IA Title: Statutory Scheme – Branded Medicines Pricing 2025 **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: 12/05/2025** **Stage: Final** **Source of intervention: Domestic** **Type of measure:** Secondary Legislation **Contact for enquiries:** dh.brandedmedicines@dhsc.gov.uk
Summary: Intervention and Options	**RPC Opinion:** Not Applicable

Cost of Preferred (or more likely) Option (in 2025 prices and present value)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£133.4m	-£8.7m	£3.0m	Non qualifying provision

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

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, working alongside the voluntary scheme for branded medicines pricing, access and growth (VPAG). The statutory scheme operates as a compulsory backstop for companies that choose not to join the voluntary scheme. The policy options proposed during this consultation process are designed to support broad commercial equivalence (BCE) of the statutory scheme with VPAG. The 2025 payment percentage for VPAG, published in December 2024, exceeds the current statutory scheme's rate by 7.4 percentage points. If DHSC did not update the statutory scheme to support BCE with VPAG, there is significant risk that the schemes may not work effectively to control the costs of branded medicines, creating risks to the financial sustainability of the NHS and patient access to medicines.

The VPAG is currently subject to an ongoing review, focusing on the terms by which payment percentages for newer medicines are set, the outcome of which may have implications for the ability of the statutory scheme to achieve BCE with VPAG from 2026. However, given consultation and legislative timelines, and the need to update statutory scheme payment percentages from the first day of a new quarter, the Department considers that it is nonetheless appropriate to proceed with this consultation response before the review has concluded in order to minimise the risk that that we fail to achieve BCE during 2025. This is also necessary to ensure stability between the voluntary and statutory schemes through BCE whilst the review, and any potential implementation process, is ongoing. Rates set in the statutory scheme in 2026 and 2027 are not intended to be considered indicative as to the outcome of the VPAG review.

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 as a BCE alternative to VPAG. In doing so, the Department will have regard to the impact on industry, the economy, and patients.

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

Six options are being considered at consultation stage, with Option 5 as DHSC's preferred option. Options 1-5 introduce a revised payment percentage from 1 July 2025 of the following: [2025, 2026, 2027]

- Business as Usual (BAU) - the current regulations remain in force with a payment percentage of 15.5%, 17.9%, and 20.1% in each of the three years covered by this appraisal period.
- Option 1 – Updates sales data, resulting in new payment percentages [22.3%, 24.2%, 26.0%].
- Option 2 – Updates sales data and introduces an Allowed Sales Growth Rate (AGR) of 2% from 2025 to 2027 and no Baseline Allowed Sales Adjustment (BASA). [24.0%, 29.3%, 34.6%].
- Option 3 – Updates sales data, AGR of 3.75%, 3.75% and 4% and BASA of £150m, £330m, and £380m in 2025, 2026, and 2027 respectively. [20.0%, 19.7%, 18.9%].
- Option 4 – Updates sales data, AGR of 3.75%, 3.75%, and 4% in 2025, 2026, and 2027 respectively and no BASA. [21.7%, 24.9%, 27.8%].
- **Option 5 Preferred** – Updated sales data, AGR of 2% and BASA of £50m, £430m, and £380m in 2025, 2026, and 2027 respectively. [23.4%, 24.3%, 26.0%].

Will the policy be reviewed? Statutory scheme payment percentages are kept under regular review to consider whether they continue to meet scheme objective and maintain BCE. This includes consideration, following the conclusion of the VPAG review, as to the impact of that review on BCE moving forward.

If applicable, set review date: Ongoing

Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	**Micro** No	**Small** Yes	**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: Karin Smyth Date: 9 June 2025

Summary: Analysis & Evidence — Business As Usual

Description: Business As Usual

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	PV Base Year 2025	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 (BAU) option is the counterfactual scenario against which other options are assessed. This option is continuing the statutory scheme headline payment rates as of the previous consultation of 15.5% in 2025, 17.9% in 2026, and 20.1% in 2027. However, in the previous statutory scheme of 2024, the best estimate of medicine sales under the scheme was forecast to be £872m (2025 – 2027) at final stage IA. The revised estimate is expected to be £783m (see summary of preferred approach for more information).

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. However, in the previous statutory scheme of 2024, the best estimate of scheme income was forecast to be £174m (2025 – 2027) at final stage IA. The revised estimate is expected to be £147m.

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 Do Nothing, the principal risk is the divergence of the statutory scheme from VPAG in terms of Broad Commercial Equivalence (BCE), destabilising how the two schemes operate together and leading to increased costs for HMG, risks to the financial sustainability of the NHS and patient access to medicines, as well as a less predictable commercial environment for companies. Growth in newer medicine sales in the voluntary scheme has been substantially higher than forecast at the point the statutory scheme headline rate was calculated, which has meant that both newer medicines measured sales (and therefore spend by the NHS) and newer medicines income to the statutory scheme are higher than originally forecast. The risk is the inherent uncertainty associated with forecasts as we have seen significant deviation in the data than what was forecasted. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

BUSINESS ASSESSMENT (BAU)

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 1

Description: We have updated the sales growth estimates seen since previous statutory scheme to reflect actual market sales (i.e. updated the sales data), resulting in new payment percentages.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: £38m	**High:** £190m	**Best Estimate:** £126m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	£0.0m		£1m	£2m
High	£0.0m		£4m	£12m
Best Estimate	£0.0m		£3m	£8m

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

Pharmaceutical companies may see a reduction in nominal profits, estimated to have a cumulative nominal value between £9m and £45m over the three-year appraisal period. Once deflated to 2025 prices and discounted, a loss of £3m to £13m may be attributable to UK shareholders.

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

Lower investment due to loss in company profits might lead to lower patient health outcomes and may lead to loss of "spillover" economic benefits if company investment in the UK falls.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	£0.0m		£14m	£41m
High	£0.0m		£69m	£203m
Best Estimate	£0.0m		£45m	£134m

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

Depending on the level of sales growth between 2025 and 2027, there may be additional net (nominal) income to the NHS (UK) of between £9m to £45m by 2027. This equates to an increase in undiscounted QALYs of 598 to 2,991 by 2027, with a 2025 present value benefit of £41m to £203m (2025 prices).

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

BCE is a long-standing policy that has been supported by the Department and most respondents in successive statutory scheme consultations. An expectation of this policy continuing is likely to have informed company commercial decision making in 2024/25, and so the option that maximises BCE will be the option that best supports a fair and predictable market for pharmaceuticals in the context of changing sales growth. In this context, while this option would represent a significant improvement on BAU, it would nonetheless be less effective in achieving this aim than Option 5. This is because on top of the headline payment percentage, VPAG companies have additional costs such as the investment programme contribution or payments on sales to the NHS of over general sales license medicines, that would otherwise not be accounted for in the 2025 payment percentage. The stability of both schemes, and therefore the benefit of the schemes in ensuring sustainable and predictable growth in branded medicines spend to support NHS and company financial planning, would be better achieved through Option 5. Furthermore, increased income to the NHS will likely support improving patient health outcomes.

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

To support achieving BCE with VPAG, assumptions around newer and older medicine sales are retained at those used for the final VPAG deal. 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 the options available relating to list price increases, detailed later. A key source of data is company returns on NHS sales – we assume that this information is accurate. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: £2.8m	**Benefits:** £0m	**Net:** £2.8m	n/a

Summary: Analysis & Evidence — Policy Option 2

Description: We have updated the sales data underpinning the calculations; Allowed Growth Rate of 2% (nominal) per annum with no baseline adjustments.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	PV Base Year 2025	Time Period Years 3	Net Benefit (Present Value (PV)) (£m)		
			Low: £69m	**High:** £346m	**Best Estimate:** £229m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.0m		£2m	£5m
High	£0.0m		£8m	£23m
Best Estimate	£0.0m		£5m	£15m

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

Pharmaceutical companies may see a reduction in nominal profits, estimated to have a cumulative nominal value between £16m and £82m over the three-year appraisal period. Once deflated to 2025 prices and discounted, a loss of £5m to £23m may be attributable to UK shareholders.

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

This option is not preferred because it results in increases to payment percentages in later years, and therefore additional costs to industry, that are disproportionate to those required to maintain BCE and a stable system for managing spend on medicines. Additionally, lower investment due to loss in company profits might lead to lower patient health outcomes and may lead to loss of "spillover" economic benefits if company investment in the UK declines.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	£0.0m		£25m	£74m
High	£0.0m		£125m	£369m
Best Estimate	£0.0m		£83m	£244m

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

Depending on the level of sales growth between 2025 and 2027, there may be increased (nominal) income to the NHS (UK) of between £16m to £82m by 2027. This equates to a change in undiscounted QALYs of 1,097 to 5,483 by 2027, with a 2025 present value (in 2025 prices) of £74m to £369m.

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

Increased income to the NHS will likely support improving patient health outcomes.

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

Option 2's NPV is £229m, which is £96m greater than that of Option 5. However, there are additional non-monetised benefits to Option 5 that make it a preferred option relative to Option 2. This includes a more stable payment percentage profile, which would support the predictability of the UK environment for life sciences. Overall, this is likely to mean Option 5 maintains greater BCE than Option 2, and we consider these non-monetised benefits to be more valuable than those of the £96m difference in NPV. Furthermore, it is likely that the difference in NPV between Option 2 and Option 5 is an overestimate, as this IA does not make assumptions to whether companies are likely to move from the statutory scheme to VPAG when payment percentages in the former significantly exceed those in the latter. To support achieving BCE with VPAG, assumptions around newer and older medicine sales are retained at those used for the final VPAG deal. 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 the options available relating to list price increases, detailed later. A key source of data is company returns on NHS sales – we assume that this information is accurate. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: n/a
Costs: £5.2m	**Benefits:** £0m	**Net:** £5.2m	

Summary: Analysis & Evidence — Policy Option 3

Description We have updated the sales data underpinning the calculations; Allowed Growth Rates of 3.75%, 3.75%, and 4% per annum in 2025, 2026, and 2027 respectively with baseline adjustments of £150m, £330m, and £380m in 2025, 2026 and 2027 respectively.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years 3**	**Net Benefit (Present Value (PV)) (£m)**		
			Low: £10m	**High:** £50m	**Best Estimate:** £33m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	£0.0m		£0m	£1m
High	£0.0m		£1m	£3m
Best Estimate	£0.0m		£1m	£2m

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

Pharmaceutical companies may see a reduction in profits, estimated to have a cumulative nominal value between £2m and £11m over the three-year appraisal period. Once deflated to 2025 prices and discounted, a loss of £1m to £3m may be attributable to UK shareholders.

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

This option is not preferred because it results in a continued significant difference in terms between the voluntary and statutory schemes, therefore, this option risks Broad Commercial Equivalence (BCE) with VPAG being undermined. Additionally, lower investment due to loss in company profits might lead to lower patient health outcomes and may lead to loss of "spillover" economic benefits if company R&D investment declines.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	£0.0m		£4m	£11m
High	£0.0m		£18m	£53m
Best Estimate	£0.0m		£12m	£35m

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

Depending on the level of sales growth between 2025 and 2027, there may be increased nominal income to the NHS (UK) of between £2m to £11m by 2027. This equates to an increase in undiscounted QALYs of 150 to 752 by 2027, valued at £11m to £53m in 2025 price and present value terms.

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

Increased income to the NHS will likely support improving patient health outcomes.

Key assumptions/sensitivities/risks	**Discount rate (%)**
To support achieving BCE with VPAG, assumptions around newer and older medicine sales are retained at those used for the final VPAG deal. 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 the options available relating to list price increases, detailed later. A key source of data is company returns on NHS sales – we assume that this information is accurate. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.	NHS 1.5% other 3.5%

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m: n/a**
Costs: £0.7m	**Benefits:** £0m	**Net:** £0.7m	

Summary: Analysis & Evidence — Policy Option 4

Description: We have updated the sales data underpinning the calculations; Allowed Growth Rates of 3.75%, 3.75%, and 4% per annum in 2025, 2026, and 2027 respectively with no baseline adjustments.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: £42m	**High:** £210m	**Best Estimate:** £139m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	£0.0m		£1m	£3m
High	£0.0m		£5m	£14m
Best Estimate	£0.0m		£3m	£9m

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

Pharmaceutical companies may see a reduction in nominal profits, estimated to have a cumulative nominal value between £10m and £50m over the three-year appraisal period. Once deflated to 2025 prices and discounted, a loss of £3m to £14m may be attributable to UK shareholders.

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

This option would be less successful than Option 5 to maintain BCE with VPAG. This is because it would result in a 2025 statutory scheme headline payment percentage that does not account for the fact that VPAG companies have additional costs (compared to statutory scheme companies) such as the investment programme contribution or payments on sales to the NHS of over general sales license medicines, while resulting in a 2027 payment percentage that is higher than required to maintain BCE. The stability of both schemes, and therefore the benefit of the schemes in ensuring sustainable and predictable growth in branded medicines spend to support NHS and company financial planning, would be better achieved through Option 5. Additionally, lower investment due to loss in company profits might lead to lower patient health outcomes and may lead to loss of "spillover" economic benefits if company R&D investment declines.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	£0.0m		£15m	£45m
High	£0.0m		£76m	£224m
Best Estimate	£0.0m		£50m	£148m

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

There may be additional nominal income to the NHS (UK) of between £10m to £50m by 2027 compared to BAU. This equates to a change in undiscounted QALYs of 663 to 3,314 by 2027, yielding a 2025 present value benefit (2025 prices) of £45m to £224m.

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

Increased income to the NHS will likely support improving patient health outcomes.

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

To support achieving BCE with VPAG, assumptions around newer and older medicine sales are retained at those used for the final VPAG deal. 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 the options available relating to list price increases, detailed later. A key source of data is company returns on NHS sales – we assume that this information is accurate. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m: n/a**
Costs: £3.1m	**Benefits:** £0m	**Net:** £3.1m	

Summary: Analysis & Evidence Policy Option 5 - Preferred

Description: We have updated the sales data underpinning the calculations; Allowed Growth Rates of 2% per annum in 2025, 2026, and 2027 respectively with baseline adjustments of £50m, £430m, and £380m in those years.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: £40m	**High:** £202m	**Best Estimate:** £133m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	£0.0		£1m	£3m
High	£0.0		£4m	£13m
Best Estimate	£0.0		£3m	£9m

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

Pharmaceutical companies may see a reduction in nominal profits, estimated to have a cumulative nominal value between £9m and £47m over the three-year appraisal period. Once deflated to 2025 prices and discounted, a loss of £3m to £13m may be attributable to UK shareholders.

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

Lower investment due to loss in company profits might lead to lower patient health outcomes and may lead to loss of "spillover" economic benefits if company R&D investment declines.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	£0.0		£15m	£43m
High	£0.0		£73m	£215m
Best Estimate	£0.0		£48m	£142m

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

There may be increased nominal income to the NHS (UK) of between £9m to £47m by 2027. This equates to an increase in undiscounted QALYs of 632 to 3,162 by 2027, valued at £43m to £215m in 2025 price present value terms.

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

BCE is a long-standing policy that has been supported by the Department and most respondents in successive statutory scheme consultations. An expectation of this policy continuing is likely to have informed company commercial decision making in 2024/25, and so the option that maximises BCE will be the option that best supports a fair and predictable market for pharmaceuticals in the context of changing sales growth. Option 5 both supports moving towards BCE between the voluntary and statutory schemes and produces a more stable headline payment percentage. Maintaining BCE supports the stability of both schemes, enabling them to work together to help to ensure value for money for the taxpayer and enable the NHS to continue investing in patients' access to new medicines and non-pharmaceutical services, in a way consistent with supporting both the life sciences sector and broader economy. Increased income to the NHS will likely support improving patient health outcomes.

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

This option brings the statutory scheme in line with VPAG, thereby delivering the policy objective of supporting BCE, whilst restricting the rise in the payment percentage to that necessary to deliver BCE. For this reason, this Option is preferred.

To support achieving BCE with VPAG, assumptions around newer and older medicine sales are retained at those used for the final VPAG deal. 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 the options available relating to list price increases, detailed later. A key source of data is company returns on NHS sales – we assume that this information is accurate. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

BUSINESS ASSESSMENT (Option 5)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m: n/a**
Costs: £3.0m	**Benefits:** £0m	**Net:** £3.0m	

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Evidence Base

Background

1. The life sciences industry is one of the most important pillars of the UK economy, contributing over £108bn a year and 304,200 jobs across the country, of which the Biopharmaceuticals sector generated almost £74bn turnover in 2021/22 and employed 150,000 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 research and development (R&D), as well as an opportunity to recoup R&D costs. These medicines will be sold under a brand name.
3. When a patent expires, competition can be driven by generic or biosimilar variants of medicines entering the market. This typically results in downwards pressure on market prices as new entrants seek to capture a proportion of the producer surplus previously enjoyed by the patent holder. Medicines can continue to be sold under a brand name when their patent expires, though typically they have to compete with new entrants.
4. In England, the 2023/24 spend on prescribed medicines, appliances, and medical devices by the NHS was approximately £20.6bn[2], of which an approximately £14.4bn[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 £19.9bn.
5. In the UK, the costs of branded health service medicines measured sales to the NHS are currently controlled within a voluntary and a statutory framework.

Voluntary scheme

6. The UK Government needs a mechanism to control the NHS branded medicines bill to ensure the long-term financial stability of the NHS and protect patient access to medicines. A series of voluntary agreements between Government and Industry have existed since 1957 to do so. The latest of these is 2024-2028 VPAG. This 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), NHS England, and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI).
7. VPAG was introduced 1 January 2024 and, after a period of transition in Q1 (January-March) 2024, brought in differentiated payment mechanisms for newer and older medicines from 1 April 2024. The payment percentage for newer medicines remains dynamic (i.e. will be amended for the start of each scheme year) and will be set to keep overall sales within allowed sales given the risk sharing elements agreed under the updated scheme. For older medicines, a basic payment percentage of 10% will apply to all eligible sales. Where no exemption is applicable, older medicines will also be allocated a top-up payment percentage of between 0% and 25%, determined with respect to the amount of price reduction observed from the Reference Price. Finally, an Investment Programme payment percentage applies to all eligible sales of VPAG members (irrespective of whether they relate to older or newer medicines). Scheme members

[1] Office for Life Sciences, Department for Business, Energy & Industrial Strategy and Department of Health and Social Care. 2024. Bioscience and health technology sector statistics 2021 to 2022. [https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021-to-2022]. All values 2021/22 prices

[2] Prescribing Costs in Hospitals and the Community - England 2023-24 | NHSBSA – accessed 22 January 2025

[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. Please note that this figure is currently under review. Prices nominal.

[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. Prices nominal

with annual NHS sales of branded health service medicines below £6 million will not be required to make payments.

8. The previous (2019-2023) VPAS scheme[5], which operated by limiting the growth in the overall branded health service medicines bill for products covered by the scheme, began on 1 January 2019 and expired on 31 December 2023. Scheme members with annual NHS sales of branded health service medicines above £5 million made payments to the Department based on the difference between allowed level of sales (which grew at 2% nominal p.a.) and actual outturn growth in measured sales of branded health service medicines. This was achieved through the calculation of a payment percentage, where companies made payments of a particular percentage of their eligible sales to bring actual outturn growth in line with allowed growth[6].
9. The VPAG is currently subject to an ongoing review, focusing on the terms by which payment percentages for newer medicines are set, the outcome of which may have implications for the ability of the statutory scheme to achieve BCE with VPAG from 2026. However, given consultation and legislative timelines, and the need to update statutory scheme payment percentages from the first day of a new quarter, the Department considers that it is nonetheless appropriate to proceed with this consultation response before the review has concluded in order to minimise the risk that that we fail to achieve BCE during 2025. This is also necessary to ensure stability between the voluntary and statutory schemes through BCE whilst the review, and any potential implementation process, is ongoing. Rates set in the statutory scheme in 2026 and 2027 are not intended to be considered indicative as to the outcome of the VPAG review.

Statutory scheme

10. Operating alongside the voluntary scheme are statutory regulations (the statutory scheme). Companies which choose not to join the voluntary scheme are automatically subject to the statutory scheme. The statutory scheme generally makes up a small proportion of branded medicines sales, most recently the companies that have opted to join the statutory scheme for 2024 made up 1.7% of voluntary and statutory scheme measured sales (estimated using 2024 data). There is a general principle of broad commercial equivalence (BCE) between the voluntary and statutory schemes to support the stability of the overall branded medicines pricing system.
11. The legislative changes we introduced following the consultation launched in March 2024 took effect on 1st January 2025. This scheme update was designed to be analogous to the updated structure of VPAG to support BCE between the voluntary and statutory schemes. Among other things, it implemented a differentiated approach to setting payment percentages for older and newer medicines, baseline adjustments to allowed sales, and matched VPAG's updated small sized company threshold.
12. Unlike the VPAG, the terms of the statutory scheme include exemptions for sales of pharmacy medicines and general sale license medicines, and sales made under public contracts and framework agreements. The public contracts and frameworks exemption 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

[5] https://assets.publishing.service.gov.uk/media/5c07b29ded915d747c45af76/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf - accessed 19 June 2024

[6] Note: VPAS applied a single payment percentage to all eligible sales, with no differentiation according to the stage of the lifecycle a product was in, or its historic price trends.

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.

14. A consultation was launched in March 2024 seeking responses to proposed policy options for updating the statutory scheme, with a consultation stage impact assessment published alongside this[7]. The final stage impact assessment retained the preferred option from consultation stage, and was introduced to Parliament in October 2024[8], with an implementation date of 1 January 2025. The implementation of the stated preferred option introduced the differentiated affordability mechanisms for newer and older medicines agreed for the voluntary scheme for branded medicines pricing, access and growth (VPAG) to the statutory scheme. It also introduced headline payment percentages for newer medicines at 15.5%, 17.9%, and 20.1% in 2025, 2026, and 2027 respectively.

15. However, newer medicines measured sales growth in 2024 was higher than expected at the time of negotiation. This resulted in the voluntary scheme headline payment percentage rising from 15.1% in Q2-Q4 2024 to 22.9% in 2025. In the absence of intervention, this would exceed the headline payment percentage for the statutory scheme, and therefore undermine the longstanding policy of broad commercial equivalence. As such, it was necessary to launch a consultation to amend the statutory scheme headline payment percentage to account for the increased newer medicines growth rates. This consultation was launched on 14 March 2025[9].

Description of options considered

16. At Consultation Stage, Option 5 was identified as the preferred option, and this is unchanged at Final Stage. The following options outline different Allowed Growth Rates and Baseline Allowed Sales Adjustments ("baseline adjustments"). An Allowed Growth Rate is the percentage growth rate of allowed sales. A baseline adjustment is an amount of money added to the allowed sales baseline in a given year. Higher allowed growth rates or higher baseline adjustments increase the value of allowed sales in a given year. All other things being equal, this will lower the payment percentage.

17. We have consulted on five non-BAU options to ensure that we considered a wide range of allowed sales growth and adjustments that support achieving BCE with VPAG. Options 1, 2, and 4 follow on from the previous final stage Impact Assessment of October 2024; in Option 4, the allowed sales growth follows on from VPAG but having no baseline adjustments allows it to have a slightly higher payment percentage profile, bringing us closer to BCE. Option 3 follows the baseline adjustments and allowed sales growth rates of VPAG. Option 5 is similar to Option 1 in that the total baseline adjustments over the course of the appraisal period is the same, however £100m of baseline adjustment in 2025 under option 1 is moved in to 2026 under option 5, while the allowed growth rates exactly match Option 1.

18. To support BCE between the statutory scheme and VPAG:

- The proposed options are differentiated by the level of Allowed Growth Rate (AGR) or baseline adjustments proposed as set-out below. Each of the non-BAU options would incorporate the latest available data (up to Q4 2024) to update payment percentages.
    - **Business as Usual (BAU)** – the current regulations remain in force with a headline payment percentage of 15.5%, 17.9%, and 20.1% for the remainder of 2025, 2026, and 2027 respectively.
    - **Option 1** – Update data and maintain BAU Allowed Growth Rate and baseline adjustments as in BAU - Allowed Growth Rate of 2% per annum with baseline adjustments of £150m, £330m, and £380m in 2025, 2026, and 2027 respectively**.**

[7] Impact assessment - Proposed update to the statutory scheme to control the cost of branded health service medicines - accessed 25 July 2024

[8] Impact assessment - Proposed update to the statutory scheme to control the cost of branded health service medicines - accessed 17 January 2025

[9] https://www.gov.uk/government/consultations/proposed-review-of-the-statutory-scheme-for-branded-medicines-pricing - accessed 8 April 2025

- **Option 2** – Update data, maintain BAU Allowed Growth Rate of 2% per annum and no baseline adjustments.
- **Option 3** – Update data and introduce Allowed Growth Rates of 3.75%, 3.75%, and 4% per annum in 2025, 2026, and 2027 respectively and baseline adjustments of £150m, £330m, and £380m in 2025, 2026 and 2027 respectively.
- **Option 4 –** Update data and introduce Allowed Growth Rates of 3.75%, 3.75%, and 4% per annum in 2025, 2026, and 2027 with no baseline adjustments.
- **Option 5 (Preferred)** – Update data, maintain allowed Growth Rate of 2% per annum and baseline adjustments of £50m, £430m, and £380m in 2025, 2026, and 2027 respectively.

19. According to the most recent available data (Q4 2024), Options 1, 3, and 4 would produce headline payment percentages for 2025 below that of VPAG's 22.9%. As such, they do not optimise broad commercial equivalence for that year given that the VPAG member companies have additional costs on top of the 22.9% rate such as for the investment programme contribution. By not having baseline adjustments, Option 2's payment percentage is deemed higher than needed by 2026 and 2027 (29.3% and 34.6% respectively) to maintain BCE with VPAG. Though we note the ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review, and the rates published for the statutory scheme are without prejudice to the outcome of the review.
20. Option 5 supports broad commercial equivalence with VPAG whilst delivering a relatively stable headline payment percentage and is therefore preferred. Option 5 matches the total baseline adjustments and allowed sales growth of Option 1, and therefore has a similar 2026 and 2027 payment percentage to Option 1. However, by delaying £100m of baseline adjustments from 2025 to 2026, the payment percentage in 2025 is higher in Option 5 than Option 1. Moreover, because that £100m of baseline adjustments does not have 2025's allowed sales growth applied to it, the total allowed sales in 2027 is £2m lower in Option 5 than Option 1 (although payment percentages are identical for 2026 and 2027). It is worth noting that other options are likely to perform better on some of the non-BCE objectives. Options with the highest payment percentage are more likely to support the financial position of the NHS and limit the cost of branded medicines. However, options with the lowest payment percentages are expected to generate greater pharmaceutical profits and therefore could be argued to generate a payment rate that best accounting for the costs of research and development, and therefore support the life sciences sector. In this impact assessment, we note the trade-offs of these objectives, but find that Option 5, by supporting BCE with VPAG whilst delivering a relatively stable headline payment percentage, is preferred.

21. Statutory scheme membership varies over time but typically represents a small minority of the overall branded medicines sector. Scheme membership decisions are for companies to take based on their own commercial circumstances. The Department does not seek to make assumptions about the reasons for the choices made by individual companies. However, it is expected that relevant factors are likely to include differences in the applicable exemptions (such as the exemption for sales of pharmacy medicines and General Sale License Medicines products in the statutory scheme) as well as differences in payment percentages and price setting rules.

Explainer – how the statutory scheme operates currently (i.e. in Business As Usual)

22. The statutory scheme currently follows an approach to setting payment percentages similar to VPAG, i.e., differentiated payment percentages for older and newer medicines. A more detailed (technical) treatment of these calculations is presented in Annex E. Below is a simplified example illustrating the calculations.

23. There are several key concepts referred to in this IA that are relevant in both the BAU and proposed policy options. These are set out below (a longer glossary of terms is included in Annex F),

- **Allowed sales –** the amount at which growth in measured sales is to be capped at through payments made by branded medicines manufacturers to DHSC. It is calculated as the Allowed Sales baseline, plus any baseline adjustments if applicable, with the allowed growth rate applied.
- **Baseline adjustment** – an amount of money added to the allowed sales baseline in a given year.
- **Eligible sales** – sales which are subject to the payment percentage. Under all policy options, sales of new active substance (NAS) are exempt from having the payment percentage applied to them.
- **Industry measured sales** – overall measured sales of branded medicines to the NHS (measured by combining relevant sales across the voluntary scheme, statutory scheme and parallel imports).
- **Headline payment percentage –** Payments are made based on a proportion of the manufacturer's eligible sales of newer medicines. This proportion is the payment percentage.
- **Older medicines basic payment percentage** – the basic payment percentage for older products to which the top up rate is added. Across all options (BAU and proposed options), this is 10.6% in 2025, 11.0% in 2026, and 10.9% in 2027 respectively.
- **Older medicines top-up payment percentage** – an additional payment percentage added to the basic payment percentage for older medicines allocated according to the level of observed price decline as set out within the differentiated approach to setting payment percentages for older medicines.

Simplified example of setting payment percentage under the BAU option

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

- Hypothetical forecast **industry measured sales** = £10,000m
- Hypothetical forecast **allowed sales** = £8,500m
- Hypothetical **allowed sales gap** (to reduce measured sales to allowed sales) = £10,000m - £8,500m = £1,500m
- Hypothetical required total payment = £1,500 (assume no parallel imports)
- Hypothetical forecast **adjusted sales (of which newer + older)** = £9,000m (£6,000m + £3,000m)
- Hypothetical forecast adjusted assumed older medicines payment = £500m
- Hypothetical forecast calculated payment from newer medicines payment = Hypothetical required total payment - Hypothetical forecast adjusted assumed older medicines payment = £1,000m*
- Hypothetical **headline payment percentage** = £1,000m / £6,000m = 16.7%
- Each company would make a payment equal to 16.7% of their newer eligible sales.

*NOTE that any gap in the required total payment, after adjusted assumed older medicines payment is deducted, will be covered by a payment from newer medicines.

Approach to setting payment percentages for older medicines

24. This update does not propose amending the approach to setting payment percentages for older medicines in any of the options considered. Under every proposed option (and by definition in the BAU option) all older medicines eligible sales will be subject to the basic payment percentage. The proposed basic payment percentages in every option are 10.6%, 11.0%, and 10.9% respectively in years 2025, 2026, and 2027. This represents the older medicines basic payment percentage in VPAG, adjusted to reflect the VPAG investment programme payment, to support BCE. Note there is no investment programme proposed for the statutory scheme, the adjustment is solely for equivalence purposes.

25. Similarly, there is no proposal to change the range of values of top-up payment percentages, nor the method by which these are to be allocated versus the BAU option. For more information, please see the previous final stage impact assessment "Approach to setting payment percentages for older medicines"[10]. For reference, the basic plus top-up payment percentages and the distribution of older medicine measured sales across these used to calculate the headline payment percentage is shown below. Note, for this final stage IA, we use the same distribution as published for VPAG 2024.

Table 1: Payment percentages for older medicines and portion of older medicines sales in band

2025 basic plus top-up payment percentage	2026 basic plus top-up payment percentage	2027 basic plus top-up payment percentage	Proportion of older medicines sales in band (ATON distribution)
10.6%	11%	10.9%	30.4%
11.6%	12%	11.9%	0.2%
12.6%	13%	12.9%	0.2%
13.6%	14%	13.9%	0.3%
14.6%	15%	14.9%	0.1%
15.6%	16%	15.9%	0.1%
16.6%	17%	16.9%	0.0%
17.6%	18%	17.9%	0.1%
18.6%	19%	18.9%	0.9%
19.6%	20%	19.9%	0.4%
20.6%	21%	20.9%	0.9%
21.6%	22%	21.9%	0.1%
22.6%	23%	22.9%	0.1%
23.6%	24%	23.9%	0.1%
24.6%	25%	24.9%	1.7%
25.6%	26%	25.9%	0.5%
26.6%	27%	26.9%	2.2%
27.6%	28%	27.9%	0.4%
28.6%	29%	28.9%	1.4%
29.6%	30%	29.9%	0.3%
30.6%	31%	30.9%	1.0%
31.6%	32%	31.9%	1.0%
32.6%	33%	32.9%	0.6%
33.6%	34%	33.9%	0.2%
34.6%	35%	34.9%	0.6%
35.6%	36%	35.9%	56.5%

26. The unadjusted forecast income from older medicines is calculated as:

[10] https://assets.publishing.service.gov.uk/media/6712445e8a62ffa8df77b36e/Impact_assessment_update_to_the_statutory_scheme_to_control_the_cost_of_branded_health_service_medicines_August_2024.pdf - 15 January 2025.

- The sum of total forecast older medicines eligible sales by statutory scheme members;
- Multiplied by the proportion of sales in each basic plus top-up payment percentage band; and
- Multiplied by the applicable basic plus top-up payment percentage.

27. For example, at individual basic + top-up payment percentage band level, if in 2025 there were £10 million of eligible older medicines sales, of which 56.5% sat in the maximum basic + top-up payment percentage band, the income generated for that band would be calculated as:

- £10m x 56.5% x 35.6% = just above £2 million.

28. The unadjusted forecast income from older medicines would be the sum of the income calculation above applied to each basic + top-up payment percentage band.

Approach to setting payment percentages for newer medicines

29. Scheme members will make payments to the Department based on the application of the headline payment percentage to their eligible sales of newer medicines. The headline payment percentage will be derived from the required payment from newer medicines, which itself is derived from the required total payment.
30. The required total payment is the difference between industry measured sales and industry allowed sales for a given year, multiplied by the measured sales of the statutory scheme and voluntary scheme as a share of industry measured sales.
31. The required payment from newer medicines across statutory scheme and voluntary scheme members is the required total payment minus the adjusted forecast payment from older medicines (calculation of this set out in Figure 1 and Annex E). For the proposed options, headline payment percentage will equal the required payment from newer medicines divided by the eligible sales of newer medicines across statutory scheme and voluntary scheme members, rounded to one decimal place. This payment percentage is applied to statutory scheme newer medicines eligible sales. Eligible sales of newer medicines are calculated as measured sales of newer medicines minus NAS Sales. The income for newer medicines is calculated by taking the statutory scheme newer medicine eligible sales and applying the statutory scheme payment percentage.
32. Please note that the above methodology is true for the proposed options but not for BAU. This is because in the previous final stage impact assessment of October 2024[11], reference was incorrectly made to statutory scheme measured sales, rather than voluntary scheme and statutory scheme measured sales. In the same approach to our amendments to Figure 1, we would also like to clarify that Annex E in the previous final stage impact assessment of October 2024 should have referred to voluntary scheme and statutory scheme measured sales to calculate the statutory scheme headline payment percentage, rather than just statutory scheme measured sales. We have updated the narrative of the methodology here, but the calculations remain unchanged. Please refer to Annex E for a more detailed description. We would also like to clarify that in the top row of Figure 1 the older medicines measured sales forecast is a fixed forecast.
33. For the statutory scheme, the proposed options headline payment percentage will be calculated for 2025, 2026 and 2027. Since Q1-Q2 2024 rates have been fixed at 15.5%, the Q3-Q4 2025 rates have been calculated accordingly to bring the average rate to what has been set for the full year 2025 for each option. Ongoing monitoring will be undertaken to compare actuals data to forecast values.
34. The adjusted forecast payment from older medicines that underpins the calculation of the forecast required payment from newer medicines is reached by applying a downwards adjustment factor to the forecast payment from older medicines. This is applied as a proportional reduction per annum in the forecast payment from older medicines to reflect the inherent

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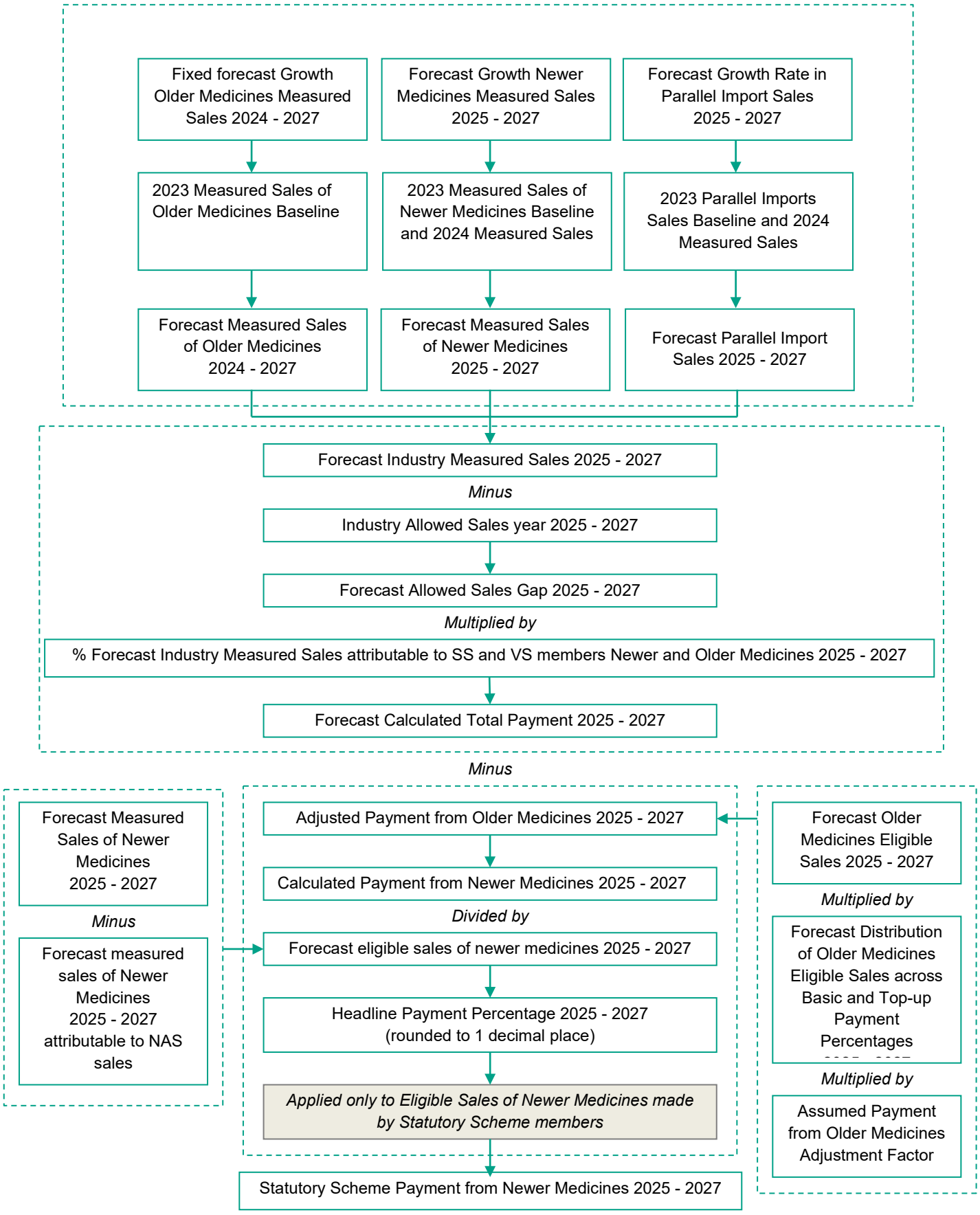
uncertainty regarding forecasting payments from older medicines over time and optimism bias. As such, it increases over time and is pre-determined at the rates shown below in Table 2.

Table 2: Forecast payment from older medicines adjustment factor

	2025	2026	2027
Forecast payment from older medicines adjustment factor	-5.8%	-8.3%	-10.5%

35. Figure 1 (below) shows the step-by-step process by which the headline payment percentage will be calculated under the preferred option.

Figure 1: Calculation of Headline Payment Percentage



Allowed Sales Growth

36. Under the Preferred Option, allowed sales grows by 2% (nominal) per annum. Increasing allowed growth beyond this (outside of the context of a time-bound negotiated voluntary agreement with mutual benefits for government and industry) could increase the risk of unsustainable growth in spending on branded medicines in the longer term. Under all options (including BAU) the VPAG risk-sharing agreement is measured such that government will absorb all risk associated with older medicines growth and payments while the industry will absorb all risk associated with newer medicines growth and payments. The risk sharing approach is a negotiated position agreed for VPAG to give confidence to suppliers of newer medicines that they would not be exposed to the consequences of the, at the time, uncertain impact of the older medicines affordability mechanism. Following this approach in the statutory scheme supports BCE and protects the continued efficacy of risk sharing in VPAG. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

37. The nominal 2% per annum allowed sales growth rate assumes that pharmaceutical companies will set their list prices taking inflationary pressures on costs into account, subject to their allowed maximum prices, applying for list price increases as appropriate. As noted in the previous Consultation Response[12], the Department considers that the branded pharmaceutical industry has relatively low exposure to inflationary pressures, as production and transportation costs of medicines are a low proportion of their overall price.

Forecast measured sales

Estimating a baseline for 2023 measured sales

38. In the previous final stage impact assessment of October 2024, the “at time of negotiation” (ATON) split of older and newer medicines was used to estimate the split of older and newer medicine sales in 2023. This was that 54.3% of medicines sales were newer, and 45.7% were older.

39. Following the previous update to the statutory scheme in October 2024, the Department concluded an exploration of estimating the proportion of sales in 2023 that were newer and older medicines. This work matched presentations in company’s Product Level Returns data for 2023 to “older” or “newer” classifications assigned to them through the Reference Pricing programme.

40. The Product Level Returns gives a revised estimate of 59.08% of medicines sales being newer and 40.92% being older. As noted in the Q4 2024 VPAG update[13], there were £13.205bn of older and newer medicines measured sales estimated in 2023. Of these, £7.801bn were estimated to be newer, as per the newer-older split.

41. To match the values used in VPAG, these estimates have been incorporated into this statutory scheme update. As the baseline of newer and older medicines sales, this change will have resulted in greater newer medicines sales in the following years (all other things being equal).

Forecasting newer medicines, older medicines, and parallel import sales for calculating payment percentages.

42. Starting from their respective 2023 measured sales baselines, we apply newer, older, and parallel import (PI) medicines spend growth rates to generate forecasts for measured sales over the appraisal period.

43. For newer medicines and parallel imports, for 2024, we follow VPAG’s year-to-date forecast for 2024 medicines sales. This involves calculating the growth rates of sales of newer medicines and PI from Q1-Q4 2023 to Q1-Q4 2024. This generates a newer medicines measured sales growth rate of 13.89% and a parallel import growth rate of -3.26% in 2024. Newer medicine and

[12] Consultation response - GOV.UK

[13] Aggregate net sales and payment information: February 2025 - GOV.UK – accessed 8 April 2025

PI growth rates after 2024 match VPAG and are the At Time of Negotiation (ATON) growth rates.

44. For older medicines growth rates, following the mechanism used within VPAG, ATON growth rates are used to calculate 2024 growth as well as 2025 and beyond.

45. The resulting measured sales growth rates and measured sales estimates used are noted below. Please note, these values will not match the values used on the GOV.UK update as those exclude SME movers for the purpose of calculating growth rates.

Table 3: Forecast measured sales for payment percentage[14]

Medicine sale	2023	2024	2025	2026	2027
Newer growth		13.9%	5.0%	6.8%	6.2%
Older growth		4.6%	5.2%	5.5%	6.3%
PI growth		-3.3%	0.5%	0.5%	0.5%
Newer (£m)	7,800	8,890	9,330	9,970	10,590
Older (£m)	5,400	5,650	5,940	6,270	6,670
PI (£m)	700	680	680	690	690

Figures rounded to nearest £10m and nearest 1 decimal point, where applicable.

Forecasting newer medicines, older medicines, and parallel import sales for calculating income

46. To calculate the income, rather than the payment percentage, slightly different estimates of medicine sales growth rates are used for older medicines and newer medicines.

47. For newer medicines, a different growth rate to payment percentage calculation is used for 2024 (14.37% versus 13.89%). The reason for this is that for calculating payment percentages, a different older medicines growth rate is used for estimating 2024 sales (ATON) compared with income (where actual data is used). This affects the Q2 2024 newer-older medicines split. This in turn impacts the estimate of Q1 2024 newer-older medicines sales split (since Q1 2024 split was not recorded but rather is estimated by the average of Q2 2024 and 2023), creating a varying estimate of newer medicines sales in Q1 2024.

48. As such, given the value of newer and older medicines measured sales in Q4 2024 is known but the same older medicines growth rate is being applied to older medicines sales, a different newer medicines sales growth is required from the income side and the payment percentage side to arrive at the observed Q4 2024 measured sales values. This explains the difference in newer medicines growth rates.

49. Older medicines growth rates are also calculated in a different way for the income side of modelling compared with payment percentages. This is because we include actual data into estimating older medicines income as far as is available.

50. Table 4 below shows the distribution of older medicines sales across basic + top-up payment percentages, excluding assumed projections for debranded sales. Please note, this distribution differs significantly from the consultation impact assessment, as it now includes findings from observed data as of 2023, but including VPAG members as of 2024. This is then adjusted to reflect debranding assumptions. Please note, 2023 product-level returns are the latest data currently available and we expect the distribution to be further updated once we receive actual 2024 data.

[14] Growth rates depicted are excluding SME movers, but the annual sales are 2023 baseline including SME movers using excluding SME movers' growth rates. The annual values will not match the values used on the GOV.UK update as those exclude SME movers for the purpose of calculating growth rates.

Table 4: Combined Outturn and Forecast Distribution of Older Medicines Sales Across Older Medicines Payment Percentages Excluding Debranded Sales (for estimating income)

Proportion of older medicines measured sales	2024	2025	2026	2027
Basic Payment Percentage	41.57%	42.18%	42.75%	43.28%
Basic + Top-up Payment Percentage 1	0.99%	1.01%	1.02%	1.03%
Basic + Top-up Payment Percentage 2	0.24%	0.25%	0.25%	0.25%
Basic + Top-up Payment Percentage 3	0.66%	0.67%	0.68%	0.69%
Basic + Top-up Payment Percentage 4	0.65%	0.66%	0.67%	0.68%
Basic + Top-up Payment Percentage 5	1.23%	1.25%	1.27%	1.28%
Basic + Top-up Payment Percentage 6	0.94%	0.95%	0.97%	0.98%
Basic + Top-up Payment Percentage 7	0.45%	0.46%	0.46%	0.47%
Basic + Top-up Payment Percentage 8	0.46%	0.47%	0.47%	0.48%
Basic + Top-up Payment Percentage 9	1.94%	1.97%	2.00%	2.02%
Basic + Top-up Payment Percentage 10	0.74%	0.75%	0.76%	0.77%
Basic + Top-up Payment Percentage 11	0.86%	0.88%	0.89%	0.90%
Basic + Top-up Payment Percentage 12	3.37%	3.42%	3.47%	3.51%
Basic + Top-up Payment Percentage 13	2.19%	2.22%	2.25%	2.28%
Basic + Top-up Payment Percentage 14	0.58%	0.59%	0.60%	0.60%
Basic + Top-up Payment Percentage 15	0.30%	0.30%	0.30%	0.30%
Basic + Top-up Payment Percentage 16	1.03%	1.04%	1.04%	1.05%
Basic + Top-up Payment Percentage 17	1.40%	1.41%	1.41%	1.42%
Basic + Top-up Payment Percentage 18	0.08%	0.08%	0.08%	0.08%
Basic + Top-up Payment Percentage 19	0.16%	0.16%	0.16%	0.16%
Basic + Top-up Payment Percentage 20	0.14%	0.14%	0.13%	0.13%
Basic + Top-up Payment Percentage 21	0.20%	0.20%	0.20%	0.19%
Basic + Top-up Payment Percentage 22	0.21%	0.20%	0.20%	0.20%
Basic + Top-up Payment Percentage 23	0.39%	0.38%	0.38%	0.37%
Basic + Top-up Payment Percentage 24	0.22%	0.21%	0.21%	0.20%
Basic + Top-up Payment Percentage 25	38.99%	38.15%	37.38%	36.66%

51. We have identified an issue with the methodology used for calculating older medicines income in the October 2024 final stage impact assessment Which led to a slight under-estimate of projected older medicines income. There are two ways of calculating the income effects of debranding, both of which produce the same result. On the payment percentage side of the model, the ATON growth rate of older medicines income is applied, followed by the ATON top-up distribution of older medicines for all years. However, to account for the loss of income due to debranding, the “adjustment for optimism bias and uncertainty” is applied to reduce income. For more information, see Table 2. The alternative way of calculating older medicines income after debranding is used on the income side of the model. This reflects the fact that for income calculations, where possible, we use actual data which will by definition reflect debranding that has already occurred. Therefore, for 2025 and beyond a lower older medicines forecast growth rate is used that accounts for debranding of sales (see older medicines growth excluding debranded sales in Table 5 below). Furthermore, the top-up payment distribution is revised in each year of 2025 – 2027, to reflect an assumption that older medicines are more likely to debrand if they face higher top-up rates. No subsequent adjustment for optimism bias and uncertainty is applied to income.
52. To note, since the consultation impact assessment the reported newer measured sales growth rates for 2024 have fallen, but the value of newer medicines measured sales in 2024 have risen. This is due to growth rates being calculated from using measured sales values excluding SME movers, which results in a lower growth rate than if the reported growth rates used including SME movers newer medicines measured sales.
53. The previous final stage impact assessment of October 2024 underestimated older medicines income by applying the adjustment for optimism bias and uncertainty in addition to the

distribution revised to deflect debranding. However, this was likely to have only a very minor effect in calculating older medicines income and would not have affected the payment percentage. We have not quantified this effect as there have been significant further updates in our modelling for this IA that help refine these calculations.

54. As a result of the differences in older medicines growth rates between the payment percentage and income side of the model, there is a different estimate of the proportion of sales attributable to the statutory scheme used in the income side of the model and the payment percentage side of the model. In the income side of the model, it is assumed in the central case for all years that 1.64% of older medicines sales across VPAG and the statutory scheme are attributable to the statutory scheme, compared with 1.65% for newer medicines. These values are used to calculate the income for the statutory scheme options. Please note, these values differ between payment percentage and income side of model due to the aforementioned differences in newer medicines growth rates and different estimates in Q1 2024 newer-older medicine split between income and payment percentage side of model.
55. The resulting growth rates used for the income side of the statutory scheme model calculations are reported below.

Table 5: Medicines sales growth and values under income side of statutory scheme[15]

Medicine sale	2023	2024	2025	2026	2027
Newer growth		14.4%	5.0%	6.8%	6.2%
Older ATON growth (including debranded sales)		4.6%	5.2%	5.5%	6.3%
Older growth (excluding debranded sales)		-3.4%	3.0%	3.5%	4.5%
PI growth		-3.3%	0.5%	0.5%	0.5%
Newer (£m)	7,800	9,010	9,460	10,110	10,730
Older (excluding debranded sales - £m)	5,400	5,370	5,530	5,720	5,980
PI (£m)	700	680	680	690	690

Figures rounded to nearest £10m and nearest 1 decimal point, where applicable.

56. The detailed description of DHSC's medicines 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.
57. Measured sales includes all sales of scheme products by companies in scope of the statutory scheme and the voluntary scheme, plus parallel import sales. Sales that are excluded from measured sales in both the BAU counterfactual and policy options are:

- **Low value sales** – products with an NHS list price of less than £2 per pack;
- **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; and
- **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.

58. The resulting forecast for measured sales in both the BAU counterfactual and under our proposed policy options is shown in the table below. The scenarios refer to different assumptions

[15] Growth rates depicted are excluding SME movers, but the annual sales are 2023 baseline including SME movers using excluding SME movers' growth rates.

under proportion of sales attributable to the statutory scheme. For more information, see “Risks and Assumptions”.

Table 6: Statutory scheme measured sales under differing scenarios, as of Q4 2024

		2025	2026	2027
Low Scenario	Forecast SS measured sales £m	75	79	84
Central Scenario	Forecast SS measured sales £m	247	261	275
High Scenario	Forecast SS measured sales £m	375	396	418

Problem under consideration and rationale for intervention

59. Since the statutory scheme was established as a payment scheme in 2018, we have sought to set its payment rates so it can achieve its objectives (as set out below) in a way that maintains BCE with the voluntary scheme. In doing so we ensure the stability of both schemes such that the statutory scheme can provide a viable alternative to the voluntary scheme, without disrupting the market or undermining the voluntary scheme, which is an important partnership between industry and Government.

60. The statutory scheme was last updated to come into effect from 1st January 2025. When the final stage impact assessment was published in October 2024[16], the calculated rate for 2025 (15.5%) was BCE to VPAG’s projected headline payment percentage in 2025 (15.3% - see VPAG Annex 3[17]). However, the 2025 VPAG headline rate, calculated using sales data to Q3 2024 (which included higher than expected newer medicines sales growth), was finalised at 22.9%[18]. This exceeds the BAU statutory scheme payment percentage by 7.4 percentage points. If newer medicines measured sales growth returns to or is close to the forecast rate in future years, the VPAG headline rate would stabilise at around this level. However, future growth forecasts are inherently uncertain, particularly in the longer term.

61. As a result of this, the BAU statutory scheme payment percentages for 2025 – 2027 are no longer considered to deliver the objective of BCE with VPAG. While the deadline to leave the voluntary scheme for 2025 has passed, so leakage in this year is not possible, the Department is proposing to update the statutory scheme to maintain the principle of BCE between the two schemes. To ensure BCE with VPAG on average across 2025, and avoid skewing the impact of this on to a relatively short time period, the Department proposes to update the statutory scheme as soon as possible within 2025.

62. For operational reasons, the statutory scheme needs to be updated on the first day of a new quarter, and 1 July 2025 is the earliest feasible date to implement an update. Delaying the update to October 2025 would require a much higher payment percentage for Q4 2025 to ensure that the average payment percentage for 2025 is broadly commercially equivalent with VPAG.

63. If the payment percentages for the statutory scheme are not brought into BCE, voluntary scheme members may become increasingly dissatisfied with the overall processes of VPAG. This may impact the integrity and stability of the voluntary scheme beyond 2025, which would likely negatively impact the certainty of NHS expenditure on medicines, as well as create a volatile commercial and investment environment for pharmaceutical firms. As such, the Department is proposing to update the statutory scheme to maintain the principle of BCE between the two schemes.

64. Collectively, these risks could undermine the stability of the schemes, and so mean that neither the statutory scheme nor the VPAG are able to achieve the pro-innovation and pro-competition ambitions set out above. Amendments to the statutory scheme are therefore required to:

[16] Impact assessment: update to the statutory scheme to control the cost of branded health service medicines – accessed 9 January 2025
[17] Annexes to the 2024 voluntary scheme for branded medicines pricing, access and growth – accessed 9 January 2025
[18] The 2024 voluntary scheme for branded medicines pricing, access and growth: payment percentage for 2025 - GOV.UK – accessed 9 January 2025

- Support BCE with VPAG;
- Address the risks above; and
- Ensure the statutory scheme safeguards the financial position of the NHS, ensures medicines are available on reasonable terms, and does so in a way that supports the life sciences sector, working alongside VPAG.

65. The consultation therefore sought views on proposed options for what the appropriate revised payment percentages for the statutory scheme could be. It primarily sought to set rates that achieve BCE and address the above risks, but to do so while establishing a clear methodology for the calculation of such rates that can act independently as a backstop to VPAG if needed. The ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review.

Policy objective

66. The objective of the policy options proposed in this update are to support achieving BCE between the statutory scheme and VPAG. This final stage IA uses the latest data currently available, which covers up to Q4 2024.
67. Please note that, more generally, 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
- To deliver the above objectives in a way consistent with supporting both the life sciences sector and broader economy.

Note on inflation assumptions

68. The headline values for this assessment are presented in 2025 prices, 2025 present value.
69. Values are specified whether they are in nominal or 2025 price terms. Values should be assumed to be undiscounted (i.e. not present value) unless otherwise specified. To estimate values at 2025 prices, the GDP deflator is used, using data from 28 March 2025[19].

Summary and preferred option with description of implementation plan

70. The preferred option is **Option 5**, i.e. to update the statutory scheme so that:

- Payment percentages are recalculated based on an allowed level of growth from the 2023 starting point and adjusted for 2024 (see “Establishing an allowed sales 2023 and 2024 baseline”).
- The allowed growth in measured sales is equivalent to nominal 2% per annum with baseline adjustments of £50m, £430m, and £380m each in year 2025, 2026, and 2027.
- Additionally, taking the 2023 and 2024 measured sales estimates as seen in ‘forecast measured sales’ section above, we calculate the forecast measured sales for 2025-2027, following exemptions, as seen in Figure 1 and Annex E.

71. The Preferred Option will be given effect via secondary legislation and there is no proposal to implement transitional arrangements post the proposed coming into effect date of 1 July 2025. The intervention will 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

[19] Impact assessment and options assessment calculator - GOV.UK– accessed 9 April 2025.

control and value for money for the NHS in a way consistent with supporting both the life sciences sector and broader economy. DHSC will continue to be responsible for the ongoing operation and enforcement of the statutory scheme.

72. As has been the case with the current statutory scheme, we will be monitoring the scheme and actual sales data. If review suggests the need for changes to the payment percentages, this could be pursued via a further secondary legislation amendment.

73. Please note that this assessment has not been scrutinised by the Regulatory Policy Committee (RPC) as 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[20]. As such, the proposals are out of scope from the definition of Regulatory Provisions as set out within para 2.3 of the Better Regulation Framework[21] guidance. This position has been confirmed previously by the Economic and Domestic Affairs Secretariat at the Cabinet Office.

Summary of aggregate costs and benefits

74. The preferred Option 5 replicates the cumulative value of allowed sales baseline adjustments agreed for VPAG over the appraisal period of 2025-2027, albeit there are differences within individual years. Conversely, Option 3 replicates the Allowed Sales Growth Rates and adjustments from VPAG in each given year. Option 4 replicates the increased Allowed Growth Rate for VPAG with zero baseline adjustments, while Option 2 has 2% p.a. Allowed Growth Rate for 2025-2027 and no baseline adjustments. Option 1 matches the same AGR and baseline adjustments as was previously consulted on in March 2024 but generates a different payment percentage due to the inclusion of up-to-date data (Options 2 – 5 also include updated data).

75. Because of the impact driven by updating the data underpinning the statutory scheme headline payment percentage calculations, in each proposed option, higher income is generated than under BAU. The overall quantified impact of all the proposed policy options is therefore a net societal benefit under low, central, and high scenarios. The proposed options also support maintaining BCE between the statutory scheme and VPAG, and therefore the long-term stability of both schemes and their ability to protect NHS budgets. Additionally, to balance the level of risk being held by industry and government, the costs will accrue to industry in terms of reduced profits to UK shareholders.

76. Because the statutory scheme membership is uncertain, we present low, central, and high forecast scenarios for this assumption. For details of the assumptions underpinning each scenario please see “Risks and Assumptions”. Whilst the central is presented as the “best estimate” each of the scenarios is considered broadly similar in plausibility.

77. Table 8 summarises the aggregate costs and benefits generated by the preferred Option 5 versus the BAU counterfactual. Rows from the summary table that feature in the overall NPV are flagged in the final row, and all figures are rounded to the nearest £1m in this high-level summary. More granular estimates are provided in the assessment of specific options sections.

78. Please note that the overall NPV becomes more positive in scenarios with a higher proportion of sales attributable to the statutory scheme, because a greater income is earned above the BAU counterfactual (even accounting for scenarios where we assume greater sales attributable to the statutory scheme in the BAU), which generates higher QALYs and therefore societal benefits.

[20] Small Business, Enterprise and Employment Act 2015. 2015. [https://www.legislation.gov.uk/ukpga/2015/26/section/22/enacted]
[21] Better_Regulation_Framework_guidance.pdf (publishing.service.gov.uk)
https://assets.publishing.service.gov.uk/media/65420ee8d36c91000d935b58/Better_Regulation_Framework_guidance.pdf

Approach to updating payment percentage midway through year (and correction to previous statutory scheme calculation)

79. The earliest possible implementation date for an updated statutory scheme would be 1 July 2025. Therefore, the current headline payment percentage, 15.5%, will continue to apply until implementation. From 1 July 2025, we propose that the payment percentages on newer medicines as outlined in the Preferred Option will be implemented.

80. To ensure an equitable approach to setting the payment percentage and to maximise Broad Commercial Equivalence, the resulting payment percentage that is set in 2025 will be such that:

    a. Taking the latest Q4 2024 data into account, the headline payment percentage for the full-year 2025 is set based on the levels of Allowed Growth Rates and Baseline Adjustments set out in each option. The resulting payment percentage would then be profiled as the set 15.5% for Q1-Q2 2025 and Q3-Q4 2025 set at the level required to, on average, deliver the intended rate for the full-year 2025.

81. Following a review of the methodology used in the previous final stage statutory scheme of October 2024, DHSC has identified an error in the calculation used for the previous statutory scheme payment percentage calculation. The previous calculation incorrectly included a Medium Sized Company Exemption (MSCE) when calculating the payment percentage. This means that the payment percentage for 2025 was set too high by 0.9 percentage points, and that it should have been 14.6% rather than 15.5%.

82. To account for this error, no changes to the above method need to be made. This is because the payment percentage set in Q3 and Q4 by the calculation in paragraph a) averages with 15.5% to achieve the target rate for 2025 for each non-BAU option. If the payment percentage had been initially set correctly for Q1 and Q2 2025 (at 14.6%), then the resulting payment percentages for Q3 and Q4 2025 to achieve each option's target 2025 average rate would have been 0.9 percentage points higher. In short, we have already accounted for the error through the method outlined in a).

Summary of preferred approach

83. We prefer Option 5 on the grounds that it maximises Broad Commercial Equivalence (BCE). BCE is maximised by (among other things) balancing a payment percentage that is compatible with the continued stability of VPAG, as well as ensuring affordability for the NHS, ensuring medicines are available on reasonable terms that account for the costs of R&D, and delivering the two policy objectives in a way consistent with supporting the life sciences sector and the broader economy. In the context of rising VPAG payment percentages, Option BAU, 1, 3 and 4, do not provide a sufficient level of stability for the continued operation of VPAG, and do not provide sufficient safeguards of the NHS. On the other hand, Option 2 results in increases to payment percentages, and therefore additional costs to industry, that are disproportionate to those required to maintain BCE and a stable system for managing spend on medicines. This leaves Option 5, which provides a stable payment percentage, which is our Preferred Option.

Table 7: summary of option payment percentage rates for newer medicines

	2025	2025 Q3 and Q4	2026	2027
BAU	15.5%	15.5%	17.9%	20.1%
Option 1	22.3%	29.1%	24.2%	26.0%
Option 2	24.0%	32.5%	29.3%	34.6%
Option 3	20.0%	24.5%	19.7%	18.9%
Option 4	21.7%	27.9%	24.9%	27.8%
Option 5	23.4%	31.3%	24.3%	26.0%
VPAG	22.9%			

Table 8: Summary of aggregate costs and benefits between BAU and Option 5

Impact on	Description of impact	Cumulative low scenario	Cumulative mid scenario	Cumulative high scenario
NHS finances (1) (nominal)	Reduced cost of branded medicines as increased payment percentages reduce costs	(+) £9m	(+) £31m	(+) £47m
NHS patients (PV, 2025 prices) (2)	Societal value QALYs not foregone due to reduced cost	(+) £43m	(+) £142m	(+) £215m
NHS patients (3)	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 to support ongoing access to cost-effective medicines.		
Pharmaceutical / life sciences industry (4) (nominal)	Reduced profit on UK sales of branded medicines driven by increased payment percentages	(-) £9m	(-) £31m	(-) £47m
Pharmaceutical / life sciences industry UK shareholders (PV, 2025 prices) (5)	Reduced profit on UK sales of branded medicines driven by increased payment percentages accruing to UK shareholders	(-) £3m	(-) £9m	(-) £13m
Overall quantified NPV (2025 prices) (2) + (5)		**£40m**	**£133m**	**£202m**

Numbers may not sum due to rounding (rounded to nearest £1m)

84. Table 9 below sets out the forecast statutory scheme income in each forecast scenario under the BAU counterfactual option.

85. As noted in the Summary, BAU is now expected to generate a different income compared to that previously forecast in the final stage impact assessment (IA) of October 2024, despite maintaining the same payment percentages. In the previous statutory scheme final IA, the best estimate of scheme income was forecast to be £174m (2025-2027), and £163 in the previous consultation impact assessment. The revised estimate is expected to be £147m. The driver for this is lower than expected branded medicines sales through the statutory scheme. This is now forecasted to be £783m for 2025-2027, compared with £872m in the previous final IA and £804m in the consultation impact assessment, despite newer branded medicine sales growth estimated in 2024 being higher than forecast ATON. The lower-than-expected branded medicines sales is due to a downward revision of the proportion of voluntary and statutory scheme sales that go through the statutory scheme (estimated at 1.88% in the previous statutory scheme final stage IA and 1.68% in the consultation scheme IA, now estimated at 1.67%). Moreover, there has been a revision in the older medicines top-up band distribution since both the consultation IA and previous final stage IA, which has meant that estimates of older medicines income have fallen under all scenarios.

Table 9: BAU expected income (nominal)

		2025	2026	2027	Cumulative
Low Scenario	SS income forecast £m	13	15	17	45
Central Scenario	SS income forecast £m	43	49	55	147
High Scenario	SS income forecast £m	65	75	84	223

Numbers may not sum due to rounding (rounded to nearest £1m)

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

86. In line with Green Book guidance, the proposed option is assessed against the counterfactual BAU option of 15.5%, 17.9%, and 20.1% payment percentages in 2025, 2026, and 2027 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.

87. We first describe establishing the 2023 and 2024 allowed sales baseline and how measured sales are forecast to grow from our 2023 measured sales baseline. Through the formula outlined in Annex E, we calculate the newer medicines payment percentage and the resulting statutory scheme income. By amending statutory scheme proportion of branded medicines measured sales (see Risks and Assumptions), we generate low and high sensitivities for costs and benefits. The aggregate cost and benefits appraisal is then presented followed by an assessment of option specific impacts.

88. The proposed options have a positive associated societal NPV. This reflects the fact that headline payment percentages are higher in the proposed options than under BAU counterfactual. This is the same for all options for all years. A key factor driving these higher payment percentages is above forecast newer medicines measured sales growth 2024. For more information on this, please see the GOV.UK update[22].

89. The preferred option also introduces baseline adjustments that match the total value of those agreed within VPAG to support maintaining BCE with VPAG.

Familiarisation costs

90. When firms enter the statutory scheme, either from the voluntary scheme or otherwise, they will be obliged to familiarise themselves with the scheme terms and understand the implications on payments. As a result of the payment percentages of the statutory scheme being changed from the Preferred Option being implemented, firms will be obliged to familiarise themselves with the new terms of the legislation. As each of the non-BAU options are only amending the newer medicines payment percentage (through updating the data underpinning the calculations and amending the values of proposed baseline adjustments and allowed sales growth rate), we anticipate firms' additional familiarisation costs should be relatively low.

91. We have used an arbitrary assumption of a central estimate of three hours of administrative time per firm, with a low and high case of two and four hours to familiarise. According to the Office for National Statistics (ONS)[23], the mean wage for "Office administrative, office support and other business activities" was £20.90[24] an hour based on the 2023 revised hourly wages. Additionally, there are employment costs estimated to be 22%[25] of nominal wages, bringing the hourly employment cost to £25.50. Inflated to 2025 prices, these are £27.36 an hour. Based on DHSC internal sources, the Department notes that as of January 2025 there are 95 firms in the statutory scheme. This value is taken as the estimate for the number of firms to be in the Scheme for the rest of the year, subject to the possibility of some firms entering or exiting the

[22] The 2024 voluntary scheme for branded medicines pricing, access and growth: payment percentage for 2025 - GOV.UK – accessed 15 January 2025
[23] Earnings and hours worked, industry by four-digit SIC: ASHE Table 16 – 2023 Revised data – Hourly Pay – Gross 2023
[24] Since the Impact Assessment is presented in 2025 prices, we assume that 2023 hourly wages are inflated to 2025 values at the same rate as prices.
[25] RPC_short_guidance_note_-_Implementation_costs__August_2019.pdf

market. This is taken to be the central (mid) scenario. Although a vast majority of these companies' sales are exempt on the grounds that they are small firms, we have conservatively assumed that all firms will have to familiarise themselves with the legislation. The low and high scenarios have been estimated from the central scenario. This generates a one-off (undiscounted) cost in 2025 prices of:

Table 10: Transition costs for firms entering the statutory scheme

Scenario	**Low**	**Mid**	**High**
Hours per firm	2	3	4
Cost per firm	£54.73	£82.09	£109.46
Number of firms	95	95	95
Total costs to firms	£5,200	£7,800	£10,400

Figures rounded to the nearest £100.

Additional requirements for auditors under all non-BAU options

92. Given the additional importance of presentation level reports in both VPAG and the statutory scheme, the Department is considering, and seeking views on, alternative methods of seeking assurance to the accuracy of these reports. Such assurance is intended to give greater confidence as to the quality of the presentation report provided. In doing so, we aim to give companies and the department greater confidence that the headline payment percentage has been calculated based on an accurate assessment of the split between newer and older medicines. This will also give greater confidence in the accuracy of the calculation of reference prices and top-up payment percentages. We are working with the ABPI in consultation with companies on what this might look like in the context of VPAG.
93. To minimise the administrative burden that additional assurance requirements will put on companies, the Department does not propose that this would take the form of a full audit. Instead, we propose that an independent auditor would conduct additional assurance procedures on presentation reports. The Department sought views on this through this consultation on what these procedures could look like in practice.
94. The costs of these requirements have not been quantified here. Payment companies will be familiar with the costs of statutory scheme audits. As such, the Department expects these requirements to be at a similar level to current audits and could be combined with current audit requirements.
95. Overall, these costs to industry are expected to be sufficiently small to warrant not quantifying as only 9 Statutory Scheme companies are payment companies that are required to provide a PLR and, therefore, be required to comply with the AUPs requirements.
96. However, the consultation asked responding companies to provide data and/or evidence on what their additional costs relating to this requirement are expected to be. Having reviewed the responses from the consultation, there was insufficient evidence provided on costs to include in this analysis.

Risks and assumptions

97. This section details the risks associated with the appraisal of the policy options. The detail of assumptions used is discussed throughout the IA so that information is not repeated here though a summary table is provided.
98. In the absence of future consultation and legislative change, the payment percentages set in the existing statutory scheme will not update and there is no under-over payment mechanism as the scheme is not time-bound.

99. The VPAG is currently subject to an ongoing review, focusing on the terms by which payment percentages for newer medicines are set, the outcome of which may have implications for the ability of the statutory scheme to achieve BCE with VPAG from 2026. However, given consultation and legislative timelines, and the need to update statutory scheme payment percentages from the first day of a new quarter, the Department considers that it is nonetheless appropriate to proceed with this consultation response before the review has concluded in order to minimise the risk that that we fail to achieve BCE during 2025. This is also necessary to ensure stability between the voluntary and statutory schemes through BCE whilst the review, and any potential implementation process, is ongoing. Rates set in the statutory scheme in 2026 and 2027 are not intended to be considered indicative as to the outcome of the VPAG review.

100. Therefore, it is worth nothing that there is a risk to BCE if the accelerated mid-scheme review leads to a significantly different outcome for VPAG than its current outcome, which may threaten BCE between the statutory and voluntary scheme. If BCE is put at risk in the future, the department may need to reconsult on the statutory scheme to maintain BCE.

101. There are significant uncertainties associated with forecasting branded medicines sales growth which increase as the forecast progresses over time. For this reason, the appraisal period is limited to three years. This aligns with the appraisal period for the previous consultation[26]. For more information, see “monitoring the scheme”. The statutory scheme has been updated annually in recent years and the Department remains committed to updating the statutory scheme, when necessary, in the future. We present low, mid, and high forecast scenarios which vary according to the proportion of total measured sales (minus parallel imports) attributable to statutory scheme members. Although the central assumption is used for the “best estimate” presented, all three are considered similarly plausible.

102. For the purpose of estimating payment percentages under the central assumption, the share of statutory scheme measured sales as a proportion of voluntary and statutory scheme measured sales is set at approximately 1.7% in each year. This is as calculated from the latest available Q4 2024 company returns data. This assumption is varied by Low and High scenarios, which assumes that 0.5% and 2.5% of statutory scheme and voluntary branded medicines sales respectively go through the statutory scheme (see below). This suggests estimated nominal statutory scheme measured sales of between £238m - £1,188m in the years 2025-2027 (depending on the forecast scenario selected) will be affected by implementation of the preferred option for updating the statutory scheme. In the low scenario we assume that the proportion of sales going through the statutory scheme is lower, resulting in lower statutory scheme income. While statutory scheme income is lower, it would be higher in VPAG. However, the total income to the NHS wouldn’t necessary be equal due to the small differences in the payment percentages applied to newer and older medicines under VPAG. This assumption is independent of separate assumptions about the overall growth of newer and older branded medicines sales to the voluntary and statutory scheme.

103. Under all options (BAU and proposed updates), the total payment from newer medicines required is calculated by netting off the adjusted assumed payment from older medicines from the calculated total payment. When calculating the adjusted assumed payment from older medicines, each option continues to mirror the values fixed under the VPAG agreement in relation to older medicines. These include older medicine measured sales growth, the distribution of older medicines eligible sales across top-up payment percentages and the risk and optimism bias adjustment factor.

104. If, once actuals data is available, the values used are found to be poor approximations of reality, payment percentages may have been set too high or too low. With regards to the latter, the risk is mitigated by the inclusion of the central uncertainty and optimism bias adjustment in the scheme calculations.

105. The Department has a well-established process to consider list price changes where they are warranted, as well as processes to maintain continuity of supply of medicines by mitigating supply risks. It is worth noting that these list price change applications typically apply to older

[26] https://www.gov.uk/government/consultations/proposed-update-to-the-statutory-scheme-to-control-the-cost-of-branded-health-service-medicines/proposed-update-to-the-statutory-scheme-to-control-the-cost-of-branded-health-service-medicines - accessed 17 January 2025.

medicines. The Department's Medicines 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. Moreover, under the statutory scheme it is possible for the Secretary of State to make a temporary exemption to a maximum price, as stated in the Branded Health Services Medicines (Costs) Regulations 2018[27], Section 10. Under these provisions, companies may make an application for a temporary exemption. The Department monitors the number of applications received.

106. While supply risk potential cannot be discounted from the increase in payment percentages resulting from the preferred option, any of these risks to supply are mitigated by the mechanisms in place for companies to apply for a permanent or temporary price increase. Furthermore, there is a low risk to overall branded medicines supply due to the low proportion of branded medicines sales that go through the statutory scheme.

107. Under the central assumption, we have modelled the statutory scheme based on its current membership of companies that have joined for 2025 and their proportion of statutory scheme + voluntary scheme branded medicines measured sales in our most recent data. We test the impact of varying this assumption in each option's low and high assumption assessment. This reflects the inherent uncertainties regarding the company level commercial incentives to do so. The purpose of this update to the statutory scheme is to ensure the two schemes are properly aligned. As a result, it is assumed that the proposals being consulted on will not drive a large shift in companies' incentives to move between schemes and, therefore, the range between low and high is relatively small.

108. The headline payment percentage calculations within this IA are predicated on company returns regarding their sales made to the NHS. We assume that this data is robust given:

- Companies' annual sales reports are independently audited to give assurance that the sales and exclusions reported have been accurately extracted from a companies' information systems and reconcile with turnover in a company's statutory accounts.
- Furthermore, the Branded Medicines Operations team undertakes validation, particularly of some sales exemptions, through detailed presentation level checks on separate presentation level reports that companies are required to provide, and which should reconcile with a company's high-level Sales Report.
- An updated 2023 measured sales of newer medicines and of older medicines baseline was calculated based on full-year 2023 company sales returns and the ratio of newer to older medicines in 2023. The ratio of newer to older medicines in 2023 was calculated from 2023 company presentation level returns. The Department of Health and Social Care (DHSC) carried out assurance activities to validate this data, and how it aligned with the returns from companies in Q2 2024, including through engagement with companies.

109. The method of calculating low and high scenarios used in this impact assessment is a departure from the approach used in previous statutory scheme impact assessments. Previously, parameters within the medicine spend forecast model (see annex A) were varied to model different medicines sales growth rates. This resulted in different payment percentage rates and different scheme incomes. However, in this impact assessment we have instead modelled low and high sensitivities by varying the proportion of measured sales, excluding parallel imports[28], that are attributable to the statutory scheme.

110. The reason for this change is that the modelling for different cohort growth rates affects statutory scheme through an unrealistic mechanism (varying payment percentages). In reality, only the "central" scenario payment percentage is relevant, and the "low" and "high" payment percentages simply reflect what payment percentages would have been set at if the measured sales growth rates had been lower or higher. However, if measured sales growth rates did transpire to vary substantially versus the forecast used to set the statutory scheme headline payment percentage, a further consultation would be required to amend the payment percentage. Another reason for this change in methodology is that previously there was no

[27] The Branded Health Service Medicines (Costs) Regulations 2018 (legislation.gov.uk) – accessed 16 August 2024.
[28] i.e. voluntary scheme measured sales and statutory scheme measured sales

differentiation between the type of measured sales growth, whereas now we have newer and older medicines. As such, the parameter that could be chosen from the medicines spend forecast model would have had a very uncertain effect on the headline payment percentage rate.

111. A more realistic sensitivity is examining the proportion of sales that could happen under the statutory scheme, which may vary over the lifetime of this statutory scheme. Varying this proportion would not affect the statutory scheme payment percentage but would instead affect the income of the scheme.

112. In this impact assessment we have used a low sensitivity of assuming that only 0.5% of sales are from the statutory scheme, and a high sensitivity with 2.5%. This compares with a central estimate of 1.67% for 2024 based on observed data to Q4 2024. However, for the purpose of income calculation, we use 1.65% for newer medicines and 1.64% for older medicines. For more information, please see “Forecasting newer medicines, older medicines and parallel import sales for calculating income.”

Table 11: Summary of assumptions used in the appraisal

Assumption	Used in	Source
2023 outturn measured sales (recorded measured sales)	2023 measured sales baseline	2023 full year company sales return and IQVIA dataset
Split of older medicine measured sales and newer medicine measured sales for 2023 matches VPAG	2023 measured sales baseline and 2024 measured sales	2023 company presentation level returns
Older medicine measured sales forecast growth 2024 - 2027 will match that published in the final VPAG deal	Older medicine measured sales forecast for 2024 – 2027	Older medicine measured sales forecast[29]
Newer medicine measured sales and parallel import sales growth forecast	Measured sales data for 2024, newer medicine and parallel import forecast for 2025 – 2027 to calculate payment percentage	Q1-Q4 2024 data to generate year-to-date estimate for 2024, ATON forecast for 2025 - 2027
Industry revenue impacts accrue to UK shareholders	Wider economic impacts	ONS Annual Business Survey ONS Index of Production time series ONS UK trade in goods by classification of product by activity time series
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 (see Annex C)
30% spillover effects of investment*		Literature review (see Annex C)
Statutory scheme sales make up 1.68% of non-PI industry sales (for payment percentage calculation)	The proportion of industry measured and allowed sales we applied to the statutory scheme	Q1-Q3 2024 sales data

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

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

113. 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 VPAG and the statutory scheme.

114. The appraisal period is three calendar years. This reflects the inherent uncertainty surrounding forecasting medicines sales as is precedent. The three-year appraisal period also covers the lifetime of the Regulations proposed, which would set the payment percentage for 2025 Q3-Q4, 2026, and 2027.

115. Where assumptions have been applied, these will be identified and described throughout at the point of use. A key uncertainty is the proportion of (voluntary + statutory scheme) measured sales made by members of the statutory scheme. As a result we present low, mid, and high

[29] Annexes to the 2024 voluntary scheme for branded medicines pricing, access and growth – accessed 23rd January 2025

scenario estimates of impacts, as determined by the proportion of sales attributable to the statutory scheme. For more information on the sensitivities, see Risks and Assumptions.

Establishing an allowed sales 2023 and 2024 baseline

116. The allowed sales baseline for 2023 was estimated at £11,577m.

117. In the statutory scheme update of October 2024, the Preferred Option needed an approach for estimating 2024 allowed sales, in order to estimate what allowed sales would be for 2025 and beyond. The agreed approach for 2024 allowed sales (to generate a "notional allowed sales") was to take 2023 allowed sales, applying a nominal growth rate of 2% to the 2023 allowed sales baseline, and adding a baseline adjustment equivalent to that agreed for 2024 in VPAG, £150m.

118. As this approach was implemented for the Preferred Option in 2024, it has also been implemented here for 2025. Table 13 below outlines the allowed sales baseline for 2024.

Table 12: Allowed sales for 2023 and 2024

Year commencing	2023	2024[30]
Nominal growth		2%
Baseline adjustment (£m)		150
Allowed sales (£m)	11,577	11,962

Costs and benefits options analysis

Option 1

119. Under option 1, the data underpinning the statutory scheme would, excluding fixed parameters under the scheme design, be updated to the latest available. However, the baseline adjustments and allowed sales growth rates are retained as the same level as under the BAU option. As such, the Allowed Sales profile in Option 1 matches that of BAU. The resulting annual Allowed Sales can be seen in Table 13.

Table 13: Option 1 Allowed sales adjustment and allowed sales

	2024	2025	2026	2027
Allowed growth rate	2%	2%	2%	2%
Allowed sales baseline adjustment £m	150	150	330	380
Allowed sales £m	11,962	12,354	12,938	13,584

120. The calculation of the headline payment percentages for newer medicines for Options 1-5 can be found in Annex E.

121. Under Option 1, the payment percentage for the full year is 22.3%, however given that the payment percentage is set at 15.5% for Q1-Q2 2025, it is uplifted to 29.1% for Q3-Q4 of 2025 for companies that made payments at the lower rate in Q1 or Q2 to achieve the average yearly rate of 22.3%. This rate is followed by 24.2% in 2026, and 26.0% in 2027 and thereafter.

NHS finances

122. Under Option 1, cumulative income to the NHS of around £54m to £268m (in nominal prices) is generated over the three-year appraisal period. This equates to a change in nominal aggregate statutory scheme income for the NHS of between £9m and £45m over the same period compared to the counterfactual.

[30] 2024 is illustrative and is not part of the policy, it is used to calculate the allowed sales for 2025.

123. To calculate the NPV of this transfer, we first convert it into the societal value of QALYs that could be generated at the margin on the frontline. We continue to use the average nominal cost per QALY at the margin on the frontline estimate of £15k per QALY.

124. This is grounded in empirical literature[31] and whilst the Department acknowledges the time that has elapsed since its production this is mitigated by the actual estimate being just under £13k per QALY in 2008 prices. Given the inherent uncertainty, this is rounded up to a cost of £15k per QALY for use in all DHSC appraisals, as set-out in established DHSC guidance. Subsequent work to validate the figure undertaken in 2023 did not recommend an update be made[32].

125. Annex D provides more information around the correct interpretation of the £15,000 per QALY figure and how it differs standard cost-effectiveness threshold range of £20-30k per QALY used in NICE appraisals. Table 16 below presents the QALY conversion calculations and the resulting present societal value of these estimated in line with the Green Book methodology (societal value £70,000 per QALY discounted at 1.5% as in paragraphs A1.64 and A1.65[33]).

126. Tables 14, 15, and 16 outline the headline payment percentage, expected income, and quantify the change in QALYs generated under Option 1 compared to the BAU counterfactual respectively.

Table 14: Option 1 Headline Payment Percentage

	2025 (Q3-Q4)	2025	2026	2027
Set rate	29.1%	22.3%	24.2%	26.0%

Table 15: Option 1 expected nominal income

		2025	2026	2027	Cumulative
Low Scenario	Older Medicines Income £m	6	6	7	19
	Newer Medicines Income £m	10	11	13	34
	Total Income £m	**16**	**18**	**20**	**54**
Central Scenario	Older Medicines Income £m	20	21	22	63
	Newer Medicines Income £m	33	38	43	114
	Total Income £m	**53**	**59**	**65**	**177**
High Scenario	Older Medicines Income £m	31	32	33	96
	Newer Medicines Income £m	49	57	65	172
	Total Income £m	**80**	**90**	**99**	**268**

Numbers may not sum due to rounding (rounded to nearest £1m)

[31] Karl Claxton, Steve Martin, Marta Soares, Nigel Rice, Eldon Spackman, Sebastian Hinde, Nancy Devlin, Peter C Smith, and Mark Sculpher. 2013. Methods for the Estimation of the NICE Cost Effectiveness Threshold. [https://www.york.ac.uk/media/che/documents/reports/resubmitted_report.pdf]

[32] Stephen Martin, Karl Claxton, James Lomas, Francesco Longo 2023. The impact of different types of NHS expenditure on health: Marginal cost per QALY estimates for England for 2016/17.

[33] https://assets.publishing.service.gov.uk/media/6645c709bd01f5ed32793cbc/Green_Book_2022__updated_links_.pdf - accessed 16 April 2025

Table 16: Monetising QALYs option 1 versus BAU

	2025	2026	2027	Cumulative
Low Scenario				
Change in income vs BAU £m (nominal)	3	3	3	**9**
Change in QALYs @ £15k/QALY (nominal)	201	200	197	**598**
Change in nominal societal value @ £70k/QALY £m	14	14	14	**42**
Change in societal value @ £70k/QALY £m (2025 prices)	14	14	13	**41**
Central Scenario				
Change in income vs BAU £m (nominal)	10	10	10	**30**
Change in QALYs @ £15k/QALY (nominal)	666	663	651	**1,980**
Change in nominal societal value @ £70k/QALY £m	47	46	46	**139**
Change in societal value @ £70k/QALY £m (2025 prices)	47	46	44	**136**
High Scenario				
Change in income vs BAU £m (nominal)	15	15	15	**45**
Change in QALYs @ £15k/QALY (nominal)	1,006	1,001	984	**2,991**
Change in nominal societal value @ £70k/QALY £m	70	70	69	**209**
Change in societal value @ £70k/QALY £m (2025 prices)	70	69	66	**206**

Numbers may not sum due to rounding (rounded to nearest QALY or £1m)

Pharmaceutical industry and its shareholders plus wider economic impacts

127. Option 1 proposes significant increases in the payment percentage compared with the BAU counterfactual. Under the central scenario, Option 1 generates a cumulative increase in nominal income to the NHS of £30m over the appraisal period compared to the counterfactual.

128. The increase in income translates to a fall in profit for the pharmaceutical industry, a proportion of which will accrue to UK shareholders and therefore be counted within the NPV calculated for the proposal. As explained in Annex B, we estimate that around 28.9% of drug spend is on UK domestic production, i.e., output generated by UK factors of production (UK-owned capital or UK labour).

129. 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.

130. Following on from the values in Table 16, Table 17 below sets out the estimated financial impact on the pharmaceutical industry under option 1, plus 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 Annex B. Please note that “Low”, “Central”, and “High” refer to proportion of sales attributable to the statutory scheme.

131. Furthermore, as a result of the fall in company profits by £30m under the best estimate, we expect there to be lower investment (see Annex B for more information). This is likely to lead to lower spillovers than under BAU and therefore lower net societal benefits. However, due to uncertainties in the methodology for calculating the economic impacts of the lower company profits (including the many different drivers of industry investment), these have not been incorporated into the main NPV calculations. For more information, see Annex C.

Table 17: Pharmaceutical industry financial impacts Option 1 versus BAU

	2025	2026	2027	Cumulative
Low Scenario				
Change in revenue for industry £m (nominal)	-3	-3	-3	**-9**
Of which accrues to UK shareholders £m (nominal)	-1	-1	-1	**-3**
UK industry financial impacts £m (2025 prices)	-1	-1	-1	**-3**
Central Scenario				
Change in revenue for industry £m (nominal)	-10	-10	-10	**-30**
Of which accrues to UK shareholders £m (nominal)	-3	-3	-3	**-9**
UK industry financial impacts £m (2025 prices)	-3	-3	-3	**-8**
High Scenario				
Change in revenue for industry £m (nominal)	-15	-15	-15	**-45**
Of which accrues to UK shareholders £m (nominal)	-4	-4	-4	**-13**
UK industry financial impacts £m (2025 prices)	-4	-4	-4	**-13**

Numbers may not sum due to rounding (rounded to nearest £1m)

Impact on patients

132. 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.

133. Under the best estimate, this option produces £30m additional income to the NHS which produces benefits to patients. However, the consequence of this is £30m lower profits to pharmaceutical company shareholders. Given our assumptions on profits in Annex B, lower investment, drawn from a loss in profits, could have detrimental consequences to the future pipeline of drugs developed in the UK which might be detrimental to patients' health outcomes in the UK.

134. Please note that the impact on patients have not directly been quantified in this impact assessment and hence, do not directly feature in the NPV values below. We consider that they are indirectly accounted for through change in patient health outcomes through loss in company profits and gain in NHS income.

135. By deducting the values of Table 17 from the values of Table 16, the overall NPV benefit can be found in Table 18. Please note that Low scenario here is equal to Low benefits minus Low cost. Overall, the net benefit of Option 1 is positive in all scenarios.

Table 18: Overall net benefit (2025 prices) Option 1

	2025	2026	2027	NPV[34]
Low scenario £m	13	13	12	**38**
Central scenario £m	44	43	41	**126**
High scenario £m	66	65	62	**190**

Numbers may not sum due to rounding (rounded to nearest £1m). Annual values reported are not net present values.

136. While Option 1 has similar payment percentages to the Preferred Option (5), its lower payment percentages could be argued to better support the life sciences sector by creating higher profits for the pharmaceutical industry. This could be argued to better account for the costs of research and development. However, because its payment percentages are beneath that of VPAG, it is not maximising broad commercial equivalence, and therefore is not the preferred option.

[34] Present value as of 2025. Healthcare costs/benefits are discounted at 1.5% per annum, all other benefits and costs at 3.5% per annum.

Option 2

137. Similar to Option 1, Option 2 also incorporates new data from Q2-Q4 2024, resulting in revised newer medicines measured sales and parallel import data compare with the BAU. The basic structure of Option 2 is identical to Option 1. The main difference from Option 1 is the exclusion of allowed sales baseline adjustments in each relevant year. Nominal allowed sales growth in Option 2 remains at 2% per annum from 2024.

Table 19: Option 2 Allowed sales adjustment and allowed sales

	2025	2026	2027
Allowed growth rate	2%	2%	2%
Allowed sales baseline adjustment £m	-	-	-
Allowed sales £m	12,201	12,445	12,694

138. The payment percentage for the full year is 24.0%, however given that the payment percentage is set at 15.5% for Q1-Q2 2025, it is uplifted to 32.5% for Q3-Q4 of 2025 for companies that made payments at the lower rate in Q1 or Q2, to achieve the average yearly rate of 24.0%.This is followed by annual headline payment percentages of 29.3% and 34.6% in 2026 and 2027 respectively. This is shown below in table 20.

NHS finances

139. Under Option 2, nominal income to the NHS of around £61m to £306m is generated over the appraisal period. This equates to a change in nominal income for the NHS of between £16m and £82m over the three-year appraisal period compared to the counterfactual.

140. Compared with Option 1 and the BAU, the allowed sales adjustment in Option 2 induced a higher headline payment percentage and income than in Option 1 by removing baseline adjustments. The NPV of the cost of Option 2 is calculated in the same manner as outlined previously in Option 1, shown in tables 20 to 22 below.

Table 20: Option 2 Headline Payment percentage

	2025 (Q3 – Q4)	2025	2026	2027
Set rate	32.5%	24.0%	29.3%	34.6%

Table 21: Option 2 Expected income (nominal)

		2025	2026	2027	Cumulative
Low Scenario	Older Medicines Income £m	6	6	7	19
	Newer Medicines Income £m	11	14	17	42
	Total Income £m	**17**	**20**	**24**	**61**
Central Scenario	Older Medicines Income £m	20	21	22	63
	Newer Medicines Income £m	35	46	58	139
	Total Income £m	**55**	**67**	**79**	**202**
High Scenario	Older Medicines Income £m	31	32	33	96
	Newer Medicines Income £m	53	69	87	210
	Total Income £m	**84**	**102**	**120**	**306**

Numbers may not sum due to rounding (rounded to nearest £1m)

Table 22: Monetising QALYs foregone Option 2

	2025	2026	2027	Cumulative
Low Scenario				
Change in income vs BAU £m (nominal)	4	5	7	**16**
Change in QALYs @ £15k/QALY (nominal)	251	360	486	**1,097**
Change in nominal societal value @ £70k/QALY £m	18	25	34	**77**
Change in societal value @ £70k/QALY £m (2025 prices)	18	25	33	**75**
Central Scenario				
Change in income vs BAU £m (nominal)	12	18	24	**54**
Change in QALYs @ £15k/QALY (nominal)	829	1,191	1,608	**3,629**
Change in nominal societal value @ £70k/QALY £m	58	83	113	**254**
Change in societal value @ £70k/QALY £m (2025 prices)	58	82	109	**249**
High Scenario				
Change in income vs BAU £m (nominal)	19	27	36	**82**
Change in QALYs @ £15k/QALY (nominal)	1,253	1,800	2,430	**5,483**
Change in nominal societal value @ £70k/QALY £m	88	126	170	**384**
Change in societal value @ £70k/QALY £m (2025 prices)	88	124	164	**376**

Numbers may not sum due to rounding (rounded to nearest QALY or £1m)

Pharmaceutical industry and its shareholders, and wider economic impacts

141. The principal impact of the proposed Option 2 for the pharmaceutical industry is that payment percentages rise versus the BAU counterfactual. This reflects the inclusion of Q2-Q4 2024 data and the removal of baseline allowed sales adjustments of £150m, £330m, and £380m in 2025, 2026 and 2027 respectively. The allowed growth rate remains unchanged at 2% per annum from a 2024 allowed sales baseline.

142. Table 23 summarises the resulting estimated impact on the pharmaceutical industry and its shareholders, including the proportion of which we estimate could accrue to UK shareholders and therefore feature in the overall NPV assessment. Furthermore, as a result of the fall in company profits by £54m under the central scenario, we expect there to be lower investment (see Annex B for more information). This is likely to lead to lower spillovers than under BAU and therefore lower net societal benefits. However, due to uncertainties in the methodology for calculating the economic impacts, these have not been incorporated into the main NPV calculations.

Table 23: Pharmaceutical industry financial impacts Option 2

	2025	2026	2027	Cumulative
Low Scenario				
Change in revenue for industry £m (nominal)	-4	-5	-7	**-16**
Of which accrues to UK shareholders £m (nominal)	-1	-2	-2	**-5**
UK industry financial impacts £m (2025 prices)	-1	-2	-2	**-5**
Central Scenario				
Change in revenue for industry £m (nominal)	-12	-18	-24	**-54**
Of which accrues to UK shareholders £m (nominal)	-4	-5	-7	**-16**
UK industry financial impacts £m (2025 prices)	-4	-5	-7	**-15**
High Scenario				
Change in revenue for industry £m (nominal)	-19	-27	-36	**-82**
Of which accrues to UK shareholders £m (nominal)	-5	-8	-10	**-24**
UK industry financial impacts £m (2025 prices)	-5	-8	-10	**-23**

Numbers may not sum due to rounding (rounded to nearest £1m)

Impact on patients

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

144. This option produces £54m additional income to the NHS which produces benefits to patients. However, the consequence of this is £54m lower profits to pharmaceutical company shareholders. Given our assumptions on profits in Annex B, lower investment, drawn from a loss in profits, could have detrimental consequences to the future pipeline of drugs developed in the UK which might be detrimental to patients' health outcomes in the UK. Furthermore, this option is not preferred because it results in increases to payment percentages in later years, and therefore additional costs to industry, that are disproportionate to those required to maintain BCE and a stable system for managing spend on medicines.

145. Please note that the impact on patients have not directly been quantified in this impact assessment and hence, do not directly feature in the NPV values below. We consider that they are indirectly accounted for through change in patient health outcomes through loss in company profits and gain in NHS income.

Table 24: Overall net benefit (2025 prices) Option 2

	2025	2026	2027	NPV
Low scenario £m	16	23	31	**69**
Central scenario £m	54	77	102	**229**
High scenario £m	82	116	154	**346**

Numbers may not sum due to rounding (rounded to nearest £1m). Annual values reported are not net present values.

146. Option 2 has higher payment percentages than the Preferred Option (5). As such, it is likely to best safeguard the financial position of the NHS by raising the most income. However, by having the highest payment rate, it is likely to perform poorly at supporting the life sciences sector since its high rate is less likely to ensure that firms costs of R&D are accounted for. Additionally, with a very high rate of 34.6% in 2027, it is unlikely to support broad commercial equivalence with VPAG. For these reasons, it is not preferred.

Option 3

147. Similar to Option 1, Option 3 also incorporates new data from Q2-Q4 2024, resulting in revised newer medicines measured sales and parallel import data compare with the BAU. The basic structure of Option 3 is identical to Option 1 and 2 in that it sets differential payment percentages for newer and older medicines. Conversely, Option 3 features a nominal allowed sales growth rate of 3.75% per annum in 2025 and 2026, rising to 4% in 2027 and baseline adjustments of £150m, £330m, and £380m in 2025, 2026, and 2027 respectively. These match VPAG.

Table 25: Option 3 Allowed sales adjustment and allowed sales

	2025	2026	2027
Allowed growth rate	3.75%	3.75%	4%
Allowed sales baseline adjustment £m	150	330	380
Allowed sales £m	12,566	13,379	14,310

148. The payment percentage for the full year is 20.0%, however given that the payment percentage is set at 15.5% for Q1-Q2 2025, it is uplifted to 24.5% for Q3-Q4 of 2025 for companies that made payments at the lower rate in Q1 or Q2, to achieve the average yearly rate of 20.0%. This is followed by annual headline payment percentages of 19.7% and 18.9% in 2026 and 2027 respectively. This is shown below in table 26.

NHS finances

149. Under Option 3, nominal income to the NHS of around £47m to £235m is generated over the three-year appraisal period. This equates to a rise in income for the NHS of between £2m and £11m over the three-year appraisal period compared to the BAU counterfactual.

150. By matching VPAG's allowed sales growth rates and baseline adjustments, this option yields the lowest payment percentages of all the non-BAU options. The payment percentage rate in 2027 is forecast to be lower than BAU, and the payment percentages are too low to achieve BCE with VPAG. The NPV of the cost of Option 3 is calculated in the same manner as outlined previously for Option 1 when compared to the BAU counterfactual.

Table 26: Option 3 Headline Payment percentage

	2025 (Q3 – Q4)	2025	2026	2027
Set rate	24.5%	20.0%	19.7%	18.9%

Table 27: Option 3 Expected income (nominal)

		2025	2026	2027	Cumulative
Low Scenario	Older Medicines Income £m	6	6	7	19
	Newer Medicines Income £m	9	9	10	28
	Total Income £m	**15**	**16**	**16**	**47**
Central Scenario	Older Medicines Income £m	20	21	22	63
	Newer Medicines Income £m	29	31	32	92
	Total Income £m	**49**	**52**	**53**	**155**
High Scenario	Older Medicines Income £m	31	32	33	96
	Newer Medicines Income £m	44	47	48	139
	Total Income £m	**75**	**79**	**81**	**235**

Numbers may not sum due to rounding (rounded to nearest £1m)

Table 28: Monetising QALYs foregone Option 3

	2025	2026	2027	Cumulative
Low Scenario				
Change in income vs BAU £m (nominal)	2	1	-1	**2**
Change in QALYs @ £15k/QALY (nominal)	133	57	-39	**150**
Change in nominal societal value @ £70k/QALY £m	9	4	-3	**11**
Change in societal value @ £70k/QALY £m (2025 prices)	9	4	-3	**11**
Central Scenario				
Change in income vs BAU £m (nominal)	7	3	-2	**7**
Change in QALYs @ £15k/QALY (nominal)	439	189	-130	**498**
Change in nominal societal value @ £70k/QALY £m	31	13	-9	**35**
Change in societal value @ £70k/QALY £m (2025 prices)	31	13	-9	**35**
High Scenario				
Change in income vs BAU £m (nominal)	10	4	-3	**11**
Change in QALYs @ £15k/QALY (nominal)	663	285	-196	**752**
Change in nominal societal value @ £70k/QALY £m	46	20	-14	**53**
Change in societal value @ £70k/QALY £m (2025 prices)	46	20	-13	**53**

Numbers may not sum due to rounding (rounded to nearest QALY or £1m)

Pharmaceutical industry and its shareholders plus wider economic impacts

151. The principal impact of the proposed Option 3 for the pharmaceutical industry is that payment percentages are reduced compared to all other non-BAU options to match the AGR

and baseline adjustments of VPAG. This will result in smaller changes in revenue than other non-BAU options.

152. Furthermore, as a result of the fall in company profits by £7m under the best estimate, we expect there to be lower investment (see Annex B for more information). This is likely to lead to lower spillovers than under BAU and therefore lower net societal benefits. However, due to uncertainties in the methodology for calculating the economic impacts of lower profits and investment, these have not been incorporated into the main NPV calculations. For more information, see Annex C.

Table 29: Pharmaceutical industry financial impacts Option 3

	2025	2026	2027	Cumulative
Low Scenario				
Change in revenue for industry £m (nominal)	-2	-1	1	**-2**
Of which accrues to UK shareholders £m (nominal)	-1	0	0	**-1**
UK industry financial impacts £m (2025 prices)	-1	0	0	**-1**
Central Scenario				
Change in revenue for industry £m (nominal)	-7	-3	2	**-7**
Of which accrues to UK shareholders £m (nominal)	-2	-1	1	**-2**
UK industry financial impacts £m (2025 prices)	-2	-1	1	**-2**
High Scenario				
Change in revenue for industry £m (nominal)	-10	-4	3	**-11**
Of which accrues to UK shareholders £m (nominal)	-3	-1	1	**-3**
UK industry financial impacts £m (2025 prices)	-3	-1	1	**-3**

Numbers may not sum due to rounding (rounded to nearest £1m)

Impact on patients

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

154. Under the best estimate, this option produces £7m additional income to the NHS which produces benefits to patients. However, the consequence of this is £7m lower profits to pharmaceutical company shareholders. Given our assumptions on profits in Annex B, lower investment, drawn from a loss in profits, could have detrimental consequences to the future pipeline of drugs developed in the UK which might be detrimental to patients' health outcomes in the UK.

155. Please note that the impact on patients have not directly been quantified in this impact assessment and hence, do not directly feature in the NPV values below. We consider that they are indirectly accounted for through change in patient health outcomes through loss in company profits and gain in NHS income.

Table 30: Overall net benefit Option 3 (2025 prices)

	2025	2026	2027	NPV
Low scenario £m	9	4	-2	**10**
Central scenario £m	29	12	-8	**33**
High scenario £m	44	18	-12	**50**

Numbers may not sum due to rounding (rounded to nearest £1m). Annual values reported are not net present values.

156. Option 3's lower payment percentage than Option 5 could be argued to better support the life sciences sector by creating higher profits for the pharmaceutical industry. This could be argued to better account for the costs of research and development. However, because its payment percentages are beneath that of VPAG, it is not maximising broad commercial equivalence, and therefore is not a preferred option.

Option 4

157. Similar to Option 1, Option 4 also incorporates new data from Q2-Q4 2024, resulting in revised newer medicines measured sales and parallel import data compare with the BAU. The basic structure of Option 4 is identical to Option 3, except there are no baseline allowed sale adjustments.

Table 31: Option 4 Allowed sales adjustment and allowed sales

	2025	2026	2027
Allowed growth rate	3.75%	3.75%	4.00%
Allowed sales baseline adjustment £m	-	-	-
Allowed sales £m	12,410	12,876	13,391

158. The payment percentage for the full year is 21.7%, however given that the payment percentage is set at 15.5% for Q1-Q2 2025, it is uplifted to 27.9% for Q3-Q4 of 2025 for companies that made payments at the lower rate in Q1 or Q2, to achieve the average yearly rate of 21.7%This is followed by annual headline payment percentages of 24.9% and 27.8% in 2026 and 2027 respectively. This is shown below in table 32.

NHS finances

159. Under Option 4, nominal income to the NHS of around £55m to £273m is generated over the three-year appraisal period. This equates to a change in income for the NHS of between £10m and £50m over the three-year appraisal period compared to the BAU counterfactual.

160. The option follows the allowed sales growth rate of Option 3 but omits the baseline adjustments. As such, it induces higher headline payment percentage and income than in the BAU counterfactual and Option 3. The NPV of the cost of Option 4 is calculated in the same manner as outlined previously for Option 1 when compared to the BAU counterfactual.

Table 32: Option 4 Headline Payment percentage

	2025 (Q3 – Q4)	2025	2026	2027
Set rate	27.9%	21.7%	24.9%	27.8%

Table 33: Option 4 Expected income (nominal)

		2025	2026	2027	Cumulative
Low Scenario	Older Medicines Income £m	6	6	7	19
	Newer Medicines Income £m	10	12	14	35
	Total Income £m	**16**	**18**	**21**	**55**
Central Scenario	Older Medicines Income £m	20	21	22	63
	Newer Medicines Income £m	32	39	46	117
	Total Income £m	**52**	**60**	**68**	**180**
High Scenario	Older Medicines Income £m	31	32	33	96
	Newer Medicines Income £m	48	59	70	177
	Total Income £m	**79**	**91**	**103**	**273**

Numbers may not sum due to rounding (rounded to nearest £1m)

Table 34: Monetising QALYs foregone Option 4

	2025	2026	2027	Cumulative
Low Scenario				
Change in income vs BAU £m (nominal)	3	3	4	**10**
Change in QALYs @ £15k/QALY (nominal)	183	220	260	**663**
Change in nominal societal value @ £70k/QALY £m	13	15	18	**46**
Change in societal value @ £70k/QALY £m (2025 prices)	13	15	18	**45**
Central Scenario				
Change in income vs BAU £m (nominal)	9	11	13	**33**
Change in QALYs @ £15k/QALY (nominal)	605	729	859	**2,194**
Change in nominal societal value @ £70k/QALY £m	42	51	60	**154**
Change in societal value @ £70k/QALY £m (2025 prices)	42	50	58	**151**
High Scenario				
Change in income vs BAU £m (nominal)	14	17	19	**50**
Change in QALYs @ £15k/QALY (nominal)	914	1,102	1,298	**3,314**
Change in nominal societal value @ £70k/QALY £m	64	77	91	**232**
Change in societal value @ £70k/QALY £m (2025 prices)	64	76	88	**227**

Numbers may not sum due to rounding (rounded to nearest QALY or £1m)

Pharmaceutical industry and its shareholders plus wider economic impacts

161. The principal impact of the proposed Option 4 for the pharmaceutical industry is that payment percentages rise compared to the BAU counterfactual as a result of removing baseline adjustments and updating data to the latest available Q4 2024 data, resulting in lower industry profits.

162. Furthermore, as a result of the fall in company profits by £33m under the best estimate, we expect there to be lower investment (see Annex B for more information). This is likely to lead to lower spillovers than under BAU and therefore lower net societal benefits. However, due to uncertainties in the methodology for calculating the economic impacts, these have not been incorporated into the main NPV calculations. For more information, see Annex C.

Table 35: Pharmaceutical industry financial impacts Option 4

	2025	2026	2027	Cumulative
Low Scenario				
Change in revenue for industry £m (nominal)	-3	-3	-4	**-10**
Of which accrues to UK shareholders £m (nominal)	-1	-1	-1	**-3**
UK industry financial impacts £m (2025 prices)	-1	-1	-1	**-3**
Central Scenario				
Change in revenue for industry £m (nominal)	-9	-11	-13	**-33**
Of which accrues to UK shareholders £m (nominal)	-3	-3	-4	**-9**
UK industry financial impacts £m (2025 prices)	-3	-3	-4	**-9**
High Scenario				
Change in revenue for industry £m (nominal)	-14	-17	-19	**-50**
Of which accrues to UK shareholders £m (nominal)	-4	-5	-6	**-14**
UK industry financial impacts £m (2025 prices)	-4	-5	-5	**-14**

Numbers may not sum due to rounding (rounded to nearest £1m)

Impact on patients

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

164. Under the best estimate, this option produces £33m additional income to the NHS (compared with BAU) which produces benefits to patients. However, the consequence of this is £33m lower

profits to pharmaceutical company shareholders. Given our assumptions on profits in Annex B, lower investment, drawn from a loss in profits, could have detrimental consequences to the future pipeline of drugs developed in the UK which might be detrimental to patients' health outcomes in the UK.

165. Please note that the impact on patients have not directly been quantified in this impact assessment and hence, do not directly feature in the NPV values below. We consider that they are indirectly accounted for through change in patient health outcomes through loss in company profits and gain in NHS income.

Table 36: Overall net benefit Option 4 (2025 prices)

	2025	2026	2027	NPV
Low scenario £m	12	14	16	**42**
Central scenario £m	40	47	54	**139**
High scenario £m	60	71	82	**210**

Numbers may not sum due to rounding (rounded to nearest £1m). Annual values reported are not net present values.

166. Option 4 has higher payment percentages than the Preferred Option (5) for 2026 and 2027. As such, it is likely to better safeguard the financial position of the NHS by raising more income. However, by having a higher payment rate, it is likely to perform more poorly at supporting the life sciences sector since its high rate is less likely to ensure that firms' costs of R&D are accounted for. Moreover, its payment rate in 2025 is below that of VPAG, so it does not maximise BCE as well as Option 5. For that reason, it is not preferred.

Option 5 - Preferred

167. Similar to Option 1, Option 5 also incorporates new data from Q2-Q4 2024, resulting in revised newer medicines measured sales and parallel import data compare with the BAU. Option 5 contains the same value of baseline adjustments as Option 1 over the period of 2025-2027. However, unlike Option 1, it maximises Broad Commercial Equivalence by having a payment percentage that slightly exceeds VPAG's in 2025, reflecting the additional cost of the investment programme contribution in VPAG.

168. Additionally, Option 5 ensures that the statutory scheme safeguards the financial position of the NHS, ensures medicines are available on reasonable terms, and does so in a way that supports the life sciences sector, working alongside VPAG.

169. By delaying the baseline adjustments of 2025 into 2026, it generates a more stable profile of payment percentage. Option 5 has nominal allowed sales growth rate of 2% per annum in each year of the appraisal period, and baseline adjustments of £50m, £430m, and £380m in 2025, 2026, and 2027 respectively. For more information on the non-monetised benefits of Option 5, see "Summary of the preferred approach".

Table 37: Option 5 Allowed sales adjustment and allowed sales

	2025	2026	2027
Allowed growth rate	2%	2%	2%
Allowed sales baseline adjustment £m	50	430	380
Allowed sales £m	12,252	12,936	13,582

170. The payment percentage for the full year is 23.4%, however given that the payment percentage is set at 15.5% for Q1-Q2 2025, it is uplifted to 31.3% for Q3-Q4 of 2025 for companies that made payments at the lower rate in Q1 or Q2, to achieve the average yearly rate of 23.4%. This is followed by annual headline payment percentages of 24.3% and 26.0% in 2026 and 2027 respectively. This is shown below in table 38.

NHS finances

171. Under Option 5 nominal income to the NHS of around £58m to £289m is generated over the three-year appraisal period. This equates to an increase in income for the NHS of between £10m and £50m over the three-year appraisal period compared to the BAU counterfactual.

172. Option 5 matches the total baseline adjustments and allowed sales growth of Option 1, and therefore has a similar 2026 and 2027 payment percentage to Option 1. However, by delaying £100m of baseline adjustments from 2025 to 2026, the payment percentage in 2025 is higher in Option 5 than Option 1. Moreover, because that £100m of baseline adjustments does not have 2025's allowed sales growth applied to it, the total allowed sales in 2027 is £2m lower in Option 5 than Option 1 (although payment percentages are identical for 2026 and 2027).

173. The NPV of the cost of Option 5 is calculated in the same manner as outlined previously for Option 1 when compared to the BAU counterfactual.

Table 38: Option 5 Headline Payment percentage

	2025 (Q3 – Q4)	2025	2026	2027
Set rate	31.3%	23.4%	24.3%	26.0%

Table 39: Option 5 Expected income (nominal)

		2025	2026	2027	Cumulative
Low Scenario	Older Medicines Income £m	6	6	7	19
	Newer Medicines Income £m	10	11	13	35
	Total Income £m	**17**	**18**	**20**	**54**
Central Scenario	Older Medicines Income £m	20	21	22	63
	Newer Medicines Income £m	34	38	43	116
	Total Income £m	**55**	**59**	**65**	**179**
High Scenario	Older Medicines Income £m	31	32	33	96
	Newer Medicines Income £m	52	57	65	175
	Total Income £m	**83**	**90**	**99**	**271**

Numbers may not sum due to rounding (rounded to nearest £1m)

Table 40: Monetising QALYs foregone Option 5

	2025	2026	2027	Cumulative
Low Scenario				
Change in income vs BAU £m (nominal)	4	3	3	**9**
Change in QALYs @ £15k/QALY (nominal)	234	201	197	**632**
Change in nominal societal value @ £70k/QALY £m	16	14	14	**44**
Change in societal value @ £70k/QALY £m (2025 prices)	16	14	13	**44**
Central Scenario				
Change in income vs BAU £m (nominal)	12	10	10	**31**
Change in QALYs @ £15k/QALY (nominal)	775	665	653	**2,093**
Change in nominal societal value @ £70k/QALY £m	54	47	46	**147**
Change in societal value @ £70k/QALY £m (2025 prices)	54	46	44	**144**
High Scenario				
Change in income vs BAU £m (nominal)	18	15	15	**47**
Change in QALYs @ £15k/QALY (nominal)	1,171	1,005	987	**3,162**
Change in nominal societal value @ £70k/QALY £m	82	70	69	**221**
Change in societal value @ £70k/QALY £m (2025 prices)	82	69	67	**218**

Numbers may not sum due to rounding (rounded to nearest QALY or £1m)

Pharmaceutical industry and its shareholders plus wider economic impacts

174. The principal impact of the proposed Option 5 for the pharmaceutical industry is that payment percentages rise compared to the BAU counterfactual to reflect the greater measured sales growth that has been identified from Q4 2024 data compared with Q1 2024 data.

175. Furthermore, as a result of the fall in company profits by £31m under the best estimate, we expect there to be lower investment (see Annex B for more information). This is likely to lead to lower spillovers than under BAU and therefore lower net societal benefits. However, due to uncertainties in the methodology for calculating the economic impacts, these have not been incorporated into the main NPV calculations. For more information, see Annex C.

Table 41: Pharmaceutical industry financial impacts Option 5

	2025	2026	2027	Cumulative
Low Scenario				
Change in revenue for industry £m (nominal)	-4	-3	-3	**-9**
Of which accrues to UK shareholders £m (nominal)	-1	-1	-1	**-3**
UK industry financial impacts £m (2025 prices)	-1	-1	-1	**-3**
Central Scenario				
Change in revenue for industry £m (nominal)	-12	-10	-10	**-31**
Of which accrues to UK shareholders £m (nominal)	-3	-3	-3	**-9**
UK industry financial impacts £m (2025 prices)	-3	-3	-3	**-9**
High Scenario				
Change in revenue for industry £m (nominal)	-18	-15	-15	**-47**
Of which accrues to UK shareholders £m (nominal)	-5	-4	-4	**-14**
UK industry financial impacts £m (2025 prices)	-5	-4	-4	**-13**

Numbers may not sum due to rounding (rounded to nearest £1m)

Impact on patients

176. 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.

177. Under the best estimate, this option produces £31m additional income to the NHS which produces benefits to patients. However, the consequence of this is £31m lower profits to pharmaceutical company shareholders. Given our assumptions on profits in Annex B, lower investment, drawn from a loss in profits, could have detrimental consequences to the future pipeline of drugs developed in the UK which might be detrimental to patients' health outcomes in the UK.

178. Please note that the impact on patients have not directly been quantified in this impact assessment and hence, do not directly feature in the NPV values below. We consider that they are indirectly accounted for through change in patient health outcomes through loss in company profits and gain in NHS income.

Table 42: Overall net benefit Option 5 (2025 prices)

	2025	2026	2027	NPV
Low scenario £m	15	13	13	**40**
Central scenario £m	51	43	41	**133**
High scenario £m	77	65	63	**202**

Numbers may not sum due to rounding (rounded to nearest £1m). All annual values are undiscounted so may not total to NPV.

179. Option 5 best maximises broad commercial equivalence of the six options. Moreover, it performs better than options BAU, 1 and 3 in safeguarding the financial position of the NHS, and better than 2 and 4 in ensuring that the rates account for the cost of research and development. Overall, it is our most preferred option.

Options conclusion summary

180. According to the most recent available data (Q4 2024), Options 1, 3, and 4 would produce headline payment percentages for 2025 below that of VPAG's 22.9%. As such, they do not optimise broad commercial equivalence for that year given that the VPAG member companies have additional costs on top of the 22.9% rate such as for the investment programme contribution. By not having baseline adjustments, Option 2's payment percentage is deemed higher than needed by 2026 and 2027 (29.3% and 34.6% respectively) to maintain BCE with VPAG. Though we note the ability to achieve BCE from 2026 onwards is subject to the outcome of the ongoing VPAG review, and the rates published for the statutory scheme are without prejudice to the outcome of the review.

181. Option 5 supports broad commercial equivalence with VPAG whilst delivering a relatively stable headline payment percentage and is therefore preferred. Although Option 5's NPV value in the central scenario is significantly lower than the central scenarios for Option 2 and marginally lower than Option 4, Option 5 is preferred as it generated a more stable payment percentage profile over the three-year appraisal period, while also achieving BCE.

182. Additionally, Option 5 ensures that the statutory scheme safeguards the financial position of the NHS, ensures medicines are available on reasonable terms, and does so in a way that supports the life sciences sector, working alongside VPAG.

183. For our low and high scenarios, we have assumed that 0.5% and 2.5% of statutory scheme and VPAG branded medicines sales respectively go through the statutory scheme. For more details on the rationale behind these scenarios, see 'Risks and Assumptions' section.

Impact on small and micro businesses

184. Businesses with NHS sales of less than £6m per annum under all policy options (including BAU) – which represents the main likely impact of the proposals on small and micro companies – are excluded from the payment percentage mechanism in the statutory scheme in the BAU and in all Options. 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.

Statutory requirements for consultation

185. 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.

186. 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.

187. 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 1-5).

Economic consequences for the life sciences industry in the United Kingdom

188. As set out above, Option 5 is expected to change the gross nominal revenues of pharmaceutical companies by between - £9m and - £47m compared to the Business As Usual option, from 2025 to 2027.

189. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. We assume that 28.9% of drug industry spend is on UK domestic production, i.e., output generated by UK factors of production (UK-owned capital or UK labour), so impacts on UK interests are assumed to be commensurately affected, with a gross nominal change in revenues of approximately - £3m to - £14m relative to the counterfactual over the three-year appraisal period. More discussion on the estimation of spillovers and investment effects of changes in company profits can be found in Annex C.

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

190. 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 rationale for intervention is to support the stability of the UK medicines pricing schemes by supporting continued BCE between the voluntary scheme and statutory scheme.

191. The proposals result in higher income associated with branded medicines to the NHS compared to the counterfactual. In the context of a fixed NHS budget, this would allow for redistribution of funding to another area. We estimate the additional income cumulatively equates to between 632 and 3,162 undiscounted QALYs by 2027 compared to the BAU Option. Patients will also 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.

192. 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.

193. Some groups are likely to be particularly affected by policies that may affect access to medicines. Previous consultations have 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[35] 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.

194. 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.

195. Certain groups, such as pregnant women and children, may be more likely to use older medicines because there is longer established evidence for their efficacy and safety. However, such groups will nonetheless benefit from a mechanism that ensures the NHS gets better value for such medicines, and furthermore such groups also make use of innovative newer medicines whose development is incentivised by these changes.

196. While the proposals mean that the department will receive higher statutory scheme payments than currently set out in the regulations, resulting in reduced profits accrued to UK shareholders, such short-term impact must be considered against the long-term stability of the mechanisms by which we control costs, and the impact of such mechanisms on the market of medicines. Protecting the stability of the system means that we will continue to receive payments

[35] Healthcare Inequalities: Access to NHS prescribing and exemption schemes in England. [https://nhsbsa-data-analytics.shinyapps.io/healthcare-inequalities-nhs-prescribing-and-exemption-schemes/https://nhsbsa-data-analytics.shinyapps.io/healthcare-inequalities-nhs-prescribing-and-exemption-schemes/] (accessed October 2023)

that will be apportioned to the NHS across the UK and will be used in the best interest of patients.

Monitoring the scheme

197. 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.

198. The current voluntary and statutory schemes are subject to a single programme of annual governance and operational review[36]. This includes quarterly publication of scheme metrics and six-monthly operational review with the industry body and observers.

199. Whilst the design of the scheme focused on minimising the additional data collection burden on suppliers, the information required to operate the proposed options will provide significant material with which to assess the process. For example:

- Scheme membership rates will demonstrate whether company behavioural responses transpire to be as anticipated.
- Sales and payment value data will enable us to directly compare what payments would have been under BAU compared with what they transpire to be if one of the proposed options is pursued.
- Annual PLR data will enable us to monitor price changes across newer and older medicines and, for the latter, different top-up percentage bands. Whilst the determinants of medicine price changes are multi-factorial, if a significant change in historic patterns coincides with the implementation of VPAG and one of the proposed options for the statutory scheme, it may be considered a factor.

200. Within the proposed changes to the statutory scheme under the Preferred Option, there are no changes proposed to the statutory scheme other than the newer medicine payment percentage (the headline payment percentage). As such, changes to the payment percentage rate are the main focus of monitoring and evaluation for this iteration of the statutory scheme.

201. As noted, the statutory scheme and the voluntary scheme are closely aligned. With the voluntary scheme covering approximately 98% of the voluntary and statutory branded medicines measured sales to the NHS, the monitoring and evaluation findings to the voluntary scheme are highly relevant to the statutory scheme. Within 2025, there will be an accelerated review and the findings of this will be considered for future versions of the statutory scheme.

202. Otherwise, the statutory scheme will closely monitor the rate of the voluntary scheme to maintain Broad Commercial Equivalence, as appropriate.

203. As noted above both the voluntary and statutory schemes are monitored regularly. Following the implementation of VPAG, a review of VPAS monitoring metrics is being conducted to tailor these more closely to VPAG and therefore (since each of them mirror the VPAG design) the proposed options for the statutory scheme[37]. This exercise will be undertaken in conjunction with partners across other government organisations and industry stakeholders which this IA does not preclude.

204. Additionally, the appraisal period of this statutory scheme has been set at three years. In keeping up with the previous consultation[38], which also intended to introduce legislation mid-way through the year, this appraisal period covers full year of when the legislation is introduced (including the previous 6 months), as well as the following two years. The justification for this is

[36] 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]
[37] https://www.gov.uk/government/publications/2024-vpag-operational-review-25-november-2024 - accessed 23rd January 2025.
[38] https://assets.publishing.service.gov.uk/media/65f443dd10cd8e001d36c665/Impact_assessment_proposed_update_to_the_statutory_scheme.pdf - accessed 29 January 2025

that we are legislating for an average headline rate in 2025. As such, it is appropriate to include in the appraisal period the whole calendar year of 2025, concluding in 2027.

205. A three-year appraisal period is shorter than many other impact assessments. As mentioned, there is considerable uncertainty associated with the statutory scheme. A measure of this is that since January 2022, there have been four amendments to the branded medicines statutory scheme[39], not including this proposed one. As such, the Department believes that three-year appraisal period is appropriate given the uncertainty of the scheme. It is recognised that some of the unintended consequences of reducing industry profits, leading to reductions in industry investment may be felt after the appraisal period. For completeness, these effects have still been noted within each option in the summary pages and description.

Findings from the consultation of March 2025

206. For the Consultation Stage, the Department welcomed consultation responses from industry on how effectively do the proposed options support BCE and the objectives of the statutory scheme. Respondents were asked to provide their view on the consultation-stage impact assessment, including whether this IA addresses impacts on businesses and patients with sufficient detail.

207. 23 responses were received to the consultation, with the majority of these from pharmaceutical companies and their trade associations.

208. 70%-80% of respondents disagreed with the proposals on rate of allowed growth, headline payment percentages, the methodology set out in the impact assessment, and whether the Secretary of State's statutory duties were met. However, 80% were in agreement with the proposal that some form of additional assurance on presentation level sales reports should be introduced.

209. Most respondents argued that the increased payment rates would be harmful to the UK life sciences ecosystem, impacting company decisions on headcount and scale of operations in the UK, and the viability of the UK as a destination for future pharmaceutical activity. They also stated that the changes in payment rates indicate that the UK does not have a stable regulatory environment for businesses to operate in, and that these changes are a result of having a hard cap on NHS medicines spending. Respondents asserted that the payment rates are not competitive with those of otherwise comparable countries in Europe and the world, although we do not agree that these schemes are directly comparable with those of the UK.

210. We assess that the proposed change is nonetheless appropriate so as to maintain broad commercial equivalence, which underpinned companies' decisions on whether to join the statutory scheme for 2025. As set out in this impact assessment, it is also necessary to ensure stability of both schemes whilst the VPAG review is ongoing – particularly as the outcome of this exercise and timelines for implementation are not yet known.

211. Most respondents disagreed with the proposed methodology used in determining the payment percentages as set out in the impact assessment. Respondents commented that they feel the methodology used in the impact assessment is flawed, as they argue that this would never result in a conclusion that a rate the Department proposes is too high, other than if it is higher than proportionate to align with the voluntary scheme. They suggest this is an inadequate framework for assessing costs against the government's core objectives for the two pricing schemes. While the Department notes the feedback on the methodology, the Department would note in response that maintaining Broad Commercial Equivalence is a key aim of the statutory scheme, and this by design ensures that the statutory scheme rate will be close to and above

[39] https://www.legislation.gov.uk/primary+secondary?title=branded%20medicines%20 – 29 January 2025

the voluntary scheme rate. Differences in the method for calculating the statutory scheme headline payment rate compared to the voluntary scheme headline payment rate (including raising the older medicines base rate to account for lack of the investment programme, the absence of the medium-sized company exemption, and the absence of under and over payments), have ensured that lower baseline adjustments to allowed sales are needed in the statutory scheme compared to the voluntary scheme to generate a similar headline payment rate. In terms of the assessment of business impacts, through looking at the impacts to UK shareholders, the Department's method is consistent with the Green Book (section 5.2), which states that "When considering proposals from a UK perspective the relevant values are viewed from the perspective of UK society as a whole...UK society generally includes UK residents and not potential residents or visitors". By extension, we keep analysis of the impacts of this policy to UK based shareholders.

212. Some respondents disagreed with the use of the £15,000 per QALY assessment, arguing that this figure is outdated and methodologically flawed. There was a suggestion that this figure should be adjusted in line with inflation. The Department remains confident that £15,000 per QALY is the best estimate of the opportunity cost per QALY in the NHS. The Department will continue to use this figure as the most recent re-assessment found it should remain at this level.

213. Respondents also commented that the government's impact assessment holds to general assumptions about the impacts to company's R&D investments and the UK's place in global companies' order of priority. Their concern is that these assumptions maintain that R&D expenditure is a static proportion of revenue in the UK, rather than a potentially sensitive element of companies' financial plans that may respond disproportionately to revenue changes.

214. Respondents also suggested that the IA did not account for the benefits to medicine launches and future R&D that could be lost under the headline payment percentages proposed in this consultation, and the overall impact on patient health of this. They stated that the department did not seek to quantify in its options appraisals the impact to patients of fewer medicines being available. Respondents therefore suggested that the government should in future conduct a full and detailed macroeconomic assessment of each of its proposed options and should also seek to quantify the impacts to patients. Respondents argued that this will be compounded over time by the loss of R&D and clinical trial activity. The Department has acknowledged in the IA that higher payment percentages could lead to lower industry profits and hence lower investment. The Department considers that a) there is a risk that the sentiment associated with a rising payment percentage in both statutory scheme and voluntary scheme may affect investment, and b) there is a risk that the size of increase in payment percentages under statutory scheme may affect the launches of new medicines, while acknowledging that the previous statutory scheme rates and the general commercial environment may have induced relatively low profit margins. It is not possible to quantify these effects in the absence of detailed commercial information about upcoming new medicine launches, which is not publicly available.

215. The Department, along with ABPI, is currently conducting an Accelerated Mid-Scheme Review (AMSR) for VPAG under which, we are considering evidence put forward by industry regarding their investment drivers and decisions. Moreover, it is worth noting that statutory scheme only accounts for 1.7% of voluntary and statutory measured sales therefore, the impact of a change to this scheme is likely to be far outweighed by VPAG, which is currently the key focus of the AMSR.

216. As it currently stands, the Department maintains that the investment decisions of companies under the Statutory Scheme are difficult to calculate under each option. We acknowledge the risks (stated above), but in the absence of detailed information about companies' upcoming investment plans, the effects on investment cannot be quantified. The limitations of the methodology were acknowledged by removal of effects on investment from the Net Present Values (NPVs) for each option. Annex C contains a detailed consideration of the many drivers which could affect investment location decisions.

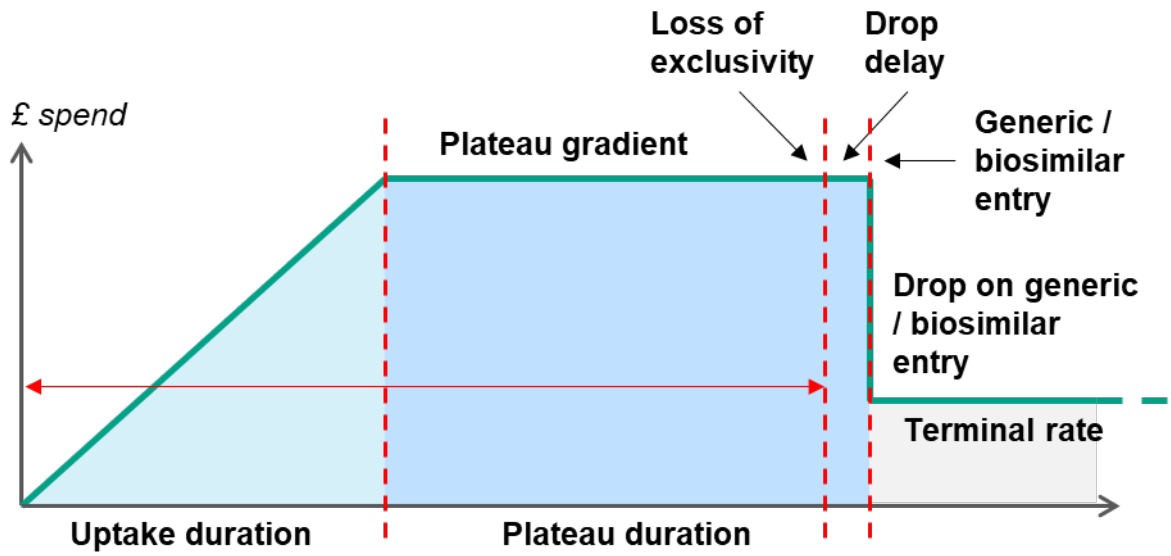
217. Some respondents argued that the methodology is flawed as it uses the 2% growth cap to calculate the rate, which they suggested is too low and will restrict the growth of the UK life sciences sector and patient access to new medicines. As set out in the consultation-stage impact assessment and in the consultation document itself, we have considered several options

for the allowed growth rate. However, the preferred option goes beyond only using a 2% allowed growth rates, and also includes baseline adjustments for 2025 – 2027 that are of a total equivalent value to that used in VPAG. This will be to the benefit of the life sciences sector. Moreover, the Department holds the view that the proposed allowed growth rate takes account of multiple factors, including the pipeline of upcoming new treatments and, ultimately, continued growth forecast in medicine sales. We consider that controlling growth at this level will allow for a viable financial envelope for the statutory scheme overall.

Annex A – Medicines 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 2027.
2. DHSC uses 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. DHSC is working with the ABPI to explore options for how to develop alternative forecasts and improve our forecast methodology. However, this work is currently in its development stage, and the outputs are uncertain.
4. 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 2: Stylised product lifecycle



5. An existing assumption of the forecast model is that a typical lifecycle is 158 months long, which is based on previous IPO (Intellectual Property Office) analysis.
6. Key parameters of the product lifecycle in the model are listed in Table 43.

Table 43: 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

7. 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.

8. 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

9. 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.

10. 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.

11. 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

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

13. 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.

14. 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

15. When a branded medicines 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.
16. 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.
17. 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

18. This reflects the blended impact of price decay once a branded medicines 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.
19. 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.
20. Plotted data was used to review and identify the proportional change in spend at the point spend stabilises.

Terminal rate

21. 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.
22. 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.
23. 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.
24. 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

25. 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 medicines).

26. 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

27. 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.

28. 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 medicines, 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.

29. 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.

30. 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.

31. 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 medicines 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.

32. 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 medicines, 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.

33. 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”).

34. The model was used to generate a series of forecast growth rates for total branded medicines spend for the period 2022 to 2027.

Annex B – Evidence underpinning industry revenue impacts accrue to UK shareholders

1. This section sets out the evidence underpinning the latest estimate of the proportion of industry revenue impacts that accrue to UK shareholders.

2. Assuming that profits are shared between the UK and overseas in the same proportion as total revenue, this implies that a corresponding proportion of the changes in profits will accrue to UK shareholders. Same as the previous final stage impact assessment in October 2024, we continue to use the assumption of the proportion of UK consumption produced in the UK as the proportion of industry revenue impacts that accrue to UK shareholders. This is calculated as the UK production consumed domestically divided by total UK consumption of pharmaceuticals (UK production consumed domestically + Pharmaceutical imports).

3. We also used ONS Index of Production time series SIC 21, Manufacture of basic pharmaceutical products and pharmaceutical preparations, which provided a more accurate share of domestically consumed pharmaceuticals produced in the UK and also the outturn growth of manufacturer turnover in 2022 and 2023.

4. Using Bioscience and health technology statistics 2021-22[40], we estimate that between 2017-18 and 2021-22, an average of 33% of life sciences turnover for companies with known ownership (excluding unknowns) was generated by companies with UK ownership. A similar estimate is found for the pharmaceutical sector more specifically. This corroborates our estimates for industry revenue impacts that accrue to UK shareholders, following assumptions in point 2, shown below.

5. According to section 8.3 of the Annual Business Survey technical report, the time series was classified as short-term indicators and should not represent absolute amounts or monetary values. The share of domestically consumed pharmaceuticals and outturn growth of manufactural turnovers were however applied to Annual Business Survey to provide a better and more recent estimate of UK consumption of pharmaceuticals.

6. Table 44 below shows the calculations of the assumption in paragraph 2 using preferred data sources.

7. Taking a five-year average to the estimate from 2020 to 2024, the latest estimate for the industry revenue impacts accrue to UK shareholders is 28.9%.

Table 44: Estimated Proportion of UK consumption produced in the UK

	2019	2020	2021	2022	2023	2024
Proportion of UK consumption produced in the UK	28.5%	29.7%	30.4%	26.5%	29.8%	27.8%

[40] BaHTSS_accompanying_data_tables_2021-22.ods – accessed 29th January 2025

Annex C – Evidence underpinning wider economic impacts approach

1. This section sets out the evidence underpinning our approach to quantifying the potential wider economic impacts of the policy options to avoid repetition in later sections. Theoretically, increased payment percentages versus the counterfactual may reduce 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.

2. 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:

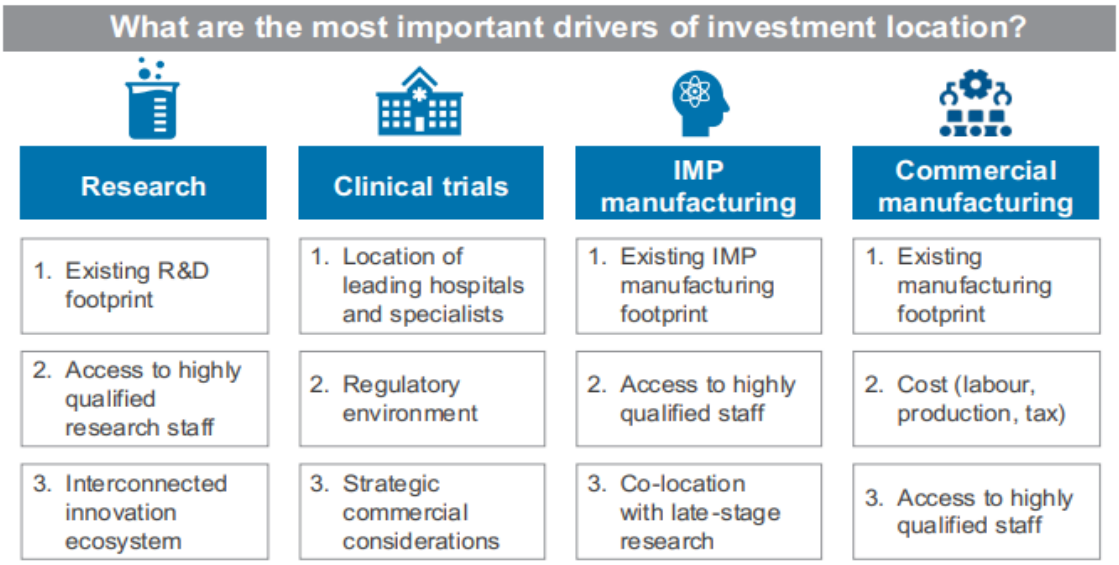
3. "6.5 Green Book appraisal is not concerned with the macroeconomic effects of spending which is the concern of government when it makes macro spending decisions on the overall level of spending and taxation."

4. "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."

5. 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.

6. In their 2021 "Factors affecting the location of biopharmaceutical investments and implications for European policy priorities" report[41] 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 3).

Figure 3: Summary of factors driving the location of biopharmaceutical investments



[41] 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]

7. Whilst cost and strategic commercial considerations feature in commercial manufacturing and clinical trials respectively, research and IMP (investigational medicinal product) manufacturing are focussed on existing footprint, access to highly qualified staff and connections with innovation and late-stage research.

8. 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[42], Cancer Drugs Fund and provisions within VPAG we consider this risk to be relatively low.

9. Research has found that R&D investment strategy decisions of firms were strongly driven by firm effects and that exposure to price regulation had little effect.

10. The "Attracting life science investments in Europe" report published in June 2021[43] 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 economic context.
    - Industrial context.
    - Life sciences innovation.
    - Healthcare environment.

11. 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.

12. 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.

13. Similarly, the 2021 EU R&D industrial investment scoreboard[44] 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.

[42] 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/]
[43] 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]
[44] 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]

14. More recently the "Startup Blink Global Ecosystem Report 2023"[45] 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.

15. 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 amounts raised, which 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.[46]

16. 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.

17. 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%[47]. There are other sources that estimate the share of revenue devoted to R&D is closer to 25%[48], and Office for Life Sciences (OLS analysis suggesting it may be nearer 15%[49]. 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%.

18. This is the upper end of the 15% to 25% range recommended for use by the OLS. We then apply the latest identified estimate for the proportion of global pharmaceutical R&D that is in the UK to estimate possible additional UK investment. In 2023 we estimate the UK's share of global R&D came to 3.6%, with global pharmaceutical R&D at around £243 billion[50] and the UK's pharmaceutical R&D summing to approximately £8.7 billion[51].

19. 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

[45] StartupBlink. 2023. Global Startup Ecosystem Index 2023. page.40. [https://lp.startupblink.com/report/]
[46] 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
[47] BEIS analysis of ONS/Business Enterprise Research and Development data
[48] Congressional Budget Office. 2021. Research and Development in the Pharmaceutical Industry. [https://www.cbo.gov/publication/57126]
[49] OLS analysis of Business Population Estimates data and Business enterprise research and development data, provided in correspondence
[50] World Preview 2024 – Pharma's Growth Boost - eBook | Evaluate. Figure sourced is $301bn in 2023, assumes average 2023 exchange rate of £1:$1.24 (accessed 29 January 2025)
[51] Business enterprise research and development, UK (designated as official statistics) - Office for National Statistics

papers[52] were considered with a mean estimate of spillover effects being valued at 34% the value of the investment and the median at 32%.

20. 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[53] and biomedical research centres and units[54] 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.

21. 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 = 3.6% and spillover impacts = 30%.

[52] James Medhurst, Joel Marsden, Angina Jugnauth, Mark Peacock, Jonathan Lonsdale. 2014. An Economic Analysis of Spillovers from Programmes of Technological Innovation Support.
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/288110/bis-14-653-economic-analysis-of-spillovers-from-programmes-of-technological-innovation-support.pdf];
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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];
Jonathan Grant and Martin J Buxton. 2018. Economic returns to medical research funding. BMJ Open 2018. 8, e022131;
Sandra Bulli. 2013. Business Innovation Investment in the UK. [https://dera.ioe.ac.uk/id/eprint/8754/1/DIUS-RR-08-13%20(2).pdf];
Nick Bloom, Brian Lucking and John Van Reenen. 2018. Have R&D Spillovers Changed? [https://cep.lse.ac.uk/pubs/download/dp1548.pdf];
Iain M. Cockburn and Rebecca M. Henderson. 2001. Publicly Funded Science and the Productivity of the Pharmaceutical Industry. In: Adam B. Jaffe, Josh Lerner, and Scott Stern. Innovation Policy and the Economy, Volume 1. pp.1-34;
Hiroyuki Odagiri and Naoki Murakami. 1992. Private and quasi-social rates of return on pharmaceutical R&D in Japan. Research Policy. 21(4), pp.335-345;
OECD. 2015. The Impact of R&D Investment on Economic Performance: A Review of the Econometric Evidence.
[https://one.oecd.org/document/DSTI/EAS/STP/NESTI(2015)8/en/pdf].

[53] 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]

[54] 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 D – Estimates of the NHS cost of providing an additional QALY, and society's valuation of a QALY

1. This Annex defines and describes two distinct, but related concepts:
    - 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[55]. 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[56] 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'.

[55] 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/]

[56] 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[57].

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.

Example IA calculation

13. Suppose a project cost £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:

14. The <u>costs</u> of the project are the QALYs that would be gained if the funds were used elsewhere in the NHS, but which are foregone if the project is undertaken. Using the standard DH estimate that one QALY is gained elsewhere for every £15,000 of funding, this gives an 'opportunity' cost of **1,000 QALYs lost**. Monetising these costs at the DHSC estimate of the social value of a QALY gives a monetary equivalent of **<u>£70m</u>**.

[57] 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]

15. 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.

16. The net benefit of the project is therefore **200 QALYs**, or, expressed in monetary terms **£14m.**

17. 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.

18. 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 into QALYs (at £15,000 / QALY), and then monetising them (at £70,000 / QALY).

Annex E – Measured sales, eligible Sales, and payment percentage calculation

Non-BAU Options

1. The non-BAU options introduce different levels of baseline adjustment and allowed growth rates, and the total allowed sales is calculated as follows.

$$Total\ Allowed\ Sales_t = (Total\ Allowed\ Sales_{t-1} + Baseline\ Adjustment_t) \times (1 + Allowed\ Growth_t)$$

Where t refers to the calendar year, e.g., 2025, 2026, or 2027. Non-BAU options use the most recent available data, i.e. up to and including Q4 2024.

In the previous impact assessment, reference was made to statutory scheme measured sales, rather than voluntary scheme and statutory scheme measured sales. In the same approach to our amendments to Figure 1, we would also like to clarify that Annex E in the previous final stage impact assessment of October 2024 should have referred to voluntary scheme and statutory scheme measured sales to calculate the statutory scheme headline payment percentage, rather than just statutory scheme measured sales. We have updated the narrative of the methodology here, but the calculations remain unchanged. It should also be noted that the BAU calculation to generate the payment percentages should have been noted as following the same method outlined here for the non-BAU options, and O refers to a non-BAU option.

2. Measured sales across industry are forecast by applying the newer medicines, older medicines, and parallel import growth rates to baseline industry measured sales (split into newer medicines, older medicines, and parallel imports) in 2023. To estimate the value of sales that belong to the voluntary and statutory scheme, we multiply industry measured sales by the proportion of sales that are newer or older in each given year.

$$Industry\ measured\ sales_t = (Industry\ measured\ sales\ _{t-1}) \times (1 + Growth\ rate_t)$$

$$Measured\ sales_{t,} = (Industry\ measured\ sales\ _t) \times (\%Measured\ sales_{VS+SS,t})$$

3. Voluntary scheme and statutory scheme measured sales are split across two categories, namely newer medicines, and older medicines. These are calculated across VPAG and the statutory scheme, as denoted by $VS + SS$.

$$Measured\ Sales_{t,VS+SS} = Measured\ Sales\ (Newer)_{t,VS+SS} + Measured\ Sales\ (Older)_{t,VS+SS}$$

4. Newer medicines measured sales are forecast incorporating the latest available actuals data. For the purpose of calculating the headline payment percentage, older medicines are grown by the same fixed forecast growth as agreed under the voluntary scheme as set-out in the scheme design. For calculating actual income projections, older medicines forecast growth is also updated to incorporate the latest available actual measured sales data.
5. The BAU and each proposed option include an exemption from eligible sales for sales of NAS under the statutory scheme. voluntary scheme and statutory scheme eligible sales, in the context of use in statutory scheme payment percentage calculations, are calculated as the sum of eligible sales (newer) and eligible sales (older) as shown below. Please note the medium size company exemption from eligible sales available in the voluntary scheme is not included in the calculations, given this is not replicated in the statutory scheme. This does not affect its inclusion in the voluntary scheme.

$$Eligible\ Sales\ (Newer)_{t,VS+SS} = Measured\ Sales\ (Newer)_{t,VS+SS} - NAS\ Sales_{t,VS+SS}$$

$$Eligible\ Sales\ (Older)_{t,VS+SS} = Measured\ Sales\ (Older)_{t,VS+SS}$$

6. Next, the Allowed Sales Gap is calculated, before being multiplied by the proportion of total measured sales that are attributable to the statutory scheme and the voluntary scheme (i.e. excluding parallel imports) to give the total payment.

$$Allowed\ Sales\ Gap_t = Total\ Measured\ Sales_t - Total\ Allowed\ Sales_t$$

$$Total\ Payment_{t,VS+SS} = Allowed\ Sales\ Gap_t \times \%\ share\ (VS + SS)$$

7. According to the differentiated approach to setting payment percentages of older products, all eligible sales of older medicines will be subject to the basic payment percentage applicable for each given year. Additionally, unless an exemption applies, older medicines will also pay a top-up payment percentage from 0% to 25% to be allocated annually at presentation level according to the observed price decline of individual branded presentations from their reference prices.
8. The adjusted payment from older medicines is calculated as follows:

$$\begin{aligned} &Adjusted\ Payment\ from\ Older\ Medicines_{t,VS+SS} \\ &\quad = \sum_P Eligible\ Sales\ (Older)_{t,P,VS+SS} \\ &\quad \times (basic\ payment\ percentage_t + \ top\ up\ payment\ percentage_P) \\ &\quad \times Forecast\ payment\ from\ older\ medicines\ adjustment\ factor_t \end{aligned}$$

Where P refers to the percentage of observed price decline of individual branded presentations. The forecast payment from older medicines adjustment factor is fixed at pre-determined values for each given year of the appraisal period, mirroring the equivalent factor applied in VPAG calculations.

9. Calculation of required payment from newer medicines:

$$\begin{aligned} &Required\ Payment\ (Newer)_{t,VS+SS} \\ &\quad = Total\ Payment_{t,VS+SS} - \ Adjusted\ Payment\ from\ Older\ Medicines_{t,VS+SS} \end{aligned}$$

10. Calculation of the headline payment percentages and actual payments would be the same under policy options:

$$SS\ Headline\ Payment\ \%_t = \frac{Required\ Payment\ (Newer)_{t,VS+SS}}{Eligible\ Sales\ (Newer)_{t,VS+SS}}\ (correct\ to\ 1\ d.p)$$

11. The actual payments projected for the statutory scheme are calculated as follows:

$$\begin{aligned} &SS\ Actual\ Payment\ (Older)_{t,} \\ &\quad = \sum_P SS\ Eligible\ Sales\ (Older\ actual)_{t,P} \\ &\quad \times (basic\ payment\ percentage_t + \ top\ up\ payment\ percentage_P) \end{aligned}$$

$$SS\ Actual\ Payment\ (Newer)_t = SS\ Eligible\ Sales\ (Newer)_{t,A,O} \times SS\ Headline\ Payment\ \%_t$$

$$SS\ Actual\ Payment\ _t = SS\ Actual\ Payment\ (Newer)\ _t + \ SS\ Actual\ Payment\ (Older)_t$$

Business as Usual (BAU) Counterfactual

12. Under the BAU, the headline payment percentages for newer medicines have been predetermined at 15.5% for 2025, 17.9% for 2026, and 20.1% for 2027. Therefore, the statutory scheme payments for newer medicines are calculated as follows below (alongside calculations for total statutory scheme income). Like the non-BAU options, we use the most recent data (Q4 2024) to calculate the income.

$$SS\ Actual\ Payment(Newer)_{2025,BAU} = SS\ Eligible\ Sales(Newer)_{2025,BAU} \times 15.5\%$$

$$SS\ Actual\ Payment(Newer)_{2026,BAU} = SS\ Eligible\ Sales(Newer)_{2026,BAU} \times 17.9\%$$

$$SS\ Actual\ Payment(Newer)_{2027,BAU} = SS\ Eligible\ Sales(Newer)_{2027,BAU} \times 20.1\%$$

$$SS\ Actual\ Payment\ _{t,BAU} = SS\ Actual\ Payment\ (Newer)\ _{t,BAU} + \ SS\ Actual\ Payment\ (Older)_{t,BAU}$$

Annex F – Glossary

- **Allowed Sales –** the amount at which growth in measured sales is to be capped at through payments made by branded medicines manufacturers to DHSC. It is calculated by the Allowed sales baseline plus any baseline adjustments if applicable, with the allowed growth rate applied.
- **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 UKHSA (or any successor body).
- **Eligible sales** – Statutory scheme sales which are subject to the payment percentage. Under all policy options, sales of new active substance (NAS) are exempt from having the payment percentage applied to them.
- **Exceptional central procurement (ECP)** – exceptional procurements conducted by a Central Government Body and managed by UKHSA (or any successor body) for the purposes of emergency preparedness, stockpiling for the national security or pandemic preparation.
- **VPAG Investment Programme** – a new joint government-industry programme to strengthen the UK's global competitiveness in led and sciences and drive innovation-led growth.
- **Low value sales** – Sales of any Scheme products by a scheme member where the NHS list price of the scheme product is less than £2.
- **Industry measured sales** – overall sales of branded medicines to the NHS (measured by combining relevant sales across the voluntary scheme, statutory scheme and parallel imports).
- **New active substance (NAS)** – Any presentation which satisfies the requirements of paragraph (10) of Regulation 9 of the statutory scheme.
- **Newer medicines** – Newer medicines are originator or originator licensee medicines where there is intellectual property protection in place for the active ingredient or ingredients (known as the Virtual Therapeutic Moiety or VTM) in the form of a Supplementary Protection Certificate (SPC). Where the active ingredient was never the subject of an SPC, newer medicines are those where less than 12-years have elapsed from the date of the first marketing authorisation for the active substance. This is taken from Market Authorisation data from MHRA and SPC data from the IPO (Intellectual Property Office). This definition follows that of VPAG.
- **Older medicines** – Scheme products that do not meet the definition of a newer medicine.
- **Parallel import –** Sales of presentations in respect of which a Parallel Import Licence has been granted and sales of any parallel distributed presentation.
- **Headline payment percentage** – Payments are made based on a proportion of the manufacturer's eligible sales of newer medicines. This proportion is the payment percentage.
- **Reference price** – Prices in accordance with Annex 4 of the 2024 voluntary scheme for branded medicines pricing, access and growth[58].
- **Small company sales** – sales by companies whose total sales of scheme products are less than £6m in the relevant calendar year.
- **Older medicines basic payment percentage** – the basic payment percentage for older products to which the top up rate is added. Across all options (BAU and proposed options) this is 10.6% in 2025, 11.0% in 2026, and 10.9% in 2027 respectively.
- **Older medicine top-up payment percentage** – an additional payment percentage added to the basic payment percentage for older medicines allocated according to the level of

[58] https://assets.publishing.service.gov.uk/media/657b2993254aaa000d050de1/Annexes-2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth.pdf - accessed 19 June 2024

observed price decline as set out within the differentiated approach to setting payment percentages for older medicines.

- **Baseline adjustment** – an amount of money added to the allowed sales baseline in a given year.
- **Exemptions from newer medicines eligible sales** – NAS sales
- **Exemptions from measured sales** - sales of scheme products by a scheme member relating to exceptional central procurements; sales of scheme products by a scheme member relating to centrally procured vaccines; small company sales; low value sales; sales of pharmacy medicines and general sale license medicines; and sales made under public contracts and framework agreements.
- **Exemptions from older medicine top-up payment percentage** - sales of plasma derived medicinal products, sales of older medicine where, for an individual scheme member, the total measured sales of scheme products across a VTM is less than £1.5m.
- **List Price** – the list price as published in the dictionary of medicines and devices (dm+d).