

Title: Statutory scheme – Branded Medicines Pricing IA No: 9534 Lead department or agency: Department of Health Other departments or agencies: N/A	Impact Assessment (IA)			
	Date: 28/08/2015			
	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 2015 prices)	In scope of One-In, Two-Out?	Measure qualifies as
£3,417m	-£34m	-£18m	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.

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 or application of a payment percentage, as set out in the consultation document, 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:

1. Apply a further price cut to products in the statutory scheme
 - 1a. Apply a further price cut, as for option 1, but also including new products
2. Require a payment by companies proportional to their sales of products in the statutory scheme
 - 2a. Require a payment, as for option 2, but also including new products

Option 2a is preferred, as it provides the greatest cost savings and net benefits.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: XXX 20XX

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro No	< 20 No	Small No	Medium 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: 03/09/2015

Summary: Analysis & Evidence

Do Nothing

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2015	PV Base Year 2015	Time Period Years 2.75	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.

However this scenario entails large NHS costs and losses of patient health, as spending on drugs grows beyond the levels envisaged in the PPRS agreement. Estimates of total additional NHS costs range from £220m to £1,410m over the remaining lifetime of the PPRS. The corresponding QALY losses range from 14,000 to 90,000.

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 0)

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

Summary: Analysis & Evidence

Policy Option 1

Description: Apply a further price to maximum prices of products in the Statutory Scheme

Price Base Year	PV Base Year	Time Period	Net Benefit (Present Value (PV)) (£m)		
2015	2015	Years 2.75	Low: 963	High: 5,700	Best Estimate: 2,549

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	n/a		
High	n/a		
Best Estimate	n/a	9	26

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'

It is possible that reducing spend on medicines will reduce R&D investment in the pharmaceutical industry, with a consequential impact on the UK economy. However any impact is expected to be minimal, and is likely to be more than outweighed by a beneficial impact on the UK economy of reducing spending on imports.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	n/a		
High	n/a		
Best Estimate	n/a	936	2,574

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 (%) 1.5%

This analysis assumes 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.

Estimates of impacts are based on company reports of NHS sales and prices for individual products, and assume these provide accurate projections of future sales after the price cut.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 13	Benefits:	Net: 13	No	N/A

Summary: Analysis & Evidence

Policy Option 1a

Description: Apply a further price to prices of products in the Statutory Scheme, including new products

Price Base Year	PV Base Year	Time Period	Net Benefit (Present Value (PV)) (£m)		
2015	2015	Years 2.75	Low: 963	High: 5,896	Best Estimate: 2,624

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	n/a		
High	n/a		
Best Estimate	n/a	10	26

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'

It is possible that reducing spend on medicines will reduce R&D investment in the pharmaceutical industry, with a consequential impact on the UK economy. However any impact is expected to be minimal, and is likely to be more than outweighed by a beneficial impact on the UK economy of reducing spending on imports.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	n/a	Optional	Optional
High	n/a	Optional	Optional
Best Estimate	n/a	964	2,650

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 (%) 1.5%

This analysis assumes 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.

Estimates of impacts are based on company reports of NHS sales and prices for individual products, and assume these provide accurate projections of future sales after the price cut.

BUSINESS ASSESSMENT (Option 1a)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 14	Benefits:	Net: 14	No	N/A

Summary: Analysis & Evidence

Policy Option 2

Description: Require companies to make a payment in proportion to their sales in the Statutory Scheme

Price Base Year	PV Base Year	Time Period	Net Benefit (Present Value (PV)) (£m)		
2015	2015	Years 2.75	Low: 1,442	High: 6,379	Best Estimate: 3,171

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	n/a		
High	n/a		
Best Estimate	n/a	12	32

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'

It is possible that reducing spend on medicines will reduce R&D investment in the pharmaceutical industry, with a consequential impact on the UK economy. However any impact is expected to be minimal, and is likely to be more than outweighed by a beneficial impact on the UK economy of reducing spending on imports.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	n/a	Optional	Optional
High	n/a	Optional	Optional
Best Estimate	n/a	1,165	3,203

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 (%)

1.5%

This analysis assumes 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. Estimates of impacts are based on company reports of NHS sales and prices, and assume these are accurate.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 17	Benefits:	Net: 17	No	N/A

Summary: Analysis & Evidence

Policy Option 2a

Description: Adjust the cut in maximum price in the Statutory Scheme to align broadly with the voluntary PPRS

Price Base Year	PV Base Year	Time Period	Net Benefit (Present Value (PV)) (£m)		
2015	2015	Years 2.75	Low: 1,624	High: 6,688	Best Estimate: 3,417

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	n/a		11
High	n/a		56
Best Estimate	n/a	12	34

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'

It is possible that reducing spend on medicines will reduce R&D investment in the pharmaceutical industry, with a consequential impact on the UK economy. However any impact is expected to be minimal, and is likely to be more than outweighed by a beneficial impact on the UK economy of reducing spending on imports.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	n/a	Optional	Optional
High	n/a	Optional	Optional
Best Estimate	n/a	1,255	3,451

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 (%) 1.5%

This analysis assumes 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. Estimates of impacts are based on company reports of NHS sales and prices, and assume these are accurate. It is also assumed that payments will be made from the full future sales of new products.

BUSINESS ASSESSMENT (Option 2a)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 18	Benefits:	Net: 18	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. Companies in the scheme make payments to the Department to cover spend above the agreed growth level, with the payment set as a percentage of their net eligible sales. Under the scheme, the bill will stay flat over the next year (2015) and will be allowed to grow slowly (1.8%, 1.8%, 1.9%) in the final three years of the scheme (2016, 2017 and 2018).

Operating alongside the PPRS are statutory regulations (the statutory scheme). Companies which choose not to join the voluntary PPRS are subject to the statutory scheme.

During the period of operation of the 2009 PPRS, which ended on 31st December 2013, 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.

Following a consultation held in 2013, the latest adjustment to price in the statutory scheme was a 15% reduction in the maximum price of branded health service medicines that were on sale on 1st December 2013.

Mechanism for the determination of annual PPRS payment percentages

As part of the overall agreement, the Department of Health and the ABPI agreed for the purpose of the PPRS a forecast of growth for branded medicines spend. The level of allowed growth rate of spend (the PPRS 'cap') was also agreed. The difference between forecasted spend and capped spend determined the initial payment percentage profile for 2014.

The payment percentage is not paid on sales of products that were launched after 31 December 2013. These sales still contribute towards measured growth and the payment percentage for all companies is proportionately increased to cover the growth due to those products. As there will be fewer new products at the beginning of the PPRS, the adjustment is relatively minor in the early years of the scheme but becomes more important in later years. Companies are only required to apply the payment percentage to sales of products launched on or before 31 December 2013.

More detail on how the PPRS payment percentage is set is included at Annex A to this assessment.

Outline method for setting payment percentage in statutory scheme

We are proposing to simplify the way that a payment percentage in the statutory scheme would be set in regulations, subject to the consultation. The aim would be to keep complexity to a minimum by simply setting a payment percentage aligned broadly with the PPRS payment percentage, rather than by including an equivalent to the PPRS Payments mechanism in the statutory scheme.

Furthermore, it would not be reasonable to expect the smaller number of companies in the statutory scheme affected by the regulations (at time of writing, twelve companies that are members of the statutory scheme are above the smaller companies threshold) to pay a higher percentage on their older products to make up for the cost of new products (in the PPRS a much larger number of companies are in the pool). Therefore, under Option 2a, we simply propose not to exclude new product sales from the payment percentage. The payment percentage would apply to sales of both older and new products.

Evidence of company incentives under current statutory scheme terms

In order to assess the need for a change in the terms of the statutory scheme, it is relevant to consider the choices and implied incentives for companies under the current statutory scheme.

Previous voluntary schemes made savings through a reduction in list price which was then mirrored in the statutory scheme. By contrast, under the 2014 PPRS instead of a list price cut, companies make payments to the Department – calculated as a percentage of their total branded medicines sales to the NHS (subject to certain exclusions and after deduction of discounts and Value Added Tax (VAT)). The current statutory scheme operates through a cut of 15% applied to the maximum price charged to the NHS on 1st December 2013 for a presentation on the market on that date (the maximum price is generally equivalent to the list price). Because the price cut in the statutory scheme applies to the published list price, and not the actual price paid by NHS organisations, the scheme produces lower savings in relative terms than the PPRS. This creates an incentive to switch from the voluntary PPRS to the statutory scheme.

When the PPRS payment percentage reaches a certain level, it will become rational for companies to switch to the statutory scheme as they can reduce the discounts they offer in order to maintain profitability. This will lead to a reduction in savings from the PPRS and an increase in costs for the NHS.

The evidence of company incentives, and the resulting behaviour under the current scheme is summarised as follows:

- Twelve companies with sales to the NHS in excess of £5million chose to enter the statutory scheme, rather than the voluntary 2014 PPRS. In total, their sales to the NHS of licensed branded medicines in 2014 amounted to £622m;
- Three companies with NHS sales in excess of £5 million subsequently left the voluntary 2014 PPRS, and entered the statutory scheme. In total, their sales to the NHS of licensed branded medicines in 2014 amounted to £42m;
- Two companies with NHS sales in excess of £5 million have given notice that they will leave the voluntary 2014 PPRS. In total, their sales to the NHS of licensed branded medicines in 2014 amounted to £38m;
- Since the PPRS began, we estimate there has been a net switch of over £100m of sales to the statutory scheme due to companies leaving the PPRS or divesting products;
- Analysis of company prices and revenues indicates that there are additional companies whose revenues would increase after switching to the statutory scheme, though they have not yet given notice of doing so.

This evidence therefore indicates that companies have significant incentives to switch from the voluntary PPRS to the current statutory scheme, under its current terms – which are therefore apparently not correctly aligned with the voluntary PPRS.

Problem and justification for intervention

The reason we are consulting on further reform to the statutory scheme is to meet the following challenges:

- The statutory scheme produces lower savings relative to the health service sales covered by the scheme than the PPRS and the gap is expected to widen;
- We need to re-align the statutory scheme savings with the PPRS in order to promote a more level playing field between companies in the two schemes and in order to encourage companies to remain in the PPRS to deliver its agreed objectives of stability and predictability to the Government and the pharmaceutical industry;
- It is currently difficult to re-align the schemes because of the differences in the mechanisms used to make savings and the differential effect that the statutory scheme price cut has on companies depending on the levels of discount they offer the NHS;
- The current regulations leave the Department with challenges relating to price controls and enforcement which we need to address.

Objectives

The objectives of the policy measures are

- to calibrate the terms of the Statutory Scheme such that companies do not have incentives to leave the voluntary PPRS, thereby avoiding spending increases beyond the level envisaged in the PPRS agreement
- to maximise the cost-effectiveness of spending on drugs in the Statutory Scheme, while ensuring continuity of supply and patient access to drugs

Options

In order to ensure that the cost of branded medicines to the NHS stays within affordable limits, we are consulting on the following options in order to better align the savings from the statutory scheme with those from the PPRS:

- Option 1:** **Price cut.** A further cut in the maximum price of presentations on sale for health service purposes on 1st December 2013, beyond the current maximum price (based on the previous 15% price cut).
- Option 1a:** **Price cut including new products.** As Option 1, and also a cut in the maximum price on 1st September 2015 of presentations introduced for sale for health service purposes after 1st December 2013.
- Option 2:** **Percentage payment by companies.** Replace the current 15% price cut on presentations on sale for health service purposes on 1st December 2013 with a payment by companies against sales of such presentations, after first deducting discounts and VAT.
- Option 2a:** **Percentage payment by companies including new products.** As Option 2, and also require a payment by companies against sales of new presentations on sale for health service purposes after 1st December 2013, after first deducting discounts and VAT.

More detail on these options, including explanations of their implementation, scope and exclusions are provided in the Consultation document accompanying this Impact Assessment.

The “do nothing” option

The primary objective of the policy is to set terms for the statutory scheme – using price cuts or payments by companies in proportion to their sales - which mean that companies currently in the voluntary scheme will not be incentivised to switch to the statutory scheme.

The magnitude of price cuts or payments in the statutory scheme that are required to achieve this objective depend on the trajectory of drug purchasing in the NHS, which in turn determines the level of the payment percentage required in the voluntary PPRS scheme. As this trajectory is uncertain, three scenarios are assessed, in which the payment percentage is low, medium or high. The corresponding terms required for the statutory scheme entail accordingly low, medium or high price cuts or payments. The “medium” scenario is used as a central estimate for this impact assessment.

- Under the **low** scenario – a payment percentage of 10% in the voluntary PPRS, it is estimated that achieving the objective of deterring switching requires a price cut in the statutory scheme of **24%**, or a payment percentage of **10%**.
- Under the **central** (“medium”) scenario – a payment percentage of 13.5% in the voluntary PPRS, it is estimated that achieving the objective of deterring switching requires a price cut in the statutory scheme of **28%**, or a payment percentage of **13.5%**.
- Under the **high** scenario – a payment percentage of 17% in the voluntary PPRS, it is estimated that achieving the objective of deterring switching requires a price cut in the statutory scheme of **33%**, or a payment percentage of **17%**.

The expected NHS cost increases (lost savings from payment less savings from price cuts), and the consequent losses of QALYs for NHS patients in each future payment percentage scenario are shown below, with the statutory scheme price cuts or payment percentage that is required to fully mitigate them. The avoidance of these cost increases is one element of the impact of the options assessed.

Scenario	NHS cost increases, £m pa			QALY losses (£2015 NPV)	Required stat. scheme price cut	Required stat. scheme payment
	2016/17	2017/18	2018/19			
Low	80	80	60	14,046	24%	10%
Med. (central)	220	230	170	39,578	28%	13.5%
High	500	520	390	90,005	33%	17%

It should be noted that the estimate of NHS cost increases in the “do nothing” option is subject to uncertainties. In particular, it assumes that all companies will switch if their expected revenues in the statutory scheme are greater than in the voluntary scheme – while in fact there may additional costs which deter or reduce switching. To the extent that companies face additional costs in switching, the figures above may over-estimate the cost increases in the “do nothing” scenario, and the consequent cost savings of the options described. However it is also possible that companies may choose to divest themselves of individual products whose sales may be greater in the statutory scheme, even though the company’s overall sales are greater in the voluntary scheme. To the extent this divestment occurs, the figures above may under-estimate the cost increases in the “do nothing” scenario, and the consequent cost savings of the options described.

The determination of the actual price cut or payment percentage required will be made after the consultation.

Government's preferred option

The economic evaluation (below) shows that Option 2a, a payment system applied to new as well as old products, would generate the greatest net economic benefit – mainly in NHS cost savings which are then available to provide additional treatments and health gain for patients. Option 2a provides the greatest savings because:

- use of a payment percentage, rather than a price cut, ensures savings can be generated from all products in the statutory scheme, regardless of the relationship between list and actual prices
- encompassing new products increases the savings

It is also important to note that use of a price cut provides less certainty in aligning the voluntary and statutory schemes than use of a payment percentage. Price cuts are applied to list prices of individual products – which may be subject to widely varying company discounts from list price, set on an individual product basis. If the application of the cut does not reduce the price of a product below the actual selling price, after discounts, there will be no savings derived from that product. Estimating the effect of price cuts on company revenues is therefore more uncertain, and depends on detailed company reports of list prices, volumes and actual selling prices – which may be subject to error or unforeseeable fluctuation. It is consequently more difficult to project the effect of a price cut on company behaviour, and their decision of whether to switch to the statutory scheme. Using a price cut could lead to variations in the impact on different companies, depending on their discounting policies – such that some companies were subject to an excessive reduction in revenues, while others are not effectively deterred from switching.

In contrast, a payment percentage is applied at the company level, to actual company revenues in aggregate, and its impact can therefore be estimated with greater confidence. Moreover using a payment percentage in the statutory scheme more closely mirrors the cost-reduction measures used in the voluntary scheme – and can therefore be calibrated more accurately to achieve the objective of deterring switching.

For further discussion of the selection of option 2a as the preferred option, see the Consultation document accompanying this Impact Assessment.

Impacts of the proposed measures

This section describes and estimates the impacts of the proposed measures.

Overview of effects on NHS drug spending and patient health

Each option will have the effect of reducing the spend on branded medicines. There are two general means by which spend will be affected:

- i) Companies will be deterred from leaving the voluntary scheme and switching to the Statutory Scheme in order to increase revenues. Switching would result in large increases in NHS costs.

The price cut or payment percentage chosen in all options will be at a level deemed sufficient to fully deter companies from leaving the voluntary PPRS. **Therefore all options will result in savings equal to the amount of increased spend due to switching in the “do nothing” option.** The avoidance of these NHS cost increases is the major impact of all options.

- ii) Spending on drugs that would be encompassed by the Statutory Scheme will be reduced, by application of the further price cut or payment system.

Each option entails a different amount of savings from drugs that would be encompassed by the Statutory scheme. These savings are added to the savings from deterred switching (i), to give the total savings expected for each option.

All options are expected to reduce NHS spending on drugs, without affecting the use of those drugs in the NHS. Therefore reductions of spending and the consequent cost savings will result in net gains of patient health, as the released funds are available to provide additional activity elsewhere in the NHS.

Projected NHS savings for each option (central estimate scenario)

Option	2016/17	2017/18	2018
Do-nothing losses from switching (saved in all options)	220	230	170
1. Total savings from further price cut	235	251	187
- Savings on spend under statutory scheme	15	21	17
1a. Total savings from further price cut, incl. new products	238	260	194
- Savings on spend under statutory scheme	18	30	24
2. Total savings from payment percentage	291	312	234
- Savings on spend under statutory scheme	71	82	64
2a. Total savings from payment percentage incl. new products	302	343	257
- Savings on spend under statutory scheme	82	113	87

Background to modelling work

PPRS companies, and those that are covered by the statutory scheme supply the Department of Health with data on the list price, net price after discounts, and volumes for each product sold to the NHS. Using this data it is possible to model the likely impact of various levels of price cut and payment percentages on company net revenues. In estimating the risk of companies leaving the PPRS, it is assumed that all companies that would expect a greater impact on net revenues in the PPRS than in the statutory scheme would leave the PPRS. This is done on a whole product portfolio basis rather than product by product basis (where the latter would result in a greater risk). Where we consider the impact of a payment percentage being applied to the statutory scheme, we can safely assume that the same level of payment percentage will have a similar effect to the PPRS payment.

The level of price cut required under different PPRS payment percentages in order to deter additional switching is then assessed – i.e. to ensure that at higher levels of payment percentage, no additional companies would be better off leaving the scheme.

Similarly, impacts on spending that is already covered by the statutory scheme relies on company reports of list prices, net prices and volumes – which are used to estimate the impact of a price cut on revenues.

There are significant levels of uncertainty surrounding these estimates.

- We are reliant on information supplied by companies, which appear to show some attributes that are difficult to incorporate in the modelling or may contain errors – e.g. negative sales,
- The data relate to 2013 company returns, so may not be wholly reflective of the current state of play in respect of discounts currently offered. There are anecdotal accounts that discounts are increasing, which if true, would render these estimates of switching risk on the low side.
- That said, global pricing arrangements - for example some other countries use UK list prices (in part) as reference in setting their regulated prices - means some companies may not wish to reduce UK list because of the potential impact on global revenues, and hence may be better off in the PPRS even if it appears they would be better off leaving from a UK perspective alone. This is impossible to model as it would require detailed information on how each product in each company's product portfolio is affected by international referencing pricing arrangements. Whilst this does not change the estimates of price cuts required in the statutory scheme to fully mitigate the risk of companies leaving the PPRS, it does mean that the estimates of savings that result from the mitigation are most probably over-estimates.

For these reasons, it is essential that readers take the results of this modelling as a guide only. Whilst all efforts have been made to take on board the latest information, there is always the possibility of errors in the analysis. These errors could of course go either way.

It is also important to note that the greatest uncertainties in projecting the impact of measures relate to price cuts – which depend on product-level analysis. In contrast, impacts of measures using payment percentage mechanisms are calculated at the level of company revenues, and are therefore subject to less uncertainty.

OPTION 1 – Further price cut to statutory scheme products

Modelling savings

This option entails the application of a further cut to the list prices of drugs currently supplied under the Statutory Scheme, beyond the 15% cut previously implemented.

However companies commonly provide NHS customers with discounts from list prices for some products. The savings realised from the cut will therefore depend on the actual selling price of drugs to the NHS, and whether the reduction to the list price exceeds any discounts.

For example, if a drug's list price was **£100**, and the maximum price following a further cut was **£72**, savings would only be realised to the extent that the drug's actual selling price, after discounts, was

greater than **£72**. If the drug's actual selling price, after discounts, was £72 or less, the cut to the list price would not realise any savings.

To estimate the actual impact of a cut to list prices, reports of list prices, volumes and actual values of sales were requested from companies in the statutory scheme.

These data were used to model the impact of a cut to the list price on actual sales, on a product-by-product basis.

Some products in the statutory scheme are supplied under "framework" agreements. Products in an existing framework agreement are exempt from the impact of the proposed price cut until the agreement expires. This exemption is reflected in the estimate of savings.

Savings are modelled assuming a price cut of **28%** (relative to the list price of products), and are assessed from the proposed inception of the measure, on 1st April 2016, until the expiry of the current PPRS agreement on 31st December 2018.

The NPV of estimated savings over this period is **£50m** (discounting at 1.5%).

To these are added the savings of **£594m** from deterring switching from the statutory scheme, to give a total NPV of cost savings of **£644m**.

As discussed in the "Background" section, projections of sales and switching behaviour after a price cut is inherently uncertain, as it depends on accurate reporting and projection of the list prices and actual prices of all individual products in the voluntary and statutory schemes.

Gain in health for NHS patients

In accordance with standard IA and Green Book practice, 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 cost savings are therefore estimated at **42,906 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 **£2,574m**.

Loss of profits for the pharmaceutical industry

The magnitude of these impacts is assessed using the approach taken in the previous Impact Assessment of the Statutory Scheme¹.

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. 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,

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/362479/Statutory_Scheme_2014_IA.pdf

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 principles².

Application of these adjustments gives an estimate for the value of lost profits of **£255m** (NPV, discounted at 3.5%). Note that this weighting is not applied when calculating the EANBC, and the Business Net Present Value – which are accordingly slightly higher.

Finally, in accordance with the recommendations of the Treasury Green Book, impacts on UK nationals and non-UK nationals are reported separately.³ 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. (In calculating the EANBC and Business NPV it is similarly assumed that 10% of impacts affect UK interests).

Therefore the value of the UK share of lost profits is **£26m**. The EANBC is **£13m**.

Further impact on the UK economy

Reducing drug spend in the NHS will reduce global revenues of pharmaceutical companies, as described above. As well as the direct reduction associated with NHS spending, there may be further reductions in global spend to the extent that other country's pricing and spending decisions are affected by those in the UK. Lower projected revenues for future products may be expected to reduce the incentive for pharmaceutical companies to invest in R&D. Reduced investment in R&D may have negative impacts on the UK economy. However any such impact is expected to be minimal, for the following reasons:

- This assessment considers a short to medium term measure and so it is unlikely to affect any R&D investments, which are typically made many years in advance of the launch and sale of resulting products.
- The majority of branded pharmaceutical company costs – and therefore ultimate impact of a change in spending – is represented by marketing. R&D spending and investment is a smaller fraction. Any change in expected revenues would therefore result in a commensurately reduced change in the amount of R&D investment.
- The impact of the change in R&D investment on the UK would be further diluted as only a small fraction of global R&D occurs in the UK. There is no obvious reason to expect that changes in UK prices would significantly affect the share of global R&D located in the UK – which is determined primarily by the availability of resources required for carrying out R&D, in particular expert labour, as found by a study of the key factors in attracting internationally mobile investments by the research-based pharmaceutical industry⁴.

For these reasons, any impact of the proposed measures on the UK economy through reduced R&D are expected to be minimal, and they have not been monetised.

Likewise, the likely positive balance of trade impact (since over 90% of pharmaceuticals consumed in the UK are imported), has not been quantified.

Net impact

The net impact of the option is the sum of the impacts on NHS patients and UK business: **£2,549m**.

Assumptions and risks

The savings estimates above are based on data provided to DH by companies in the statutory scheme, and the results assume these data are accurate. It is apparent that some of the data submitted may be inconsistent, and contain errors. DH are endeavouring to clarify these inconsistencies with companies.

² See Distribution: Annex 5 in HMT Green Book.

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

⁴ <http://www.nera.com/publications/archive/2007/key-factors-in-attracting-internationally-mobile-investments-by-.html>

This analysis assumes that list prices can be reduced without jeopardising supply of products. If it becomes apparent that supply of a product is threatened, the cut in list price may not be applied. To the extent that this circumstance arises, the savings estimated here would be reduced.

Sensitivity analysis

The corresponding net impacts for low and high trajectory scenarios are shown below.

Scenario	Required stat. scheme price cut	NHS cost savings, £m (NPV)	UK lost profits, £m (NPV)	Net impact, £m (NPV)	EANBC, £m
Low	24%	243	10	963	5
Med. (central)	28%	644	26	2,549	13
High	33%	1,439	57	5,700	30

OPTION 1a – Further price cut to statutory scheme products, including new products

Modelling savings

Under this option, additional savings would be generated from new products that are not part of the current statutory scheme, but which are expected to be encompassed in the scheme in the future.

Initial forecasts of new spending, and the corresponding list prices and actual prices, were provided by NHS England. Expected savings on new products were calculated as for option 1.

The estimated additional savings have a NPV of **£19m**, giving a total NPV for savings from the statutory scheme of **£69m**.

Addition of the savings from deterred switching gives a total NPV of savings of **£663m**, corresponding to provision of **44,169** additional QALYs, valued at a total of **£2,650m**.

Loss of profits for the pharmaceutical industry

The additional cost savings to the NHS lead to corresponding losses in profits for the pharmaceutical industry. Using the calculation methodology above, the NPV of lost UK profits is valued at: **£26m**. The EANBC is **£14m**.

Net impact

The net impact of the option is the sum of the impacts on NHS patients and UK business: **£2,624m**.

Assumptions and risks

In addition to the assumptions and risks identified for option 1, the estimated impacts for option 1a included the assumption that savings can be fully applied to new products in the statutory scheme. To the extent that this is not possible, the additional savings will be reduced.

Sensitivity analysis

The corresponding net impacts for low and high trajectory scenarios are shown below.

Scenario	Required stat. scheme price cut	NHS cost savings, £m (NPV)	UK lost profits, £m (NPV)	Net impact, £m (NPV)	EANBC, £m
Low	24%	243	10	963	5
Med. (central)	28%	663	26	2,624	14
High	33%	1,489	59	5,896	31

OPTION 2 – Application of a payment percentage to statutory scheme products

Modelling savings

Under this option, companies in the statutory scheme would be required to make a payment to the NHS of a proportion of their actual NHS sales derived from products currently in the scheme.

Savings are estimated using company reports of actual NHS sales of products in the statutory scheme, accounting for products exempted under “framework” agreements, as for option 1.

Savings are modelled assuming a payment of **13%** of NHS sales, assessed from the proposed inception of the measure, on 1st April 2016, until expiry of the current PPRS agreement on 31st December 2018.

The NPV of estimated savings over this period is **£207m** (discounting at 1.5%). To these are added the savings of **£594m** from deterring switching from the statutory scheme, to give a total NPV of cost savings of **£801m**.

Gain in health for NHS patients

In accordance with standard IA and Green Book practice, 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 cost savings are therefore estimated at **53,382 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 **£3,203m**.

Loss of profits for the pharmaceutical industry

The additional cost savings to the NHS lead to corresponding losses in profits for the pharmaceutical industry. Using the calculation methodology above, the NPV of lost UK profits is valued at: **£32m**. The EANBC is **£17m**.

Net impact

The net impact of the option is the sum of the impacts on NHS patients and UK business: **£3,171m**.

Assumptions and risks

The savings estimates above are based on data provided to DH by companies in the statutory scheme, and the results assume these data are accurate. It is apparent that some of the data submitted may be inconsistent, and contain errors. DH are endeavouring to clarify these inconsistencies with companies.

This analysis assumes that payments can be reduced without jeopardising supply of products. If it becomes apparent that supply of a product is threatened, the cut in list price may not be applied. To the extent that this circumstance arises, the savings estimated here would be reduced.

Sensitivity analysis

The corresponding net impacts for low and high trajectory scenarios are shown below.

Scenario	Required stat. scheme payment	NHS cost savings, £m (NPV)	UK lost profits, £m (NPV)	Net impact, £m (NPV)	EANBC, £m
Low	10%	364	14	1,442	8
Med. (central)	13.5%	801	32	3,171	17
High	17%	1,611	64	6,379	33

OPTION 2a – Application of a payment percentage, including new products

Modelling savings

Under this option, additional savings would be generated from new products that are not part of the current statutory scheme, but which are expected to be encompassed in the scheme in the future.

Initial forecasts of new spending were provided by NHS England. Expected savings on new products were calculated as for option 2.

The estimated additional savings have a NPV of **£62m**, giving a total NPV for savings from the statutory scheme of **£269m**.

Addition of the savings from deterred switching gives a total NPV of savings of **£863m**, corresponding to provision of **57,513** additional QALYs, valued at a total of **£3,451m**.

Loss of profits for the pharmaceutical industry

The additional cost savings to the NHS lead to corresponding losses in profits for the pharmaceutical industry. Using the calculation methodology above, the NPV of lost UK profits is valued at: **£34m**. The EANBC is **£18m**.

Net impact

The net impact of the option is the sum of the impacts on NHS patients and UK business: **£3,417m**

Assumptions and risks

In addition to the assumptions and risks identified for option 2, the estimated impacts for option 2a included the assumption that savings can be fully applied to new products in the statutory scheme. To the extent that this is not possible, the additional savings will be reduced.

Sensitivity analysis

The corresponding net impacts for low and high trajectory scenarios are shown below.

Scenario	Required stat. scheme payment	NHS cost savings, £m (NPV)	UK lost profits, £m (NPV)	Net impact, £m (NPV)	EANBC, £m
Low	10%	410	16	1,624	8
Med. (central)	13.5%	863	34	3,417	18
High	17%	1,689	67	6,688	35

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.

Annex A

1. Extract from Chapter 6 of 2014 PPRS ‘PPRS Payment Mechanism’
2. Annexes 3 and 4 PPRS

CHAPTER 6 – PPRS Payment Mechanism

Introduction

Recognising the current state of the global economy, the Department and ABPI have agreed that instead of the headline price adjustments which have been a feature of recent PPRSs a limit is introduced on growth in the overall cost of the branded medicines purchased by the NHS from members of the scheme. An important purpose is to provide Government with surety on the level of NHS expenditure on branded health service medicines supplied by scheme members. The scheme remains a portfolio-wide profit regulatory scheme which permits modulation in the market.

In outline and without prejudice to the requirements set out in paragraphs 6.4-6.47 below, scheme members will make percentage payments based on the difference between allowed percentage growth and actual percentage growth in NHS expenditure on branded medicines. The percentage payments will apply to products on the market at 31 December 2013 subject to the exemptions set out below. Allowed percentage growth has been agreed for the five years of the scheme. The difference between the allowed percentage growth and an agreed forecast percentage growth gives an initial estimate of percentage payments. An initial percentage payment has been set for the first year and this will not change. In subsequent years, the actual percentage growth will be reviewed versus the forecast and the initial estimate of payment percentages for the future years will be adjusted to reflect actual percentage growth, any over or underpayment from the previous year and a revised forecast percentage growth for the following years. In the last year, the payment percentage will be based on the forecast percentage growth calculated at the end of the previous year and there will be no adjustment and/or payment to reflect the actual percentage growth in the last year. This is known as the “PPRS Payment Mechanism”.

The key terms used to describe the PPRS Payment Mechanism are set out in paragraphs 6.4-6.10 below. This scheme sets out the Allowed Growth Rate of Measured Spend for each year of the scheme. Scheme members will make payments (“PPRS Payments”) to the Department for Measured Spend which is above the Allowed Growth Rate of Measured Spend, according to the rules set out in the scheme.

Definitions

“Sales of Scheme Products” means: sales of all products covered by the scheme (as defined at paragraphs 3.14-3.19), including central procurements. Sales of Scheme Products will be calculated net of all discounts, but including sales that relate to Brand Equalisation deals and excluding parallel imports i.e. medicines which are imported and supplied to the NHS by a party other than the scheme member or a company that is affiliated to the scheme member such as a parent company.

“Sales of PPRS Products” means: Sales of Scheme Products as defined in paragraph 6.4 above, but excluding sales that relate to Brand Equalisation deals. Brand Equalisation

occurs where a scheme member offers dispensing contractors, whether directly or through wholesalers, additional discounts or rebates on branded medicines that result in them dispensing their brand against a generic prescription where there is a competitor generic presentation available.

“Measured Spend” means: Sales of PPRS Products as defined at paragraph 6.5 above supplied by scheme members in the scheme, including sales of new products, but excluding the following:

The following central procurements:

Exceptional central procurements out-with the normal annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation);

Procurements of centrally supplied vaccines;

Sales by smaller companies, defined as companies with Sales of Scheme Products of less than £5m in the previous calendar year.

“Sales Covered by the PPRS Payment” means: Sales of PPRS Products as defined at paragraph 6.5 above including biosimilars and line extensions of products originally introduced before 31 December 2013 but excluding the following:

The following central procurements:

Exceptional central procurements out-with the normal annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation);

Procurements of centrally supplied vaccines;

Sales by smaller companies defined as companies with Sales of Scheme Products of less than £5m in the previous calendar year;

Sales of new products as defined in paragraph 6.10 below.

“Growth Rate of Measured Spend” means: the percentage growth in Measured Spend between one calendar year and the following calendar year.

“Allowed Growth Rate of Measured Spend” means: The Allowed Growth Rate of Measured Spend in each year of the scheme. The Allowed Growth Rates for each year of the scheme are set out in Annex 3 and remain fixed for the duration of the scheme.

“New Products Share of Measured Spend” means: The percentage of Measured Spend which is accounted for by sales of new products. For this purpose, new products are defined as follows: products introduced after 31 December 2013 following the granting of an EU or UK new active substance marketing authorisation from the appropriate licensing body. This does not include biosimilars or line extensions of products originally introduced before 31 December 2013.

Summary of Methodology

To meet the objective set out in paragraph 6.1, the Allowed Growth Rate for 2014 is 0% and then for each subsequent year is 0%, 1.8%, 1.8%, 1.9%. The Allowed Growth Rates for each year of the scheme will remain fixed. There is a pre-agreed profile of PPRS Payment percentages for the five years of the scheme (expressed as percentages of the Sales Covered by the PPRS Payment) derived from the initial

forecast Growth Rate of Measured Spend and the Allowed Growth Rate of Measured Spend. Annex 3 sets out the Allowed Growth Rates of Measured Spend, and the initial profile of PPRS Payment percentages. Annex 3 also sets out the initial forecasts of Growth Rate of Measured Spend and the initial forecasts of New Products Share of Measured Spend.

The PPRS Payment percentage which applies in 2014 is 3.74%. If the Measured Spend grows faster or slower than the initial forecast Growth Rate, the payment percentage profile will be adjusted according to the process set out in Annex 4 and applied to the remaining period of the scheme. The first adjustment will apply to year two (2015) based on outturn Growth Rate of Measured Spend for year one (2014). The adjustments will be based on actual growth rates compared to forecast, and corrections for any previous under or over-payments will be pro-rated over the remaining period. Annex 5 sets out the detailed methodology and calculation formulas for calculating PPRS Payments in each year of the scheme.

Any adjustments to the profile of PPRS Payment percentages for future years will be set in advance of the year concerned and communicated in quarter four of the previous year. In order to ensure a prompt closure of the scheme, the PPRS Payment for the final year will be adjusted based on 2013-2017 outturn actuals and over or underpayments from those years. There will be no payment either by companies or the Department in the 2019 financial year to correct for differences between 2018 forecast and outturn for Measured Spend.

The adjustments will be made to ensure that the Allowed Growth Rate of Measured Spend is not exceeded. If the outturn of the growth rate is lower than the Allowed Growth Rate and the payment for that year is set at zero, the Department will not make net payments to bring growth rate up to the Allowed Growth Rate.

Annex 6 provides further details on the data sources that will be used for the PPRS Payment Mechanism. There will be an independent reconciliation exercise completed during 2016 to compare company data with administrative data on outturn in 2013, 2014 and 2015, to follow up any inconsistencies and correct any errors.

Arrangements for Making PPRS Payments

Each scheme member will make a payment to the Department of Health which is the PPRS Payment percentage multiplied by their Sales Covered by the PPRS Payment. The PPRS Payment percentage for each year, set in advance of that year, will apply uniformly to each scheme member (excluding smaller companies, defined at paragraph 6.31 below). The PPRS Payment percentage will be applied to the company's Sales Covered by the PPRS payment as defined at paragraph 6.7 above.

The PPRS Payment will be paid in quarterly instalments by individual companies at the same time as the Quarterly Sales Reports are submitted. Payment and Quarterly Sales Reports will be due within one month of the end of each quarter of the calendar year. The Quarterly Sales Report should be completed in accordance with the guidance at Annex 7 and using the Sales Report pro-forma at Annex 7, appendix 1).

In the case of chemical entities on the market at 31 December 2013 which are subsequently transferred or sold on, and remain in the ultimate ownership of the company which held them on 31 December those sales should form part of that company's sales for the purposes of calculating and making payments by scheme

members, unless already captured elsewhere in the industry-wide calculations (i.e. there will be no double counting of sales when it comes to PPRS Payments).

Annexes 3 and 4 of PPRS

Annex 3: Forecasts, Allowed Growth Rates and Initial Profile of Payment Percentages

1. The table below sets out for each year of the scheme the agreed:

- initial forecast Growth Rate of Measured Spend (F%);
- Allowed Growth Rate of Measured Spend (AGR);
- initial forecast of New Products Share of Measured Spend (NP%);
- initial annual payment percentage for companies in the scheme (P1);
- estimated future annual payment percentages (FP2-5).

	2014	2015	2016	2017	2018
Initial forecast Growth Rate of Measured Spend (F%)	3.87%	3.52%	3.86%	2.14%	3.09%
Allowed Growth Rate of Measured Spend (AGR)	0%	0%	1.8%	1.8%	1.9%
Initial forecast of New Products Share of Measured Spend (NP%)	0.47%	1.85%	3.37%	5.13%	7.01%
Initial annual payment percentage (P%1)	3.74%				
Estimated future annual payment percentages (2015-2018) (FP%2, FP%3, FP%4, FP%5)		7.13%	9.92%	9.92%	9.92%

2. The Allowed Growth Rate of Measured Spend percentage (AGR) figures will remain fixed as above for the whole period of the scheme and will not be revised.
3. The payments apply to Sales Covered by the PPRS Payment, as defined at paragraph 6.7 of Chapter 6.
4. As new products are exempt from the PPRS Payments, but are included in the Measured Spend, the payment percentage is proportionately increased to take account of the percentage of new products and the resulting payment shortfall.
5. The first annual payment percentage (P1) will be 3.74% of Sales Covered by the PPRS Payment in 2014. This is based on the agreed forecast Growth Rate of Measured Spend for 2014 and will deliver a 0% growth rate for 2014 for those sales. All other payment

percentages (P2, P3, P4 and P5) depend on how the forecast growth rate compares to outturn for the remaining years of the scheme, and will be adjusted on an annual basis, as explained in Annexes 4 and 5.

6. The second annual payment percentage (FP2) is expected to be 7.13% of Sales Covered by the PPRS payment in 2015. The actual payment percentage (P2) will depend on how the outturn compares to the joint forecast, but will be set such that there is a 0% Growth Rate of Measured Spend for 2015.
7. There is a smoothed payment percentage for the last three years of the scheme, and that is why the last three payment percentages (FP3, FP4 and FP5) are expressed as a constant percentage of 9.92% for 2016, 2017 and 2018. The smoothed forecast payment percentage for these last three years of the scheme is calculated as the sum of the forecast Measured Spend for the last three years of the scheme minus the sum of the forecast allowed Measured Spend for the last three years. This number is expressed as a percentage of forecast Sales Covered by the PPRS Payment.
8. Annex 5 sets out the methodology in more detail and the calculation formulae which will be used.

Annex 4: Adjustments to Profile of Payments

Adjustment of forecast growth rates

1. The forecast growth rates for the remaining years of the scheme are adjusted to take account of the outturn for the previous year. The adjustments are outlined in the Table below (paragraph 17). Annex 5 sets out the methodology in more detail and the calculation formulae which will be used in each year of the scheme.
2. The forecast Growth Rate of Measured Spend (F%) is adjusted following the methodology set out below. In order to avoid volatility, and only for the first adjustment of the scheme in year two the correction of the forecast growth rate is half of the difference between the actual growth rate for year one and the forecast growth rate for year one. The difference could be a positive or negative figure and is expressed as a percentage. This is added to the initial forecast growth rate for each of the subsequent years to produce the adjusted forecast growth rate for each year.
3. For years three and following the correction is the average of the differences between actual growth rate and forecast growth rate for each previous year of the scheme. This is added to the initial forecast growth rate for each of the subsequent years to produce the adjusted forecast growth rate for each year.

Adjustment of forecast New Products Share of Measured Spend

4. The first adjustment to the New Products Share of Measured Spend will be in November 2014, which will affect the forecasted New Products Share of Measured Spend for 2015 to 2018. The original forecasted New Products Share of Measured Spend for 2015 to 2018 will be adjusted in an additive way based on the difference between the original forecasted share and the outturn share. The outturn share will be based on company reported sales for new products in quarter two 2014 and quarter three 2014 multiplied by two. This will give a first estimate for the sales of new products for 2014.
5. In November 2015, the first outturn data for the New Products Share of Measured Spend in 2015 will be available. The forecast sales of new products for 2015 will be estimated based on company reported sales for new products in quarter two and quarter three of 2015 multiplied by two. The New Products Share of Measured Spend for 2016, 2017 and 2018 will then be adjusted in percentage terms (i.e. in a multiplicative way) based on the average ratio in 2014 (based on audited data) and 2015 (based on first outturn data for this year).
6. For the last three years of the scheme, the New Products Share of Measured Spend will be adjusted based on a rolling two year average. Thus, for example, in November 2016 the forecast New Products Share of Measured Spend for 2017 and 2018 will be adjusted based on the average error for 2015 (based on audited data) and 2016 (based on first outturn – quarter two and quarter three multiplied by two).

Adjustment of payment percentages

7. The 'error' in the payment due in a given year is the difference between the actual cash payment made, and the payment that would have been made had the forecast been accurate. This figure could be either positive or negative. For each year there is an initial error figure calculated on the basis of unaudited outturn data and a revised error figure calculated on the basis of audited outturn data. This is illustrated in the table below (paragraph 17). Due to end year dates for Statutory Accounts, it is possible that audited outturn will not cover the full year for the year in question. What follows assumes that all audited data is available the following year. How differing end year statutory accounts are dealt with is covered in paragraph 16 below.
8. The error is spread equally over the remaining scheme years, and the new payment percentage takes this and the revised forecast growth rates into account.
9. The smoothed payment percentages for 2016, 2017 and 2018 is the total forecast payment for the remaining years of the scheme divided by the sum of the adjusted forecast net spend on sales covered by the PPRS payment adjusted for the payment error for each of the remaining years of the scheme. This number is expressed as a percentage of the revised spend on sales covered by the PPRS payment.
10. In the event that the outturn of the Growth Rate of Measured Spend is lower than the Allowed Growth Rate of Measured Spend, the payment for that year is set at zero. If adjustments to the future payment cannot compensate for Industry overpayments during the early stages of the scheme, then the Department will refund companies the full amount of the payment each company has made for the years when the payment percentage is adjusted to zero.

Timing of the adjustments

11. The initial base 2013 calendar year Measured Spend outturn will be captured in a Sales Report completed by scheme members by the end of March 2014 broken down into quarters. This will be independently audited by September 2014. Scheme members will use the Sales Report pro-forma at Annex 7, Appendix 1) for both the quarterly and annual report of sales in the baseline year. The annual baseline year sales report will be audited according to the requirements set out at paragraphs 6.24-6.30 of Chapter 6.
12. Outturn of Measured Spend is calculated following the close of the third quarter of each calendar year. The outturn is the actual Measured Spend for the twelve months ending in September – i.e. including the fourth quarter of the previous calendar year. This is in order that the adjustments can be calculated and set in advance of the following calendar year. For the adjustment to the 2015 payment percentage in November 2014 this will be based on January to September 2014 versus the same period in 2013. Once the Audited Annual Reports for 2013 and 2014 have been received, the outturn Growth Rate of Measured Spend for 2014 will be calculated by comparing the twelve months 1 January 2013 to 31 December 2013 with the twelve months 1 January 2014 to 31 December 2014. This will apply to the calculation of the year 3 (2016) payment.
13. Following the independent audit of the accounts after the end of each year (expected to be completed by September of the following year) any corrections necessary to the

aggregated outturns are then fed into the calculation of the adjustment of the payment percentage for the year after. So for year one (2014) any corrections to the outturn following the audited accounts received by September 2015 in year two will be fed into the adjustment calculations for the payment percentage for years three and following (2016, 2017 and 2018). See table in paragraph 17 for more details.

14. Where the auditors recommended approach for accounting for Sales Covered by the PPRS Payment differs from the approach adopted by the scheme member, the scheme member will adopt the methods recommended by the auditors for future Sales Reports.
15. Each time a scheme member leaves or joins the scheme and/or exceeds/falls below the smaller company exemption the baseline outturn figures will be adjusted to include the outturn sales for all of the scheme members who are members of the scheme at the time the adjustment is carried out and only those scheme members. Scheme members that join the scheme after the end of the third quarter in any calendar year will need to submit a Sales Report for the last quarter of that year within one month and an Audited Annual Sales Report for that year within nine months of the end of that year in order for their sales to be included in the baseline year in which they joined the scheme. The calculation of the outturn Growth Rate of Measured Spend for any year will exclude any scheme members where there is not sales data for both that and the previous year. The best available data will be used at each point that adjustments are made (this could include part year audited and part year unaudited data). When audited data becomes available this will be used to make further corrections as necessary.
16. All scheme members will be required to submit their Audited Annual Sales Report within nine months of the end of the scheme member's financial year. Where the financial year end date differs from the end of the calendar year (31 December) the best available data will be used at each point that adjustments are made (this could include part year audited and part year unaudited data). When audited data becomes available this will be used to make further corrections as necessary. This also covers data relating to the baseline period (2013). It is also possible that information may come to light, for example during the reconciliation exercise, that means that additional adjustments are required to the Measured Spend and therefore the forecasts and payment percentages, which are not set out in the table at paragraph 17. This will be agreed with the auditors on the basis of how to best represent measured spend historically and for future adjustments.

Timetable for adjustments

17. The payment percentages are adjusted each year to the attached timetable. There is a reconciliation exercise with administrative data carried out in 2016 as described in paragraphs 6.37-6.40 of Chapter 6. Bracketed adjustments are calculated and applied in the same exercise and result in a single adjustment to the payment percentage for the year they apply to (plus knock on adjustments to the profile for expected payment percentages for the remaining years of the scheme).

Outturn year	Payment percentage profile adjusted for Years	Based on actual spend for	Calculated when	Applies to payment in Year
Year 1 - 2014	Years 2-5	Audited 9 months ending 30/9/13 Unaudited 9 months ending 30/9/14	Sept 2014 Nov 2014	Year 2 – 2015 (P2)
Year 1 - 2014	Years 3-5	Audited 12 months ending 31/12/13 Audited 12 months ending 31/12/14	Sept 2014 Nov 2015	Year 3- 2016 (P3)
Year 2 - 2015	Years 3-5	Unaudited 12 months ending 30/9/15	Nov 2015	Year 3 – 2016 (P3)
Years 1 & 2 – 2014 & 2015	Years 4-5	Audited & reconciled 12 months ending 31/12/14 Audited & reconciled 12 months ending 31/12/15	Nov 2016	Year 4 – 2017 (P4)
Year 3 - 2016	Years 4-5	Unaudited 12 months ending 30/09/16	Nov 2016	Year 4 – 2017 (P4)
Year 3 - 2016	Year 5	Audited 12 months ending 31/12/16	Nov 2017	Year 5 – 2018 (P5)
Year 4 - 2017	Year 5	Unaudited 12 months ending 30/9/17	Nov 2017	Year 5 – 2018 (P5)