**Title:**
Impact assessment to permit a 0.2% increase in the list price of branded medicines supplied by manufacturers and suppliers under the statutory scheme from January 2012

**IA No:** 6050

**Lead department or agency:**
Department of Health

**Other departments or agencies:**

# Impact Assessment (IA)

**Date:** 07/12/2011

**Stage:** Final

**Source of intervention:** Domestic

**Type of measure:** Primary legislation

**Contact for enquiries**:
Dani Lee
020 797 22983

## Summary: Intervention and Options

**RPC Opinion:** Pending agreement

| Cost of Preferred (or more likely) Option | | | | |
|---|---|---|---|---|
| **Total Net Present Value** | **Business Net Present Value** | **Net cost to business per year** (EANCB on 2009 prices) | **In scope of One-In, One-Out?** | **Measure qualifies as** |
| -£14.8m | £0.2m | -£0.2m | No | NA |

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

The NHS spends about £9 billion a year on branded prescription medicines in the UK. Sections 260 to 262 of the National Health Service Act 2006 set out the powers of the Secretary of State relating to the Pharmaceutical Pricing Regulation Scheme (PPRS) to control the prices of branded medicines. The same legislation also sets out powers to control prices under a statutory scheme for manufacturers and suppliers who are not members of the PPRS. The statutory scheme is intended to be similar in effect to the PPRS, and each year we adjust the statutory scheme to reflect the PPRS. Following this pattern, the 0.2% price increase in 2012 in the PPRS, should be applied to the statutory scheme.

**What are the policy objectives and the intended effects?**

The Regulations safeguard the financial position of the NHS by ensuring that the price cut agreed with the industry as part of the PPRS also applies to companies in the statutory scheme. Following this pattern, the statutory scheme should be amended so that the 0.2% price increase in 2012 in the PPRS, should be applied to the statutory scheme. The only change that will be effected by these regulations is to adjust the price cut compared with 1st December 2008 from 5.7% to 5.5%.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

The Government has considered the following options:

Option 1 – no adjustment to the 5.7% price cut currently set out in regulations.

Option 2: amend the regulations so that the 0.2% price increase under the PPRS from January 2012 to bring the statutory scheme in line with the PPRS. This is the preferred option.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** 01/2013

| | | | | | |
|---|---|---|---|---|---|
| Does implementation go beyond minimum EU requirements? | | | No | | |
| Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base. | **Micro** No | **< 20** No | **Small** No | **Medium** No | **Large** No |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | | **Traded:** n/a | **Non-traded:** n/a | |

***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) that the benefits justify the costs.***

Signed by the responsible Minister: ***Earl Howe*** Date: ***8th December 2011***

# Summary: Analysis & Evidence

Policy Option 1

**Description:**

**FULL ECONOMIC ASSESSMENT**

| Price Base Year 2011 | PV Base Year n/a | Time Period Years 1 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** | **High:** | **Best Estimate:** -14.8 |

| 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** | 15 | | | **15** |

**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 £15m for 2012. This has been adjusted 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.

**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.

| 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** | 0.2 | | | **0.2** |

**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 £0.2m. This has been adjusted by four factors: reduced spend by the NHS, sales and marketing costs, profits accruing to UK shareholders, and redistributive impacts.

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

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 applied only to companies on the statutory scheme as of 2010.

**BUSINESS ASSESSMENT (Option 1)**

| Direct impact on business (Equivalent Annual) £m: | | | In scope of OIOO? | Measure qualifies as |
|---|---|---|---|---|
| **Costs:** | **Benefits:** 0.2 | **Net:** 0.2 | No | NA |

# Introduction

This document relates to the Health Service Branded Medicines (Control of Prices and Supply of Information) (No2) Regulations (referred to as “the Regulations” in this document)

The Regulations limit the maximum price of prescription only, branded medicines supplied to the National Health Service (NHS) and require manufacturers and suppliers of branded pharmaceuticals to provide the Department of Health with information on sales income and discounts. These requirements only apply to any company that is *not* a member of the Pharmaceutical Price regulation Scheme (PPRS) to control the prices of branded health service medicines.

# Purpose and intended effect

## Objective

The Department proposes to allow a price rise of 0.2% under the statutory scheme from 1st January 2012. This is part of an overall policy to control the prices of branded medicines in order to safeguard the financial position of the NHS.

## Background

The PPRS is the mechanism that the Department of Health (on behalf of the UK Health Departments) uses to control the prices of branded medicines. 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 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 applies to those manufacturers and suppliers of branded medicines who are not members of the statutory scheme.

The PPRS 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;

Although the Department has seen the majority of companies choosing to join the PPRS, the statutory scheme is a fall-back to the PPRS and safeguards the financial position of the NHS. Continuing these measures implies a 0.2% statutory price rise in January 2012, to match the PPRS agreement.

# Consultation

Under the National Health Services Act 2006, the Secretary of State is required to consult with the industry body before implementing the 0.2% price increase, and for these purposes, the Department of Health consulted Association of the British Pharmaceutical Industry (ABPI) as the industry body.

## One In One Out (OIOO)

Advice was sought from the Better Regulation Executive (BRE) regarding whether the underlying statutory scheme was in scope of OIOO. The BRE's view is that the underlying statutory scheme is *not* within scope of OIOO as it is a contractual obligation.

## Options

The Department has identified the following options:

Option 1 – no adjustment to the 5.7% price cut currently applied to the statutory scheme. This would mean changes under the PPRS scheme in terms of a 0.2% price increase from January 2012 will not apply to manufacturers and suppliers under the statutory scheme.

Option 2: (this is the preferred option) - to amend the regulations so that the statutory scheme is brought in line with the 0.2% price increase under the PPRS from January 2012. This would apply to those companies who chose not to be members of the PPRS. The measures include a price rise of 0.2%, 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 0.2% 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 only firms under the statutory scheme.

## 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 four 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;

iii) only 6% of global pharmaceutical company profits are returned to UK Plc[2]; and

iv) the shareholders of pharmaceutical companies are likely to relatively wealthy and will be disproportionately affected by the changes 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].

[2] ONS, Standard Industrial Classification (SIC) 24.4 in Annual Business Inquiry (2007). Data for the UK pharmaceutical industry in 2007 show output of £15.8bn, and exports of £15.1bn, resulting in **£731m** of UK production consumed domestically. Added to total pharmaceutical imports that year of £11.4bn, total UK consumption of pharmaceuticals in 2007 was £12.2bn. The proportion of UK consumption produced in the UK is therefore only **6% (£731m/£12.2bn).**

[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 approximately £9bn in 2009/10 on branded pharmaceuticals[6].

*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 to the NHS arising from the price rise (for firms under the statutory scheme) are estimated to be in the region of **£6.2mn** (UK) in primary care[8] in **2012**.

The total NHS budget is fixed, in a given period. Any funds committed to new policies must therefore be reallocated away from some other use, elsewhere in the NHS. To fully reflect the impact of a particular policy, it is important to consider the effect of reallocating funds away from this alternative use. As explained in Annex 2, spending an additional £1 in the NHS is estimated to provide benefits to patients worth £2.40. The full social value of the cost to the NHS of this price rise is therefore **£15mn**.

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

[6] DH Finance.

[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 four factors: reduced NHS spending on medicines (as cash is required to fund the price rise); greater sales and marketing costs; profits diverted out of the UK; and redistributive effects.

*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 distribution margin.

*Reduced sales due to impact on NHS 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 approximately 8% of its budget in 2009/10 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[12].

---

[9] DH Finance.

[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.

[12] Gagnon & Lexchin (2008). The cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the US, *PLoS* Med 5 (1). It is further assumed that advertising of these products is not socially beneficial – which seems likely to be true, given that they have been on the market for many years by the time of generic entry.

*Profits accruing to the UK*

In accordance with the recommendations of the Treasury Green Book, impacts on UK and foreign nationals are reported separately. It is assumed that UK residents own only 6% of the world's capital in the pharmaceutical industry[13], and therefore the remaining 94% of profits are likely to flow abroad. This value should be treated with caution as it is an average and may not relate to all companies in question.

*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 in global pharmaceutical companies. These individuals are likely to be, on average, relatively wealthy – because those with the greatest wealth will own the greatest shareholdings, and will be affected disproportionately by changes in profits. It is necessary to adjust the scale of this impact to reflect the relative wealth of its recipients. Assuming conservatively that they are, on average, in the fourth quintile of income, the Treasury Green Book recommends application of a distributional weighting of 0.75.

Using these adjustments, the gain to the pharmaceutical industry in additional profits is therefore estimated to be **£0.2mn** in **2012**. Once again, this will be applied to all firms on the statutory scheme only.

## Net benefit

The net impact of the price rise is calculated as a loss of **£14.8m** per year. This includes the 2.4 adjustment to take account of the benefits to patients foregone, as explained in Annex 2.

[13] ONS, Standard Industrial Classification (SIC) 24.4 in Annual Business Inquiry (2007). Data for the UK pharmaceutical industry in 2007 show output of £15.8bn, and exports of £15.1bn, resulting in **£731m** of UK production consumed domestically. Added to total pharmaceutical imports that year of £11.4bn, total UK consumption of pharmaceuticals in 2007 was £12.2bn. The proportion of UK consumption produced in the UK is therefore only **6% (£731m/£12.2bn).**

## Enforcement sanctions and monitoring

Option 2 would be enforced under sections 262(1), 263(1) 266(1) and 272(7) 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 PPRS would be subject to the continuing statutory measures to control the prices of branded medicines, and the price rise of 0.2% in January 2012.

# 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 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[14].

## 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.

[14] 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.

# Other Specific Impact tests

## 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 0.2% change in the price of pharmaceuticals should have a differential negative impact on rural areas.

# Equality Impact Assessment

**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 Brinlee

**Name:** Mike Brinlee

**Directorate:** Medical Directorate

# Annexes

## 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];<br>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] |

# Annex 2: Measuring the Opportunity Cost of NHS Spending

The total NHS budget is fixed, in a given period. Any funds committed to new policies must therefore be reallocated away from some other use, elsewhere in the NHS. To fully reflect the impact of a particular policy, it is important to consider the effect of reallocating funds away from this alternative use. The impact of reallocation is the policy's true cost – or "opportunity cost" – that must be measured in Impact Assessments.

To calculate the impact of reallocating funds to a new policy, it is necessary to determine how much benefit would have been realised from the alternative use of those funds. This can be done using DH's standard estimates of the amount of benefits generated by NHS treatments "at the margin" that may be withdrawn if the availability of funding is reduced. These marginal treatments have been estimated to provide health benefits - measured in Quality Adjusted Life Years (QALYs) - at a *cost* of £25,000 per QALY. Importantly, however, society is currently estimated to *value* these QALYs more than twice as highly - at £60,000.

This 2.4:1 ratio of benefits to costs implies that the alternative use of a given quantity of NHS funds will generate benefits valued 2.4 times as highly. This means that any policy which involves spending from the NHS budget will deprive society of benefits worth 2.4 times as much (before the policy's own benefits are taken into account). Similarly, any cost saving measure that releases NHS budget to be spent elsewhere is expected to provide benefits valued at 2.4 times the cost saving.

To correctly reflect the cost impacts of policies and programmes, all effects on the NHS budget should therefore be multiplied by 2.4 in order to calculate their true cost to society. This adjustment reflects the amount of benefits lost by diverting spending to the policy in question – and it follows that the policy should itself generate greater benefits, in order to provide an overall positive impact.