Title: 2018 Statutory Scheme – Branded Medicines Pricing	Impact Assessment (IA)
IA No: 9553	**Date: 12/07/2018**
Lead department or agency: Department of Health and Social Care	**Stage: Consultation**
Other departments or agencies: N/A	**Source of intervention: Domestic**
	Type of measure: Secondary legislation
	Contact for enquiries: Samuel 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**
£1,158m	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 voluntary and a statutory scheme. 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 1st of 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, while ensuring continuity of supply and patient access to drugs and to safeguard the financial position of the NHS by constraining the costs of branded health service medicines under the statutory scheme within 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%, 15.8% and 21.7% for 2019 through to 2021.

These options are evaluated for a period of 3 years, from Jan 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: 18/07/2018

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 as
Costs:	**Benefits:**	**Net:**	Yes/No	IN/OUT/Zero net cost

Summary: Analysis & Evidence

Policy Option 1

Description: New annual payment percentages of 9.9%, 15.8% and 21.7% 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	£3.1m	**£9.2m**

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

UK shareholders in pharmaceutical companies: Pharmaceutical company revenues are reduced by £163m by 2021, with consequent loss of profits for UK shareholders valued at £6.8m 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	Total Benefit (Present Value)
Low			
High			
Best Estimate	N/A	£389m	**£1,167m**

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

NHS patients: NHS costs (UK) are reduced by £162m by 2021, enabling the provision of additional treatments and services estimated to provide NHS patients with an additional 10,854 QALY by 2021, valued at £947.5m.
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 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 PPRS is under negotiation we assume that any impacts of switching between schemes is negligible

BUSINESS ASSESSMENT (Option 1)

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

2018 Statutory Scheme – Draft Impact Assessment for Consultation

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).

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 sales stayed flat in 2014 and 2015 and were allowed 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 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 a level which is considered affordable to the NHS. To this end, the DHSC and the pharmaceutical industry have made a voluntary agreement – the 2014 PPRS – which limits the 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 above £5 million make percentage payments based on the difference between allowed percentage growth and actual percentage growth in NHS expenditure on branded medicines. 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 PPRS is currently being negotiated for 2019 onwards.

7. In conjunction with the voluntary PPRS, 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 PPRS. 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. The overarching aim of both the statutory scheme and the voluntary scheme is to ensure the overall 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. Based on the Department's forecast of overall branded medicines spend, applying 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 7.9%.

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 measures are

- to increase the cost-effectiveness of spending on drugs covered by the statutory scheme, while ensuring continuity of supply and patient access to 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%, 15.8% and 21.7% 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 Jan 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.

"Business as Usual" Option

15. 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.

16. Spend under the statutory scheme is assumed to grow in line with DHSC's branded medicines spend forecast, at 6.7%, 8.2% and 8.8% annually between 2019 and 2021. For details of the underpinning model for this forecast, see Annex A at the end of this document.

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 a payment percentage to sales in the statutory scheme

Description of option

18. Under this option, a set of payment percentages (of 9.9% in 2019, 15.8% in 2020, and 21.7%) 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.

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

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

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. Spend under the statutory scheme in this option is also assumed to grow in line with DHSC's branded medicines spend forecast, at 6.7%, 8.2% and 8.8% annually between 2019 and 2021.

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.

Direct impacts on NHS sales

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

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.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

34. NHS and patient health gainsThe 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. 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

36. 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.

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

Calculation of impact on NHS sales

38. 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

39. Total sales of branded health service medicines by qualifying company, based on the latest returns provided to DHSC for 2017, are **£1,000m**. This is uprated by branded health service medicines growth to get forecast values for 2019 through to 2021.

Exclusion of low-cost presentations

40. 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.

41. 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

42. 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.

43. 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).

44. 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.

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

46. Framework agreements typically have a length of between 1 and 4 years. We use data on current framework agreements from 2017 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 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), **£693m** are likely to be encompassed in such agreements in 2017. The proportions for each of the payment percentage categories for the period under consideration are presented below. The values have been uprated in line with our growth forecast to get estimates for 2019 – 2021.

Table 1: % of frameworks under exemption, 7.8% payment percent, and new proposal

Do Nothing - Business as usual			
Year:	**2019**	**2020**	**2021**
Framework agreements spend (exempt) (£m)	768	831	904
Framework agreements exempt	23.0%	5.2%	2.2%
Framework agreements under 2017 Statutory Scheme 7.8%	77.0%	94.8%	97.8%

Option 1 - New payment % and frameworks agreed after Jan 2019 not exempt			
Year:	**2019**	**2020**	**2021**
Framework agreements spend (£m)	768	831	904
% Framework agreements exempt	23.0%	5.2%	2.2%
% Framework agreements under 2017 Statutory Scheme 7.8%	51.4%	28.3%	10.8%
% Framework agreements under new payment percentage	25.6%	66.5%	87.0%

47. Note that while we assume that when Agreements renew at the same value and length, 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.

48. 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

49. 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.

50. 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**.

51. 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**.

52. 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%.

53. The increase in sales due to relieving the 15% price cut is therefore **£6m**. Information on current frameworks was used to derive an estimate of **£2m** for the amount of these sales encompassed by a framework agreement – and which therefore would not increase in price. The net increase in sales is therefore estimated to be **£4m**, and sales under the statutory scheme are adjusted to **£1,004m.**

Effect of proposed payment percentages

54. 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 **£99m** would have been due to the Department under the statutory scheme. Under the proposed option, a payment of **£262m** would have been due to the Department.

The net effect of the policy is therefore a **£163m** saving to the Department in 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 2: Effect of proposed payment percentages on NHS finances

Year: **Do Nothing - Business as usual (£m)**	**2019**	**2020**	**2021**	***NPV***
Qualifying sales under do nothing (including frameworks)	918	1,141	1,269	
Framework agreements exempt	23%	5%	2%	
Framework agreements under 2017 Statutory Scheme 7.8%	77%	95%	98%	
Payment (£m)	71	89	99	251

Year: **Option 1 - New payment % and frameworks agreed after Jan 2019 not exempt (£m)**	**2019**	**2020**	**2021**	***NPV***
Framework agreements spend	768	831	904	
Qualifying sales (excluding framework agreements)	327	354	385	
% Framework agreements exempt	23%	5%	2%	
% Framework agreements under 2017 Statutory Scheme 7.8%	51%	28%	11%	
% Framework agreements under new payment percentage	26%	66%	87%	
Payment (£m)	83	162	262	489
Savings for option 1 against do nothing (£m)	11	72	163	237

55. 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

56. 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[1]. The increased savings of £163m therefore correspond to a gain of **10,854 QALYs** for patients in the NHS by 2021.

[1] 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/

57. These health gains are monetised using their estimated societal value[2] of **£60,000**, to give an annual impact valued at **£651m by 2021**.

Benefits to UK economy from improved patient health

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

59. 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[3]. Applied to the estimated QALY gains described above, this corresponds to a benefit valued at **£220m** for the period under consideration.

60. In total, the benefits from these savings are estimated to be £801m by 2021, and have a value of £1,167m over the period in consideration.

Table 3: 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)	11.0	72.5	162.8	236.9
QALYs generated elsewhere in the NHS @£15,000/QALY	733	4,832	10,854	
Social Value of QALYs @£60,000/QALY (£m)	44.0	289.9	651.2	947.5
Value of economic consequences of health gained @ £13,925/ QALY	10.2	67.3	151.1	219.9
Total benefits (£m)	54.2	357.2	802.4	1,167.4

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

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

Loss of profits for UK shareholders in pharmaceutical companies

62. 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.

63. In the long-run, changes in companies' revenues will not 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.

64. Empirical estimates of the proportion of the reduction in gross profits that will translate into loss of profits for shareholders are not available. However the Department for Business, Energy and Industrial Strategy Skills (BEIS) has provided an estimate that **30%** of pharmaceutical revenue is ordinarily taken as profits, giving an estimate of lost profits of **£49m in 2021**. This estimate is necessarily based on consideration of the most reasonable assumption, since empirical data to inform the estimate is not available. The pharmaceutical industry as a whole is global so, overall, the majority of NHS drug spending will accrue to overseas interests. BEIS estimate, based on analysis of trade information, that around **10%** of drug spend is on domestic production – that is, output generated by UK factors of production (UK-owned capital or UK labour). Assuming that returns to capital are shared between the UK and overseas in the same proportion as total returns, this implies that a corresponding proportion of the reduction in profits will accrue to UK shareholders, amounting to **£4.9m** in 2021[4].

65. The NPV of distribution adjusted lost profits to UK shareholders are estimated to be £4.9m over the period under consideration.

Impact on UK R&D spill-overs

66. 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[5] – of

[4] 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.

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

which a portion may be in the UK, providing "spill-over" losses to the UK economy.

67. The proportion of pharmaceutical company revenues devoted to R&D has been estimated[6] 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.

68. 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[7].

69. Applying the estimates above to the projected decrease in pharmaceutical revenues gives a loss of **£1.8m by 2021** to the UK economy from reduced 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.

Table 4: Costs to industry from lost profits and R&D spill-overs foregone

Year: **Costs**	**2019**	**2020**	**2021**	**NPV**
Lost profits to pharmaceutical company shareholders (£)	3.3	21.7	48.8	67.5
UK lost profits to shareholders (£)	0.3	2.2	4.9	6.8
Proportion of revenue invested in R&D in UK (£)	0.4	2.6	5.9	8.1
Lost UK benefits through reduced R&D investment (£)	0.1	0.8	1.8	2.4
Total costs (£)	0.4	3.0	6.6	9.2

Net monetised impacts

70. The total benefits of the proposed option, compared to the 'business as usual' option, are valued at **£1,167m**, over the period under consideration, while the total costs are estimated at **£9.2m** – giving a net benefit of **£1,158m**. See summary of results on the next page.

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

[7] Estimate provided in ccorrespondence

Summary of results

Year:	**2019**	**2020**	**2021**	***NPV***
Benefits				
Savings from option 1 against 'business as usual' (£)	11.0	72.5	162.8	236.9
QALYs generated elsewhere in the NHS @£15,000/QALY	733	4,832	10,854	
Social Value of QALYs @£60,000/QALY	44.0	289.9	651.2	945.7
Value of economic consequences of health gained @ £13,925/ QALY	10.2	67.3	151.1	219.9
Total benefits (£)	54.2	357.2	802.4	1,167.4
Costs				
UK lost profits to shareholders (£m)	0.3	2.2	4.9	6.8
Lost UK benefits through reduced R&D investment (£m)	0.1	0.8	1.8	2.4
Total costs (£)	0.4	3.0	6.6	9.2
Net benefits (£)	53.7	354.3	795.7	1,157.8

Sensitivities and key assumptions

Branded Medicines Spend Forecast

71. A key set of parameters underpinning our analysis 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.

72. 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.

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%

73. 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

74. 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.

75. The table below presents the impact on branded medicines growth of a cohort growth high/low scenario. It is noted that over the three year horizon considered, changes to the cohort growth 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	6.7%	8.2%	8.8%
Base	6.7%	8.2%	8.8%
Low	6.7%	8.2%	8.6%

76. 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	11.0	72.3	162.5
Base	11.0	72.3	162.5
Low	11.0	72.3	162.1

77. 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.

78. 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).

79. 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%	8.5%	9.1%
Base	6.7%	8.2%	8.8%
Low	6.3%	7.8%	8.5%

80. 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	11.1	73.3	165.0
Base	11.0	72.5	162.8
Low	10.9	71.6	160.4

81. Our analysis suggests that under the high scenario for plateau growth, savings under Option 1 would be £2.2m more than estimated in our base scenario by 2021. For the low scenario, savings under Option 1 would be £2.4m less than our base scenario by 2021. This implies that for our high scenario we undershoot our allowed growth rate by 0.2 percentage points by 2021 and for our low scenario we overshoot our allowed growth rate by 0.03 percentage points by 2021.

82. 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.

83. 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 a high and low scenarios for this parameter of +/- 5 percentage points, and present the impact on branded medicines growth below:

84. 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	7.1%	8.9%	9.9%
Base	6.7%	8.2%	8.8%
Low	6.3%	7.5%	7.9%

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

Year	2019	2020	2021
High	11.1	73.4	166.4
Base	11.0	72.5	162.8
Low	10.9	71.6	159.4

86. Our analysis suggests that under the high scenario for cohort growth, savings under Option 1 would be £3.6m more than estimated in our base scenario by 2021. For the low scenario, savings under Option 1 would be £3.4m less than our base scenario by 2021. This implies that for our high scenario we undershoot our allowed growth rate by 0.04 percentage points by 2021 and for our low scenario we overshoot our allowed growth rate by 0.04 percentage points by 2021.

87. 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.

88. Note however, that, there are alternate forecasts for the evolution of the global pharmaceuticals market[8], 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)

89. 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.

90. Secondary care growth using our forecast model is estimated to be 10.2%, 11.9% and 11.6% between 2019 and 2021 compared to 6.7%, 8.2% and 8.8% forecast for overall branded medicines growth.

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

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

[8] 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.

Table 5: Costs and Benefits of policy if framework agreements grew as a proportion of sales under the statutory scheme

Year:	**2019**	**2020**	**2021**	***NPV***
Benefits (£m)				
Savings for option 1 against do nothing (£m)	9.8	69.5	160.1	230.2
QALYs generated elsewhere in the NHS @£15,000/QALY	654	4,630	10,674	
Social Value of QALYs @£60,000/QALY (£m)	39.2	277.8	640.4	920.8
Value of economic consequences of health gained @ £13,925/ QALY	9.1	64.5	148.6	213.7
Total benefits (£m)	48.4	342.3	789.0	1,134.5
Costs (£m)				
UK lost profits to shareholders (£m)	0.3	2.1	4.8	6.6
Lost UK benefits through reduced R&D investment (£m)	0.1	0.8	1.7	2.4
Total costs (£m)	0.4	2.8	6.5	8.9
Net benefits (£m)	48.0	339.5	782.5	1,125.1

93. The net savings under this scenario are **£160m by 2021**, i.e. £3m less than the £163m savings in main scenario presented in this impact assessment. The costs to industry are slightly less as well, at **£4.8m in 2021**, compared to £4.9m in the main scenario. The lost benefits to the UK through R&D investment are also less at **£1.7m in 2021**, compared to £1.8m in the main scenario. The net benefits under this scenario are **£782m in 2021** compared to £795m in the main scenario.

94. 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, i.e. frameworks prices will 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.

Interactions with on-going PPRS negotiations

95. This impact assessment assumes that there will be a 2019 PPRS negotiated that is broadly commercially equivalent to the statutory scheme. However, a scenario where there is no PPRS negotiated and all branded medicines spend is controlled by the statutory scheme is presented below[9].

96. The baseline of total branded medicines sales is expected to be **£9,081m** in 2018, net of the expected payment received in 2018 from the 2014 voluntary scheme. Using our standard branded medicines growth estimate, branded

[9]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.

medicines spend is expected to increase up to **£12,023m** by 2021. In our analysis, we have assumed that the proportion of branded medicines under the different framework spend categories as the same for all companies as for the companies that are currently under the statutory scheme.

97. Based on this, we calculate savings to the NHS of **£13m** in 2019, **£516m** in 2020, **£1,257m** in 2021. This generates **83,768 QALYs** by 2021. This health gained over this period is valued at **£6,860m**. The benefits derived from the wider economic consequences over this period are valued at **£1,592m**. Thus, the total benefits over this period are valued at **£8,452m**.

98. As above, the savings to the NHS are lost revenue to pharmaceutical companies. As above, 30% of revenues are assumed to be profits, and 10% of profits are assumed to accrue to UK shareholders. In addition, the value of lost profits is adjusted to reflect the relative wealth of its recipients by a factor of 70%. Therefore, the cost to UK shareholders, over the period under consideration is valued at **£49m**.

99. The costs to the UK economy from the R&D spill-overs forgone are valued at **£18m** 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 **£66m** over the period.

100. Thus, the net benefits under this scenario would be valued at **£8,382m**.

Table 6: Costs and Benefits if all branded medicines were under the statutory scheme

Year:	**2019**	**2020**	**2021**	***NPV***
Benefits (£m)				
Savings for option 1 against do nothing (£m)	12.7	515.9	1,256.5	1,715.0
QALYs generated elsewhere in the NHS @£15,000/QALY	849	34,394	83,768	
Social Value of QALYs @£60,000/QALY (£m)	51.0	2,063.6	5,026.1	6,859.8
Value of economic consequences of health gained @ £13,925/ QALY	11.8	478.9	1,166.5	1,592.1
Total benefits (£m)	62.8	2,542.5	6,192.6	8,451.9
Costs (£m)				
UK lost profits to shareholders (£m)	0.4	15.5	37.7	48.8
Lost UK benefits through reduced R&D investment (£m)	0.1	5.6	13.6	17.6
Total costs (£m)	0.5	21.0	51.3	66.4
Net benefits (£m)	62.3	2,521.5	6,141.3	8,381.9

Accuracy of company returns

101. 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.

Future NHS use of products in the statutory scheme

102. 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 the prices of branded medicines are ordinarily significantly greater than their costs of supply. The Department has not seen any evidence that the new scheme, including application of the payment percentage alongside other provisions, would affect the supply of branded health service medicines. However, these risks are considered further in the sensitivity section below.

Switching between schemes

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

104. 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, as the levels of payment in the two schemes are designed to achieve broad commercial equivalence, any difference in savings or payments between the schemes is expected to be minimal. While any such switching may entail administrative costs for companies, these are – by definition – expected to be less than the benefits companies foresee from switching. Therefore the assumption of no effects from switching is likely to lead, if anything, to an over-estimate of any net negative impact on companies.

Uncertainties and Risks

Risks of a higher payment percentage

105. 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.

106. Moving from a 7.8% payment percentage to 21.7% payment percentage, almost a 3 fold increase, may generate additional risks and uncertainties. For example, if this higher payment percentage were to more materially affect global R&D decisions.

107. As the UK is 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.

108. 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.

109. 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. 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.

110. 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 a highly uncertain external environment – for example the uncertainty caused by the UK's exit from the UK could potentially lead to large shifts in exchange rates or impose additional costs that could negatively affect industry's ability to supply important medicines at a reasonable rate of return. This risk is partly mitigated through an existing facility within the statutory scheme to allow for companies to apply for price increases for specific products to mitigate any risks to medicines supply.

111. In addition, any wider risks to medicines supply are mitigated through the Department's commitment to an annual review of the statutory scheme which will allow the department to react to these issues if they emerge and make adjustments to the scheme if significant supply issues emerge.

112. 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 that no negative supply effects were observed, 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

113. This impact assessment assumes that there will be no switching between the PPRS and the statutory scheme as it intended that the two schemes be broadly commercially equivalent. 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 ought to be minimal. 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.

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

Impact on small businesses

115. 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

116. The Government’s assessment continues to be that there is no detrimental impact on particular protected groups or on health inequalities. By generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide treatments and services to patients across the NHS, including those with protected characteristics. The Government also recognises the necessity for provisions to allow for either temporary or permanent increases in maximum price in order to address short term or long term supply problems and ensure continued adequate supply of essential medicines. Further detail on this is provided in Chapter 7 of the consultation document.

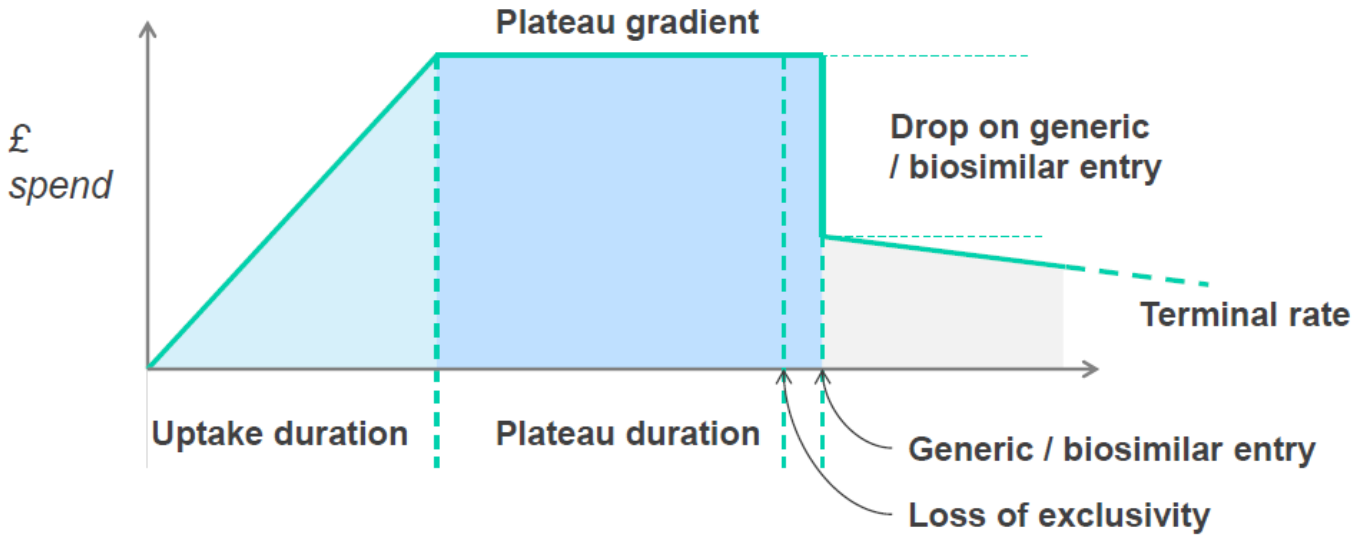
Annex A: Medicines Forecast Model

117. 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.

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

119. Figure A1 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 A1: Product lifecycle and key parameters



120. Key parameters of the product lifecycle in the model are:

121. **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).

122. **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.

123. **Plateau gradient**

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

124. Gap between loss of exclusivity and generic entry

When a branded medicine loses 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 market and for these 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.

125. **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.

126. Terminal rate

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

127. 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

128. The estimation of parameters was carried out using two data sources. For primary care medicines, NHS BSA prescribing data10 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.

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

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

130. Table A1 below shows the parameter values used for producing the central forecast.

Table A1: Parameter values 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%

131. 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.

132. 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.

133. 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

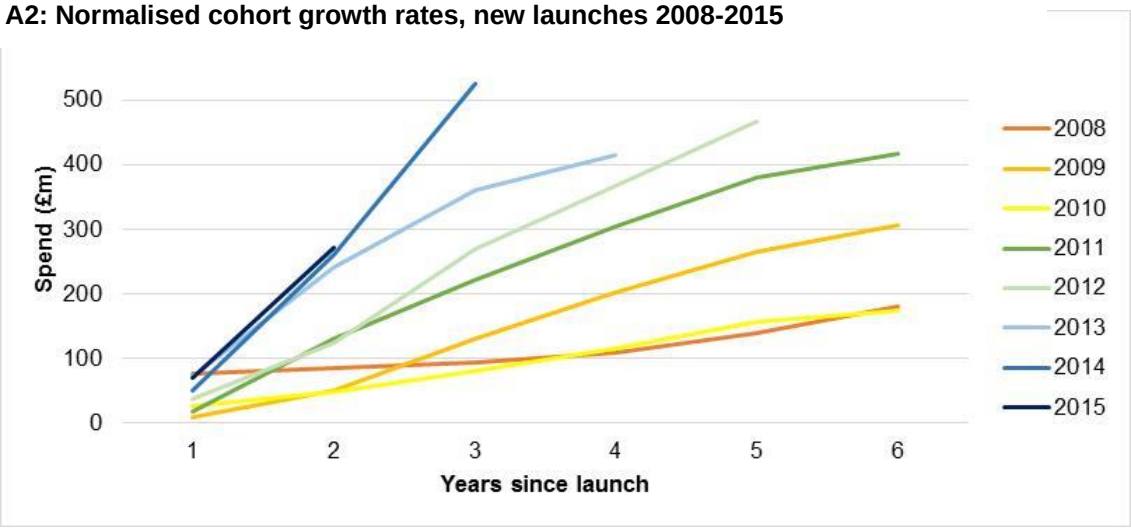
plateau growth. However, increasingly pharmaceutical companies pursue an R&D strategy based around the licensing of additional indications for new therapeutic purposes, which may launch some years after the original indication came to market. Market prognosis reports show this is a particularly prominent 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.

134. 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.

135. 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").

136. We can also look at data on historic medicines spend split by annual launch cohort in the same way, displayed in **Error! Reference source not found.** 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

Figure A2: Normalised cohort growth rates, new launches 2008-2015



reached one year after their launch.

137. 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).

138. 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.

139. 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

140. 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.

141. 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.

142. 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

143. 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.

144. 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.

145. 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

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

147. 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

148. 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)

149. 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

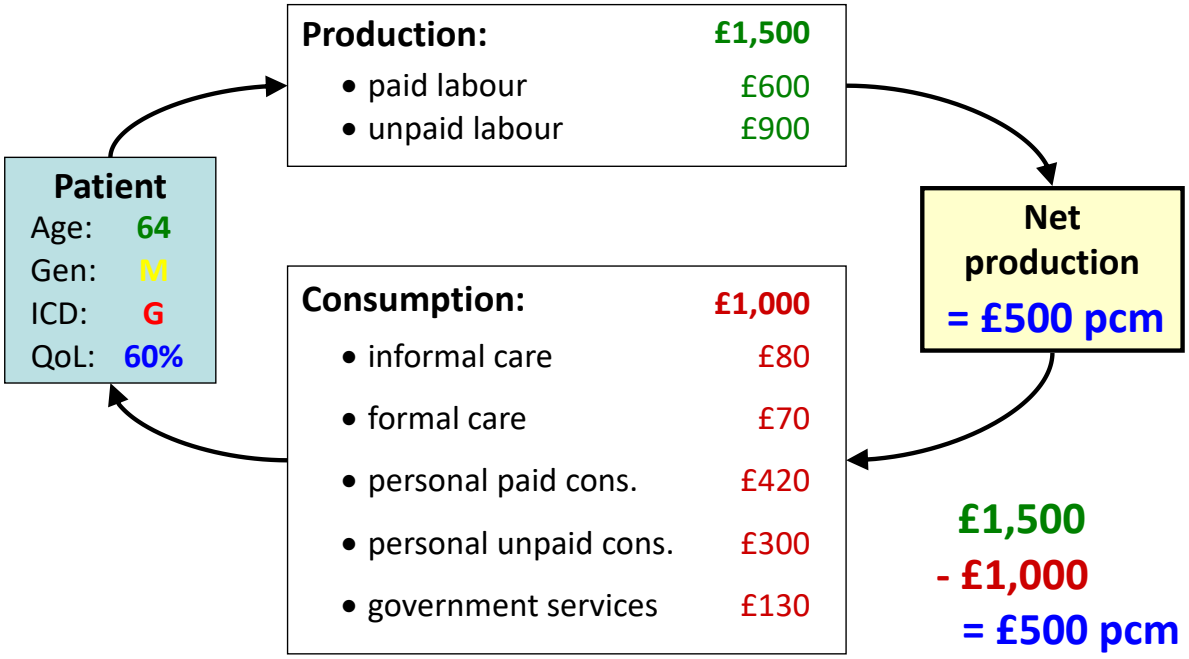
150. DHSC, in collaboration with external experts, has developed a mechanism by which each element of net production – and therefore the total amount of net production – can be estimated for a patient, given their

- *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

151. 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.

152. 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.



153. 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

154. 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.

155. 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.

156. 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.

157. 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

158. The table below shows the estimated £net production generated per QALY in a selection of diseases[11]. WSIs are also shown in £net production per £ of spending, assuming a marginal cost-effectiveness of £15,000 / QALY for treatments in all conditions.

[11] Based on analytical model of January 2015.

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

159. 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

160. 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.

161. 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**

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

163. 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.

164. 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

165. 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.

166. 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**

167. 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).

168. 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