Title: Statutory scheme – Branded Medicines Pricing **IA No:** 9545 **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:**	**Impact Assessment (IA)** **Date: 06/03/2018** **Stage: Consultation response** **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Helen Lovell, 0207 210 4366 Kathryn Glover, 0207 210 5534

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 2017 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£163m	N/A	N/A	No	In/out/zero net cost

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

In order to limit the costs of branded health service medicines to a level which is considered affordable to the NHS, the Government and the pharmaceutical industry body, the ABPI, entered into a voluntary agreement to ensure the branded medicines bill stayed within affordable limits – the Pharmaceutical Price Regulation Scheme ("the PPRS 2014"). There is also a statutory scheme for those companies who do not wish to participate in the voluntary scheme. Parallel statutory regulations are required to broadly align the two schemes and ensure companies outside this voluntary agreement contribute to limiting drug spend to affordable levels.

The current statutory scheme regulations specify maximum selling prices for health service medicines covered by the scheme by requiring a 15% reduction of prices as at 1st December 2013. However the actual selling prices of many products are below this level, implying that the 15% price cut is not itself reducing the price at which the health service medicines are being sold. Companies are not therefore contributing to limiting NHS medicines spend to affordable levels in the same way as PPRS companies, who also tend to have actual selling prices below their list prices and pay a percentage of actual sales in payments through the PPRS. Action is therefore required to ensure products in the statutory scheme contribute appropriately to efforts to regulate the cost of medicines to the NHS.

What are the policy objectives and the intended effects?

The purpose of the statutory scheme is to safeguard the financial position of the NHS by ensuring similar levels of savings to the NHS on branded health service medicines, from both schemes i.e. in terms of payments as a proportion of the total sales made by members of each scheme.

The intended effects are to increase savings for the NHS from branded medicines, and provide corresponding additional benefits to NHS patients, including maintaining supply.

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

A single proposed option has been considered: to change statutory regulations from a price-cut mechanism only, to a mechanism which controls prices and requires companies to make payments to the Secretary of State based on their actual sales – thereby broadly mirroring the mechanism used in the PPRS 2014.

Will the policy be reviewed? It will be reviewed annually.

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: Lord O'Shaughnessy Date: 8th March 2018

Summary: Analysis & Evidence

Do Nothing

Description: Do Nothing

Price Base Year 2017	PV Base Year 2017	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -

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

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

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

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

N/A

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

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

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

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

N/A

Key assumptions/sensitivities/risks

Discount rate (%)

N/A

BUSINESS ASSESSMENT (Option 0)

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

Summary: Analysis & Evidence

Policy Option 1

Description: Apply a 7.8% payment percentage to qualifying sales in the statutory scheme

Price Base Year 2017	PV Base Year 2017	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: 163

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	n/a		n/a	
High	n/a		n/a	
Best Estimate	n/a		n/a	**1.1**

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

UK shareholders in pharmaceutical companies: Pharmaceutical company revenues will be reduced by £33m, with consequent loss of profits for UK shareholders valued at £0.7m.

Wider UK economy: Reduced revenue for pharmaceutical companies is expected to result in reduced investment in R&D, including in the UK, with consequent loss of spill-over benefits for the UK economy valued at £0.4m.

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

None identified

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	n/a		n/a	
High	n/a		n/a	
Best Estimate	n/a		n/a	**164**

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

NHS patients: NHS costs (UK) will be reduced by £33m, enabling the provision of additional treatments and services estimated to provide NHS patients with an additional 2,213 QALYs, valued at £133m.

Wider UK economy: Improved patient health is expected to lead to wider economic benefits, for example through increased productivity and reduced need for formal and informal care, valued at £31m.

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

None identified

Key assumptions/sensitivities/risks **Discount rate (%)** n/a

Assumptions:

- Any impacts of switching between schemes is negligible
- Company returns data on NHS sales are accurate.
- Products where price is limited by current 15% discount vs list will rise to 5% discount vs list
- Supply of products will be economically viable following application of the payment percentage

BUSINESS ASSESSMENT (Option 1)

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

Background

1. In the UK, the costs of branded health service 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 Government and Northern Ireland (which includes the health departments of England, Wales, Scotland and Northern Ireland), and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI).

2. Unlike the previous (2009) PPRS (and its predecessor agreements), which put in place controls on the prices of branded health service medicines through a series of price adjustments, which were in turn mirrored by the statutory scheme, the PPRS 2014 operates through a different mechanism. Instead of a reduction in list price, the voluntary scheme limits the growth in the overall branded health service 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 stayed flat in 2015 and is allowed to grow slowly (1.8%, 1.8%, 1.9%) in the final three years of the scheme (2016, 2017 and 2018).

3. Operating alongside the PPRS are statutory regulations (the statutory scheme). Companies which choose not to join the PPRS 2014 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 2009.

4. 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.

5. In 2015, following the introduction of the 2014 PPRS, the Government consulted on changes to the statutory scheme to bring it back into alignment with the PPRS. The responses to that consultation led the Government to conclude that it needed to put its powers to introduce a payment based on sales into the statutory scheme beyond doubt. The Health Service Medical Supplies (Costs) Act 2017 amends the NHS Act 2006 to make provision for this, and the Government now proposes to make regulations to implement a revised statutory scheme.

Problem and justification for Government intervention

6. Suppliers of branded medicines typically hold patents which enable monopoly supply of products at high prices to the NHS. In addition, medicines which are required to have a brand name by the MHRA (which may be out of patent) are generally not as interchangeable as unbranded generics. Therefore, competitive forces will act more slowly and less effectively, which means that decreases in actual selling prices are likely to be lower. For both reasons, Government action is required to limit spending on branded health service medicines to a level which is considered affordable to the NHS. To this end, the Department of Health and the pharmaceutical industry have made a voluntary agreement – the PPRS 2014 – which limits the growth in the overall branded medicines bill for products covered by the scheme. The 2014 PPRS introduces a limit on growth in the overall cost of branded medicines purchased by the NHS from members of the scheme. Scheme members with annual NHS sales above £5 million make percentage payments based on the difference between allowed percentage growth and actual percentage growth in NHS expenditure on branded medicines. The payment percentage for 2017 is 4.75% and it was agreed that the payment percentage for 2018 would fall within 2.38% and 7.8%. In December 2017, it was confirmed that the payment percentage for 2018 will be 7.8%.

7. As the PPRS is voluntary, statutory regulations are required to limit spending on products supplied by companies who choose not to join the PPRS. These regulations are referred to as the "statutory scheme". The terms of the current statutory scheme provide for the application of a 15% discount to the prices of qualifying products, compared to their list prices as of 1st December 2013

8. However evidence from company returns shows that most products in the statutory scheme have actual selling prices that are more than 15% below their NHS list prices and therefore the statutory scheme has no effect on their sales revenue. Companies in the statutory scheme are not therefore contributing to limiting NHS medicines spend to affordable levels in the same way as PPRS companies, who also tend to have actual selling prices below their list prices, and pay a percentage of actual sales in payments through the PPRS.

9. Additionally, the fundamental difference in approach to generating savings between the two schemes creates uncertainty for Government and companies in predicting the savings generated, and may incentivise inefficient switching between schemes.

10. Action is therefore required to change the statutory scheme so that it is consistent with the voluntary scheme, in terms of its mechanism and the level of savings generated from qualifying sales, and to ensure that the impact on the level of spend on branded health service medicines overall is broadly similar to the PPRS agreement.

Objectives

11. The objectives of the policy measures are

    - to safeguard the financial position of the NHS by ensuring similar limits on the costs of branded health service medicines, and the approach taken to generate them, to those of the voluntary PPRS i.e. in terms of payments as a proportion of the total sales made by members of each scheme

    - to increase the cost-effectiveness of spending on drugs in the statutory scheme, while ensuring continuity of supply and patient access to drugs.

Evaluation of options

12. Two options are considered: the option to "do nothing"; and an option to apply a payment percentage of 7.80% to qualifying product sales in the statutory scheme.

13. These options are evaluated for a period of 1 year, from April 2018 to April 2019.

"Do Nothing" Option

14. A counterfactual or 'do nothing' scenario is considered in which it is assumed that the Government continues to apply a price cut at the current level of 15%.

15. Under this option products in the statutory scheme whose actual selling prices are not affected by the current price cut will continue to avoid contributions to the savings required to ensure that the NHS drugs bill is held at affordable levels.

Option 1: apply a payment percentage to sales in the statutory scheme

Description of option

16. Under this option a payment percentage would be applied to qualifying sales to the NHS by companies in the statutory scheme.

17. Sales by statutory scheme companies encompassed by existing framework agreements and contracts, sales of low-cost presentations (with a cost of less than £2.00), and companies with sales of <£5m pa would be excluded from the payment.

18. The payment percentage for 2017 is 4.75% and it was agreed that the payment percentage for 2018 would fall within 2.38% and 7.80%. In December 2017, it was confirmed that the payment percentage for 2018 will be 7.8%.

Overview of effects

19. This section gives a brief narrative overview of the effects of the policy. The following sections explain the calculations of each effect in more detail.

Direct impacts on NHS sales

20. The primary impact of the policy is the effect it would have on reducing the cost on the NHS of sales of branded health service medicines. Most ultimate impacts, on NHS patients and manufacturers and suppliers, result from the impact that the payment percentage has on the cost of NHS sales. The only additional impact results from the costs to companies of providing additional information.

21. The application of the payment percentage on the sales income (and therefore on the amount for which the health service medicines are purchased) would replace the current 15% price cut applied to the list price. This would allow manufacturers and suppliers to increase the amount at which they sell their health service medicines. However, the Department does not expect the removal of the 15% price cut to result in all manufacturers and suppliers increasing their actual selling prices by 15%. See below for an explanation and analysis of the effects of relieving the 15% price cut requirement.

22. Additionally, the application of a payment percentage to qualifying sales will have the effect of reducing the net cost to the NHS of qualifying sales in the statutory scheme.

23. It is assumed that supply of products will not be affected by the application of the payment percentage. See *Future NHS use of products in the statutory scheme*, below, for consideration of this assumption.

24. Detailed calculation of the impact on the cost of NHS sales is given in the section *Calculation of impact on NHS spend*, below.

Consequent impacts on NHS patients and further consequences for the wider economy

25. The application of a payment percentage is expected to reduce the cost of net sales to the NHS, and thereby generate savings to the NHS budget. These savings will be used to fund additional NHS treatments and services which will benefit patients and generate additional health gains.

Improvements in patient health are expected to lead to consequent economic benefits through increased productivity, and reduced use of resources such as social care.

26. Detailed calculations of these impacts are provided in the sections NHS and patient health gains, and Benefits to UK economy from improved patient health, below.

Consequent impacts on pharmaceutical industry profits

27. The reduction of sales income for branded health service medicines, and the increased costs of reporting information will lead to a commensurate reduction in net revenue for pharmaceutical companies, both UK based and overseas. A proportion of this reduction in net revenue will result in lost profits for UK shareholders in pharmaceutical companies.

28. Detailed calculations of these impacts are provided in the section *Loss of profits for UK shareholders in pharmaceutical companies*, below.

Consequent impacts on UK economy from reduced R&D investment

29. The reduction of NHS revenues may lead to a reduction in investment in R&D, of which a proportion may affect the UK. A reduction in R&D investment would lead to reduced benefits to the UK economy from associated spill-over effects.

30. Detailed calculations of these impacts are provided in the section *Impact on UK R&D spill-overs*, below.

Costs to companies of providing information

31. The proposals entail requiring companies to submit information on their sales to the NHS, in order to calculate the payments due. This is expected to impose an additional burden of administration on companies. Detailed calculation of this impact is provided in the section *Costs to companies of providing information*, below.

Calculation of impact on NHS spend

32. Calculations are all based on returns made by companies reporting their sales to the NHS – including data on list prices, volumes and amount of revenues per product purchased in different NHS settings (i.e. through community pharmacies, hospitals and dispensing doctors).

Sales by statutory scheme companies

33. Total sales to the NHS by qualifying companies, based on the latest returns provided to DH for 2016, are £1,044m.

Exclusion of low-cost presentations

34. The terms of the current statutory scheme exclude presentations with a cost of less than **£2.00**. This exclusion is also proposed to apply in the new statutory scheme.

35. Sales of presentations whose list price is less than £2.00 amount to **£18m**.

Exclusion of sales covered by existing framework agreements

36. The terms of the current statutory scheme exclude sales of products which are procured by the NHS through framework agreements in effect at the moment of inception of the proposed scheme (i.e. on April 1st 2018).

37. The amount of sales that will be encompassed in framework agreements and contracts (made under Public Contract Regulations) at the inception of the new system is not known, as agreements may be made between now and the inception of the system. However analysis of data on current framework agreements indicate that, of the qualifying sales identified above (i.e. which are not affected by the low cost exemption), **£559m** are likely to be encompassed in such agreements, and therefore excluded from the payment mechanism. This figure represents an increase compared to the estimates made in the consultation stage IA, as we have since received more detailed data on current framework agreements.

38. The amount of current sales that would therefore qualify for the payment percentage is **£468m**. This figure will increase over time as extant frameworks and contracts expire, and new frameworks and contracts take their place which are within scope of the payment percentage.

Effect of relieving the 15% price cut

39. Sales and volumes of products in the statutory scheme were used to infer actual selling prices, which were compared – where applicable – to NHS list prices.

40. To calculate the effect of relieving the 15% price cut, products were first identified whose actual selling prices were between 14% and 16% below their 2013 NHS list prices, where applicable. Prices of these products were assumed to be actively limited by the 15% list price cut, and might therefore be expected to rise when the 15% cut was relieved. Annual sales of these products were **£71m**.

41. It is not possible to determine exactly the effect of relieving the 15% price cut on these products. The prices of some products may be expected to rise to their list prices – but some would be expected to reach a maximum price determined by market forces, as is observed for the majority of products. Evidence is not available to empirically determine the extent to which prices of these products will be affected. Therefore, to reflect the likelihood that not all products affected by the relief of the 15% price cut would rise all the way to the level of their full list prices, it is assumed that products in this category rise to the level of list prices with a discount of **5%**. This results in an increase in sales of these products from £71m to **£80m**.

42. To illustrate the sensitivity of the results to this assumption, the corresponding figure for sales if all products that appear to be affected by the 15% price cut were to rise to the level of list prices would be £84m. In the context of overall spend (and the overall impact of the payment percentage), this difference represents a proportionate change of less than 1%.

43. The increase in sales due to relieving the 15% price cut is therefore **£8m**. Information on current frameworks was used to derive an estimate of **£5m** for the amount of these sales encompassed by a framework agreement – and which therefore would not increase in price. The net increase in sales is therefore estimated to be **£4m**.

44. Adding this amount to the quantity of qualifying sales at current prices (£468m, above) gives a final total for qualifying sales of **£4m**.

Effect of applying payment percentage

45. The proposed policy would entail the payment by companies of 7.80% of affected sales to the NHS. This is estimated to generate total payments of **£37m.**

46. Total spending after the roll-back of the 15% price cut, and the application of the payment percentage is therefore £1,011m. Net savings, on the counterfactual spend of £1,044m, are therefore £33m over the one-year period under consideration.

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

Costs to companies of providing information

48. Exact costs for companies of providing information relating to the scheme are not known. The calculations below therefore reflect consideration of the most reasonable expectation, based on understanding of the typical processes involved in providing the requisite information.

49. The costs to companies and to the Department of supplying and reviewing information relating to maximum price setting and amendment are expected to be substantially unchanged, as the activities and resources required are considered to be similar to those required under the current arrangements.

Costs to companies qualifying for the payment percentage

50. Qualifying companies affected by the payment percentage are required to complete unaudited quarterly sales reports, estimated to entail **2 days** of administrative employee time. This figure has been revised since the Consultation Stage IA in light of feedback from respondents that our initial estimates were too low, and following extensive internal discussions on companies' experiences of the information requirements within the existing PPRS scheme. Assuming a day entails **8 hours** of paid employment, at an hourly cost[1] of **£16.79**, with additional costs of employment[2] ("on costs") of **30%**, this amounts to a cost per report of **£349**. Across the 17 companies currently estimated to be affected by the payment percentage this amounts to a total cost of **£23,748** over the period under consideration.

51. Qualifying companies are also required to provide audited annual reports, incurring estimated auditors' fees of £10,000 per report, and requiring 3 days of administrative time by a company employee. Using the approach to calculation set out above, this amounts to an estimated cost of £10,524 per report, and £178,905 in total.

Costs to companies with NHS sales of less than £5m pa

52. Smaller companies in the statutory scheme, whose sales to the NHS are below £5m pa, are not affected by the payment percentage. However they will be required to provide information on their sales.

53. There are estimated to be **111** such companies in the statutory scheme to which the payment percentage will not apply. The total costs to these companies of providing unaudited reports, using the calculation approach set out above, are estimated to be **£38,765**.

54. In addition to the unaudited reports, these companies may also be required to provide audited sales reports. It is likely that these requests would be by exception rather than routine. As a prudent assumption, it is estimated that up to **4** of these companies will be required to provide

[1] Based on data from the Annual Survey of Hours and Earnings 2016 on the gross median hourly wage for the Pharmaceutical Manufacturing and Wholesale industries

[2] From UK Standard Cost Model - see http://webarchive.nationalarchives.gov.uk/20121106104725/http://www.bis.gov.uk/files/file44505.pdf

audited annual sales reports. The total costs to these companies of providing audited reports, using the calculation approach set out above, are estimated to be **£42,095**.

Total costs to companies of providing information

55. The total cost to companies is estimated at £283,513.

NHS and patient health gains

56. 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[3]. The increased savings of £33m therefore correspond to a gain of **2,213 QALYs** for patients in the NHS.

57. These health gains are monetised using their estimated societal value[4] of £60,000, to give an annual impact valued at **£133m**.

Benefits to UK economy from improved patient health

58. Improving the health of patients is expected to result in consequent economic benefits through increased productivity (both in paid and unpaid work) and reduced need for resources such as formal and informal social care.

59. DH standard methodology for measuring these wider economic impacts gives an estimate of £13,925 of net benefit per QALY generated at the margin in the NHS[5]. Applied to the estimated QALY gains described above, this corresponds to a benefit valued at **£31m** for the period under consideration.

Loss of profits for UK shareholders in pharmaceutical companies

60. Pharmaceutical companies will see a reduction in revenues commensurate with the increase in savings for the NHS, and the costs of providing additional information – resulting in a reduction in the profits gained by shareholders in pharmaceutical companies.

61. In the long-run, changes in companies' revenues will not impact shareholders' profitability, since shareholders are always expected to ultimately make the risk-adjusted market return on capital. However in the short run – which arguably applies in this case - shareholders may receive a lower rate of return than under the "do nothing" option, and therefore a rate that is lower than the market rate.

62. Empirical estimates of the proportion of the reduction in gross profits that will translate into loss of profits for shareholders are not available. However the Department for Business, Energy and Industrial Strategy Skills (BEIS) has provided an estimate that **30%** of pharmaceutical revenue is ordinarily taken as profits, giving an estimate of lost profits of **£10m**. This estimate is necessarily based on consideration of the most reasonable assumption, since empirical data to inform the estimate is not available. This assumption was further tested through the consultation. The large

[3] The DH estimate of the cost at which an additional QALY is gained or lost in the NHS is £15,000. This figure is based on a published estimate of the cost per QALY at the margin in the NHS. For further explanation see https://www.york.ac.uk/che/research/teehta/thresholds/

[4] See p23 in https://www.gov.uk/government/publications/quantifying-health-impacts-of-government-policy

[5] See Annex A: Estimating the economic impacts of health conditions and treatments

majority of respondents appeared content and did not make any further comments. Where respondents did directly address this issue, the advice was that the 30% estimate was likely to be on the high side (which in turn suggests that impact on shareholders would be lower). Based on these considerations, we continue to use our assumption that 30% of pharmaceutical revenue is ordinarily taken as profits, as based on the consultation, this is likely to result in a prudent estimate of the impact on shareholders.

63. The pharmaceutical industry as a whole is global so, overall, the majority of NHS drug spending will accrue to overseas interests. BEIS estimate, based on analysis of trade information, 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 a corresponding proportion of the reduction in profits will accrue to UK shareholders, amounting to **£1.0m** over the period under consideration.

64. 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[6], giving a value of lost profits of **£0.7m** over the period in question.

Impact on UK R&D spill-overs

65. As described above, the proposed measures are expected to reduce the net revenues of pharmaceutical companies, compared to the "do nothing" option, which may result in reduced profits to shareholders. However the reduction in net revenue may also result in decreased investment in R&D[7] – of which a portion may be in the UK, providing "spill-over" losses to the UK economy.

66. The proportion of pharmaceutical company revenues devoted to R&D has been estimated[8] at 36%. Of this, not more than 10% would be expected to be invested in the UK, according to the UK's proportion of the global pharmaceutical industry set out above.

67. 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 societal benefits, compared to other uses. The Department for Business, Enterprise, Investment and Skills estimates the value of these additional benefits to be **30%** of the value of the investment[9].

68. Applying the estimates above to the projected decrease in pharmaceutical revenues gives a loss of **£0.4m** to the UK economy from reduced R&D investment over the period under consideration.

69. As part of the consultation we received no specific comments about the above calculations, however many respondents flagged the risk that decreasing NHS spending on pharmaceuticals

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

[7] 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.

[8] BEIS analysis of ONS/Business Enterprise Research and Development data

[9] Estimate provided in correspondence

would make the UK a less attractive location for foreign direct investment in R&D in the UK. However the available evidence and reasoning 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[10], and there is no obvious reason why siting of R&D facilities should be affected by demand or procurement for final products in the local market. A report by the OECD in 2008[11] similarly finds that there is little reason to believe that providing favourable market conditions -e.g. high prices – will be a significant determinant of firms' decisions where to establish headquarters and undertake R&D in particular. For instance, despite the favourable pricing policy of the Canadian government and agreements with industry to increase R&D investment, pharmaceutical R&D activities have not increased significantly in Canada. Whilst the consultation responses noted that spend on medicine would play a factor in investment decisions, it was acknowledged that this would not be the only factor. Overall, our assessment of the evidence continues to suggest that such a consideration would be secondary. As a result, any impact relating to NHS spending, or "demand-side" factors is therefore not considered likely to be significant[12].

[10] 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

[11] OECD. "Pharmaceutical Pricing Policies in a Global Market", OECD Health Policy Studies, OECD Publishing (2008).

[12] DH assessment – based on evidence and reasoning cited above – has been confirmed by BEIS in correspondence

Net monetised impacts

70. The total benefits of option 1, compared to the 'do nothing' option, are valued at **£164m**, over the period under consideration, while the total costs are estimated at **£1.1m** – giving a net benefit of **£163m**.

Summary of results

Payment percentage	7.80%
Savings, £m	33.20
Cost to companies of providing information, £m	0.3
QALYs gained elsewhere in NHS	2,213
Social value of QALY gains, £m	133
Value of economic consequences of health gain, £m	31
Lost profits to shareholders, £m	10
UK lost profits to shareholders, £m	1.0
Distribution-weighted UK lost profits, £m	0.7
Lost UK benefits through reduced R&D investment, £m	0.4
	0
Total costs, £m	1.1
Total benefits, £m	164
Net benefits, £m	163

Key assumptions

Accuracy of company returns

71. The analysis above is based on company returns data reporting sales values, volumes and prices for products supplied to the NHS. The results presented assume that these returns are accurate.

Future NHS use of products in the statutory scheme

72. The analysis assumes that companies will continue to supply products to the NHS after implementation of the payment percentage. This assumption is considered reasonable, as the prices of patented medicines are ordinarily significantly greater than their costs of supply. For out of patent branded medicines, we assume the market will continue to determine the most efficient price level to secure adequate supply. The Department has not seen any evidence that the new scheme, including application of the payment percentage alongside other provisions, would affect the supply of branded health service medicines.

Switching between schemes

73. It is assumed that there will be no significant ultimate effects, in either scenario, from companies switching between schemes.

74. The "do nothing" option entails no change to the system applied to companies in either scheme. It therefore seems reasonable to assume that there will be no significant changes or switching over the period evaluated – and therefore no significant impacts, to the NHS or companies, from switching.

75. Option 1 will entail a change for companies affected, who will make greater payments to the NHS as a result. Some of these companies could choose to switch to the voluntary PPRS. However, as the levels of payment in the two schemes are designed to be comparable, any difference in savings or payments between the schemes are expected to be minimal. While any such switching may entail administrative costs for companies, these are – by definition – expected to be less than the benefits companies foresee from switching. Therefore the assumption of no effects from switching is likely to lead, if anything, to an over-estimate of any net negative impact on companies.

Magnitude of "roll back" effect on prices if the 15% cut is relieved

76. The proposed measure entails relieving the current maximum price requirements for products in the statutory scheme, before then applying a payment percentage to company revenues.

77. Companies are expected to increase prices where they are limited by this maximum level. It is not possible to directly calculate the magnitude of price rises, but the assumption is made, based on consideration of the most reasonable expectations for the effect of relieving the 15% price cut, that affected products will be priced on average at 5% below list price. This assumption recognises the likelihood that commercial considerations will lead companies to naturally limit the prices of some products at some level beneath the list price – while also reflecting the fact that companies are not permitted to raise prices above list price, without agreement of the Secretary of State.

Statutory requirements for consultation

78. Under the terms of new subsection (1A) of section 263 of the NHS Act 2006 the Secretary of State is required to consult on certain factors. These are:

    - The economic consequences for the life sciences industry in the United Kingdom
    - The consequences for the economy of the United Kingdom
    - The consequences for patients to whom any health service medicines are to be supplied and for other health service patients.

79. Sections 266(4) and 266(4A) of the NHS Act 2006 also requires the Secretary of State to bear in mind the need for medicinal products to be available for the health service on reasonable terms and the costs of research and development.

80. These factors have been considered during the consultation, with our final analysis below, using analysis presented in the main evaluation of the proposal, above (based on the central scenario of a 7.80% payment percentage).

Economic consequences for the Life Sciences Industry in the United Kingdom

81. As explained above, the proposed policy is expected to reduce the gross revenues of pharmaceutical companies by £33m.

82. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated by BEIS[13] to represent not more than 10% of the global industry, so impacts on UK interests are commensurately reduced, with a gross reduction of revenues of not more than £3.3m, of which reduced profits to UK shareholders are estimated to amount to no more than £1.0m, as shown above. The reduction in revenue is estimated to translate to a reduction in UK R&D investment not exceeding £1.2m, with consequent net economic losses not exceeding £0.4m, as shown above.

83. In addition to these effects through lost profits for UK shareholders and lost benefits from R&D investment in the UK, there may be some impact through reduced employment of administrative and marketing staff in the UK. These have not been calculated independently, but estimates of changes in profits and R&D spend above imply that the gross change in spend on these functions could not exceed £1.1m.

84. As part of the consultation, the issue of the UK's departure from the European Union was raised in addition to other uncertainties in the business environment, and it was argued that the impacts of the proposed policy needed to be considered in conjunction with these wider factors. It is important to note that the purpose of this Impact Assessment is to identify the effects of the proposed policy only. At any point in time, businesses will be experiencing a range of external factors that may affect them either positively or negatively, but it is not feasible to consider all of these within an IA. The impact of wider business factors would only form part of this consideration if evidence were to suggest that the impacts of the proposed policy would be significantly different depending on these wider factors. As the proposed payment percentage would apply to all branded medicines entering the UK supply chain, irrespective of their country of origin, we do not anticipate that the UK's departure from the European Union would significantly alter the impacts of the proposed policy.

[13] Estimate provided in correspondence

The consequences for the economy of the United Kingdom

85. Beyond the economic consequences for the UK life sciences industry, the policy is expected to have impacts on the wider UK economy.

86. By generating savings from the branded drugs bill which enable the provision of additional NHS treatments and services the policy is expected to increase UK patient health, with beneficial consequences for the UK economy through increased workforce productivity and reduced need for formal and informal care. The estimated value of these benefits is £31m, as explained above.

87. As the pharmaceutical industry is global, spending on pharmaceuticals mainly leaves the UK as payment for imports. In contrast, spending on other types of NHS activity is more likely to accrue to UK interests – mainly labour employed by the NHS. Therefore reducing the NHS spend on pharmaceuticals and increasing spend on other activities is likely to lead to an increase in the UK balance of trade, with consequent benefits for standards of living. These impacts have not been quantified.

88. As part of the consultation, respondents were concerned that the proposed policy did not fully recognise the importance of the Life Sciences Industry for the UK economy, as was recently outlined in the Life Sciences Industrial Strategy. The development of the Life Sciences Industrial Strategy was an industry led project bringing together a diverse sector comprised of large and small companies, both UK-based and international, from across the medical technology, biopharmaceutical, and digital sectors, as well as charities, academia and the NHS. Government is now working with the life sciences sector to consider the strategy in more detail and specifically what action can be taken forward in partnership between Government and industry to consolidate and build on the strength of the sector. As previously discussed, the available evidence and reasoning 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.

The consequences for patients to whom any health service medicines are to be supplied and for other health service patients

89. As explained above, supply of medicines to NHS patients is not expected to be affected by these measures, implying that there will be no negative consequences for patients receiving health service medicines.

90. The expected savings from the proposals will lead to provision of additional NHS treatments and services to other NHS patients generating 2,213 additional QALYs, valued at £133m.

Impact on small businesses

91. Businesses with NHS sales of less than £5m pa are excluded from the payment percentage mechanism in the statutory scheme – which represents the main likely impact of the proposals on companies. In terms of the classification of businesses, this exclusion has been interpreted to imply that only “Medium” and “Large” businesses are in scope of the proposals.

92. However, as set out in the section *Costs to companies of providing information*, above, all companies in the statutory scheme will be required to comply with the certain information requirements – although the magnitude of these costs is likely to be significantly less than the impact on these companies if they were not excluded from the payment percentage mechanism.

Equalities impact

93. We have considered the views and evidence put forward in the 2015 consultation response and during the passage of the Health Service Medical Supplies (Costs) Act 2017 through Parliament, 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.

94. A detailed assessment of the impact of the policy on the Secretary of State's statutory duties has been published in the consultation response.

Annex A: Estimating the economic impacts of health conditions and treatments

Background

95. Health interventions provide benefits to patients which are commonly measured in Quality-Adjusted Life Years (QALYs – the universal unit or currency of health). However they may also have other economic impacts, on other individuals and the rest of society – for instance in enabling a patient to return to work, and therefore contribute more to tax revenues (and require less benefits), or in changing a patient's utilisation of resources such as residential social care, or informal care provided by their family.

96. These economic impacts of treatments beyond health have previously been termed "Wider Societal Impacts" (WSIs) or "Wider Societal Benefits" (WSBs). This annex proposes a definition of these impacts in terms of the patient's net production – their contribution or production of resources, net of their consumption or utilisation of resources – and sets out a systematic approach to measuring net production based on routinely available data.

97. Finally it provides initial results of the estimation of the amount of net production generated by typical treatments in different disease areas, and in the marginal activity of the NHS.

Definition of economic impacts of health conditions and treatments in terms of the patient's net economic contribution to society

98. The approach described is founded on the principle that any resources a patient contributes or produces, net of resources they utilise or consume, are available for others in society to use and benefit from. Similarly, if a patient utilises or consumes resources in excess of the resources they contribute or produce, then those resources must inevitably be provided by society, and are not available for others to consume and benefit from. If a treatment changes the production or consumption of resources by a patient, then it will change the amount of resources available for others to benefit from.

99. For example, suppose a patient with a particular condition produced **£1500** worth of resources per month – through their labour, paid or unpaid. If they consumed **£1000** of resources per month, for instance in the normal goods and services used in everyday life, but possibly also by needing social care, or informal care by family – then, in this perspective, they would be judged to provide net production worth **£500** per month.

100. Suppose that a treatment improves the patient's health, such that they now contribute **£1600** worth of resource per month. This increased amount might reflect the fact that they are able to work more. They may also utilise fewer resources, perhaps because they require less care by their family. Suppose they now consume resources worth **£900** per month, giving net production of **£700** per month. This would imply that the effect of the treatment was to increase the patient's net production by **£200** per month. If the duration of the treatment's effect was 5 months, the total impact on net production – and the value of the benefits realised by society beyond the patient themselves – would be **£1000**.

Elements of net resource contribution

101. For convenience of analysis, the production and consumption of resources by the patient are divided into sub-elements.

102. For *production* these are

    - Paid production – that is, labour provided for a salary or other payment. (Note that this is the only element of net production that contributes directly to GDP).
    - Unpaid production – including domestic work, child care and volunteering

103. For *consumption* these are

    - Formal care – social care paid for by the patient, their family or Government
    - Informal care – including care provided by family and friends
    - Personal paid consumption – including goods and services used in everyday life, such as housing, food, clothes, travel and entertainment
    - Personal unpaid consumption –utilisation of unpaid production, as above
    - Government consumption – using services provided directly by Government, including education and health services (but excluding those directly related to the condition in question)

104. It is important to note that this categorisation is intended to be substantially complete. While there may be practical reasons why the categories of production and consumption defined above do not capture certain exceptional impacts – for instance "external" or direct effects on others through crime – it is considered that this definition of net production encompasses, in principle, all general economic impacts of patients and their treatments.

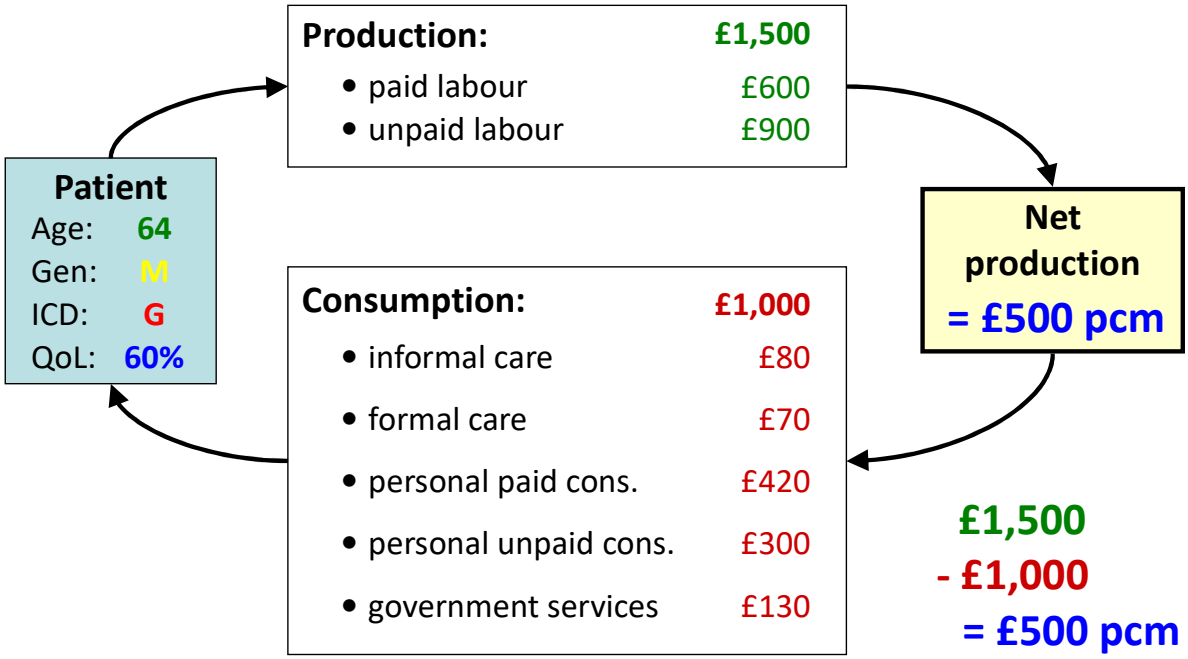
Estimating net resource contribution for patients in different health states

105. DH, in collaboration with external experts, has developed a mechanism by which each element of net production – and therefore the total amount of net production – can be estimated for a patient, given their

    - *Age*
    - *Gender*
    - *Type of health condition* - defined according to the International Classification of Disease (ICD)
    - *Quality of Life* (QoL) *score* – on the standard EQ5D scale in which 100% represents full health, and 0% is considered equivalent to death

106. For a given patient, the net production calculation gives an estimate of the resource impact of the patient in each element of production and consumption.

107. So, for example, a **male** patient aged **64** with migraine (ICD = **G**) and QoL of **60%** might be estimated to generate **£500** worth of net production per month (illustrative figures). This sum may be composed of the elements of production and consumption, as set out below.



108. The calculations for each element are generated using data and modelling from a variety of sources – some existing datasets, as well as analysis that has been specifically carried out or commissioned to support the development of this approach. It has been extensively reviewed by external academic collaborators, and in a series of expert workshops. Details of this analysis, and the data used, are available on request.

Estimating economic impacts of health interventions

109. The mechanism described above allows the net production rate (eg in £ pcm) for a single patient to be estimated, given only the four inputs of age, gender, ICD and QoL. In principle it is straightforward to use this calculation to estimate the net production impact of a treatment – by comparing the progression of patients' diseases over time with the treatment and its comparator, and calculating the change in net production in the same way as quality of life (QoL) profiles over time are used to calculate incremental QALY gains.

110. However there are practical difficulties in applying the net production calculation to treatments or interventions with patient populations that vary across the inputs of age, gender and QoL. In particular, net production is highly non-linear with respect to age.

111. To address this issue, a *reference calculation* has been developed which provides an estimate of the net production impact of typical treatments in all disease areas across the NHS. This calculation uses reference estimates which include all the information required to calculate the net production (expressed per QALY of health gain) provided by typical treatments in each of 1281 diseases (ICDs). Given knowledge of the indicated ICD, this dataset can therefore be used to calculate (or look up) the estimated net production per QALY of health gain for that ICD.

112. The accuracy of the above estimate will depend on the degree to which the reference estimates are representative of the actual treatment population (as well as the accuracy of the models estimating the individual elements of net production).

Estimates of economic impacts by disease area

113. The table below shows the estimated £net production generated per QALY in a selection of diseases[14]. WSIs are also shown in £net production per £ of spending, assuming a marginal cost-effectiveness of £15,000 / QALY for treatments in all conditions.

Code	Disease	£WSI / QALY	£WSI / £NHS
F03	Dementia	40,068	2.67
M05	Rheumatoid arthritis	37,745	2.52
E11	Diabetes	30,969	2.06
M81	Osteoporosis	23,483	1.57
F30	Depression	22,826	1.52
F20	Schizophrenia	19,625	1.31
G35	Multiple sclerosis	18,573	1.24
L40	Psoriasis	17,884	1.19
G20	Parkinson's disease	16,950	1.13
J45	Asthma	16,267	1.08
G40	Epilepsy	16,031	1.07
displ	***(average displaced QALY)***	**13,925**	**0.93**
C53	Cervical cancer	11,248	0.75
E66	Obesity	8,524	0.57
C50	Breast cancer	8,072	0.54
I64	Stroke	-1,350	-0.09
C18	Colon cancer	-2,262	-0.15
C61	Prostate cancer	-5,178	-0.35
C64	Kidney cancer	-7,249	-0.48
I21	Acute myocardial infarction	-8,223	-0.55
I26	Embolisms, fibrillation, thrombosis	-10,705	-0.71
J10	Influenza	-14,982	-1.00
C90	Myeloma	-17,249	-1.15
C92	Myeloid leukaemia	-18,108	-1.21
C22	Liver cancer	-25,867	-1.72
C34	Lung cancer	-29,135	-1.94
C25	Pancreatic cancer	-46,141	-3.08

114. Disease areas vary significantly in the value of net production they are estimated to provide per QALY of health gain. The most significant determinant of variation between disease areas is the extent to which treatments improve quality of life, or extend life. Improving *quality of life* is typically associated with increases in production and decreases in consumption – so an increase in net production overall. However *extending life* typically increases consumption. In conditions such as cancer, where quality of life is low and life has to be extended for long periods to gain 1 QALY, the impact of increased consumption – with little associated increased production – can imply large negative net production impacts per QALY gained.

[14] Based on analytical model of January 2015.

Estimate of economic impacts for rheumatoid arthritis treatment

115. The results above show aggregated estimates of net production impacts for a selection of disease areas. However detailed results are available which show the components of the impact of net production for treatments in specific disease areas.

116. The table below shows the detailed results for *rheumatoid arthritis*.

	£WSI per QALY gained
Total production	**26,849**
Paid production	11,276
Unpaid production	15,573
Total consumption	**-10,896**
Residential care	-1,765
Informal care	-13,157
Private paid consumption	1,492
Private unpaid consumption	1,946
(Childcare consumption)	0
Govt consumption	588
Net production (prod - cons)	**37,745**

117. The net production impacts of a typical treatment for *rheumatoid arthritis* are disaggregated into the elements of production and consumption.

118. For example, a treatment which provides 1 QALY to the population of patients suffering with rheumatoid arthritis is estimated to result in **£11,276** of additional paid production. The total net production impact is estimated to be **£37,745** per QALY of health gain.

119. As discussed above, treatments which improve QoL tend to have greater (more positive) net production impacts than those which improve LoL – as they tend to increase production, and decrease consumption. *Rheumatoid arthritis* is a good example of a condition where treatments tend to increase QoL – and the above results are based on estimates that **96%** of QALY gains from treating this condition come through QoL improvement, rather than LoL extension (data not shown). This is the main explanation for the high estimated net production impact of treatments for *rheumatoid arthritis.*

Economic impact of spending at the margin in the NHS

120. The set of reference estimates described above also contains information on the distribution of the marginal QALY (or £ of spending) across the 1284 disease areas, and across each age and gender bin. This allows an estimate to be made of the net production impact associated with the notional QALY (or £) at the margin in the NHS – that is, the net production impact of treatments that are provided or withdrawn if funds are allocated to or from central NHS funding.

121. The table below shows the results of this analysis, disaggregated into the elements of net production – and also into the components of marginal activity that provide improvements in quality of life, or length of life.

	£WSI per QALY gained
Total production	**22,701**
Paid production	9,398
Unpaid production	13,303
Total consumption	**8,776**
Residential care	-249
Informal care	-2,612
Private paid consumption	4,384
Private unpaid consumption	5,164
(Childcare consumption)	41
Govt consumption	2,047
Net production (prod - cons)	**13,925**

122. For example, the marginal activity in the NHS is estimated to provide a total of **£9,398** of *paid production* per QALY. It is worth noting that this element of net production contributes directly to GDP. As it is estimated to cost £15,000 to provide a QALY at the margin in the NHS, this implies that each £1 spent at the margin generates **63p** in direct contribution to GDP through reduced sickness absence (£9,398 / £15,000).

123. The total net production impact of activity at the margin is estimated to be **£13,925** per QALY gained or displaced. This implies that each £1 spent at the margin in the NHS budget provides **93p** of additional net production.

Further information

A more detailed explanation of the calculations described here can be found at: http://onlinelibrary.wiley.com/store/10.1002/hec.3130/asset/supinfo/hec3130-sup-0003-Appendix_B.docx?v=1&s=d33250dd9797bce52c335c126fe06f5b3902c4c6