Title: Updating the Statutory Scheme controlling the costs of branded health service medicines **IA No:** 9586 **RPC Reference No:** **Lead department or agency:** Department of Health and Social Care **Other departments or agencies: N/A**	Impact Assessment (IA) **Date: 04/05/2022** **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** dh.brandedmedicines@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2021 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£4,360m to £6,690m	£m	£m	Out of Scope

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

In the UK, the overall costs of branded health service medicines are controlled by a Statutory and Voluntary Scheme (VPAS); the latter having been agreed with industry. It is intended the schemes work together cohesively and in a complementary fashion and as such that broad commercial equivalence is maintained between them so that each may be a viable option. The objectives of the Statutory Scheme are to safeguard the financial position of the NHS, to ensure medicines are available on reasonable terms, and to do so in a way that supports the life sciences sector. It is considered that the de facto 2022 and 2023 Statutory Scheme payment percentages of 10.9% are set too low and thus not expected to meet the Government's objectives for the scheme in the light of higher-than-forecast growth in sales of branded medicines in 2021.

What are the policy objectives of the action or intervention and the intended effects?

The objective of the intervention is to ensure the Statutory Scheme achieves its aims of effectively controlling NHS expenditure on branded medicines in 2022 and 2023 and is broadly commercially equivalent with the Voluntary Scheme. In doing so, to have regard to the impact on industry, the economy and patients.

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 de facto 2022 and 2023 payment percentages of 10.9% as set by the Branded Health Service Medicines (Costs) Regulations 2018 (as amended) ('the Regulations'); and an option to apply new annual payment percentages in 2022 and 2023 of 14.3% (profiled as 10.9% for Q1 and Q2 and 17.7% for Q3 and Q4 for the companies that made scheme payments in Q1 and Q2) and 24.4% respectively. Wider medicine pricing goals cannot be achieved without a regulatory intervention.
We have been unable to incorporate inflation into our calculations of impacts, however we have provided the reasons for the omission and included a discussion around its possible impacts.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Likely by end of 2023

Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	**Micro** No	**Small** No	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister Lord Kamall Date: 26/05/2022

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 applying 2022 and 2023 payment percentages of 10.9% 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'

Maximum of 5 lines

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, the risks are (i) the Statutory Scheme failing to meet its objectives to ensure the overall branded medicines bill to the NHS remains affordable and delivers value for money for the NHS, ensuring payments made are reasonable and do not overly impact supply or research and development, (ii) companies in the VPAS leaving at the first opportunity to enter the Statutory Scheme; (iii) reputational damage to the VPAS scheme (since broad commercial equivalence will not be achieved).	

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 14.3% (profiled as 10.9% for Q1 and Q2 and 17.7% for Q3 and Q4) and 24.4% for 2022 and 2023 respectively.

FULL ECONOMIC ASSESSMENT

Price Base Year 2021	PV Base Year 2021	Time Period Years 2	Net Benefit (Present Value (PV)) (£m)		
			Low: £4,360 m	**High: £6,690 m**	**Best Estimate: N/A**

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**£100m**
High	Optional		Optional	**£160m**
Best Estimate				

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

Depending on the level of sales growth in 2022 and 2023 and subsequent behavioural effects (scheme switching) UK shareholders in pharmaceutical companies would see a loss of profits under this option of between £100m to £150m by 2023. Furthermore, we might see decreased investment in R&D, including in the UK, with consequent spill-over costs for the UK economy valued between £10m and £20m by 2023.

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

Potential risks are discussed throughout the IA.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**£4,470m**
High	Optional		Optional	**£6,850m**
Best Estimate				

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

Depending on the level of sales growth in 2021, 2022 and 2023 and subsequent behavioural effects (scheme switching) there may be additional net benefits to the NHS (UK) of between £4,590m to £7,050m by 2023, impacting the number of additional treatments and services, providing between 65,570 and 100,730 more QALYs by 2023, valued at £4,470m to £6,850m in NPV terms.

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 helping to maintain broad commercial equivalence with the VPAS

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

There is inherent uncertainty around growth in branded medicines sales 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. Impacts on potential price increases are excluded from the headline NPV but are included in further scenario analysis. The potential impacts of high inflation on pharmaceutical companies' profits and viability have not been incorporated into the analysis. This isn't possible due to the uncertainties arising from the mechanisms the Department controls relating to price, and as such the Department is unable to estimate how inflation might affect our forecasts, and consequently the impacts of the policy.

BUSINESS ASSESSMENT (Option 2)

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

Background

1. The life sciences industry is one of the most important pillars of the UK economy, contributing over £88.9bn a year and 268,000 jobs across the country, of which the Biopharmaceuticals sector generated £61.3bn turnover in 2020 and employed 129,000 people[1].

2. When a new medicine is launched it will typically be under patent, with the suppliers of health services medicines holding these patents enjoying monopoly supply of products at high prices to the NHS. This high price enables the supplier to not only enjoy profits, but also to recoup investment in Research and Development (R&D) of the new medicine (and R&D into other products that don't make it to launch). These medicines will be sold under a brand name.

3. When a patent expires, generic variants of medicines which are typically cheaper than their branded counterparts can be sold and supplied. Medicines can continue to be sold under a brand name when their patent expires, though typically they have to compete with generic competitors.

4. In England, the 2020/21 spend on medicines by the NHS was approximately £16.7bn[2], of which an estimated £12.5bn[3] was on branded medicines.

5. Government action is required to limit spending on branded health service medicines to ensure the overall branded medicines bill to the NHS remains affordable whilst delivering value for money for the NHS. In the UK, the costs of branded health service medicines are controlled under the Voluntary and Statutory Schemes.

Voluntary Scheme

6. The 2019 Voluntary Scheme for branded medicines pricing and access (VPAS)[4] 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 Scotland, Wales and Northern Ireland), and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). The VPAS expires on 31 December 2023. The VPAS 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 to the Department based on the difference between allowed growth and actual outturn growth in sales of branded health service 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 actual outturn growth in line with allowed growth.

Statutory Scheme

7. In conjunction with the Voluntary Scheme, the 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 VPAS. The Regulations are referred to as the "Statutory Scheme". The terms of the current Statutory Scheme provide for the application of a 10.9% payment percentage on qualifying sales in 2021 and subsequent years. These payment percentages aim to

[1] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020

[2] https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202021

[3] Based on estimates of historic shares of generic/branded medicines in primary care and secondary care

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

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	2022	2023
Current Statutory Scheme Payment Percentage	9.9%	7.4%	10.9%	10.9%	10.9%

8. 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.

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

9. Previous Statutory Scheme Impact Assessments[5] have taken into account exemptions from payment due to sales under framework agreements when calculating the income that is expected to be received from the scheme, and subsequently the impacts of the policy options. However, the current low levels of framework sales, as a result of expected framework expiries and companies joining the VPAS, mean we have been unable to incorporate them into our calculations. Doing so would jeopardise our duty of confidentiality. Due to the anticipated low levels of framework sales in 2022 and 2023 there is no substantive impact on the conclusions and results are broadly the same as if they had been factored in the calculations. Further details about framework sales can be found in Annex D.

Overarching Aim/Objectives of the Statutory Scheme and of the intervention

10. An overarching aim of both the Statutory Scheme and the Voluntary Scheme is to ensure the overall branded medicines bill to the NHS remains affordable and delivers value for money for the NHS, ensuring payments made are reasonable and do not overly impact supply or research and development. It is intended that both schemes work together cohesively and in a complementary fashion to achieve this aim and, as such, that broad commercial equivalence is maintained between them.

11. 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 2020 and were based on forecasted NHS sales of branded health service medicines using the best available data at the time (data to September 2019).

12. Based on more recent sales data (to December 2021) growth in sales between 2020 and 2021 was substantially higher than forecast when the current payment percentages were set. As such, the current Statutory Scheme payment percentages are lower than is expected to be required. Furthermore, as VPAS payment percentages automatically adjust to observed sales, the current Statutory Scheme payment percentages are lower than required to maintain broad commercial equivalence between the schemes.

13. 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 higher Statutory Scheme payment percentages which account for the higher-than-forecast growth in 2021, whilst still ensuring growth in branded health service medicines spend is

[5] https://www.gov.uk/government/consultations/branded-medicines-statutory-scheme

constrained to a level which will deliver overall economic benefits and patient health gains. This proposed option maintains the same allowed growth rate as was used previously, though the Department will continue to keep the Statutory Scheme under review.

14. In the view of the Department the objectives of the Statutory Scheme remain appropriate. Setting payment percentages higher than would be required to control growth to the allowed growth rate would not be consistent with those objectives and with the previously consulted on methodology.

15. The Department carried out a 6-week consultation on the proposals set out in this Impact assessment. We have considered the feedback received and have addressed specific questions in the relevant sections below. Further details can be found in the accompanying consultation response.

Reasons for Government Intervention

2021 Higher than forecast growth in Measured Sales

16. In the 2020 consultation, the Statutory Scheme payment percentages were calculated by comparing an allowed growth rate to NHS sales of branded health service medicines with a forecast of future growth. The 2018 to 2019 outturn growth rate of Measured Sales of branded health service medicines was calculated as being January-September 2019 compared to the same period in 2018 (year-to-date growth), resulting in growth of 1.11%. The growth rates from 2019 to 2020 and from 2020 to 2021 were based on a forecast in line with the VPAS methodology[6].

17. Since the 2020 consultation we have received data up to December 2021 (details published March 2022[7]) from which we have whole year actual outturn growth to 2021.

Table 2 –Measured sales growth rates

Total Measured Sales growth	2018 to 2019	2019 to 2020	2020 to 2021
Previous growth (as of Q3 2019 data)	1.11%**	4.05%*	5.08%*
Updated growth (as of Q4 2021 data)	1.69%	2.08%	9.48%

**Forecast growth, **Year-to-date growth*

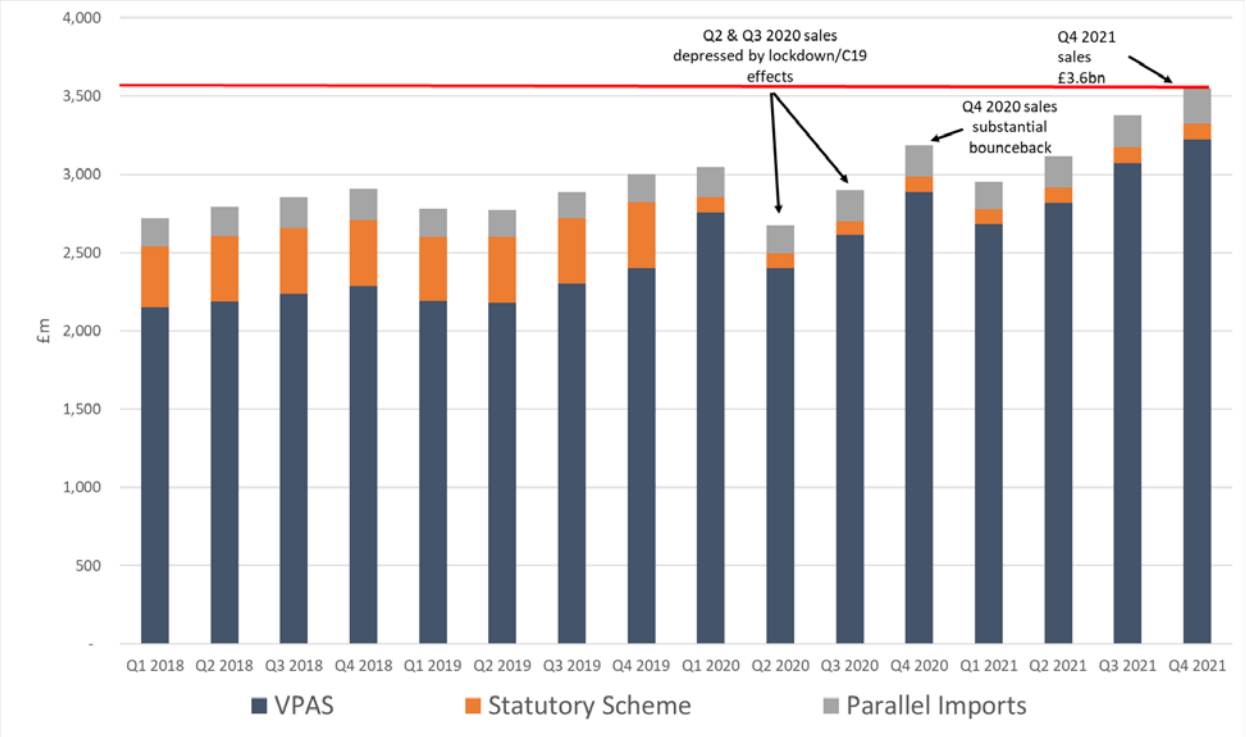
18. Table 2 shows slightly higher growth from 2018 to 2019 using the updated data, and slightly lower growth for 2019 to 2020. However, growth for 2020 to 2021 is substantially greater than our previous forecast: 9.48% compared to 5.08%.

19. In 2020, April-June (Q2) and to a lesser extent July-September (Q3) saw atypically low levels of measured sales. Conversely, in 2021 the same time periods saw much higher sales, with Q3 seeing record sales of branded medicines. Both Q2 and Q3 2021 recorded over 15% growth compared to the same quarter in 2020, whilst Q4 2021 saw quarterly growth of 11%. Consequently, measured growth from 2020 to 2021 has been high. In 2021 growth is 9.48%, compared to 2.08% full year growth in 2020. A contributing factor to these growth profiles is likely to be COVID-19 and subsequent lockdown effects.

[6] Annex 5, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1046017/voluntary-scheme-for-branded-medicines-pricing-and-access-annexes.pdf

[7] https://www.gov.uk/government/collections/voluntary-scheme-quarterly-net-sales-and-payment-information

Figure 1 – Quarterly Measured Sales



20. There are various factors which may have influenced the high growth rate of measured sales of branded health service medicines in 2021, such as:

- <u>High sales (Covid-19).</u> Covid-19 is likely to have contributed to the record high sales for two reasons:
    - There is a substantial backlog of unmet need due to the slowdown of elective and semi-elective treatments during the Covid-19 lockdown. As the NHS works through this backlog, we expect to see greater than normal use of medicines (see high levels of growth between Q2 2020 and Q2 2021).

    - As more is known about the treatment of Covid-19 there will be an increase in the use of licensed branded medicines to support Covid-19 patients.

- <u>High sales (non Covid-19).</u> We have seen high sales of new medicines, for example for treatment of cystic fibrosis and spinal muscular atrophy. We have also seen increased sales of seasonal flu vaccines as uptake of flu vaccines has increased substantially. The VPAS annex[8] shows that projected sales growth in 2021 at the time of scheme agreement was 8.57%, suggesting that Covid-19 cannot be solely assumed to account for the high sales recorded.

- <u>Lack of high value patent expiries in 2021.</u> Previous years saw patent protection expire on high value medicines (such as adalimumab) allowing cheaper alternatives to enter the market which contributed to lower overall spend.

2022 and 2023 Forecast Revisions

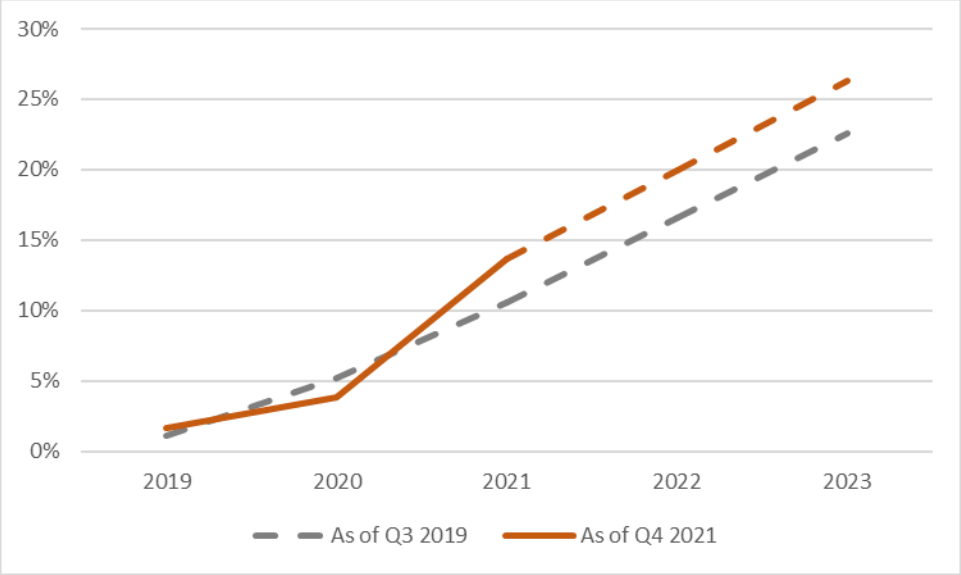
21. The VPAS provides a mechanism to revise the forecast of branded medicines sales in line with actual outturn sales data. At a high level, this mechanism compares cumulative outturn growth against cumulative forecast growth and adjusts future forecast growth by this ratio. This mechanism was agreed with the Association of the British Pharmaceutical Industry (ABPI) as part of the VPAS negotiations and therefore the Department believes it is

[8] Annex 3, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1046017/voluntary-scheme-for-branded-medicines-pricing-and-access-annexes.pdf

appropriate to use for the purposes of setting Statutory Scheme payment percentages. This approach was used in the previous consultation and will also assist in maintaining "broad commercial equivalence" between the schemes.

22. Under this mechanism and using data as of December 2021 compared to data as of September 2019 (as was used in the previous consultation), forecast growth of branded medicines sales is revised from 5.45% to 5.56% in 2022 and 5.16% to 5.26% in 2023. We use these revised growth figures to set the proposed payment percentages under the preferred option. See annex C for further details on the revised forecast of growth.

Figure 2 – Measured Sales cumulative growth



Note: Solid line = observed growth, Dashed line = forecast growth
Note: As of Q3 2019 - 2019 is year-to-date growth

23. Figure 2 compares the actuals/forecast cumulative growth from 2018 to 2023 as of the Q3 2019 and Q4 2021 data and a deviation can clearly be seen at 2021; when actual growth was much greater than forecast. This gap in 2022 and 2023 between the previous and new forecasts of cumulative growth demonstrate that a change in the Statutory Scheme payment percentage is needed in order to ensure the scheme's objectives can be achieved.

24. Actual prices paid by the NHS are confidential, so there are few good publicly available sources of forecast growth in pharmaceutical sales after confidential discounts to compare our revised forecast against. However, a number of organisations produce reports both at global and UK level covering sales at list prices.

25. These have broadly followed historic trends but cannot be directly compared but are mostly supportive of our adjusted forecasts for 2022 and 2023:

26. A report by EvaluatePharma[9] in 2021 shows higher growth in 2022 than in 2020 (bookending an exceptional 2021), with growth in 2023 being higher than in 2022.

27. In light of the more recent data, IQVIA in their 2022 report[10] have increased their growth of UK medicine spend forecasts versus some of their earlier reports[11].

28. General inflation is currently high. This has not been incorporated into the forecasts as they are a projection of trends. This presents a risk, however the Department is maintaining the

[9] https://www.evaluate.com/thought-leadership/pharma/evaluate-pharma-world-preview-2021-outlook-2026

[10] https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022

[11] https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends-outlook-to-2025

approach that has previously been agreed with the pharmaceutical industry and which aligns with modelling in previous impact assessments.

29. Furthermore, the Department has several mechanisms for controlling prices, such as maximum prices and NHS list prices, which are both fixed. These will only change following companies' applications for review so incorporating these sorts of decisions into the forecast model is not feasible. Given this, there is a risk of underestimating future spend; if a significant number of companies successfully applied for price increases, then medicines spend would rise further than forecasted within this IA.

Maintaining broad commercial equivalence

30. Unlike the Statutory Scheme, the VPAS payment percentage automatically adjusts in response to observed growth. As a result (and following the high 2021 growth), the calculated VPAS payment percentage increased from 5.1% in 2021 to 19.1% in 2022, although a subsequent scheme amendment brought the 2022 rate down 4.1%-points to 15%. The VPAS payment percentage for 2023 is projected to increase further to 23.7% (based on data up to Q4 2021), in part because of the effect of deferred payments resulting from the amendment of the 2022 payment percentage.

31. As a result, at current rates, the Statutory Scheme is no longer broadly commercially equivalent with VPAS. The Statutory Scheme payment percentage is meaningfully lower than VPAS in 2022 and likely substantially lower than VPAS in 2023.

32. Furthermore, the Statutory Scheme payment percentage across those two years has not been subject to an adjustment equivalent to the VPAS amendment. This presents a particular risk to the stability of the schemes and therefore to the objective of ensuring the overall branded medicines bill remains affordable. This is because it would allow VPAS scheme members to benefit from the 4.1%-point reduction in 2022 but then leave to join the Statutory Scheme and so avoid paying back the consequential increase in the VPAS payment percentage in 2023, thereby leaving the NHS financially disadvantaged by the amendment.

Key concepts

33. 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).

- Modelled Measured Sales: Voluntary Scheme, Statutory Scheme and Parallel Imports Sales as per the VPAS calculation model, which are 2018 baseline sales grown by either calculated growth rates or forecasted growth.

- 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.

Simplified example of setting payment percentages

The simplified hypothetical scenario below demonstrates how the above concepts interact.

- Hypothetical forecast **Modelled Measured Sales** = £10,000m
- Hypothetical forecast **Allowed Sales** = £9,500m
- Hypothetical required payment (to reduce measured sales to allowed sales) = £10,000m - £9,500 = £500m
- Hypothetical **payment percentage** = £500m / £10,000m * 100 = 5%
- Each company would make a payment equal to 5% of their eligible sales

34. The growth of NHS sales of branded health service medicines is assessed through Measured Sales. The 2018 Measured sales baseline for the growth calculation and modelled sales to 2021 can be seen in the table below; these numbers are based on updated outturns as of data up to Q4 2021.

Table 3 – Modelled Measured sales elements

£m	2018	2019	2020	2021
Voluntary Scheme	8,847	9,093	10,551	11,601
Statutory Scheme	1,650	1,668	379	399
Parallel Imports	771	697	766	805
Total Measured Sales	11,268	11,458	11,696	12,805

Objectives

35. 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.

36. 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 Regulations, continue to support the objectives of the scheme. Whilst we continue to support the broad approach, we used in deriving the current payment percentages, they do not reflect the exceptionally high growth in sales of branded medicines in 2021. Therefore, maintaining such payment percentages may not limit the growth in costs of branded health service sufficiently or may not ensure medicines are available on reasonable terms, accounting for the costs of research and development.

37. The objective of the intervention is to ensure the Statutory Scheme achieves its aims of effectively controlling NHS expenditure on branded medicines in 2022 and 2023 and is broadly commercially equivalent with the Voluntary Scheme. In doing so, to have regard to the impact on industry, the economy and patients.

Description of Options

Preferred Option

38. This impact assessment considers the impact of the proposal to adjust the 2022 and 2023 Statutory Scheme payment percentage to levels required to control sales in the light of higher-than-expected growth to 2021. For the calendar years of 2022 and 2023, in light of revised forecast growth rates, payment percentages of 14.3% and 24.4% would be appropriate. As with any forecast, there is inherent uncertainty regarding the revised forecast, and as such if future sales of branded medicines grow differently to expected, it may result in the revised payment percentages having been set too high or too low.

39. Given constraints on timings to amend payment percentages, the payment percentage for the first and second quarters of 2022 cannot be amended from 10.9%. Therefore, for companies who make payments at the rate of 10.9% under the Statutory Scheme in either of the first two quarters of 2022, the payment percentage is proposed to be 10.9% (as per current Regulations) until 30th June 2022 and 17.7% from 1st July until 31st December 2022. These figures are intended to give an overall average payment percentage which is expected to be equivalent to 14.3% for 2022. The payment percentage of 14.3% will apply to members of the Statutory Scheme who make their first payment after the second quarter of 2022.

Business as Usual Option

40. 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 2022 and 2023 of 10.9%.

41. These options are evaluated for the period from 1st July 2022 (the point at which the new Regulations would enter force) to December 2023. If no change was made to the payment percentages before December 2023, 10.9% would continue into 2024 and beyond.

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

42. 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 largely mirrors the VPAS 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.

43. 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%). Such changes could be used to derive alternative policy options with higher payment percentages, resulting in additional income for the NHS across the UK. Again, the Department has continued with the principles outlined in the 2018 consultation and therefore, has not included such options in this impact assessment.

44. The Department continues to keep the Statutory Scheme under review and is likely to issue a more wide-ranging consultation on the Statutory Scheme in 2023.

Business as Usual Option

45. A counterfactual or Business As Usual (BAU) position is considered in which the 2022 and 2023 payment percentages of 10.9% continue to apply as per the current regulations. These are considered under two growth scenarios:

- Scenario A: a higher growth scenario based upon the latest adjusted forecast as per the latest outturns; and

- Scenario B: a lower growth scenario where 2022 growth is modified to be 2%-points lower than the adjusted forecast used in scenario A. The 2023 forecast is subsequently impacted by the mechanistic adjustment, and is also lower than in scenario A.

46. Under Business as Usual the Statutory Scheme payment percentage for 2022 and 2023 are substantially lower than the confirmed 2022 and projected 2023 equivalent VPAS rates, so it is likely there would be behavioural impacts upon members of the schemes. Scheme members may:

- Stay as members of the Statutory Scheme (SS) or VPAS; or
- Seek to join the Statutory Scheme from the VPAS at the earliest opportunity, and thus pay the lower payment percentage;
- Seek to join the VPAS from the Statutory Scheme at the earliest opportunity, though they would pay a higher payment percentage

Leaving the Voluntary Scheme

47. The earliest opportunity current VPAS members can chose to leave the VPAS is for the 2023 calendar year. As the Statutory Scheme payment percentage in 2023 under BAU will be 10.9%, companies may be inclined to join the Statutory Scheme and leave the VPAS, where they would otherwise have been paying a projected, but currently highly uncertain, 23.7% (under the higher growth scenario).

48. Five companies which were Statutory Scheme members in 2021 and whose sales contribute to Measured Sales have joined the VPAS for 2022. As such, we assume they will remain in the Voluntary Scheme for the duration of time under consideration in this Impact Assessment.

49. Without the Department making the proposed amendments to the Statutory Scheme payment percentages, it is likely that a large number of companies would opt to leave the VPAS to pay the lower payment percentage in 2023. This would be a particular problem because it would allow VPAS companies to benefit from the agreed 4.1%-point reduction in the VPAS payment percentage for 2022, but not to pay the consequential increase to the VPAS payment percentage in 2023, leaving the NHS financially disadvantaged by the VPAS amendment.

50. However, company scheme moves would in all likelihood depend upon their specific portfolio of branded sales, and the value they place on being part of the wider Voluntary Scheme agreement. Whilst companies can give notice of their intention to leave the VPAS at any time before 30th September each year, membership takes effect from the 1st January in each calendar year. Therefore, in the counterfactual behavioural response we might expect an increase in Statutory Scheme membership from 1st January 2023. There is a potential risk that in order to leave the VPAS sooner, companies could default on their VPAS commitments during 2022, in which case they would be automatically moved into the Statutory Scheme. However, we believe this to be unlikely because companies within the Voluntary Scheme are committed to use their best endeavours not to manipulate or undermine the Voluntary Scheme in a way which conflicts with the purpose and objectives.

51. Companies with high proportions of their sales exempted from payment under the VPAS through the New Active Substance exemption (NAS) or Medium Size Company exemption (MSCE) may continue to find it beneficial to remain in the VPAS despite the lower payment percentage in the Statutory Scheme. The NAS and MSCE exemptions are not present in the Statutory Scheme, meaning if these companies moved to the Statutory Scheme, they would be required to pay a payment percentage on a greater proportion of their sales.

Leaving the Statutory Scheme

52. The earliest opportunity current Statutory Scheme members can choose to join the VPAS is for the 2023 calendar year. As the Statutory Scheme payment percentage in 2023 under BAU will be 10.9%, it is unlikely companies would be inclined to join the VPAS, where they would otherwise have been paying a projected, but currently highly uncertain, 23.7% (under the higher growth scenario).

Business as Usual Scenarios – Summary

53. To estimate a potential impact of these behavioural effects, we have created two scenarios to capture the impacts of companies switching between schemes. Scenario A assumes growth as per the current adjusted forecast and is termed 'higher' growth; the VPAS payment percentage is the projected 23.7% in 2023. Scenario B assumes a lower level of growth; subsequently the dynamic VPAS payment percentage falls to a projected 19.7% in 2023. In both the Business as Usual scenarios we hold the Statutory Scheme payment percentage at 10.9%.

54. The assumption of VPAS sales moving into the Statutory Scheme in 2023 is informed by data covering VPAS exempted sales (NAS and MSCE) in 2021. Using historic levels of exemptions allows us to estimate an effective 2023 VPAS payment percentage[12] at company level, with the assumption that companies with an effective 2023 payment percentage in the VPAS greater than the 2023 Statutory Scheme payment percentage will join the Statutory Scheme. There is some uncertainty about the behavioural response of companies in such a situation, including the potential changing composition of their portfolio of sales and any value they place on being part of the overarching Voluntary Scheme agreement. As the companies remaining in the VPAS under the BAU scenarios will by definition have proportionally large levels of their sales exempt from payment as either NAS or MSCE, the estimate of NAS/MSCE share in 2023 is increased relatively.

55. It is unlikely any Statutory Scheme members would join the VPAS in 2023 under BAU, as the Statutory Scheme payment percentage of 10.9% is lower than the equivalent VPAS rate in both the lower and higher scenarios. However, similar to companies joining the Statutory Scheme instead, there is some uncertainty about the behavioural response of companies due to considerations such as the actual composition of companies' portfolio of sales and the value placed on being part of the overarching VPAS agreement.

Table 4– Business as Usual Scenario Summary

	Scenario A – Higher Growth	**Scenario B – Lower Growth**
Modelled Measured Sales Growth	2022 – 5.56% 2023 – 5.26%	2022 – 3.56% 2023 – 4.54%
2023 VPAS Payment %	23.7%	19.7%
2023 Statutory Scheme Payment %	10.9%	10.9%
Switch **Leave VPAS for Statutory Scheme**	0% in 2022, 98.7% of 2023 sales move	0% in 2022, 96.6% of 2023 sales move
Switch **Leave Statutory Scheme for VPAS**	0% in 2022, 0% in 2023	0% in 2022, 0% in 2023

[12] Effective Payment Percentage: Companies pay the VPAS payment percentage on all eligible sales which is Measured Sales less NAS and MSCE exemptions. For example, given the 2023 projected VPAS payment percentage is 23.7%, if a VPAS company had more than 54% of their sales exempt from payment, the average payment percentage they would pay on all their sales would be less than the Statutory Scheme payment percentage of 10.9% under BAU. As such they would likely pay less in the VPAS in 2023 than in the Statutory Scheme despite the greater payment percentage in the VPAS.

Preferred Option: revise payment percentages for 2022 and 2023

Description of Option

56. Under this option, payment percentages are revised to levels required to control branded medicines sales in the light of higher-than-expected growth since the previous payment percentages were set. To cover the calendar years of 2022 and 2023, payment percentages of 14.3% and 24.4% respectively would be required. However, given the timing of amendments to Regulations, payment percentages for companies who make scheme payments in quarter one or quarter two of 2022 will be 10.9% for the first two quarters of the calendar year and 17.7% for the remaining two 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.

57. We received consultation responses stating that the allowed growth rate of 1.1% per annum was inappropriate to balance affordability versus reward for industry. However, the Department has seen no evidence showing that this allowed growth rate (which was present under the previous voluntary scheme on average between 2014 and 2018 and under the Statutory Scheme from 2018 to present) has resulted in insufficient reward for industry, although the impact of growth rates will of course be kept under regular review.

58. In reaching these payment percentages, the calculated Statutory Scheme payment percentage for 2022 was manually adjusted down by 4.1%-points to arrive at the annual rate of 14.3%. This is to mirror the similar adjustment made in the VPAS for the 2022 payment percentage which was set at 15% compared to a calculated rate of 19.1%. The Statutory Scheme payment percentage for 2023 has factored in this decrease in 2022 payments to ensure there is no loss of income resulting for the NHS. These adjustments are necessary to ensure broad commercial equivalence between the schemes and to avoid the risk of VPAS members who benefited from the scheme amendment leaving the scheme in 2023 to avoid paying the consequential payment percentage increase. Further details of this adjustment can be seen below, and the calculations are shown in Annex B.

59. We received responses to this consultation arguing we should delay setting the 2023 payment percentage until there is more certainty about the 2023 VPAS payment percentage. We do not believe a delay is necessary however as Statutory Scheme rates were set for multiple years in the 2018 and 2020 consultations despite uncertainty about future VPAS rates. Additionally, should the eventual 2023 VPAS payment percentage be different to the current projection such that broad commercial equivalence is not maintained, Government is committed to further consultation.

Impact of Scheme Movers on over- and under-payments

60. In 2019, there were 21 payment companies in the Statutory Scheme with modelled measured sales totalling £1,668m. Twelve of these payment companies moved into the VPAS for 2020.

61. Of the remaining nine Statutory Scheme payment companies in 2020 (who had 2020 modelled measured sales totalling £379m), two moved into the VPAS for 2021, and another was no longer a payment company in 2021. Conversely, a company that was previously excluded from making payments in the Statutory Scheme became a payment company in 2021, resulting in seven payment companies in the Statutory Scheme in 2021.

62. Without factoring in growth between years, the scheme movers have meant that modelled Statutory Scheme sales have fallen from £1,668m in 2019 to £399m in 2021 as of Q4 2021 data.

63. We know that additional companies have opted to leave the Statutory Scheme and join the VPAS for 2022, which will lower the Statutory Scheme sales further still. The actual sales data for 2022 has not been received yet however, as such these known scheme changes do not feed into the modelled 2022 sales or calculation of the proposed changes to the 2022 and 2023 payment percentages. However, we have taken the movers into account when calculating the impact of the proposed changes.

Table 5 – Actual and Updated data Statutory Scheme payment percentages

	2019	2020	2021	Average
Actual Statutory Scheme Payment Percentage	9.9%	7.4%	10.9%	9.4%
Updated Data Statutory Scheme Payment Percentage	6.2%	7.1%	14.2%	9.2%

64. Had we had updated data (as of Q4 2021) when setting the 2019, 2020 and 2021 Statutory Scheme payment percentages, we would have set them at 6.2%, 7.1% and 14.2% respectively: an average of 9.2%. The average of the actual payment percentages is 9.4%, demonstrating very little difference and showing that over the three-year period, had scheme membership remained broadly stable, a similar level of payments would have been made.

65. In the previous consultation, the 2020 and 2021 payment percentages were adjusted to ensure allowed growth was met on average from 2018 to 2023. This was achieved through the calculation of the modelled over-payment from the setting of the 2019 payment percentage in absolute terms (i.e. in £m), rather than in relative terms (i.e. in %).

66. Due to the notable scheme membership changes in 2020 and despite the average payment percentage based on updated data being similar to those actually set, a modelled over-payment is still being carried through from 2019. This has the effect of distorting and overly depressing the calculated 2022 and 2023 payment percentages in the Statutory Scheme, which is an effect not seen in the VPAS due to the substantially greater level of sales in the VPAS.

Changes to the calculation to ensure the Statutory Scheme meets its objectives

67. In order to ensure the Statutory Scheme meets its objectives we have made three key changes to the calculation approach used in the previous consultation:

- Modelled over- and under-payments
    - In keeping with the 2020 consultation, the Government believes it is appropriate to set payment percentages that control branded medicines growth on average over several years.
    - As previously outlined, the large amount of scheme movers from the Statutory Scheme to the VPAS in 2020 (and to a lesser extent in 2021), has meant that despite the average payment percentage between 2019 and 2021 being broadly equal to that set with Q4 2021 data, the absolute modelled over-payment in 2019 would overly depress the 2022 and 2023 payment percentages if it was still included in the calculation.
    - We have therefore not adjusted the calculation to account for over- or under-payments from previous years. This is because the substantial majority of statutory scheme payment companies from previous years have since left the scheme, and so any adjustments would have an impact on the remaining companies that would be disproportionate to their original over or underpayment
    - It should be stressed the over- and under-payments used in the model previously were based on ‘modelled’ payments, rather than actual. Indeed, due to the high levels of framework exemptions in 2019, whilst the modelled payment was £165m, the actual payment was £87m.

- Data used in setting 2022 and 2023 payment percentages

    - In the 2020 consultation we used data to September 2019 to set both the 2020 and 2021 payment percentages. However, for the preferred option this time we propose setting the 2022 payment percentage using data which runs to data to September 2021 (Q3 2021), and the 2023 payment percentage using data to December 2021 (Q4 2021).

    - This approach better aligns us with the calculation methodology and timings in the VPAS which has the benefit of helping to maintain broad commercial equivalence. The VPAS payment percentage set for 2022 was informed by data to September 2021 so it is appropriate that we do likewise for the Statutory Scheme. The 2023 VPAS payment percentage will be set using the latest data available at the time it is set (data to September 2022) so it is appropriate that the 2023 Statutory Scheme payment percentage also uses the latest data available (in this case up to December 2021).

- Manual amendment to the 2022 payment percentage

    - The 2022 VPAS payment percentage was set at 15%, which was the result of an agreement with ABPI[13]. The calculated 2022 VPAS payment percentage was 19.1%, but in the amendment document[14] it is stated that *"[e]xceptional growth in total Measured Sales of branded medicines in 2021, resulting in part from demand related to the coronavirus (COVID-19) pandemic, has led to a sharp increase in the calculated payment percentage for 2022. Whilst this is evidence of the scheme adjusting for high growth as intended, the parties recognise the impact of this on scheme members as well as the current high levels of uncertainty around underlying sales growth".* This is a 4.1%-point decrease on the calculated payment percentage for 2022 in the VPAS.

    - In order to maintain broad commercial equivalence, we believe it is appropriate to make the same adjustment to the 2022 Statutory Scheme payment percentage. Therefore, whilst it was calculated at 18.4%, it has been lowered by 4.1%-points to 14.3%.

    - The 2023 payment percentage calculation factors in this lower 2022 level to ensure that between 2022 and 2023 an average level of allowed growth is maintained. The 2023 payment percentage using data to December 2021 factors in the lower 2022 payment percentage level.

Timing of implementation

68. If it were possible to have implemented the revised 2022 payment percentage from 1st January 2022, it would be set at 14.3%. 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 2022 will not come into effect until the 1st July 2022. An effect of this delay will be that between 1st January 2022 to 30th June 2022 (where the 10.9% payment percentage applies in the Statutory Scheme) it is likely that lower payments are made than required to control allowed sales growth to 1.1%.

69. As such the revised payment percentage for the remainder of 2022 (1st July to 31st December) will take account of this effect. This will only apply to companies who made payments in either of the first two quarters of 2022, to ensure that any companies that join the Statutory Scheme after the first two quarters of 2022, and/or who start making payments

[13] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1048454/First-voluntary-scheme-amendment-January-2022.pdf
[14] Ibid

after the first two quarters of 2022 are not disproportionately disadvantaged due to lower payments paid by other scheme members earlier in the year.

70. The 2022 Statutory Scheme payment percentage currently in the Regulations (10.9%) would apply between 1st January 2022 to 30th June 2022. In practice, the Regulations will apply as follows:

- For companies that are Statutory Scheme members and make a payment in either of the first two quarters of 2022, they will pay a payment percentage of 10.9% on sales in Q1-Q2 2022, followed by 17.7% on sales in Q3-Q4 2022.

- For companies that join the Statutory Scheme after Q2 2022, and/or do not make a scheme payment in either Q1 or Q2 2022, they will pay a payment percentage of 14.3% on any sales made under the Statutory Scheme in Q3-Q4 2022.

Withdrawal of Supply

71. There is the risk that companies might choose 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.

72. We received consultation responses stating the preferred option may impact supply through the decision by companies to delay or pause launching new products or that there may be shortages with list price increases an ineffective mitigation. However, the consultation responses did not identify sufficient evidence of previous payment percentage increases impacting supply and evidence of future impact was speculative. Furthermore, the impact of recent increases in VPAS payment percentages are being monitored and presently this has not identified any supply impacts that could not be resolved through business as usual processes.

73. Our assessment continues to be that this risk is remote, due to the following mitigations: incentives for innovative products in the VPAS, the well-established processes for the Department to consider list price increases and the NHS to consider net price increases where they are warranted, and by business as usual processes to maintain continuity of supply of medicines.

74. These processes are monitored closely to 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.

75. We received consultation responses that argued that the allowed growth rates in both VPAS and the Statutory Scheme would lead to real terms growth decreasing as a result of the high inflation currently seen, and that this could exacerbate supply issues. The argument follows that the higher the payment percentage the greater the pressure on companies' ability to absorb the increasing cost inflation. This could lead to companies requesting price increases to mitigate the impact of inflation on their profit margins.

76. Where the price increases are granted, we would expect to see a higher cost to the NHS, albeit partly mitigated by the higher payment percentages. This increased medicine spend could lead to revisions of our forecasting and as such future VPAS and Statutory Scheme payment percentage increases. Where price increases are not granted, the cost of inflation would be felt by the company and its profits. They in turn could react by cutting costs and/or reducing production, which would have possible supply risks for the NHS. However, any supply risks would be considered in the initial price increase decision, mitigating risks to supply.

77. Whilst data to the end of 2022 is not yet available it is likely that by the end of the year, growth in allowed sales will have declined in real terms when taking into account unusually high expected inflation. However, total spending on medicines, when including sales that are

not subject to the scheme's affordability mechanisms, has to date grown above CPI, although we cannot reliably forecast real terms growth in 2022. It is also not possible to assess how much more likely the risks associated with high inflation are likely to materialise under the two different policy options presented in this IA. Finally, we consider the mitigations the Department has would be effective in managing any inflation-related supply issues.

78. By maintaining broad commercial equivalence, the Department considers that the effects of inflation will impact companies in both the VPAS and Statutory Scheme equally, and as such we do not expect to see significant scheme movement induced by rising inflation in the preferred policy option.

Companies raising serious concerns

79. Failure to take action on revisions to the payment percentages would mean a lack of broad commercial equivalence between the Statutory Scheme and the VPAS and could subsequently damage the reputation of the Government's relationship with the life sciences industry. This could 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 £88.9bn a year and 268,000 jobs across the country[15].

80. The objective of the proposed changes is to ensure the Statutory Scheme achieves its aims of effectively controlling NHS expenditure on branded medicines in 2022 and 2023 and maintains broad commercial equivalence with the VPAS. This helps mitigate a risk of companies raising serious concerns and so we do not consider specific scenarios associated with these considerations.

Preferred Option Scenarios – Summary

81. Like in the Business as Usual calculation, we have created two scenarios to capture the potential behavioural impacts of companies switching between schemes. Scenario A assumes growth as per the current adjusted forecast and is termed 'higher' growth; the VPAS payment percentage is the projected 23.7% in 2023. Scenario B assumes a lower level of growth; subsequently the dynamic VPAS payment percentage falls to a projected 19.7% in 2023. In the preferred option scenarios, we change the Statutory Scheme percentage to 14.3% in 2022 and 24.4% in 2023.

82. The assumption of Statutory Scheme sales moving into the VPAS in 2023 is informed by adopting a behavioural assumption that if the 2023 Statutory Scheme payment percentage is greater than the 2023 VPAS payment percentage, then companies would choose to move into the VPAS for 2023. This is an extreme assumption and is not suggesting that all companies will make the choice to move.

83. Under both the high growth and low growth scenarios we therefore assume that all companies will leave the Statutory Scheme in 2023. This is because the 2023 Statutory Scheme payment percentage, 24.4%, is higher than the projected 2023 VPAS payment percentage in both the high and low growth scenarios, 23.7% and 19.7%, respectively. This behavioural impact is entirely dependent upon future growth and as stated previously, 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 revision to these payment percentages.

[15] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020

Table 6– Preferred Option Scenario Summary

	Scenario A – Higher Growth	Scenario B – Lower Growth
Modelled Measured Sales Growth	2022 – 5.56% 2023 – 5.26%	2022 – 3.56% 2023 – 4.54%
2023 VPAS Payment %	23.7%	19.7%
2023 Statutory Scheme Payment %	24.4%	24.4%
Switch **Leave VPAS for Statutory Scheme**	0% in 2022, 0% of 2023 sales move	0% in 2022, 0% of 2023 sales move
Switch **Leave Statutory Scheme for VPAS**	0% in 2022, 100% in 2023	0% in 2022, 100% in 2023

Evaluation of Impacts

Sales by Statutory Scheme companies

84. Total modelled sales of branded health service medicines by qualifying companies, based on the data to Q4 2021, are £399m for the UK. This incorporates actual sales for January to December 2021 to get forecast values for 2022 through to 2023. All figures in this impact assessment, unless otherwise stated, are presented at the UK level.

85. Observed Statutory Scheme sales are expected to fall compared to modelled sales in 2022 as five companies which contributed to Measured Sales in 2021 have agreed to join the VPAS for 2022 – so the sales of these companies should result in an equivalent rise in VPAS sales. To help maintain confidentiality, an estimate of remaining 2022 Measured Sales has been presented in this IA to ensure individual company sales cannot be divined. Furthermore, all figures related to the impact of the policy have been rounded to the nearest £10m to add an additional layer of obfuscation.

Sales covered by extant Framework agreements

86. As mentioned previously, contrary to the 2020 consultation, we are not including extant framework agreements in the calculation of the impact of the proposed Statutory Scheme payment percentages due to confidentiality restrictions.

Effect of proposed payment percentages

87. Qualifying sales under each payment scenario under Business As Usual and the preferred option are presented below. In 2023, under the Business As Usual option, a net payment of between £1,400m to £1,430m would have been due to the Department. Under the preferred option, a net payment of between £2,380m to £2,940m would have been due to the Department.

88. The net effect of the policy therefore is an impact on savings between £980m and £1,510m to the Department by 2023, where the additional savings would be reinvested in the health service. The figures for all years under consideration are presented in table 11. The Net Present Value of this revenue stream is between £960m and £1,470m.

89. 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.

90. The calculations are all based on returns made by companies reporting their sales of health service medicines. Five companies who contribute to 2021 Statutory Scheme Measured Sales have opted to join the VPAS for 2022. This expected drop in 2022 Statutory Scheme measured sales (and subsequently payments) has been estimated with the figures rounded

to £10m to protect confidentiality. As such, please note that the totals may not sum due to rounding.

Table 7– Business as Usual (Scenario A – Higher growth)

High Growth - Expected Sales **Do Nothing - Business as usual**	**2022**	**2023**
Base Voluntary Scheme Measured Sales (£m)	12,640	13,350
Additional Voluntary Scheme Sales moving from SS (£m)	-	-
Base Statutory Scheme (SS) Measured Sales (£m)	60	70
Additional SS sales moving from Voluntary Scheme (£m)	-	12,800
Adjusted Voluntary Scheme Measured Sales (£m)	12,640	550
Adjusted Statutory Scheme Measured Sales (£m)	60	12,870

High Growth - Expected Payments **Do Nothing - Business as usual**	**2022**	**2023**	***NPV***
Voluntary Scheme Payment percentage	15.0%	23.7%	
Voluntary Scheme exclusion from payment percentage	7.2%	78.4%	
Voluntary Scheme Payment (£m)	1,760	30	1,760
Statutory Scheme Payment percentage	10.9%	10.9%	
Statutory Scheme Payment (£m)	10	1,400	1,370
Total Payment (£m)	1,770	1,430	3,132

Table 8– Business as Usual (Scenario B – Lower growth)

Low Growth - Expected Sales **Do Nothing - Business as usual**	**2022**	**2023**
Base Voluntary Scheme Measured Sales (£m)	12,390	12,990
Additional Voluntary Scheme Sales moving from SS (£m)	-	-
Base Statutory Scheme (SS) Measured Sales (£m)	60	70
Additional SS sales moving from Voluntary Scheme(£m)	-	12,200
Adjusted Voluntary Scheme Measured Sales (£m)	12,390	790
Adjusted Statutory Scheme Measured Sales (£m)	60	12,260

Low Growth - Expected Payments **Do Nothing - Business as usual**	**2022**	**2023**	***NPV***
Voluntary Scheme Payment percentage	15.0%	19.7%	
Voluntary Scheme exclusion from payment percentage	7.2%	62.3%	
Voluntary Scheme Payment (£m)	1,720	60	1,760
Statutory Scheme Payment percentage	10.9%	10.9%	
Statutory Scheme Payment (£m)	10	1,340	1,300
Total Payment (£m)	1,730	1,400	3,063

Table 9– Preferred Option (Scenario A – Higher growth)

High Growth - Expected Sales **Preferred Option - New Payment percentage (Mid year)**	**2022**	**2023**
Base Voluntary Scheme Measured Sales (£m)	12,640	13,350
Additional Voluntary Scheme Sales moving from SS (£m)	-	70
Base Statutory Scheme (SS) Measured Sales (£m)	60	70
Additional SS sales moving from Voluntary Scheme (£m)	-	-
Adjusted Voluntary Scheme Measured Sales (£m)	12,640	13,420
Adjusted Statutory Scheme Measured Sales (£m)	60	-

High Growth - Expected Payments **Preferred Option - New Payment percentage (Mid year)**	**2022**	**2023**	***NPV***
Voluntary Scheme Payment percentage	15.0%	23.7%	
Voluntary Scheme exclusion from payment	7.2%	7.5%	
Voluntary Scheme Payment (£m)	1,760	2,940	4,590
Statutory Scheme Payment Percentage Legacy	10.9%	10.9%	
Statutory Scheme Payment Percentage Mid-year	17.7%	24.4%	
Statutory Scheme Measured Sales at Legacy (£m)	30		
Statutory Scheme Measured Sales at Mid-year (£m)	30		
Statutory Scheme Payment (£m)	10	-	10
Total Payment (£m)	1,770	2,940	4,600

Table 10– Preferred Option (Scenario B – Low growth)

Low Growth - Expected Sales **Preferred Option - New Payment percentage**	**2022**	**2023**
Base Voluntary Scheme Measured Sales (£m)	12,390	12,990
Additional Voluntary Scheme Sales moving from SS (£m)	-	70
Base Statutory Scheme (SS) Measured Sales (£m)	60	70
Additional SS sales moving from Voluntary Scheme (£m)	-	-
Adjusted Voluntary Scheme Measured Sales (£m)	12,390	13,060
Adjusted Statutory Scheme Measured Sales (£m)	60	-

Low Growth - Expected Payments **Preferred Option - New Payment percentage**	**2022**	**2023**	***NPV***
Voluntary Scheme Payment percentage	15.0%	19.7%	
Voluntary Scheme exclusion from payment	7.2%	7.5%	
Voluntary Scheme Payment (£m)	1,720	2,380	4,010
Statutory Scheme Payment Percentage Legacy	10.9%	10.9%	
Statutory Scheme Payment Percentage Mid-year	17.7%	24.4%	
Statutory Scheme Measured Sales at Legacy (£m)	30		
Statutory Scheme Measured Sales at Mid-year (£m)	30		
Statutory Scheme Payment (£m)	10	-	10
Total Payment (£m)	1,730	2,380	4,020

Table 11– Difference in payments

Difference in payments **(Preferred option less Business as usual)**	**2022**	**2023**
High Growth (£m)	<5	1,510
Low Growth (£m)	<5	980

Impact on NHS

91. The application of a higher payment percentage in 2022 and 2023 is expected to impact the net cost of branded health service medicines sales to the NHS. Future growth and the size of any behavioural impacts will influence the net effect of increasing the 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. This is in the context of a fixed-funding NHS envelope, so any increase in costs within this area will have an impact on other budgets within the NHS. Conversely a decreased net cost (so a net gain) would result in increased funding for additional NHS treatments and services.

92. 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

93. 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 changes to R&D investment

94. The impact on 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.

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

96. We have received consultation responses that argued that high payment percentages in general will affect boardroom sentiment about UK domestic medicine pricing, and as a result companies may decide to move current or future R&D investment away from the UK to other countries. Respondents argued that this would effectively reduce the UK's share of pharmaceutical R&D spend over and above the proportion of any global reduction in R&D expenditure we would expect to see felt in the UK, although respondents acknowledged that drivers of R&D decisions are likely to be multifactorial.

97. As highlighted in the consultation stage impact assessment, the available evidence and reasoning suggests 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[16], and that siting of R&D facilities should not be affected by demand or procurement for final products in the local market. A 2008 report by the OECD[17] found little reason to believe that providing favourable market conditions - e.g., higher prices – will be a significant determinant of companies' decisions where to establish headquarters and undertake R&D in particular. For example, 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. Furthermore, 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[18].

98. We have reviewed the evidence submitted by respondents and maintain the Department's view that, due to the global nature of the pharmaceutical industry, consideration of price controls for final products is likely to be secondary to supply side factors in driving investment decisions, however we acknowledge that there is uncertainty surrounding this relationship. We are keen to continue discussions with industry about the available evidence but were unable to identify from the literature a quantifiable impact of the claimed reduction in UK based R&D.

99. Therefore, though an impact of the preferred option could be decreased global R&D, of which a proportion of the reduction would be to UK-based R&D, we have not included costs from decreased investment in the siting of R&D facilities in the UK relative to other countries but will continue to .

NHS and patient health gains

100. 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[19]. The impacted savings of between £980m to £1,510m therefore

[16] 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.

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

[18] Pfizer & PwC, Driving Global Competitiveness of the UK's Life Sciences Ecosystem For the benefit of UK patients, the economy and the NHS, 2017

[19] 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/

correspond to a change of between 65,570 and 100,730 QALYs for patients in the NHS by 2023

101. These health gains are monetised using their estimated societal value[20] which is valued at £70,000 a QALY in 2020/21 prices but was previously £60,000 in 2014 prices. This is because following the publication of the consultation IA[21] in March 2022, the Green Book (guidance issued by HM Treasury on how to appraise policies) updated this valuation. The monetisation of the policy impact has also been updated to account for this guidance change, with the societal value of a QALY at £70,000. Accordingly, the estimated health gains give an annual impact valued at between £4,470m to £6,850m by 2023.

102. To help ensure transparency, the impacts calculated using the societal value of a QALY at £60,000 (as per the draft consultation IA) is included in Annex F.

103. In total, the benefits from these savings have a positive NPV value of between £4,360m to £6,690m over the period in consideration.

Table 12– Monetising benefits from improved patient health and wider economic consequences

Scenario High Growth	**2022**	**2023**	***NPV***
Benefits			
Savings for option 1 against do nothing (£m)	<5	1,510	1,470
QALYs generated elsewhere in the NHS @£15,000/QALY	150	100,730	
Social Value of QALYs @£70,000/QALY (£m)	10	7,050	6,850
Total benefits (£m)	10	7,050	6,850

Scenario Low Growth	**2022**	**2023**	***NPV***
Benefits			
Savings for option 1 against do nothing (£m)	<5	980	960
QALYs generated elsewhere in the NHS @£15,000/QALY	140	65,570	
Social Value of QALYs @£70,000/QALY (£m)	10	4,590	4,470
Total benefits (£m)	10	4,590	4,470

Loss of profits for UK shareholders in pharmaceutical companies

104. 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.

105. 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.

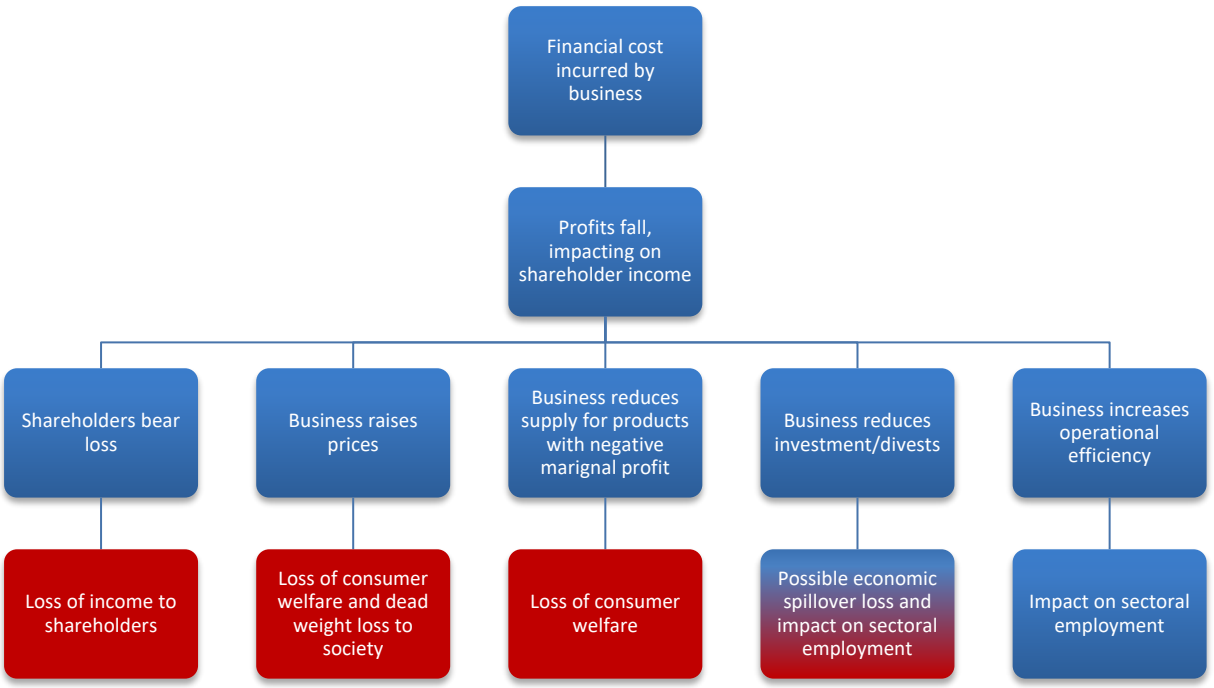
106. The figure below sets out in more detail the flow of impacts stemming from a reduction in sales revenue due to the payment mechanism – only those impacts shaded in red in the figure below are counted towards the net societal impact of a policy, while impacts in blue can be offset from an aggregate perspective. As an example, loss in sectoral employment

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

[21] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1060817/20220304_Statutory_scheme_impact_assessment_v2.0_15MARCH__1_.pdf

would not be considered a net societal loss, as the labour employed would be utilised in other sectors following a policy change.

Figure 3 – Overview of net societal impact of increased financial costs to business



107. The impact in shareholder income is equivalent to the changed revenue at approximately **£980m-£1,510m by 2023**. Following the previous impact assessment we continue to use an estimate provided by the Department for Business Energy and Industrial Strategy (BEIS), 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 approximately **£100m-£150m by 2023.**

108. The NPV of distribution adjusted profits to UK shareholders are estimated to be approximately **£90m-£140m** over the period under consideration.

Impact on UK R&D spill-overs

109. The impact in net revenue may also result in altered investment in R&D[22] – of which a portion may be in the UK, providing "spill-over" impacts on the UK economy.

110. 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

[22] 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.

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.

111. In the previous impact assessment we used an estimate that the proportion of pharmaceutical company revenues devoted to R&D was 36%[23]. There are other sources that estimate the share of revenue devoted to R&D is closer to 25%[24], and OLS analysis suggesting it may be nearer 15%[25]. It is likely that the proportion fluctuates over time and across different companies or parts of the sector, so we have decided it is prudent to apply caution and to assume the higher level of R&D activity, 36%, which attributes higher costs to this policy.

112. As set out above, roughly 10% of this R&D spend would be expected to be invested in the UK, according to the UK's proportion of the global pharmaceutical industry. This loss of R&D investment has been estimated to be worth £40m-£50m by 2023[26]. To put this in context, this compares to total pharmaceutical R&D investment in the UK in 2019 of £4.8 billion[27].

113. 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. As stated in previous impact assessment, BEIS estimates the value of these additional benefits to be 30% of the value of the investment[28].

114. Applying the estimates above to the projected change in pharmaceutical revenues gives an impact close to **£10m-£20m by 2023** to the UK economy from altered R&D investment.

Table 13 – Costs to industry from lost profits and R&D spill-overs foregone

Scenario High Growth			
Costs	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<5	1,510	1,410
UK lost profits to shareholders (£m)	<1	150	140
Invested in UK R&D (£m)	<1	50	
Lost UK benefits through reduced R&D investment (£m)	<1	20	20
Total costs (£m)	<1	170	160

Scenario Low Growth			
Costs	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<5	980	920
UK lost profits to shareholders (£m)	<1	100	90
Invested in UK R&D (£m)	<1	40	
Lost UK benefits through reduced R&D investment (£m)	<1	10	10
Total costs (£m)	<1	110	100

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

[24] Research and Development in the Pharmaceutical Industry | Congressional Budget Office (cbo.gov)

[25] OLS analysis of Business Population Estimates data and Business enterprise research and development data, provided in correspondence

[26] This figure has been included for context and does not directly contribute to the final NPV figure.

[27] Life Sciences Competitiveness Indicators 2021 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1007243/Life_Science_Competitiveness_Indicators_2021_report_final.pdf

[28] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/859212/statutory-scheme-to-control-costs-of-branded-medicines-impact-assessment.pdf

Net monetised impacts

Table 14 – Net benefits

Scenario High Growth	2022	2023	NPV
Net benefits (£m)	10	6,880	6,690

Scenario Low Growth	2022	2023	NPV
Net benefits (£m)	10	4,480	4,360

115. The total benefits of the proposed option, compared to the Business As Usual option, valued in a range at between **£4,470m and £6,850m**, over the period under consideration, while the total costs are estimated at approximately **£100-£160m**, giving a net benefit in a range of between **£4,360m and £6,690m**. See the summary of results below.

Summary of results

Table 15– Scenario A results

Scenario A

Scenario High Growth **Benefits**	2022	2023	*NPV*
Savings for option 1 against do nothing (£m)	<5	1,510	1,470
QALYs generated elsewhere in the NHS @£15,000/QALY	*150*	*100,730*	
Social Value of QALYs @£70,000/QALY (£m)	10	7,050	6,850
Total benefits (£m)	10	7,050	6,850

Scenario High Growth **Costs**	2022	2023	NPV
Lost profits to pharmaceutical company shareholders (£m)	<5	1,510	1,410
UK lost profits to shareholders (£m)	<1	150	140
Invested in UK R&D (£m)	<1	50	
Lost UK benefits through reduced R&D investment (£m)	<1	20	20
Total costs (£m)	<1	170	160

Net benefits (£m)	10	6,880	6,690

Table 16– Scenario B results

Scenario B

Scenario Low Growth	**2022**	**2023**	***NPV***
Benefits			
Savings for option 1 against do nothing (£m)	<5	980	960
QALYs generated elsewhere in the NHS @£15,000/QALY	*140*	*65,570*	
Social Value of QALYs @£70,000/QALY (£m)	10	4,590	4,470
Total benefits (£m)	10	4,590	4,470

Scenario Low Growth			
Costs	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<5	980	920
UK lost profits to shareholders (£m)	<1	100	90
Invested in UK R&D (£m)	<1	40	-
Lost UK benefits through reduced R&D investment (£m)	<1	10	10
Total costs (£m)	<1	110	100
Net benefits (£m)	10	4,480	4,360

Unmonetized impacts

Companies raising serious concerns

116. As described in earlier sections, maintaining broad commercial equivalence between the Statutory Scheme and VPAS helps to mitigate a risk of companies raising serious concerns about the effective operation of the schemes. These impacts are not monetised.

Impact on medicine supply

117. 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 and the NHS have established processes to seek to mitigate such risks. Therefore, these impacts have not been monetised.

Further scenario analysis

Behaviour effects: List price increases or selling price increases

Effective price increases

118. Under the preferred option, companies may find that with higher payment percentages 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. Alternatively, companies may increase the selling price by reducing discounts on their sales. The former approach requires an application to the Department, while the latter does not require an application, though may require negotiation of contractual arrangements.

119. Previous impact assessments concerning changes to the Statutory Scheme have included estimated impacts of price increases. However, in previous consultations we received responses flagging that our assumptions regarding the extent and likelihood of list

price increases being both made and accepted could be improved. Therefore, we have included these impacts as a further scenario, and not as part of the headline Net Present Value figures.

120. This further scenario is an extreme behavioural response where there are atypical high levels of selling price increases and/or list price increase applications (with all price increases granted) to counter the payment percentage increases. This does not indicate Departmental expectation on, for example, any expected success in price increase applications but rather is presented as an extreme behavioural scenario.

121. The extent and degree to which companies may seek list/selling price increases cannot be known and such price increases may or may not be granted by the Department – each request is considered on its own merits. However, it may be that any list/selling price increase can be expected to cover the difference between what they are paying at a 10.9% payment percentage, and what they would be paying if we were controlling growth of allowed sales to 1.1%.

122. For the purposes of this further scenario analysis, we assume that under the preferred option, the Department would hypothetically grant list price increases and/or companies would increase their selling prices to the level at which the net effect in 2022 of the 14.3% payment percentage is equal to the previous 10.9% payment percentage: a hypothetical price increase of 4.0%.

123. With respect to one hypothetical medicine that is granted a list price increase, or increases the selling price, by 4.0%, as shown below, this is a price increase such that the value of net sales (at higher prices) facing a payment percentage of 14.3% remains unchanged when compared to 10.9% - the 2021 Statutory Scheme payment percentage.

Table 17– 2022 Statutory Scheme List/Selling Price Increase Example

Price	Payment Percentage	Sales Revenue after paying payment percentage
100	10.9%	89.1 [=100*(1-10.9%)]
104.0	14.3%	89.1 [=104*(1-14.3%)]

124. With a larger difference between the previous 2023 payment percentage of 10.9% and the proposed percentage of 24.4%, we calculate that companies may seek a price increase of up to 13.3%, in addition to the 4.0% from 2022, in order to leave sales revenue unaffected by the payment percentage change.

Table 18– 2023 Statutory Scheme List/Selling Price Increase Example

Price	Payment Percentage	Sales Revenue after paying payment percentage
104	14.3%	89.1 [=104*(1-14.3%)]
117.9	24.4%	89.1 [=117.9*(1-24.4%)]

125. As such, with respect to this one hypothetical medicine that was granted a price increase, the preferred option 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.

126. We make a further adjustment for companies in the VPAS. For this particular scenario analysis, we assume that the levels of price increases/list price increase applications remains typical in 2022 as the negotiated 2022 payment percentage is lower than would have been set through pure calculation approach. However, for 2023 we assume that the VPAS companies increase their selling process/apply for price increases to nullify the impact of the rise in VPAS percentage from 15.0% in 2022 to 23.7% under the higher growth scenario and 19.7% in the lower growth scenario in 2023. We calculate this an increase of

selling/list price of 11.4% on all non-exempt VPAS sale under the higher growth scenario and 5.9% under the lower growth scenario.

Table 19– 2023 VPAS Higher Growth List/Selling Price Increase Example

Price	Payment Percentage	Sales Revenue after paying payment percentage
100	15.0%	85 [=100*(1-15.0%)]
111.4	23.7%	85 [=111.4*(1-23.7%)]

Table 20– 2023 VPAS Lower Growth List/Selling Price Increase Example

Price	Payment Percentage	Sales Revenue after paying payment percentage
100	15.0%	85 [=100*(1-15.0%)]
105.9	19.7%	85 [=105.9*(1-19.7%)]

127. 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 elements of medicine spend not covered by the Statutory (or Voluntary) Scheme such as 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 VPAS, and so would result in additional cost pressures.

128. The methodology used in the main section did not include price increases, giving an estimate that the net benefit was between £3,720m and £5,710m.

129. Including price increases, for both the higher and lower growth scenarios the total benefits are valued at between £1,610m and £1,670m, resulting in the net benefit estimate (after total costs netted off) changing to £1,560m and £1,620m.

Table 21 – Summary of further scenario analysis

High Growth **Benefits**	**2022**	**2023**	***NPV***
Savings for option 1 against do nothing (£m)	<1	430	420
QALYs generated elsewhere in the NHS @£15,000/QALY	*<5*	*28,600*	
Social Value of QALYs @£70,000/QALY (£m)	<1	2,000	1,940
Total benefits (£m)	<1	2,000	1,940

Lower Growth **Benefits**	**2022**	**2023**	***NPV***
Savings for option 1 against do nothing (£m)	<1	410	400
QALYs generated elsewhere in the NHS @£15,000/QALY	*<5*	*27,600*	
Social Value of QALYs @£70,000/QALY (£m)	<1	1,930	1,880
Total benefits (£m)	<1	1,930	1,880

High Growth			
Costs	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<1	430	400
UK lost profits to shareholders (£m)	<1	40	40
Invested in UK R&D (£m)	<1	20	
Lost UK benefits through reduced R&D investment (£m)	<1	<5	<5
Total costs (£m)	<1	50	40
Net benefits (£m)	<1	1,950	1,900

Lower Growth			
Costs	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<1	410	390
UK lost profits to shareholders (£m)	<1	40	40
Invested in UK R&D (£m)	<1	10	
Lost UK benefits through reduced R&D investment (£m)	<1	<5	<5
Total costs (£m)	<1	50	40
Net benefits (£m)	<1	1,890	1,830

Statutory requirements for consultation

130. Under the terms of 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.

131. 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.

132. 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 10.9% payment percentage between 2022 - 2023).

Economic consequences for the Life Sciences Industry in the United Kingdom

133. As explained earlier in the document, the preferred option is expected to impact the gross revenues of pharmaceutical companies by between -£920m and -£1,410m.

134. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated by BEIS[29] 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 approximately -£90m to -£140m relative to the counterfactual.

[29] Estimate provided in correspondence

The change in revenue is estimated to translate to a decrease in UK R&D of up to £20m by 2021.

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

Impact on Small Businesses

136. 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

137. The Government’s assessment continues to be that this proposal will have no detrimental impact on those who share protected characteristics as defined by the Equality Act 2010, in particular those with disabilities. 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. In the same way, these proposals will help reduce inequality between the benefits all people can obtain from the NHS. Further detail on this is provided in the consultation document.

Annex A – Reference Table

Table 22 – Reference table of growth rates and payment percentages

		2019	2020	2021	2022	2023
Growth Rates	**Original Forecast**	5.72%	6.84%	8.57%	9.21%	8.76%
	Previous Outturn Measured Sales Growth (based on Q1-Q3 2019 to Q1-Q3 2019)	1.11%				
	Previous Measured Sales Growth Forecast	N/A	4.05%	5.08%	5.45%	5.16%
	Outturn Measured Sales Growth	1.69%	2.08%	9.48%	N/A	N/A
	Revised Measured Sales Growth Forecast	N/A	N/A	N/A	5.56%	5.26%
	Growth Rate of Allowed Sales – Statutory Scheme	1.10%	1.10%	1.10%	1.10%	1.10%
Payment %s	**Statutory Scheme Payment Percentages – Current (applied to all non-exempt sales)**	9.9%	7.4% (Profiled as 14.7% for Q1 and 5% for Q2-Q4)	10.9%	10.9%	10.9%
	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%	7.8%	7.8%
	Statutory Scheme Payment Percentages – Proposed (applied to all non-exempt sales)	N/A	N/A	N/A	14.3% (Profiled as 10.9% for Q1-Q2 and 17.7% for Q3-Q4)	24.4%
	Voluntary Scheme Payment Percentages	9.6%	5.9%	5.1%	15.0%	Projected 23.7%

Annex B – 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 also known as frameworks.

2. 2022 and 2023 payment percentages have been calculated that would deliver an allowed level of branded health service medicines sales as follows: The 2022 payment percentage has been calculated using data to Q3 2021, and the 2023 payment percentage has been calculated using data to Q4 2021.

2022 Payment Percentage

3. Initially the Total Measured Sales is calculated using Q3 2021 data:

$$Total\ Measured\ Sales_{tA} = VS\ Measured\ Sales_{tA} + SS\ Measured\ Sales_{tA} + Parallel\ Import\ Sales_{tA}$$

4. Where *VS* refers to the VPAS, *SS* refers to the Statutory Scheme, $_t$ refers to the calendar year, e.g., 2022 and $_A$ refers to Q3 2021 data. Next, the Total Allowed Sales is calculated:

$$Total\ Allowed\ Sales_{tA} = (Total\ Measured\ Sales_{2018A} - Payments_{2018A}) \times (1 + 1.1\%)^n$$

5. Where *Payments* 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:

$$Total\ Payment_{tA} = Total\ Measured\ Sales_{tA} - Total\ Allowed\ Sales_{tA}$$

6. As explained in preferred option description, the modelled over- and under-payments between 2019 to 2021 have not been accounted for in the 2022 and 2023 payment percentage calculation. Two payment percentages will be calculated for 2022, and one for 2023. This is due to the delay in being able to implement the 2022 payment percentage until the 1st July 2022, prior to which Statutory Scheme members will pay the 2022 payment percentage of 10.9% already in the Regulation. As such, for scheme members who made scheme payments in either of the first two quarters of 2022, the anticipated under delivery of payment between 1st January 2022 and 30th June 2022 is factored into the payment percentage for the remainder of 2022. Scheme members that join the Statutory Scheme after the first two quarters of 2022 and/or who did not make scheme payments in either of the first two quarters of 2022 will not have this under delivery factored in the payment percentage.

7. The payment percentages for 2022 are now calculated. First the required Statutory Scheme payment for 2022 is calculated:

$$SS\ Payment_{2022A} = \left(\frac{SS\ Measured\ Sales_{2022A}}{Total\ Measured\ Sales_{2022A}} \times Total\ Payment_{2022A}\right)$$

8. The 2022 payment percentage for scheme members that join the Statutory Scheme after the first two quarters of 2022 and/or did not make payments in either of the first two quarters of 2022 is calculated below:

$$Payment\ Percentage_{2022i} = \left(\frac{SS\ Payment_{2022A}}{SS\ Measured\ Sales_{2022A}}\right) - 4.1\%points$$

9. This payment percentage is referred to as *Payment percentage$_{2022i}$*. As outlined earlier in the preferred option description, the 2022 payment percentage has been adjusted to maintain commercial equivalence with the Voluntary Scheme. This is achieved by adjusting the

calculated payment percentage in line with the Voluntary Scheme 4.1%-point reduction. See earlier in the impact assessment for further details of this adjustment.

10. Following this, the 2022 payment percentage Q3 and Q4 2022 for scheme members that made payments in either of the first two quarters of 2022 at 10.9% is calculated. First the anticipated remaining required payment from 1st July 2022 after the payment of 10.9% from 1st January has been factored in is calculated:

$$SS\ Balance\ Payment_{2022A} = (Payment\ Percentage_{2022i} \times SS\ Measured\ Sales_{2022A}) - (SS\ Measured\ Sales_{2022A} \times Q1Q2shareA \times 10.9\%)$$

11. Where 10.9% refers to the current 2022 payment percentage already in Regulations, and Q1Q2share is the estimated share of annual Statutory Scheme sales which will occur between 1st January 2022 and 30th June 2022 as of Q3 2021 data, which stands at 49.9%. The payment percentage to be applied from 1st July 2022 can be seen below.

$$Payment\ Percentage_{2022ii} = \frac{SS\ Balance\ Payment_{2022A}}{SS\ Measured\ Sales_{2022A} \times (1 - Q1Q2shareA)}$$

12. This Q3 and Q4 2022 payment percentage is referred to as *Payment percentage$_{2022ii}$*.

2023 Payment Percentage

13. The 2023 payment percentage is calculated using data to Q4 2021. Many of the elements required in the calculation of the 2023 payment percentage are calculated using the same methodology as outlined above in the 2022 payment percentage, however Q4 2021 data is used rather than Q3 2021.

14. As 4.1%-points were removed from the 2022 payment percentage, this effective under-delivery is considered in the 2023 payment percentage and is calculated as below:

$$SS\ 2022\ under\ deliveryB = SS\ Payment_{2022B} - \big((SS\ Measured\ Sales_{2022B} \times Q1Q2shareB \times 10.9\%) + (SS\ Measured\ Sales_{2022B} \times (1 - Q1Q2shareB) \times Payment\ Percentage_{2022ii})\big)$$

15. Where B refers to Q4 2021 data.

16. The Statutory Scheme payment for 2023 is then calculated as:

$$SS\ Payment_{2023B} = \left(\frac{SS\ Measured\ Sales_{2023B}}{Total\ Measured\ Sales_{2023B}} \times Total\ Payment_{2023B}\right) + SS\ 2022\ under\ deliveryB$$

17. The 2023 payment percentage is then calculated as:

$$Payment\ Percentage_{2023} = \frac{SS\ Payment_{2023B}}{SS\ Measured\ Sales_{2023B}}$$

Table 23 – Breakdown of 2022 Payment Percentage Calculation (using Q3 2021 data)

Element, UK	2022
2019 Voluntary Scheme Measured Sales Growth - Forecast	6.10%
Statutory Scheme Measured Sales Growth - Forecast	6.00%
Parallel Imports Growth- Forecast	0.97%
2019 Voluntary Scheme - Measured Sales (£m)	12,416
Statutory Scheme - Measured Sales (£m)	424
Parallel Imports - Measured Sales (£m)	775
Statutory Scheme as a % of Overall Measured Sales	3.1%
Overall Measured Sales (£m)	13,615
Overall Growth	5.79%
Allowed Sales (£m)	11,110
Allowed Growth	1.1%
Expected Total Payment (£m)	2,505
Expected Statutory Scheme Payment (£m)	78
Legacy Payment %	10.90%
Unadjusted Annual 2022 Payment %	18.40%
Manual Adjustment to Annual 2022 Payment %	-4.10%
Adjusted Annual 2022 Payment %	14.30%
Payment from Adjusted Annual 2022 Payment % (£m)	61
Statutory Scheme - Measures Sales subject to legacy % (£m)	210
Statutory Scheme - Measures Sales subject to revised % (£m)	213
Part year payment at legacy % (£m)	23
Remaining payment required (£m)	38
Part Year (from July) 2022 Payment %	17.70%
Final Annual Payment %	**14.30%**
Final Part Year (from July) 2022 Payment %	**17.70%**

Table 24 – Breakdown of 2023 Payment Percentage Calculation (using Q4 2021 data)

Element, UK	2022	2023
2019 Voluntary Scheme Measured Sales Growth - Forecast	5.88%	5.63%
Statutory Scheme Measured Sales Growth - Forecast	5.78%	5.47%
Parallel Imports Growth- Forecast	0.93%	-0.42%
2019 Voluntary Scheme - Measured Sales (£m)	12,283	12,974
Statutory Scheme - Measured Sales (£m)	422	445
Parallel Imports - Measured Sales (£m)	812	809
Statutory Scheme as a % of Overall Measured Sales	3.1%	3.1%
Overall Measured Sales (£m)	13,517	14,228
Overall Growth	5.56	5.26
Allowed Sales (£m)	11,106	11,228
Allowed Growth	1.1%	1.1%
Expected Total Payment (£m)	2,412	3,000
Expected Statutory Scheme Payment (£m)	75	94
Legacy Payment %	10.90%	10.90%
Revised Annual 2022 Payment %	14.30%	
Revised Part Year (from July) 2022 Payment %	17.70%	
Statutory Scheme - Measures Sales subject to legacy % (£m)	209	
Statutory Scheme - Measures Sales subject to revised % (£m)	213	
Part year payment at legacy % (£m)	23	
Part year payment at revised % (£m)	38	
2022 under-delivery (£m)	15	
Adjusted expected 2023 Payment (£m)		109
Final Annual Payment %	**14.30%**	**24.40%**
Final Part Year (from July) 2022 Payment %	**17.70%**	

Annex C – 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 previous impact assessments[30].

3. To maintain broad commercial equivalence with the VPAS, the forecast has been revised using the latest outturn data (up to Q4 2021) in the identical approach used in the VPAS[31]. At a high level, this mechanism compares cumulative outturn growth against cumulative forecast growth and adjusts future forecast growth by this ratio.

4. The table below shows the forecast of the previous consultation and impact assessment 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 25 – Previous and revised forecasts of branded sales

	2019	2020	2021	2022	2023
Previous Forecast	1.11%**	4.05%	5.08%	5.45%	5.16%
Revised Forecast	1.69%*	2.08%*	9.48%*	5.56%	5.26%

**Observed growth, **Year-to-date growth*

[30] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761064/impact-assessment-2018-statutory-scheme-branded-medicines-pricing.pdf

[31] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1046017/voluntary-scheme-for-branded-medicines-pricing-and-access-annexes.pdf

Annex D – Frameworks

1. 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.

2. Table 26 highlights the rationale for excluding framework sales from the income calculation. In 2019 there were £1,032m in exempted framework sales, which fell to £345m in 2020 and £202m in 2021. This decrease will continue through to 2022 as a result of further framework expiries and of additional companies leaving the Statutory Scheme for the VPAS.

Table 26 – Statutory Scheme Sales, Framework Sales and Payments

	2019	2020	2021
Net Sales	£1,668m	£379m	£399m
Aggregate net sales covered by the applicable annual Statutory Scheme payment	£635m	£34m	£197m
Resulting aggregate Statutory Scheme payment	£63m	£2m	£22m
Net sales of extant frameworks and public contracts subject to 7.8% payment	**£311m**	**£17m**	**£17m**
Resulting Statutory Scheme 7.8% payment	£24m	£1m	£1m
Net sales of extant frameworks and public contracts subject to 0% payment	**£722m**	**£328m**	**£185m**
Total resulting Statutory Scheme payment	£87m	£4m	£23m

Annex E - 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:
    a. The cost per QALY provided "at the margin" in the NHS;
    b. 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[32]. 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 (£70,000)

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 **£70,000**, based on analysis by the Department for Transport of individuals' willingness to pay to avoid mortality risks[33].

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 £70,000, 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:

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

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

- The costs of the project are the QALYs that would be gained if the funds were used elsewhere in the NHS, but which are foregone if the project is undertaken. Using the standard DH estimate that one QALY is gained elsewhere for every £15,000 of funding, this gives an 'opportunity' cost of **1,000 QALYs lost**. Monetising these costs at the DH estimate of the social value of a QALY gives a monetary equivalent of **£70m**.
- The benefits 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 **£84m**.
- The net benefit of the project is therefore **200 QALYs**, or, expressed in monetary terms **£14m.**

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 £70,000 / QALY).

Annex F - Transparency estimates: Impacts using the previous societal valuation of a QALY at £60,000.

1. Following the publication of the consultation IA in March 2022, the Green Book (guidance issued by HM Treasury on how to appraise policies) updated the societal value a QALY from £60,000 at 2014 prices to £70,000 in 2020/21 prices . Following this the monetisation of the impact has also been updated to account for this guidance change, with the societal value of a QALY at £70,000.

2. The estimates of the impacts with the societal value of a QALY at £60,000 are included below for transparency. The higher and lower growth scenarios are identical to the main calculations save for the societal value of a QALY. Tables 27 and 28 are replicated versions of tables 15 and 16, the only difference being the use of the £60,000 QALY value, rather than the £70,000 used in the main document.

Table 27 – Higher growth transparency estimates

Transparency estimates: Scenario High Growth	**2022**	**2023**	***NPV***
Benefits			
Savings for option 1 against do nothing (£m)	<5	1,510	1,470
QALYs generated elsewhere in the NHS @£15,000/QALY	*150*	*100,730*	
Social Value of QALYs @£60,000/QALY (£m)	10	6,040	5,870
Total benefits (£m)	10	6,040	5,870

Transparency estimates: Scenario High Growth			
Costs	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<5	1,510	1,410
UK lost profits to shareholders (£m)	<1	150	140
Invested in UK R&D (£m)	<1	50	
Lost UK benefits through reduced R&D investment (£m)	<1	20	20
Total costs (£m)	<1	170	160
Net benefits (£m)	10	5,880	5,710

Table 28 – Lower growth transparency estimates

Transparency estimates: Scenario Low Growth **Benefits**	**2022**	**2023**	***NPV***
Savings for option 1 against do nothing (£m)	<5	980	960
QALYs generated elsewhere in the NHS @£15,000/QALY	*140*	*65,570*	
Social Value of QALYs @£60,000/QALY (£m)	10	3,930	3,830
Total benefits (£m)	10	3,930	3,830

Transparency estimates: Scenario Low Growth **Costs**	**2022**	**2023**	**NPV**
Lost profits to pharmaceutical company shareholders (£m)	<5	980	920
UK lost profits to shareholders (£m)	<1	100	90
Invested in UK R&D (£m)	<1	40	-
Lost UK benefits through reduced R&D investment (£m)	<1	10	10
Total costs (£m)	<1	110	100
Net benefits (£m)	10	3,830	3,720