Title: 2018 Statutory Scheme – Branded Medicines Pricing	Impact Assessment (IA)
IA No: 9553	**Date: 02/11/2018**
Lead department or agency: Department of Health and Social Care	**Stage: Final**
Other departments or agencies: N/A	**Source of intervention: Domestic**
	Type of measure: Secondary legislation
	Contact for enquiries: Sam Jackson 02079726082

Summary: Intervention and Options

RPC Opinion: Not Applicable

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**
£1,144m	N/A	N/A	No	In/out/zero net cost

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

In the UK, the costs of branded health service medicines are determined within a statutory and a voluntary scheme, if the latter is agreed with industry. Under both schemes, a payment percentage is calculated to ensure that that actual growth is in line with allowed growth. Following a consultation held in 2017, a 7.8% payment percentage on sales under the statutory scheme was introduced to limit spend on branded medicines under the statutory scheme from 1 April 2018. It is considered that a 7.8% payment percentage going forward does not deliver the Government's objective of constraining branded medicines spending growth to within allowable limits and therefore payment percentages will have to be amended from 2019 onwards.

What are the policy objectives and the intended effects?

The objectives of the policy measures are to increase the cost-effectiveness of spending on drugs in the statutory scheme, in a manner consistent with promoting continuity of supply and patient access to clinically and cost-effective drugs and to safeguard the financial position of the NHS by constraining the growth of branded health service medicines expenditure under the statutory scheme to allowable limits.

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

Two options are considered: the option "business as usual", i.e. the continuity of the application of a 7.8% payment percentage during 2019 - 2021; and an option to apply new annual payment percentages of 9.9%, 14.7% and 20.5% for 2019 through to 2021.

These options are evaluated for a period of 3 years, from January 2019 to December 2021.

Will the policy be reviewed? It **will** be reviewed. **If applicable, set review date: December 2019**

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: ..... Date: 02/11/2018

Summary: Analysis & Evidence — Business as Usual

Description: **Business as Usual**

Price Base Year 2018	PV Base Year 2018	Time Period Years 3	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 "Business as Usual" option is the counterfactual scenario, against which other options are assessed. This option is a 7.8% payment percentage on qualifying sales under the statutory scheme over the period under consideration. 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 "Business as Usual" 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**
Costs:	**Benefits:**	**Net:**	Yes/No	IN/OUT/Zero net cost

Summary: Analysis & Evidence — Policy Option 1

Description: New annual payment percentages of 9.9%, 14.7% and 20.5% on qualifying sales for 2019 through to 2021

Price Base Year 2018	PV Base Year 2018	Time Period Years 3	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: £1,158m

COSTS (£m)	Total Transition (Constant Price)	Average Annual (Constant Price)	Total Cost (Present Value)
Low			
High			
Best Estimate	N/A	£8.1m	**£25m**

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

UK shareholders in pharmaceutical companies: Pharmaceutical company revenues are reduced by £152m by 2021, with consequent loss of profits for UK shareholders valued at £22.6m over the period under consideration.

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 £2.4m over the period.

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

None identified but potential risks are flagged in the risks and uncertainties section of the IA.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			
High			
Best Estimate	N/A	£390m	**£1,170m**

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

NHS patients: NHS costs (UK) are reduced by £152m by 2021, enabling the provision of additional treatments and services estimated to provide NHS patients with an additional 10,123 QALY by 2021, valued at £950m.

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 £220m over the period under consideration.

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

None identified

Key assumptions/sensitivities/risks — **Discount rate (%)** — NHS 1.5% / other 3.5%

There is inherent uncertainty around the branded medicines spend forecast and underpinning parameters
We assume that supply of products remains economically viable following application of the payment percentage and that there are no major supply shocks during the implementation period.
A key source of data is company returns on NHS sales – we assume that this information is accurate.
Although the new voluntary scheme is under negotiation we assume that if it is agreed any impacts of switching between schemes is negligible.

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

2018 Statutory Scheme – Final Impact Assessment

Background

1. In the UK, the costs of branded health service medicines are controlled within a voluntary and a statutory framework. The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary scheme agreed between the Department of Health and Social Care (DHSC), on behalf of the UK Government (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). The current (2014) PPRS scheme expires on 31 December 2018.

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 2014 PPRS 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, allowed sales stayed flat in 2014 and 2015 and were set to grow slowly (1.8%, 1.8%, and 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 2014 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 line with annual price adjustments in the 2009 PPRS.

4. In 2015, following the introduction of the 2014 PPRS, the Government consulted on changes to the statutory scheme to bring it back into broad commercial equivalence 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 amended the NHS Act 2006 to make provision for this, and the Government made regulations to implement an updated statutory scheme.

5. Following a consultation held in 2017, a 7.8% payment percentage on sales under the statutory scheme was introduced to limit spend on branded health service medicines under the statutory scheme from 1st of April 2018.

Reasons for Government intervention

6. Suppliers of branded health services medicines typically hold patents which enable monopoly supply of products at high prices to the NHS. Government action is required to limit spending on branded health service medicines to ensure the overall branded medicines bill to the NHS remains within allowable limits. To this end, the DHSC and the pharmaceutical industry have made a voluntary agreement – the 2014 PPRS – which limits growth in the overall branded medicines bill for products covered by the scheme. The 2014 PPRS introduced a limit on growth in the overall cost of branded health service medicines. Scheme members with annual NHS sales of branded health service medicines above £5 million make payments based on the difference between allowed growth and actual growth in NHS expenditure on branded medicines. A payment percentage is calculated to bring actual growth in line with allowed growth. In December 2017, it was confirmed that the payment percentage for 2018 would be 7.8%. However, the 2014 PPRS is coming to an end in 2018 and a new voluntary scheme is currently subject to negotiations. If agreed it would take effect from 1 January 2019 onwards.

7. In conjunction with the voluntary scheme, a set of regulations ensure that there are similar limits on the cost of branded health service medicines supplied by those companies that choose not to join the scheme These regulations are referred to as the "statutory scheme". The terms of the current statutory scheme provide for the application of a 7.8% payment percentage on qualifying sales.

8. An overarching aim of both the statutory scheme and the voluntary scheme is to ensure the overall branded medicines bill to the NHS remains within allowable limits. This aim is unlikely to be achieved under a 'business as usual' option in which the payment percentage in the statutory scheme is retained at 7.8% going forward, which was set in order to align commercially with the 2014 PPRS Based on the Department's forecast of overall branded medicines spend, retaining a 7.8% average payment percentage over the period 2019-2021 would result in a compound annual growth rate (CAGR) of branded medicines sales after application of the payment percentage of 6.7%. This would see growth significantly beyond the NHS budget settlement and is unsustainable for the funding of other aspects of the health service.

9. Furthermore, negotiations are currently ongoing between DHSC and the pharmaceutical industry on a successor agreement to the 2014 PPRS, to become operational from 1st January 2019. If no agreement on a successor scheme can be reached, all companies would become subject to the statutory scheme.

10. The current payment percentage applied to statutory scheme sales stands at 7.8%, and was set in 2018 to mirror the payment percentage applied for the 2018 calendar year in the 2014 PPRS. In response to the 2017 consultation on changes to the statutory scheme, the Government set out its intention to review this payment percentage during 2018. This Impact Assessment considers the effects of a "do nothing" option of keeping the payment

percentage of 7.8%, and a proposed option of setting payment percentages such that the forecast level of growth in branded health service medicines spend is constrained to a lower level, delivering higher overall economic benefits and patient health gains.

Objectives

11. The objectives of the policy measure are:

    - to increase the cost-effectiveness of spending on drugs covered by the statutory scheme, in a manner consistent with continuity of supply and patient access to clinically and cost effective drugs

    - to safeguard the financial position of the NHS by constraining the costs of branded health service medicines under the statutory scheme;

    - to ensure that payments to be made under the scheme are reasonable in all the circumstances, bearing in mind in particular the need for medicinal products to be available for the health service on reasonable terms, and the costs of research and development

Evaluation of options

12. This impact assessment considers the impact of the proposal to apply a set of new annual payment percentages of 9.9%, 14.7% and 20.5% for 2019 through to 2021 (‘the Proposal’). It is compared to the position if there was no change, i.e. the continuity of the application of a 7.8% payment percentage during 2019 – 2021.

13. These options are evaluated for a period of 3 years, from January 2019 to December 2021.

14. It is noted that negotiations around a successor voluntary scheme to the 2014 PPRS are currently ongoing; the proposals evaluated in this Impact Assessment do not prejudge the outcome of these negotiations.

15. Under both options, spend is assumed to grow in line with DHSC’s branded medicines spend forecast, at 0.0% 5.8%, 7.0% and 8.7% annually between 2018 and 2021. For details of the underpinning model for this forecast, see Annex A at the end of this document. Note that these forecast figures have been updated from the draft consultation IA, as latest spend data has been included in the forecast model to give revised estimates. The new estimates are lower than estimates used in the draft IA.

"Business as Usual" Option

16. A counterfactual or 'business as usual' scenario is considered in which it is assumed that the Government continues to apply a 7.8% payment percentage over the period under consideration.

17. The terms of the current statutory scheme exclude sales of products which are sold under contracts with a contracting authority based on a framework agreement or supplied under a public contract (henceforth, "Agreements") which were extant at the date of coming into force of the 2018 Statutory Scheme Regulations (i.e. entered into on the following an invitation to tender that closed [henceforth, "entered into"] on or after 1st April 2018). Relevant medicines sold under Agreements entered into on or after 1st April 2018 will qualify for a 7.8% payment percentage on sales.

The proposed option: apply revised payment percentages to sales in the statutory scheme

Description of option

18. Under this option, a set of payment percentages (of 9.9% in 2019, 14.7% in 2020, and 20.5% in 2021) would be applied to qualifying sales of health service medicines by companies in the statutory scheme in the years 2019 to 2021. The payment percentages are calculated to limit the growth rate of branded health service medicines sales consistent with the average annual growth rate agreed in the 2014 voluntary scheme, which was an average of 1.1% per annum growth.

19. Payment percentages have been calculated that would deliver a given allowed level of branded health service medicines sales as follows:

$$Payment\ percentage = \left(1 - \frac{\text{Allowed relevant medicines sales}}{\text{Total forecast relevant medicines sales}}\right) * 100$$

20. Alternatively, the payment percentage in each year can be derived as a function of a predetermined allowed growth rate and the forecast growth rate for branded medicines sales:

$$Payment\ percentage_t = 1 - \prod_{i=1}^{t}\left(\frac{1 + a_i}{1 + E[g_i]}\right) * 100$$

where *a_i* is the allowed growth rate of total relevant medicines sales in year *i*, and E[*g_i*] is the expected (forecast) growth rate of branded medicines sales

in year *i*.

21. The table below sets out the relevant figures (in millions) which have been used to determine the payment percentage from 2019 to 2021:

Table 1: Calculation of payment percentages

England, £ million	**2018**	**2019**	**2020**	**2021**
1. Forecast % growth[1]	0.0%	5.8%	7.0%	8.7%
2. Forecast relevant sales	9,098	9,616	10,268	11,135
3. Allowed relevant sales	8,569	8,664	8,759	8,855
4. Difference [2 – 3]		953	1,509	2,280
5. Payment % [4 / 2]		9.9%	14.7%	20.5%

22. Sales under Agreements entered into on or before 1st April 2018, sales of low-cost presentations (with a cost of less than £2.00), companies with sales of <£5m pa, voluntary scheme presentations, as well as parallel imports and parallel distributed presentations would be excluded from the payment.

23. The terms of the proposed statutory scheme exclude sales of products which are procured by the NHS through current Agreements entered into on or before 1st April 2018.

24. For procurement under Agreements entered into between the 1st of April 2018, and the 1st of January 2018, a 7.8% payment percentage is applied on sales.

25. For procurement under Agreements entered into on or after the 1st of January 2019, the proposed payment percentages will apply.

26. In addition, the scope of health services medicines captured by the payment mechanism, price controls, and information requirements would be amended to explicitly include all biological medicines, including biosimilars and those marketed under a combination of INN and company name. As there are currently no biosimilars marketed under a combination of INN and company name in the statutory scheme, this proposal is not assumed to have quantifiable effects for the purposes of this Impact Assessment.

Overview of effects

27. 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.

[1] See paragraph 21 of the Impact Assessment

28. The primary impact of the policy is the effect it would have on reducing the cost on the NHS of branded health service medicines. Most ultimate impacts, on NHS patients, manufacturers and suppliers, result from the impact that the payment percentage has on the cost of NHS sales.

29. 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.

30. 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.

31. Detailed calculations of the impact on the cost of NHS sales are presented in the section *Calculation of impact on NHS*, below.

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

32. The application of a payment percentage is expected to reduce the net cost of branded health service medicines 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.

33. 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.

34. The reduction of revenue from sales to the NHS will lead to a commensurate reduction in net revenue for pharmaceutical companies. A proportion of this reduction in net revenue will result in lost profits for UK shareholders in pharmaceutical companies.

35. As part of the consultation, we received comments questioning why we only considered the portion of lost revenues that would accrue to UK shareholders. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The Green Book guidance clearly states that in assessing costs and benefits of policies, we are to consider UK societal impacts only.[2] The UK is estimated by BEIS[3] to represent not more than 10% of the global industry, so impacts on UK interests are commensurately reduced.

[2] In paragraph 2.11 the Green Book states: "The relevant costs and benefits are those for UK society overall, not just to the public sector or originating institution. They include costs and benefits to business, households, individuals and the not-for-profit sector. Assessing the costs and benefits across all affected groups matters as a relatively low-cost public sector option, such as a new regulation, may have significant costs for businesses or households."

[3] Estimate provided in correspondence

36. In addition, comments received in the consultation argue that all the lost profits will be borne by shareholders (both UK and non-UK), instead of only 30% of profits as set out in this IA. In the draft consultation IA, we had presented the impact on shareholders after mitigating responses from shareholders. That is to say, that in response to a fall in revenue, shareholders would pass on some of the losses either through laying-off some resources, generating operational efficiencies, etc. While we continue to believe that the scenario we presented is entirely plausible, we do acknowledge that there are several uncertainties around what the ultimate impact on businesses and the economy will be. Thus, we are now addressing this uncertainty by presenting only first-order impact on shareholders, i.e. before they respond to mitigate their losses, either by reducing investment or increasing operational efficiency.

37. 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

38. The reduction of NHS revenues may lead to a reduction in investment in research and development (R&D) expenditure, 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.

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

40. 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 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[4], 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[5] similarly finds that there is little reason to believe that providing favourable market conditions - e.g. higher 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. Even a Pfizer funded report on the UK Life Sciences Ecosystem acknowledges that workforce & skills, academic & leading-edge science are central in determining competitiveness in the sector.[6]

[4] E.g. "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

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

[6] https://www.pfizer.co.uk/pfizer-commissioned-report-pwc-strategy-driving-global-competitiveness-uks-life-sciences-ecosystem

41. 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[7].

Calculation of impact on NHS sales

42. Calculations are all based on returns made by companies reporting their sales of health service medicines – 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

43. Total sales of branded health service medicines by qualifying company, based on the latest returns provided to DHSC for 2017, are **£1,000m** for the UK. This is uprated by branded health service medicines growth to get forecast values for 2019 through to 2021. All figures in the IA are also presented at the UK level. In-year data on sales for 2018 received so far are in line with the figures for 2017.

Exclusion of low-cost presentations

44. 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.

45. Sales of presentations whose list price is less than £2.00 amount to **£15m** in 2017. This is also uprated in line with branded health service medicines growth to arrive at forecast values for 2019 through to 2021.

Exclusion of sales covered by extant Agreements

46. The amount of sales that will be made under Agreements entered into after 1st April 2018 to 1st January 2019, the assumed date of coming into force of the proposed changes, is not known, as agreements may be made between now and 1st January 2019.

47. The terms of the proposed statutory scheme exclude from the application of the payment percentage any sales of presentations under Agreements entered into on or before the date of coming into force of the 2018 Regulations (i.e. on April 1st, 2018).

48. Similarly, for sales under Agreements entered into between 1st of April 2018, and the 1st of January 2018, a 7.8% payment percentage would be applied.

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

49. For sales under Agreements entered into on or after the 1st of January 2019, the proposed payment percentages would apply

50. Framework agreements typically have a length of between 1 and 4 years. We use updated data from the draft consultation IA on current framework agreements 12 months prior to 1st of September 2018 to estimate what proportion of framework exemption sales are exempt, due a payment percentage of 7.8% and the subject to the new proposed payment percentages. We assume that when a framework agreement after 1st September 2018 ends, a new framework agreement of the same value and length replaces it. 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), **£620m** are likely to be encompassed in such agreements in 2018. Based on this analysis, the proportions of framework spend for each of the payment percentage categories for the period under consideration are presented below.

Table 2: % of frameworks under exemption, 7.8% payment percent, and new proposal

Year:	**2018**	**2019**	**2020**	**2021**
Do Nothing - Business as usual (£m)				
Framework agreements spend (excluding low cost)	620	656	701	763
Framework agreements exempt	72%	13%	2%	0%
Framework agreements under 2017 Statutory Scheme 7.8%	28%	87%	98%	100%

Year:	**2018**	**2019**	**2020**	**2021**
Option 1 - New payment % and frameworks agreed after Jan 2019 not exempt (£m)				
Framework agreements spend (excluding low cost)	620	656	701	763
% Framework agreements exempt	72%	13%	2%	0%
% Framework agreements under 2017 Statutory Scheme 7.8%	28%	3%	3%	2%
% Framework agreements under new payment percentage	0%	84%	96%	98%

51. Note that the analysis to estimate total future framework spend and to estimate the proportion of new frameworks for each of the relevant periods has been conducted separately. While for the latter we assume that when Agreements renew at the same value and length, to estimate the former, the branded medicines spend growth rate is applied to ensure that Agreement spend remains the same proportion of branded medicines spend as currently. This is done for simplicity and consistency in our analysis. However, Agreements cover primarily secondary care medicines and therefore ought to have a different growth rate than overall branded health service medicines. Given that secondary care medicines are forecast to grow at a higher rate, this would mean that the proportion of branded health service medicines under Agreements would be growing over time. We present results using a forecast for secondary care medicines to uprate spend on framework agreements for the period under consideration in the ‘Sensitivities’ section.

Adjustments made to data to reflect 'rollback' effect of 15% price reduction

52. The data being used for analysis is before the 7.8% payment percentage was in place in 2018, and during the period a 15% price reduction to list prices was applied under the statutory scheme. We identify where this price cut was 'binding', i.e. effective in reducing prices, and make adjustments to sales to 'rollback' spend to reflect prices without a 15% reduction. 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.

53. 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 **£50m**.

54. 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 £50m to **£56m**.

55. 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 **£59m**. In the context of overall spend (and the overall impact of the payment percentage), this difference represents a proportionate change of less than 1%.

56. The increase in sales due to relieving the 15% price cut is therefore **£6m**. Information on current frameworks is used to adjust these increases 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 **£2m**, and sales under the statutory scheme are adjusted to **£1,003m.**

Effect of proposed payment percentages

57. Qualifying sales and relevant proportions of framework spend under each payment scenario under 'do nothing' and the proposed option are presented below. In 2021 in the 'do nothing' scenario, a payment of **£95m** would have been due to the Department under the statutory scheme. Under the proposed option, a payment of **£247m** would have been due to the Department.

58. The net effect of the policy is therefore a **£152m** saving to the Department by 2021, which would be reinvested in the health service. The figures for all

years under consideration are presented in the table. The Net Present Value of this revenue stream is **£237m.**

Table 3: Rebate under do nothing and Option 1

Year: **Do Nothing - Business as usual (£m)**	**2018**	**2019**	**2020**	**2021**
Branded Medicines Growth	0.00%	5.80%	7.00%	8.70%
Total sales under statutory scheme (after rollback)	1,003	1,060	1,134	1,233
Framework agreements spend (excluding low cost)	620	656	701	763
Low cost exemptions	15	16	17	19
Qualifying sales under do nothing (excluding frameworks)	368	388	416	451
Payment percentage	7.80%	7.80%	7.80%	7.80%
Framework agreements exempt	72%	13%	2%	0%
Framework agreements under 2017 Statutory Scheme 7.8%	28%	87%	98%	100%
Payment (£m)		75	86	95

Year: **Option 1 - New payment % and frameworks agreed after Jan 2019 not exempt (£m)**		***2019***	***2020***	***2021***
Branded Medicines Growth	0.00%	5.80%	7.00%	8.70%
Total sales under statutory scheme (after rollback)	1,003	1,060	1,134	1,233
Framework agreements spend (excluding low cost)	620	656	701	763
Low cost exemptions	15	16	17	19
Qualifying sales (excluding framework agreements)	367	388	415	452
Payment percentage		9.90%	14.70%	20.50%
% Framework agreements exempt	72%	13%	2%	0%
% Framework agreements under 2017 Statutory Scheme 7.8%	28%	3%	3%	2%
% Framework agreements under new payment percentage	0%	84%	96%	98%
Payment		95	161	247

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

NHS and patient health gains

60. The increased savings for the Department will release funds for use in providing additional treatments and services to patients in the NHS. DHSC estimates that the NHS provides an additional Quality Adjusted Life Year (QALY, the standard unit of health) for every **£15,000** of additional spending[8]. The increased savings of £152m therefore correspond to a gain of **10,123 QALYs** for patients in the NHS by 2021.

[8] The DHSC 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/

61. These health gains are monetised using their estimated societal value[9] of **£60,000**, to give an annual impact valued at **£607m by 2021**.

Benefits to UK economy from improved patient health

62. 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.

63. DHSC 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[10]. Applied to the estimated QALY gains described above, this corresponds to a benefit valued at **£141m** by 2021 for the period under consideration.

64. In total, the benefits from these savings are estimated to be £748m by 2021, and have a value of £1,170m over the period in consideration.

Table 4: Monetising benefits from improved patient health and wider economic consequences

Year: **Benefits (£m)**	**2019**	**2020**	**2021**	***NPV***
Savings for option 1 against do nothing (£m)	19.8	74.9	151.8	237.4
QALYs generated elsewhere in the NHS @£15,000/QALY	1,318	4,996	10,123	
Social Value of QALYs @£60,000/QALY (£m)	79.1	299.8	607.4	949.7
Value of economic consequences of health gained @ £13,925/ QALY	18.4	69.6	141.0	220.4
Total benefits (£m)	97.5	369.3	748.3	1,170.2

Loss of profits for UK shareholders in pharmaceutical companies

65. Pharmaceutical companies will see a reduction in revenues commensurate with the increase in savings for the NHS, resulting in a reduction in the profits gained by shareholders in pharmaceutical companies.

66. In the long-run, changes in companies' revenues may not have a noticeable impact shareholders' income, 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 "business as usual" option, and therefore a rate that is lower than the market rate.

67. In our draft IA that was put out for consultation, we had presented the impact on shareholders after mitigating responses from shareholders. That is to say, that in response to a fall in revenue, shareholders would pass on some of the

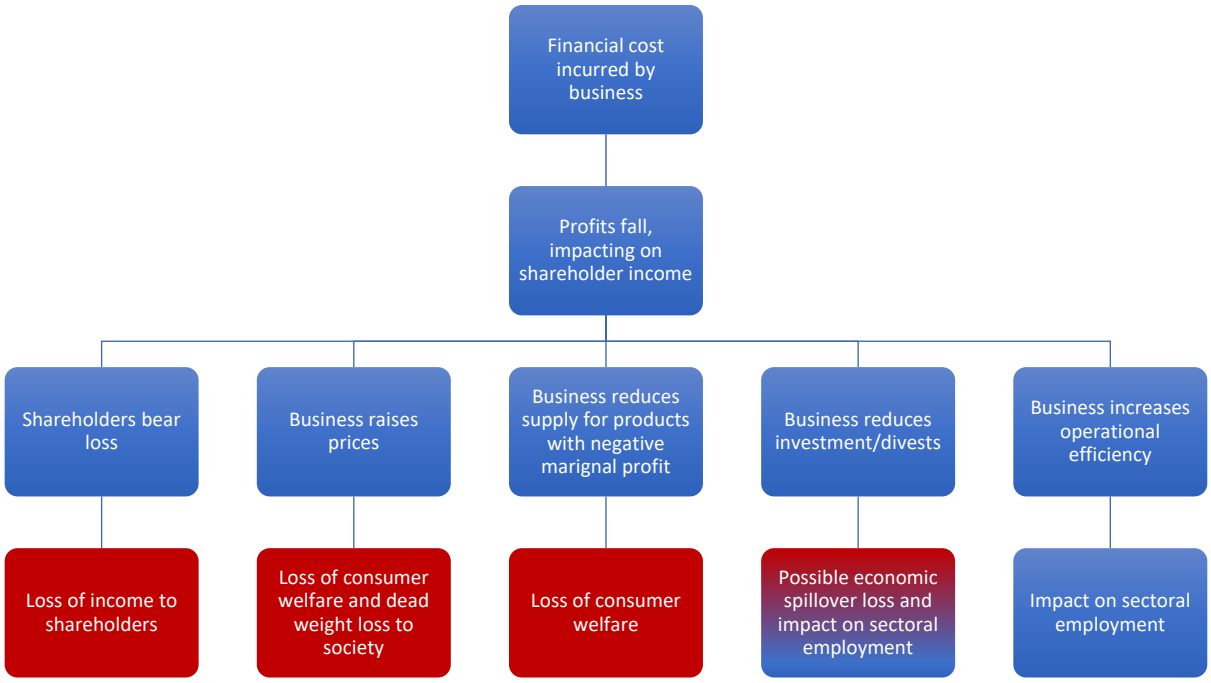
[9] See p23 in https://www.gov.uk/government/publications/quantifying-health-impacts-of-government-policy

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

losses either through laying-off some resources, generating operational efficiencies, etc. We had presented a scenario 30% or losses were born by shareholders, while the rest of the losses were mitigated through operational efficiencies and laying-off some resources.

68. The figure below sets out in more detail the flow of impacts stemming from a reduction in sales revenue due to the payment mechanism – only those impacts shaded in red in the figure below are counted towards the net societal impact of a policy, while impacts in blue can be offset from an aggregate perspective. As an example, loss in sectoral employment would not be considered a net societal loss, as the labour employed would be utilised in other sectors following a policy change.

Figure 1: Overview of net societal impact of increased financial costs to business



69. However, we received comments in the consultation suggesting that a loss of revenue would fall on shareholders only. As can be seen in the Figure, we consider this to be only the first-order impact prior to any mitigating responses from shareholders. While we continue to believe that the scenario we presented is entirely plausible, we do acknowledge that there are several uncertainties around what the ultimate impact on businesses and the economy will be. Thus, we are now addressing this uncertainty by presenting only first-order impact on shareholders, i.e. before they respond to mitigate their losses, either by reducing investment or increasing operational efficiency.

70. Thus, the loss to shareholder income is equivalent to the lost revenue at **£152m by 2021**. 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 **£15.2m by 2021**[11].

71. The NPV of distribution adjusted lost profits to UK shareholders are estimated to be **£22.6m** over the period under consideration.

Impact on UK R&D spill-overs

72. As described above, the proposed measures are expected to reduce the net revenues of pharmaceutical companies, compared to the "business as usual" option, which may result in reduced profits to shareholders. However, the reduction in net revenue may also result in decreased investment in R&D[12] – of which a portion may be in the UK, providing "spill-over" losses to the UK economy.

73. Earlier we have presented only the first order impacts to shareholders from the loss of revenue. However, here we consider equilibrium impacts if this results in the reduction of R&D investment in the pharmaceutical sector in the UK. That is, this represents the potential loss in economic spill-overs, if companies choose to invest in a competitor country rather than the UK. Thus, this represents a scenario where we might expect the proportion of R&D investment in the UK to fall to a lower level in the long-term.

74. The proportion of pharmaceutical company revenues devoted to R&D has been estimated[13] 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.

75. 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[14].

76. Applying the estimates above to the projected decrease in pharmaceutical revenues gives a loss of **£1.6m by 2021** to the UK economy from reduced

[11] Although the Impact Assessment for the 2018 changes to the Statutory Scheme also considered further distributional adjustments to take into account the relative wealth of shareholders, this adjustment has not been applied in this Impact Assessment. The updated advice from the HMT Green Book only recommends undertaking distributional adjustment where policy proposals are anticipated to have significantly different effects on different groups. As no evidence was available to suggest that UK shareholders would have significantly different characteristics to the rest of the UK population (for example if pension funds represented a significant proportion of shareholders, this could reflect the interests of a wide groups of society) such an adjustment was not judged to be appropriate under new Green Book rules.

[12] 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.

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

[14] Estimate provided in ccorrespondence

R&D investment over the period under consideration. The total value of the lost UK benefits from reduced R&D investment is £2.4m over the period under consideration. To put this in context, this compares to total pharmaceutical R&D investment in the UK in 2016 of £4.1 billion.

Table 5: Costs to industry from lost profits and R&D spill-overs foregone

Year: **Costs (£m)**	**2019**	**2020**	**2021**	***NPV***
Lost profits to pharmaceutical company shareholders (£m)	19.8	74.9	151.8	226.0
UK lost profits to shareholders (£m)	2.0	7.5	15.2	22.6
Proportion invested in R&D in the UK (£m)	0.7	2.7	5.5	8.1
Lost UK benefits through reduced R&D investment (£m)	0.2	0.8	1.6	2.4
Total costs (£m)	2.2	8.3	16.8	25.0

Net monetised impacts

77. The total benefits of the proposed option, compared to the 'business as usual' option, are valued at **£1,170m**, over the period under consideration, while the total costs are estimated at **£25m** – giving a net benefit of **£1,144m**. See the summary of results on the next page.

Summary of results

Year:	2019	2020	2021	*NPV*
Benefits				
Savings from option 1 against 'business as usual' (£)	19.8	74.9	151.8	237.4
QALYs generated elsewhere in the NHS @£15,000/QALY	1,318	4,996	10,123	
Social Value of QALYs @£60,000/QALY	79.1	299.8	607.4	949.7
Value of economic consequences of health gained @ £13,925/ QALY	18.4	69.6	141.0	220.4
Total benefits (£)	97.5	369.3	748.3	1,170.2
Costs				
UK lost profits to shareholders (£m)	2.0	7.5	15.2	22.6
Lost UK benefits through reduced R&D investment (£m)	0.2	0.8	1.6	2.4
Total costs (£)	2.2	8.3	16.8	25.0
Net benefits (£)	95.3	361.0	731.5	1,143.8

Sensitivities and key assumptions

Branded Medicines Spend Forecast

78. Central to the estimates presented in this IA is the branded medicines spend forecast over the period under consideration. If our estimate of growth is greater than the actual outturn, then the savings to the NHS would be lower than presented here. Equally, if our estimate is lower than the outturn, then the savings to the NHS could be greater than what is presented here. Equally, if the estimate of growth is greater than the actual outturn, the target allowed sales would also not be met.

79. A key set of parameters that underpin the branded medicines forecast is presented below. For more details on the parameters and how they impact the branded growth forecast, see Annex A.

Table 6: Parameters underpinning the branded medicines forecast

Parameter	Primary care		Secondary care	
	Non-biological	**Biological**	**Non-biological**	**Biological**
Uptake duration	80 months	80 months	70 months	70 months
Plateau duration	78 months	78 months	88 months	88 months
Plateau gradient	-1%p.a.	1%p.a.	5%p.a.	8%p.a.
Loss of exclusivity/generic entry gap	6 months			
Drop on generic entry	70%	45%	70%	45%
Terminal growth rate	0%			
Cohort growth rate	10%	10%	0%	2/0%

80. We consider the sensitivity of our analysis to different values of the parameters presented above. Below we present the impact on estimated branded medicines growth of changing those parameters that the model is most sensitive to, and therefore on the savings from proposed policy changes. The high and low scenarios tested reflect the range of uncertainty for a given parameter. While all parameters in the model were tested for sensitivity, here we present only those key parameters with the most significant impact on our model:

Parameter	Sensitivity
Uptake Duration	+/-20%
Plateau growth	+/- 5 percentage points
Cohort growth	+/- 5 percentage points

81. Uptake duration measures the time between product launch (derived from the first significant expenditure on the molecule in our data source) and the point at which the trend in expenditure changes (often due to the target patient population having been reached). We consider a +/- 20% change in the uptake duration to test sensitivity of this parameter on branded medicines growth and our savings estimates.

82. The table below presents the impact on branded medicines growth of an uptake duration high/low scenario. It is noted that over the three-year horizon considered, changes to the uptake duration do not materially affect estimated aggregate growth rates, as the overall share of new medicines in total medicine spend is relatively low.

Scenario	2019	2020	2021
High	5.8%	7.0%	9.0%
Base	5.8%	7.0%	8.7%
Low	5.8%	6.6%	7.8%

83. The impact of changes to the branded medicines growth rate on the savings in £m of Option 1 are as follows:

Scenario	2019	2020	2021
High	19.8	74.9	152.2
Base	19.8	74.9	151.8
Low	19.8	74.7	149.9

84. For the period under consideration, 2019 -2021, our high and low scenario for uptake duration results in no significant changes to the savings estimates, and therefore there would be no impact of the high and low scenarios on our allowed growth rate.

85. Next, consider the plateau gradient parameter in the forecast model. This is the rate of change in spend between end of uptake period and patent expiry, estimated from observed change of spend in data. The plateau gradient captures the countervailing effects of competition within a therapeutic class (when the cannibalisation of a product's sales by new competitors can limit the sales even for a patented medicine) and new indications through license extensions for a molecule being marketed in later life (which will increase sales by expanding the patient population).

86. We test a high and low scenario for this parameter of +/- 5 percentage points. A +/- 5% percentage point change in the plateau growth rate results in following high/low scenarios for branded medicines growth:

Scenario	2019	2020	2021
High	7.1%	8.2%	9.9%
Base	5.8%	7.0%	8.7%
Low	4.5%	5.9%	7.8%

87. For these branded medicines growth scenarios, the savings under Option 1 in £m for the period under consideration are given below:

Scenario	2018	2019	2020
High	20.1	77.0	157.7
Base	19.8	74.9	151.8
Low	19.5	73.0	146.7

88. Our analysis suggests that under the high scenario for plateau growth, savings under Option 1 would be £5.9m more than estimated in our base scenario by 2021. For the low scenario, savings under Option 1 would be £5.1m less than our base scenario by 2021. This implies that for our high scenario we undershoot our allowed growth rate by 0.4 percentage points by 2021 and for our low scenario we overshoot our allowed growth rate by 0.3 percentage points by 2021.

89. We now consider a high and low scenario for the cohort growth parameter. Historic medicines spend split by annual launch cohort shows that for more recently launched products, spend at each given point in their lifecycle is higher than was observed for the cohorts launched in earlier years at the equivalent point in their lifecycle. In effect, expenditure for the totality of all products launched in 2015, one year after their launch, grows more steeply and reaches a higher point than expenditure on the totality of products in 2014 had reached one year after their launch. This effect is assumed to continue throughout the forecast period and is captured in the model through the estimation of an annual cohort growth rate parameter.

90. Our central forecast assumes that there is 10% cohort growth on primary care medicines, 0% on secondary care non-biological medicines, and 20% on secondary care biological medicines. We test high and low scenarios for this parameter of +/- 5 percentage points, and present the impact on branded medicines growth below:

91. The table below presents the impact on branded medicines growth of a +/- 5 percentage point change in our cohort growth parameter as our high and low scenario.

Year	2019	2020	2021
High	6.1%	7.6%	9.8%
Base	5.8%	7.0%	8.7%
Low	5.4%	6.4%	7.8%

92. This results in an impact on savings in £m under Option 1 as follows

Year	2019	2020	2021
High	19.9	75.7	154.9
Base	19.8	74.9	151.8
Low	19.7	74.2	149.1

93. Our analysis suggests that under the high scenario for cohort growth, savings under Option 1 would be £3.1m more than estimated in our base scenario by 2021. For the low scenario, savings under Option 1 would be £2.7m less than our base scenario by 2021. This implies that for our high scenario we undershoot our allowed growth rate by 0.3 percentage points by 2021 and for our low scenario we overshoot our allowed growth rate by 0.2 percentage points by 2021.

94. Savings under option 1 are most sensitive to the cohort growth parameter of the parameters we've tested. These scenarios are testing holding all other parameters constant. There could be a combination of changes to these parameters that taken together may have a more significant impact than any changes to each parameter.

95. Note however, that, there are alternate forecasts for the evolution of the global pharmaceuticals market[15], but these are not necessarily reflective of UK growth. These cover overall medicines expenditure, i.e. both branded and generic medicines, rather than the branded market covered by the statutory scheme. These forecasts are based on the list prices expenditure, which is not the price paid by the NHS or other procurers.

Framework sales forecast (using secondary care forecast)

96. The analysis set out above assumes that framework spend grows in line with overall branded medicines spend growth. However, framework spend is entirely within secondary care and therefore could be growing at a different rate compared to overall branded medicines spend growth. This does impact our savings estimate during 2019-2021 as spend on framework agreements already in place grow at a higher rate and some proportion of these are exempt or pay a lower payment percentage.

97. Secondary care growth using our forecast model is estimated to be 3.9%, 9.0%,12.1% and 13.8% between 2018 and 2021 compared to 0.0%, 5.8%, 7.0% and 8.7% forecast for overall branded medicines growth.

98. In the scenario below, we consider if sales under statutory scheme grow in line with branded spend but framework agreements grow in line with secondary care spend. This results in a higher proportion of sales under the statutory scheme being exempt during the period over consideration, as

[15] See EvalutePharma http://www.evaluategroup.com/public/Reports/EvaluatePharma-World-Preview-2018.aspx which forecasts a 6.4% annual growth in pharmaceutical expenditure globally for the period 2018-2024 and IQVIA Institute "2018 and Beyond: Outlook and Turning Points" https://www.iqvia.com/institute/reports/2018-and-beyond-outlook-and-turning-points which forecasts a range of annual growth of 2-5% in pharmaceutical expenditure in the UK for the period 2018-2022.

spend under framework agreements grows as a proportion of spend. Thus, the savings under this scenario are less than Option 1 presented above.

99. Below net impacts are considered using secondary care spend forecast applied to framework agreements growth only.

Table 7: Impact on costs and benefits if framework spend grew at secondary care growth rates

Year:	**2019**	**2020**	**2021**	***NPV***
Benefits (£m)				
Savings for option 1 against do nothing (£m)	11.0	58.9	139.4	201.3
QALYs generated elsewhere in the NHS @£15,000/QALY	731	3,925	9,296	
Social Value of QALYs @£60,000/QALY (£m)	43.9	235.5	557.8	805.2
Value of economic consequences of health gained @ £13,925/ QALY	10.2	54.7	129.4	186.9
Total benefits (£m)	54.0	290.1	687.2	992.1
Costs (£m)				
UK lost profits to shareholders (£m)	1.1	5.9	13.9	19.1
Lost UK benefits through reduced R&D investment (£m)	0.1	0.6	1.5	2.1
Total costs (£m)	1.2	6.5	15.5	21.2
Net benefits (£m)	52.8	283.6	671.8	969.8

100. The net savings under this scenario are **£139m by 2021**, i.e. £13m less than the £152m savings in main scenario presented in this impact assessment. The costs to shareholders are slightly less as well, at **£13.9m in 2021**, compared to £15.2m in the main scenario. The lost benefits to the UK through R&D investment are also less at **£1.5m in 2021**, compared to £1.6m in the main scenario. The net benefits under this scenario are **£967m in 2021** compared to £795m in the main scenario.

101. Note that there may be some endogeneity between payment percentages applied under the statutory scheme and the prices of medicines and overall spend under framework agreements in the short-term, should frameworks prices rise in response to the increased in payment percentage. However, as exemptions lapse on new framework agreements, there should be no impact on savings over the long-term, even though the proportion of spend that is under framework agreements may change over time. There may be some interaction and longer-term impacts on the growth of branded medicines spend, though.

102. We have not considered here the impact of price increases in frameworks on the branded medicines forecast. We acknowledge that there are possible feedback effects of price increases under frameworks, or elsewhere, on the medicines forecast. However, the Department's commitment to an annual review of the statutory scheme will allow the department to react to these issues if they emerge and make adjustments to the scheme if prices increase significantly. We believe that the annual review mechanism ensures, albeit

with a lag, that as price increases feedback into the forecast model we can adjust the payment percentages if deemed appropriate.

Interactions with on-going PPRS negotiations

103. This impact assessment assumes that a negotiated voluntary agreement to replace the 2014 PPRS from 2019 will be agreed that attracts the same share of overall branded medicines expenditure as the 2014 PPRS. However, a scenario where there is no PPRS negotiated and all branded medicines spend is controlled by the statutory scheme is presented below[16].

104. The baseline of total branded medicines sales is expected to be **£10,889m** in the UK in 2018, net of the expected payment received in 2018. Using our standard branded medicines growth estimate, branded medicines spend is expected to increase up to **£13,393m** by 2021.

105. Updated analysis suggests that the proportion of sales under frameworks for companies currently in the PPRS is much lower than for statutory scheme. In the draft IA, we had assumed that proportion of spend for all branded sales was the same as for companies in the statutory scheme. New analysis suggests that the proportion of all branded health service medicine sales under framework agreements for current members of the 2014 PPRS is 28%. Additionally, we also have new estimates for low cost exemptions within the whole branded medicines sector – earlier, we had simply scaled up low cost exemption in proportion to spend. The tables below present the impact on the rebate under 'business as usual' and Option 1.

Table 8: Impact on rebate under business as usual and option 1 in a scenario with no PPRS negotiated

Year: **Do Nothing - Business as usual (£m)**	**2018**	**2019**	**2020**	**2021**	***NPV***
Branded Medicines Growth	0.00%	5.80%	7.00%	8.70%	
Total sales under statutory scheme (after rollback)	10,889	11,517	12,318	13,393	
Framework agreements spend (excluding low cost)	3,035	3,210	3,433	3,733	
Low cost exemptions	84	89	95	103	
Qualifying sales under do nothing (excluding frameworks)	7,770	8,218	8,790	9,557	
Payment percentage	7.8%	7.8%	7.8%	7.8%	
Framework agreements exempt	79%	20%	1%	0%	
Framework agreements under 2017 Statutory Scheme 7.8%		80%	99%	100%	
Payment (£m)		841	951	1,037	2,743

[16]The counterfactual remains a payment percentage of 7.8%. Due to the objective of achieving broad commercial alignment between the two schemes, this payment applied to both schemes in 2018.

Year:	2018	2019	2020	2021	*NPV*
Option 1 - New payment % and frameworks agreed after Jan 2019 not exempt (£m)					
Branded Medicines Growth	0.00%	5.80%	7.00%	8.70%	
Total sales under statutory scheme (after rollback)	10,889	11,517	12,318	13,393	
Framework agreements spend (excluding low cost)	3,035	3,210	3,433	3,733	
Low cost exemptions	84	89	95	103	
Qualifying sales (excluding framework agreements)	7,770	8,218	8,790	9,557	
Payment percentage		9.9%	14.7%	20.5%	
% Framework agreements exempt	79%	20%	1%	0%	
% Framework agreements under 2017 Statutory Scheme 7.8%		2%	1%	1%	
% Framework agreements under new payment percentage		78%	98%	99%	
Payment		882	1,300	1,963	4,013

106. Based on the net effect of the rebates in either scenario presented above, we consider the cost and benefits under this scenario below:

Table 9: Net impacts of scenario where there is no PPRS negotiated

Year:	2019	2020	2021	*NPV*
Benefits (£m)				
Savings for option 1 against do nothing (£m)	41.1	349.3	926.3	1,265.3
QALYs generated elsewhere in the NHS @£15,000/QALY	2,738	23,285	61,751	
Social Value of QALYs @£60,000/QALY (£m)	164.3	1,397.1	3,705.1	5,061.2
Value of economic consequences of health gained @ £13,925/ QALY	38.1	324.2	859.9	1,174.6
Total benefits (£m)	202.4	1,721.3	4,565.0	6,235.8
Costs (£m)				
UK lost profits to shareholders (£m)	4.1	34.9	92.6	120.1
Lost UK benefits through reduced R&D investment (£m)	0.4	3.8	10.0	13.0
Total costs (£m)	4.6	38.7	102.6	133.1
Net benefits (£m)	197.8	1,682.6	4,462.3	6,095.6

107. Under this scenario, there are savings to the NHS of **£41m** in 2019, **£349.3m** in 2020, **£926m** in 2021. These additional resources enable the NHS to generate an additional **61,751 QALYs** by 2021. This health gain is valued at **£5,061.2m**. The benefits derived from the wider economic consequences over this period are valued at **£1,175m**. Thus, the total benefits over this period are valued at **£6,236m**.

108. As above, the savings to the NHS are lost revenue to pharmaceutical companies and shareholders in the first instance. Therefore, the cost to UK shareholders, over the period under consideration is valued at **£120m**.

109. The costs to the UK economy from the R&D spill-overs forgone are valued at **£13m** over the period under consideration. These are calculated using the parameters set out in 'Impact on R&D spill-overs'. The total costs are therefore valued at **£133m** over the period.

110. Thus, the net benefits under this scenario would be valued at **£6,096m**.

Future NHS use of products in the statutory scheme

111. The analysis assumes that companies will continue to supply health service medicines after implementation of the new payment percentages. This assumption is considered reasonable, as for the majority of branded medicines, prices are ordinarily significantly greater than their costs of supply. For products which face unique and costly production processes there remains a risk for loss of supply. However, provisions are made available for such products to apply for price increases in order to mitigate the risk of loss of supply. In the sensitivity below, we address the impact of granting price increases to such products in order mitigate any potential supply-side risks.

Impact of prices increases to mitigate potential supply-side risks on blood/plasma products

112. As part of the consultation, we received specific comments regarding the impact of the policy on blood plasma protein therapies. We accept that the characteristics of blood plasma protein therapies, and the associated market, are unique, given the need for human donation, the lengthy and complex manufacturing processes, and the long-term consequent limitations in global supply. We also accept that this may create inter-country competition, given that demand exceeds supply.

113. We also acknowledge that blood plasma protein therapies are not substitutable, or necessarily interchangeable. To support patient access to effective medicines, supply of a range of comparator blood products is important.

114. However, the Department believes that price increase provisions and the ability to reflect new maximum list prices under frameworks are the most appropriate mechanisms to mitigate this risk, because under the statutory factors against which the Department considers requests, we can review the relevant evidence for each individual product and set the economically optimal price.

115. While blood plasma protein therapies face particular challenges around production lead-in times, they do not preclude companies from applying for price increases sufficiently in advance to be able to secure a price increase where necessary in time for their internal sourcing and production processes. We have seen this in practice in a recent price increase application by a blood product manufacturer, which was made in advance of the actual supply decision on similar grounds, and was granted by the Department.

116. Therefore, it is reasonable to assume that price increases demonstrably can provide the necessary flexibility to respond to the unique circumstances of blood product manufacturers.

117. In this section, we will consider impact on the payments of a scenario whereby price increases of a level such that blood plasma products remain revenue neutral after the application of a payment percentage would be granted.

118. Under the Statutory Scheme, estimated total spend on blood products under frameworks in England is approximately £251m in the 12 months prior to 1st of September 2018. We assume that all spend on blood products is under frameworks. Uprating this to the UK, we have an estimate of £315m. This is grown using the overall branded medicines forecast to get values for subsequent years.

119. The increase in prices is then netted off against the rebate to present the total rebate after prices increases for blood products against a 'business as usual' central estimate and Option 1 central estimate. The results suggest that by 2021 an increase in prices to ensure that after applying a 7.8% payment percentage companies remain revenue neutral against our business as usual option give result in the loss of £25m rebate. Further increasing this price increase ensure they remain revenue neutral at 9.9%, 14.7% and 20.5% results in a further £67m loss to the rebate.

Table 10: Impact of prices increases to blood products on the total rebate

£m	Total rebate in 2021 under a scenario with:		Net impact on rebate from increase of blood prices
	No increase in prices of blood products	Increase in prices of blood products	
Business as usual (7.8%)	95	70	-25
Option1: New payment %s	247	180	-67

120. Thus, compared to our central scenario of £152m in payments by 2021, a price increase to ensure all blood products remain revenue neutral after the application of payment percentages would result loss of rebate of the order of £92m, and resulting in a rebate equivalent to £60m in 2021. The financial costs to businesses would also be needing to be considered – these would be the same as in the central scenario presented in the IA of approximately £16.8m by 2021.

121. Thus, even in an extreme scenario, where all blood products are granted a revenue neutral price increase, we would expect the NPV of proposed policy to be positive.

Accuracy of company returns

122. The analysis above is based on company returns data reporting sales values, volumes and prices for health service medicines. The results presented assume that these returns are accurate.

Impact of feedback of price increases on branded medicines forecast

123. We have not explicitly considered here the impact of price increases granted for certain products or within frameworks on the branded medicines forecast. It is possible that through the price increase provision, we see increases in prices of products which result in an increase in the medicines forecast. We acknowledge that there are possible feedback effects of price increases under frameworks, or elsewhere, on the medicines forecast.

124. As stated earlier, the Department's commitment to an annual review of the statutory scheme will allow the department to react to these issues if they emerge and make adjustments to the scheme if significant price increases are granted. If an increase in the medicines forecast is partly driven by increases in prices granted by price increase provision, the Department will apply discretion and only increase payment percentage if deemed appropriate.

Switching between schemes

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

126. The proposed option will entail a change for companies affected, who will make greater payments to the Department as a result. Some of these companies could choose to switch to the voluntary PPRS. However, the two schemes are intended to achieve broad commercial equivalence, which we believe is likely to result in limited levels of switching. 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.

Uncertainties and Risks

Risks of a higher payment percentage

127. This Impact Assessment assumes that the costs associated with a higher payment percentage are limited to short term costs on UK shareholders and on UK R&D. However, as payment percentages move away from the current levels, there is increased uncertainty about the impact on industry and patients and whether our parameter estimates for costs to industry and lost benefits to the UK from R&D are accurate.

128. Moving from a 7.8% payment percentage to 20.5% payment percentage, may generate additional risks and uncertainties. For example, if this higher

payment percentage were to affect global R&D decisions differently from lower levels of payment percentages.

129. As the UK market accounts for a relatively small part of global pharmaceutical revenues (c. 3%), the impact of reduced revenues in the UK should not have a significant impact on commercial investment decisions of the pharmaceutical industry. As such, we would not expect any changes to the global pipeline of drugs in development as result of these higher payment percentages.

130. However, there may be a risk that additional negative boardroom sentiment would lead to decisions not to invest in R&D in the UK, potentially further harming the UK economy. Ultimately the size of this risk is not known as the extent to which negative sentiment has a material impact on commercial decision making is not clear. However, we would expect these decisions be taken on commercial merits. The available evidence on decisions to invest in R&D suggest that these are largely based on supply side factors, such as availability of skilled workforce etc., and so it is unlikely that reduced revenues from the UK will result in less R&D investment in the UK. It is also worth noting, small companies, which might be more heavily reliant on UK revenues, are exempt from the statutory scheme.

131. Companies have argued that there may also be greater selectivity or delay of which new products are brought to the UK market if the UK is judged to be a less profitable place for these products. However commercial attractiveness also reflects a multitude of other factors where the UK does and will continue to perform strongly (unaffected by these proposals) such as the market value of a NICE assessment, a UK list price and the co-location with clinical trials. We have therefore received no firm evidence which supports the contention that companies would – in the round – logically wish to no longer prioritise UK launches. The ultimate consequence of this decision would depend on the expected cost effectiveness of these products. Where products are unlikely to be cost effective, we would not anticipate any net impacts on patient health as a consequence. Assuming instead that these new products had a cost effectiveness equivalent to the estimated marginal cost effectiveness of the NHS as a whole, the impact on patient health would be neutral.

132. Finally, there may also be wider issues related to the supply of existing medicines as we move to significantly higher payment percentages, such as shortages within the supply-chain. This risk may be confounded due to uncertainties in the external environment. For example, if the UK exits the EU without a deal, supply chains for these products may be affected by changes to border processes and procedures. However, we have put in place a dedicated team to support suppliers in making arrangements for stockpiling, suppliers are already taking action and our plans build on this. Our dedicated support team will work with suppliers to understand the impact of stockpiling arrangements and help them develop plans to minimise any costs of additional stockpiling. Further, supply risks are partly mitigated through an existing facility within the statutory scheme to allow for companies to apply for price increases for specific products where they can evidence that supply is uneconomic.

133. In addition, any wider risks to medicines supply are mitigated through the annual review mechanism, which will allow the department to react to these issues if they emerge and make adjustments to the scheme if supply becomes systematically uneconomic.

134. Furthermore, the combination of the forecast expenditure and the payment percentages set out result in an expected annual growth rate of nominal branded health service medicine sales consistent with the average growth rate allowed under the 2014 voluntary scheme. The experience of the 2014 voluntary scheme showed no evidence of systemic and material negative supply effects for branded medicines, and the financial returns of PPRS members indicate that companies were able to earn reasonable returns under the scheme.

Risk of companies switching between schemes

135. This impact assessment assumes that there will be no switching between a voluntary and the statutory scheme. However, there is a possibility that there is switching between the schemes. If there is broad commercial equivalence between the schemes, the difference in savings would be limited. The costs to industry must by definition be less in the case of switching as otherwise there would not be an incentive to switch between the schemes.

136. However, if the schemes are not broadly commercially equivalent, there could be greater incentives for companies to switch that could result in lower savings to the NHS.

Statutory requirements for consultation

137. 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:

138. The economic consequences for the life sciences industry in the United Kingdom

139. The consequences for the economy of the United Kingdom

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

141. 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.

142. These factors were considered during the consultation with initial analysis below, using analysis presented in the main evaluation of the proposal, above (based on the central scenario of 9.9%, 14.7% and 20.5% payment percentage between 2019 - 2021).

Economic consequences for the Life Sciences Industry in the United Kingdom

143. As explained earlier in the document, the proposed policy is expected to reduce the gross revenues of pharmaceutical companies by £152m.

144. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated by BEIS[17] 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 £15.2m relative to the counterfactual. The reduction in revenue is estimated to translate to a reduction in UK R&D investment not exceeding £1.6m, with consequent net economic losses not exceeding £25m relative to the counterfactual, as shown above.

145. 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. However, this is simply the sector cost, and does not reflect net UK economy costs as these factors could be employed elsewhere in the economy.

146. As part of the consultation, some respondents expressed concern about the effects of EU exit and other uncertainties in the business environment, and argued that the impacts of the proposed policy needed to be considered in conjunction with these wider factors. Whilst we acknowledge that these wider factors might impact the UK pharmaceutical landscape, it is important to note that the purpose of this Impact Assessment is to identify the effects of the proposed policy only. Although EU exit is likely to have its own impact on companies, this can be viewed as part of the prevailing business environment. 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 EU exit would significantly alter the impacts of the proposed policy.

The consequences for the economy of the United Kingdom

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

148. 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 £1,170m over the period under consideration, as set out earlier in the document.

149. As part of the consultation, respondents were concerned that the proposed policy did not fully recognise the importance of the Life Sciences Industry for

[17] Estimate provided in correspondence

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 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

150. 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. We have quantified the impact of the loss of payments to provide revenue neutral prices increases for blood products which is £92m in 2021. We believe that the price increase provision is sufficient to mitigate the risk of loss of supply to patients. More details are provided in the post-consultation response.

151. The expected savings from the proposals will lead to provision of additional NHS treatments and services to other NHS patients generating 10,123 additional QALYs, valued at £607m by 2021.

Impact on small businesses

152. 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.

Equalities impact

153. 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 increases in maximum price in order to address uneconomic supply and seek to achieve continued adequate supply of essential and cost-effective medicines. Further detail on this is provided in Chapter 7 of the consultation document.

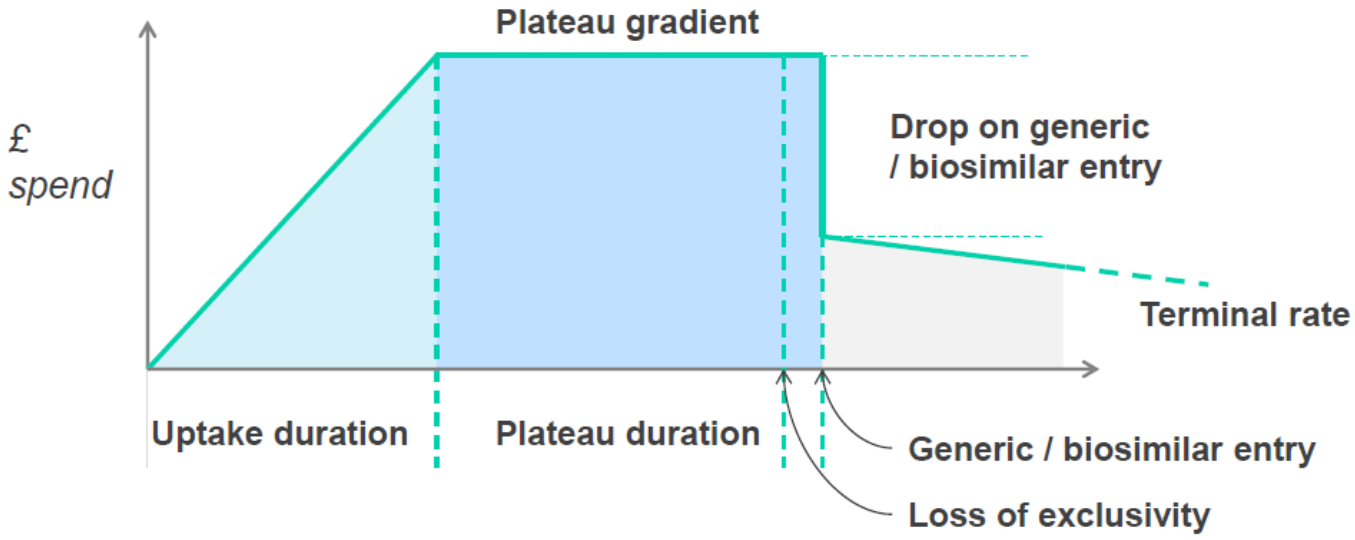
Annex A: Medicines Forecast Model

154. In order to determine the payment percentages required to deliver the Government's overall allowable growth rate as set out in policy option 1, the value of total sales of branded medicines has to be forecast. The payment percentage can then be set based on the difference between forecast sales and the allowed level of sales.

155. The forecasting methodology is based around a lifecycle approach to expenditure.

156. Figure 1 outlines the different phases in a product lifecycle, together with the key parameters for which values have been estimated for as part of the modelling. We have taken an evidence-driven, statistical approach to deriving these parameters using observations of historical data.

Figure 2: Product lifecycle and key parameters



Key parameters of the product lifecycle in the model are:

157. **Uptake duration**
Measures the time between product launch (derived from the first significant expenditure on the molecule in our data source) and the point at which the trend in expenditure changes (often due to the target patient population having been reached). The method by which the value for the parameter has been calculated (together with the cohort growth assumption, see below) is through a best fit of historic data for spend on products launched from 2008. Uptake gradient is not estimated as a fixed parameter; rather it is generated based upon the individual product data (i.e. continuing the existing trend).

158. **Plateau duration**
Taken as the time between the end of the uptake phase and patent expiry. The date of patent expiry has been taken from known sources for each molecule. This is predominantly a UK database which includes

Supplementary Patent Certificates and similar extensions. The European date is used in any cases where these were not available.

159. **Plateau gradient**
Rate of change in spend between end of uptake period and patent expiry, estimated from observed change of spend in data.

160. **Gap between loss of exclusivity and generic entry**
When a branded medicine losses exclusivity (due to the expiry of their intellectual property) it is likely that a generic or biosimilar competitor will enter the market, causing expenditure to drop. We have approximated this reduction in expenditure through a step-change. In many cases, the drop in expenditure will be more gradual due to the time required to either for the competitors to enter the markets and for generic or biosimilar medicines to get used. In order to avoid over-estimating, the speed with which this reduction can be achieved we have incorporated a delay between loss of exclusivity and observable drop in spend.

161. **Drop on generic/biosimilar entry**
This reflects the blended impact of price decay once a branded medicine goes off patent (as generic, branded generics and biosimilars typically seek to obtain market share through lowering prices) and a volume shift as prescribers move from branded to generic medicines. The parameter is estimated by looking at the percentage point difference in the level of expenditure before and after patent expiry for non-biological medicines. For biological medicines, initial estimates were clinically validated and revised upwards to account for expected larger price declines in future due to policy intervention, namely the stated objective of NHS England to increase the uptake of biosimilar medicines.

162. **Terminal rate**
Estimated from actual spend data; as estimates were not materially different from zero, the terminal growth rate is estimated to be 0% in the model

163. Following patent expiry, we have applied an assumption regarding the proportion of expenditure on a molecule that can be attributed to expenditure on the branded originator and expenditure on the generics. This has been validated by examining data according to manufacturer to establish

164. The estimation of parameters was carried out using two data sources. For primary care medicines, NHS BSA prescribing data18 for the period February 2008 to March 2017 was used. For secondary care medicine, Pharmex, which is a recording system used for invoices by hospital pharmacies, data for the period January 2007 to March 2017 was used. These are England only sources, and therefore a standard scaling factor of 1.25 has been applied to approximate to UK spend.

165. The product lifecycle parameters have been estimated at a category level for four different categories of medicines that from our data evidently behaved differently over their lifecycle. The model distinguishes between biological and

[18] See https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data

non-biological medicines, and separate sets of parameters have been estimated for both categories for primary and secondary care sales.

Table 11: Parameter value overview

Parameter	Primary care: **Non-biological**	Primary care: **Biological**	Secondary care: **Non-biological**	Secondary care: **Biological**
Uptake duration	80 months	80 months	70 months	70 months
Plateau duration	78 months	78 months	88 months	88 months
Plateau gradient	-1%p.a.	1%p.a.	5%p.a.	8%p.a.
Loss of exclusivity/generic entry gap	6 months	6 months	6 months	6 months
Drop on generic entry	70%	45%	70%	45%
Terminal growth rate	0%	0%	0%	0%
Cohort growth rate	10%	10%	0%	20%

166. We used our parameters to generate the forecast differently depending on whether a product is already launched, and therefore has a reliable time series of historic expenditure to create an individual forecast, or whether it is a recent or future launch, where we do not have this capability.

167. For products already on the market that were launched prior to 2015 ("established products"), we applied the set of parameters estimated for that particular category of medicine to the individual historic spend data to generate an individual product lifecycle. The product lifecycle is aligned to the loss of exclusivity date (see Plateau duration above). The plateau duration and uptake duration periods are defined in relation to this. For example, a primary non-biological product with a loss of exclusivity date in January 2025 would have a plateau period defined as July 2018 to January 2025 and an uptake period defined as November 2011 to July 2018.

168. The plateau gradient parameter captures a particularly complex market dynamic. This is because it is representing the stage of a lifecycle where there are most likely to be two counteracting effects on the trend for molecules in our historic dataset, which our methodology captures and incorporates into the forward projection. The first is competition within a therapeutic class, when the cannibalisation of a given product's sales from new, branded competitors succeeds in capturing some of the market share of the medicine, despite it still being protected from generic competitors by the patent. In addition to the potential impact on share, the manufacturer may reduce the price of the product to ensure it remains competitive. This would result in a negative

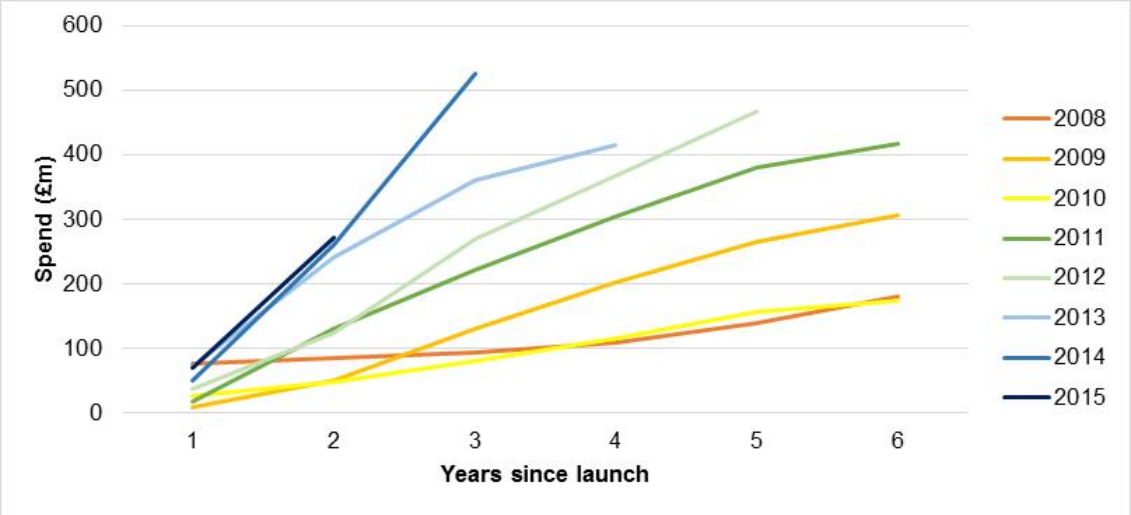
impact on plateau growth. However, increasingly pharmaceutical companies pursue an R&D strategy based around the licensing of additional indications for new therapeutic purposes, which may launch some years after the original indication came to market. Market prognosis reports show this is a particularly prominent trend in oncology. This will increase sales and create a positive growth, even after the main period of uptake has ended, by expanding the patient population that could be eligible for treatment.

169. Our analysis established that in primary care, the two effects broadly cancel out, resulting in trends of -1 and 1 per cent respectively for non-biological and biological medicines. However, our analysis shows that the former effect is outweighed by the latter for biological medicines in secondary care, reflected in a high plateau gradient. The result is that we do expect secondary care medicines launches over the last decade to still contribute to the overall trend of branded medicines growth.

170. For products launched after 2015 ("recent launches"), where there is either only a short series of historical data or no expenditure at all, we have applied the parameters to the aggregated total expenditure for all products launched or to be launched during the course of that year, which we term an annual cohort. The lifecycle is generated as these cohorts. This approach is also applied to assumed products launched in future (i.e. from 2019 onwards – termed "future launches").

171. We can also look at data on historic medicines spend split by annual launch cohort in the same way, displayed in Figure 2 below. When we do this normalised disaggregation, it shows that for more recently launched products, spend at each given point in their lifecycle is higher than was observed for the cohorts launched in earlier years at the exact equivalent point in their lifecycle. In effect, expenditure for the totality of all products launched in 2015, one year after their launch, grows more steeply and reaches a higher point than expenditure on the totality of products in 2014 had reached one year after their launch.

Figure 3: Normalised cohort growth rates, new launches 2008-2015



172. This effect is assumed to continue throughout the forecast period and is captured in the model through the estimation of an annual cohort growth rate parameter. This parameter was calculated (together with the uptake duration) to best match the observed spending profile for products launched since 2008. It explains why the impact of new medicines in our forecast is assumed to increase over time. The size of future cohorts is scaled however only to the lifecycle shape of the most recent cohorts (2015, 2016 and 2017).

173. We have looked at aggregated trends across settings, therapy area and type of molecule and triangulated this with expert opinion and analyst views. We believe the trends suggest our model is face valid.

174. The model was used to generate a series of forecast growth rates for total branded medicines spend for the period 2018 to 2023. These growth rates were then applied to the level of relevant sales in 2018 which is required for the calculation of the payment percentage

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

Background

175. 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.

176. 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.

177. 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

178. 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.

179. 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.

180. 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

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

182. 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

183. 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)

184. 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.

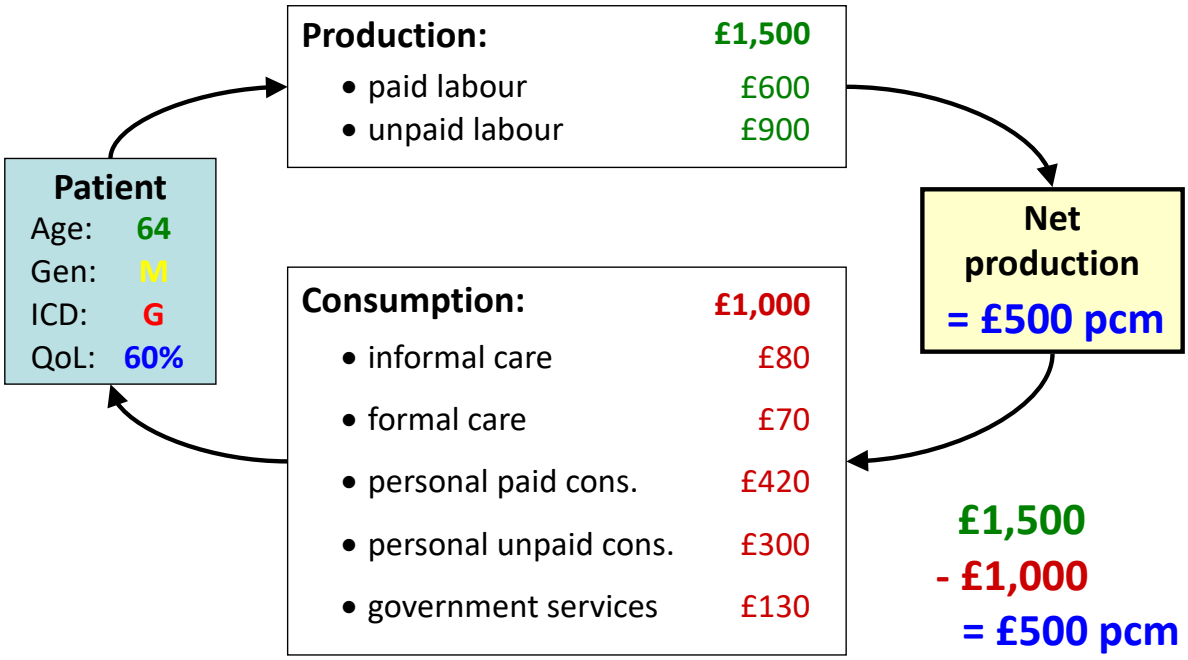
Estimating net resource contribution for patients in different health states

185. DHSC, 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

186. 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.

187. 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.



188. 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

189. The mechanism described above allows the net production rate (e.g. 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.

190. 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.

191. 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.

192. 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

193. The table below shows the estimated £net production generated per QALY in a selection of diseases[19]. 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

[19] Based on analytical model of January 2015.

194. 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.

Estimate of economic impacts for rheumatoid arthritis treatment

195. 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.

196. 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**

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

198. 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.

199. As discussed above, treatments which improve QoL tend to have greater (more positive) net production impacts than those which improve Length of Life (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

200. 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.

201. 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**

202. 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).

203. 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

Annex C - Estimates of the NHS cost of providing an additional QALY, and society's valuation of a QALY

204. This Annex defines and describes two distinct, but related concepts:

    i) The cost per QALY provided "at the margin" in the NHS;

    ii) The societal value of a QALY.

205. It then provides an illustrative example of how these two figures are used in DHSC Impact Assessments.

The cost per QALY "at the margin" in the NHS (£15,000)

206. The NHS budget is limited, in any given time period. This means that there are potential activities, or beneficial uses of funds, which would generate QALYs but which cannot be undertaken because the budget is fully employed. If additional funds were given to the NHS, additional QALYs would be generated by funding these activities. Similarly, if funds were taken from the NHS, QALYs would be lost - as some activity "at the margin" could no longer be funded and would necessarily be discontinued.

207. The cost per QALY "at the margin" is an expression of how many QALYs are gained (or lost) if funds are added to (or taken from) the NHS budget. It has been estimated by a team led by York University, and funded by the Medical Research Council, to be £12,981[20]. Expressed in £2016, and adjusted to give an appropriate level of precision, DHSC interprets this estimate as a cost per QALY at the margin of **£15,000**.

208. This implies that every £15,000 re-allocated from some other use in the NHS is estimated to correspond with a loss of 1 QALY. Conversely, any policy which releases cost savings would be deemed to provide 1 QALY for every £15,000 of savings released.

The social value of a QALY (£60,000)

209. Society values health, as individuals would prefer to be healthy and to avoid death. This value can be expressed as a monetary "willingness to pay" for a QALY – the unit of health.

210. The value society places on a QALY is also, in principle, a matter of empirical fact that may be observed. DHSC currently estimates this value to be **£60,000**, based on analysis by the Department for Transport of individuals' willingness to pay to avoid mortality risks[21].

211. Note that the estimated social value of a QALY significantly exceeds the estimated cost of providing a QALY at the margin in the NHS. This implies that the value to society of NHS spending, at the margin, significantly exceeds

[20] See http://www.york.ac.uk/che/research/teehta/thresholds/ and links therein

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

its cost. Adding £15,000 to the NHS budget would provide 1 QALY, valued at £60,000, according to these estimates.

Example Impact Assessment calculation

212. Suppose a project costs **£15m** – and these costs fall on the NHS budget. It is expected to generate health gains to patients amounting to **1,200 QALYs**.

213. The costs and benefits, and the overall net benefit of the project would be calculated as follows:

- The costs of the project are the QALYs that would be gained if the funds were used elsewhere in the NHS, but which are foregone if the project is undertaken. Using the standard DHSC estimate that one QALY is gained elsewhere for every £15,000 of funding, this gives an 'opportunity' cost of **1,000 QALYs lost**. Monetising these costs at the DHSC estimate of the social value of a QALY gives a monetary equivalent of **£60m**.
- The benefits of the project are simply the QALYs gained – that is **1,200 QALYs gained**. Monetising these costs using the DHSC estimate of the social value of a QALY gives a monetary equivalent of **£72m**.
- The net benefit of the project is therefore **200 QALYs**, or, expressed in monetary terms **£12m.**

214. In principle, costs and benefits in the above example can be expressed either in QALYs or in £, and give the same (correct) result. However, many projects have other impacts besides NHS costs and QALYs, and it is important to be able to express all the impacts in the same currency. For example, a project might generate cost savings to business, which are denominated in £s.

215. This is why normal DHSC practice is to convert all ultimate impacts into £, as recommended in the HMT Green Book. For costs falling on the NHS budget this means converting them first in to QALYs (at £15,000 / QALY), and then monetising them (at £60,000 / QALY).

216. Note that the effect of this conversion is to multiply the NHS costs by 4, in order to give their true £ value. Another way to view this conversion is to say a project will have to provide monetary gains worth at least 4x the direct NHS costs in order to provide a net benefit.