| **Title:** Autumn 2022 update to the Statutory Scheme controlling the costs of branded health service medicines<br>**IA No: XXXX**<br>**RPC Reference No:**<br>**Lead department or agency:**<br>Department of Health and Social Care<br>**Other departments or agencies: N/A** | **Impact Assessment (IA)**<br>**Date: 29th November 2022**<br>**Stage:** Consultation<br>**Source of intervention:** Domestic<br>**Type of measure:** Secondary Legislation<br>**Contact for enquiries:**<br>dh.brandedmedicines@dhsc.gov.uk |
|---|---|
| **Summary: Intervention and Options** | **RPC Opinion:** Not Applicable |

| **Cost of Preferred (or more likely) Option** (in 2022 prices) | | | |
|---|---|---|---|
| **Total Net Present Social Value**<br>**£77m to £86m** | **Business Net Present Value**<br>£m | **Net cost to business per year**<br>£m | **Business Impact Target Status**<br>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 2023 Statutory Scheme payment percentage of 24.4% is 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 2022.

**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 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:

1. Business as Usual, i.e. the application of the 2023 payment percentage of 24.4% as set by the Branded Health Service Medicines (Costs) Regulations 2018 (as amended) ('the Regulations');
2. An option to apply a new annual payment percentage in 2023 of 27.5% (profiled as 24.4% for Q1 and 28.6% for Q2 to Q4 for the companies that made scheme payments in Q1).

While we have not incorporated inflation into our calculations of impacts, we have provided the reasons for the omission and included a discussion around its possible impacts.

**Will the policy be reviewed?** We expect to review this policy in response to negotiations for a new Voluntary Scheme to succeed VPAS, which we anticipate will come into effect from 1 January 2024. Review of the Statutory Scheme is likely to reflect the timescales and outcome of any negotiations **If applicable, set review date:** n/a

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

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

Signed by the responsible SELECT SIGNATORY: ______________ Date: ______________

# Summary: Analysis & Evidence

Business As Usual

**Description:** Business As Usual

**FULL ECONOMIC ASSESSMENT**

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

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

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

The Business As Usual option is the counterfactual scenario, against which other options are assessed. This option is applying a 2023 payment percentage of 24.4% 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) reputational damage to the VPAS scheme (since broad commercial equivalence will not be achieved), which could impact on negotiations for future voluntary schemes as the current scheme draws to a close.

**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 percentage of 27.5% (profiled as 24.4% for Q1 and 28.6% for Q2 to Q4) for 2023.

**FULL ECONOMIC ASSESSMENT**

| Price Base Year 2022 | PV Base Year 2022 | Time Period Years 1 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low: £77 m** | **High: £86 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 | **£2m** |
| **High** | Optional | | Optional | **£2m** |
| **Best Estimate** | | | | |

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

UK shareholders in pharmaceutical companies would see a loss of profits under this option of £2m 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 at less than £1m 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 | **£79m** |
| **High** | Optional | | Optional | **£88m** |
| **Best Estimate** | | | | |

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

Depending on the level of sales growth in 2022 and 2023, there may be additional net benefits to the NHS (UK) of between £77m to £86m by 2023, impacting the number of additional treatments and services. This will provide between 1,151 and 1,275 more QALYs by 2023, valued at £79m to £88m 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 3.5% |
|---|---|---|

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. The potential impacts of high inflation on pharmaceutical companies' profits and viability have not been incorporated into our calculations of impacts. This is due to the uncertainties arising from the mechanisms the Department controls relating to price, which mean we are unable to calculate 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 £94.2bn a year and 282,000 jobs across the country, of which the Biopharmaceuticals sector generated £64.2bn turnover in 2021 and employed 136,000 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 2021/22 spend on medicines by the NHS was approximately £17.8bn[2], of which an estimated £13.6bn[3] was on branded medicines. Should the central rebates from arrangements the NHS have agreed with pharmaceutical companies be included, the total cost would be approximately £17.2bn.

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 14.3% payment percentage on qualifying sales in 2022 and 24.4% in 2023 (see Table 1). These payment percentages aim to

[1] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021

[2] https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122

[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% | 14.3% | 24.4% |

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 option. In the March 2022 Statutory Scheme consultation, framework sales were not incorporated into calculations, on the basis that low levels of framework sales meant including them in calculations would jeopardise our duty of confidentiality. Due to further framework expiries, there are now no extant framework sales, so there is no impact on our conclusions or results from this category of sales.

*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 initially set in 2020 and were revised in March 2022 based on forecasted NHS sales of branded health service medicines using the best available data at the time (data to December 2021).

12. Based on more recent sales data (to September 2022) growth in sales between 2021 and 2022 will be 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 2022, whilst still ensuring growth in branded health service medicines spend is constrained to a level which will deliver overall economic benefits and patient health gains.

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

Whilst we discuss the aim of maintaining broad commercial equivalence between the Statutory Scheme and VPAS, a discussion of the impact of changes in sales growth on the VPAS payment percentage and subsequent impact on VPAS sales and payment income is out of the scope of this Impact Assessment. The proposed option presented in this Impact Assessment maintains the same allowed growth rate as was used previously, though we will continue to keep the Statutory Scheme under review through our established governance processes and will consider further consultation if the objectives of the Statutory Scheme are no longer being met. Further consultation is likely in 2023 on the statutory scheme, alongside negotiations on a new voluntary scheme agreement with the pharmaceutical industry.

14. Our view is that 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. As the price adjustment in the Statutory Scheme would only apply to companies who chose to sell to the NHS market, and not to companies who exclusively sell to the private healthcare market in the UK, this Impact Assessment does not require approval from the Regulatory Policy Committee.

16. We will carry out a 6-week consultation on the proposals set out in this Impact assessment.

# Reasons for Government Intervention

*2022 Higher than forecast growth in Measured Sales*

17. In the 2020 and 2022 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, 2020 to 2021 and 2021 to 2022 were based on a forecast in line with the VPAS methodology[6].

18. Since the March 2022 consultation we have received data up to September 2022 (details published November 2022[7]).

**Table 2 –Measured sales growth rates**

| Total Measured Sales growth | 2018 to 2019 | 2019 to 2020 | 2020 to 2021 | 2021 to 2022 |
|---|---|---|---|---|
| **Previous growth (as of Q4 2021 data)** | 1.69% | 2.08% | 9.48% | 5.56%* |
| **Updated growth (as of Q3 2022 data)** | 1.75% | 1.98% | 9.44% | 7.61%* |

**Forecast growth*

19. Table 2 shows slightly higher growth from 2018 to 2019 using the updated data, and lower growth for 2019 to 2020. Growth for 2020 to 2021 is slightly lower using the updated data. However, year-to-date growth for 2021 to 2022 is substantially greater than our previous forecast: 7.61% compared to 5.56%.

20. 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 Q4 seeing record sales of branded medicines. Both Q1 and Q2 2022 recorded at least 10% growth compared to the same quarter in 2021. However, Q3 2022 saw lower growth relative to the same quarter in the previous year at 4.4%. In 2022 growth is 7.61%, compared to

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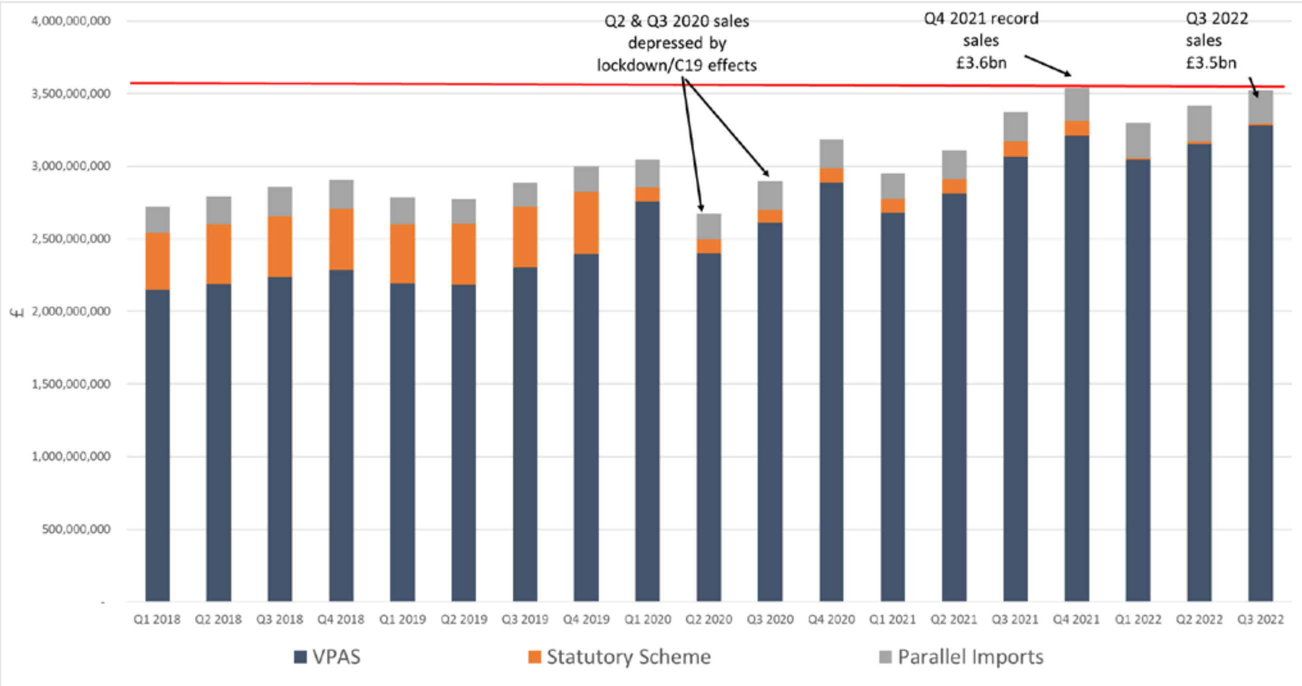
[6] Annex 5, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1046017/voluntary-scheme-for-branded-medicines-pricing-and-access-annexes.pdf

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

9.44% full year growth in 2021 and 1.98% full year growth in 2020. A contributing factor to these growth profiles is likely to be COVID-19 and subsequent lockdown effects.

**Figure 1 – Quarterly Measured Sales**




21. There are various factors which may have influenced the high growth rate of measured sales of branded health service medicines in 2022, such as:

- High sales (Covid-19). Covid-19 is likely to have contributed to the continued growth in sales as the NHS continues to work through the backlog of elective and semi elective treatments following the slowdown in these treatments during lockdowns. The NHS set out an ambition to deliver over 10% more elective activity than before the pandemic (ie 2019/20) in 2022/23[8]. We expect to see continued high use of medicines as the NHS continues to work through this backlog.

- High sales (non Covid-19). We have seen continued uptake of new medicines, resulting in continued sales growth.

- Growth in parallel imports: The first two quarters of 2022 saw high growth in parallel imports of medicines which contributed to growth in measured sales.

22. Whilst growth in sales has been greater than was forecast as of the most recent Statutory Scheme consultation, growth is in line with forecasts made in 2018 when VPAS was agreed and the Statutory Scheme was first constituted as a payment scheme.

*2023 Forecast Revisions*

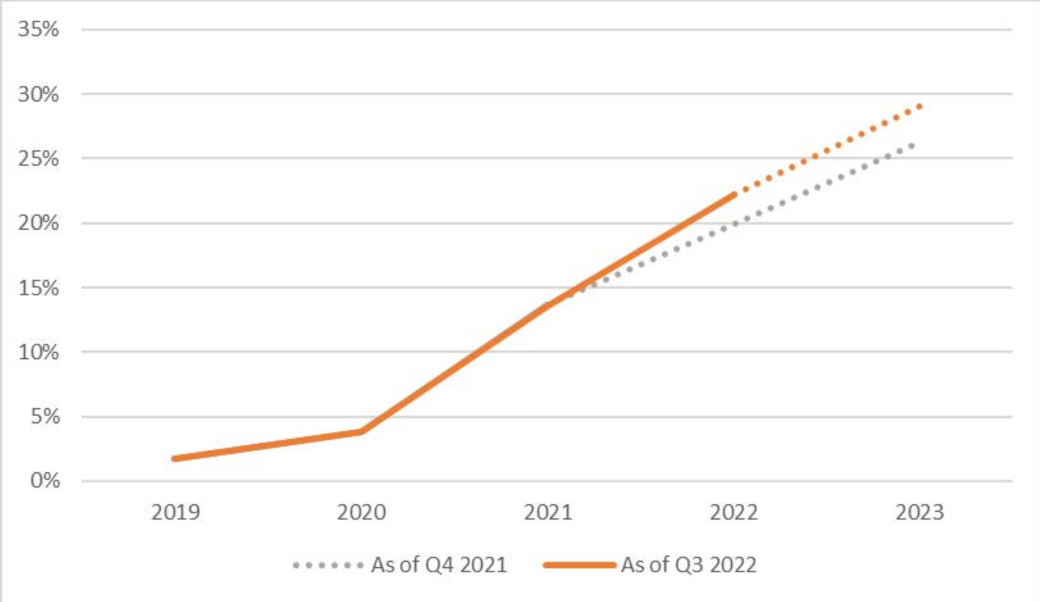
23. The VPAS provides a mechanism to revise the forecast of branded medicines sales in line with actual outturn sales data. At a high level, this mechanism compares cumulative outturn growth against cumulative forecast growth and adjusts future forecast growth by this ratio. This mechanism was agreed with the Association of the British Pharmaceutical Industry (ABPI) as part of the VPAS negotiations and therefore we consider it is appropriate to use for the purposes of setting Statutory Scheme payment percentages. This approach was used in

[8] NHS England, Elective recovery planning supporting guidance (April 2022), https://www.england.nhs.uk/wp-content/uploads/2021/12/B1269-elective-recovery-planning-supporting-guidance.pdf p4

the previous consultation and will also assist in maintaining “broad commercial equivalence” between the schemes.

24. Under this mechanism and using data as of September 2022 compared to data as of December 2021 (as was used in the previous consultation), year-to-date growth of branded medicines sales in 2022 is revised from 5.56% to 7.61%, and forecast growth is revised from 5.26% to 5.63% 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 (2022 = Q3 year-to-date), Dashed line = forecast growth*

25. Figure 2 compares the actuals/forecast cumulative growth from 2018 to 2023 as of the Q4 2021 and Q3 2022 data and a deviation can clearly be seen at 2021; when forecast growth based on Q3 2022 data was much greater than forecast growth based off Q4 2021 data. 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 to ensure the scheme’s objectives can be achieved.

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

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

- 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].

27. General inflation is currently high. This has not been incorporated into the forecasts as they are a projection of trends. This presents a risk that high inflation will result in sales growth above forecast, and as a result that calculated payment percentage will be set too low.

[9] https://www.evaluate.com/thought-leadership/pharma/world-preview-2022-report

[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

However, in this scenario, the Department has the capacity to use the additional sales data to consult on increasing the payment percentage to the required level.

28. 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; all else being equal, if a significant number of companies successfully applied for price increases, then medicines spend may rise further than forecasted within this IA. Further description of how we have considered inflationary impacts is included below.

*Maintaining broad commercial equivalence*

29. 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 will increase further to 26.5% (based on data up to Q3 2022), in part because of the effect of deferred payments resulting from the amendment of the 2022 payment percentage.

30. As a result, at current rates, the Statutory Scheme is no longer broadly commercially equivalent with VPAS. The de facto Statutory Scheme payment percentage will be meaningfully lower than VPAS in 2023.

### *Key concepts*

31. 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

32. 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 Table 3 below; these numbers are based on updated outturns as of data up to Q3 2022.

**Table 3 – Modelled Measured sales elements**

| £m | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|
| **Voluntary Scheme** | 8,847 | 9,093 | 10,546 | 11,589 |
| **Statutory Scheme** | 1,650 | 1,673 | 379 | 400 |
| **Parallel Imports** | 770 | 698 | 767 | 806 |
| **Total Measured Sales** | 11,266 | 11,464 | 11,691 | 12,795 |

# Objectives

33. 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.

34. We continue 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 2022. 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.

35. The objective of the intervention is to ensure the Statutory Scheme achieves its aims of effectively controlling NHS expenditure on branded medicines in 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*

36. This impact assessment considers the impact of the proposal to adjust the 2023 Statutory Scheme payment percentage to levels required to control sales in the light of higher-than-expected growth to 2022. For the calendar year of 2023, in light of revised forecast growth rates, a payment percentage of 27.5% 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.

37. Given constraints on timings to amend payment percentages, the payment percentage for the first quarter of 2023 cannot be amended from 24.4%. Therefore, for companies who make payments at the rate of 24.4% under the Statutory Scheme in the first quarter of 2023, the payment percentage is proposed to be 24.4% (as per current Regulations) until 31st March 2023 and 28.6% from 1st April until 31st December 2023. These figures are intended to give an overall average payment percentage which is expected to be equivalent to 27.5% for 2023. The payment percentage of 27.5% will apply to members of the Statutory Scheme who make their first payment after the second quarter of 2023.

*Business as Usual Option*

38. The preferred option is compared to the position if there was no change, i.e., the application of the payment percentage currently in the Regulations for 2023 of 24.4%.

39. These options are evaluated for the period from 1st April 2023 (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, 24.4% would continue into 2024 and beyond.

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

40. 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, we have 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.

41. 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, we have continued with the principles outlined in the 2018 consultation and therefore, has not included such options in this impact assessment.

42. We continue to keep the Statutory Scheme under review and further consultation is likely in 2023 on the statutory scheme, alongside negotiations on a new voluntary scheme agreement with the pharmaceutical industry..

## Business as Usual Option

43. A counterfactual or Business As Usual (BAU) position is considered in which the 2023 payment percentage of 24.4% continues to apply as per the current regulations. These are considered under three growth scenarios:

- Scenario A: a central growth scenario based upon the latest adjusted forecast as per the latest outturns;
- Scenario B: a lower growth scenario where 2023 growth is modified to be 5%-points lower than the adjusted forecast used in scenario A; and
- Scenario C: a higher growth scenario where 2023 growth is modified to be 5%-points higher than the adjusted forecast used in scenario A.

44. In previous Statutory Scheme Impact Assessments, proposed amendments to payment percentages have required evaluation of the behavioural impacts upon members of the schemes. If a meaningful difference between Statutory Scheme and Voluntary Scheme payment percentages were allowed to arise, Scheme members could:

    - Stay as members of the Statutory Scheme (SS) or VPAS; or
    - Seek to join the Statutory Scheme from the VPAS at the earliest opportunity;
    - Seek to join the VPAS from the Statutory Scheme at the earliest opportunity

45. There is now less uncertainty about scheme movement, as the deadline for companies to give notice of their intention to leave VPAS for 2023 has passed. Companies seeking to join the Statutory Scheme from the VPAS is therefore fixed in both the Business As Usual and Preferred Option scenarios.

*Leaving the Voluntary Scheme*

46. Companies are required to give notice of intention to leave the VPAS before 30th September each year, with membership taking effect from 1st January each calendar year. The deadline for current VPAS members to choose to leave the VPAS for 2023 has already passed. As the Statutory Scheme payment percentage in 2023 under BAU will be 24.4%, there was a possibility that a significant number of companies may have been inclined to join the Statutory Scheme and leave the VPAS, where they would otherwise have been paying a now confirmed payment percentage of 26.5%.

47. However, company scheme moves 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. Furthermore, we demonstrated commitment to maintaining broad commercial equivalence between the payment percentages in the two schemes through the amendment to Statutory Scheme payment percentages earlier this year. VPAS members may therefore have been unwilling to switch to the Statutory Scheme, despite lower current payment percentages, due to confidence that we would uplift these percentages.

48. Two companies which were VPAS members in 2022 and whose sales contribute to Measured Sales have left the VPAS for 2023. The total Measured Sales for these companies in Q1 to Q3 2022 make up approximately 4% of the total Measured Sales for all VPAS members, indicating there has not been a large-scale movement into the Statutory Scheme from VPAS.

49. There is a potential risk that in order to leave the VPAS before the end of the scheme, companies could default on their VPAS commitments during 2023, in which case they would be automatically moved into the Statutory Scheme. However, we consider 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 of the Scheme.

50. 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*

51. 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 24.4%, it is unlikely companies would be inclined to join the VPAS, where they would otherwise have been paying a now confirmed 26.5%.

## Business as Usual Scenarios – Summary

52. We have created three scenarios to capture the impacts of differential sales growth in 2023. Scenario A assumes growth as per the current adjusted forecast and is termed 'central' growth; the VPAS payment percentage is 26.5% in 2023. Scenario B assumes a 5%-point lower level of sales growth in 2023, whereas Scenario C assumes a 5%-point higher level of sales growth. In both Scenario B and Scenario C, the VPAS payment percentage remains at 26.5% in 2023. These scenarios are outlined in Table 4 below.

53. In all the Business as Usual scenarios we hold the Statutory Scheme payment percentage at 24.4%.

54. In the previous Statutory Scheme Impact Assessment, we created a low sales growth scenario for 2022 and then adjusted our forecast of the VPAS payment percentage in 2023 and sales growth for 2023 based on this lower growth in 2022. This enabled us to estimate a potential impact of lower sales growth on companies switching between schemes.

55. There is now considerably less uncertainty around scheme movement and the VPAS payment percentage for 2023, as outlined above. As a result, we have created our growth scenarios based on 2023 sales growth, with the VPAS payment percentage remaining constant across each of the scenarios modelled in this Impact Assessment.

56. We have modelled an extreme range for sales growth in 2023, with a 10-percentage point difference between our higher and lower sales growth estimates. Using the central growth estimate of 5.63% for 2023, this range results in the low growth estimate taking a growth value below the lowest observed modelled measured sales growth value since the start of the 2019 Statutory Scheme (1.75% in 2019) and the high growth estimate taking a value above the highest observed modelled measured sales growth (9.44% in 2021). This provides additional confidence that our final impact estimates are robust to uncertainty around sales growth.

57. The modelling of VPAS sales moving into the Statutory Scheme in 2023 is informed by data on which companies have given notice of their intention to move. To maintain alignment with the VPAS payment percentage calculation, these modelled sales from known movers into the Statutory Scheme are not included when setting the 2023 Statutory Scheme payment percentage.

58. It is unlikely any Statutory Scheme members would join the VPAS in 2023 under BAU, as the Statutory Scheme payment percentage of 24.4% 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 – Central Growth | Scenario B – Lower Growth | Scenario C – Higher Growth |
|---|---|---|---|
| **2023 Modelled Measured Sales Growth** | 5.63% | 0.63% | 10.63% |
| **2023 VPAS Payment %** | 26.5% | 26.5% | 26.5% |
| **2023 Statutory Scheme Payment %** | 24.4% | 24.4% | 24.4% |
| **Switch Leave VPAS for Statutory Scheme** | 3.9% of 2023 sales move | 3.9% of 2023 sales move | 3.9% of 2023 sales move |
| **Switch Leave Statutory Scheme for VPAS** | 0% in 2023 | 0% in 2023 | 0% in 2023 |

## Preferred Option: revise payment percentages for 2023

## Description of Option

59. 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 year of 2023, a payment percentage of 27.5% would be required. However, given the timing of amendments to Regulations, payment percentages for companies who make scheme payments in quarter one of 2023 will be 24.4% for the first quarter of the calendar year and 28.6% for the remaining three quarters. These payment percentages have been calculated to limit growth of branded health service medicines sales consistent with the annual growth aspired to in the previous Statutory Scheme consultation, which was 1.1% per annum.

60. We received consultation responses to the March 2022 Statutory Scheme Impact Assessment stating that the allowed growth rate of 1.1% per annum was inappropriate to balance affordability versus reward for industry. However, we have 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.

61. In the previous Statutory Scheme Impact Assessment, 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.

*Impact of Scheme Movers on over- and under-payments*

62. In 2019, there were 21 payment companies in the Statutory Scheme with modelled measured sales totalling £1,673m. Twelve of these payment companies moved into the VPAS for 2020.

63. 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.

64. Without factoring in growth between years, the scheme movers have meant that modelled Statutory Scheme sales have fallen from £1,673m in 2019 to £400m in 2021 as of Q3 2022 data. A further four payment companies moved from the Statutory to the Voluntary Scheme in 2022.

65. In previous updates to the Statutory Scheme, the payment percentages were adjusted to ensure allowed growth was met on average between 2018 and 2023. Over time, the membership changes described above resulted in a modelled overpayment in the scheme, which was carried forward up to the previous consultation 2022. In light of the distorting and overly depressing effect this was having on the payment percentage, this modelled underpayment was removed from the calculation of the payment percentage in the scheme in 2022 as a one-off adjustment to address this effect.

66. 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** | 6.3% | 7.1% | 14.2% | **9.2%** |

67. Had we had updated data (as of Q3 2022) when setting the 2019, 2020 and 2021 Statutory Scheme payment percentages, we would have set them at 6.3%, 7.1% and 14.2% respectively: an average of 9.2% (see Table 5). 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.

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

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

- Data used in setting 2023 payment percentages
    - We have used data to September 2022 (Q3 2022) to set the 2023 payment percentage. 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 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.
- 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[12]. The calculated 2022 VPAS payment percentage was 19.1%, but in the amendment document[13] 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*

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

*sales growth".* This is a 4.1%-point decrease on the calculated payment percentage for 2022 in the VPAS.

- In the previous Statutory Scheme Impact Assessment, the same adjustment was made to the 2022 Statutory Scheme payment percentage. Therefore, whilst it was calculated at 18.4%, it was 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 September 2022 factors in the lower 2022 payment percentage level.

*Timing of implementation*

69. If it were possible to have implemented the revised 2023 payment percentage from 1st January 2023, it would be set at 27.5%. 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 2023 will not come into effect until the 1st April 2023. An effect of this delay will be that between 1st January 2023 to 31st March 2023 (where the 24.4% 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%.

70. As such the revised payment percentage for the remainder of 2023 (1st April to 31st December) will take account of this effect. This will only apply to companies who made payments in either of the first quarter of 2023, to ensure that any companies that join the Statutory Scheme after the first quarters of 2023, and/or who start making payments after the first quarters of 2023 are not disproportionately disadvantaged due to lower payments paid by other scheme members earlier in the year.

71. The 2023 Statutory Scheme payment percentage currently in the Regulations (24.4%) would apply between 1st January 2023 to 31st March 2023. In practice, the Regulations will apply as follows:

- For companies that are Statutory Scheme members and make a payment in the first quarter of 2023, they will pay a payment percentage of 24.4% on sales in Q1 2023, followed by 28.6% on sales in Q2-Q4 2023.

- For companies that join the Statutory Scheme after Q1 2023, and/or do not make a scheme payment in Q1 2023, they will pay a payment percentage of 27.5% on any sales made under the Statutory Scheme in Q2-Q4 2023.

*Withdrawal of Supply*

72. 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.

73. In the previous Statutory Scheme Impact Assessment, 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.

74. 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.

75. 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.

*Inflation*

76. There is a potential impact on company behaviour from high inflation. Companies may find that with higher levels of inflation, the continued sale of certain products becomes uneconomical due to rising production costs. They may therefore increase the selling price of their products up to the list price limit by reducing discounts on their sales or approach the Department to request list price increases to some of their branded products to maintain supply. The former approach does not require any application to the Department, though may require negotiation of contractual arrangements, whereas the latter requires an application to the Department.

77. If companies increase their selling prices and/or successfully apply for list price increases, this could result in nominal sales growth in 2023 being above forecast. As a result, there is a risk that the Statutory Scheme payment percentage calculated in this impact assessment could be set too low to limit nominal growth in branded medicine sales to 1.1%. The risk of surpassing the nominal growth target is potentially higher in a high inflation environment. In this scenario, the cost of branded medicines to the NHS would grow beyond 1.1% and there would be a reduction in the benefits from patient health gains resulting from NHS spending elsewhere.

78. Where price increases are not granted, supply of medicines could be impacted, and patient outcomes may ultimately be affected. In this scenario, the cost of inflation would be felt by the company and its profits, who in turn could react by cutting costs and/or reducing production. This would result in possible supply risks for the NHS. There could potentially therefore be a trade-off between selling price increases and supply reductions in determining the overall effect of inflation on the NHS branded medicines bill. However, any supply risks would be considered in the initial price increase decision, mitigating risks to supply.

79. There are a number of mitigating factors which limit the risk from inflation within this Impact Assessment. Firstly, in the eventuality that the Statutory Scheme payment percentage has been set too low, the Department maintains the capability to consult on and change the payment percentage to the required level. Our upper growth estimate for sales growth in 2023 is also 5-percentage points higher than forecast, allowing us to test the impact on payment income if nominal sales growth is higher than expected in 2023. As we are setting the 2023 Statutory Scheme payment percentage using the same sales data (Q3 2022) as the 2023 VPAS, there is no risk that high levels of inflation will cause a commercial divergence between the two schemes in the preferred policy option. Finally, we are considering a relatively short time period of one year, in which companies may have little scope to rapidly increase prices due to contractual agreements.

*Companies raising serious concerns*

80. 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[14].

81. The objective of the proposed changes is to ensure the Statutory Scheme achieves its aims of effectively controlling NHS expenditure on branded medicines in 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

82. As in the Business as Usual calculation, we have created three scenarios to model scheme payments under different levels of sales growth. Scenario A assumes growth as per the current adjusted forecast and is termed 'central' growth; the VPAS payment percentage is the projected 26.5% in 2023. Scenario B assumes a 5-percentage point lower level of growth; Scenario C assumes a 5-percentage point higher level of growth. As discussed above (see paragraph 55), this range has been chosen to reflect the range of sales growth we could reasonably expect for 2023 based on historical growth values. The VPAS payment percentage remains the same across all growth scenarios. In the preferred option scenarios, we change the Statutory Scheme percentage to 27.5% in 2023 (see Table 6 below).

83. All Statutory Scheme members are modelled as remaining in the scheme under the preferred option, despite paying the higher payment percentage. Statutory Scheme membership has reduced considerably since the start of VPAS, as outlined above. Modelling which individual companies would leave the Statutory Scheme for VPAS would require us to make assumptions about individual company decisions.

**Table 6– Preferred Option Scenario Summary**

| | **Scenario A – Central Growth** | **Scenario B – Lower Growth** | **Scenario C – Higher Growth** |
|---|---|---|---|
| **2023 Modelled Measured Sales Growth** | 5.63% | 0.63% | 10.63% |
| **2023 VPAS Payment %** | 26.5% | 26.5% | 26.5% |
| **2023 Statutory Scheme Payment %** | 27.5% | 27.5% | 27.5% |
| **Switch**<br>**Leave VPAS for Statutory Scheme** | 3.9% of 2023 sales move | 3.9% of 2023 sales move | 3.9% of 2023 sales move |
| **Switch**<br>**Leave Statutory Scheme for VPAS** | 0% in 2023 | 0% in 2023 | 0% in 2023 |

## Evaluation of Impacts

*Sales by Statutory Scheme companies*

84. Total modelled sales of branded health service medicines by qualifying companies in the Statutory Scheme, based on the data to Q3 2022, are ~£40m for the UK in 2022. This incorporates actual sales for January to September 2022 to get projected 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 rise compared to modelled sales in 2023 as two companies which contributed to Measured Sales in the VPAS in 2022 have agreed to join the Statutory Scheme for 2023 – so the sales of these companies should result in an equivalent fall in VPAS sales. Expected sales are the same in both the Business as Usual

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

and Preferred Option scenarios as the scheme movers for 2023 are modelled the same in both scenarios (see Table 7). To help maintain confidentiality, an estimate of the 2023 Measured Sales of the scheme movers 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 £1m to add an additional layer of obfuscation.

*Effect of proposed payment percentages*

86. 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 £3,178m to £3,521m would have been due to the Department (see Table 8). Under the preferred option, a net payment of between £3,196m to £3,540m would have been due to the Department (see Table 9).

87. The net effect of the policy therefore is an impact on savings between £17m and £19m to the Department by 2023, where the additional savings would be reinvested in the health service. The figures for 2023 are presented in Table 10. The Net Present Value of this revenue stream is between £17m and £18m.

88. 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.

89. The calculations are all based on returns made by companies reporting their sales of health service medicines. Two companies who contribute to 2022 VPAS Measured Sales have opted to join the Statutory Scheme for 2023. This expected rise in 2023 Statutory Scheme measured sales (and subsequently payments) has been estimated with the figures rounded to £1m to protect confidentiality. As such, please note that the totals may not sum due to rounding.

**Table 7–Expected Sales**

| *Expected Sales* | | **2023** | |
|---|---|---|---|
| **Do Nothing - Business as usual (£m)** | ***Low*** | ***Central*** | ***High*** |
| Base Voluntary Scheme Measured Sales | 12,815 | 13,505 | 14,195 |
| Additional Voluntary Scheme Sales moving from SS | - | - | - |
| | | | |
| Base Statutory Scheme (SS) Measured Sales | 42 | 44 | 47 |
| Additional SS sales moving from Voluntary Scheme | 501 | 528 | 555 |
| | - | - | - |
| **Adjusted Voluntary Scheme Measured Sales** | 12,314 | 12,977 | 13,640 |
| **Adjusted Statutory Scheme Measured Sales** | 544 | 573 | 602 |

### Table 8– Business as Usual Expected Payments

| *Expected Payments*<br>**Do Nothing - Business as usual (£m)** | *Low* | **2023**<br>*Central* | *High* | *Low* | **NPV**<br>*Central* | *High* |
|---|---|---|---|---|---|---|
| Statutory Scheme Payment percentage | 24.4% | 24.4% | 24.4% | | | |
| Statutory Scheme Payment (£m) | 133 | 140 | 147 | 131 | 138 | 145 |
| Voluntary Scheme Payment percentage | 26.5% | 26.5% | 26.5% | | | |
| Voluntary Scheme exclusion from Payment | 6.7% | 6.7% | 6.7% | | | |
| Voluntary Scheme Payment (£m) | 3,046 | 3,210 | 3,374 | 3,001 | 3,162 | 3,324 |
| **Total Payment (£m)** | 3,178 | 3,349 | 3,521 | 3,131 | 3,300 | 3,469 |

### Table 9-Preferred Option Expected Payments

| *Expected Payments*<br>**Preferred Option - New Payment percentage (Split-year) (£m)** | *Low* | **2023**<br>*Central* | *High* | *Low* | ***NPV***<br>*Central* | *High* |
|---|---|---|---|---|---|---|
| Statutory Scheme Payment Percentage Legacy | 24.4% | 24.4% | 24.4% | | | |
| Statutory Scheme Payment Percentage Split-year | 28.6% | 28.6% | 28.6% | | | |
| Statutory Scheme Measured Sales at Legacy (£m) | 133 | 140 | 147 | | | |
| Statutory Scheme Measured Sales at Split-year (£m) | 411 | 433 | 455 | | | |
| Statutory Scheme Payment (£m) | 150 | 158 | 166 | 148 | 156 | 164 |
| Voluntary Scheme Payment percentage | 26.5% | 26.5% | 26.5% | | | |
| Voluntary Scheme exclusion from Payment | 6.7% | 6.7% | 6.7% | | | |
| Voluntary Scheme Payment (£m) | 3,046 | 3,210 | 3,374 | 3,001 | 3,162 | 3,324 |
| **Total Payment (£m)** | 3,196 | 3,368 | 3,540 | 3,148 | 3,318 | 3,487 |

### Table 9– Difference in payments

| **Difference in payments**<br>**(Preferred option less Business as usual)** | **2023** |
|---|---|
| High Growth (£m) | 19 |
| Central Growth (£m) | 18 |
| Low Growth (£m) | 17 |

*Impact on NHS*

90. The application of a higher payment percentage in 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.

91. 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*

92. 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*

93. 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.

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

95. Previous consultation responses 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.

96. As highlighted in the previous Statutory Scheme 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[15], 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[16] found little reason to consider 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[17].

97. We maintain our 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.

98. 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

[15] 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.

[16] OECD. “Pharmaceutical Pricing Policies in a Global Market”, OECD Health Policy Studies, OECD Publishing (2008).

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

decreased investment in the siting of R&D facilities in the UK relative to other countries but will continue to engage with industry on this issue.

## NHS and patient health gains

99. 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[18]. The impacted savings of between £17m to £19m therefore correspond to a change of between 1,151 and 1,275 QALYs for patients in the NHS by 2023 (see Table 11).

100. These health gains are monetised using their estimated societal value[19] which is valued at £70,000 a QALY in 2020/21 prices as per the updated Green Book (guidance issued by HM Treasury on how to appraise policies) valuation. Accordingly, the estimated health gains give an annual impact valued at between £81m to £89m by 2023.

101. In total, the benefits from these savings have a positive NPV value of between £79m to £88m over the period in consideration.

**Table 10– Monetising benefits from improved patient health and wider economic consequences**

| | | 2023 | | | NPV | |
|---|---|---|---|---|---|---|
| **Benefits (£m)** | *Low* | *Central* | *High* | *Low* | *Central* | *High* |
| Savings for option 1 against do nothing (£m) | 17 | 18 | 19 | 17 | 18 | 19 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | 1,151 | 1,213 | 1,275 | | | |
| Social Value of QALYs @£70,000/QALY (£m) | 81 | 85 | 89 | 79 | 84 | 88 |
| **Total benefits (£m)** | 81 | 85 | 89 | 79 | 84 | 88 |

## Loss of profits for UK shareholders in pharmaceutical companies

102. 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.

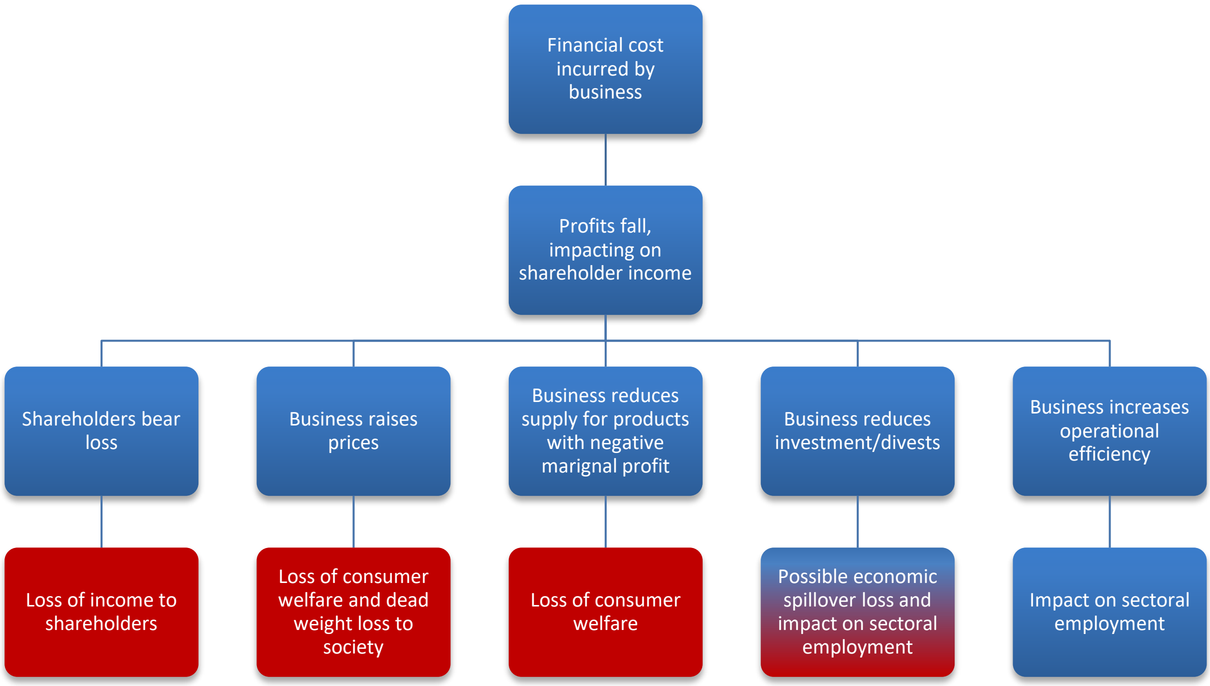
103. In the long-run, changes in companies' revenues may not have a noticeable impact on shareholders' income, since shareholders are always expected to ultimately make the risk-adjusted market return on capital. However, in the short run shareholders may receive an adjusted rate of return.

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

[18] 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/

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

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




105. The impact in shareholder income is equivalent to the changed revenue at approximately **£17m-£19m 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 **£2m by 2023** (see Table 12).

106. The NPV of distribution adjusted profits to UK shareholders are estimated to be approximately **£2m** over the period under consideration.

### Impact on UK R&D spill-overs

107. The impact in net revenue may also result in altered investment in R&D[20] – of which a portion may be in the UK, providing "spill-over" impacts on the UK economy.

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

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[20] 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.

109. In the previous impact assessment we used an estimate that the proportion of pharmaceutical company revenues devoted to R&D was 36%[21]. There are other sources that estimate the share of revenue devoted to R&D is closer to 25%[22], and OLS analysis suggesting it may be nearer 15%[23]. 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.

110. 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 £1m by 2023[24]. To put this in context, this compares to total pharmaceutical R&D investment in the UK in 2020 of £5.0 billion[25].

111. 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, we consider 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[26].

112. Applying the estimates above to the projected change in pharmaceutical revenues gives an impact less than **£1m by 2023** to the UK economy from altered R&D investment. We are only using a one year time period to model these costs, as further consultation on the Statutory Scheme is likely in 2023 on the statutory scheme, alongside negotiations on a new voluntary scheme, as VPAS expires at the end of 2023.

### Table 11 – Costs to industry from lost profits and R&D spill-overs foregone

| | 2023 | | | NPV | | |
|---|---|---|---|---|---|---|
| **Costs (£m)** | ***Low*** | ***Central*** | ***High*** | ***Low*** | ***Central*** | ***High*** |
| Lost profits to pharmaceutical company shareholders (£m) | 17 | 18 | 19 | 17 | 18 | 18 |
| **UK lost profits to shareholders (£m)** | 2 | 2 | 2 | 2 | 2 | 2 |
| Invested in UK R&D (£m) | 1 | 1 | 1 | | | |
| **Lost UK benefits through reduced R&D investment (£m)** | <1 | <1 | <1 | <1 | <1 | <1 |
| **Total costs (£m)** | 2 | 2 | 2 | 2 | 2 | 2 |

## Net monetised impacts

### Table 12 – Net benefits

| *Net Benefits* | **2023** | **NPV** |
|---|---|---|
| **Higher Growth** | 87 | 86 |
| **Central Growth** | 83 | 82 |
| **Lower Growth** | 79 | 77 |

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

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

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

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

[25] Life Sciences Competitiveness Indicators 2022 (Life science competitiveness indicators 2022 - GOV.UK (www.gov.uk))

[26] 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

113. The total benefits of the proposed option, compared to the Business As Usual option, valued in a range at between **£79m and £88m** present value, over the period under consideration, while the total costs are estimated at approximately **£2m** present value, giving a net benefit in a range of between **£77m and £86m**. See Table 13 for the net benefits and Table 14 for the summary of results.

### Summary of results

#### Table 13– Summary of Results

| *Scenario B* | | 2023 | | | NPV | |
|---|---|---|---|---|---|---|
| **Benefits (£m)** | ***Low*** | ***Central*** | ***High*** | ***Low*** | ***Central*** | ***High*** |
| Savings for option 1 against do nothing (£m) | 17 | 18 | 19 | 17 | 18 | 19 |
| QALYs generated elsewhere in the NHS @£15,000/QALY | 1,151 | 1,213 | 1,275 | - | - | - |
| Social Value of QALYs @£70,000/QALY (£m) | 81 | 85 | 89 | 79 | 84 | 88 |
| **Total benefits (£m)** | 81 | 85 | 89 | 79 | 84 | 88 |
| *Scenario B* | | **2023** | | | **NPV** | |
| **Costs (£m)** | ***Low*** | ***Central*** | ***High*** | ***Low*** | ***Central*** | ***High*** |
| Lost profits to pharmaceutical company shareholders (£m) | 17 | 18 | 19 | 17 | 18 | 18 |
| **UK lost profits to shareholders (£m)** | 2 | 2 | 2 | 2 | 2 | 2 |
| Invested in UK R&D (£m) | 1 | 1 | 2 | | | |
| **Lost UK benefits through reduced R&D investment (£m)** | <1 | <1 | <1 | | | |
| **Total costs (£m)** | 2 | 2 | 2 | 2 | 2 | 2 |
| **Net benefits (£m)** | 79 | 83 | 87 | 77 | 82 | 86 |

### Unmonetized impacts

*Companies raising serious concerns*

114. 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*

115. 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.

## Statutory requirements for consultation

116. 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.

117. 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.

118. 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 24.4% payment percentage between 2022 - 2023).

*Economic consequences for the Life Sciences Industry in the United Kingdom*

119. As explained earlier in the document, the preferred option is expected to impact the gross revenues of pharmaceutical companies by between -£17m and -£19m.

120. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated by BEIS[27] 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 -£2m relative to the counterfactual. The change in revenue is estimated to translate to a decrease in UK R&D of less than £1m by 2023.

121. 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.

*The consequences for the economy of the United Kingdom*

122. As set out elsewhere in this assessment, we expect to see impact on the UK's share of global R&D investment worth £1m from this change, with a reduction of spill-over benefits to the UK worth under £1m by 2023. We also identify potential impacts on UK shareholders estimated to be around £2m in the same period.

123. This is a relatively small impact in overall terms and is likely to be highly specific, as the change will only apply to investments made in or by companies who are members of the Statutory Scheme in 2023. As such, we expect only limited consequences for the wider UK economy.

124. Moreover, the additional savings generated from this update help to ensure that the NHS can continue to invest in other services which may generate their own benefits. As the majority of pharmaceutical ownership, investment and production is overseas, reinvestment in other NHS services may result in equal or greater benefits for wider UK economy if the spill over benefits of this investment are more likely to occur in the UK.

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

125. The purpose of our preferred option is to help ensure that NHS spending on medicines continues to be affordable, allowing continued NHS investment in uptake of the most clinically and cost-effective medicines to the benefit of patients as well as investment in other patient services. The main impact of this specific proposed update is to ensure the stability of the UK medicine pricing schemes; our assessment remains that ensuring the good operation of the schemes means the NHS can continue to use its funds in the best interest of patients.

[27] Estimate provided in correspondence

126. Moreover, the financial savings to the NHS as a result of these changes can be reinvested into the health system to provide greater patient benefits, estimated to provide between 1,151 and 1,275 additional QALYs by 2023.

127. As set out in (72-75 above) previous similar consultations have raised the possibility that increased payment percentages may make some medicines uneconomical to supply, resulting in a negative impact on patients' access to medicines. We consider that effective mitigations are already in place should individual medicines become uneconomical to supply without such mitigations. These are expected to be effective in maintaining patients' access to medicines.

## Impact on Small Businesses

128. 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. Furthermore, the majority of modelled measured sales in the Statutory Scheme for 2023 are made up by large, multinational companies.

## Equalities Impact

129. 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 15 – 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 Q4 2021 data)** | *1.69%* | *2.08%* | *9.48%* | *N/A* | *N/A* |
| | **Previous Measured Sales Growth Forecast** | N/A | *N/A* | *N/A* | *5.56%* | *5.26%* |
| | **Outturn Measured Sales Growth** | 1.75% | 1.98% | 9.44% | 7.61% | N/A |
| | **Revised Measured Sales Growth Forecast** | N/A | N/A | N/A | N/A | 5.63% |
| | **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% | 14.3% (Profiled as 10.9% for Q1-Q2 and 17.7% for Q3-Q4) | 24.4% |
| | **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 | N/A | 27.5% (Profiled as 24.4% for Q1 and 28.6% for Q2-Q4) |
| | **Voluntary Scheme Payment Percentages** | 9.6% | 5.9% | 5.1% | 15.0% | 26.5% |

# 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. The 2023 payment percentage has been calculated using data to Q3 2022, to deliver an allowed level of branded health service medicine sales.

2023 Payment Percentage

3. Initially the Total Measured Sales is calculated using Q3 2022 data:

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

4. Where *VS* refers to the VPAS, *SS* refers to the Statutory Scheme, $t$ refers to the calendar year, e.g., 2023. Next, the Total Allowed Sales is calculated:

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

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:

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

6. As explained in preferred option description, the modelled over- and under-payments between 2019 to 2021 have not been accounted for in the 2023 payment percentage calculation. 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:

$$\begin{aligned} SS\ 2022\ under\ delivery \\ = SS\ Payment_{2022} - ((SS\ Measured\ Sales_{2022} \times Q1Q2share_{2022} \times 10.9\%) \\ + (SS\ Measured\ Sales_{2022} \times (1 - Q1Q2share_{2022}) \times 17.7\%)) \end{aligned}$$

7. Where 10.9% and 17.7% refer to the current 2022 payment percentages already in Regulations, and $Q1Q2share_{2022}$ is the estimated share of annual Statutory Scheme sales which occurred between 1st January 2022 and 30th June 2022 as of Q3 2022 data, which stands at 49.5%.

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

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

9. Two payment percentages will be calculated for 2023. This is due to the delay in being able to implement the 2023 payment percentage until the 1st April 2023, prior to which Statutory Scheme members will pay the 2023 payment percentage of 24.4% already in the Regulation. As such, for scheme members who made scheme payments in the first quarter of 2023, the anticipated under delivery of payment between 1st January 2023 and 31st March 2023 is factored into the payment percentage for the remainder of 2023. Scheme members that join the Statutory Scheme after the first quarter of 2023 and/or who did not make scheme payments in the first quarters of 2023 will not have this under delivery factored in the payment percentage.

10. The 2023 payment percentage for scheme members that join the Statutory Scheme after the first quarter of 2023 and/or who did not make scheme payments in the first quarters of 2023 is calculated as:

$$Payment\ Percentage_{2023_{\mathrm{i}}} = \frac{SS\ Payment_{2023}}{SS\ Measured\ Sales_{2023}}$$

11. Following this, the 2023 payment percentage Q2 to Q4 2023 for scheme members that made payments in the first quarter of 2023 at 24.4% is calculated. First the anticipated remaining required payment from 1st April 2023 after the payment of 24.4% from 1st January has been factored in is calculated:

$$SS\ Balance\ Payment_{2023} = (Payment\ Percentage_{2023i} \times\ SS\ Measured\ Sales_{2023}) - (SS\ Measured\ Sales_{2023}\ \times Q1share_{2023}\ \times 24.4\%)$$

12. Where 24.4% refers to the current 2023 payment percentage already in Regulations, and $Q1share_{2023}$ is the estimated share of annual Statutory Scheme sales which will occur between 1st January 2023 and 31st March 2023 as of Q3 2022 data, which stands at 24.4%. The payment percentage to be applied from 1st April 2023 can be seen below.

$$Payment\ Percentage_{2023ii} = \frac{SS\ Balance\ Payment_{2023}}{SS\ Measured\ Sales_{2023}\ \times\ (1 - Q1share_{2023})}$$

13. This Q2 to Q4 2023 payment percentage is referred to as *Payment percentage*$_{2023ii}$.

### Table 16 – Breakdown of 2023 Payment Percentage Calculation (using Q3 2022 data)

| Element, UK | 2022 | 2023 |
|---|---|---|
| 2019 Voluntary Scheme Measured Sales Growth - Forecast | 9.82% | 6.11% |
| Statutory Scheme Measured Sales Growth - Forecast | -89.49% | 5.93% |
| Parallel Imports Growth- Forecast | 23.91% | -0.45% |
| | | |
| 2019 Voluntary Scheme - Measured Sales (£m) | 12,728 | 13,505 |
| Statutory Scheme - Measured Sales (£m) | 42 | 44 |
| Parallel Imports - Measured Sales (£m) | 998 | 994 |
| | | |
| Statutory Scheme as a % of Overall Measured Sales | 0.3% | 0.3% |
| | | |
| Overall Measured Sales (£m) | 13,768 | 14,543 |
| Overall Growth | 7.61% | 5.63% |
| | | |
| Allowed Sales (£m) | 11,104 | 11,226 |
| Allowed Growth | 1.1% | 1.1% |
| | | |
| Expected Total Payment (£m) | 2,664 | 3,317 |
| Expected Statutory Scheme Payment (£m) | 8.1 | 10.1 |
| | | |
| Legacy Payment % | 10.9% | 24.4% |
| | | |
| Revised Annual 2022 Payment % | 14.3% | |
| Revised Part Year (from July) 2022 Payment % | 17.7% | |
| | | |
| Statutory Scheme - Measures Sales subject to legacy % (£m) | 21 | |
| Statutory Scheme - Measures Sales subject to revised % (£m) | 21 | |
| Part year payment at legacy % (£m) | 2 | |
| Part year payment at revised % (£m) | 4 | |
| | | |
| 2022 under-delivery (£m) | 2 | |
| Adjusted expected 2023 Payment (£m) | | 12 |
| | | |
| Final Annual Payment % | | **27.5%** |
| Final Part Year (from July) 2022 Payment % | | **28.6%** |

# 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[28].

3. To maintain broad commercial equivalence with the VPAS, the forecast has been revised using the latest outturn data (up to Q3 2022) in the identical approach used in the VPAS[29]. 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.

**Table 17 – Previous and revised forecasts of branded sales**

| | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|---|---|---|---|---|
| **Previous Forecast** | 1.69%* | 2.08%* | 9.48%* | 5.56% | 5.26% |
| **Revised Forecast** | 1.75%* | 1.98%* | 9.44%* | 7.61%** | 5.63% |

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

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

29 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 - 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[30]. Expressed in 2016, and adjusted to give an appropriate level of precision, we interpret 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. We currently estimate this value to be **£70,000**, based on analysis by the Department for Transport of individuals' willingness to pay to avoid mortality risks[31].
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:

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

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

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

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).