Department of Health

Health Service Medical Supplies (Costs) Bill Impact Assessment

September 2016

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Health Service Medical Supplies (Costs) Bill Impact Assessment

The Health Service Medical Supplies (Costs) Bill Impact Assessment is made up of two individual Impact Assessments:

Impact assessment for the amendment of powers to enable the Government to control the cost of health service medicines

Summary: The Bill's medicines cost measures will amend primary legislation only. No policies will be directly implemented as a result of these changes. The objective is to allow the Government to implement a statutory scheme for controlling the cost of medicines based on a payment mechanism, and to better align the way the statutory scheme and voluntary 2014 Pharmaceutical Price Regulation Scheme work. Implementation would require additional future changes to secondary legislation and an additional IA to assess cost effectiveness. This IA provides an illustration of the costs or benefits of the legislation, by comparing consequences of implementing a payment percentage of 7.8% in the statutory scheme compared to the consequences of the 'do nothing' option. This level of payment mechanism is estimated to generate savings of £88m pa, compared to the "do nothing" option. The total net present value would be £350m pa.

Impact assessment for powers to enable the Government to obtain information on medicines supplied to the health service

Summary: The Bill's information measures will amend primary legislation only. No policies will be directly implemented as a result of these changes. Their implementation would require additional future changes to secondary legislation and additional IAs to assess their cost effectiveness. This IA therefore summarises that there are no identified costs or benefits of this change to primary legislation and presents an indication of affected groups from the measures that might be implemented in future via secondary legislation.

Title: Amendment of powers to enable the Government to control the cost of health service medicines IA No: XXX Lead department or agency: Department of Health Other departments or agencies:	Impact Assessment (IA) Date: 15/09/2016 Stage: Consultation Source of intervention: Domestic Type of measure: Primary legislation
Summary: Intervention and Options	RPC Opinion: N/A

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2015 prices)	In scope of One-In, Two-Out?	Measure qualifies as
£350m pa	-£3m pa	£3m pa	No	N/A

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

NHS spending on medicines has been limited by successive Pharmaceutical Price Regulation Scheme (PPRS) agreements between Government and industry. However the agreed scheme is voluntary – so a statutory scheme is required to ensure that broadly equivalent savings are achieved if companies choose not to join the voluntary scheme.

The 2014 PPRS includes a mechanism requiring companies to pay a defined percentage of their sales revenue back to the Department. The Department consulted on a similar payment mechanism in the statutory scheme. Industry responses questioned the Government's powers to do this through regulations. The Department has decided that amendments to clarify primary legislation are needed to put beyond doubt that the Secretary of State has the powers to implement a payment mechanism.

The statutory scheme currently operates through a cut in list price. A payment mechanism is more efficient and equitable, and more likely to ensure spending overall is consistent with the PPRS agreement.

What are the policy objectives and the intended effects?

The objective is to allow the Government to implement a statutory scheme based on a payment mechanism, in order to better align the way the statutory scheme and voluntary 2014 PPRS work, and to reduce or eliminate the inefficiencies and inequity associated with a cut in list price.

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

Do nothing

Amend the existing powers to put beyond doubt that the Secretary of State may limit the costs of health service medicines by requiring pharmaceutical manufacturers and suppliers to make payments to the Department.

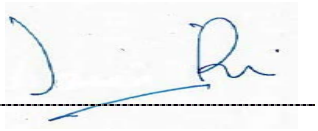
Option 1 is preferred as it enables the Government to achieve its objective.

Will the policy be reviewed?

It will be reviewed.

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes/No	< 20 Yes/No	Small Yes/No	Medium Yes/No	Large Yes/No
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 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: 06/09/2016

Summary: Analysis & Evidence Do Nothing

Price Base Year 2016	PV Base Year 2016	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price)	Average Annual (excl. Transition)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	-	-	0

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

In the "do nothing" scenario, the government would continue to use a 15% price cut mechanism, leading to uneven distribution of savings across companies and less certainty of the ultimate savings realised. Spending on branded medicines would be expected to be an estimated £88m pa higher than if those companies had paid the same payment percentage as in the PPRS.

(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'

If the Government implements a statutory scheme based on list price cuts rather than a payment mechanism, the impact will be distributed unequally among companies, causing inefficiency and inequity.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			0

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

The 'do nothing' scenario assumes the Government will continue to implement a statutory scheme based on a list price cut of 15%, and that future savings from this level of price cut are consistent with estimated current savings.

BUSINESS ASSESSMENT (Option 0)

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

Summary: Analysis & EvidencePolicy Option 1

Description: Clarify the Government's power to implement a statutory PPRS using a payment percentage

Price Base Year 2016	PV Base Year 2016	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: 350 pa

COSTS (£m)	Total Transition (Constant Price)	Average Annual (excl. Transition)	Total Cost (Present Value)
Low			
High			
Best Estimate	0	3	3 pa

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

To the extent that a statutory scheme using a payment mechanism will achieve a greater level of savings than "do nothing", this will result in a reduction in revenues for pharmaceutical companies, and a reduction in profits for shareholders. The loss to UK shareholders is valued at £1.8m pa.

Reduced pharmaceutical company revenues are also expected to lead to a reduction in investment in research and development (R&D), and consequent losses of spill-over benefits for the UK economy, valued at £1.0m pa.

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

N/A

BENEFITS (£m)	Total Transition (Constant Price)	Average Annual (excl. Transition)	Total Benefit (Present Value)
Low			
High			
Best Estimate	0	353	353 pa

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

Cost savings to the NHS will allow provision of additional treatments and services to patients. These are estimated to lead to health gains of 5,887 Quality Adjusted Life Years pa, with a value of £353m pa.

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

Implementing a payment mechanism in future statutory schemes will reduce or eliminate the inefficiencies and inequities associated with the list price cut implemented in the "do nothing" option. These unquantified effects will mainly benefit companies.

Key assumptions/sensitivities/risks N/A

Analysis is of an illustrative scenario based on a future statutory PPRS designed to prevent further switching from the voluntary scheme, which is estimated to require a 7.8% payment. This is compared to a counterfactual scenario in which the current price cut of 15% continues, and generates savings consistent with current estimated savings. The actual level of a payment percentage or further price cut will be subject to further consultation upon Royal Assent.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:				In scope of OITO?	Measure qualifies
Costs: 3	Benefits: 0	Net: -3		No	N/A

Background

The National Health Service Act 2006 (sections 261-266) provides powers for the Secretary of State for Health to limit prices and limit profits of manufacturers and suppliers of health service medicines and allows for a voluntary scheme and a statutory scheme. Pharmaceutical companies can choose to be a member of either scheme. However, those companies which are not a member of the voluntary scheme are automatically within scope of the statutory scheme.

Voluntary agreements between the Department of Health and the Association of British Pharmaceutical Industry (ABPI) have been in place since the 1950s and are normally agreed on a five year term. The current voluntary scheme, the 2014 Pharmaceutical Price Regulation Scheme (PPRS) commenced in January 2014 and for the first time included a payment mechanism. The payment mechanism requires scheme members to pay a defined percentage of the value of their sales revenue back to the Department if the growth in NHS spend exceeds a pre-agreed level.

The Department consulted on changes to implement a similar payment mechanism in the statutory scheme. The proposals arose due to the need to address a number of challenges including:

- the need to better align the way the statutory scheme and voluntary 2014 PPRS work, to move towards a more level playing field between companies in the two schemes;
- that the statutory scheme produces lower savings relative to the voluntary scheme;
- that a number of companies are leaving the voluntary scheme or divesting products into the statutory scheme, reducing total sales under the PPRS by £157m over the duration of the current scheme.

The consultation on the proposed reform of the statutory scheme closed in December 2015.

Problem

Overview

Industry responses to the consultation questioned the Government's powers to introduce a payment mechanism through regulations. The Department has decided that amendments to primary legislation are needed to clarify the powers and put beyond doubt that a payment mechanism is allowed, given the vires points raised by the pharmaceutical industry.

Using a payment mechanism for the statutory scheme would be a more efficient and equitable approach than a cut in list prices, and would have the highest likelihood of achieving a broadly equivalent levels of savings as were intended when the PPRS was agreed, as explained in detail below.

Alternative mechanisms for achieving savings on statutory scheme branded medicines

The purpose of the statutory scheme is to deliver broadly equivalent levels of savings on branded medicines as those which were intended when the PPRS was agreed – even if companies choose not to join the voluntary scheme. This entails making savings against NHS spend on branded medicine spend (after deduction of VAT and discounts) for companies who do not join the voluntary scheme.

This section compares the use of payment percentage and list price cut mechanisms to achieve the required level of savings.

Payment mechanism

In this approach, a percentage is applied to the actual sales each company makes to the NHS, and the resulting amount is repaid to the NHS.

For example, if a company makes NHS sales of £1m, an 8% payment would mean the company repaid £80,000 to the NHS.

Using a payment mechanism, a given level of savings can be achieved directly. For example, if required savings are 8% of NHS spend, then an 8% payment can be applied evenly to all sales. All companies are affected in proportion to their sales, and there is high confidence that net spending will be at the agreed level.

It is also necessary, as with the 2014 PPRS, to cap list prices (not allow them to increase) in order to avoid the savings being eroded by price increases. This means that the payment percentage acts in a similar way as a cut in average selling prices, delivering a real saving to the NHS, while being much simpler to administer. However there would need to be a provision to allow companies to request a price increase if needed to maintain supplies of essential medicines. This was proposed in the consultation on reforms to the statutory scheme which closed in December 2015 and remains our intent. The Government is committed to carrying out further consultation on regulations to implement a payment mechanism, subject to Royal Assent.

List price cut mechanism

In this approach, a reduction is applied to the published list prices for each medicine covered by the relevant scheme.

For example, if the published list price of a medicine is £100, an 8% list price cut would mean the medicine could not be sold for more than £92.

It is important to note that published list prices can be significantly higher than actual selling prices. Actual selling prices are effectively independent of list prices, and competitive forces do not impact on list prices. Actual selling prices, as a proportion of list prices, vary widely for NHS medicines – from 20% to 100% of the list price.

This means that a cut applied to list prices will only affect a product's sales if the list price is reduced below the actual selling price. In the example above, if the actual selling price of the medicine was £80, then the 8% list price cut is likely to have no effect and make no savings for the NHS. This does not mean, however, that the NHS does not need to make the savings on products offering discounts, as these still represent a significant cost to the NHS and their prices remain significantly higher than would be expected in, for example, fully competitive generics markets.

Furthermore the list price cuts can only be applied directly to prices in primary care and only directly affect the reimbursement price for community pharmacy. List price cuts will not make savings in secondary care as the actual price is set through procurement by secondary healthcare providers, unless the cut in the companies' list price for community sales brings the price below the actual selling price in secondary care.

Therefore, in order to achieve a given rate of savings overall, a greater level of list price cut is required – because the list price cut will only realise savings from a proportion of the products, while some will be unaffected.

For example, suppose 8% savings were required from a set of two products with equal sales, and that one product's actual selling price is half of its list price, while the other product's actual and list prices are the same. In this case, a 16% list price cut would be required – and the savings would be realised entirely from the latter product, with the other product unaffected.

Applying list price cuts can therefore lead to widely differing savings rates for individual products and companies. While in principle it may still be possible to generate the required savings overall, there are important reasons why this approach may not be preferred:

Inequity. The uneven distribution of savings across companies may be considered inequitable.

Risking supply (and savings). Products with relatively low list prices, compared to actual selling prices, will be disproportionately affected – such that the price at which they can sell to the NHS could eventually fall below the economic cost of supply. This could lead either to interruptions to supply or, more likely, measures to restore the price – which would mean the required savings are not achieved.

Uncertainty of outcomes. The ultimate savings realised by list price cuts depend on the actual selling prices (and volumes) for affected products – data which may be unavailable, or which may require expenditure of resources to collect. Savings ultimately realised will also depend on the competitive circumstances across product markets – which will determine the ability of companies to change prices and maintain supply. These factors may not be known, which means that the outcomes of applying a given list price cut may be highly uncertain.

International reference pricing effects. To the extent that other countries use UK list prices (net of price cuts) as references in setting their prices, there may be a loss of revenue to companies elsewhere as a result of list price cuts in the UK.

Overall, list price cuts can lead to inefficiency, inequity and uncertainty. It is also possible that a given level of savings cannot be made with list price cuts, if the distribution of those savings is unequal to the extent that supply of some products becomes uneconomic.

Mixed mechanisms

As well as the potential disadvantages of list price cuts as a mechanism for achieving required levels of savings, there are additional drawbacks to applying different (or mixed) mechanisms in the voluntary and statutory schemes. For example, the mechanism of the voluntary PPRS is, in effect a payment percentage – while the current statutory scheme uses a list price cut.

The loss of income to an individual company under a list price cut will depend on factors such as their list prices relative to actual selling prices, and the degree to which they supply primary or secondary care. However the loss of income under a payment percentage will depend solely on their actual sales to the NHS.

Every individual company will therefore face a different loss of income under each mechanism. If the voluntary and statutory schemes use different mechanisms, it follows that each individual company will face a different loss of income under each scheme. Therefore, if any company chooses to enter the statutory scheme, it must be because they expect less reduction of income, which implies lower savings to the NHS than are required in the voluntary scheme, and lower than the level agreed in the PPRS.

In contrast, if both schemes use broadly the same mechanism, the revenues and savings for companies in both schemes should be broadly consistent (to a first approximation). Therefore, even if companies choose to enter the statutory scheme, the savings generated from their sales should be broadly equivalent to those that would have been achieved in the voluntary scheme.

Comparison of approaches: theory and evidence

As described above, a required rate of savings may be achieved directly in a statutory scheme using a payment mechanism – which may be expected to provide a given level of savings with a high level of confidence, as its effects are applied to actual NHS sales, and are evenly distributed across products and companies.

Conversely, list price cuts do not directly provide a given level of savings, so their results are uncertain. Because they entail uneven distribution of savings, list price cuts required to achieve a given level of savings will always be greater than the rate required (and the corresponding payment percentage) – which leads to potential inefficiencies and inequity, as described above, and a risk that the required level of savings cannot be achieved.

These conclusions are supported by evidence of losses of savings from the current statutory schemes:

Evidence of switching and loss of savings in PPRS

The original statutory scheme associated with the current PPRS entailed a 15% price cut – substantially higher than the 3.74% payment percentage applied in the voluntary scheme. Nevertheless, even a price cut at this level was not sufficient to deter switching.

In 2014, fifteen companies above the threshold (1) at which the price cut applied chose to enter the statutory scheme, with UK sales of £693m in 2014 after application of the 15% price cut. In 2015, one of those companies left to join the PPRS and 4 companies with sales above the threshold left the PPRS to enter the statutory scheme. In addition there were a number of divestments of sales from PPRS companies to companies in the statutory scheme. There have been no divestments from the statutory scheme to the PPRS. Since the PPRS began, we estimate there has been a net switch of over £157m pa of sales to the statutory scheme due to companies leaving the PPRS or divesting products. It is anticipated that future sales will be greater by an additional £286m pa, due to entry of new products to the statutory scheme.

The PPRS payment percentage required to achieve the agreed level of spend going forward from 2016 has been estimated at 7.8%. Data on sales and prices for these companies can be used to estimate the savings that would be made from these sales if a 7.8% payment percentage were applied to the statutory scheme instead of the current 15% price cut.

The results indicate that additional savings of £88m pa would be made by applying a payment percentage going forward, rather than the price cut currently in operation. As the savings under a payment percentage are consistent with the savings achieved through the PPRS agreement, this sum represents the on-going loss to the NHS compared to the expected level of savings under the PPRS.

Evidence of list price cut required to deter further switching in current PPRS

Based on the current PPRS payment percentage profiled for 2016, 2017 and 2018 of 7.8%, the risk of loss of PPRS payments through switching of sales to the statutory scheme, if it remains as now with a list price cut of 15%, is estimated to be £26m per calendar year.

As described above, using list price cuts rather than payment percentages result in savings being generated disproportionately from a subset of products, while others provide no savings. For this reason, it may be expected that a higher list price cut would be required to achieve a given outcome – while the required payment percentage would naturally equal the required rate of savings.

Data from spending in the PPRS have been used to calculate the levels of list price cuts required to achieve the same effect, in terms of deterrence of switching, as various levels of payment percentage (or savings rate). This analysis confirms that the required list price cuts are substantially above the savings rate required (and the corresponding level of payment percentage).

Payment percentage level	Required list price cut
5%	18%
10%	24%
15%	30%

[1] Companies with health service sales of branded medicines below £5 million a year are not affected by the price cut

For example, if the savings rate in the voluntary PPRS, and the corresponding payment percentage level are 10%, this analysis indicates that a 24% price cut would be required in the statutory scheme, in order to deter additional switching.

The higher the price cut required to achieve a given outcome, the greater the inefficiencies and inequities created – as described previously. These inefficiencies and inequities are not quantified here, but will be greater for a larger level of price cut.

Objectives

The objective is to allow the Government to implement a statutory scheme based on a payment mechanism, in order to achieve the levels of spend agreed in the PPRS, and to reduce or eliminate the inefficiencies and inequity associated with a cut in list price.

Evaluation of options

Two options are considered: the option to "do nothing"; and an option to create primary powers to clarify the use of payment percentage mechanisms for the statutory scheme.

The proposal will put beyond doubt that the Government may introduce a payment mechanism as an option for future proposals. However it is important to note that implementation of such a scheme would be the subject of a detailed proposal and consultation, and a separate Impact Assessment of the actual costs and benefits consequent to the particular scheme proposed.

Quantitative analysis in this Impact Assessment is therefore intended to explain the problem, and to illustrate the general properties of different types of scheme. The expected costs and benefits of future specific schemes are not evaluated here – though indicative annual impacts of the proposed measure are presented for illustrative purposes. These estimates do not take account of any possible exemptions which might be decided upon in respect of the specific scheme (2), and assume full implementation following expiry of any procurement frameworks extant at the time the regulations were brought into force.

"Do Nothing" Option

As explained above, the current proposals are for the Government to take powers that would put beyond doubt that it is able to consider the option of a payment mechanism for the statutory PPRS in future.

To describe the possible effects of the measures proposed quantitatively an illustrative comparison is made of the potential consequences if they are, or are not implemented.

To this end, a counterfactual or 'do nothing' scenario is used in which it is assumed that the Government continues to apply a price cut at the current level of 15%. The possible impacts of using a payment mechanism - if this were to be the Government's decision in future - are illustrated with respect to this base-line, in the evaluation of Option 1.

In considering this 'do nothing' scenario, and the possible future options, it is important to note that continuing to apply a price cut at the current level of 15% is not expected to be sufficient to deter further switching to the statutory scheme, or to avoid consequent losses of savings for the NHS. The level of price cut required to deter such switching is estimated at 22%, based on current data of sales and price. Even at this level of price cut, the overall savings from the statutory scheme are estimated at £18m pa, substantially less than the £88m pa that would be derived from the corresponding payment percentage of 7.8%.

It is worth noting that, in principle, price cuts above 22% could be used, with the objective of reducing the loss in savings. However these would lead to greater inefficiencies and inequities, as described above (see "Problem"). Moreover it is likely that some of the products affected would become unviable.

As well as the direct financial consequences illustrated above, there may also be risks of inequitable effects on companies, as savings are distributed unevenly across products, and inefficient use of resources associated with the avoidance of price cuts. These effects are not quantified here.

Option 1: create primary powers to clarify the use of payment percentage mechanisms for statutory PPRS. Under this option a proposed Bill would:

- amend the existing powers to put beyond doubt that the Secretary of State may limit the costs of health service medicines by requiring pharmaceutical manufacturers and suppliers

[2] The estimates do, however, exclude sales of Pharmacy and General Sale List (P&GSL) medicines – i.e. they only include sales of Prescription Only Medicines. This is the basis of the current statutory scheme and the Government has decided following the 2015 consultation that it will continue to exclude P&GSL sales from the statutory scheme.

to make payments to the Department either instead of, or in combination with, measures to limit their prices directly or control their profits.

- allow the Secretary of State to recover payments from manufacturers and suppliers of health service medicines in exercising those powers and, where necessary, enforce such payments through the courts (following the right of appeal to a Tribunal).

The effects of this option are evaluated below, using an illustrative scenario.

Direct effect: increased savings

To illustrate the effects of this option, the consequences of implementing a payment percentage of 7.8% are compared to the consequences of continuing with the current price cut of 15%, as described in the 'do nothing' option.

This level of payment mechanism is estimated to generate savings of £88m pa, compared to the "do nothing" option.

It should be noted that achieving this level of savings is consistent with the level of spending agreed in the PPRS.

This change in savings to the NHS will result in benefits for NHS patients, losses for shareholders in pharmaceutical companies, and reduced spill-overs from R&D in the UK, as described below.

NHS and patient health gains

The increased savings for the NHS will release funds for use in providing additional treatments and services to patients elsewhere in the NHS. DH estimates that the NHS provides an additional Quality Adjusted Life Year (QALY, the standard unit of health) for every £15,000 of additional spending. The increased savings of £88m therefore correspond to a gain of 5,887 QALYs pa for patients in the NHS.

These health gains are monetised using their estimated societal value of £60,000, to give an annual impact valued at £353m pa.

Loss of profits for shareholders in pharmaceutical companies

Pharmaceutical companies will see a reduction in revenues commensurate with the increase in savings for the NHS, and this will result in a reduction in the profits gained by shareholders in 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.

The Department for Business, Energy and Industrial Strategy(BEIS) estimates that 30% of pharmaceutical revenue is taken as ordinary profits, giving an estimate of lost profits of £26m pa.

In accordance with the Treasury Green Book, impacts on UK nationals and non-UK nationals are reported separately (3). The pharmaceutical industry as a whole is global so, overall, the majority of NHS drug spending will accrue to overseas interests. BIS 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). Assuming that returns to capital are shared between the UK and overseas in the same proportion as total returns, this implies that 10% of the increased profits accrue to UK shareholders, or £2.6m pa.

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

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. As required by Treasury Green Book, the value of lost profits is adjusted to reflect the relative wealth of its recipients. Assuming conservatively that shareholders are, by appropriately weighted average, in the fourth quintile of income gives a weighting of 0.7 to be applied to profits (4), giving a value of lost profits of £1.8m pa.

Impact on UK R&D spill-overs

As described above, the proposed measures are expected to decrease the revenues of pharmaceutical companies – and part of this decrease in revenue may result in reduced profits to shareholders. However some of the decrease in revenue may result in decreased investment in R&D (5) – of which a portion may be in the UK, providing "spill-over" losses to the UK economy.

The proportion of pharmaceutical company revenues devoted to R&D has been estimated (6) at 36%. Of this, 10% is expected to be invested in the UK, according to the UK's proportion of the global pharmaceutical industry set out above.

Investment in R&D is not, of itself, a net benefit (as it represents deployment of resources that would otherwise have found some other use). However, the Department considers that R&D investment leads to "spill-over" effects – for example through the generation of knowledge and human capital - which generate net benefits. The Department for Business and Skills estimates the rate of these additional benefits at 30% of the value of the investment (7).

Applying the estimates above to the projected decrease in pharmaceutical revenues gives an annual loss of £1.0m pa to the UK economy from reduced R&D investment.

It has been suggested that decreasing NHS spending on pharmaceuticals would make the UK a less attractive location for foreign direct investment (FDI) in R&D in the UK. However the available evidence and rationale indicates that supply side factors, such as availability of expert scientific labour and favourable tax conditions, are of greatest significance in the decision to locate R&D activity (8). Any impact relating to NHS spending, or "demand-side" factors would only be expected if other factors were equal, and is not considered likely to be significant (9).

Net monetised impacts

The net impact of option 1, compared to the 'do nothing' option, is a benefit of £350m pa.

Un-monetised benefits

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

[5] In the long run, private capital markets should invest in R&D on the basis of the expected return of potential projects expected to provide profits above the market rate of return. The amount of R&D invested would therefore only change if the expectation of profits from investments for future products were to change. However short term friction in financing may mean that companies fund R&D for future products using revenues from current products – such that changes in current revenues would have an effect on R&D, as modelled here.

[6] Dept. for Business, Innovation and Skills analysis of ONS/BERD data

[7] Estimate provided in correspondence

[8] Eg "Key Factors in Attracting Internationally Mobile Investments by the Research Based Pharmaceutical Industry", NERA Consulting for UK Trade and Investment, and the Association of the British Pharmaceutical Industry, September 2007.
http://www.nera.com/content/dam/nera/publications/archive1/PUB_MobileInvestments_Sep2007.pdf

[9] Advice of Department for Business, Innovation and Skills

In addition to the increased savings estimated above, implementing a payment percentage would reduce or eliminate the inefficiencies and inequities associated with the list price cut implemented in the “do nothing” option. These effects constitute an unquantified benefit of this option.

Equalities Impact

We have considered the views and evidence put forward in the consultation response of how the proposals might affect groups protected by the public sector equalities duties and health inequalities duties. The Government’s assessment continues to be that there is no detrimental impact on particular protected groups or on health inequalities. By generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide treatments and services to patients across the NHS, including those with protected characteristics. The Government also recognises the necessity for provisions to allow for either temporary or permanent increases in maximum price in order to address short term or long term supply problems and ensure continued adequate supply of essential medicines.

Title: Amendment of powers to enable the Government to require information on medicines and other supplies supplied to the health service	Impact Assessment (IA)
	Date: 15/09/2016
IA No: XXX	Stage: Consultation
Lead department or agency:	Source of intervention: Domestic
Department of Health	
Other departments or agencies:	Type of measure: Primary legislation
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 2015 prices)	In scope of One-In, Two-Out?	Measure qualifies as
£m	£m	£m	No	In/out/zero net cost

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

The Government does not have sufficient powers to collect information on the sale and purchase of health service medicines and other supplies by manufacturers, wholesalers, and dispensers (including pharmacies and GP practices that dispense or supply medicines and other supplies) in order to continue to run the drugs reimbursement system effectively and to provide transparency for the Government on the cost of drugs used by the health service. This leads to asymmetry of information which can enable actors in the supply chain to inappropriately increase NHS costs.

What are the policy objectives and the intended effects?

The objective is to collect information on the sale and purchase of health service medicines and other supplies by manufacturers, wholesalers, and dispensers.

The intended effects are

a) to eliminate the risk of non-compliance with current voluntary arrangements for collecting information to ensure the continued effective running of the reimbursement system for dispensers;

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

Do nothing

Create powers to allow the Secretary of State to make regulations to require any person involved in the manufacture or supply of health service medicines and other supplies for health services use (appliances and borderline substances) to provide information to the Secretary of State about the cost of those medicines (and other supplies)

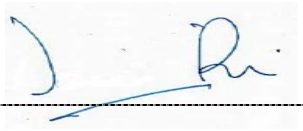
Will the policy be reviewed?

It will be reviewed.

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence	Micro Yes/No	< 20 Yes/No	Small Yes/No	Medium Yes/No	Large Yes/No

Base.					
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 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: 06/09//2016

Summary: Analysis & Evidence Do Nothing

Description: Do Nothing

Price Base Year 2015	PV Base Year 2015	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -

COSTS (£m)	Total Transition (Constant Price)	Average Annual (excl. Transition)	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'

N/A

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

Under this option, the Government would continue to rely on the current voluntary arrangements to collect the information necessary to run the reimbursement system for dispensers effectively and to provide transparency for the Government on the cost of drugs used by the health service. The voluntary arrangements do not encompass all of the market which would perpetuate the asymmetry of information and inappropriate NHS costs referred to above.

BENEFITS (£m)	Total Transition (Constant Price)	Average Annual (excl. Transition)	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'

N/A

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

N/A

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

BUSINESS ASSESSMENT (Option 0)

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

Summary: Analysis & EvidencePolicy Option 1

Description: Create primary powers to allow regulations to require information

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

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

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

N/A

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

The main costs will be on manufacturers, wholesalers and dispensers. These costs have not been quantified, as their magnitude will not be known until after consultation on subsequent regulations. The burden is currently carried only by those participating in voluntary agreements.

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

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

N/A

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

Patients and health service users will benefit as the cost savings from efficiency improvements due to the measure are used to fund more treatments and services. These benefits have not been quantified, as their magnitude will not be known until after consultation on subsequent regulations, and subsequent policies (were they to emerge) to realise potential savings in the supply of medicines and other supplies.

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

N/A

BUSINESS ASSESSMENT (Option 1)

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

Background

The NHS in England spends approximately £15.1bn on medicines per year (£8.5bn in primary care, £6.6bn in secondary care) and a further £2.8bn on pharmaceutical service (pharmacy remuneration through the community pharmacy contractual framework). This is the second largest block of NHS expenditure (after pay costs). The Department and the NHS needs to ensure that best value is achieved through the pricing and supply arrangements.

In primary care, the NHS does not directly buy medicines; rather dispensers act as the 'agent' for the NHS (the NHS being 'the principal'). Pharmacies (or GP practices when they dispense or supply medicines) buy the medicines and the NHS reimburses the cost of these medicines. The system relies on competition throughout the supply chain – dispensers seek out the best prices, wholesalers compete on price and service, and manufacturers (where there is competition, mainly in the generics sector) compete on price.

The Problem

The Government does not have sufficient powers to collect information on the sale and purchase of health service medicines by manufacturers, wholesalers or dispensers in order to continue to run the reimbursement system for dispensers effectively and to provide transparency for the Government on the cost of drugs used by the health service. In this analysis, references to "medicines" include medical appliances, borderline substances and other supplies used for health service purposes.

The principal-agent relationship (as described above), relies on alignment of incentives across the principal and the various parties acting as agents. In the main this can be expected to work well, as dispensers, wholesalers and manufacturers have incentives to purchase and supply at lowest cost driven by competition. However, even where this is the case, the principal may not benefit fully if there is asymmetry of information – i.e. actors in the supply chain may be able to appropriate some of the benefit that should in fact accrue to the principal. This could occur because of:

- Gaming/manipulation of the pricing and reimbursement system in order to retain cost benefits that should be passed on to the principal;
- Tacit collusion between players in the supply chain – e.g. between some suppliers and purchasers;
- Inefficiencies in the supply chain, where government intervention may result in better value for money for tax payers.

Currently the Department receives information on the supply of medicines through a limited number of voluntary agreements with the industry, as set out below.

Margin Survey (Community Pharmacy)

The community pharmacy margin survey is where we monitor the difference between invoice prices compared to reimbursement prices of a sample of around 350 drugs (150 brands, 150 generics and 30 'specials'), for a sample of 240 independent pharmacies (5 or less outlets) – 10 per month. The results of the margin survey are used in negotiations with the Pharmaceutical Services Negotiation Committee to inform adjustments to reimbursement prices to deliver the agreed funding as part of the community pharmacy contractual framework.

Although compliance is generally good, not all companies comply (the compliance rate of community pharmacies in 2015/16 is 91%) and full disclosure (e.g. of all statements) is not always provided, which may raise some concerns regarding the accuracy of the information.

Scheme M

Under Scheme M participating manufacturers (currently 19) provide sales value and volume information for a limited number (though generally the most commonly used) generic medicines – just under 1,000 product lines. Not all companies choose to be members of Scheme M, therefore there is incomplete coverage. Scheme M data is used as the basis for the setting of Category M drug reimbursement prices.

Scheme W

Scheme W participating wholesalers (currently 8) provide purchase and sales value and volume information for a limited number (though generally the most commonly used) generic medicines – just under 1,000 product lines. Not all companies choose to be members of Scheme W, therefore there is incomplete coverage. Scheme W data is used as supporting / cross reference information for Category M drug reimbursement prices.

Specials

A similar voluntary arrangement to Scheme M exists for suppliers of unlicensed medicines (commonly known as 'specials'). There are currently 8 specials manufacturers supplying data.

Pharmaceutical Price Regulation Scheme (PPRS)

Under the Pharmaceutical Price Regulation Scheme (PPRS), certain sales information is gathered to enable the Department to operate the scheme. For companies with sales of £5 million or more, this includes quarterly unaudited high level information and an annual audited version of this information. The Department uses this to ascertain, amongst other things, total net sales of PPRS products and sales covered by the PPRS payment. It also identifies various exclusions from the PPRS payment. In addition, unaudited annual presentation level data is required from scheme members on an annual basis. This provides information on net sales and volumes and levels of discounts and breaks the information down into various sales channels, including primary care; homecare; and other customers.

Other aspects of the PPRS require different forms of information to be provided. For example, sales information to monitor price reductions under the rules on modulation; annual financial return information to enable the Department to measure a company's profits from it sales of branded medicines to the health service; information about the launch of new medicines.

Statutory branded medicines pricing scheme

Currently the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 (as amended) allow the Department to gather sales information from companies that are not members of the voluntary PPRS. The regulations, which apply to any manufacturer or supplier of branded health service medicines with sales to the health service of £5 million or more, stipulate that the information, which includes net sales and volumes and levels of discounts, to be provided at presentation level and broken into various sales channels (e.g. retail pharmacies; health service hospitals). Where the information has been audited, an audited copy of it should be provided to the Department.

Though these arrangements help generate some information with respect to the operation of subsets of the supply chain, as noted above, coverage is not comprehensive in terms of the range of products supplied, nor suppliers to the market. In most cases the information can only be used for limited purposes and cannot be used to analyse whether there is manipulation to

hide cost benefits, tacit collusion or inefficiencies which mean that the principal is not accruing the cost benefit it should on behalf of the tax payer.

Objective

The objective is to collect information on the sale and purchase of health service medicines by manufacturers, wholesalers and dispensers.

The intended effects are to:

- eliminate the risk of non-compliance with current voluntary arrangements for collecting information to ensure the continued effective running of the reimbursement system for dispensers; and
- provide greater transparency for the Government on the cost of drugs used by the health service. The ultimate objective is to achieve best value for money in terms of the supply of medicines to the health service.

By improving the reimbursement arrangements and securing greater transparency, this may allow the Government to satisfy itself that the market for medicines is functioning effectively. For example, in the area of generic medicine reimbursement, without having adequate data to inform reimbursement prices the only option for the Government may be to have a scheme that limits the prices of generic medicines. The ability to obtain information on costs and prices/revenues from any supplier of health service medicines will help identify where problems are occurring more generally, and would feed into policy options that may address these problems in a way that could achieve better value for money.

Options

'Do Nothing' option

In this scenario, we would be reliant, as now, on current voluntary arrangements. Voluntary arrangements have been reasonably successful in obtaining valuable information on, for example, independent community pharmacy purchase prices, and ex-factory/ex-wholesaler prices for some of the larger volume generic medicines. However, as noted elsewhere, this does not give comprehensive coverage and there is no reserve power to require the players in the supply chain to provide the information required both to ensure the continued effective running of the reimbursement system for dispensers and to identify and tackle problems with the system.

Option 1: Create primary powers to allow regulations to require information

Under this option, a new power would be created to allow the Secretary of State to make regulations to require any person involved in the manufacture, supply or distribution of health service medicines to provide information to the Secretary of State about the cost of those medicines (and other supplies). A new power would also allow the Secretary of State to share the information collected within Government and with contractors working for any part of Government.

In order to secure compliance, it is also proposed that the Department should be able, if necessary, to impose penalties on any operators in the supply chain that refuse to comply. The proposed limits are a single penalty not exceeding £100,000 or a daily penalty not exceeding £10,000 for every day on which the contravention occurs or continues.

The policy intention is that information can be used to make Drug Tariff determinations. It must also be possible to use the information to enable the Secretary of State to secure greater

efficiency and effectiveness in the supply chain for health service medicines. This option would allow the Department access to information held by any supplier of health service medicines on their costs, and would allow that information to be used for more extensive analysis of the general workings of the market. It is not envisaged (and indeed it would be infeasible) to demand comprehensive information on, for example, every transaction between two parties in the supply chain on an on-going basis. However, having the ability to access information from a wider range of suppliers, e.g. average purchase or selling prices across a wide range of products, would allow DH to explore areas where there may be concerns regarding the operation of the market – for example if there is unexplained variation in costs. It is proposed that the power should be exercised through regulations, which are made following consultation with organisations representing the affected parties.

Analysis of Costs and Benefits

This section discusses the impacts of policy option 1.

Direct Impacts

The affected parties will largely comprise UK manufacturers, wholesalers and pharmacies in the private sector; though some may be part of the NHS (e.g. some NHS trusts engage in manufacturing and wholesaling). GP practices that dispense medicines and practices that supply medicines as part of personal administration (e.g. flu vaccines) would also be affected

Manufacturers and wholesalers are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA), who have supplied data on the number of license holders as below.

Type of company	License-holders in UK
Medicines Manufacturers	772
Appliances	9156
Parallel Importers	57
Wholesalers	2340
Specials	282

There are around 11,800 NHS community pharmacies in England.

The number of GP practices is 7,875 (2014) in England of which just over 1,000 dispense medicines.

Currently the burden of providing information falls only on those participating in voluntary arrangements. In theory, the proposed legislation could affect any one of these suppliers. However, it is not envisaged that every player in the market would be asked to provide comprehensive information on all activities. More likely is that some sectors may be asked to provide selected information at certain times. We are proposing the power should only be exercised through regulations following consultation setting out in more detail what information will be requested and from whom, including proposals in relation to small and micro businesses. This will be accompanied with a full impact assessment when the scope etc. becomes clear.

DH will also be impacted in terms of administrative costs related to collection and analysis of the data.

Indirect impacts

The indirect impacts may emerge as a result of any action that may be taken in the light of analysis of the information received in order to improve the efficiency with which the health service purchases medicines. It is impossible to foresee what such action may be, but the impacted groups are likely to be as for direct impacts.

Costs

The cost to business of providing the required information will not be clear until we have consulted on subsequent regulations setting out the precise coverage and detail of what will be required.

However, for illustration we discuss below some rough estimates of the costs of providing information under current voluntary and statutory arrangements. That is not to say that the data requirements will be structured in such a way that make the below directly comparable with what will be requested. However, we will consult and seek information on the costs of provision of data when secondary legislation is considered.

Margin Survey

The current arrangements simply require sampled pharmacies to provide invoices (and monthly statements from their suppliers) for all their purchases to the NHS Business Services Authority (NHS BSA), who make copies, and return the originals to the pharmacy. The cost to pharmacies is therefore assessed to be negligible.

The NHS BSA process the information according to margin survey protocols. This is estimated to cost in the region of £200,000 per annum (staff costs / associated overheads, and other running costs). Further, DH analysts' time in analysing the data is estimated to cost circa £150,000 per annum.

Scheme M

Manufacturers that are members of Scheme M (currently 19) provide sales volume and revenue data for just fewer than 1,000 product lines, on a quarterly basis. We estimate that the cost to companies providing this information to be in the region of £36,000 per year (staff costs and overheads, total costs across all companies).

The Department incurs costs in the region of £80,000 in processing and analysing the data for the purposes of setting Category M drug reimbursement prices. This includes Scheme W processing costs.

Scheme W

Wholesalers that are members of these schemes (currently 8) provide sales volume and revenue data for just under 1,000 product lines, on a quarterly basis. We estimate that the cost to companies providing this information to be in the region of £16,000 per year (staff costs and overheads, total costs across all companies).

Specials

A similar scheme to Scheme M exists for specials manufacturers (currently 8 participating companies), who provide sales volumes and prices for approximately 430 products. We estimate that the cost to companies providing this information to be in the region of £17,000 per year (staff costs and overheads, total costs across all companies).

General

It is important to note that the above serves as an illustration only to give some general contextual background with reference to the sort of information that is currently collected. It is

important to note that there are nearly 20,000 reimbursement lines for which a reimbursement cost has been reported. Further, many of these products will come in multiple pack sizes.

Notwithstanding the relatively low cost of collecting the information under the various schemes mentioned above (and the fact that most well run businesses will have this information already as part of their management information systems), to gather information on each and every reimbursed product line could therefore result in a quite a large cost. However, it is not envisaged that we would require comprehensive information, nor to cover every product reimbursed. Options will be explored in consultation with stakeholders, and a full IA will be undertaken, when considering the secondary legislation. One of the options we would want to explore is for information on supplies from manufacturers and suppliers to be broken down as accurately as is reasonably possible by country of the UK. The provision of pharmaceutical services is a matter devolved to each of the Devolved Administrations. Therefore in order to understand the costs in the various parts of the supply chain relating to each of the four UK health services it would be necessary to break down information by country.

Benefits

The main benefit will result from the analysis of the data and any policies that may emerge as a result, which would be expected to accrue to the NHS. These potential benefits may comprise:

- Financial savings to the NHS
- Greater resilience in the reimbursement system
- Greater resilience in the supply chain
- Reassurance that the NHS is achieving value for money

By their very nature, these benefits can be classified as indirect.

In the main, financial benefits to the NHS can be expected to be accompanied by losses to the sectors affected. However, to the extent that any policies bring about more competitive markets, this has some benefits to the sector where the most efficient will be able to thrive. The consultation process for any Regulations will highlight any risks.

Risks and mitigations

The risks associated with these powers may comprise:

- Inappropriately high cost burden on suppliers - This will of course depend on the amount and complexity of information requested. However we will consult on any proposals regarding what information will be requested of whom, and the mechanisms for transfer of data etc in order to minimise costs, and ensure proportionality.
- Information is collected and no policy options emerge – i.e. the cost has been incurred when no subsequent (beneficial) government intervention is identified. Whilst this is a possibility, the statutory powers would in any case provide a statutory back-up to ensure the continuity of the current reimbursement system, where companies are not complying and in case further companies refuse to cooperate with the current voluntary arrangements. It is also an intangible benefit to have reassurance across the NHS that value for money is being achieved.

Equalities Impact

The Government's assessment is that there is no detrimental impact on particular protected groups or on health inequalities. By generating greater efficiency in the supply of medicines for

the NHS, the proposals should have a positive impact by generating savings and increasing the resources available to provide treatments and services to patients across the NHS, including those with protected characteristics. However, the Government will review the impact on a continuing basis, including during any consultation for Regulations and as part of any further policy development process.