Title:
Statutory scheme for pricing branded medicines
IA No: 5184

Lead department or agency:
Department of Health

Other departments or agencies:
N/A

Impact Assessment (IA)

Date: 18/06/2013

Stage: Consultation

Source of intervention: Domestic

Type of measure: Secondary legislation

Contact for enquiries: Stephen Lock

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

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**
£1,256.8m	-£25m(UK)	£6m(UK)	No	NA

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

The market for branded prescription medicines is not a conventional market, since manufacturers hold patents that provide temporary monopolies over supply of their products. The Government cannot therefore rely on external market forces to provide socially optimal outcomes, and must take action - as one principal purchaser, on behalf of the NHS - to manage the prices paid for medicines. The voluntary Pharmaceutical Price Regulation Scheme (PPRS), which is currently being renegotiated, allows government to control the prices of branded medicines. A statutory scheme is in place to cover companies who decide not to join, or withdraw from the PPRS, but this scheme needs to be aligned more closely to the PPRS.

What are the policy objectives and the intended effects?

The objective is to ensure that the Government safeguards the financial position of the NHS, and therefore patient health, whilst maintaining research incentives, and supply, in the event that some companies do not sign up to, or withdraw from, the voluntary scheme, or in the event that a voluntary scheme is not agreed. It will achieve this by making changes to the current statutory scheme so that it reflects key elements of the existing PPRS, ensuring that the provisions are robust, and introduces a new price adjustment. It is the intention that the price adjustment is similar - in its effect - to that in the new PPRS.

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

Option 1 / Do nothing: The current statutory scheme would continue, and no price adjustment would apply.
Options 2, 3 & 4: Apply a 10%, 15% or 20% downward price adjustment to drugs sold under the existing statutory scheme, based on the regulations underpinning the current scheme.
Option 5: Apply a price adjustment, based on updated regulations, which reflect key elements of the existing PPRS:
- Change the exemption to the price adjustment established by the £450,000 low cost presentation provision, to an exemption for total company revenues of less than £5m, and
- Base the price adjustment on average selling price, rather than list price, for sales to hospitals.
This is the preferred option. For simplicity - and to illustrate the impact of these changes - the calculations are based on a 15% downward price adjustment.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 01/2015

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** Yes	**Large** Yes
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, 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: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing, i.e. a price cut of 0%, with existing regulatory features

FULL ECONOMIC ASSESSMENT

Price Base Year N/A	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** N/A

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

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

N/A

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

N/A

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

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

N/A

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

N/A

Key assumptions/sensitivities/risks — **Discount rate (%)** N/A

N/A

BUSINESS ASSESSMENT (Option 1)

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

Summary: Analysis & Evidence

Policy Option 2

Description: Downward price adjustment of 10%, with existing regulatory features

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** £404.4m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	~£0		£17.7m	**£79.7m**

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

Pharmaceutical companies will see a reduction in revenues as a result of the policy options proposed. The bearers of this loss (which will be reflected in share prices) are the (UK and foreign) shareholders in global pharmaceutical companies.

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

The impact on global incentives for R&D are likely to be insignificant.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	N/A	**Optional**
High	N/A		N/A	**Optional**
Best Estimate	£0		£101.3m	**£484.1m**

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

As a result of the proposed options, the NHS will pay lower prices for drugs, resulting in lower costs of medicines, an increase in provision of treatments to NHS patients and, as a result, a gain in patient health across the NHS.

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

None identified.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

The Government would prefer to reach agreement on a new voluntary scheme with the industry. However, in the event of failure to reach agreement, the statutory measures would apply to all companies, in which case the costs and benefits reported would be more than 10-fold bigger. Estimates of the impact are based on an assumption that supply remains unchanged - companies may refuse to supply if the changes proposed mean that profits would be maximised by not supplying to the UK.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £1.8m,UK	**Benefits:** £0	**Net:** -£1.8m,UK	No	NA

Summary: Analysis & Evidence

Policy Option 3

Description: Downward price adjustment of 15%, with existing regulatory features

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** £606.5m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	~£0		£26.6m	**£119.6m**

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

Pharmaceutical companies will see a reduction in revenues as a result of the policy options proposed. The bearers of this loss (which will be reflected in share prices) are the (UK and foreign) shareholders in global pharmaceutical companies.

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

The impact on global incentives for R&D are likely to be insignificant.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	£0		£151.9m	**£726.1m**

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

As a result of the proposed options, the NHS will pay lower prices for drugs, resulting in lower costs of medicines, an increase in provision of treatments to NHS patients and, as a result, a gain in patient health across the NHS.

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

None identified.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

The Government would prefer to reach agreement on a new voluntary scheme with the industry. However, in the event of failure to reach agreement, the statutory measures would apply to all companies, in which case the costs and benefits reported would be more than 10-fold bigger. Estimates of the impact are based on an assumption that supply remains unchanged - companies may refuse to supply if the changes proposed mean that profits would be maximised by not supplying to the UK.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £2.7m,UK	**Benefits:** £0	**Net:** -£2.7m,UK	No	NA

Summary: Analysis & Evidence

Policy Option 4

Description: Downward price adjustment of 20%, with existing regulatory features

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** £808.7m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	~£0		£35.5m	**£159.5m**

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

Pharmaceutical companies will see a reduction in revenues as a result of the policy options proposed. The bearers of this loss (which will be reflected in share prices) are the (UK and foreign) shareholders in global pharmaceutical companies.

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

The larger the price adjustment, the more detrimental the potential impact on innovation and the supply of valuable medicines.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	£0		£202.6m	**£968.2m**

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

As a result of the proposed options, the NHS will pay lower prices for drugs, resulting in lower costs of medicines, an increase in provision of treatments to NHS patients and, as a result, a gain in patient health across the NHS.

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

None identified.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

The Government would prefer to reach agreement on a new voluntary scheme with the industry. However, in the event of failure to reach agreement, the statutory measures would apply to all companies, in which case the costs and benefits reported would be more than 10-fold bigger. Estimates of the impact are based on an assumption that supply remains unchanged - companies may refuse to supply if the changes proposed mean that profits would be maximised by not supplying to the UK.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £3.5m,UK	**Benefits:** £0	**Net:** -£3.5m,UK	No	NA

Summary: Analysis & Evidence

Policy Option 5

Description: Update regulations to make them more robust - using a 15% downward price adjustment in the calculations to illustrate the impact of proposed changes

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** £1256.8m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	~£0		£55.1m	**£248.1m**

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

Pharmaceutical companies will see a reduction in revenues as a result of the policy options proposed. The bearers of this loss (which will be reflected in share prices) are the (UK and foreign) shareholders in global pharmaceutical companies.

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

The impact on global incentives for R&D are likely to be insignificant.
Administrative costs - both to pharmaceutical companies and the Department of Health - may be greater than that estimated (particularly in the transition period). However, the additional administrative costs are still likely to be relatively small.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	**N/A**
High	N/A	N/A	N/A	**N/A**
Best Estimate	£0		£314.9m	**£1504.9m**

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

As a result of the proposed options, the NHS will pay lower prices for drugs, resulting in lower costs of medicines, an increase in provision of treatments to NHS patients and, as a result, a gain in patient health across the NHS.

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

None identified.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

The Government would prefer to reach agreement on a new voluntary scheme with the industry. However, in the event of failure to reach agreement, the statutory measures would apply to all companies, in which case the costs and benefits reported would be more than 10-fold bigger. Estimates of the impact are based on an assumption that supply remains unchanged - companies may refuse to supply if the changes proposed mean that profits would be maximised by not supplying to the UK.

BUSINESS ASSESSMENT (Option 5)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £5.5m,UK	**Benefits:** £0	**Net:** -£5.5m,UK	No	NA

Evidence Base (for summary sheets)

Background

Pharmaceutical Price Regulation Scheme

The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement made between the Department of Health, on behalf of the UK Health Departments, and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). The PPRS puts in place controls on the prices of branded drugs sold to the NHS. 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.

The PPRS was last negotiated in 2008, with the current scheme coming into force on 1 January 2009 for a period of five years. Notice of termination of the scheme was given in December 2012, and negotiations are now underway on a successor scheme, which will operate from 1 January 2014.

Statutory Price Control

In 2008, the Department of Health consulted on the introduction of regulatory provisions to put in place statutory price controls on the sales of prescription only, branded drugs to the NHS which were not covered through participation in a voluntary PPRS agreement. Unlike the PPRS, it was not proposed that prescribed OTC drugs would be covered. The purpose was to safeguard the financial position of the NHS by ensuring that:

- Some price controls continued to operate after the termination of the 2005 PPRS on 31 August 2008 and until a new PPRS was agreed; and
- Once a PPRS scheme was agreed, for any companies that decided not to join there would still be some control on the prices they charged.

The requirements for this statutory scheme were set out in The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008, which also amend The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007.

The principal elements of the statutory scheme include:

- Establishing a maximum price which can be charged for the supply of a specific drug;
- Setting out the information which companies are required to provide to enable price control mechanisms to operate;
- Providing for certain exemptions to elements of the scheme in relation to low cost presentations; and
- Setting out provisions to cover the enforcement of the scheme.

Problem under consideration

The market for branded prescription medicines is not a conventional market, since manufacturers hold patents that provide temporary monopolies over supply of their products. The Government cannot therefore rely on external market forces to provide socially optimal outcomes, and must take action – as a one principal purchaser, on behalf of the NHS - to manage the prices paid for medicines.

In order to ensure socially optimal outcomes and efficient use of public money, the Government must control prices to ensure that the NHS achieves good value for money for drugs, recognise its duty, as a ‘good global citizen’, to incentivise innovation in the pharmaceutical industry, and maintain supply of valuable medicines:

- The Government must ensure that the NHS gets good value for money from spend on drugs, so that it can maximise the health of patients. The National Institute for Health and Clinical Excellence (NICE) helps to ensure that the price set by manufacturers at launch is such that the drug is cost-effective for the NHS. In many cases, this results in the NHS paying full value for branded drugs at launch. This means that, overall, NHS patients typically lose as much health from treatments displaced as are provided by the new drug, at its launch price. Over the course of drugs’ patents, the

Government seeks to get a better deal from NHS spend on drugs, so that it can provide more treatments to patients in the NHS, and therefore make patients overall better off.

- Research & Development (R&D) investment leads to future benefits through the discovery of more medicines, which provide net benefits to patients (mainly after patent expiry). Companies decide to invest in R&D on the basis of the profits they expect from discovering new medicines. Price controls for existing medicines might create the expectation of *lower* profits for future medicines, which might lead firms to invest *less* in R&D – leading to the discovery of fewer drugs, and fewer benefits to patients. However:
    - The UK cannot significantly affect total incentives for R&D, as it is only a small part of the market. Nevertheless, the Government has decided to act as a 'Good Global Citizen' when determining the socially optimal price to pay for drugs (that is, make its fair contribution towards incentivising investment in R&D). This avoids the possibility that other countries could follow suit if the UK Government cut prices excessively.
    - It is plausible, on the basis of on-going work[1] that paying the full value price for new drugs for the entire patent period may over-incentivise investment in R&D. At some point the additional gains from further investment, in a given time period, must diminish. The most beneficial avenues of research will already be addressed, and further investment would either replicate the research already conducted, or would be targeted to medicines of progressively less value to society.
- The Government must also recognise that, as profit maximisers, pharmaceutical companies could refuse to supply valuable drugs at lower prices because, for example, the effect that a low price could have on international reference pricing.

The voluntary Pharmaceutical Price Regulation Scheme (PPRS) allows government to control the prices of branded medicines set by monopoly providers through a price adjustment(s) which is agreed at the time the PPRS is introduced. This allows Government to get good value for money for the NHS, maintain supply of valuable medicines and recognise its duty as a 'good global citizen' to incentivise innovation. The current scheme will expire on 31st December 2013. The Government is seeking to agree a new voluntary, non-contractual scheme to replace the PPRS.

A statutory scheme is also in place so that companies that choose not to join, or who withdraw from, the PPRS, are also covered by some form of price control. However, this is limited in scope and does not provide the same level of coverage as the PPRS, for example, it does not place controls on average selling prices. Should an increasing number of companies opt out of the PPRS, or should no agreement be reached on the new PPRS, then the NHS will effectively be forced to pay higher prices. This will result in a relatively greater cost of medicines, a reduction in provision of other treatments to NHS patients and, as a result, a loss in patient health across the NHS. The better the deal the NHS gets from drug spend, the more treatments it can give to other patients in the NHS, leaving patients overall better off.

Policy objective

The objective of this policy is to ensure that the Government gets as good value for money as possible from spend on branded drugs, in order to safeguard the financial position of the NHS – and therefore patient health – whilst maintaining research incentives and supply, in the event that some companies do not sign up to, or withdraw from, the voluntary scheme, or no agreement is reached on the new voluntary scheme. It will achieve this by making changes to the current statutory scheme to make it more robust, and to align it more closely to the provisions of the PPRS, in particular applying price adjustments on average selling prices in secondary care.

The key changes the Government proposes to make to the statutory scheme include:

1. Establishing revised reference prices;
2. Introducing a new price adjustment;
3. Changing the exemption to the price adjustment established by the £450,000 low cost presentation provision, to an exemption for total company revenues of less than £5m (in line with the PPRS);

[1] See Annex 2 in the consultation stage IA for Value-Based Pricing, at http://www.dhsspsni.gov.uk/value-based_pricing_impact_assessment.pdf

4. Introducing price controls on average selling prices within hospitals; and
5. Making provisions for line extensions.

The details of each proposed change is described in more detail in the consultation document. Since the expected marginal impact of a) and e) is small, the analysis in the IA focuses on the key changes described under b), c) and d). The options considered are set out in the following section.

Policy options

Option 1 / Do nothing: The current statutory scheme would continue, and no price adjustment would apply. (Note that there may be discounts negotiated by local commissioners and providers locally, but we assume that the global effect of this would be small.) While this would maintain supply of valuable medicines and recognise the government's duty as a 'good global citizen' to incentivise innovation, it would not ensure that the NHS got good value for money from drugs spend.

The impacts of alternative options are estimated in comparison to this.

Option 2: Apply a downward price adjustment of 10% to drugs sold under the existing statutory scheme, based on the regulations underpinning the current scheme. This would allow Government to get good value for money for the NHS, maintain supply of valuable medicines and recognise the government's duty as a 'good global citizen' to incentivise innovation.

Option 3: Apply a downward price adjustment of 15% to drugs sold under the existing statutory scheme, based on the regulations underpinning the current scheme. This would allow Government to get better value for money for the NHS, whilst also maintaining supply of valuable medicines and recognising the government's duty as a 'good global citizen' to incentivise innovation.

Option 4: Apply a downward price adjustment of 20% to drugs sold under the existing statutory scheme, based on the regulations underpinning the current scheme. This would also allow Government to get good value for money for the NHS. However, the larger the price adjustment, the more detrimental the potential impact on innovation and the supply of valuable medicines.

Option 5: Apply a price adjustment, based on updated regulations, which reflect key elements of the existing PPRS:

- Change the exemption that applies to *products* with annual revenue from sales to the NHS of **£450k** or less, to exempt *companies* with annual revenues from sales to the NHS of **£5m** or less. An exemption exists in the voluntary and statutory scheme to protect relatively small companies from price adjustments. Since the low cost exemption in the current scheme is measured through the English community pharmacy data, medicines that are sold wholly in secondary care are not measured through this sales data system and so are effectively exempt from any price controls – whatever the value of their sales or size of the firm. This has led to distortions, since relatively large companies can benefit from exemption from price adjustments, and profit maximising companies can avoid facing price adjustments by setting up separate (relatively large) companies selling drugs mostly to secondary care. The new exemption should mean that only genuinely small firms benefit from exemptions from the price adjustment, while minimising the incentive for the distortionary behaviour described.
- Base the price adjustment on average selling price, rather than list price, for sales to hospitals. Typically, hospitals negotiate substantial discounts on drug list prices. These discounts will typically exceed the value of the price adjustment required by the statutory scheme, meaning that the price adjustment does not have any impact on prices paid by the NHS. The Government proposes that the statutory scheme be revised to apply the price adjustment to Average Selling Prices (ASPs) in hospitals, aligning it to the general approach in the PPRS. The ASP is an average of the prices paid by all hospitals for a specific drug, taking account of all discounts negotiated with the supplier. Price adjustment will then be applied to the ASP, thereby ensuring that the price adjustment does impact on prices paid by the NHS, and that discounts are not eroded.

This is the preferred option. For simplicity - and to illustrate the impact of these changes - the calculations are based on a 15% downward price adjustment.

General scenarios

The impact of the options could depend on the general scenario in which they are implemented. There are 2 potential scenarios that could occur following the introduction of new voluntary and statutory schemes in 2014:

- Scenario 1: All companies enter the new 2014 voluntary PPRS.
- Scenario 2: The companies currently covered by the statutory scheme remain covered by the new 2014 statutory scheme, while the new 2014 voluntary PPRS operates for all other companies.

Those companies most likely to be affected by any change to the statutory scheme are those companies currently in the statutory scheme. Companies currently in the statutory scheme choose to be in the scheme presumably because it is beneficial to them (eg they have low sales to primary care, and high sales to secondary care, which are protected from the price adjustment under the £450k exemption rule described earlier). Changing the statutory scheme is therefore likely to affect them. Since the statutory scheme and voluntary scheme would be aligned under the proposals, the impact of them moving to either will be identical - the impacts of Scenarios 1 and 2 are therefore likely to be the same.

Analysis of Costs and Benefits

There are two main potential impacts of each option:

Gain in health for NHS patients

As a result of the proposed options, the NHS will pay lower prices for drugs, resulting in lowers costs of medicines. Lower expenditure on drugs within a fixed budget devolved to Clinical Commissioning Groups and other NHS commissioning bodies will liberate funds to allow an increase in the provision of other treatments to NHS patients.

In order properly to estimate the impact of the proposals, it is necessary to estimate the consequential gain in patient health across the NHS. NICE uses a threshold of £25,000 per Quality Adjusted Life Year to estimate the health benefits provided by marginal treatments in the NHS. Hence, it is reasonable to assume that reduced spending upon the drugs subject to the lower prices will create improved health outcomes, measured in QALYs, as shown in the table below.

In order to compare the value of these gains in health on the same basis as the costs of the policy options, the health gain must be valued from a societal perspective, based upon estimates of what individuals are willing to pay for their own health gain, following HMT guidance upon the valuation of non-market goods. The Department of Health derives its valuation of a QALY from the estimates of the mean willingness to pay (WTP) for a Prevented Fatality employed by the Department of Transport and other government departments, resulting in an estimated QALY value of £60,000.

Loss in profit for shareholders of pharmaceutical firms (both UK & non-UK nationals)

Pharmaceutical companies will see a reduction in revenues as a result of the policy options proposed. The bearers of this loss are the shareholders in global pharmaceutical companies. In the long-run, changes in companies' revenues will not impact shareholders profitability, since shareholders will always make the risk-adjusted market return on capital. However, in the short run, we may expect shareholders to receive a lower rate of return, and therefore a rate that is lower than the market rate. We assume that 60% of lost revenue would have been taken as profits, after allowing for administration and sales and marketing costs. 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 decreased with a price adjustment, 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 lower, there must be lower returns to sales and marketing expenditure)[2]. This reduction in spending on sales and marketing would reduce company costs, and partially offset the loss of revenue after the price adjustment.

Shareholders are likely to be, on average, relatively wealthy – because those with wealth will own the greatest shareholdings, and will be affected disproportionately by the change in profits. It is necessary to

[2] 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.

adjust the scale of the impact of loss in profits to reflect the relative wealth of its recipients. Assuming conservatively that they are, on average, in the fourth quintile of income, it is appropriate to apply a weighting of 0.7 when calculating the social value of the benefits, in accordance with Treasury Green Book principles.[3]

Finally, in accordance with the recommendations of the Treasury Green Book, impacts on UK nationals and non-UK nationals are reported separately.[4] The Department for Business, Innovation and Skills estimate that 10% of drug spend is on domestic production - that is, output generated by UK factors of production (UK-owned capital or UK labour). We estimate the returns to capital in total, and then assume that these are shared between the UK and overseas in the same proportion that total returns (total spend) are shared between the UK and overseas. This implies that 10% of profits (the return to capital) accrue to UK shareholders, and 90% accrue to foreign shareholders.

[3] See Distribution: Annex 5 in HMT Green Book.

[4] See Chapter 5, footnote 4 of HMT Green Book.

The following tables show preliminary monetised estimates of the impacts of the proposed options. The costs and benefits are expressed first annually, and then in present value terms over a 5 year period. The latter is consistent with the expected duration of the voluntary PPRS.

The Impact Assessment then describes the methodology underlying these estimates, summarises other, non-monetised impacts.

Average annual impacts of proposed options, 2014 prices

Option	QALYs gained	Gain in health for NHS patients, pa	Loss in profit for UK national shareholders, pa (*distribution weighted*)	Loss in profit for non-UK shareholders, pa (*distribution weighted*)	Administrative costs to companies, pa	Global net benefit, pa
1	-	£0m	£0m	£0m	£0m	£0m
2	*1,688*	£101.3m	-£1.8m	-£16m	£0m	£83.6m
3	*2,532*	£151.9m	- £2.7m	-£23.9m	£0m	£125.3m
4	*3,376*	£202.6m	-£3.5m	-£31.9m	£0m	£167.1m
5	*5,248*	£314.9m	-£5.5m	-£49.6m	-£0.04m	£259.7m

Impacts of proposed options, over 5 years, with discounted health benefits (at 1.5%) and costs (at 3.5%), 2014 prices

Option	QALYs gained	Gain in health for NHS patients	Loss in profit for UK national shareholders (*distribution weighted*)	Loss in profit for non-UK shareholders (*distribution weighted*)	Administrative costs to companies	Global net present value
1	-	£0m	£0m	£0m	£0m	**£0m**
2	*8,068*	£484.1m	-£8m	-£71.8m	£0m	**£404.4m**
3	*12,102*	£726.1m	-£12m	-£107.7m	£0m	**£606.5m**
4	*16,137*	£968.2m	-£15.9m	-£143.5m	£0m	**£808.7m**
5	*25,081*	£1504.9m	-£24.8m	-£223.1m	-£0.17m	**£1256.8m**

Option 1: Do nothing

The current statutory scheme would continue, and no price adjustment would apply. The impacts of alternative options are estimated in comparison to this.

Options 2-4: Apply price adjustments

Under options 2-4, a price adjustment would be applied to drugs sold under the existing statutory scheme, based on the regulations underpinning the current scheme. The Government is consulting on 3 options for the price adjustment:

- 2: a **10%** downward price adjustment
- 3: a **15%** downward price adjustment
- 4: a **20%** downward price adjustment

This section describes the data used and assumptions made in estimating the impact of Options 2-4.

Gain in health for NHS patients

Under the current regulations underpinning the statutory scheme, price adjustments are *de facto* applied only to sales to primary care – and only if the revenues from sales to primary care exceed £450k for a given product.

Analysis of the 2010 Prescription Cost Analysis (PCA) suggests that total reimbursement to pharmacists for prescription only medicines sold to primary care by companies not participating in the PPRS and therefore under the statutory scheme in England was £386m in 2010 (uprated to 2014 prices using the HMT deflator).[5] Uprating this, in order to approximate the total impact on the UK (assuming that sales in England account for 80% of the total), leads to a total of **£483m**.

The price reimbursed to pharmacy does not necessarily equate to that paid to pharmaceutical companies, and therefore their revenues. We assume that, on average, a discount of 12.5% from pharmaceutical companies is received throughout the supply chain. Company revenues are therefore estimated at **£423m**.

Multiplying £423m by a price adjustment of **10%**, **15%** and **20%**, gives a total estimate of financial gains to the NHS of **£42m**, **£64m** and **£85m** pa, respectively.

This could purchase **1,700**, **2,500** or **3,400** QALYs in the NHS, valued at **£101m**, **£152m** or **£203m** pa, respectively.

Loss in profit for shareholders of pharmaceutical firms

We assume that **60%** of the revenue lost would have been taken as profits by shareholders in the pharmaceutical industry. Applying the price adjustments being considered as options, gives estimates of **£25m**, **£38m** or **£51m** in total lost profit.

As these profits would have accrued to shareholders who are likely to be at upper end of the second highest quintile of wealth, we apply a weighting of **0.7**, to get a cost of **£18m**, **£27m** or **£36 m**.

It is assumed that **10%** by value of shares in the pharmaceutical industry are held by UK nationals (**£1.8m**, **£2.7m** or **£3.6m**), and **90%** accrue to non-UK nationals (**£16.0m**, **£24.0m** or **£32.0m**).

Option 5: Move to average selling prices for determining price adjustments, and replacing the £450k exemption

Under Option 5, some loop-holes that prevent the price adjustment being applied to the full revenue made by companies on sales of drugs would be closed. This would involve:

- applying a price adjustment to drugs sold to hospitals, which currently benefit from the exemption that applies to products with annual revenue from sales *de facto* to primary care of £450k or less, and

[5] See Annex A for details of this estimate. Note that we assume that reimbursement to pharmacists for medicines sold to primary care in 2013 will not be substantially different from this.

- base the price adjustment on average selling price for sales to hospitals, rather than list price – since there is a risk that basing price adjustments on list price would erode discounts.

This section describes the data used and assumptions made in estimating the incremental impact of Option 5. Note that, for simplicity - and to illustrate the impact of these changes - the calculations are based on a 15% downward price adjustment.

Gain in health for NHS patients

Analysis of 2010 Pharmex data suggests that the total cost to hospitals from drugs sold to secondary care under the statutory scheme is £362m (uprated to 2014 prices, using HMT deflators).[6] Uprating this, in order to approximate the total impact on the UK (assuming that sales in England account for 80% of the total), leads to a total of **£453m**.

Multiplying **£453m** by a price adjustment of **15%** gives a total estimate of financial gains to the NHS of **£68.0m**.

This gives health gain to patients valued at **£163.1m**.

Note that this assumes that:

- All revenue from sales to hospitals that are currently exempt under the £450k exemption would not be exempt under the new £5m exemption rules, because it seems reasonable to expect that these firms are relatively large, since these companies would have been joined the voluntary PPRS (instead of the statutory scheme) if they would have been exempt from a price adjustment under the £5m exemption rule in the PPRS.
- All revenue from sales to primary care that are currently exempt under the £450k exemption would remain exempt from the price cut under the new proposed £5m exemption rule. Since the exemption of drugs with sales to primary care of £450k or less was designed to reflect the £5m exemption per company in the PPRS, this assumption appears reasonable.

Loss in profit for shareholders of pharmaceutical firms

Lost profit for UK national shareholders is estimated at **£2.9m**, and for non-UK national shareholders at **£25.6m**.

Admin Costs for Firms

In order to estimate ASPs, and track progress on delivering on price adjustments against the ASPs, companies would be required to submit annual returns on sales of their products. The Regulations stipulate that all companies must provide this data, so that price adjustments could be applied under the statutory scheme in the event of a company exiting the voluntary scheme. There are currently 150 companies in the voluntary 2009 PPRS, and 38 in the statutory scheme. Since firms in the PPRS are already required to submit this data, the marginal cost to them of the proposed change is zero (or minimal). However, companies in the statutory scheme are not required to provide this data. Although some companies do provide quarterly returns under the statutory scheme (so that the change to administrative costs might be less), most companies do not provide this information. We estimate that, on average, it would take each company **4** FTE days to complete the return per year (with a FTE day valued at **£250**) – the administrative cost is likely to be higher for bigger companies (or will have more sales to record), and less for smaller companies. The total administrative cost of submitting annual returns is therefore estimated at **£38k** pa.

There may also be an administrative burden to companies from putting in place procedures to monitor delivery of the price adjustment against the reference average cost price, and dealing with any issues that arise. It is difficult to predict what issues will arise, or how burdensome they will be, as it will depend on the final design of the statutory scheme. However, they are likely to be higher during transition to the new scheme.

Note that companies under the voluntary PPRS supply this data as a matter of course, with no major problems. We therefore believe that the administrative costs are proportionate.

[6] We assume that cost to hospitals for medicines in 2013 will not be substantially different from this. The details of the analysis underlying this estimate is in Annex A. We assume that none of this revenue is currently subject to a price cut under the current statutory scheme.

'Admin Costs to DH'

There will be some additional administrative burden from processing additional data provided by companies. This is likely to be relatively small, and so we have not monetised this additional burden.

There is likely to be additional administrative costs from dealing with any issues that arise with the scheme. As above, they will depend on the final design of the statutory scheme but are likely to be higher during transition to the new scheme.

Risks and assumptions

This section outlines the main assumptions made in estimating the impact of the proposals outlined in this Impact Assessment, and the uncertainty around them. In the course of the consultation, comments on the validity of these assumptions would be welcome.

Risk that a voluntary scheme is not agreed

The Government would prefer to reach agreement on a new voluntary scheme with the industry. However, the Department also needs to safeguard the financial position of the NHS – and therefore patient health – in the event of failure to reach agreement. In this event, the statutory measures would apply to all companies (including those currently in the voluntary PPRS), in which case the costs and benefits reported in this IA would be more than 10-fold bigger (as the majority of branded pharmaceutical companies are currently covered by the voluntary scheme).

Supply response

The analysis assumes that supply remains unchanged following the proposed change to the statutory scheme. There is a risk that pharmaceutical companies would refuse to supply at the lower price – for example, because of the effect that a low price might have on their profitability when taking account of international reference pricing. This is considered further in the Competition Assessment, below.

Size of the impact on NHS patients and companies shareholders

It is possible that the analysis underestimates the effect of the proposed options on NHS patients and companies shareholders, since:

- Pharmex data excludes expenditure on some products that would be subject to a price adjustment under Option 4. For example, drugs used for home care would be subject to a price adjustment, but expenditure on these products is not captured by the Pharmex dataset.
- The analysis assumes that all revenue from sales to hospital that is exempt under the £450k *per product* exemption applied only to sales to primary care, would no longer be exempt under the new £5m *per company* exemption. This may overestimate the financial cost savings to the NHS if some companies' sales would remain exempt under the new rules.
- There is a risk that companies could set up smaller subsidiary companies with revenue from sales of less than £5m, to avoid the price adjustment under the new exemption, thereby reducing the financial savings to the NHS from the price adjustment. However, this risk is considered small since there is no evidence of this occurring in the PPRS, in which the same exemption applies.

However, there may also be a risk that we have overestimated the effect of NHS patients and companies' shareholders since, under the statutory scheme, there are no powers of auditing the sales and revenue figures provided as evidence of delivery of the price adjustment. Potential mitigations of this risk will be explored during consultation – for example, options include incentivising the provision of good and accurate data through penalties for providing poor quality data.

Estimating the impact on shareholders

Preliminary analysis suggests that:

- 60% of lost revenue would have been taken as profits, after allowing for manufacturing administration and sales and marketing,
- 10% by value of shares in the pharmaceutical industry are held by UK nationals.

We will consider whether it is possible – and proportionate – to conduct further analysis in order to assure the robustness of these estimates.

Wider impacts

Competition Assessment

Overview

This section provides analysis of the potential impact of the proposed changes to the statutory scheme, 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 changes are 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[7].

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

Although it is observed, and generally accepted, that prices far exceed marginal production costs for virtually all branded pharmaceuticals, there is a risk that pharmaceutical companies would refuse to supply at lower prices – for example, because of the effect that a low price might have on their profitability when taking account of international reference pricing. The scale of this risk will be explored during consultation.

Impact on the ability of suppliers to compete

As described above, a major basis of competition in branded pharmaceuticals is sales and marketing. The proposed changes will reduce 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. Overall, the price adjustment is not expected to have any significant socially detrimental effect through an impact on competition.

Small Firms Impact Test

The Department proposes changing the exemption to the price adjustment established by the £450,000 low cost presentation provision, to an exemption for total company revenues of less than £5m (in line with the PPRS). The new exemption will take account of the total revenue of companies, rather than considering sales from one product in one setting of the health care sector. The new exemption should mean that only genuinely small firms benefit from exemptions from the price adjustment, while minimising the incentive for the distortionary behaviour by larger firms. Note that, since the price adjustment is proportional to revenue made by firms, it is considered that any price adjustment applied to relatively small firms would be proportional (i.e. large firms with more revenue will face a bigger impact from any price adjustment than a smaller firm with less revenue).

The Department also proposes requiring all companies to provide data on average selling prices, so that price adjustments could be applied under the statutory scheme in the event of a company exiting the voluntary scheme. This is not expected to impose disproportionate impacts on small firms, as the administrative requirements would be proportional and limited, as identified elsewhere in this IA.

The Department will seek the views of industry on the impact on small firms through the consultation on the revisions to the statutory scheme.

Wider Environmental Impact Test

The Department does not envisage any environmental impact resulting from the proposals.

[7] 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.

Public Sector Equality Duty

The Department does not envisage the proposed policy impacting differently on people on grounds of age, disability, race, religion or belief, gender, sexual orientation, pregnancy or maternity, or gender reassignment. The reasons are that the costs of branded medicines dispensed on a NHS prescription are paid for by the Government. Neither the prescriber or the patient pays the cost of their prescription medicine, and the amount paid as part of their prescription charge, where applicable, is not related to the cost of the medicine. 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. The Department will seek views on whether any impacts have been missed through the consultation on the revisions to the statutory scheme.

A reduction in the price of medicines will have an impact on the profits of the pharmaceutical companies supplying branded medicines. The consultation will also seek views on whether the proposals will have any adverse impact on the continuity of supply of medicines for NHS patients.

Health and Well-Being

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.

Human Rights

The Department does not envisage any adverse impact on human rights as a result of the proposals.

Rural Proofing

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

Justice Impact Test

The Department does not envisage that the proposals will have a significant impact on the justice system.

Sustainable Development

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

Proportionality Approach

It has not been possible to quantify and monetise the full impact of each option. Since this is a consultation stage IA, we will continue to refine estimates of the impact of the policy options, in light of responses from consultees.

One In Two Out (OITO)

The proposals described should be out of scope of 'One In Two Out'. Commenting on the IA in 2012 which accompanied the amendment to the price adjustment in the statutory scheme, the RPC accepted that the statutory scheme was out of scope of OIOO because it is a contractual obligation. The statutory scheme is akin to procurement; in the absence of this scheme (and the PPRS), the Government would need to negotiate with pharmaceutical companies on the prices of individual drugs to secure socially optimal outcomes and efficient use of public funding, as the temporary monopoly status afforded by drug patents means there is no downward pressure on prices from external market forces.

Summary and preferred option with description of implementation plan

The preferred option is **Option 5**, in which:

- The exemption that applies to *products* with annual revenue from sales to the NHS of **£450k** or less, is changed to exempt *companies* with annual revenues from sales to the NHS of **£5m** or less. Since the low cost exemption in the current scheme is measured through the English community pharmacy data, medicines that are sold wholly in secondary care are not measured through this sales data system and so are effectively exempt from any price controls – whatever the value of their sales or size of the firm.
- The price adjustment is based on average selling price, rather than list price, for sales to hospitals and wholesalers. Since hospitals often get discounts, the average selling price is often significantly below the list price. Adjusting the maximum price through the statutory scheme (ie the list price) does not therefore necessarily lead to a reduction in the actual prices that hospitals pay in the current system.

<u>Implementation Plan</u>

The PPRS Operations Team in the Department of Health will be responsible for implementing the statutory alternative to the voluntary scheme, and will take this forward in a similar way to the existing statutory scheme. In broad terms, this will involve requests to all pharmaceutical companies that supply branded medicines to the NHS to provide the information necessary for the Department to operate the statutory regulations. DH will publish data to make it clear which presentations of branded medicines are covered by a price adjustment; monitor that the regulations are being adhered to, including that appropriate list price and average selling price adjustments have been implemented; liaise with companies on issues that arise; and enforce penalties where necessary.

Annex A: Estimating revenue of statutory companies

The following companies have been identified as being under the statutory scheme:

Altana Pharma Limited
Arrow Generics Limited
Auden McKenzie Div. Ltd
Baxter
Beiersdorf UK Ltd
Borg Medicare
Cambridge Healthcare Supplies Limited
Ceuta Healthcare Ltd
CSL Behring UK Limited
EUSA Pharma
Forum Health Products Limited
Fresenius Kabi Ltd
Genus Pharmaceuticals
Gilead Science Ltd
Grifols UK Limited
HRA Pharma UK & Ireland
Johnson & Johnson MSD (McNeil Healthcare (UK) Ltd)
Kent Pharmaceuticals Ltd
Leo
Lexon ((UK) Limited
Manx Healthcare
Meda Pharmaceuticals Limited
Movianto
Myogen GmbH
Napp Pharmaceutical Holdings
Norgine Pharmaceuticals Limited
Novartis Consumer Health
Octapharma Limited
Otsuka Pharmaceuticals (UK) Ltd
Ratiopharm UK Limited
Reckitt Benckiser
Sandoz Ltd
Septodont Ltd
Seven Seas Ltd
Sinclair Pharmaceuticals UK Limited
Torbet Laboratories Limited
ViiV Healthcare Limited
Wockhardt UK Ltd

Pharmex collects information on the:

- Drug name
- Manufacturer name
- Purchase price

The purchase price – or revenue – can be disagreggated to observe revenue from sales to primary and secondary care. This allows us to observe total revenue from sales to secondary care for the manufacturers identified as being under the statutory scheme.

The Prescription Cost Analyses (collected by the NHS Information Centre) collects information on the:

- Drug name
- Manufacturer name
- Net ingredient cost, i.e. cost of the all drugs sold before discounts and excluding dispensing costs

Observing the net ingredient cost by manufacturer allows us to observe sales to primary care for the manufacturers identified as being under the statutory scheme.

Annex B: Sources

HMT Green Book: http://www.hm-treasury.gov.uk/data_greenbook_index.htm

Pharmex: https://www.cmu.nhs.uk/wwwapps/pharmexupload/

Prescription Cost Analysis: http://www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx

HMT deflator: http://www.hm-treasury.gov.uk/data_gdp_fig.htm