluntary pricing scheme or in case of failure to reach agreement on a new voluntary pricing scheme. It is intended to achieve this by preventing companies from raising branded pharmaceutical prices, which would force the NHS to pay more for the same quantity of medicines currently supplied.

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

The Government has considered the following two options following consultation:

i. No intervention - in which case companies will be free to raise prices for branded pharmaceuticals

ii. Introduce statutory measures to cap the maximum prices of branded medicines from 1 September 2008. 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. (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 September 2009.

Ministerial Sign-off For Final Proposal 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:

Alan Johnson, Secretary of State for Health..... Date: 19th July 2008

Summary: Analysis & Evidence

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

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	
£	
Average Annual Cost (excluding one-off)	
£ -£240m	

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

Protection of NHS from price rises following expiry of PPRS, conservatively estimated at 3%. These would lead to reduced spending on health services and benefits for NHS consumers.

Total Cost (PV) **-£240m**

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

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	
One-off **Yrs**	
£	
Average Annual Benefit (excluding one-off)	
£ -£240m	

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

Shareholders in the global pharmaceutical industry do not gain the additional profits they would have made by raising prices after expiry of PPRS price controls.

Total Benefit (PV) **-£240m**

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

Effect of increased parallel imports on price rises, reducing the additional company profits.

Effect of greater sales and marketing costs after price rises.

Key Assumptions/Sensitivities/Risks

The scenarios described would only arise if a voluntary scheme is not agreed with companies. It is considered likely that such an agreement will be reached.

Price Base Year 2008	Time Period Years	**Net Benefit Range** (NPV) **£ 0**	**NET BENEFIT** (NPV Best estimate) **£ 0**

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			1 September 2008	
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?	Yes	Yes	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 current PPRS scheme expires at the end of August after the Government gave six months' notice on the scheme at the end of February. The Government and the ABPI have reached agreement on key components of the scheme, though further discussions are required before agreement is finalised and a new voluntary scheme can be implemented.

If a voluntary scheme is not agreed, companies will be free to raise prices of pharmaceuticals, unconstrained by any regulation or control. This could result in the NHS paying significant extra costs for the same medicines – which will reduce the spending available for other treatments.

The Government has consulted[5] on proposals to implement a statutory scheme to control the prices of branded NHS medicines. The consultation, published on 18th June 2008, was in two parts. The deadline for responses to the first part which was on the proposal to introduce a statutory cap on the maximum prices of branded medicines ended on 15th July 2008. The consultation the second part which was on implementation of a price cut for branded medicines continues until 25th September 2008. We will publish a summary of responses when the consultation as a whole is completed.

Purpose and intended effect

Objective

The Department proposes to introduce statutory measures to control the prices of branded medicines from 1 September 2008 when the current scheme expires 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

At the beginning of August 2007, the Secretary of State for Health announced the Government's intention to renegotiate the PPRS. The three reasons for the Government concluding that it is necessary to renegotiate the PPRS are:

- In February 2007, the Office of Fair Trading (OFT) published a report on the PPRS, which recommended that the scheme should be reformed. The OFT concluded that the pricing system should have a more value-based approach in order to deliver greater

[5] See http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_085523

benefit to patients and that reform could deliver better value for money for the NHS. A more value based approach would also ensure that the production of clinically and cost-effective innovative products is properly incentivised and rewarded.

- The NHS will be required to make significant efficiency savings over the next three years as part of the Comprehensive Spending Review (CSR). The Government has concluded that it is reasonable for pharmaceuticals, as the largest element of NHS expenditure after pay, to contribute to the efficiency savings that need to be delivered.
- In June 2007, a High Court appeal ruling undermined crucial parts of the PPRS and put in jeopardy the effective operation of the scheme and the delivery of savings from the 7% price cut agreed in 2005.

The Government published its interim response to the OFT report on 2nd August 2007, at the same time as the Department announced its intention to renegotiate the PPRS. This set out the principles, which Government would take into account in discussing proposals with the industry and making further proposals as part of the renegotiation of the PPRS:

- Delivering value for money
- Encouraging and rewarding innovation
- Assisting the uptake of new medicines
- Providing stability, sustainability and predictability

The Secretary of State for Health advised the ABPI in July of the Government's intention to start renegotiations in the autumn of 2007 with a view to reaching agreement on a new voluntary scheme to start as early as possible in 2008.

On 29th February, the Department of Health gave six months' notice to the ABPI and to scheme members in accordance with paragraph 5.1 of the scheme to terminate the current agreement. This means that the 2005 PPRS will terminate on 31st August 2008. (Whilst on previous occasions, it has been possible to terminate PPRS agreements by mutual consent, it is the Department's view, following the court case, that six months' notice is necessary to terminate the current agreement.)

The Government would prefer to reach agreement on a new voluntary scheme with the industry. The Government and the ABPI have reached agreement on key components of the scheme, though further discussions are required before agreement is finalised and a new voluntary scheme can be implemented.

However, the Department also needs to safeguard the financial position of the NHS by ensuring a replacement to the current PPRS is in place for all companies when the current scheme ceases. There may be companies who choose not to sign up to the new voluntary scheme, or the Government and the ABPI may not reach agreement before the current scheme expires. The Department therefore intends to introduce statutory measures to replace the 2005 PPRS from 1st September 2008. These statutory measures would apply to those companies who chose not to sign up to any new voluntary scheme or in the event of failure to reach agreement. Statutory measures cannot apply to any company who is a member of a voluntary scheme.

Options

The Department has identified two options:

Option 1: No change - in which case the effective expiry of the PPRS will leave the NHS exposed to price increases

Option 2: Introduce statutory measures to control the prices of branded medicines from 1 September 2008 in place of the current scheme 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. These measures would cap the maximum prices for branded pharmaceuticals at their final level set under the PPRS.

This option includes information requirements to monitor the proposed price controls and their impact.

The proposed scheme includes 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, rising to a maximum of 50% for the fifth or subsequent contraventions.

The proposed scheme will expire after one year, 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.

Following consultation, the Government's preferred option is Option 2.

Analysis of Costs and Benefits

This section identifies the major expected impacts of the proposed statutory cap in the maximum price of branded pharmaceuticals. It should be noted that controls on the prices of branded medicines already exist in the form of the PPRS, which expires on 31st August. The proposed cap therefore effectively prolongs the status quo.

The analysis evaluates the difference between two scenarios: the base-line situation in which prices rise on expiration of the PPRS; and the impact of the proposals to cap maximum prices, and prevent these price rises.

It should be noted that the statutory cap in maximum prices will only be implemented in the event that agreement is not reached on a voluntary scheme. Therefore any expected costs and benefits should be considered in the light of the probability that such a scheme *will* be agreed – in which case the statutory cap in maximum prices would not need to be applied.

The costs and benefits of applying a statutory cap are considered below as they apply to the pharmaceutical industry (who would benefit from price rises on expiration of the PPRS) and the NHS (for whom price rises would incur a cost).

Description of major expected effect: prevention of a rise in the price of branded pharmaceuticals

Without the proposed statutory cap on the maximum price of pharmaceuticals, manufacturers will be free to raise prices when the PPRS expires if they are not members of a new scheme.

Private companies have commercial objectives, and are obliged to maximise the profits they return to their shareholders. It is therefore to be expected that companies would respond to the expiration of the PPRS price controls by raising prices, in order to increase their profits.

The degree to which prices would be raised is impossible to forecast with certainty. This analysis therefore considers an illustrative – and probably rather conservative – scenario, in which companies raise the prices for branded pharmaceuticals by an average of 3%.

The Regulations will apply for twelve months after which time they will expire[6]. Costs and benefits are therefore considered only over this period.

If companies fail to adhere to the maximum price levels the scheme provides for recovery of excess payments, with an additional premium. If applied, this sanction would impose additional costs on any companies contravening the scheme. However it is assumed in this analysis that companies will not contravene the scheme.

Costs: avoiding additional costs for the NHS[7]

The proposed cap on maximum prices will have the effect of avoiding additional costs for the NHS, which would otherwise be expected as a result of the price rises. This section calculates the magnitude of additional costs that would be avoided, in the event that the cap on maximum prices is implemented – assuming that prices would otherwise rise by 3%.

The NHS in the UK is expected to have spent over £9bn in 2008 on branded pharmaceuticals[8].

Price rises would not be effective on all of this spending, because some of the additional payments to manufacturers is passed on to the supply chain – of which pharmacies take a

[6] This is necessary 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.

[7] 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.

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

significant proportion. Because the profits made by pharmacies are limited, this additional spending will be returned to the NHS under the existing "clawback" system. Generally manufacturers allow the supply chain a 12.5% discount from the list price of branded pharmaceuticals [9] . The impact of price rises would apply to spending on branded pharmaceuticals net of this discount.

Allowing for the effect of the supply chain discount results in a £240m increase in expenditure during the year in which this proposal would be effective, in the scenario of a 3% price rise on expiry of the PPRS.

It is assumed that, over the short time period considered, the NHS would not reduce its consumption of branded pharmaceuticals as a result of the 3% price rise considered on expiration of the PPRS. If price rises were significantly higher this assumption may not hold, and the NHS might reduce consumption of pharmaceuticals. However the cost impacts in such a scenario would be expected to far exceed those modelled here – so the scenario evaluated can confidently be regarded as conservative.

Therefore the net impact of the proposed policy would be a cost saving of £240m for the NHS, in the case of a 3% price rise after PPRS expiry.

Benefits: prevention of increased profits in the pharmaceutical industry[10]

If they are able to raise prices on expiry of the PPRS, branded pharmaceutical manufacturers' revenues will grow by exactly the same amount as the increase in NHS spending.

As described above, it is assumed that the volume of pharmaceuticals would not change. Therefore the companies would occur no additional costs of production or distribution.

It is possible that the availability of greater revenues would give companies stronger incentives to spend on sales & marketing. To the extent that this is true, price rises would lead companies to benefit by less than the additional spending on drugs. The proposed cap on maximum prices would therefore have a net benefit – as the savings for the NHS would then outweigh the increased profits of companies. However this analysis makes the conservative assumption that companies will not change their sales & marketing spending.

The proposed scheme would impose some additional requirements for companies to provide information on their prices. These costs are considered to be effectively negligible, in comparison to the changes in spending described. They are therefore not included in this analysis.

An increase in pharmaceutical prices could also lead to an increase in parallel imports – branded medicines purchased in other countries, and imported for sale to UK pharmacies. This would tend to reduce the profits made by manufacturers from price rises. In order to generate a conservative estimate of the net benefit of a maximum price cap, this possible effect is ignored. To the extent that the effect actually occurs, this would reduce pharmaceutical company profits from price rises, and would therefore reduce the loss of profits associated with caps in maximum prices.[11]

The result of price rises would therefore be that company profits increase by the amount of additional NHS spending.

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

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] Parallel importing companies would gain income that would tend to offset this effect - but the costs they sustain must mean that the profits they gain are less than the profits lost by pharmaceutical companies.

The estimated impact of the cap in maximum prices is therefore that company profits are reduced by £240m in the year in which it applies, in the case of a 3% price rise after PPRS expiry.

Impacts on R&D and investment

It is considered that the proposed cap on maximum prices will have no effect on the long-term incentives for companies to invest in R&D generally, and in the UK in particular. This is because the effective duration of the scheme is too short to effect long-term R&D investment incentives, and because the impact of UK profits on global R&D and investment in UK R&D is not thought to be significant[12].

Net benefit

The net benefit of the cap of maximum prices is zero – as the cost savings to the NHS are exactly offset by the profits lost by companies.

This is a conservative scenario, based on the assumptions that companies would not increase their sales and marketing expenditure under price rises, and that there would be no increase in parallel imports. In reality, it is probable that price rises would induce companies to spend some additional resources on sales and marketing, and would cause an increase in parallel imports. Both these effects would mean that the profits companies gained from price rises would be less than the additional costs to the NHS – so that the effect of preventing price rises would be a net benefit to society.

The above analysis assumes that society gains an equal benefit for funds spent in the NHS as funds spend by private individuals. However this is generally held not to be true: the standard cost which the NHS has to pay for unit of health gain is normally estimated to generate benefits valued at around twice as much[13].

Redistributive effects

It is important to note that the profits pharmaceutical companies would earn by raising prices would be directly transferred from the NHS – and would imply commensurately fewer patients in the NHS. This represents an important redistribution of wealth, which is not reflected in the net benefit figure reported above.

The reduction in profits for pharmaceutical companies will be sustained as a loss by shareholders in these companies. The majority of these investors will be foreign nationals, so the transfer represents a large net benefit to the UK, and a net loss to the rest of the world.

Because the impact on individual investors will be weighted by the number of shares they own, any change in profits will disproportionately affect the wealthiest investors – who own the most shares. However, the benefits for the NHS will be shared on an individual basis between

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[12] Because the UK represents <4% of the global market for pharmaceuticals, even a long-term increase in UK profits is unlikely to significantly change the incentives for companies to invest in R&D. Moreover, it is not clear whether global incentives for R&D are insufficient – or whether they are already inefficiently high. Finally, the existence of a significant connection between UK prices – even in the long run – and incentives to invest in R&D in the UK has been clearly rejected by the OFT (http://www.oft.gov.uk/advice_and_resources/resource_base/market-studies/price-regulation), and in a study by NERA commissioned by the ABPI (http://www.nera.com/Publication.asp?p_ID=3277).

13 The cost to the NHS of purchasing an additional Quality Adjusted Life Year (QALY) – the standard unit of health benefit – is generally held to be around £25,000. However society's value for a QALY is usually estimated as around £50,000. Therefore every £1 spent in the NHS generates a benefit for society of £2.

patients[14]. Therefore, the cap of maximum prices will cause a progressive redistribution of wealth.

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 September 2008 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.

The measures include information requirements that are based on those already set out 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 and information will be required on a monthly basis. 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.

In the Department's view the burden on companies in providing this information will be similar to that which already applies in providing information under the existing voluntary scheme or regulations.

The measures 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.

Implementation and Delivery Plan

Staff in Medicines Pharmacy and Industry Group will be responsible for the implementation and enforcement of this policy.

14 To see this difference, compare the result of distributing a sum evenly between ten individuals, or among ten shareholders. Individuals will simply receive a tenth of the sum. But shareholders would receive an amount determined by the number of shares they owned. If there is any variation in the number of shares own, those with the most shares will receive the largest allocations.

Specific Impact tests

Competition Assessment

The proposals do not result in any reduction in profits for companies compared to those currently available. Companies will be able to reduce prices (and increase them again thereafter provided they do not exceed the maximum price. Therefore no detrimental impact on competition is expected compared to the current arrangements.

For a full discussion of the impact of pharmaceutical price changes on competition, see the "Consultation on a statutory scheme to control the prices of branded NHS medicines"[15].

Small Firms Impact Test

The proposed cap of maximum prices is not expected to have a differential effect on small firms. There is an exemption from the information provisions for companies who have supplied branded medicines for health service use to the value of less than £25 million.

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 a positive impact on health, to the extent that they protect NHS funds currently used to provide treatments for patients.

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.

[15] http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_085523

Equality Impact Assessment

The Department has carried out an Equality Impact Assessment on the introduction of a statutory scheme to control the prices of branded NHS medicines at the consultation stage [16]. This Assessment found that the prices of pharmaceuticals were not expected to have any differential impact on individuals on grounds of their race, gender, transgender, disability, age, sexual orientation, religion or belief. These findings apply directly to the proposal for capping the maximum prices of branded pharmaceuticals.

[16] http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_085523

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