| **Title:** Statutory scheme to control costs of branded health service medicines<br>**IA No:** 9555<br><br>**RPC Reference No:**<br>**Lead department or agency:**<br>Department of Health and Social Care<br>**Other departments or agencies: N/A** | Impact Assessment (IA) |
|---|---|
| | **Date: 21 January 2020** |
| | **Stage: Consultation** |
| | **Source of intervention:** Domestic |
| | **Type of measure:** Secondary legislation |
| | **Contact for enquiries:**<br>statutory_scheme_consultation@dhsc.gov.uk |

## Summary: Intervention and Options

**RPC Opinion:** RPC Opinion Status

| **Cost of Preferred (or more likely) Option** | | | |
|---|---|---|---|
| **Total Net Present Social Value** | **Business Net Present Value** | **Net cost to business per year** | **Business Impact Target Status**<br>Qualifying provision |
| -£231m to £27m | NA | NA | |

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

In the UK, the overall costs of branded health service medicines are controlled by a statutory and voluntary scheme; the latter having been agreed with industry. Scheme members make payments as a percentage of their sales to ensure that actual growth is in line with allowed growth. It is considered that the 2020 and 2021 statutory scheme payment percentages of 14.7% and 20.5% respectively are not expected to meet the Government's objectives for the scheme in the light of lower than expected growth in sales of branded medicines.

**What are the policy objectives and the intended effects?**

The objective is to balance the need to control branded medicines expenditure, and achieve broad commercial equivalence with the voluntary scheme, with the need to have regard for the research and development activities of pharmaceutical firms and the supply of branded pharmaceutical medicines. The effect of the policy will be to continue to offer a commercially viable alternative to the voluntary scheme.

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

Two options are considered: business as usual, i.e., the application of the 2020 and 2021 payment percentages of 14.7% and 20.5% respectively which are currently in the Branded Health Service Medicines (Costs) Regulations 2018 (the Regulations); and an option to apply new annual payment percentages in 2020 and 2021 of 7.4% (profiled as 14.7% for Q1, and 5.0% for Q2-4 for the companies that made scheme payments in Q1) and 10.9% respectively.

These options are evaluated for the period from 1st April 2020 (at which point new regulations would enter force) to December 2021.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** Apr/21

| Does implementation go beyond minimum EU requirements? | | N/A | | |
|---|---|---|---|---|
| Is this measure likely to impact on international trade and investment? | | No | | |
| Are any of these organisations in scope? | **Micro**No | **Small**<br>No | **Medium**<br>Yes | **Large**<br>Yes |
| What is the CO$_2$ equivalent change in greenhouse gas emissions?<br>(Million tonnes CO$_2$ equivalent) | | **Traded:**<br>N/A | **Non-traded:**<br>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 SELECT SIGNATORY: _____ Date: _____

# Summary: Analysis & Evidence

Business as Usual

**Description:** Business as usual

**FULL ECONOMIC ASSESSMENT**

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

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

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

The business as usual option is the counterfactual scenario, against which other options are assessed. This option is 2020 and 2021 payment percentages of 14.7% and 20.5% respectively as per the current Regulations 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'**

| 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'**

| Key assumptions/sensitivities/risks | Discount rate (%) | |
|---|---|---|

Under business as usual, companies would face increasing payment percentages, without an accompanying level of growth in their underlying sales. This may result in (i) companies switching into the voluntary scheme (where payment percentages would be lower); or (ii) companies apply for list price increases to ensure supply remains affordable; or, in extreme cases, (iii) companies withdrawing supply of branded medicinal products in the UK.

**BUSINESS ASSESSMENT (Option 1)**

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: |
|---|---|---|---|
| Costs: | Benefits: | Net: | |

# Summary: Analysis & Evidence

## Policy Option 1

**Description:** New annual payment percentages of 7.4% (profiled as 14.7% for Q1, and 5.0% for Q2-4) and 10.9% for 2020 and 2021 respectively

### FULL ECONOMIC ASSESSMENT

| Price Base Year 2019 | PV Base Year 2019 | Time Period Years 2 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | Low: -£231m | High: £27m | Best Estimate: N/A |

| COSTS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | | | | **-£27m** |
| **High** | | | | **£237m** |
| **Best Estimate** | | | | **N/A** |

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

Depending on the scale of behavioural response under business as usual (scheme switching; price increases; supply reduction) there may be additional net costs to the NHS (UK) of between -£54m to £169m by 2021, impacting the number of additional treatments and services, providing between 2,818 fewer and 906 more QALYs by 2021, valued at -£237m to £27m in NPV terms.  Given the evidence of companies joining the voluntary scheme during December 2019, the best estimate is likely to be closer to the lower cost estimate.

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

None identified but potential risks are included throughout the IA.

| BENEFITS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | | | | **-£1m** |
| **High** | | | | **£6m** |
| **Best Estimate** | | | | **N/A** |

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

Depending on the scale of behavioural response under business as usual UK shareholders in pharmaceutical companies would see benefits under this option of -£1m to £6m.  Furthermore, we might see increased investment in R&D, including in the UK, with consequent spill-over benefits for the UK economy valued at up to £2m.  Given the evidence of companies joining the voluntary scheme during December 2019, the best estimate is likely to be close to the low benefit estimate.

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

There is an unmonetized benefit in terms of meeting the objectives for the statutory scheme and limiting the risk of companies raising serious concerns with the Department over it making no changes to the scheme in light of lower than expected growth in branded medicines sales.

| Key assumptions/sensitivities/risks | Discount rate (%) | NHS 1.5% / other 3.5% |
|---|---|---|

There is inherent uncertainty around growth in branded medicines spend and therefore over the appropriate payment percentages. We assume that supply of products remains economically viable following application of these payment percentages. A key source of data is company returns on NHS sales – we assume that this information is accurate. Wider social benefits of changes in health spending are excluded from the headline NPV but are included in further scenario analysis.

### BUSINESS ASSESSMENT (Option 2)

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: |
|---|---|---|---|
| Costs: | Benefits: | Net: | |
| | | | |

# Statutory scheme to control costs of branded health service medicines

## Background

1. 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. In the UK, the costs of branded health service medicines are controlled under a voluntary and statutory framework.

*Voluntary Scheme*

2. The 2019 Voluntary scheme for branded medicines pricing and access (2019VS)[1] 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, Scotland, Wales and Northern Ireland), and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). The 2019VS expires on 31 December 2023.

3. The 2019VS 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. This is achieved through the calculation of a payment percentage, where companies make payments of a particular percentage of their eligible sales in order to bring expected growth in line with allowed growth.

*Statutory Scheme*

4. 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 2019VS. These Regulations are referred to as the "statutory scheme". The terms of the current statutory scheme provide for the application of a 9.9% payment percentage on qualifying sales in 2019, and payment percentages of 14.7% and 20.5% in 2020 and 2021 respectively. These payment percentages aim to control the growth of NHS sales of branded health service medicines within the scheme to a nominal 1.1% per annum.

### Table 1 – Current Statutory Scheme payment percentages in Regulations

|  | 2019 | 2020 | 2021 |
|---|---|---|---|
| **Current Statutory Scheme Payment Percentages** | 9.9% | 14.7% | 20.5% |

5. The terms of the statutory scheme include exemptions for sales under public contracts and framework agreements. This covers:

- Full exclusion for sales of products which are sold under contracts which were extant at the date of coming into force of the 2018 Statutory Scheme Regulations (i.e. entered into before 1st April 2018).

- Agreements entered into on or after 1st April 2018, but before 1st January 2019, will qualify for a 7.8% payment percentage on sales.

- Agreements entered into on or after the 1st of January 2019, the payment percentage laid out in the Regulations will apply.

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[1] https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access

6. 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, ensuring payments made are reasonable and do not overly impact supply or research and development.

7. This aim is unlikely to be achieved under a business as usual option in which the statutory scheme payment percentages are unchanged. These were set in 2018 and were based on forecasted NHS sales of branded health service medicines.

8. Based on the three-quarters of available data, growth in those sales between 2018 and 2019 was lower than forecast. So the current statutory scheme payment percentages in 2020 and 2021 are set higher than is expected to be required.

9. The Regulations include an obligation to review the scheme annually. What is more, in response to the 2018 consultation on changes to the statutory scheme[2], the Department, at paragraph 2.13, specifically stated:

   > *"The annual review mechanism will allow the Department to consider the ongoing appropriateness of allowable growth rate and payment percentages"*

10. This Impact Assessment considers the effects of a business as usual option of keeping the statutory scheme payment percentages unchanged, and a proposed option of setting new lower statutory scheme payment percentages which account for the lower-than-expected growth in 2019, whilst still ensuring growth in branded health service medicines spend is constrained to a level which will deliver overall economic benefits and patient health gains. This proposed option maintains the same allowed growth rate as previously, though the Department will continue to keep the statutory scheme under review through the annual review mechanism.

# Reasons for Government intervention

11. There are a number of key concepts used in this Impact Assessment:

    - *Measured Sales*: overall sales of branded medicines to the NHS (measured by combining relevant sales across the Voluntary Scheme, Statutory Scheme and Parallel Imports).

    - *Allowed Sales*: growth in measured sales is designed to be capped at the allowed growth rate (1.1%) through payments made by branded medicines manufacturers to DHSC. These payments are the passed on to NHS England and NHS Improvement and the Devolved Administrations.

    - *Payment percentages*: payments are made based on a proportion of the manufacturers eligible sales (i.e. Measured Sales excluding certain exemptions). This proportion is the payment percentage.

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[2] Published 3rd December 2018:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761015/consultation-response-statutory-scheme-to-control-costs-of-branded-health-service-medicines.pdf

12. The table below is a reference table of different percentages which feature in the IA, which can be referred to for clarification.

### Table 2 – Reference table

| | | 2019 | 2020 | 2021 |
|---|---|---|---|---|
| Growth Rates | **Initial Measured Sales Growth Forecast** | 5.72% | 6.84% | 8.57% |
| | **Outturn Measured Sales Growth (Q1-Q3 2018 to Q1-Q3 2019)** | 1.11% | N/A | N/A |
| | **Revised Measured Sales Growth Forecast** | N/A | 4.05% | 5.08% |
| | **Growth Rate of Allowed Sales - Statutory Scheme** | 1.10% | 1.10% | 1.10% |
| Payment Percentages | **Statutory Scheme Payment Percentages - Current (applied to all non-exempt sales)** | 9.9% | 14.7% | 20.5% |
| | **Statutory Scheme Payment Percentages - (applied only to sales from Frameworks entered into between 1st April 2018 and 31st Dec 2018)** | 7.8% | 7.8% | 7.8% |
| | **Statutory Scheme Payment Percentages - Proposed (applied to all non-exempt sales)** | N/A | 7.4% (profiled as 14.7% for Q1, and 5.0% thereafter) | 10.9% |
| | **Voluntary Scheme Payment Percentages** | 9.6% | 5.9% | 9.0% (estimated) |

*Lower than forecast growth in Measured Sales*

13. The growth of NHS sales of branded health service medicines is assessed through Measured Sales.  The 2018 Measured sales baseline for the growth calculation can be seen in the table below; these numbers are based on the latest outturns as of data up to Q3 2019[3].

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[3] https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-payment-percentage-for-2020

### Table 3 – Measured sales elements

| £m | 2018 |
|---|---|
| **2019 Voluntary Scheme** | 8,867 |
| **Statutory Scheme** | 1,643 |
| **Parallel Imports** | 599 |
| **Total Measured Sales** | 11,109 |

14. In the previous consultation on the statutory scheme (which closed on 19th October 2018), the forecast growth rate of Measured Sales of branded health service medicines between 2018 and 2019 was 5.72%. Since this consultation, we have received three quarters worth of measured sales data, and the growth rate of measured sales between January-September 2019, compared to the same period in 2018 is 1.11% (details published on 13th December 2019[4]).

### Table 4 – Measured sales growth rate

| Total Measured Sales growth | 2018 to 2019 |
|---|---|
| **Initial Forecast** | 5.72% |
| **Latest outturn growth (Q1-Q3 2018 to Q1-Q3 2019)** | 1.11% |

15. Various factors which may influence the growth rate of measured sales of branded health service medicines were discussed in the previous consultation, such as the uptake of new medicines and generic/biosimilar entry to the market from medicines in which patent protection has expired. There is some indication that the purchasing and procurement of certain branded medicines have been more effective in reducing the Department's relevant spend than was initially expected. This has contributed to the growth in measured sales of branded health service medicines being lower than forecast. These activities have included procurement of medicines to cure Hepatitis C, low cost versions of adalimumab as well as other commercial activities. NHS England have stated[5]:

> *"The Hepatitis C procurement is the latest in a series of 'smart deals' the NHS has delivered to drive value for the taxpayer and benefits for patients. These include a £300 million saving after negotiating deals with five manufacturers on low cost versions of the health service's most costly drug, adalimumab; striking the first full access deal in Europe for CAR-T therapy which can potentially cure some children and adults with blood cancers where other treatments have failed; and reaching a deal to make the life-extending lung cancer drug pembrolizumab, available for routine use on the NHS."*

16. The statutory scheme payment percentages currently laid out in Regulations were calculated using the forecast described in the previous consultation and to result in an allowed level of branded health service medicines sales growing at 1.1% per annum.

17. As the outturn growth of measured sales of branded health service medicines is lower than forecast, it would follow that the payment percentage for 2019 (and consequently 2020 and 2021) has been set at too high a rate, which would result in the allowed level of branded health service medicines sales growing at below 1.1% per annum.

*Forecast Revisions*

18. The 2019VS provides a mechanism to revise the 2018 forecast of branded medicines sales in line with actual sales data. At a high level, this mechanism compares cumulative outturn growth against cumulative forecast growth and adjusts future forecast growth by this ratio. This mechanism was agreed with the Association of the British Pharmaceutical Industry (ABPI) as part of the 2019VS negotiations and therefore the Department believes it is appropriate to use for the
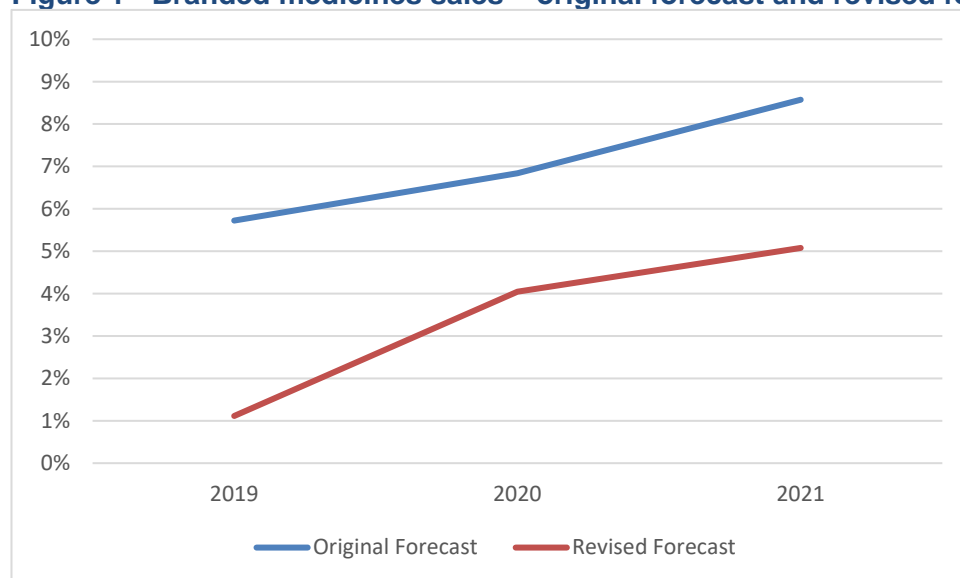
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[4] ibid

[5] https://www.england.nhs.uk/2019/04/nhs-england-strikes-world-leading-deal-to-help-eliminate-hepatitis-c/

purposes of setting Statutory Scheme payment percentages. This will also assist in maintaining "broad commercial equivalence" between the schemes.

19. Under this mechanism, expected growth of branded medicines sales is revised from 6.84% to 4.05% in 2020 and 8.57% to 5.08% in 2021.  We use these revised growth figures to set the proposed payment percentages under the preferred option.

**Figure 1 - Branded medicines sales – original forecast and revised forecast growth rates**



*Note: the 2019 growth rate in the revised forecast is based on the latest outturn growth rate of 1.11%*

## Objectives

20. The objectives of the Statutory Scheme are:

- To limit the growth in costs of branded health service medicines to safeguard the financial position of the NHS;

- To ensure medicines are available on reasonable terms, accounting for the costs of research and development; and

- To deliver the above objectives in a way consistent with supporting both the life sciences sector and broader economy.

21. The Department continues to support these objectives for the statutory scheme.  However, we do not think that the current payment percentages, as set out in the 2018 Regulations, support the final objective of the scheme.  In particular, the current payment percentages may not be seen as reasonable in the light of low growth in sales of branded medicines and therefore maintaining such payment percentage may not be considered supportive of the life sciences sector. It could also potentially jeopardise the availability of medicinal products on reasonable terms.

## Description of options

*Preferred option*

22. This impact assessment considers the impact of the proposal to adjust the 2020 and 2021 statutory scheme payment percentage to levels required to control sales in the light of lower than expected growth.  For the calendar years of 2020 and 2021, in light of revised forecast growth rates, payment percentages of 7.4% and 10.9% would be appropriate. As with any forecast, there is inherent uncertainty regarding the revised forecast, and as such if future sales of branded

medicines grows differently to expected, it may result in the revised payment percentages having been set too high or too low.

23. Given constraints on timings to amend payment percentages, the payment percentage for the first quarter of 2020 cannot be amended from 14.7%. Therefore, the payment percentage for companies who make payments under the statutory scheme in the first quarter of 2020 is proposed to be 14.7% until 31st March 2020 (as per current Regulations) and 5.0% from 1st April until 31st December. These figures are intended to give an overall average payment percentage which is expected to be equivalent to 7.4% for 2020. The payment percentage of 7.4% will also apply to members of the statutory scheme who make their first payment after the first quarter of 2020.

*Business as usual option*

24. The preferred option is compared to the position if there was no change, i.e., the application of the payment percentages currently in the Regulations for 2020 and 2021 of 14.7% and 20.5% respectively.

25. These options are evaluated for the period from 1st April 2020 (the point at which the new Regulations would enter force) to December 2021.

*Other possible options (not considered as part of this Impact Assessment)*

26. There are a number of ways in which payment percentages could be set for the statutory scheme. For example, they could be set using a calculation methodology distinct from the approach laid out in the preferred option (which mirrors the 2019VS calculation). However the Department has continued with the principle of broad commercial equivalence between the schemes as it allows the two schemes to work cohesively together and provides companies with a viable choice. An alternative approach in setting the payment percentages may not uphold such equivalence.

27. Alternatively, payment percentages could be set using the overarching principles and calculation approaches outlined, but with changes to key inputs, such as the forecast growth in measured sales or the growth rate for allowed sales (currently 1.1%). Again, the Department has continued with the principles outlined in the 2018 consultation and therefore, has not included such options in this impact assessment.

28. However, the Department will continue to keep the statutory scheme under review through the annual review mechanism.

## Business as usual option

29. A counterfactual or business as usual scenario is considered in which the 2020 and 2021 payment percentages of 14.7% and 20.5% continue to apply as per the current Regulations.

30. As the statutory scheme payment percentage for 2020 (14.7%) is substantially higher than for the same period under the 2019VS (5.9%), it is likely that there would be behavioural impacts upon members of the schemes. Current statutory scheme members may:

- Stay as members of the statutory scheme; or

- Seek to join the 2019VS at the earliest opportunity, and thus pay a lower payment percentage; or

- Apply for price increases of certain branded drugs. Such price increases may or may not be granted by the Department – each request is considered on its own merits.

31. In extreme circumstances, companies may withdraw supply of medicines. This would only be in the case where it is not economical for them to make sales of such medicines (and thus incur the payment percentage) and that any price increases they may have applied for were not granted.

32. Furthermore, under the business as usual option companies may raise serious concerns with the Department and question why, despite previous commitments by the Department, there does not appear to be broad commercial equivalence between the two schemes.

*Join the 2019 Voluntary Scheme*

33. As the payment percentage in 2020 for the 2019VS is 5.9%, companies may be inclined to join the 2019VS and leave the statutory scheme, where they would otherwise have been paying 14.7%.

34. Twelve companies which were statutory scheme members in 2019 and whose sales contribute to Measured Sales have joined the 2019VS for 2020.  As such, we exclude their sales from consideration in this Impact Assessment. Without the Department making the proposed amendments to the statutory scheme payment percentages, it is likely that some more companies would opt to join the 2019VS to pay the lower payment percentage. However, this would in all likelihood depend upon their specific portfolio of branded sales. Whilst companies can give notice of their intention to join the 2019VS at any time, membership takes effect from the 1st January in each calendar year.  Therefore in this scenario we might expect a further increase in 2019VS membership from 1st January 2021.

35. Companies with high proportions of sales under public contracts and framework agreements, where they were entered into prior to 1st April 2018 would continue to have these particular branded sales excluded from making any payment (until the Agreements expire). For these companies, it may be beneficial for them to continue within the statutory scheme in 2020, even with the greater payment percentage compared to the 2019VS, as they benefit from Agreement exclusion which is not present in the 2019VS.

36. Companies which join the 2019VS for 2020 will not cease to make payments, as rather than being subject to the statutory scheme payment percentage, they will be subject to the 2019VS payment percentage (which is set at 5.9% in 2020).

*Apply for price increases*

37. As the growth of measured sales of branded medicines is lower than forecast between 2018 and 2019, it means that the payment percentages of 9.9% in 2019 and 14.7% in 2020 are controlling the calculated growth of allowed sales to below the aim of 1.1%.

38. Under the counterfactual therefore, companies may find that lower growth in sales, coupled with higher payment percentages means that the continued sale of certain products becomes uneconomical.  They may therefore approach the Department to request list price increases to some of their branded products to maintain supply.

39. Whilst the extent and degree to which companies may seek price increases cannot be known, it may be that any request might reasonably be expected to be for the difference between what they are paying at 14.7% payment percentage, and what would they would be paying if we were controlling growth of allowed sales to 1.1%.

40. However, for the purposes of this Impact Assessment we assume that under business as usual, the Department would hypothetically grant price increases to the level at which the net effect of the 14.7% payment percentage is equal to the previous 9.9% payment percentage: hypothetical price increases of 5.6%. With respect to one hypothetical medicine that is granted a price increase of 5.6%, as shown below, this is a price increase such that the value of net sales (at higher prices) facing a payment percentage of 14.7% remains unchanged when compared to 9.9% - the 2019 statutory scheme payment percentage.

**Table 5 - Price increase assumption**

| Price | Payment Percentage | Sales revenue after paying payment percentage |
|-------|--------------------|-----------------------------------------------|
| 100   | 9.9%               | 90.1 [=100*(1-9.9%)]                          |
| 105.6 | 14.7%              | 90.1 [=105.6*(1-14.7%)]                       |

41. As such, with respect to this one hypothetical medicine that was granted a price increase of 5.6%, the counterfactual would result in both higher government expenditure (though higher prices on the branded medicine) as well as higher income (through the higher payment percentages). In sales terms, this may give a similar net effect to lower payment percentages without commensurate price increases.

42. However, there is the potential that this could result in a net additional cost to government, as any allowed increase to drug prices could result in greater expenditure on VAT and wholesaler margin. These elements are costs that are borne by the NHS in purchasing medicines (i.e. part of NHS financial expenditure) but are not captured in the value of sales by manufacturers (and therefore measured under the scheme). Neither of these cost elements can be recovered through payments under the statutory scheme or 2019VS, and so would result in additional cost pressures.

*Withdrawal of supply*

43. There is the risk that companies might chose to withdraw supply of branded medicines in the event of higher payment percentages which are not accompanied by similarly high levels of branded medicines growth.

44. This risk is considered to be remote, as the Department has a well-established process to consider list price increases where they are warranted as well as processes to maintain continuity of supply of medicines.

45. In general, these processes would ensure that any disbenefits to UK society remain limited and that such disbenefits would be lower than agreeing an appropriate price increase. Therefore we do not consider any specific scenarios related to withdrawal of supply.

*Companies raising serious concerns*

46. In the consultation response to the previous statutory scheme consultation, it was stated by the Department that:

> *"each year the 2018 Regulations will be reviewed. If there is evidence that the payment percentages are no longer appropriate to deliver the objectives of the scheme, the Department will be able to consult on revisions to these payment percentages".*

47. The objective to deliver the statutory scheme in a way consistent with supporting the life sciences sector implies that payments made under the scheme should be "reasonable". However, currently payments are expected to control growth of allowed sales to a level below 1.1% and therefore the Department believes the current payment percentages under the statutory scheme may not be the most appropriate.

48. Furthermore, failure to take action on revisions to the statutory scheme may damage the reputation of the Government's relationship with the life sciences industry and may lead to a loss of confidence in the voluntary and statutory pricing schemes which help manage the affordability of branded medicines. The life sciences industry is one of the most important pillars of the UK economy, contributing over £70bn a year and 240,000 jobs across the country[6].

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[6] Office for Life Sciences – Strength and Opportunity 2017: the landscape of the medical technology and biopharmaceutical sectors in the UK (2018) - www.gov.uk/government/publications/ bioscience-and-health-technologydatabase-annual-report-2017

49. Again, given the more remote risk of this scenario, we do not consider specific scenarios associated with these considerations.

# Business as usual scenarios - summary

50. To estimate a potential impact of these behavioural effects, we have created two scenarios to capture the impacts of companies switching between schemes or being granted price increases. Scenario A assumes no behavioural effects; no further company switching and no price increases. Scenario B assumes a high level of behavioural responses; price increases of 5.6% for all sales not exempted from payment in 2020 and 2021, and movement of all expected 2020 statutory scheme sales into the 2019VS in 2021.

51. The assumption of all statutory scheme sales moving into the 2019VS in 2021 is informed by data covering framework exemptions; with a high level of exempted framework sales potentially being a key driver for companies remaining in the statutory scheme over the 2019VS[7]. Where sales have moved into the 2019VS payments made under the Voluntary scheme are factored into the calculation. In the scenario where some statutory scheme sales are granted price increases in 2020, and then subsequently move into the 2019VS in 2021, the additional sales (due to price increases) are also moved over. This would have a small impact on the overall level of industry wide Measured Sales, and therefore on future 2019VS payment percentages. However, any impact on future payment percentages (as a result of granting price increases), for both the 2019VS and Statutory Scheme, is not expected to be material and is outside the appraisal period of this impact assessment. Therefore it has been excluded from this analysis.

52. These scenarios set the potential extremes in the behavioural responses under business as usual, and do not indicate Departmental expectation on for example, any expected success in price increase applications. The likely behavioural effects are expected to lie between these two scenarios. Given the evidence of twelve companies joining the 2019VS during December 2019 (taking effect from January 2020), we expect the most likely outcome of the business as usual scenario to be closer to Scenario B (High behavioural response).

**Table 6 - Business as usual Scenario Summary**

| | *Scenario A – No behavioural effects* | *Scenario B– High behavioural response* |
|---|---|---|
| **Stay (remain in Statutory Scheme)** | All expected sales (both 2020 and 2021) | All expected sales in 2020 None in 2021 |
| **Switch (move to Voluntary Scheme)** | None | None in 2020 All expected sales in 2021 |
| **Price increase of 5.6% (apply for Price Increases)** | None | All non-exempted sales |
| **Withdraw supply** | Not quantified | Not quantified |
| **Companies raising serious concerns** | Not quantified | Not quantified |

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[7] This assumption of all sales moving into the 2019VS in 2021 is based on company level estimates of framework exemptions in 2021. It uses the assumption that under the counterfactual statutory scheme payment percentages, a company would require their portfolio of measures sales to be made of at least 60% of framework sales subject to a 0% payment percentage, for the relative payment on the remaining sales subject to the statutory scheme payment percentage to be lower than if all their measured sales were subject to the 2019VS payment percentages.

# Preferred option: revise payment percentages for 2020 and 2021

## Description of option

53. Under this option, payment percentages are revised to levels required to control branded medicines sales in the light of lower than expected growth.  To cover the calendar years of 2020 and 2021, payment percentages of 7.4% and 10.9% would be required. However, given the timing of amendments to Regulations, payment percentages for companies who make scheme payments in the first quarter of 2020 will be 14.7% for the first quarter of the calendar year and 5.0% for the remaining three quarters. These payment percentages have been calculated to limit growth of branded health service medicines sales consistent with the annual growth aspired to in the previous statutory scheme consultation, which was 1.1% per annum. Details of the calculations are shown in Annex A.

54. Similar to the previous statutory scheme consultation and in line with the 2019VS, the growth of Measured sales is calculated on an industry wide basis (i.e. incorporating 2019VS measured sales, statutory scheme measured sales and Parallel Imports). This consistency of approach means that appropriate payment percentages are set across both schemes, regardless of scheme membership.

55. Government believes it is appropriate to set payment percentages that control branded medicines growth on average over a number of years.  Therefore, should payment percentages have been set too low (or too high), future payment percentages will be raised (or lowered) to ensure allowed growth is met on average.  This is in keeping with the principle of "broad commercial equivalence" with the 2019VS, a principle described in the previous statutory scheme consultation response.

56. So, in summary, the proposed 2020 and 2021 statutory scheme payment percentages take account of the degree to which the 2019 payment percentage was set higher than required in the light of actual (rather than forecast) growth.

*Timing of implementation*

57. If it were possible to have implemented the revised 2020 payment percentage from 1st January 2020, it would be set at 7.4%. However as a consequence of the time required to change the statutory scheme Regulations after the requisite sales data needed to make the calculations became available, the revised payment percentage for 2020 will not come into effect until the 1st April 2020. An effect of this delay will be that between 1st January 2020 to 31st March 2020 (where the 14.7% payment percentage applies in the statutory scheme) it is likely that greater payments are made than required to control allowed sales growth to 1.1%.

58. As such the revised payment percentage for the remainder of 2020 (1st April to 31st December) will take account of this effect. This will only apply to companies who made payments in the first quarter of 2020, to ensure that any companies that join the statutory scheme after the first quarter of 2020, and/or who start making payments after the first quarter 2020 do not disproportionately benefit from higher payments paid by other scheme members earlier in the year.

59. The 2020 statutory scheme payment percentage currently in the Regulations (14.7%) would apply between 1st January 2020 to 31st March 2020. In practice, the Regulations will apply as follows:

    - For companies that are Statutory Scheme members and make a payment in the first quarter of 2020, they will pay a payment percentage of 14.7% on sales in Q1 2020, followed by 5.0% on sales in Q2-Q4 2020.

    - For companies that join the statutory scheme after Q1 2020, and/or do not make a scheme payment in Q1 2020, they will pay a payment percentage of 7.4% on any sales made under the statutory scheme in Q2-Q4 2020.

# Preferred option scenarios – summary

60. To estimate a potential impact of behavioural effects under the Preferred Option, we have created two scenarios to capture the impacts of companies switching between schemes. Scenario A assumes no behavioural effects; no company switching and no price increases. Scenario B assumes a high level of behavioural responses; movement of all expected sales into the 2019VS in 2021[8]. This figure is the same as under the business as usual option because the company level returns held by the Department (covering their portfolios of sales), indicate that the same scheme movements might take place under either option. Where sales have moved into the 2019VS, payments made under the 2019VS are factored into the calculation.

61. These scenarios set the potential extremes in the behavioural responses under the preferred option, with the likely outcome expected to lie between these two scenarios. Given the evidence of companies joining the 2019VS during December 2019 (with effect from January 2020), we expect the most likely outcome of the preferred option to be close to Scenario B (High behavioural response).

**Table 7 – Preferred Option Scenario Summary**

| | *Scenario A – No behavioural effects* | *Scenario B– High behavioural response* |
|---|---|---|
| **Stay** (remain in Statutory Scheme) | All expected sales (both 2020 and 2021) | All expected sales in 2020 None in 2021 |
| **Switch** (move to Voluntary Scheme) | None | None in 2020 All expected sales in 2021 |
| **Price increase of 5.6%** (apply for Price Increases) | None | None |
| **Withdraw supply** | Risk mitigated | Risk mitigated |
| **Companies raising serious concerns** | Risk mitigated | Risk mitigated |

# Evaluation of Impacts

*Sales by statutory scheme companies*

62. Total sales of branded health service medicines by qualifying company, based on the latest returns provided to DHSC for 2019, are £1,638m for the UK. This incorporates actual sales for January to September 2019 but is uprated by the latest Measured Sales of branded health service medicines growth to get forecast values for 2019 through to 2021. All figures in this impact assessment are also presented at the UK level. These figures are expected to fall in 2020 as twelve companies which contribute to Measured Sales have agreed to join the 2019VS for 2020 – so the sales of these companies will should result in an equivalent rise in 2019VS sales. 2020 statutory scheme measured sales are estimated to be £419m, based on company level estimates of company share of overall measured sales.

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[8] This movement of sales into 2019VS in 2021 is based on company level estimates of framework exemptions in 2021. It uses the assumption that under the preferred option statutory scheme payment percentages, a company would require their portfolio of measures sales to be made of at least 25% of framework sales subject to a 0% payment percentage, for the relative payment on the remaining sales subject to the statutory scheme payment percentage to be lower than if all their measured sales were subject to the voluntary scheme payment percentages.

63. The terms of the statutory scheme provide some exemptions for sales under extant agreements (as described in paragraph 6). Framework agreements typically have a length of between 1 and 4 years. Analysis of data on current framework agreements and current levels of framework sales exemptions indicate that in 2019 £726m of sales are likely to be exempted from payment at the 0% level, and £293m are likely to be exempt at the 7.8% level. Based on this analysis, and assuming forecast growth of statutory scheme sales applies to framework sale, the levels of framework sales for each of the payment percentage categories for the period under consideration are presented below.

64. As there is an assumption that all statutory scheme sales will move to the 2019VS in 2021 under Scenario B, there are no expected exempted framework sales in 2021 for Scenario B. This is based on company level returns.

## Table 8 - % of frameworks under exemption for Scenarios A and B

| *Framework Exemptions*<br>**Scenario A £m** | **2019** | **2020** | **2021** |
|---|---|---|---|
| Framework agreements spend exempted at 0% | 726 | 168 | 1 |
| Framework agreements spend exempted at 7.8% | 293 | 1 | - |

| *Framework Exemptions*<br>**Scenario B £m** | **2019** | **2020** | **2021** |
|---|---|---|---|
| Framework agreements spend exempted at 0% | 726 | 168 | - |
| Framework agreements spend exempted at 7.8% | 293 | 1 | - |

*Effect of proposed payment percentages*

65. Qualifying sales and relevant proportions of framework spend under each payment scenario under business as usual and the preferred option are presented below. In 2021, under the business as usual option, a net payment of between £24m to £90m would have been due to the Department. Under the preferred option, a net payment of between £37m to £48m would have been due to the Department.

66. The net effect of the policy is therefore is an impact on savings between -£42m and £14m to the Department by 2021, where additional savings would otherwise have been 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 between -£59m and £7m.

67. This change in savings to be reinvested in the NHS will result in impacts to the benefits seen through improving the health of NHS patients, and lead to changes in income for shareholders in pharmaceutical companies, and adjusted spill-overs from R&D in the UK, as described below.

68. Calculations are all based on returns made by companies reporting their sales of health service medicines. Twelve companies who contribute to 2019 statutory scheme Measured Sales have opted to join the 2019VS for 2020. This expected drop in Statutory scheme measured sales (and subsequently payments) has been factored into the calculations below.

## Table 9 - Scenario A (Business as usual)

| Scenario A | 2019 | 2020 | 2021 |
|---|---|---|---|
| **Do Nothing - Business as usual (£m)** | | | |
| Base Statutory Scheme Measured Sales (£m) | 1,683 | 419 | 441 |
| Additional sales through price increases (£m) | - | - | - |
| Sales moving to the Voluntary Scheme (£m) | - | - | - |
| **Adjusted Statutory Scheme Measured Sales** (£m) | 1,683 | 419 | 441 |
| | | | |
| Framework agreements spend exempted at 0% (£m) | 726 | 168 | 1 |
| Framework agreements spend exempted at 7.8% (£m) | 293 | 1 | - |
| Statutory Scheme Payment percentage | 9.9% | 14.7% | 20.5% |
| Statutory Scheme Payment (£m) | | 37 | 90 |
| | | | |
| Voluntary Scheme Payment percentage | 9.6% | 5.9% | 9.0% |
| Voluntary Scheme exclusion from payment | 2.4% | 4.8% | 6.3% |
| Voluntary Scheme movers Payment (£m) | | - | - |
| | | | |
| **Total Payment (£m)** | | 37 | 90 |
| Total Payment net of Price increase (£m) | | 37 | 90 |

## Table 10 - Scenario B (Business as usual)

| Scenario B | 2019 | 2020 | 2021 |
|---|---|---|---|
| **Do Nothing - Business as usual (£m)** | | | |
| Base Statutory Scheme Measured Sales (£m) | 1,683 | 419 | 441 |
| Additional sales through price increases (£m) | - | 14 | 15 |
| Sales moving to the Voluntary Scheme (£m) | - | - | 456 |
| **Adjusted Statutory Scheme Measured Sales** (£m) | 1,683 | 433 | - |
| | | | |
| Framework agreements spend exempted at 0% (£m) | 726 | 168 | - |
| Framework agreements spend exempted at 7.8% (£m) | 293 | 1 | - |
| Statutory Scheme Payment percentage | 9.9% | 14.7% | 20.5% |
| Statutory Scheme Payment (£m) | | 39 | - |
| | | | |
| Voluntary Scheme Payment percentage | 9.6% | 5.9% | 9.0% |
| Voluntary Scheme exclusion from payment | 2.4% | 4.8% | 6.3% |
| Voluntary Scheme movers Payment (£m) | | - | 38 |
| | | | |
| **Total Payment (£m)** | | 39 | 38 |
| Total Payment net of Price increase (£m) | | 25 | 24 |

## Table 11 - Scenario A (Preferred Option)

| Scenario A | 2019 | 2020 | 2021 |
|---|---|---|---|
| **Preferred Option - New Payment percentage** | | | |
| Base Statutory Scheme Measured Sales (£m) | 1,683 | 419 | 441 |
| Additional sales through price increases (£m) | - | - | - |
| Sales moving to the Voluntary Scheme (£m) | - | - | - |
| **Adjusted Statutory Scheme Measured Sales** (£m) | 1,683 | 419 | 441 |
| | | | |
| Framework agreements spend exempted at 0% (£m) | 726 | 168 | 1 |
| Framework agreements spend exempted at 7.8% (£m) | 293 | 1 | - |
| Payment Percentage Legacy | 9.9% | 14.7% | 20.5% |
| Payment Percentages revised | 9.9% | 5.0% | 10.9% |
| Statutory Scheme Measured Sales subject to legacy percentage (£m) | | 60 | |
| Statutory Scheme Measured Sales subject to revised percentage (£m) | | 191 | |
| Statutory Scheme Payment (£m) | | 18 | 48 |
| | | | |
| Voluntary Scheme Payment percentage | 9.6% | 5.9% | 9.0% |
| Voluntary Scheme exclusion from payment | 2.4% | 4.8% | 6.3% |
| Voluntary Scheme movers Payment (£m) | | - | - |
| | | | |
| **Total Payment (£m)** | - | 18 | 48 |
| Total Payment net of price increase (£m) | | 18 | 48 |

## Table 12 - Scenario B (Preferred Option)

| Scenario B | 2019 | 2020 | 2021 |
|---|---|---|---|
| **Preferred Option - New Payment percentage** | | | |
| Base Statutory Scheme Measured Sales (£m) | 1,683 | 419 | 441 |
| Additional sales through price increases (£m) | - | - | - |
| Sales moving to the Voluntary Scheme (£m) | - | - | 441 |
| **Adjusted Statutory Scheme Measured Sales (£m)** | 1,683 | 419 | - |
| | | | |
| Framework agreements spend exempted at 0% (£m) | 726 | 168 | - |
| Framework agreements spend exempted at 7.8% (£m) | 293 | 1 | - |
| Payment Percentage Legacy | 9.9% | 14.7% | 20.5% |
| Payment Percentage revised | 9.9% | 5.0% | 10.9% |
| Statutory Scheme Measured Sales subject to legacy percentage (£m) | | 60 | |
| Statutory Scheme Measured Sales subject to revised percentage (£m) | | 191 | |
| Statutory Scheme Payment (£m) | | 18 | - |
| | | | |
| Voluntary Scheme Payment percentage | 9.6% | 5.9% | 9.0% |
| Voluntary Scheme exclusion from payment | 2.4% | 4.8% | 6.3% |
| Voluntary Scheme movers Payment (£m) | | - | 37 |
| | | | |
| **Total Payment (£m)** | | 18 | 37 |
| Total Payment net of price increase (£m) | | 18 | 37 |

**Table 13 – Difference in payments**

| Difference in payments (Preferred option less Business as usual) | 2020 | 2021 |
|---|---|---|
| Scenario A (£m) | -18 | -42 |
| Scenario B (£m) | -6 | 14 |

*Impact on NHS*

69. The application of a lower payment percentage in 2020 and 2021 is expected to impact the net cost of branded health service medicines sales to the NHS. The size of any behavioural impacts will influence the net effect of lowering payment percentages to the NHS budget. In the event of an increased net cost, this will reduce the funding for additional NHS treatments and services which will be a loss to patients and reduce health gains. Conversely a decreased net cost (so a net gain) would result in increased funding for additional NHS treatments and services.

70. Detailed calculations of these impacts are provided in the sections *"NHS and patient health impacts"*, and *"Impacts on the UK economy from changes to patient health"*, below.

*Impact on Pharmaceutical Companies*

71. The impact on the revenue from sales to the NHS will lead to a commensurate impact in net revenue for pharmaceutical companies. A proportion of this change in net revenue will result in altered profits for UK shareholders in pharmaceutical companies.

*Consequent impacts on UK economy from reduced R&D investment*

72. The impact on NHS revenues may lead to a change in investment in research and development (R&D) expenditure, of which a proportion may affect the UK. An increase or decrease in R&D investment would impact the benefits to the UK economy from associated spill-over effects.

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

74. As part of previous consultations we received no specific comments about the above approach, 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[9], and that siting of R&D facilities should not be affected by demand or procurement for final products in the local market. A report by the OECD in 2008[10] 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[11].

75. Whilst the consultation responses noted that spend on medicine would play a factor in investment decisions, it was acknowledged that this would not be the only factor. Overall, our assessment of the evidence continues to suggest that such a consideration would be secondary. As a result, any impact relating to NHS spending, or "demand-side" factors, is therefore not considered likely to be significant[12].

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[9] 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

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

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

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

76. So, whilst the impact of the preferred option could *increase* the net spend on pharmaceuticals in the UK, we do not include any benefits from increase investment in siting R&D facilities in the UK as a result of these amendments.

# NHS and patient health gains

77. The change in savings for the Department will impact 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[13]. The impacted savings of between -£42m to £14m therefore correspond to a change of between **-2,818 and 906 QALYs** for patients in the NHS by 2021.

78. These health gains are monetised using their estimated societal value[14] of £60,000, to give an annual impact valued at between -£169m to £54m by 2021.

79. In total, the benefits from these savings have a negative NPV value of between -£237m and £27m over the period in consideration.

**Table 14 - Monetising benefits from improved patient health and wider economic consequences**

| *Scenario A*<br>**Benefits (£m)** | **2020** | **2021** | *NPV* |
|---|---|---|---|
| Savings for option 1 against do nothing (£m) | -18 | -42 | -59 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | -1,232 | -2,818 | |
| Social Value of QALYs @£60,000/QALY (£m) | -74 | -169 | -237 |
| **Total benefits (£m)** | -74 | -169 | -237 |

| *Scenario B*<br>**Benefits (£m)** | **2020** | **2021** | *NPV* |
|---|---|---|---|
| Savings for option 1 against do nothing (£m) | -6 | 14 | 7 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | -430 | 906 | |
| Social Value of QALYs @£60,000/QALY (£m) | -26 | 54 | 27 |
| **Total benefits (£m)** | -26 | 54 | 27 |

# Loss of profits for UK shareholders in pharmaceutical companies

80. Pharmaceutical companies will see an increase or decrease in revenues commensurate with the change in savings for the NHS, altering the profits gained by shareholders in pharmaceutical companies.
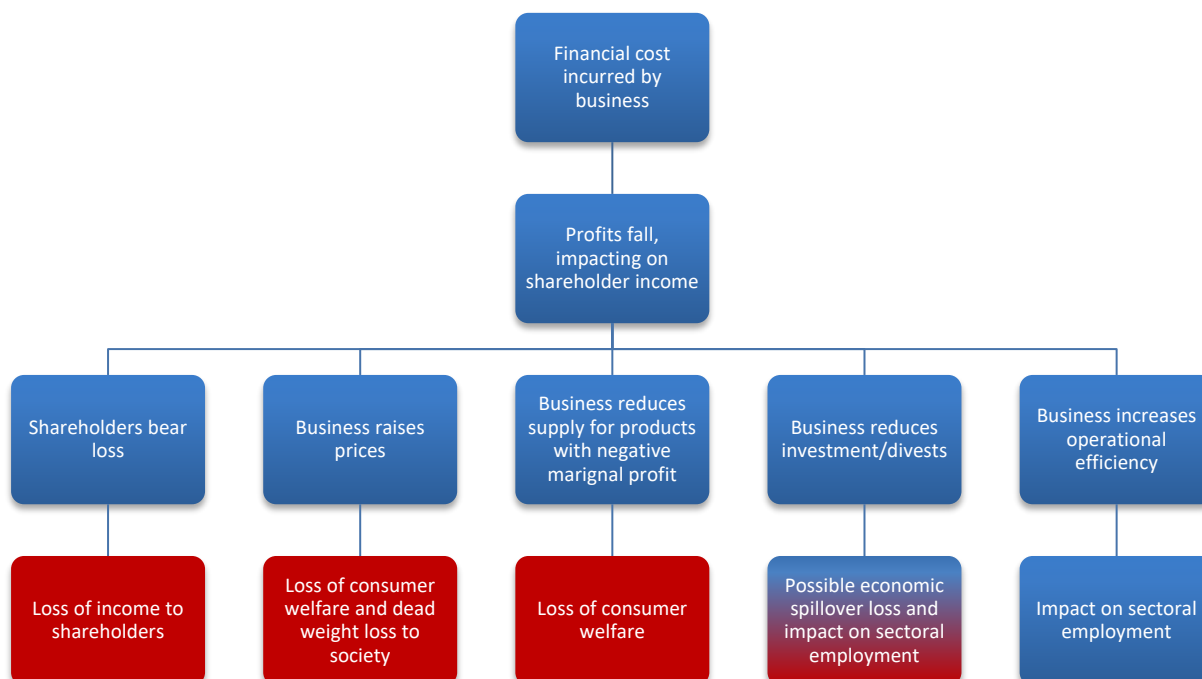
81. In the long-run, changes in companies' revenues may not have a noticeable impact on shareholders' income, since shareholders are always expected to ultimately make the risk-adjusted market return on capital. However, in the short run shareholders may receive an adjusted rate of return.

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[13] 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/

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

82. 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*



83. The impact in shareholder income is equivalent to the changed revenue at between **-£14m and £42m by 2021**. The Department for Business Energy and Industrial Strategy (BEIS) estimate, based on analysis of trade information, that around 10% of drug spend is on UK 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 changes in profits will accrue to UK shareholders, amounting to between **-£1m and £4m by 2021.**

84. The NPV of distribution adjusted profits to UK shareholders are estimated to be between **-£1m and £6m** over the period under consideration.

## Impact on UK R&D spill-overs

85. As described above, the preferred option is expected to impact the net revenues of pharmaceutical companies, compared to the business as usual option which may impact profits to shareholders. However, the impact in net revenue may also result in altered investment in R&D[15] – of which a portion may be in the UK, providing "spill-over" impacts on the UK economy.

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[15] 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.

86. Earlier we presented only the first order impacts to shareholders from the change of revenue. However, here we consider equilibrium impacts if this results in a change in R&D investment in the pharmaceutical sector in the UK. That is, this represents the potential change in economic spill-overs, if companies choose to either invest in a competitor country rather than the UK, or visa-versa. Thus, this represents a scenario where we might expect the proportion of R&D investment in the UK to be impacted in the long-term.

87. The proportion of pharmaceutical company revenues devoted to R&D has been estimated at 36%[16]. 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 as set out above.

88. 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. BEIS estimates the value of these additional benefits to be 30% of the value of the investment[17].

89. Applying the estimates above to the projected change in pharmaceutical revenues gives an impact between **£0 to £1m by 2021** to the UK economy from altered R&D investment over the period under consideration. The total value of the impacted UK benefits from increased R&D investment is between £0m to £2m over the period under consideration. To put this in context, this compares to total pharmaceutical R&D investment in the UK in 2017 of £4.3 billion[18].

**Table 15 - Costs to industry from lost profits and R&D spill-overs foregone**

| *Scenario A* Costs (£m) | 2020 | 2021 | NPV |
|---|---|---|---|
| Lost profits to pharmaceutical company shareholders (£m) | -18 | -42 | -57 |
| **UK lost profits to shareholders (£m)** | -2 | -4 | -6 |
| Invested in UK R&D (£m) | -1 | -2 | |
| **Lost UK benefits through reduced R&D investment (£m)** | -0 | -0 | -1 |
| Total costs (£m) | -2 | -5 | -6 |

| *Scenario B* Costs (£m) | 2020 | 2021 | NPV |
|---|---|---|---|
| Lost profits to pharmaceutical company shareholders (£m) | -6 | 14 | 6 |
| **UK lost profits to shareholders (£m)** | -1 | 1 | 1 |
| Invested in UK R&D (£m) | 0 | 0 | |
| **Lost UK benefits through reduced R&D investment (£m)** | 0 | 0 | 0 |
| Total costs (£m) | -1 | 2 | 1 |

# Net monetised impacts

90. The total benefits of the proposed option, compared to the business as usual option, valued in a range at between **-£237m and £27m**, over the period under consideration, while the total costs are estimated at between **-£6 and £1m** – giving a net benefit in a range of between **-£231m and £27m**. See the summary of results below.

**Summary of results**

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

[17] Estimate provided in correspondence

[18] Life Sciences Competitiveness Indicators 2019
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/811347/life-sciences-competitiveness-data-2019.pdf

*Scenario A*

| *Scenario A*<br>**Benefits (£m)** | **2020** | **2021** | *NPV* |
|---|---|---|---|
| Savings for option 1 against do nothing (£m) | -18 | -42 | -59 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | -1,232 | -2,818 | |
| Social Value of QALYs @£60,000/QALY (£m) | -74 | -169 | -237 |
| **Total benefits (£m)** | -74 | -169 | -237 |

| *Scenario A*<br>**Costs (£m)** | **2020** | **2021** | **NPV** |
|---|---|---|---|
| Lost profits to pharmaceutical company shareholders (£m) | -18 | -42 | -57 |
| **UK lost profits to shareholders (£m)** | -2 | -4 | -6 |
| Invested in UK R&D (£m) | -1 | -2 | |
| **Lost UK benefits through reduced R&D investment (£m)** | -0 | -0 | -1 |
| **Total costs (£m)** | -2 | -5 | -6 |
| **Net benefits (£m)** | -72 | -164 | -231 |

*Scenario B*

| *Scenario B*<br>**Benefits (£m)** | **2020** | **2021** | *NPV* |
|---|---|---|---|
| Savings for option 1 against do nothing (£m) | -6 | 14 | 7 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | -430 | 906 | |
| Social Value of QALYs @£60,000/QALY (£m) | -26 | 54 | 27 |
| **Total benefits (£m)** | -26 | 54 | 27 |

| *Scenario B*<br>**Costs (£m)** | **2020** | **2021** | **NPV** |
|---|---|---|---|
| Lost profits to pharmaceutical company shareholders (£m) | -6 | 14 | 6 |
| **UK lost profits to shareholders (£m)** | -1 | 1 | 1 |
| Invested in UK R&D (£m) | 0 | 0 | |
| **Lost UK benefits through reduced R&D investment (£m)** | 0 | 0 | 0 |
| **Total costs (£m)** | -1 | 2 | 1 |
| **Net benefits (£m)** | -25 | 53 | 27 |

# Unmonetized impacts

*Companies raising serious concerns*

91. As described in earlier sections, maintaining payment percentages under the statutory scheme that are in line with the governments stated objectives helps to mitigate a risk of companies raising serious concerns about the effective operation of the of the statutory scheme. These impacts are not monetised.

*Impact on medicines supply*

92. There is a remote and limited risk that companies facing higher statutory scheme payment percentages, without an accompanying level of growth in their sales, would choose to withdraw supply of certain branded medicines from the UK market.  However, the Department has established processes to seek to mitigate such risks. Therefore, these impacts have not been monetised.

# Further Scenario Analysis

## Benefits to UK economy from improved patient health

93. Previous impact assessments concerning changes to the statutory scheme have included the benefits to the wider UK economy from improvements to patient health. 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.

94. However, the estimates of these values have not been revised for some time.  Therefore, we have included these impacts as a further scenario, and not as part of the headline Net Present Value figures.

95. The previously used 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[19].

96. Applied to the estimated QALY impact described above, this corresponds to a benefit valued at between -£39m and £13m by 2021 for the period under consideration.

97. In this further scenario where the economic health gains are included in the calculation, the total benefits of the preferred option compared to the business as usual option, are valued at between **-£292m and £34m** over the period under consideration. The total costs are estimated at between **-£6 and £1m** – giving a net benefit of between **-£285m and £34m**. See the summary of results below.

**Summary of further scenario results**

*Scenario A – including wider social benefits*

| Scenario A – including economic health gains<br>Benefits (£m) | 2020 | 2021 | *NPV* |
|---|---|---|---|
| Savings for option 1 against do nothing (£m) | -18 | -42 | -59 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | -1232 | -2818 | |
| Social Value of QALYs @£60,000/QALY (£m) | -74 | -169 | -237 |
| Value of economic consequences of health gained @ £13,925/ QALY | -17 | -39 | -55 |
| **Total benefits (£m)** | -91 | -208 | -292 |

| Scenario A – including economic health gains<br>Costs (£m) | 2020 | 2021 | NPV |
|---|---|---|---|
| Lost profits to pharmaceutical company shareholders (£m) | -18 | -42 | -57 |
| **UK lost profits to shareholders (£m)** | -2 | -4 | -6 |
| Invested in UK R&D (£m) | -1 | -2 | |
| **Lost UK benefits through reduced R&D investment (£m)** | -0 | -0 | -1 |

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[19] See Annex C: Estimating the economic impacts of health conditions and treatments

| | | | |
|---|---|---|---|
| **Total costs (£m)** | -2 | -5 | -6 |
| **Net benefits (£m)** | -89 | -204 | -285 |

*Scenario B – including wider social benefits*

| Scenario B – including economic health gains Benefits (£m) | 2020 | 2021 | NPV |
|---|---|---|---|
| Savings for option 1 against do nothing (£m) | -6 | 14 | 7 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | -430 | 906 | |
| Social Value of QALYs @£60,000/QALY (£m) | -26 | 54 | 27 |
| Value of economic consequences of health gained @ £13,925/ QALY | -6 | 13 | 6 |
| Total benefits (£m) | -32 | 67 | 34 |

| Scenario B – including economic health gains Costs (£m) | 2020 | 2021 | NPV |
|---|---|---|---|
| Lost profits to pharmaceutical company shareholders (£m) | -6 | 14 | 6 |
| **UK lost profits to shareholders (£m)** | -1 | 1 | 1 |
| Invested in UK R&D (£m) | 0 | 0 | |
| **Lost UK benefits through reduced R&D investment (£m)** | 0 | 0 | 0 |
| Total costs (£m) | -1 | 2 | 1 |
| **Net benefits (£m)** | -31 | 65 | 34 |

# Statutory requirements for consultation

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

- The economic consequences for the life sciences industry in the United Kingdom

- The consequences for the economy of the United Kingdom

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

99. 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.

100. These factors are considered in this 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*

101. As explained earlier in the document, the preferred option is expected to impact the gross revenues of pharmaceutical companies by between -£6 and £57m.

102. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated by BEIS[20] to represent not more than 10% of the global industry, so impacts on UK interests are commensurately affected, with a gross change in revenues of between -£1m and £6m relative to the counterfactual. The change in revenue is estimated to translate to an increase in UK R&D of up to £2m.

103. In addition to these effects through increased profits for UK shareholders and increased benefits from R&D investment in the UK, there may be some impact through increased employment of administrative and marketing staff in the UK. However, this is simply the sector benefit, and does not reflect net UK economy benefit as these factors could be employed elsewhere in the economy.

# Impact on small businesses

104. 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

105. The Government's assessment continues to be that there is no detrimental impact on those who share protected characteristics as defined by the Equalities Act 2010 on health inequalities. By generating savings for the NHS, the proposals should have a positive impact through ensuring the effective operation of the scheme, thus ensuring the resources available to provide treatments and services to patients across the NHS, including those with protected characteristics. Further detail on this is provided in Chapter 5 of the consultation document.

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[20] Estimate provided in correspondence

# Annex A – Payment Percentage calculation

1. In line with the setting of the current statutory scheme payment percentages, payments will be calculated assuming there are no Agreements exemptions from payments and we have, for example, actually received 9.9% of statutory scheme measured sales in 2019 as payment.

2. 2020 and 2021 payment percentages have been calculated that would deliver an allowed level of branded health service medicines sales as follows.

3. Initially the Total Measured Sales is calculated:

$$Total\ Measured\ Sales_t = VS\ Measured\ Sales_t + SS\ Measured\ Sales_t + Parallel\ Import\ Sales_t$$

4. Where *VS* refers to the 2019VS, *SS* refers to the Statutory scheme, and $_t$ refers to the calendar year, e.g., 2020. Next, the Total Allowed Sales is calculated:

$$Total\ Allowed\ Sales_t = (Total\ Measured\ Sales_{2018} - Payment_{2018}) \times (1 + 1.1\%)\wedge n$$

5. Where *Payment* refers to 2018 payments received by the NHS from the PPRS and Statutory scheme, 1.1% is used as the allowed growth rate and *n* refers to the number of the year from 2019 ,where 2019 = 1, 2020 = 2 etc. Next, the Total Payment is calculated:

$$Total\ Payment_t = Total\ Measured\ Sales_t - Total\ Allowed\ Sales_t$$

6. Similar to the 2019VS, the over delivery of statutory scheme 2019 payments will be removed from forecast required payment in future years. To be consistent with the 2019VS the apportionment of the 2019 statutory scheme over delivery will be amortised up to 2023 (after which the 2019VS expires). This is calculated as below:

$$SS\ Amortised\ 2019\ Over\ delivery = \frac{(SS\ Measured\ Sales_{2019} \times 9.9\%) - \left(\frac{(SS\ Measured\ sales_{2019})}{(Total\ Measured\ Sales_{2019})} \times Total\ Payment_{2019}\right)}{4}$$

7. The 2019 payment percentage of 9.9% is applied to 2019 statutory scheme Measured Sales to calculate the value of payment modelled under the payment mechanism. It is divided by 4, as the over delivery of payment in 2019 is amortised over the following years up to 2023.

8. As outlined in the description, two payment percentages will be calculated for 2020, and one for 2021. This is due to the delay in being able to implement the 2020 payment percentage until the 1st April 2020, prior to which statutory scheme members will pay the 2020 payment percentage of 14.7% already in the Regulation. As such, for scheme members who made scheme payments in the first quarter of 2020, the anticipated over delivery of payment between 1st January 2020 and 31st March 2020 is factored into the payment percentage for the remainder of 2020. Scheme members that join the statutory scheme after the first quarter of 2020 and/or who did not make scheme payments in the first quarter of 2020 will not have this over delivery factored in the payment percentage.

9. The payment percentage for scheme members who made scheme payments in the first quarter of 2020, which will apply from 1st April 2020 is calculated below, where first required statutory scheme payment for 2020 is calculated:

$$SS\ Payment_{2020} = \left(\frac{(SS\ Measured\ sales_{2020})}{(Total\ Measured\ Sales_{2020})} \times Total\ Payment_{2020}\right) - SS\ Amortised\ 2019\ Over\ delivery$$

10. Following this, the anticipated remaining required payment from 1st April 2020 after the payment of 14.7% from 1st January has been factored in is calculated:

$$SS\ Balance\ Payment_{2020} = SS\ Payment_{2020} - (SS\ Measured\ sales_{2020} \times Q1share \times 14.7\%)$$

11. Where 14.7% refers to the current 2020 payment percentage already in Regulations, and *Q1share* is the estimated share of annual statutory scheme sales which will occur between 1st

January 2020 and 31st March 2020[21], which stands at 23.9%. The payment percentage to be applied from 1st April 2020 can be seen below.

$$Payment\ percentage_{2020a} = \frac{SS\ Balance\ Payment_{2020}}{SS\ Measured\ Sales_{2020} \times (1 - Q1share)}$$

12. This payment percentage is referred to as *Payment percentage_{2020a}*.

13. For scheme members that join the statutory scheme after the first quarter of 2020, and/or did not make scheme payments in the first quarter of 2020, the payment percentage is calculated as below:

$$Payment\ percentage_{2020b} = \frac{SS\ Payment_{2020}}{SS\ Measured\ Sales_{2020}}$$

14. This payment percentage is referred to as *Payment percentage_{2020b}*.

15. The 2021 payment percentage is calculated with the same methodology as the *Payment percentage_{2020b}* approach.

## Table 16 – Calculation of payment percentages

| Element, UK | 2019 | 2020 | 2021 |
|---|---|---|---|
| **2019 Voluntary Scheme - Forecast** | 1.14% | 4.28% | 5.32% |
| **Statutory Scheme - Forecast** | 2.44% | 4.16% | 5.22% |
| **Parallel Imports - Forecast** | -2.84% | 0.10% | 0.75% |
| | | | |
| **2019 Voluntary Scheme - Measured Sales (£m)** | 8,968 | 9,352 | 9,849 |
| **Statutory Scheme - Measured Sales (£m)** | 1,683 | 1,753 | 1,845 |
| **Parallel Imports - Measured Sales (£m)** | 582 | 583 | 587 |
| | | | |
| **Statutory Scheme as a % of Overall Measured Sales** | 15.0% | 15.0% | 15.0% |
| | | | |
| **Overall Measured Sales (£m)** | 11,233 | 11,687 | 12,281 |
| **Overall Growth (£m)** | 1.11% | 4.05% | 5.08% |
| | | | |
| **Allowed Sales (£m)** | 10,592 | 10,709 | 10,827 |
| **Allowed Growth** | 1.1% | 1.1% | 1.1% |
| | | | |
| **Expected Total Payment (£m)** | 645 | 983 | 1,459 |
| **Expected Statutory Scheme Payment (£m)** | 97 | 147 | 219 |
| | | | |
| **Legacy Payment %** | 9.90% | 14.70% | 20.50% |
| **2019 Modelled Payment (£m)** | 167 | | |
| **2019 Over-/Under-delivery (£m)** | 71 | | |
| **Amortised Over-/Under-delivery (£m)** | | 18 | 18 |
| | | | |
| **Adjusted Expected Payment (£m)** | | 129 | 201 |
| | | | |
| **Annual Payment Percentage** | | **7.40%** | **10.90%** |

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[21] This estimate is based on the average of Q1 share of measured sales under the PPRS from 2013 to 2018.

| | | |
|---|---|---|
| **Statutory Scheme - Measured Sales subject to Legacy % (£m)** | 421 | |
| **Statutory Scheme - Measured Sales subject to revised % (£m)** | 1,333 | |
| **Part year payment at legacy payment % (£m)** | 62 | |
| **Remaining payment required (£m)** | 68 | |
| | | |
| **Payment % (2020 from April)** | **5.00%** | **10.90%** |

16. Sales under extant framework agreements or public contracts 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, 2019VS presentations, as well as parallel imports and parallel distributed presentations would be excluded from the payment.

# Annex B – Revised Forecast

1. In order to determine the payment percentages required to deliver the Government's overall allowable growth rate as set out in the preferred option, 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.

2. The forecasting methodology is based around a lifecycle approach to expenditure, which has been detailed in the previous consultation.

3. To maintain broad commercial equivalence with the 2019VS, the forecast has been revised using the latest outturn data (up to Q3 2019) in the identical approach used in the 2019VS[22]. At a high level, this mechanism compares cumulative outturn growth against cumulative forecast growth and adjusts future forecast growth by this ratio.

4. The impact of the adjustment is subject to a 50% dampening factor for the first year's revision, to acknowledge that the forecast is being adjusted by a single data point and so limit the magnitude of the adjustment.

5. In the 2019VS, this dampening factor will not be applied when adjusting the growth forecast for the second year's revision – that is, when forecasting a revised 2021 growth rate using data up to Q3 2020. As such the total cumulative error from 2019 to 2020 in outturn growth compared to forecast will be used to adjust the growth forecast for 2021, and so calculate the 2021 payment percentage for the 2019VS.

6. A consequence of this is that the 2021 growth forecast when calculated in 2020 will likely be further adjusted once the dampening factor is removed and growth in 2020 (based on the four quarters up to Q3 2020) is determined.

7. The table below shows the original forecast and the revised forecast of growth of branded sales. Note the revised 2019 growth rate of branded sales is the latest outturn of 2019 growth, rather than a true forecast.

### Table 17 - Original and revised forecasts of branded sales

|                      | 2019  | 2020  | 2021  |
|----------------------|-------|-------|-------|
| **Original Forecast** | 5.72% | 6.84% | 8.57% |
| **Revised Forecast**  | 1.11% | 4.05% | 5.08% |

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[22] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761835/voluntary-scheme-for-branded-medicines-pricing-and-access-annexes.pdf

# Annex C: Estimating the economic impacts of health conditions and treatments

*Background*

1. 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.

2. 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.

3. 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*

4. 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.

5. 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.

6. 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**.
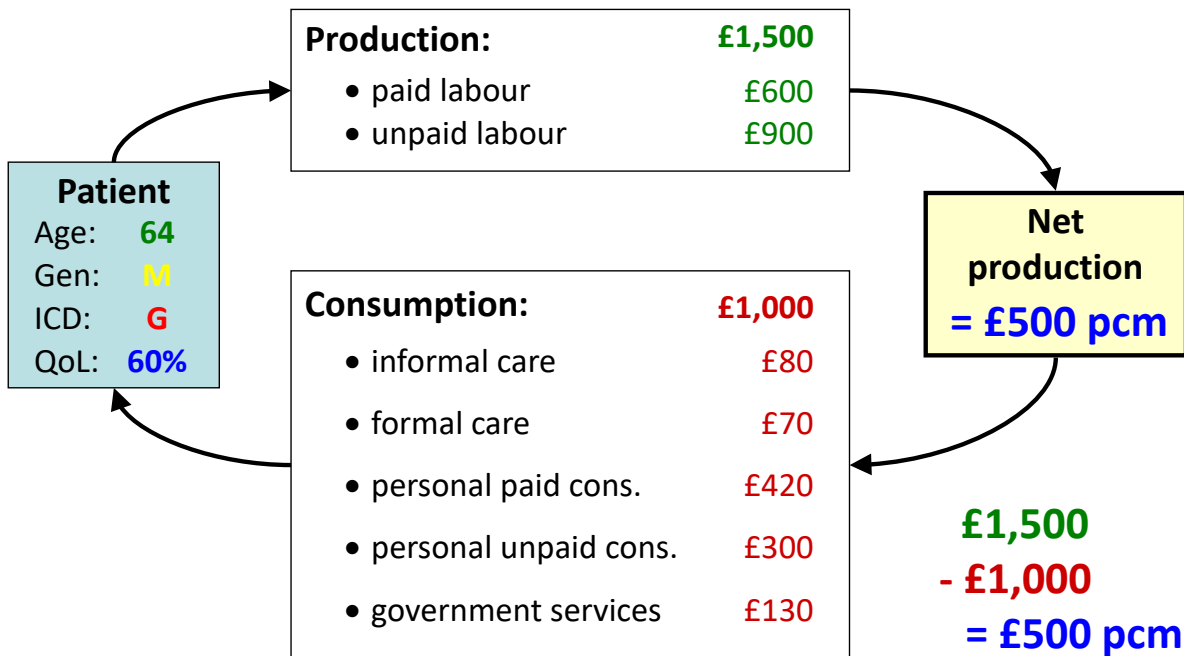
### Elements of net resource contribution

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

8. For *production* these are

- <u>Paid production</u> – 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

9. 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)

10. 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*

11. 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

12. 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.

13. 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.

| Production: | £1,500 |
| --- | --- |
| • paid labour | £600 |
| • unpaid labour | £900 |

**Patient**
Age: **64**
Gen: **M**
ICD: **G**
QoL: **60%**

**Net production**
**= £500 pcm**

| Consumption: | £1,000 |
| --- | --- |
| • informal care | £80 |
| • formal care | £70 |
| • personal paid cons. | £420 |
| • personal unpaid cons. | £300 |
| • government services | £130 |

**£1,500**
**- £1,000**
**= £500 pcm**

14. 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*

15. 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.

16. 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.

17. 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.

18. 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**

32

19. The table below shows the estimated £net production generated per QALY in a selection of diseases[23]. 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 |

20. 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

21. 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.

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

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[23] Based on analytical model of January 2015.

| | £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** |

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

24. 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.

25. 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*

26. 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.

27. 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** |

28. 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).

29. 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 D - Estimates of the NHS cost of providing an additional QALY, and society's valuation of a QALY

1. 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.

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


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

3. 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.

4. 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[24].  Expressed in £2016, and adjusted to give an appropriate level of precision, the Department interprets this estimate as a cost per QALY at the margin of **£15,000**.

5. 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)*

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

7. The value society places on a QALY is also, in principle, a matter of empirical fact that may be observed.  The Department 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[25].

8. 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 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

9. 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**.

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

- The <u>costs</u> 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 DH estimate that one QALY is gained elsewhere for every £15,000 of funding,

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

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

this gives an 'opportunity' cost of **1,000 QALYs lost**.  Monetising these costs at the DH estimate of the social value of a QALY gives a monetary equivalent of **£60m**.

- The <u>benefits</u> of the project are simply the QALYs gained – that is **1,200 QALYs gained**. Monetising these costs using the DH estimate of the social value of a QALY gives a monetary equivalent of **£72m**.

- The <u>net benefit</u> of the project is therefore **200 QALYs**, or, expressed in monetary terms **£12m.**

11. 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.

12. This is why normal DH 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).

13. 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.