Title: Statutory scheme – Branded Medicines Pricing **IA No:** 5192 **Lead department or agency:** Department of Health **Other departments or agencies:** N/A	**Impact Assessment (IA)** **Date:** 22/09/2014 **Stage: Consultation** **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Cathleen Schulte 020 7972 6539

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, Two-Out?**	**Measure qualifies as**
£156	-£2m	-£2m	No	N/A

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 monopoly supplies of their products. The Government therefore cannot rely on external market forces and must take action to manage the prices of medicines.

The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement with an agreed limit on growth of the branded medicines bill. In the PPRS companies make payments to the Department on any growth exceeding the agreed limit. Companies choosing not to enter the PPRS are subject to a Statutory Scheme, which provides a direct limit on the maximum price. In order for the whole branded medicines pricing system to operate in a fair and consistent way, the Department needs to ensure that the voluntary and statutory schemes are broadly equivalent and achieve the same level of savings. Presently this requires the Department to consult on proposals for a further adjustment to the maximum price and on strengthening the information provisions in the statutory scheme.

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. It is proposed that this may require an adjustment of the cut in maximum price in the Statutory Scheme to maintain the integrity of the branded medicines pricing system and a broad equivalence between the voluntary and statutory schemes.

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

The options considered are:

Do nothing – in which case drug spending may exceed the levels intended in the PPRS agreement, imposing excessive costs on the health service and depriving patients of treatments and services which would improve their health.

Option 1 – adjust the cut in maximum price specified by the Statutory Scheme, such that its effect broadly mirrors the level of spend projected in the PPRS agreement, and avoids the imposition of excessive costs on the health service, while also strengthening the information requirements of scheme to allow the Department to enforce the provisions in fair and consistent way.

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

Does implementation go beyond minimum EU requirements?			Yes / No / 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: George Freeman. Date: 3/10/14

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -

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	-		-	**-**

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

The "do nothing" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero, by definition.

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	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

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

The "do nothing" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero, by definition.

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

N/A

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

N/A

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes/No	IN/OUT/Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Adjust the cut in maximum price in the Statutory Scheme to align broadly with the voluntary PPRS, and strengthen the scheme's information requirements FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 156

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	2		2	**2**

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

Loss of profit to UK shareholders in the pharmaceutical industry, as excessive drug prices and spending, beyond the levels envisaged in the voluntary PPRS, are avoided.

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

The impact on global incentives for R&D are likely to be insignificant. While it is conceivable that there may be some further impact on revenues due to international reference pricing, any impact on company profits is expected to be absorbed in the normal process of capital re-allocation, such that investments continue to receive returns consistent with the risk-adjusted rate of return to capital.

There may also be increased costs to business through a greater requirement for administration when providing additional information. However it is expected that these costs will be negligible, because the collection and retention of this information is already required for accounting purposes. Additional costs will only be incurred if and when the Department requests that the information is reported.

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	158		158	**158**

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

Patients and health service users will benefit as the cost savings from the measure are used to fund more treatments and services.

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

N/A

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

This analysis assumes the actual level of cut in maximum price in the Statutory Scheme, and the measures taken to improve information requirements, will be sufficient to fully offset the effect of higher than expected spending and payments in the voluntary PPRS. Estimates of the impact are based on an assumption that supply of medicines remains unchanged – there is a provision in the statutory scheme for companies to apply to the Department to increase its prices if continuous supply is threatened.

BUSINESS ASSESSMENT (Option 2)

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

Background

In the UK, the prices of branded medicines are determined within a voluntary and a statutory framework.

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).

Unlike the previous (2009) PPRS (and its predecessor agreements), which put in place controls on the prices of branded medicines sold to the NHS through a series of price adjustments, which were in turn mirrored by the statutory scheme, the 2014 PPRS operates through a different mechanism. The scheme continues to control the maximum prices and profits from the sale of branded medicines to the NHS but instead of a reduction in list price, the scheme limits the growth in the overall branded medicines bill for products covered by the scheme. Under the scheme, the bill will stay flat over the next two years and will be allowed to grow slowly (1.8%, 1.8%, 1.9%) in the final three years of the scheme.

Operating alongside the PPRS are statutory regulations (the statutory scheme). The powers of the statutory scheme are derived from the NHS Act 2006 and are set out in two principal sets of regulations, the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 S.I. 2007/1320 and the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 S.I. 2008/3258.

The two sets of regulations govern different aspects of the scheme. The 2008 Regulations cover price control and its enforcement while the 2007 Regulations set out the information needed to determine whether a manufacturer or supplier has been selling the relevant medicines at a price above that provided for under the 2008 (No. 2) Regulations.

In a series of amendment regulations that were made every year, the prices of branded medicines covered by the statutory scheme were adjusted in alignment with annual price adjustments in the PPRS. In 2013, the Department of Health further amended the two principal regulations with the following key provisions:

- a change in reference price to 1 December 2013;
- a 15% reduction in the maximum price of branded health service medicines that were on sale on 1 December 2013;
- the removal of the £450k low-cost presentation exemption, in order to capture sales from companies selling into secondary care;
- revised information requirements requiring companies to provide annual information on sales income and discounts.

The Department consulted on a number of further proposals, principally the application of the price adjustment to average selling prices in hospitals. In the Government response to the consultation, the Department acknowledged the complexity of this issue and the concerns raised by stakeholders and has decided not to introduce the proposal as part of the 2013 (amendment) regulations.

The following section presents the economic evaluation of the proposed measures.

The final section provides a Macroeconomic Conditions Review.

Economic evaluation

The proposed policy measures comprise two related elements:

- a reduction in the maximum price level permitted in the Statutory Scheme; and
- a requirement for companies to keep data on actual selling prices and to provide such information on request to the Department if the Department considers there may have been a breach of the regulation limiting price. These measures address related problems, although their impacts are substantially the same to the extent that they both avoid the risk of excessive spending on medicines. Therefore this analysis considers a single “do nothing” scenario (option 1), in which neither measure is taken, and a single outcome scenario

(options 2) in which both measures are taken. We will evaluate responses to the consultation and the implementation of a further adjustment of the maximum price will depend on a range of factors as set out in the consultation document. However, the Department needs to improve its ability to operate the scheme in a fair and consistent way and therefore, all other things being equal, Option 2 is our preferred approach. .

Problem, and justification for Government intervention

The proposed policy measures address two related problems:

- the asymmetry between cuts in maximum price specified in the Statutory Scheme and the agreed spending limits and resulting payments made by companies in the voluntary PPRS, which risks lower savings from companies already in the statutory scheme as opposed to those in the PPRS and also incentivising companies to enter the Statutory Scheme, resulting in higher health service spending on medicines overall and loss expected savings to the NHS;
- weakness in the requirement for information in case of a possible breach, which mean accurate pricing data is not available to enable the fair and consistent operation of the Statutory Scheme , which may reduce savings and possibly provide further incentive for companies to enter the Statutory Scheme, in turn resulting in excessive higher spending on medicines overall.

These problems are explained further below.

(i) Asymmetry between the cut in maximum price specified in the Statutory Scheme, and the agreed spending limits and resulting payments in the voluntary PPRS

In order to provide incentives for investment in R&D, medicines are permitted a period of market exclusivity, during which they are able to gain high prices under the patent mechanism. Because normal market forces do not operate during this period, the Government must intervene to limit prices of branded medicines, in order to safeguard the finances of the NHS, and its ability to meet the health needs of the population of England and Wales, while ensuring appropriate access to medicines and providing the pharmaceutical industry with incentives to invest in R&D.

The Government manages spending on branded medicines by means of a voluntary mechanism agreed with the Pharmaceutical Industry, in which total spending on branded medicines in forthcoming years is limited to an agreed amount. This mechanism is the Pharmaceutical Price Regulation Scheme (PPRS) which will operate for five years starting from 1 January 2014.

Unlike the previous (2009) PPRS (and its predecessor agreements) which operated via a series of price adjustments, which were in turn mirrored by the statutory scheme, the 2014 PPRS operates through a different mechanism. The scheme continues to control the maximum prices and profits from the sale of branded medicines to the NHS, but instead of a reduction in list price, the scheme limits the growth in the overall branded medicines bill for products covered by the scheme. Under the scheme, the bill will stay flat over the next two years and will be allowed to grow slowly (1.8%, 1.8%, 1.9%) in the final three years of the scheme.

In order to ensure that spending on branded health service medicines stays at the agreed level, any growth above this level will result in industry making payments to the Department. The payments are based on the difference between the agreed forecast growth level and the allowed growth level and will be adjusted annually if actual growth in the current year is above or below the agreed forecast.

The Impact Assessment accompanying the consultation on the 2013 statutory (amendment) regulations was prepared at a time when the PPRS was being negotiated and therefore referred to the mechanisms of the 2009 PPRS, i.e. a series of agreed, annual price adjustments.

Participation by individual companies in the PPRS is voluntary. Therefore a parallel system is also required to manage the pricing of medicines supplied by companies who choose not to enter the PPRS. This system is the Statutory Scheme.

As set out in the consultation and Impact Assessment accompanying the Statutory Scheme regulations of 2013[1], the purpose of the Scheme is to provide a system that manages medicine pricing and spending

[1] http://www.legislation.gov.uk/uksi/2013/2881/impacts

in a way that is broadly aligned with the level of savings envisaged within the PPRS, if companies choose not to join the PPRS. This is achieved by applying a cut in maximum price to medicines falling outwith the PPRS, in such a way as to achieve broadly the effect of the limit on spending specified in the PPRS agreement.

As stated above, the payments that companies that have joined the PPRS will make to the Department are based on the difference between the allowed percentage growth and the actual percentage growth in NHS spend on branded medicines. Companies will make a percentage payment (the 'payment percentage') on net sales of products covered by the scheme (the 'measured spend').

The 2014 PPRS sets out the estimated payment percentage based on a set of agreed annual growth rate forecasts. The Department has received the PPRS Q1 and Q2 aggregated sales data for 2014 which indicates that there has been higher than profiled growth in measured spend in the PPRS in the first half of 2014 (5.52% compared to the agreed forecast of 3.87%). Depending on growth in PPRS Q3, the 2015 PPRS payment percentage may be higher than profiled. If growth in quarter 3 continued at the same rate as in the first part of the year the payment percentage would be close to 10% as opposed to profiled 7.13%. This creates a higher than expected risk of switching from the voluntary to the statutory scheme in the early years.[2]

Because actual spending in the PPRS has exceeded the projections on which the original Statutory Scheme was based, the two systems may well become misaligned. The result of this misalignment would be that companies might foresee greater revenues and profits by entering the Statutory Scheme, given the current level of cut in maximum price it entails. To the extent that companies enter the Statutory Scheme this will increase overall spending on the drugs used in the NHS, and thereby worsen outcomes for NHS patients unjustifiably. Government intervention may therefore be required to realign the provisions of the Statutory Scheme to be consistent with the levels of spending and payment agreed in the PPRS, in order to prevent excessive increases in overall drug spending and to maintain spending at the levels envisaged in the PPRS agreement.

(ii) Failures in the requirements for information

In order to limit spending on medicines in accordance with the PPRS agreement and associated schemes, and to apply the limits on maximum prices for medicines in a fair and consistent way, the Department may from time to time require accurate information on actual prices paid by the NHS for medicines so that it can confirm whether there has been a breach in the regulations on price control and if there has been a breach determine the level of recovery required under the regulations. The statutory scheme operates as the default price control mechanism, and companies that do not join the voluntary PPRS will by default fall under the regulations. It is therefore important that the Department is better able to enforce the regulations and the limit on maximum price.

Since the inception of the PPRS, it has become apparent that the regulations currently do not sufficiently enable the Department to identify the actual selling price ('the amount that the person actually received') of any presentation. Therefore, for the purposes of enforcement and the ability to calculate a recoverable sum when it considers that there has been a breach, the Department is consulting on how it can strengthen the scheme's information requirements.

The Department is able to identify if there is evidence that there has been a breach in the limit on maximum price by monitoring NHS list prices which are provided to the Department or, in rare cases where there is no published NHS list price, by monitoring the average selling price of presentations using the information provided under the revised information requirements in the 2013 Regulations.

The 2013 Regulations amended the information requirements set out in the 2007 Regulations. Under Regulation 3, as amended, a manufacturer or supplier of branded health services medicines must, to the extent that the information is available to it, provide the Secretary of State with information on the sales income in respect of each presentation and the total number of these presentations, and any discounts that were applied, on a regular basis (annually from 2015 onwards) and within a specified time period.

The regulations do not yet require a company to provide the actual price of a presentation for a defined period (as may be required by the Department to calculate the 'recoverable sum'). Schedule 1 of the

[2] A number of companies have already chosen not to join the voluntary scheme, even with relatively small levels of payment and a price cut of 15% in the statutory arrangements. This can only be because they are financially advantaged under the statutory arrangements. The corollary is that the NHS is losing out in terms of savings. Reliable information is not available for these particular companies to estimate the amount of lost savings that have resulted.

Health Service Branded Medicines (Control of Prices and Supply of Information)(No.2) Regulations 2008 (as amended) defines the recoverable sum as "the difference between the amount which a person would have received had the product been supplied at the maximum price and the amount that the person actually received". In order to calculate the amount the company actually received it is necessary to have information on the actual selling price of the presentations concerned for the period concerned. Currently the regulations only require companies to provide information on average selling prices on an annual basis.

Failure to identify the actual selling price may mean the Department is not able to apply the limit on maximum prices, imposing higher costs on the NHS budget.

Objectives

The objectives of the policy measures are to:

- adjust the cut in maximum price in the Statutory scheme to align it with agreed spending limits and resulting payments made by companies in the voluntary PPRS, in order to maintain the overall level of drug spending outcomes envisaged in the PPRS; and
- to improve the ability of the Department to request pricing information, and enable application of penalties to companies that do not provide the information as provided in the regulations

Option 1: "Do nothing"

Without Government intervention, the misalignment between the PPRS mechanism and the statutory scheme, and the absence of accurate pricing information, may lead to loss of savings from companies already in the statutory scheme as compared to the PPRS. It may also lead some companies, acting rationally, to enter the statutory scheme, in order to realise greater revenues. This could lead to increases in NHS costs beyond the level envisaged in the PPRS agreement.

The exact level of increase in costs due to companies entering the Statutory Scheme in future cannot be known, because:

- the exact future spending within the PPRS, and the corresponding payments are not known; and
- the decisions of companies to enter the Statutory Scheme cannot be predicted with certainty – as they depend on many factors outwith the NHS, such as possible "reference pricing" effects in other countries

For these reasons, an illustrative scenario is used to estimate the NHS cost increases that may plausibly result from the asymmetry between the PPRS and the statutory scheme and the failure to collect accurate pricing information. The estimate below is based on the assumption that the current rate of growth in measured spend will continue at the rate of 5.51% (based on 2014 Q1 and Q2 data).

Year	Annualised outturn growth (measured spend)	PPRS payment percentage	Potential loss of savings (expressed as % of PPRS payment (%)	Payment due (before switching) (£m)	Estimated loss of payment (£m)
2015	5.52%	9.72%	8.9%	444	39.4

As shown above, modelling of company product portfolios suggests that **£39m** of savings could be lost in 2015 under the "do nothing" option, should companies decide to switch into the statutory scheme under the current measured spend growth profile.[3]

In assessing the impacts of the policy option proposed, the "do nothing" option is considered as the counterfactual. The impact of policy options are estimated relative to the "do nothing" scenario. As

[3] This is potential lost revenue, as we are not certain that all companies that might benefit from switching will do so.

shown below, this implies that the main effect of the proposed policy option is in mitigating the increase in NHS costs that would be expected under the "do nothing" option.

Option 2: adopt an adjusted cut in maximum price in the Statutory Scheme, and improve information requirements

Two measures are proposed under this option:

- adjust the cut in maximum price in the Statutory Scheme to better align it with savings in the PPRS given the likely level of the PPRS payment; and
- improve the information requirements, and enable the application of penalties for companies who do not provide the required information.

Adjustment to the cut in maximum price

The exact level of the cut in maximum price is not specified – as it will depend on the level of cut in maximum price that is required to maintain the overall level of savings envisaged in the PPRS agreement.

Increasing the level of cut in maximum price in the Statutory Scheme will reduce the incentives for companies to enter the Scheme. It will thereby reduce the costs that would be incurred by the NHS when companies enter the Statutory Scheme.

This analysis assumes that the ultimate level of cut in maximum price in the Statutory Scheme, and the improvements to information requirements, are sufficient to maintain the levels of spending envisaged in the PPRS agreement. The general effect of this option would therefore be to mitigate fully the NHS cost increases expected in the "do nothing" scenario.

The ultimate impacts of this policy, in terms of NHS costs and effects on company revenues and profits, are considered in detail below.

Improvement in information requirements

In this option, it is proposed that the regulations should be amended to apply additional requirements on manufacturers and suppliers to:

- record and keep information on the actual price charged for each sale for health service purposes of each of their presentations covered by the Regulations, on a continuous basis, and
- provide on request information to the Department, setting out the actual amount charged for health service purposes in respect of specified presentation(s) and for specified time period(s) as set out in writing by the Department.

The effect of this measure would enable the Department to confirm whether or not a breach in the maximum price has in fact occurred (if this is in doubt) and if so to make an accurate demand for payment of the recoverable sum.

The ultimate impacts of this measure will be to reduce drug spending and NHS costs, by reducing the degree to which the maximum price cannot be enforced through the existing information mechanisms, as explained below.

Impacts of the proposed measures

This section describes and estimates the impacts of the proposed measures. The magnitude of these impacts is assessed using the approach taken in the previous Impact Assessment of the Statutory Scheme.[1]

Gain in health for NHS patients

As explained above, the impact of the proposed measure would be to mitigate fully the incentives companies would have to enter the statutory scheme, and thereby offset the lost savings to the NHS that this would incur. The effect on NHS finances would therefore be to realise cost savings equal to the cost impacts foreseen in the "do nothing" option.

The expected cost savings are therefore **£39m** in 2015/16.

In accordance with standard IA and Green Book practice, these impacts are translated into their opportunity costs and monetised to give their social value.

In this case, the release of cost savings will generate funds that are used to provide treatments and services elsewhere in the NHS, thereby generating additional health benefits to patients – which are conventionally measured in Quality-Adjusted Life Years (QALYs). The standard DH assumption is that one QALY is provided at the margin in the NHS for a cost of £15,000. The corresponding health gains that are realised from the £39m cost savings are therefore estimated at **2,627 QALYs**.

The societal value of these QALY gains are calculated using the DH standard estimate of the societal value of a QALY of £60,000, to give an estimated value of **£158m**.

Loss of profits for the pharmaceutical industry

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. 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). This reduction in spending on sales and marketing would reduce company costs, and partially offset the loss of revenue after the price adjustment.

This analysis assumes that **60%** of lost revenue would have been taken as profits, after allowing for administration and sales and marketing costs. This corresponds to a loss in profits of **£24m**.

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 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[4]. Application of this weighting gives a value for lost profits of **£17m**.

Finally, in accordance with the recommendations of the Treasury Green Book, impacts on UK nationals and non-UK nationals are reported separately.[5] The Department for Business, Innovation and Skills estimate that around 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.

Therefore the value of the UK share of lost profits is **£2m**.

Other impacts

Under this option, there may also be increased costs to business through a greater requirement for administration. However it is expected that these costs will be negligible, because the collection and retention of this information is already required in the existing system. Additional costs will only be incurred if and when the Department requests that they are reported.

Net impact of option 2

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

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

The net impact of health gains for patients, and lost profits for UK shareholders in the pharmaceutical industry is **£156m**.

Macroeconomic conditions review

In order to comply with the EU Transparency Directive, the Government is required to review policies annually, in order to ensure they remain consistent with general macro-economic conditions.

As described in the main text of this Impact Assessment, the purpose of the Statutory Scheme is to provide a framework for pricing of branded medicines which mirrors and supports the levels of pricing and overall spend agreed in the voluntary PPRS scheme. The PPRS is based on an agreed "joint profile" for growth in drug spending; the overarching objectives of the PPRS include to provide stability and predictability to both the Government and the industry and to support the NHS by ensuring that the branded medicines bill stays within affordable limits The objective of the measures evaluated in this Impact Assessment is to ensure the Statutory Scheme continues to mirror and support these levels of pricing and overall spend.

The PPRS scheme, and the joint profile for spending on branded medicines agreed with industry was negotiated in the context of the best expectations of all parties in respect of the future profile of NHS finances. The scheme recognises the need to strike a balance to promote the common interests of patients, the NHS, the industry and the taxpayer. It is therefore considered that the terms of the PPRS, and the corresponding provisions of the Statutory Scheme – amended as described in this Impact Assessment, in order to maintain alignment with the PPRS – are agreed in such a way as to anticipate the future path of NHS financing. Accordingly it is considered that the terms of the PPRS, and the provisions of the Statutory Scheme remain consistent with macro-economic conditions and NHS financing.