IA Title: Statutory Scheme – Branded Medicines Pricing

IA No: n/a

RPC Reference No: n/a

Lead department or agency: Department of Health and Social Care

Other departments or agencies: NHS England

Impact Assessment (IA)

Date: 4 December 2023

Stage: Development/Options

Source of intervention: Domestic

Type of measure: Secondary Legislation

Contact for enquiries:
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Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2022 prices)

Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
-£24,230m	£m n/a	£m n/a	Non qualifying provision

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 currently controlled by a Statutory Scheme and a Voluntary Scheme (VPAS); the latter having been agreed with industry and due to expire at the end of 2023. The objectives of the Statutory Scheme are to safeguard the financial position of the NHS, ensure medicines are available on reasonable terms, and to do so in a way that supports the life sciences sector. The Statutory Scheme payment percentage for 2023 of 27.5% will continue for each year after if no change is made to the regulations. Updating the Statutory Scheme to take account of the latest data and the context of the 2019 VPAS expiring at the end of 2023 ensures that payment percentages are set according to a clear and justified methodology.

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

The objective of the intervention is to support the Statutory Scheme continuing to achieve its objectives post 2023 and ensure it is viable whether as an alternative to a successor voluntary scheme or as a standalone scheme in absence of this. 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)

Five options were considered at consultation stage. At final stage, Option 1b is progressed as the preferred option and is the option considered against the BAU in this Impact Assessment. The Department however notes that, whilst on the basis of consultation responses and the progress of voluntary scheme negotiations the Lifecycle Adjustment (LCA) mechanism is not deemed desirable in the Statutory Scheme for 1 January 2024, it remains committed to the principle of ensuring sustainable spending on older medicines and open to the future implementation within the Statutory Scheme of policies designed to achieve this – including those required to maintain broad commercial equivalence with any future voluntary scheme. The options assessed are:

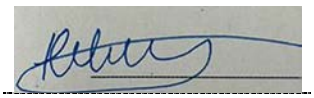
- Business as Usual (BAU) – the current regulations remain in force with a payment percentage of 27.5% in each of the three years covered by this appraisal period and no change to exemptions.
- Option 1a – maintain current Statutory Scheme structure, introduce measured sales exemptions for centrally procured vaccines (CPV) and exceptional central procurement (ECP), increase the allowed growth cap to 2% per annum.
- **Option 1b preferred** – maintain the structure of the current Statutory Scheme, introduce an exemption from eligible sales for New Active Substances (NAS) for 36 months from its first Marketing Authorisation (MA), introduce exemptions from measured sales for CPV and ECP and increase the allowed growth cap to 2% per annum. While all the options proposed set payment percentages using a clear and justified methodology, 1b is our preferred option since the range of exemptions in this option best support the scheme's objective in relation to patients' access to medicines. This option is sufficiently flexible to accommodate a version of the Lifecycle Adjustment if, following further policy consideration, such a mechanism is to be consulted on in the future.
- Option 2a – introduce a Lifecycle Adjustment design with 2% allowed growth per annum where a greater proportion of payments apply to older products without competition and exemptions from measured sales for CPV and ECP.
- Option 2b – introduce a Lifecycle Adjustment design with 2% allowed growth per annum where a greater proportion of payments are required from older products without competition, exemptions from measured sales for CPV and ECP and a 36 month from MA exemption from eligible sales for NAS.

The impacts of each of these options were quantified and monetised in the consultation stage Impact Assessment[1]. Each of these options is within the same financial envelope, with broadly the same overall costs and NPV, subject to rounding of payment percentages.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Q4 2024

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

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

Signed by the responsible Minister:  Date: 4 December 2023

[1] https://assets.publishing.service.gov.uk/media/64e32404bc2b52000da003ba/impact-assessment-review-scheme-cost-branded-medicines-updated-21-august-2023.pdf

Summary: Analysis & Evidence — Business As Usual

Description: Business As Usual

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	PV Base Year 2022	Time Period Years 3	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

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	0		0	0

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 the 2023 payment percentage of 27.5%, 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'

As above, under the business-as-usual option by definition impacts are zero.

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	0		0	0

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.

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

As above, under the business-as-usual option by definition impacts are zero.

Key assumptions/sensitivities/risks	Discount rate (%)	n/a

Under Business as Usual, the principal risk is that the Statutory Scheme payment percentage may not be set according to a clear and justified methodology.

BUSINESS ASSESSMENT (BUA)

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

Summary: Analysis & Evidence — Policy Option 1b

Description: Maintain the structure of the current Statutory Scheme, introduce a 36 month from Marketing Authorisation (MA) exemption from eligible sales for New Active Substances (NAS), introduce exemptions from measured sales for CPV and ECP and increase the allowed growth cap to 2% per annum.

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	**PV Base Year** 2022	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -£25,980m	**High:** -£22,260m	**Best Estimate:** -£24,230m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	£26,520m
High	Optional		Optional	£22,720m
Best Estimate				£24,740m

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

Depending on the level of sales growth between 2024 and 2026, there may be additional net costs to the NHS (UK) of between £5,080m to £5,930m by 2026. This equates to an estimated 338,460 to 395,470 fewer QALYs by 2026, valued at £22,720m to £26,520m in present value terms (i.e. before estimated benefits are netted off).

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

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	£540m
High	Optional		Optional	£460m
Best Estimate				£500m

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

Depending on the level of sales growth to 2026, pharmaceutical companies may see an increase in profits estimated at between £5,080m and £5,930m, of which £510m to £590m may accrue to UK shareholders by 2026.

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

By updating the Statutory Scheme to take account of the latest data and the context of the 2019 VPAS expiring at the end of 2023, we ensure that payment percentages are set according to a clear and justified methodology. Doing so supports the perceived rationality of the UK market and protects from a potential deterioration in industry sentiment towards the UK that might otherwise result fromthe roll over of a 2023 payment rate that was set in the context of an extant voluntary scheme and with a one-off adjustment of 4.1 percentage points to account for a 2022 scheme amendment. Including a New Active Substance exemption from eligible sales and CPV and ECP exemption from measured sales may support continued access to these products.

Key assumptions/sensitivities/risks	**Discount rate (%)**
There is inherent uncertainty around future 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 given the options available relating to list and net price increase applications to mitigate supply issues. A key source of data is company returns on NHS sales – we assume that this information is accurate.	NHS 1.5% other 3.5%

BUSINESS ASSESSMENT (Option 1b)

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

Evidence Base

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 generate profits, and provides an incentive to invest in R&D and an opportunity to recoup R&D costs. 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 prescribed medicines, appliances, and medical devices by the NHS was approximately £17.8bn[2], of which an estimated £13.3bn[3] was on branded medicines. Should the central rebates from arrangements the NHS have agreed with pharmaceutical companies be included[4], the total cost of prescribed medicines, appliances, and medical devices would be approximately £17.2bn[5].

5. In the UK, the costs of branded health service medicines are currently controlled within a voluntary and a statutory framework.

Voluntary Scheme

6. The Voluntary Pricing and Access Scheme (VPAS) is a voluntary scheme agreed between the Department of Health and Social Care (DHSC), on behalf of the UK Government (which includes the health departments of England, Wales, Scotland and Northern Ireland), and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI).

7. The current (2019) VPAS scheme, which operates by limiting the growth in the overall branded health service medicines bill for products covered by the scheme, began on 1 January 2019 and expires on 31 December 2023. 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 level of sales (which grows at 2% nominal p.a.) and actual outturn growth in measured 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.

[1] Office for Life Sciences, Department for Business, Energy & Industrial Strategy and Department of Health and Social Care. 2022. Bioscience and health technology sector statistics 2021. [https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021]
[2] NHS Business Services Authority. 2022. Prescribing Costs in Hospitals and the Community - England 2021/22. [https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122]
[3] Based on updated DHSC estimates of share of medicine spend and share of branded spend. New approach estimates split of medicine and non-medicine spend in primary and secondary care from the published BSA spend data, and models estimate of branded spend within this.
[4] These are rebates from arrangements NHSE have agreed with pharmaceutical companies in negotiations to commission a variety of treatments both in the cancer drugs fund (CDF) and in routine commissioning. This includes treatments for both rare diseases and more common conditions
[5] NHS Business Services Authority. 2022. Prescribing Costs in Hospitals and the Community - England 2021/22. [https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122]

Statutory Scheme

8. Operating alongside VPAS are statutory regulations (the Statutory Scheme). Companies which choose not to join the voluntary scheme are automatically subject to the Statutory Scheme. There is a general principle of broad commercial equivalence between the voluntary and Statutory Schemes, with growth in allowed sales in the Statutory Scheme, being 1.1% nominal p.a. since 2019 (compared to 2% in VPAS).

9. Broad commercial equivalence does not require the schemes to be identical, but to achieve comparable terms to the Voluntary Scheme. In practice, this has been achieved by limiting the growth rate of branded health service medicines sales in the Statutory Scheme to the average annual growth rate agreed in the 2014 to 2018 voluntary scheme of 1.1% per annum (compared to 2% in VPAS). Furthermore, there are benefits that were included in the voluntary scheme from 2019 to 2023 but not for the Statutory Scheme, namely the exemption from eligible sales of New Active Substances (NAS) and Medium Sized Company (MSC) Exemption and the exemption from measured and eligible sales for centrally procured vaccines (CPV) and exceptional central procurement (ECP).

10. Note this statutory scheme proposal is intended to act as both analternative to a future voluntary scheme and as a standalone proposal in the event of no voluntary scheme being agreed. As a result some benefits that were previously only included in the voluntary scheme have been replicated in the proposed statutory scheme, namely the exemption from eligible sales of NAS Exemption and exemption from measured and eligible sales for CPV and ECP.

11. The Statutory Scheme payment percentage for 2023 was calculated at 27.5% (on average for the year, in practice this equated to payment percentages of 24.4% and 28.6% in Q1 2023 and Q2-Q4 2023 respectively) based on data up to September 2022. In the absence of further legislation, the 27.5% payment percentage would continue to apply in each year after.

12. 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.

13. Previous Statutory Scheme IAs 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. There are now no relevant extant framework sales, so there is no impact on our conclusions or results from this category of sales.

Key concepts

14. There are a number of key concepts used in this IA:

    - **Measured Sales**: Overall sales of branded medicines to the NHS (measured by combining relevant sales across VPAS, Statutory Scheme and Parallel Imports). Certain exemptions from measured sales exist under the current Statutory Scheme. Additionally, the preferred option introduces further exemptions compared to the BAU scenario. See the Forecast Measured Sales and Description of Policy Option sections below, which provide further details.
    - **Allowed Sales**: In the policy options, growth in measured sales is designed to be capped at the allowed sales level which grows at 2% nominal p.a., through payments made by branded medicines manufacturers to DHSC. These payments are then passed on to NHS England and the Devolved Administrations.

- **Eligible sales**: Statutory Scheme sales which are subject to the payment percentage. Under the preferred option, some sales will be exempt from having the payment percentage applied to them.
- **Payment percentages**: The proportion applied to manufacturer's eligible sales value to calculate their required payment.

Simplified example of setting payment percentages

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

- Hypothetical forecast **Measured Sales** = £10,000m
- Hypothetical forecast **Allowed Sales** = £9,000m
- Hypothetical required payment (to reduce measured sales to allowed sales) = £10,000m - £9,000m = £1,000m
- Hypothetical forecast **Eligible Sales** = £9,500m
- Hypothetical **payment percentage** = £1,000m / £9,500m * 100 = 10.5%
- Each company would make a payment equal to 10.5% of their eligible sales

15. **For the purposes of this impact assessment, we are assuming all applicable sales will be subject to the Statutory Scheme (rather than any potential future VPAS) from 2024 to 2026.** This is a necessary approach given the current VPAS expires on 31 December 2023. However, **if there is a new voluntary scheme agreed** covering at least the years 2024 to 2026, we anticipate a potentially large proportion of sales would be controlled by the voluntary scheme. For example, currently approximately 95% of sales are made by companies that are members of the 2019 VPAS. We cannot pre-judge the outcome of future Voluntary Scheme negotiations and so do not make assumptions regarding a future Voluntary Scheme or the split of sales between this and a future Statutory Scheme. However, this does illustrate the potential scale to which the estimated impact of adjusting the Statutory Scheme within this impact assessment could be an overestimate if a future Voluntary Scheme were to be agreed.

Problem under consideration and rationale for intervention

16. We aim to maintain affordability of branded medicines spend across the NHS. By controlling growth in the cost of medicines we ensure value for money for the taxpayer and enable the NHS to continue investing in patient access to new medicines. Historically this has been delivered via:
    - Voluntary Schemes of various designs which are agreed between DHSC and NHSE on behalf of Devolved Administrations and industry. Since 2014 these have operated by Government receiving payments from pharmaceutical companies if sales exceed the allowed cap.
    - A Statutory Scheme for branded medicine pricing which applies to companies that do not opt into the Voluntary Scheme.
17. The statutory scheme was last updated in April 2023 when the payment percentage was set to 27.5%. This will continue into future years if no scheme amendments are made, meaning that pharmaceutical companies who are subject to the scheme would continue to make payments at this level. In the event that no successor to VPAS is agreed, all companies would become members of the statutory scheme by default (currently the vast majority of companies are members of VPAS).
18. The policy 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.

19. Pursuing intervention will deliver payment percentages that are set according to a clear and justified methodology. Doing so supports the perceived stability of the UK market and protects from a potential deterioration in industry sentiment towards the UK that might otherwise result from:
    - The roll over of a 2023 payment rate that was set in the context of an extant voluntary scheme; and
    - Included a one-off adjustment of 4.1 percentage points to account for a 2022 scheme amendment.
20. This is against a backdrop of a changing medicine pricing landscape. Pharmaceutical innovations have enabled the effective treatment and prevention of a wide range of illnesses; however, many new medicines have increasingly come with high associated prices. Health systems are witnessing large increases in the cost of certain types of medicines and pharmaceutical pricing is a growing challenge.
21. A further change is the expiry of the current voluntary scheme, VPAS, at the end of 2023. The current Statutory Scheme is considered less able to adapt and continue to meet its objectives in the future - whether this is alongside a successor voluntary scheme or as a standalone scheme in the absence of this.
22. Since 2019 almost all branded sales have been subject to VPAS, which as part of its design has exemptions from payment for certain sales related to specific centrally procured vaccines (CPV) and exceptional central procurement (ECP). These sales would be subject to payment under the current Statutory Scheme despite most if not all of these sales currently being made by members of VPAS where they are exempt. A substantial value of sales would therefore experience a step change from exempt to in scope of payment percentages in the counterfactual. The BAU counterfactual therefore does not reflect the reality that little, if any, income is currently generated from these sales.
23. For CPV and ECP sales by current VPAS members the lack of an exemption in the Statutory Scheme, currently available under VPAS, and payment percentage of 27.5% in the counterfactual effectively equates to an immediate 27.5% reduction in revenue from these sales. Whilst current statutory scheme members have a 27.5% payment percentage set for 2023 already, in VPAS this is slightly lower at 26.5% and sales of NAS are exempt from payment. Sales of NAS products currently made by members of VPAS would therefore see the same associated revenue impact as CPV and ECP sales under the counterfactual.
24. Although this implies little to no direct price impact for sales that do not relate to CPV, ECP or NAS, continuing the 2023 payment percentage in 2024, 2025 and 2026 would fail to reflect more recent sales data, divorcing the payment rate from observed market conditions. Furthermore, as noted the 2023 Statutory Scheme payment percentage included an additional 4.1% points to reflect an agreement to shift a portion of the payment percentage rise for 2022 into 2023 made within VPAS. This was replicated in the Statutory Scheme to maintain broad commercial equivalence between the two.
25. The counterfactual could therefore be considered to over-adjust for this historic transfer of payment between two distinct years and result in an effective decrease in allowed growth for most companies as, since 2019, the majority of sales have been covered by VPAS with a 2% allowed growth rate. This creates a risk of undermining the perceived rationality of the UK market.
26. Conversely, the preferred option would maintain the effective allowed growth for most companies as, since 2019, the majority of sales have been covered by VPAS with a 2% allowed growth rate. It could also support the perceived stability of the UK market and protect from a potential deterioration in industry sentiment towards the UK that might otherwise result from the roll over of a 2023 payment rate.

27. Whilst this increases NHS net-spending on branded medicines compared to the BAU counterfactual it would maintain for most companies, and for the NHS, broadly the same commercial terms that have operated since 2019. The Government believes this demonstrates an appropriate balance between the scheme objectives.

28. We have identified and assessed the impacts on the key affected groups noted below:

    - NHS organisations.
    - The pharmaceutical/life sciences industry and its shareholders.
    - NHS patients.
    - The UK economy.

29. The regulation under consideration in this impact assessment only impacts companies which choose to sell to the NHS. The Department therefore considers the proposals to be in connection with procurement as set out in section 22 of the Small Business Enterprise and Employment Act 2015[6]. As such, the Statutory exclusion "Procurement 22(4)(b)" applies to the proposals, and they are deemed to be exempt from the Better Regulation Framework[7].This position has been confirmed previously by the Economic and Domestic Affairs Secretariat at Cabinet Office.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

30. We have used the latest data available to us to underpin the calculations set out in this impact assessment. This is constrained by the timetable of companies submitting data returns under the terms of the current VPAS and Statutory Scheme.

31. The appraisal period is three calendar years. This reflects the inherent uncertainty surrounding forecasting medicines sales and is consistent with the timeframe covered by the 2018 Statutory Scheme impact assessment[8]. The three year appraisal period also covers the lifetime of the Regulations proposed, which would set the payment percentage for 2024, 2025 and 2026.

32. Where assumptions have been applied these will be identified and described throughout at the point of use. A key aspect of the analysis is DHSC's forecast of future growth in branded medicines spend. This is inherently uncertain and as a result we present low, mid and high scenario estimates of impacts.

33. The option of introducing a Lifecycle Adjustment was considered at consultation stage however, we are not proceeding with this option. Respondents to the consultation raised a number of questions about the version of the LCA proposed in the consultation as an initial policy proposal. The Department remains open to potentially implementing a version of a Lifecycle Adjustment mechanism in the statutory scheme in the future subject to further consideration and policy development.

34. Under the preferred option there is a new exemption from both growth measurement and scheme payment for sales relating to centrally procured vaccines (CPV) and exceptional central procurement (ECP). These sales are exempted under the current VPAS. The purpose of the CPV exemption is to support the UK in maintaining access to specific vaccines; and the purpose of the ECP exemption is to support an effective supply of medicines in preparation for or in response to pandemic situation (whilst ensuring Government decisions about when stockpiles for pandemic preparedness should be purchased does not impact the payment percentage).

[6] Small Business, Enterprise and Employment Act 2015. 2015. [https://www.legislation.gov.uk/ukpga/2015/26/section/22/enacted]
[7] Department for Business, Energy & Industrial Strategy. 2020. Better Regulation Framework: Interim Guidance. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/916918/better-regulation-guidance.pdf]
[8] The Branded Health Service Medicines (Costs) (Amendment) Regulations 2023. 2023. [https://www.legislation.gov.uk/uksi/2023/239/regulation/2/made]

35. These exemptions (in VPAS) functioned effectively during the Covid-19 pandemic and helped to facilitate the supply of vaccines and emergency procurements. Government considers that, in order to provide certainty about the future of these exemptions, there is a case for their inclusion in the statutory scheme.

Summary of consultation responses

36. We received a total of 102 responses to the consultation, mostly from the pharmaceutical industry. More detail is set out in the consultation response, however, respondents:

- strongly support maintaining broad commercial equivalence between the statutory scheme and any voluntary scheme agreed in principle
- raised concerns about the proposals for LCA on both principled and practical grounds, including about the operational viability of the mechanism proposed. Several respondents did though indicate support for the principle of ensuring sustainable spending on older medicines by setting higher payment rates for older products where competition is not acting effectively to reduce prices.
- raised concerns about the level of allowed growth and resulting payment percentages proposed. They argued that 2% allowed growth was too low, would damage the UK life sciences sector and would signal that government is not prepared to pay a fair price for medicines. They argued that this, in turn, would negatively impact the launch of medicines and deter investment in the UK. Many responses criticised economic analysis of the proposals in the impact assessment, arguing that it was too limited in both its scope and the options considered, or that the assumptions it made were incorrect.
- mostly strongly supported the proposed exemptions but argued that more generous or further exemptions were necessary.

Description of options considered

37. At final stage, Option 1b is progressed as the preferred option. This was selected rather than option 1a as introducing an exemption for New Active Substances is preferred due to the commercial incentives it provides for developing innovative medicines. The option of introducing a Lifecycle Adjustment was considered at consultation stage however, we are not proceeding with this option as it is not deemed desirable in the Statutory Scheme for 1 January 2024. Respondents to the consultation raised a number of questions about the version of the LCA proposed in the consultation as an initial policy proposal.

38. That said, the Department would remain open to potentially implementing a version of a Lifecycle Adjustment mechanism in the future. Our aim is to update the payment percentages to take account of the latest data and the context of the 2019 VPAS expiring at the end of 2023. In doing so we ensure that payment percentages are set according to a clear and justified methodology and ensure the fixed payment rates under BAU do not continue into 2024. Doing so supports the perceived rationality of the UK market and protects from a potential deterioration in industry sentiment towards the UK that might otherwise result from:

- The roll over of a 2023 payment rate that was set in the context of an extant voluntary scheme; and
- with a one-off adjustment of 4.1 percentage points to account for a 2022 scheme amendment.
- **Business as Usual (BAU)** – the current regulations remain in force with a payment percentage of 27.5%[9] in each of the three years covered by this appraisal period and no change to exemptions.

[9] The Branded Health Service Medicines (Costs) (Amendment) Regulations 2023. 2023. [https://www.legislation.gov.uk/uksi/2023/239/regulation/2/made]

- **Preferred option (1b)** – maintain the structure of the current Statutory Scheme, introduce an exemption from eligible sales for New Active Substances (NAS) for 36 months from its first Marketing Authorisation (MA, introduce exemptions from measured sales for CPV and ECP and increase the allowed growth cap to 2% per annum.
- **Option 1a** (not progressed) – maintain the structure of the current Statutory Scheme, introduce exemptions from measured sales for centrally procured vaccines (CPV) and exceptional central procurements (ECP) and increase the allowed sales cap growth to 2% per annum.
- **Option 2a** (not progressed) – introduce a new Lifecycle Adjustment structure with 2% allowed growth per annum where a greater proportion of payments are required from older products without competition and exemptions from measured sales for CPV and ECP.
- **Option 2b** (not progressed) – introduce a new Lifecycle Adjustment structure with 2% allowed growth per annum where a greater proportion of payments are required from older products without competition, exemptions from measured sales for CPV and ECP and a 36 month from MA exemption from eligible sales for NAS.

39. The Business as Usual option reflects a payment percentage of 27.5% as, under the existing regulations, this is the payment percentage that would apply if no further intervention was pursued. This is the appropriate counterfactual in-line with guidance set out in HM Treasury's Green Book[10] which states at paragraph 4.8:

    "Business As Usual (BAU) in Green Book terms is defined as the continuation of current arrangements, as if the proposal under consideration were not to be implemented. This is true even if such a course of action is completely unacceptable. The purpose is to provide a quantitative benchmark, as the "counterfactual" against which all proposals for change will be compared."

40. The proposed options are evaluated for the period from 1st January 2024 (the point at which the new Regulations would enter force) to 31st December 2026. If no change was made the Regulations before December 2023, the current Statutory Scheme including its payment percentage of 27.5% and current exemptions, would continue in each year after.

41. The preferred option includes a 2% allowed growth rate per annum, an increase from the 1.1% that applied in the statutory scheme between 2019 and 2023. Raising the allowed growth rate above 2% per year increases the risk that net spend on branded medicine rises to the extent that there is resultant unsustainable budget pressure on the NHS. This could negatively impact the delivery of NHS services, and therefore patient outcomes.

42. There are no non-regulatory options considered within this IA. This reflects that a future voluntary scheme (i.e., a non-regulatory option) would be agreed through negotiations with industry. The Statutory Scheme will apply to any companies that do not choose membership of a future voluntary scheme if agreed, or to all sales of in-scope branded medicines if no future voluntary scheme can be agreed in negotiations.

Lifecycle Adjustment mechanism: background and rationale

43. The option of introducing a Lifecycle Adjustment was considered at consultation stage however, we are not proceeding with this option The Department however notes that, whilst on the basis of consultation responses and the progress of voluntary scheme negotiations the Lifecycle Adjustment mechanism is not deemed desirable in the Statutory Scheme for 1 January 2024, it remains committed to the principle of ensuring sustainable spending on older medicines and open to the future implementation within the Statutory Scheme of policies designed to achieve this – including those required to maintain broad commercial equivalence with any future voluntary scheme.

[10] HM Treasury. 2022. The Green Book: appraisal and evaluation in central government. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063330/Green_Book_2022.pdf]

44. The medicines market relies on the "innovation paradigm", meaning that new medicines achieve high prices at the start of their lifecycle, but low towards the end. This means new innovations are awarded Intellectual Property (IP) protection that enables them to command this high price, typically above the opportunity cost to the NHS. and older medicines are expected to face price competition from generics and biosimilars, resulting in prices falling towards the cost of supply, and below the opportunity cost to the NHS. Whilst this system has been instrumental in enabling innovation in and patient access to medicines, it does not always operate exactly as intended due to the complexities of the medicines market. For instance, in VPAS presentation level returns for 2021[11] a large proportion of sales through products launched before 2009 had data submitted by a single supplier only. Lack of price competition in older products could increase the cost of medicines to the NHS and so increase scheme payment percentages, including those paid by newer innovations.

45. The current statutory scheme largely operates on a one-size-fits-all basis, other than where an exemption applies, with the same payment percentage charged regardless of how long a medicine has been on the market or whether that medicine is subject to competitive pressure on prices.

46. In the consultation, Government proposed consideration of options for how the statutory scheme payment percentages are set to distinguish between medicines at different stages in the product lifecycle or subject to different levels of competition. The aim of the proposals was to support the innovation paradigm by allowing for higher prices for new originators but expecting lower prices for older products.

47. The consultation tested the proposal that, by requiring additional payments from older products in markets where there appears to be little or no competition, we can create financial headroom to reduce the payments required on new innovations or older products in more competitive markets. If achieved this would be a pro-innovation and pro-competition measure and would support our objective of rewarding the use of both innovative and competitive medicines in the UK.

48. The consultation therefore considered the introduction of a Lifecycle Adjustment mechanism (LCA) that would apply to older medicines only. Under the consultation proposals products subject to the LCA would be liable for a higher "supplemental" payment percentage if operating in a market with lower competition, and a lower payment percentage if operating in a more competitive market. The intention of the proposals was that the additional revenues generated from older products in less competitive markets would allow for a reduction in the headline payment percentage paid by new originator products, whilst still controlling overall sales growth to 2% each year.

49. Respondents to the consultation raised a number of questions about the version of the LCA proposed in the consultation as an initial policy proposal. Policy options require further consideration, including to understand the implications of any model proposed or implemented through voluntary scheme negotiations. Government will consider the consultation responses – in particular with respect to whether competition at Virtual Medicinal Product (VMP) level is the most appropriate mechanism for allocating payment percentages to older products.Furthermore, Government will consider evidence provided about the potential impact of these and any future older products proposals on the market for unbranded medicines and parallel imports, including risks related to de-branding, and whether action would be required with respect to these markets to mitigate.For this reason, option 1b is our preferred option at this moment in time.

Policy objective

50. The objectives of the Statutory Scheme remain unchanged, i.e.:

- 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

[11] Note these remain incomplete (coverage estimated at circa 80%) and unvalidated.

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

51. The Department considers that, by updating the Statutory Scheme to take account of the latest data and the context of the 2019 VPAS expiring at the end of 2023, we ensure that payment percentages are set according to a clear and justified methodology. Doing so supports the perceived rationality of the UK market and protects from a potential deterioration in industry sentiment towards the UK that might otherwise result from the roll over of a 2023 payment rate that was set in the context of:

    - An extant voluntary scheme; and
    - A one-off adjustment of 4.1 percentage points to account for a 2022 scheme amendment.

52. Updating the Statutory scheme this way is considered to be more compatible with the latter two policy objectives.

Summary and preferred option with description of implementation plan

53. The preferred option is to update the Statutory Scheme so that it retains its current structure and:

    - Payment percentages are recalculated based on an allowed level of growth from the calculated 2023 starting point rather than remaining fixed at 27.5%.
    - The allowed growth in measured sales is equivalent to nominal 2% per annum.
    - The exemption from measured and eligible sales for CPV and ECP and from eligible sales only for New Active Substances (NAS) currently applied in VPAS are introduced in the Statutory Scheme.

54. The preferred option will be given effect via secondary legislation and there is no proposal to implement transitional arrangements. The intervention would support the Statutory Scheme objectives of ensuring medicines are available on reasonable terms, accounting for the costs of research and development. And to deliver cost control and value for money for the NHS in a way consistent with supporting both the life sciences sector and broader economy.

55. The arrangements are proposed to come into effect from 1 January 2024. The Department would continue to be responsible for the ongoing operation and enforcement of the Statutory Scheme.

56. As has been the case with the current Statutory Scheme, if subsequently received actual sales data is not consistent with the payment percentages calculated (based on forecasts grounded in currently available data) these may be reviewed. If review suggests change to the payment percentages, this could be pursued via a further secondary legislation amendment which would be subject to consultation.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

57. In line with Green Book guidance, the preferred option is assessed against the counterfactual BAU option of continuing 27.5% payment percentages as per the current Regulations. The impacts on each key group identified previously are considered in turn before being aggregated into an overall Net Present Value (NPV) assessment.

58. We first describe establishing the 2023 allowed sales baseline and how measured sales are forecast to grow from this in each of our forecast scenarios. The aggregate cost and benefits appraisal is then summarised followed by a more in-depth assessment of the preferred option.

Risks and assumptions

59. This section details the risks associated with the appraisal of the proposed options. The detail of assumptions used is discussed throughout the IA so that information is not repeated here though a summary table is provided.

60. There are significant uncertainties associated with forecasting branded medicine sales growth which increase as the forecast progresses over time. For this reason, the appraisal period is limited to three years, and we present low, mid and high forecast scenarios. Although the mid forecast is used for the "best estimate" presented, all three are considered similarly plausible.

61. The preferred option has a significantly negative associated societal NPV. This reflects the fact that payment percentages are lower in almost all cases compared to the BAU counterfactual. Additionally, two categories of products that are in scope of the current Statutory Scheme and exempt from VPAS are proposed to be exempt from the future Statutory Scheme. This accounts for over half of the negative societal NPV despite the exemption of these sales from VPAS meaning it is currently likely little, if any, income is generated from these sales.

62. The lower payment percentages are further driven in part by the latest data indicating a slowdown in branded medicine sales growth in Q2 2023, which was not available at the time the current Statutory Scheme payment percentage was calculated. However, comparing with the consultation stage where Q4 2022 sales data were used, parallel import sales were updated to reflect our best understanding of the data from 2018, and the removal of an element of double counting as a result. As the removal was uneven throughout the years, the payment percentages slightly increased for this final stage impact assessment.

63. The 2023 payment percentage also included an adjustment of 4.1% points to maintain broad commercial equivalence with VPAS where agreement was made to defer some of the increase in 2022 payment percentages into 2023. Continuing with a payment percentage that includes this adjustment element may control future sales to a lower level of growth than intended and thereby may not support the perceived rationality of the UK market, with potential deterioration in industry sentiment towards the UK a possible result.

64. The proposed options all include an increase in the allowed growth rate from 1.1% as in the current scheme to 2% per annum from a 2023 allowed sales baseline. This is consistent with the approach underpinning the current Statutory Scheme's 1.1% allowed growth, i.e., it equals the average allowed growth of the preceding voluntary scheme. Calculation of the allowed sales starting point in 2023 is described in the later "Establishing a forecast allowed sales 2023 baseline" section.

65. The Department has a well-established process to consider list price changes and the NHS to consider net price changes where they are warranted, as well as processes to maintain continuity of supply of medicines.

66. The Department's Medicine Supply Team works closely with MHRA, the pharmaceutical industry, NHS England and others operating in the supply chain to help prevent shortages and to ensure that risks to patients are minimised.

Table 1: Summary of assumptions used in appraisal

Assumption	Used in	Source
Low forecast branded spend growth	Sales forecast, required payment and payment percentage calculation	• DHSC medicine spend forecast • DHSC measured sales figures as of Q2 2023
Central forecast branded spend growth		
High forecast branded spend growth		
10% of industry revenue impacts accrue to UK shareholders	Wider economic impacts	• Historic UK output from the ONS Annual Business Survey • Import/export data from UK overseas trade in goods statistics[12]
25% of industry revenue impacts invested globally*		• ONS Business Enterprise Research & Development (BERD) time series and upper end of OLS advised range
3.1% UK share of global investment*		• Literature review
30% spillover effects of investment*		• Literature review

* Used in illustrative only assessment of possible investment effects, not part of the key monetised impacts or the NPV.

Forecast measured sales

67. The detailed description of DHSC's medicine spend forecast methodology and the assumptions underpinning our forecast scenarios is provided in annex A. This section sets out how measured sales estimates are derived, and the forecast growth rates subsequently applied to these in each scenario.

68. Measured sales includes all sales of scheme products by companies in scope of the Statutory Scheme, plus parallel import sales. Note for the purposes of this impact assessment we are assuming all applicable sales will be subject to the Statutory Scheme (rather than any potential future voluntary scheme). Sales that are excluded from measured sales in both the BAU counterfactual and proposed options are:

    - **Low value sales** – products with an NHS list price of less than £2 per pack; and
    - **Small company sales** – sales by companies whose total sales of scheme products are less than £5m in the calendar year preceding the relevant calendar year.

69. Measured sales that are included in the BAU counterfactual and excluded in the proposed options are:

    - **Centrally procured vaccines (CPV)** – vaccines procured for use in national immunisation programmes that are recommended or advised by the Joint Committee on Vaccination and Immunisation (JCVI), and which have been purchased by central government and managed by the UK Health Security Agency (UKHSA) or a successor body.
    - **Exceptional central procurement (ECP)** – medicines procured for the purposes of emergency preparedness, stockpiling for national security or pandemic preparation, and which have been purchased by central government and managed by the UK Health Security Agency (UKHSA) or a successor body.

[12] ONS Annual Business Survey (2021) Standard Indistrial Classification (SIC) 21 manufacture of basic pharmaceutical products and pharmaceutical preparations. HMRC Trade data for UK overseas trade in goods statistics. UK production consumed domestically divided by Total UK consumption of pharmaceuticals (UK production consumed domestically + Pharmaceutical imports)gives the proportion of UK consumption produced in the UK. For 2021 (the last year we have complete data for) this proportion was 8.4% which supports the continued use of the 10% assumption.

70. VPAS currently provides exemptions where medicines are procured by central government, specifically vaccines and those purchased for emergency use. These exemptions are known as Centrally Procured Vaccines (CPV) and Exceptional Central Procurements (ECP). These purchases are made by central government bodies and not the NHS[13]. The purpose of the exemptions is to facilitate the UK's vaccine supply and support emergency (such as pandemic) preparedness. The current Statutory Scheme does not exempt these sales and therefore neither does our BAU counterfactual.

71. This introduces further uncertainty into the BAU counterfactual forecast as sales classified within the CPV and ECP categories have not been forecast for these purposes previously. In the initial consultation stage impact assessment we assumed our forecast growth in branded medicines spend was reasonably applicable to these product groups and noted our intention to verify and update this if required. For this final stage impact assessment we have consulted with the relevant parties at UKHSA and produced an estimated forecast growth rate tailored to these groups based on expected continuation of current programmes and procurements of new programmes in these product groups.

72. These exemptions (in VPAS) during the Covid-19 pandemic and helped protect supply and maintain market stability. They are likely to support ongoing vaccine supply and future emergency preparedness. Government considers that, in order to provide certainty about the future of these exemptions given VPAS expires 31 December 2023, there is a case for their inclusion in the statutory scheme.

73. This change would mean that sales classified as ECP or CPV would not count towards measured sales in the proposed options for the Statutory Scheme. They would therefore not affect the level of measured growth in the scheme, which features in the payment percentage calculation, nor would Statutory Scheme members be required to make payments on their sales of ECPs and CPVs.

74. To demonstrate the scale of impact this could have, we have constructed scenarios for the impact on implied allowed growth under a cap scenario. Please note these are purely illustrative as the BAU counterfactual has a fixed payment percentage.

75. If we add forecast 2023 CPV and ECP sales to both allowed and measured sales the implied compound annual growth allowed between 2024 and 2026 is slightly higher than 2% irrespective of forecast scenario:

    - Low forecast scenario 2.02%.
    - Central forecast scenario 2.03%.
    - High forecast scenario 2.04%.

76. If the required payment from sales of CPV and ECP is added on to all other required income with no change to allowed sales the implied compound annual growth allowed between 2024 and 2026 is at around 2% irrespective of forecast scenario:

    - Low forecast scenario 1.99%.
    - Central forecast scenario 2.05%.
    - High forecast scenario 1.91%.

77. The resulting forecast for measured sales in the BAU counterfactual and under our proposed policy options (for the latter these are equivalent across the options) is shown in the table below.

[13] Note that under business-as-usual arrangements any income generated by payments on sales of these products would flow to DHSC and be apportioned between the NHS and Devolved Administrations. Any different arrangements where income could be transferred to the Central Government Body making the purchase would represent a departure from standard practice. Therefore, this loss of income versus the counterfactual is translated into the societal value of QALYs foregone in our appraisal.

Table 2: Forecast measured sales – BAU vs proposed options

		2024	2025	2026
Low Scenario	BAU measured sales forecast £m	19,760	19,830	20,590
	Preferred option measured sales forecast £m	14,910	15,500	16,280
	Difference £m	-4,850	-4,330	-4,310
Central Scenario	BAU measured sales forecast £m	19,900	20,100	21,040
	Preferred option measured sales forecast £m	15,020	15,710	16,640
	Difference £m	-4,880	-4,390	-4,410
High Scenario	BAU measured sales forecast £m	20,050	20,390	21,550
	Preferred option measured sales forecast £m	15,130	15,940	17,040
	Difference £m	-4,920	-4,460	-4,520

Numbers may not sum due to rounding (rounded to nearest £10m).

Summary of aggregate costs and benefits

78. As noted previously, continuing to apply the payment percentage calculated for 2023 in 2024, 2025 and 2026 is not considered to fully support the Statutory Scheme's latter two objectives or to be reflective of the changing environment.

79. Based on the latest available data and removing the adjustment relating to previous year's under-payments, the average 2023 Statutory Scheme payment percentage would be 21.2% (with a profile of 24.4% in Q1 and 20.0% from Q2 to Q4). Furthermore, the policy options propose an increase in the allowed growth rate from 1.1% in the current Statutory Scheme to 2% per annum going forwards and to exempt sales relating to CPV and EPC.

80. The preferred option (1b) therefore has a significantly negative associated societal NPV. This reflects the fact that payment percentages are lower compared to the BAU counterfactual. This is because under latest data the payment percentages would be lower than currently set. The 2023 payment percentage also included an adjustment of 4.1% points to maintain broad commercial equivalence with VPAS where agreement was made to defer some of the increase in 2022 payment percentages into 2023. Finally because of the introduction of the CPV and ECP exemption in the preferred option there is no income recouped on sales of these products whereas under the BAU scenario there would be. In reality the majority if not all of sales of these product groups are made by VPAS members and so there is no real income lost. These reduced payment percentages increase costs which we convert into societal value QALY's foregone due to increased cost. This can be viewed in the context that we would expect the cost-per-QALY of new medicines to be higher than the general marginal cost-per-QALY because medicines will be sold at a premium during the period of patent protection. The NHS subsequently benefits from purchasing medicines at far lower cost-per-QALYs following patent expiry. This is because the medicines market relies on the "innovation paradigm" explained in paragraph 44. The negative NPV is in part due to the baselining effects of how we are considering CPV/ECP and we anticipate would be substantially reduced in the event of a new voluntary scheme agreement. Furthermore, given considerations about the sustainability of the counterfactual payment percentage, and associated risk, we consider it appropriate to to proceed with the preferred option.

81. There are also unquantified benefits in ensuring payment percentages are set according to a clear and justified methodology. Doing so supports the perceived rationality of the UK market and protects from a potential deterioration in industry sentiment towards the UK that might otherwise result from the roll over of a 2023 payment rate that was set in the context of an extant voluntary scheme and with a one-off adjustment of 4.1 percentage points to account for a 2022 scheme amendment.

82. Because the future growth in branded medicines spend is inherently uncertain we present low, central, and high forecast scenarios. For details of the forecast methodology and assumptions underpinning each scenario please see annex A. Whilst the central is presented as the "best estimate" each of the scenarios is considered broadly similar in plausibility.

83. Rows from the summary table that feature in the overall NPV are flagged (NPV) in the “impact on” column and all figures are rounded to the nearest £10m in this high level summary. More granular figures are provided in the assessment of specific options sections.

84. Although initially counter-intuitive, note that the overall NPV becomes less negative in scenarios with higher forecast growth in branded medicines spend. This is because the preferred option operates with a dynamic payment percentage calibrated to 2% allowed nominal growth, whereas the BAU option has a fixed payment percentage. In dynamic cap scenarios payment percentages, and therefore income generated, rise with higher rates of branded medicine spend growth to recoup all spend above the allowed level, whereas fixed payment percentages do not change.

Table 3: Summary of aggregate costs and benefits between BAU and option 1b

Impact on	Description of impact	Cumulative low scenario	Cumulative mid scenario	Cumulative high scenario
NHS finances	Increased cost of branded medicines as reduced payment percentages increase costs	£5,930m	£5,530m	£5,080m
NHS patients (NPV)	Societal value QALYs foregone due to increased cost	£26,520m	£24,740m	£22,720m
NHS patients	Support to continuing/improving access to innovative branded medicines	Unquantified – patient benefits in supporting continued access to new and innovative medicines, via introduction of a NAS exemption		
NHS patients	Continue supporting patient access to cost-effective medicines	Unquantified – Patients will benefit from a scheme that sets payment rates to achieve predictable and sustainable growth in net sales of medicines so as to support ongoing access to cost-effective medicines.		
NHS patients	Ongoing support to vaccine supply and future emergency preparedness	Unquantified – patient benefits in terms of supporting access to vaccines generally and supporting future emergency preparedness		
Pharmaceutical / life sciences industry	Increased profit on UK sales of branded medicines driven by reduced payment percentages	£5,930m	£5,530m	£5,080m
Pharmaceutical / life sciences industry UK shareholders (NPV)	Increased profit on UK sales of branded medicines driven by reduced payment percentages accruing to UK shareholders	£540m	£500m	£460m
Overall quantified NPV		**-£25,980m**	**-£24,230m**	**-£22,260m**

Table 4: BAU expected income

		2024	2025	2026	Cumulative
Low Scenario	Total £m	5,210	5,230	5,440	15,880
	Of which is from CPV and ECP £m	1,330	1,190	1,180	3,710
Central Scenario	Total £m	5,250	5,310	5,560	16,110
	Of which is from CPV and ECP £m	1,340	1,210	1,210	3,760
High Scenario	Total £m	5,290	5,390	5,700	16,380
	Of which is from CPV and ECP £m	1,350	1,230	1,240	3,820

Numbers may not sum due to rounding (rounded to nearest £10m).

Establishing a forecast allowed sales 2023 baseline

85. The preferred option has a financial envelope equivalent to nominal allowed sales growth of 2% per annum from 2023. Furthermore, we are assuming that all companies could be subject to the Statutory Scheme from 2024. This differs from the current situation where companies can be members of VPAS or Statutory Scheme with 2% and 1.1% allowed growth respectively.

86. Therefore, we need to calculate a new allowed sales 2023 baseline from which to forecast allowed sales in 2024, 2025 and 2026. It is not the intent of the Statutory Scheme to "clawback" the difference in allowed sales between VPAS and the Statutory Scheme between 2019 and 2023. Therefore, establishing a baseline allowed sales by uprating total allowed sales in 2018 by 1.1% was rejected.

87. The situation is further complicated by scheme movers across the current VPAS period 2019 to 2023. We therefore estimated an allowed sales baseline by uprating 2018 total allowed sales by 1.96% per annum. This is the weighted average of the allowed 1.1% and 2% growth rates when we apply the proportion of sales expected within the Statutory Scheme and VPAS in 2023. Under this approach **our starting point in 2023 for allowed sales is £11.6bn under the proposed options.**

Table 5: Allowed sales at all proposed options

	2023	2024	2025	2026
Allowed sales £m	11,596	11,827	12,064	12,305

Option 1a – not progressed

88. Under option 1a, the structure of the current Statutory Scheme would remain unchanged in that it would operate with an allowed growth cap from the 2023 starting baseline described previously. The key differences are the starting baseline estimated for 2023 described previously, the application of a 2% per annum nominal allowed growth rate from this and the exclusion of CPVs and ECPs from both measured and (by default) eligible sales.

89. All sales in scope of the Statutory Scheme would be subject to the same payment percentage, calculated as:

$$\frac{(Measured\ sales - Allowed\ sales) \times \frac{Statutory\ scheme\ measured\ sales}{Measured\ sales}}{Statutory\ scheme\ eligible\ sales}$$

90. Under option 1a, Statutory Scheme measured sales and Statutory Scheme eligible sales are identical. Nominal forecast measured and allowed sales plus the implied required income in each forecast scenario were presented in the previous forecast measured sales section. This is not repeated here and instead group specific impacts of the aggregate change are considered.

91. We are not proceeding with this option as it does not include an exemption for New Active Substances as options 1b and 2b do. This exemption is geared to incentivising the launch of new and innovative products in the UK. It provides strong commercial incentives for the launch of new products in the form of freedom of list pricing and exemptions from payments for innovative medicines containing NAS.

Option 1b – preferred option

92. Under the preferred option 1b, the structure of the current Statutory Scheme would again remain unchanged in that it would operate with an allowed growth cap from the 2023 starting baseline described previously. Like option 1a, 2% per annum nominal allowed growth is applied from the starting 2023 baseline and CPVs and ECPs are excluded from both measured and (by default) eligible sales.

93. The key difference from option 1a is that a group of products termed 'New Active Substances' (NAS) are also excluded from eligible sales for 36 months from Marketing Authorisation (MA). This exemption is geared to incentivising the launch of new and innovative products in the UK and as such supports the schemes objectives inrelation to patients access to innovative medicines.

94. NAS sales are currently exempted from VPAS which includes strong commercial incentives for the launch of new products in the form of freedom of list pricing and exemptions from payments for innovative medicines containing NAS. In view of this incentive and the fact that the majority of companies are VPAS members, the exemption from eligible sales is replicated in the Statutory Scheme under this option to continue the pro-innovation approach, the regulations already permit the department to include NAS status as a consideration when setting a list price.

95. The calculation of the payment percentage does not alter between option 1a and option 1b, though the latter results in greater payment percentages as the same payment is being drawn as in option 1a but from a smaller value of eligible sales (due to the NAS exemption in option 1b):

$$\frac{(Measured\ sales - Allowed\ sales) \times \frac{Statutory\ scheme\ sales}{Measured\ sales}}{Statutory\ scheme\ eligible\ sales}$$

NHS finances

96. Under option 1b income to the NHS of around £9.9bn to £11.3bn is generated over the three year appraisal period. This equates to a reduction in income for the NHS of between £6.3bn and £5.3bn over the three year appraisal period compared to the counterfactual.

97. The NAS exemption in option 1b has very little impact on the income, though does increase the payment percentage, with any small differences in income being due to the rounding of the payment percentages to one decimal place. The NPV of the cost of option 1b is calculated in the same manner as outlined previously in option 1a.

Table 6: Option 1b Payment percentage and expected income

		2024	2025	2026	Cumulative
Low Scenario	Payment percentage	21.3%	22.7%	25.0%	
	Income forecast £m	2,920	3,250	3,770	9,950
Central Scenario	Payment percentage	21.9%	24.0%	26.8%	
	Income forecast £m	3,010	3,460	4,110	10,580
High Scenario	Payment percentage	22.6%	25.3%	28.9%	
	Income forecast £m	3,120	3,680	4,500	11,300

Numbers may not sum due to rounding (rounded to nearest £10m).

Table 7: Monetising QALYs foregone option 1b

	2024	2025	2026	Cumulative
Low Scenario				
Change in income vs BAU £m	-2,290	-1,980	-1,660	-5,930
QALYs foregone @ £15k/QALY	152,450	132,040	110,990	395,470
Nominal societal value @ £70k/QALY £m	10,670	9,240	7,770	27,680
Present value QALYs foregone £m	10,360	8,840	7,320	26,520
Central Scenario				
Change in income vs BAU £m	-2,240	-1,840	-1,450	-5,530
QALYs foregone @ £15k/QALY	149,040	122,720	96,940	368,700
Nominal societal value @ £70k/QALY £m	10,430	8,590	6,790	25,810
Present value QALYs foregone £m	10,130	8,220	6,390	24,740
High Scenario				
Change in income vs BAU £m	-2,170	-1,700	-1,200	-5,080
QALYs foregone @ £15k/QALY	144,900	113,630	79,920	338,460
Nominal societal value @ £70k/QALY £m	10,140	7,950	5,590	23,690
Present value QALYs foregone £m	9,850	7,610	5,270	22,720

Numbers may not sum due to rounding (rounded to nearest 10 QALYs or £10m).

Pharmaceutical industry and its shareholders plus wider economic impacts

98. The principal impact of the proposed option 1b for the pharmaceutical industry is that payment percentages reduce to reflect an allowed growth rate of 2% from a 2023 allowed sales baseline which exclude NAS, CPV and ECP sales. All companies and in-scope products would continue to pay the same payment percentage with the exception of NAS, CPV and ECP sales which would move to be exempt from the Statutory Scheme.

99. This drives a reduction in the income required from industry across the three year appraisal period compared to the counterfactual. A proportion of this increase in profit will accrue to UK shareholders and therefore be counted within the NPV calculated for the proposal. As noted previously, we continue to use a legacy assumption that around 10% of drug spend is on UK domestic production, i.e., output generated by UK factors of production (UK-owned capital or UK labour).

100. 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.

101. Table 8 below sets out the estimated financial benefit to the pharmaceutical industry under option 1b, our estimate of the UK shareholder element of this for inclusion in the NPV and its present value. These are all calculated as described in the “evidence underpinning wider economic impacts” annex.

Table 8: Pharmaceutical industry financial impacts option 1b

	2024	2025	2026	Cumulative
Low Scenario				
Revenue benefit for industry £m	2,290	1,980	1,660	5,930
Of which accrues to UK shareholders £m	230	200	170	590
Present value industry financial impacts £m	210	180	150	540
Central Scenario				
Revenue benefit for industry £m	2,240	1,840	1,450	5,530
Of which accrues to UK shareholders £m	220	180	150	550
Present value industry financial impacts £m	210	170	130	500
High Scenario				
Revenue benefit for industry £m	2,170	1,700	1,200	5,080
Of which accrues to UK shareholders £m	220	170	120	510
Present value industry financial impacts £m	200	150	100	460

Numbers may not sum due to rounding (rounded to nearest £10m).

Impact on patients

102. Patients will benefit from a scheme that sets payment rates to achieve predictable and sustainable growth in net sales of medicines so as to support ongoing access to cost-effective medicines.

103. The unquantified benefit around supporting access to new and innovative products may be enhanced due to the addition of an exemption from eligible sales for NAS.

Table 9: Overall NPV benefit option 1b

	2024	2025	2026	Cumulative
Low scenario £m	-10,140	-8,660	-7,170	-25,980
Central scenario £m	-9,920	-8,050	-6,270	-24,230
High scenario £m	-9,640	-7,450	-5,170	-22,260

Numbers may not sum due to rounding (rounded to nearest £10m).

Option 2a – not progressed

104. Under option 2a, the structure of the Statutory Scheme would differ from the current approach, notably with the inclusion of a “Lifecycle Adjustment” (LCA) methodology. Under the proposed LCA there would have been differential payment percentages for older products, depending on their level of competition, and newer products.

105. We are not proceeding with this option as it does not include an exemption for New Active Substances as option 1b and 2b do. This exemption is geared to incentivising the launch of new and innovative products in the UK. It provides strong commercial incentives for the launch of new products in the form of exemptions from payments for innovative medicines containing NAS.

Option 2b – not progressed

106. The basic structure of option 2b is similar to option 1b in that 2% per annum nominal allowed growth is applied from the starting 2023 baseline and CPVs and ECPs are excluded from both measured and (by default) eligible sales. As well as the inclusion of a NAS exemption from eligible sales.

107. The key difference from the current approach and option 1b is the inclusion of a “Lifecycle Adjustment” (LCA) methodology. Under LCA there are differential payment percentages for older products, depending on their level of competition, and newer products.

108. We are not proceeding with this option. Respondents to the consultation raised a number of questions about the version of the LCA proposed in the consultation as an initial policy proposal. The Government remains open to implementing a version of the LCA in the statutory scheme, subject to further consideration and policy development required to implement the LCA.

Impact on small and micro businesses

109. Businesses with NHS sales of less than £5m per annum 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.

Statutory requirements for consultation

110. 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.

111. 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.

112. These factors are considered in this Impact Assessment within the options analysis presented above, and using the analysis presented below (based on overall consideration of options 1b and 2b).

Economic consequences for the life sciences industry in the United Kingdom

113. As set out above, option 1b is expected to increase the gross revenues of pharmaceutical companies by between £5.1bn and £5.9bn compared to the business as usual option to 2026.

114. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated to represent not more than 10% of the global industry, so impacts on UK interests are assumed to be commensurately affected, with a gross change in revenues of approximately £510m-£590m relative to the counterfactual over the period in question.

115. For illustrative purposes only, if we assume that the increased revenues under the preferred option are invested in the same proportion as companies typically invest in areas such as R&D, the change in revenue could translate to an increase in UK life sciences investment, including R&D of around £50m by 2026, with associated spill-overs worth £10m in the same period. Annex B notes the methodology behind this estimate.

116. In addition to the impacts on gross revenues, the preferred option includes measures which aim to provide additional commercial rewards for NAS. Suppliers of NAS products would be expected to see greater relative benefits accruing to them than suppliers of non-NAS products as a deliberate effect of the policy design.

The consequences for the economy of the United Kingdom

117. As set out above, theoretically, the preferred option could increase funding for global pharmaceutical investment, a proportion of which may located in the UK. For illustrative purposes only, if we assume this proportion would be in line with the UK's estimated share of global R&D it equates to investment worth around £50m, with associated spillover benefits to the UK worth around £10m to 2026. We also identify potential increased returns to UK shareholders estimated to between £510m and £590m in the same period compared to the counterfactual.

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

118. The purpose of all options is to support NHS spending on medicines continuing to be affordable, enabling continued NHS investment in uptake of the most clinically and cost effective medicines to the benefit of patients, and investment in other patient services. The main impact of this specific proposed update is to support 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.

119. The proposals result in higher net costs associated with branded medicines to the NHS compared to the counterfactual. In the context of a fixed NHS budget, this would require redistribution of funding from another area. We estimate the additional costs to equate to between 338,460 and 395,470 fewer QALYs by 2026. However, patients will benefit from a scheme that sets payment rates to achieve predictable and sustainable growth in net sales of medicines so as to support ongoing access to cost-effective medicines.

120. Ensuring the continued sustainability of NHS medicines spending is intended to support the equality duties in relation to the scheme, since it ensures the continued availability of medicines and enables the NHS to use revenues, including those from the statutory scheme, in the best interest of patients, including those with protected characteristics.

121. Some groups are likely to be particularly affected by policies that may affect access to medicines. The original consultation noted specific groups where illness and use of medicines tend to be higher than in the rest of the population. These groups include those sharing protected characteristics, such as older people and those with long term health conditions. NHS data[14] also indicates that the most deprived 20% of the national population (as identified by the national Index of Multiple Deprivation (IMD)) generally receives more prescription items than the rest of the population, and that prescribing peaks at an earlier age in this group.

122. Our assessment remains overall that ensuring the sustainability of the medicines pricing system and securing access to medicines is likely to benefit all patients in the NHS, including those with protected characteristics. It is also likely to benefit those specific groups that make greatest use of prescription products, including older people and those in the most deprived 20% of the population.

123. Consultation responses argued that the proposed payment percentages would disincentivise supply of some products, which could impact patients due to the withdrawal of unviable products. Discussions about the impacts of the rates proposed on supply are set out above. Our assessment remains that we do not expect impacts on the supply of medicines given the available mitigations in the scheme. However, ensuring the sustainability of the medicines pricing system and access to medicines is likely to be in the interest of all patients who share protected characteristics, and any additional spend on medicines would need to be balanced against the impact on other NHS services that also benefit patients.

[14] *Healthcare Inequalities: Access to NHS prescribing and exemption schemes in England*, healthcareInequalitiesScrollytellR (shinyapps.io) (accessed October 2023)

124. Respondents to the consultation also argued that the payment percentages proposed would have a negative impact on pharmaceutical research and development investment in the UK. While our view remains that on balance, supply side factors are likely to be of greatest impact in decisions about such investments, we note in this context that price control schemes in general are more likely to impact decisions about the location of late-stage than early-stage trials, as the location of late-stage trials may be more influenced by commercial considerations about where to launch a new medicine. We therefore consider that the risk to access to be slightly elevated for patients who access new medicines through clinical trials. However, the greater impact on clinical trial activity will come from considerations related to the agreement of a voluntary scheme. We also consider that, on balance, the overall objective of ensuring sustainable NHS spending on medicines will benefit patients.

125. Respondents also argued that some elements of the LCA proposals in the consultation would have a negative impact on the supply of certain older medicines under the LCA, with resulting impacts on specific groups who made use of such products. For example, consultation responses identified that the LCA, in the form proposed, could reduce incentives to supply versions of products formulated for children or for individuals who might be unable to take regular forms of medicinesas a result of health conditions or disabilities. Following consideration of consultation responses, we no longer plan to introduce the LCA in the statutory scheme.

126. The additional exemptions included in the scheme, which are designed to facilitate access to medicines compared to the counterfactual, are also likely to promote access to medicines for specific groups sharing protected characteristics. The exact nature of the groups varies on a case by case basis but the exemptions, for example, facilitate access to vaccines which benefit younger people and children, or those who are vulnerable to certain illnesses for which these vaccines provide protection.

127. Similarly, the inclusion of new commercial incentives for the rapid launch of innovative products is likely to benefit patients with particular conditions which tend to be most targeted for NAS launches. This include areas such as Oncology, neurology, and immunology, which have seen rising shares of new launches in recent years[15].

Monitoring the scheme

128. Each, year the government will consider the payment percentages set in the scheme against the objectives set out for it in the consultation. Should this consideration identify areas in which the terms of the scheme as set out following consultation no longer meet these objectives, government would likely bring forward consultation proposals to update the scheme.

129. The current voluntary and statutory schemes are subject to a single programme of annual governance and operational review[16]. This includes, quarterly publication of scheme metrics and six monthly operational review with the industry body and observers. Should a successor voluntary scheme be agreed, it is expected that this arrangement would continue, subject to any changes agreed by the parties to a negotiated agreement.

[15] IQVIA, *Global Trends in R&D 2023* (2023) https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2023 (accessed October 2023)

[16] Department of Health and Social Care. 2023. 2019 voluntary scheme for branded medicines pricing and access operational review minutes. [https://www.gov.uk/government/collections/2019-voluntary-scheme-for-branded-medicines-pricing-and-access-operational-review-minutes]

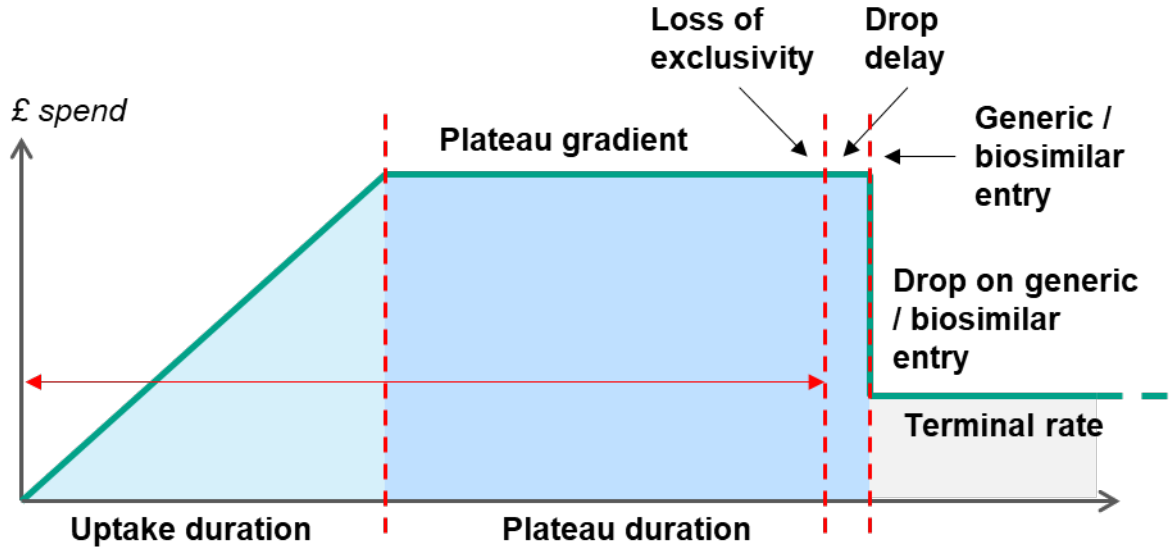
Annex A – Medicine Spend Forecast

1. To determine the impact of the different policy options, the value of total sales of branded medicines must be forecast through to 2026.

2. We use a medicine spend forecast to derive growth rates. The forecasting methodology is based around a lifecycle approach to expenditure, where for older molecules we forecast on a molecule-by-molecule basis, making assumptions about typical lifecycles of spend. For more recent molecules, where we have a shorter spend history, we forecast on an aggregated cohort basis.

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

Figure 1: Stylised product lifecycle



4. An existing assumption of the forecast model is that a typical lifecycle is 158 months long, which is based on previous IPO analysis.

5. Key parameters of the product lifecycle in the model are listed in Table 23.

Table 10: Parameter value overview

Parameter	Primary care: **Non-biological**	Primary care: **Biological**	Secondary care: **Non-biological**	Secondary care: **Biological**
Uptake duration	96 months	81 months	71 months	103 months
Plateau duration	62 months	77 months	87 months	55 months
Plateau gradient	3% p.a.	5% p.a.	-2% p.a.	1% p.a.
Loss of exclusivity/generic entry gap	9 months	0 months	7 months	9 months
Drop on generic entry	44%	0%	43%	18%
Terminal growth rate	1%	1%	1%	0%
Cohort growth rate	5%	5%	5%	5%

Uptake duration

6. Represents the time between product launch and the point at which the trend in expenditure changes (often due to the target patient population having been reached). The method by which the value for the parameter has been calculated is through analysis of historic data for spend on products launched from January 2009 to March 2015 (to be able to observe spend for at least seven years post launch). A combination of statistical trend analysis and manual review was used to identify the end of the uptake point. Where identified, the number of months from launch to end of uptake was calculated then weighted by average annual spend over the uptake period.

7. Uptake gradient is not estimated as a fixed parameter; rather it is generated based upon the individual product data (i.e. continuing the existing trend). The proportion of uptake plus plateau period spent in uptake phase was applied to 158 months to maintain consistency with the key assumption that a typical lifecycle in 158 months and avoid artificially extending uptake phase.

Plateau duration

8. Represents the time between the end of the uptake phase and patent expiry. The date of patent expiry has been taken from known sources for each molecule where available and assumed to be 12.5 years post launch where unavailable.

9. The method by which the value for the parameter has been calculated is through analysis of historic data for spend on all available molecules with launch date pre-January 2012 and loss of exclusivity date post January 2012. This was to enable observation of the time between launch and loss of exclusivity for as many molecules as possible, without limiting to molecules where whole launch to loss of exclusivity is observed. A combination of statistical trend analysis was used, coupled with manual review, to identify “end of uptake” point. Where “end of uptake” was identified, the number of months from end of uptake to loss of exclusivity (the plateau period) was calculated then weighted average spend over the plateau period.

10. The proportion of uptake plus plateau period spent in plateau phase was applied to 158 months to maintain consistency with the key assumption that a typical lifecycle in 158 months and avoid artificially extending plateau phase.

Plateau gradient

11. Represents the rate of change in spend between end of uptake period and patent expiry, estimated from observed change of spend in data.

12. The method by which the value for the parameter has been calculated is through analysis of historic data for spend on all available molecules with launch date pre-January 2012 and loss of exclusivity date post January 2012. This was to enable observation of the time between launch and loss of exclusivity for as many molecules as possible, without limiting to molecules where whole launch to loss of exclusivity is observed. Where “end of uptake” was not identified, the average plateau length observed was applied.

13. The log timeseries of spend data from the end of the uptake phase to loss of exclusivity (or latest date available if this isn’t in observed timeseries) was used to calculate the slope of the timeseries for each molecule – this is the approximate monthly growth rate. The molecule level monthly growth rates were weighted by total spend across the plateau (molecules in plateau for longer time therefore have a higher weighting).

Gap between loss of exclusivity and generic entry

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

15. The method by which the value for the parameter has been calculated is through analysis of historic data for spend on all available molecules where we can observe at least one year of spend pre loss of exclusivity date and three years of spend post loss of exclusivity date.

16. Plotted data was used to review and identify the start of spend dropping and the end of spend dropping, where the months between loss of exclusivity and drop starting is the mid-point between start of spend drop and end of spend drop.

Drop on generic/biosimilar entry

17. This reflects the blended impact of price decay once a branded medicine goes off patent (as generic, branded generics and biosimilars typically seek to obtain market share through lowering prices) and a volume shift as prescribers move from branded to generic medicines.

18. The method by which the value for the parameter has been calculated is through analysis of historic data for spend on all available molecules where we can observe at least one year of spend pre loss of exclusivity date and three years of spend post loss of exclusivity date.

19. Plotted data was used to review and identify the proportional change in spend at the point spend stabilises.

Terminal rate

20. Represents the rate of change in spend after loss of exclusivity and the initial drop of spend as per the drop of generic/biosimilar entry parameter

21. The method by which the value for the parameter has been calculated is through analysis of historic data for spend on all available molecules where the loss of exclusivity date is before March 2019 – so that we can observe at least three years of spend data post loss of exclusivity.

22. A combination of statistical trend analysis, coupled with manual review, was used to identify “start of terminal phase”. This is the point spend stops dropping post loss of exclusivity – where relevant – and terminal phase assumed to start. Where “start of terminal phase” was not identified, it was assumed the terminal phase started three years after loss of exclusivity.

23. The log timeseries of spend data from the “start of terminal phase” to the latest data available (March 2022) was used to calculate the slope of the timeseries for each molecule – this is the approximate monthly growth rate. This was then weighted using the average annual spend during the terminal phase.

Cohort growth rate

24. Represents the rate of change in spending impact of future cohorts of new launches. Looking at the past ten years, we see that the spending impact of cohorts of new launches are heavily influenced by high cost drug classes, with most launches having a relatively steady spending impact. For example high cost drug classes launched in 2014 (hepatitis C) and 2020 (cystic fibrosis), and in 2021 (advanced therapy medicinal product to treat spinal muscular atrophy, combination cancer medicine).

25. Pharmaceutical pipelines are becoming more complex, targeted and expansive; taking account of the large uncertainties when trying to predict the spend impact of future launches, we feel a positive cohort growth assumption of 5% is justified.

Parameter overview

26. Following patent expiry, we have applied an assumption regarding the proportion of expenditure on a molecule that can be attributed to expenditure on the branded originator and expenditure on the generics.

27. The estimation of parameters was carried out using two spend data sources. For primary care medicines, NHS BSA prescribing data for the period January 2009 to March 2022 was used. For secondary care medicine, Pharmex, which is a recording system used for invoices by hospital pharmacies, data for the period January 2009 to March 2022 was used. These are England only sources, and therefore a standard scaling factor of 1.25 has been applied to approximate UK spend.

28. The product lifecycle parameters have been estimated at a category level for four different categories of medicines that from our data evidently behaved differently over their lifecycle. The model distinguishes between biological and non-biological medicines, and separate sets of parameters have been estimated for both categories for primary and secondary care sales.

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

30. For products already on the market that were launched prior to 2018 (“established products”), we applied the set of parameters estimated for that particular category of medicine to the individual historic spend data to generate an individual product lifecycle. The product lifecycle is aligned to the loss of exclusivity date (see Plateau duration above). The plateau duration and uptake duration periods are defined in relation to this.

31. The plateau gradient parameter captures a particularly complex market dynamic. This is because it is representing the stage of a lifecycle where there are most likely to be two counteracting effects on the trend for molecules in our historic dataset, which our methodology captures and incorporates into the forward projection. The first is competition within a therapeutic class, when the cannibalisation of a given product’s sales from new, branded competitors succeeds in capturing some of the market share of the medicine, despite it still being protected from generic competitors by the patent. In addition to the potential impact on share, the manufacturer may reduce the price of the product to ensure it remains competitive. This would result in a negative impact on plateau growth. However, increasingly pharmaceutical companies pursue an R&D strategy based around the licensing of additional indications for new therapeutic purposes, which may launch some years after the original indication came to market. Market prognosis reports show this is a particularly prominent trend in oncology. This will increase sales and create a positive growth, even after the main period of uptake has ended, by expanding the patient population that could be eligible for treatment.

32. For products launched after 2018 (“recent launches”), where there is either only a short series of historical data or no expenditure at all, we have applied the parameters to the aggregated total expenditure for all products launched or to be launched during the course of that year, which we term an annual cohort. The lifecycle is generated as these cohorts. This approach is also applied to assumed products launched in future (i.e. from April 2022 onwards – termed “future launches”).

33. The model was used to generate a series of forecast growth rates for total branded medicines spend for the period 2022 to 2026.

Annex B – Evidence underpinning wider economic impacts approach

130. This section sets out the evidence underpinning our approach to quantifying the potential wider economic impacts of the proposed options to avoid repetition in later sections. Theoretically, reduced payment percentages versus the counterfactual may increase funding available for investment by the pharmaceutical industry at a global level, a portion of which may be in the UK. These impacts have not been included in the NPV calculations and are for illustrative purposes only.

131. We use the same formulaic approach to estimate the potential impact of the change in payment percentages versus the counterfactual on UK investment as in previous impact assessments. This reflects the methodology set-out for central government appraisal and evaluation in the Green Book, which notes at paragraphs 6.5 and 6.6 respectively:

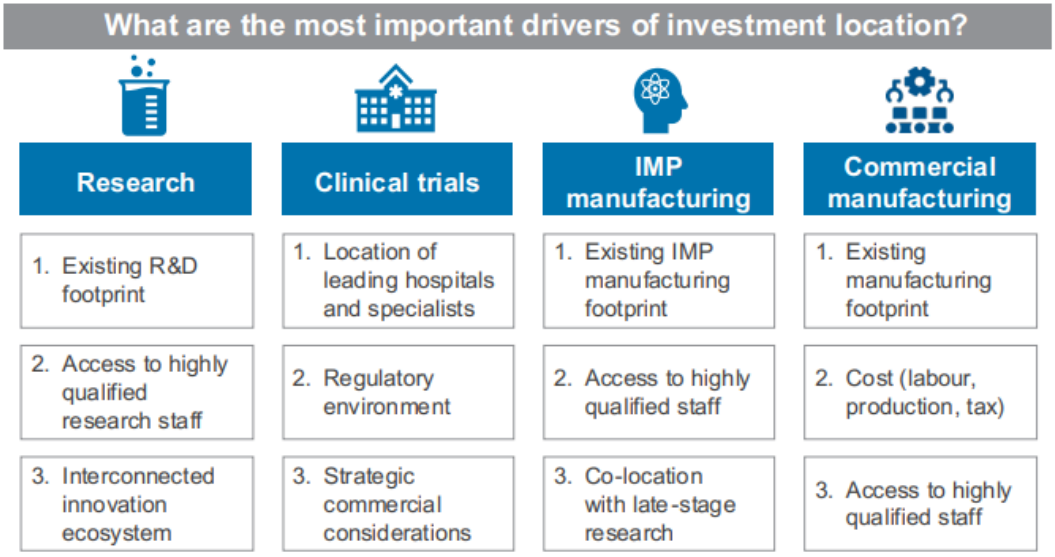
"6.5 Green Book appraisal is not concerned with the macroeconomic effects of spending which is the concern of government when it makes macro spending decisions on the overall level of spending and taxation."

"6.6 Therefore, changes to Gross Domestic Product (GDP), or Gross Value Added (GVA) or the use of Keynesian type multipliers arising from different options cannot provide useful information for choosing between options within a scheme and are therefore not part of the Green Book appraisal process. However, macro variables may well form part of the higher level analytical research that informs identification of policy, and policy priorities."

132. The drivers of pharmaceutical investment scale and location decisions are complicated, multi-faceted and may differ for different types of investment, as demonstrated in the literature around the drivers for investment location decisions discussed below.

133. In their 2021 "Factors affecting the location of biopharmaceutical investments and implications for European policy priorities" report[17] Charles River Associates considered research hub, clinical trial, and investigational and commercial manufacturing investment decisions separately. The summary of their findings is shown below (figure 15 page 56).

Figure 15: Summary of factors driving the location of biopharmaceutical investments



134. Whilst cost and strategic commercial considerations feature in commercial manufacturing and clinical trials respectively, research and IMP manufacturing are focussed on existing footprint, access to highly qualified staff and connections with innovation and late stage research.

[17] Tim Wilsdon, Hannah Armstrong, Antun Sablek and Peter Cheng. 2022. Factors affecting the location of biopharmaceutical investments and implications for European policy priorities. [https://efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf]

135. With respect to clinical trials the report highlighted inconsistencies between statistical analyses and qualitative decision-maker interview findings. The former showed positive correlation between price regulation and location of clinical trials, whilst the latter suggested that, although important, price regulation is not a key driver of clinical trial location decisions. A possible explanation was suggested that in the short-term price regulation may not significantly impact location decisions but longer term policies leading to a decline in the clinical standard of care may deter clinical trial investment if clinical guidelines do not provide a suitable comparator for an innovative clinical trial. Given the routes for innovative medicines to reach the UK market, including the Innovative Medicines Fund[18], Cancer Drugs Fund and provisions within VPAS we consider this risk to be relatively low.

136. Shaikh et al (2020)[19] found the negative impact of price regulation on cash flow and profitability drove a negative relationship between exposure to price regulation and R&D before firm fixed effects were included. Once firm fixed effects were included however, the results were not significant. They concluded "the findings suggest that investment decisions of firms are most likely driven by long-run inter-firm differences, and that firm effects strongly determine firm strategies in terms of R&D investment".

137. The "Attracting life science investments in Europe" report published in June 2021[20] was an initiative of the Biomed alliance, Europabio and Johnson & Johnson. They assessed 14 European countries against 21 indicators to analyse the country's attractiveness for Life Sciences investments. The criteria selected were grouped into the four themes noted below, which demonstrate the breadth of factors involved in decision making.

    - Social and economical context.
    - Industrial context.
    - Life sciences innovation.
    - Healthcare environment.

138. The UK performed at or above the median on 16 of the indicators tested, with particularly high performance in life science publications and clinical trials. Only Germany had fewer than 5 below median indicators in the rest of the sample. The 5 indicators where the UK fell below the sample median were:

    - Political stability and absence of violence.
    - Labour productivity.
    - Life science trade balance (exports – imports).
    - Pharmaceutical spending.
    - Size of Med Tech market.

139. This provides another indication of the complexity and multi-factorial Life Science investment decision process and that, whilst the UK did not perform highly on pharmaceutical spending, it was strong in other areas.

[18] NHS England. 2021. NHS England announces new Innovative Medicines Fund to fast-track promising new drugs. [https://www.england.nhs.uk/2021/07/nhs-england-announces-new-innovative-medicines-fund-to-fast-track-promising-new-drugs/]

[19] Mujaheed Shaika, Pietro Del Giudice and Dimitrios Kourokils, 2021. Revisiting the Relationship Between Price Regulation and Pharmaceutical R&D Investment. Applied Health Economics and Health Policy. 19(2021), page.217-229. [https://link.springer.com/article/10.1007/s40258-020-00601-9]

[20] Seboio Health Policy Consulting. 2021. Attracting Life Science Investments in Europe. [https://www.janssen.com/emea/sites/www_janssen_com_emea/files/life_science_attractiveness_july.pdf]

140. Similarly, the 2021 EU R&D industrial investment scoreboard[21] highlighted the importance of availability of venture capital and ease of forming start-up companies can be particularly important for high risk projects. It subsequently cites 2020 OECD statistics that showed the UK had the second highest total venture capital funding and also ranked second in CEOMAGAZINE's 2021 ranking of the most start-up friendly countries based on interviews with 195,000 CEOs. In both measures the US was ranked first.

141. More recently the "Startup Blink Global Ecosystem Report 2023"[22] cited the UK as having the second most innovative start-up ecosystem in the world (again behind the US), a position which has been consolidated since 2017.

142. The Life science competitiveness indicators 2022 found that amongst comparator countries, the UK ranked second behind the USA in terms of estimated life science inward foreign direct investment (FDI) capital expenditure in 2021.The UK had the sixth highest number of life science initial public offerings (IPOs) and associated amount raised in 2021. The USA and China were the leaders in terms of both the count of IPOs and amount raised, and were substantially higher than all other comparator countries. Similarly, the UK life science industry has seen increasing levels of equity finance raised since 2012, but companies in the USA and China raised substantially more.[23]

143. On the UK Research environment the Life science competitiveness indicators 2022 found that whilst the UK government has a high budget allocation for health research & development (R&D), coming behind only the USA and Japan, the UK generally places around the centre of the rankings for R&D performed by government, higher education and private non-profit sectors. R&D performed by the 4 sectors (government, higher education, private non-profit, and business), as a percentage of gross domestic product (GDP), remained stable between 2014 and 2018 for the UK. For clinical trials, the UK has a longer length of time between first application to a regulatory authority and the first patient receiving a first dose compared to most comparator countries. In the UK, the set-up and recruitment of patients takes longer than the approval process. The UK recruits a similar number of patients to clinical trials as countries such as France and Canada, but substantially fewer than the USA. Amongst comparator countries, the UK, Italy and France were the leaders in terms of producing high quality research in medical sciences publications in 2021.Overall, the literature suggests that price regulation is likely to be one element of investment location decisions. But that these decisions are highly complicated, encompassing a wide range of factors, and furthermore the weight of price regulation in decision making may differ by the type of investment. Our view remains that supply side factors are of greatest impact compared to demand side factors in company decisions about where to locate globally mobile investments.

144. For illustrative purposes only, we have estimated the possible impact on investment of the increased industry revenue generated by the proposals versus the counterfactual. We used an estimate that the proportion of pharmaceutical company revenues devoted to R&D was 36%[24]. There are other sources that estimate the share of revenue devoted to R&D is closer to 25%[25], and OLS analysis suggesting it may be nearer 15%[26]. Whilst it is likely that the proportion fluctuates over time and across different companies or parts of the sector, we have opted to update our assumption regarding the proportion of revenue that may be directed towards R&D investment to 25%.

[21] European Commission. 2021. The 2021 EU industrial R&D investment scoreboard. [https://op.europa.eu/en/publication-detail/-/publication/02ab5f6a-c9bd-11ec-b6f4-01aa75ed71a1/language-en/format-PDF/source-257925010]

[22] StartupBlink. 2023. Global Startup Ecosystem Index 2023. page.40. [https://lp.startupblink.com/report/]

[23] OLS competitiveness indicators 2022 https://www.gov.uk/government/publications/life-science-sector-data-2022/life-science-competitiveness-indicators-2022#executive-summary-of-the-uks-performance-in-the-lscis

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

[25] Congressional Budget Office. 2021. Research and Development in the Pharmaceutical Industry. [https://www.cbo.gov/publication/57126]

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

145. This is the upper end of the 15% to 25% range recommended for use by the Office for Life Sciences (OLS). We then apply the latest identified estimate for the proportion of global pharmaceutical R&D that is located in the UK to estimate possible additional UK investment. In 2020 we estimate the UK's share of global R&D came to 3.1%, with global pharmaceutical R&D at £161 billion[27] and the UK's pharmaceutical R&D summing to just over £5 billion[28].

146. Note that 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 "spillover" effects, for example through the generation of knowledge and human capital, which generate net societal benefits compared to other uses. We have updated the evidence base underpinning the level of spillover effects that might be reasonably expected from an increase in pharmaceutical investment. The results of 10 academic papers were considered with a mean estimate of spillover effects being valued at 34% the value of the investment and the median at 32%.

147. Of the 10 papers the two identified as having the highest relevance for use here related to the UK, were focused on investment in science and innovation[29] and biomedical research centres and units[30] and published in 2014 and 2020 respectively. Across these two papers, the lower estimate of investment spillover effects was 20% and the higher was 58%. We therefore concluded that continuing to use our assumption of spillover effects valuing 30% of the amount invested was reasonable and prudent. We remain open to receiving further evidence on this point.

148. As a result, we calculate the wider economic impacts of investment spillover effects as:

$$Change\ in\ company\ revenue\ \times\ Proportion\ of\ revenue\ invested\ in\ R\&D \times\ UK\ share\ global\ pharmaceutical\ R\&D\ \times Spillover\ impacts$$

Where proportion of revenue invested in R&D = 25%, UK share of global pharmaceutical investment = 3.1% and spillover impacts = 30%.

[27] Evaluate Pharma. 2022. World Preview 2022 Outlook to 2028: Patents and Pricing. page. 20. [https://www.evaluate.com/thought-leadership/pharma/world-preview-2022-report]

[28] Office for National Statistics. 2021. R&D BUS: PG H - Total intramural R&D – Pharmaceuticals. [https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/timeseries/dlcd/berd]

[29] Frontier Economics. 2014. Rates of return to investment in science and innovation. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/333006/bis-14-990-rates-of-return-to-investment-in-science-and-innovation-revised-final-report.pdf]

[30] Joyce Craig, Ana Castro Avila, Veronica Dale, Karen Bloor and Nick Hex. 2020. Estimating the Economic Value of NIHR Biomedical Research Centres and Units. [https://www.york.ac.uk/media/healthsciences/documents/Estimating%20the%20Economic%20Value%20of%20NIHR%20Biomedical%20Research%20Centres%20and%20Units.pdf]

Annex C – 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:
    - The cost per QALY provided "at the margin" in the NHS and how this differs from the £30k cost effective threshold used by NICE;
    - The societal value of a QALY.
2. It then provides an illustrative example of how these two figures are used in DHSC IAs.

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[31]. Whilst there are inherent uncertainties surrounding any such estimates, subsequent studies commissioned by DHSC have found a range of values broadly consistent with this figure. Expressed in 2016 prices, 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 £15,000 cost per QALY at the margin is a pragmatic, simplifying assumption grounded in academic research to assess the opportunity cost of allocation of NHS and DHSC funds. It is used to estimate how much benefit is derived from marginal spending, and is not a firm estimate, prediction or commitment.
6. This differs from the Incremental Cost Effectiveness Ratio (ICER) considered by NICE in the economic analysis that informs their guideline recommendations. Their guidance[32] states that where there is no clear dominant strategy, i.e. one that is both more effective and less costly, the ICER should be considered.
7. For example, cost per QALY generated is calculated as the difference in mean cost divided by the difference in mean QALYs for one strategy compared with the next most effective alternative strategy. If one intervention appears to be more effective than another, the Guideline Development Group (GDG) will have to decide whether the increase in cost associated with the increase in effectiveness represents reasonable 'value for money'.

[31] Karl Claxton, Steve Martin, Marta Soares, Nigel Rice, Eldon Spackman, Sebastian Hinde, Nancy Devlin, Peter C Smith and Mark Sculpher. Health Opportunity Costs (Estimating health opportunity costs in the NHS and other health care systems): Methods for estimation of the NICE cost-effectiveness threshold. [https://www.york.ac.uk/che/research/teehta/thresholds/]

[32] National Institute for Health and Care Excellence. 2012. The guidelines manual: Process and Methods – 7 Assessing cost effectiveness. [https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness]

8. Furthermore, the guidance states that at chapter 7.3:

"NICE has never identified an ICER above which interventions should not be recommended and below which they should. However, in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. Where advisory bodies consider that particular interventions with an ICER of less than £20,000 per QALY gained should not be provided by the NHS they should provide explicit reasons (for example that there are significant limitations to the generalisability of the evidence for effectiveness). Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of NHS resources will specifically take account of the following factors.

- *The degree of certainty around the ICER. In particular, advisory bodies will be more cautious about recommending a technology when they are less certain about the ICERs presented in the cost-effectiveness analysis.*
- *The presence of strong reasons indicating that the assessment of the change in the quality of life is inadequately captured, and may therefore misrepresent, the health gain.*
- *When the intervention is an innovation that adds demonstrable and distinct substantial benefits that may not have been adequately captured in the measurement of health gain.*

As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgement about its acceptability as an effective use of NHS resources should make explicit reference to the relevant factors considered above. Above a most plausible ICER of £30,000 per QALY gained, advisory bodies will need to make an increasingly stronger case for supporting the intervention as an effective use of NHS resources with respect to the factors considered above."

9. Whilst the two are not dissimilar concepts, they are distinct from one another and should not be considered interchangeable. This impact assessment continues to follow DHSC guidance in using the estimated average cost per QALY generated at the margin on the frontline of £15,000.

The social value of a QALY (£70,000)

10. 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.

11. 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[33].

12. 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.

[33] Department of Health and Social Care. 2013. Quantifying Health Impacts of Government Policy. page.23. [https://www.gov.uk/government/publications/quantifying-health-impacts-of-government-policy]

Example IA calculation

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

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

14. 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.

15. This is why standard DHSC practice is to convert all ultimate impacts into £, as recommended in the HMT Green Book. For costs falling on the NHS budget this means converting them first in to QALYs (at £15,000 / QALY), and then monetising them (at £70,000 / QALY).

Annex D – Glossary

- **Allowed Sales –** in the policy options, growth in measured sales is designed to be capped at the allowed sales level which grows at 2% nominal p.a., through payments made by branded medicines manufacturers to DHSC.
- **Centrally procured vaccines (CPV**) – vaccines procured by a Central Government Body for national immunisation programmes that are approved by the Joint Committee on Vaccination and Immunisation (JCVI) and managed by Public Health England (or any successor body); and
- **Eligible sales** – Statutory Scheme sales which are subject to the payment percentage. Under certain policy options, some sales may be exempt from having the payment percentage applied to them.
- **Exceptional central procurement (ECP)** – exceptional procurements conducted by a Central Government Body and managed by Public Health England (or any successor body) for the purposes of emergency preparedness, stockpiling for the national security or pandemic preparation.
- **Low value sales** – Sales of any Scheme Products by a Scheme Member where the NHS list price of such Scheme Product is less than £2
- **Measured Sales** – overall sales of branded medicines to the NHS (measured by combining relevant sales across VPAS, Statutory Scheme and Parallel Imports).
- **New Active Substance** – Any Presentation which satisfies the requirements of paragraph (10) of Regulation 9 of the Statutory Scheme.
- **Parallel Import –** Sales of Presentations in respect of which a Parallel Import Licence has been granted and Sales of any parallel distributed presentation
- **Payment percentage** – Payments are made based on a proportion of the manufacturer's eligible sales. This proportion is the payment percentage.
- **Small company sales** – sales by companies whose total sales of scheme products are less than £5m in the calendar year preceding the relevant calendar year.

Annex E – Measured Sales, Eligible Sales and Payment Percentage Calculation

Business as Usual (BAU)

1. In line with the setting of the current Statutory Scheme, measured sales under BAU will be calculated assuming there are no exemptions from payments also known as frameworks.

2. The 2024, 2025 and 2026 sales and payment has been calculated using data to Q4 2022 and DHSC's forecast of future growth in branded medicines spend.

3. Initially the Total Measured Sales is calculated using Q4 2022 data:

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

Where *SS* refers to the Statutory Scheme under BAU option, $_t$ refers to the calendar year, e.g., 2024, 2025 and 2026, $_A$ refers to Q4 2022 data and BAU refers to under BAU option

4. In view of that no non-regulatory options are considered within this IA, current VPAS sales are considered as SS sales and VPAS centrally procured vaccines (CPV) and exceptional central procurement (ECP) sales which are excluded from the current VPAS will be included in the SS sales baseline.

$$\begin{aligned} &SS\ Measured\ Sales_{tA,BAU} \\ &\quad = Existing\ SS\ Measured\ Sales_{tA} + Existing\ VS\ Measured\ Sales_{tA} \\ &\quad + Existing\ VS\ CPV\ Sales_{tA} + Existing\ VS\ ECP\ Sales_{tA} \end{aligned}$$

5. Since no exemption are introduced in BAU and payment percentage is fixed at 27.5% from 2024 to 2026 in BAU, projected SS payment are as follows:

$$SS\ Actual\ Payment_{tA,BAU} = SS\ Measured\ Sales_{tA,BAU} \times 27.5\%$$

Non-BAU Options

6. Different from BAU, as all the remaining options introduces measured sales exemptions for CPV and ECP, the SS measured sales and total measured sales will not include VPAS CPV and ECP sales. Due to the low current SS measured sales value as of Q4 2022, it is assumed that there are no CPV and ECP sales in current SS measured sales.

$$Total\ Measured\ Sales_{tA,non\ BAU} = SS\ Measured\ Sales_{tA,non\ BAU} + Parallel\ Import\ Sales_{tA}$$

$$SS\ Measured\ Sales_{tA,non\ BAU} = Existing\ SS\ Measured\ Sales_{tA} + Existing\ VS\ Measured\ Sales_{tA}$$

7. Because of the intervention of allowed sales baseline and allowed sales growth, the Total Allowed Sales is calculated as follows:

$$Total\ Allowed\ Sales_{2023A} = (Total\ Measured\ Sales_{2018A} - Payments_{2018A}) \times (1 + 1.96\%)^5$$

$$Total\ Allowed\ Sales_{tA} = Total\ Allowed\ Sales_{2023A} \times (1 + 2\%)^{t-2023}$$

Where Payments refers to 2018 payments received by the NHS from the PPRS and Statutory Scheme, 1.96% is used as the allowed growth rate from 2018 to 2023 and 2% is used as the allowed growth rate from 2023.

8. Next, the Total Payment and the required Statutory Scheme payment is calculated:

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

$$SS\ Required\ Payment_{tA,non\ BAU} = Total\ Payment_{tA,non\ BAU} \times \frac{SS\ Measured\ Sales_{tA,non\ BAU}}{Total\ Measured\ Sales_{tA,non\ BAU}}$$

9. With different sales exemptions and Lifecycle Adjustment (LCA) approach, the payment percentages under the remaining options differ and are calculated as below.

Option 1a

10. Without sales exemptions, no LCA and the modelled over- and under-payments between 2019 to 2023 having not been accounted for 2024 payment percentage calculation, the required Statutory Scheme payment percentages for 2024, 2025 and 2026 are calculated and rounded to the nearest one decimal place:

$$SS\ Eligible\ Sales_{tA,1a} = SS\ Measured\ Sales_{tA,non\ BAU}$$

$$SS\ Payment\ \%_{tA,1a} = \frac{SS\ Required\ Payment_{tA,non\ BAU}}{SS\ Eligible\ Sales_{tA,1b}}\ (correct\ to\ 1\ d.p.)$$

11. While the required Statutory Scheme payment is the same under the remaining options, due to the payment percentage is rounded, the actual income is therefore slightly different among the four options.

$$SS\ Actual\ Payment_{tA,1a} = SS\ Eligible\ Sales_{tA,1a} \times SS\ Payment\ \%_{tA,1a}$$

Option 1b

12. With New Active Substances (NAS) sales exemptions being introduced, NAS sales would be removed from eligible sales:

$$SS\ Eligible\ Sales_{tA,1b} = SS\ Measured\ Sales_{tA,non\ BAU} - SS\ NAS\ Sales_{tA,non\ BAU}$$

13. Calculation of the payment percentages and actual payments would be the same under option 1a:

$$SS\ Payment\ \%_{tA,1b} = \frac{SS\ Required\ Payment_{tA,non\ BAU}}{SS\ Eligible\ Sales_{tA,1b}}\ (correct\ to\ 1\ d.p)$$

$$SS\ Actual\ Payment_{tA,1b} = SS\ Eligible\ Sales_{tA,1b} \times SS\ Payment\ \%_{tA,1b}$$

Option 2a

14. With LCA, SS measured sales is split into three types of product sales, namely newer product sales, older products that satisfies sufficient threshold of competition and older products that do not satisfy a sufficient threshold of competition.

$$\begin{aligned} SS\ Measured\ Sales_{tA,2a} \\ &= SS\ Measured\ Sales\ (Newer)_{tA,2a} \\ &+ SS\ Measured\ Sales\ (Older\ with\ Competiton)_{tA,2a} \\ &+ SS\ Measured\ Sales\ (Older\ without\ Competition)_{tA,2a} \end{aligned}$$

15. Since options 2a does not have NAS exemption, no sales reduction is applied to SS eligible sales.

$$SS\ Eligible\ Sales\ (Newer)_{tA,2a} = SS\ Measured\ Sales\ (Newer)_{tA,non\ BAU}$$

$$SS\ Eligible\ Sales\ (Older\ with\ Competiton)_{tA,2a} = SS\ Measured\ Sales\ (Older\ with\ Competiton)_{tA,non\ BAU}$$

$$SS\ Eligible\ Sales\ (Older\ without\ Competition)_{tA,2a} = SS\ Measured\ Sales\ (Older\ without\ Competition)_{tA,non\ BAU}$$

16. Older products with sufficient competition will have a fixed payment percentage of 10% from 2024 to 2026 and those without sufficient competition will have a fixed payment percentage of 36% in 2024, 38% in 2025 and 40% in 2026.

$$SS\ Actual\ Payment\ (Older\ with\ Competition)_{tA,2a} = SS\ Eligible\ Sales\ (Older\ with\ Competiton)_{tA,2a} \times\ 10\%$$

$$SS\ Actual\ Payment\ (Older\ without\ Competition)_{tA,2a} = SS\ Eligible\ Sales\ (Older\ without\ Competiton)_{tA,2a} \times SS\ Payment\ \%\ (Older\ without\ Competition)_{t}$$

17. Next, the required payment for newer products and corresponding payment percentage is calculated as follows:

$$SS\ Required\ Payment\ (Newer)_{tA,2a} = SS\ Required\ Payment_{tA,non\ BAU} - SS\ Actual\ Payment\ (Older\ with\ Competition)_{tA,2a} - SS\ Actual\ Payment\ (Older\ without\ Competition)_{tA,2a}$$

$$SS\ Payment\ \%\ (Newer)_{tA,2a} = \frac{SS\ Required\ Payment\ (Newer)_{tA,2a}}{SS\ Eligible\ Sales\ (Newer)_{tA,2a}}\ (correct\ to\ 1\ d.p)$$

18. Finally, the actual payment is calculated as follows:

$$SS\ Actual\ Payment\ (Newer)_{tA,2a} = SS\ Eligible\ Sales\ (Newer)_{tA,2a} \times SS\ Payment\ \%\ (Newer)_{tA,2a}$$

$$SS\ Actual\ Payment_{tA,2a} = SS\ Actual\ Payment\ (Newer)_{tA,2a} + SS\ Actual\ Payment\ (Older\ with\ Competition)_{tA,2a} + SS\ Actual\ Payment\ (Older\ without\ Competition)_{tA,2a}$$

Option 2b

19. Like option 2a, eligible sales are split into newer product sales, older products that is with competition and older products that is without competition. However, with NAS exemption, NAS sales are removed from newer product sales.

$$SS\ Measured\ Sales_{tA,2b} = SS\ Measured\ Sales\ (Newer)_{tA,2b} + SS\ Measured\ Sales\ (Older\ with\ Competiton)_{tA,2b} + SS\ Measured\ Sales\ (Older\ without\ Competition)_{tA,2b}$$

$$SS\ Eligible\ Sales\ (Newer)_{tA,2b} = SS\ Measured\ Sales\ (Newer)_{tA,non\ BAU} - SS\ NAS\ Sales_{tA,non\ BAU}$$

$$SS\ Eligible\ Sales\ (Older\ with\ Competiton)_{tA,2b} = SS\ Measured\ Sales\ (Older\ with\ Competiton)_{tA,non\ BAU}$$

$$SS\ Eligible\ Sales\ (Older\ without\ Competition)_{tA,2b} = SS\ Measured\ Sales\ (Older\ without\ Competition)_{tA,non\ BAU}$$

20. The remaining calculation under option 2b is the exact same as option 2a as follows:

$$SS\ Actual\ Payment\ (Older\ with\ Competition)_{tA,2b} = SS\ Measured\ Sales\ (Older\ with\ Competiton)_{tA,2b} \times 10\%$$

$$SS\ Actual\ Payment\ (Older\ without\ Competition)_{tA,2b} = SS\ Measured\ Sales\ (Older\ without\ Competiton)_{tA,2b} \times\ SS\ Payment\ \%\ (Older\ without\ Competition)_{t}$$

$$SS\ Required\ Payment\ (Newer)_{tA,2b} = SS\ Required\ Payment_{tA,non\ BAU} - SS\ Actual\ Payment\ (Older\ with\ Competition)_{tA,2b} - SS\ Actual\ Payment\ (Older\ without\ Competition)_{tA,2b}$$

$$SS\ Payment\ \%\ (Newer)_{tA,2b} = \frac{SS\ Required\ Payment\ (Newer)_{tA,2b}}{SS\ Eligible\ Sales\ (Newer)_{tA,2b}}\ (correct\ to\ 1\ d.p)$$

$$SS\ Actual\ Payment\ (Newer)_{tA,2b} = SS\ Eligible\ Sales\ (Newer)_{tA,2b} \times SS\ Payment\ \%\ (Newer)_{tA,2b}$$

$$SS\ Actual\ Payment_{tA,2b} = SS\ Actual\ Payment\ (Newer)_{tA,2b} + SS\ Actual\ Payment\ (Older\ with\ Competition)_{tA,2b} + SS\ Actual\ Payment\ (Older\ without\ Competition)_{tA,2b}$$