IA Title: Statutory Scheme – Branded medicines Pricing **IA No:** n/a **RPC Reference No:** n/a **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:** NHS England	**Impact Assessment (IA)** **Date: 21 February 24** **Stage: Development/Options** **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 2024 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
-£160m	£m n/a	£m n/a	Non qualifying provision

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

In the UK, the overall costs of branded health service medicines are currently controlled by a Statutory Scheme and a Voluntary Scheme. The statutory scheme is set out in regulations, the Branded Health Service Medicines (Costs) Regulations 2018 ('Statutory Scheme' or the '2018 Regulations'). The previous Voluntary Scheme Voluntary scheme for branded medicines pricing and access (VPAS) agreed with industry expired at the end of 2023 has been replaced by Voluntary Scheme for Branded Medicines Pricing, Access, and Growth (VPAG). 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 VPAG. We previously consulted on a new statutory scheme for 2024 to update payment percentages according to the latest available data and to support it operating as either a standalone scheme were agreement not reached on a new Voluntary Scheme for branded medicines pricing, access and growth (VPAG) or in conjunction with a new Voluntary Scheme. As VPAG has now been agreed, the Statutory Scheme operates as a legal backstop for companies that choose not to join the voluntary scheme, we are consulting on further changes designed to support Broad Commercial Equivalence (BCE) of the Statutory Scheme with VPAG. If DHSC does not update the Statutory scheme then it will not support BCE between the two schemes and so there is significant risk that the schemes do not work effectively to control the costs of branded medicines, creating risks to the financial sustainability of the NHS and patient access to medicines.

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, to have regard to the impact on industry, the economy, and patients.

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

Four options are assessed in this IA with option 2 as the preferred option:

- Business as Usual (BAU) - the current regulations remain in force with a payment percentage of 21.9%, 24.0% and 26.8% in each of the three years covered by this appraisal period and no change to exemptions.
- Option 1 - Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2% allowed growth per annum and increase the small company sales threshold from £5m to £6m.
- Option 2 - Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2% allowed growth per annum, baseline adjustments of £150m, £150m and £330m in 2024, 2025 and 2026 respectively and increase the small company sales threshold from £5m to £6m.
- Option 3 - differentiated approach to setting payment percentages for newer medicines and older medicines with 2%, 3.75% and 3.75% allowed growth per annum in 2024, 2025 and 2026 respectively and increase small company sales threshold from £5m to £6m.

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. **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: ..... Date: .....

Summary: Analysis & Evidence — Business As Usual

Description: Business As Usual

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	PV Base Year 2024	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 payment rates as of the previous consultation of 21.9% in 2024, 24.0% in 2025 and 26.8% in 2026. We do not model an assumption for the number of companies that joined VPAG in 2024 choosing to move to the Statutory Scheme in subsequent years. This reflects the inherent uncertainties regarding the company level commercial incentives to do so.

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

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

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	0		0	0

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

The Business As Usual option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero.

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

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

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

Under Business as Usual, the principal risk is the divergence of the statutory scheme from VPAG in terms of broad commercial equivalence, destabilising how the two schemes operate together and therefore leading to increased costs for HMG and a less predictable commercial environment for companies.

BUSINESS ASSESSMENT (BUA)

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

Summary: Analysis & Evidence — Policy Option 1

Description: Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2% allowed growth per annum and increase the small company sales threshold from £5m to £6m.

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	**PV Base Year** 2024	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -£111m	**High:** -£35m	**Best Estimate:** -£75m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	£113m
High	Optional		Optional	£36m
Best Estimate				£77m

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

Depending on the level of sales growth between 2024 and 2026, there may be additional net costs to the NHS (UK) of between £8m to £25m by 2026. This equates to an estimated 517 to 1,643 fewer QALYs by 2026, with a societal value of £36m to £113m in present value terms (before estimated benefits are netted off).

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

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	£2m
High	Optional		Optional	£1m
Best Estimate				£2m

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

Depending on the level of sales growth to 2026, pharmaceutical companies may see an increase in profits estimated at between £8m and £25m, of which circa £1m to £2m may accrue to UK shareholders by 2026.

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

The main non-monetised benefits of this option are bringing the statutory scheme in line with the structure of VPAG to support Broad Commercial Equivalence between the two Schemes. Furthermore, the differentiated approach to setting payment percentages is considered supportive of both competition and innovation in the life sciences sector.

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

There is inherent uncertainty around future growth in branded medicines sales and therefore over the appropriate payment percentages. We assume that supply of products remains economically viable following application of these payment percentages given the options available relating to list and net price increase applications to mitigate supply issues, as well as the exemptions proposed from older medicines top-up payment percentages. A key source of data is company returns on NHS sales – we assume that this information is accurate. There is a further risk that this option does not meet the aim of Broad Commercial Equivalence as retaining 2% allowed growth rate per annum could be considered, compared to the VPAG agreed in December 2023, punitive to the extent that the voluntary nature of VPAG could be called into question.

BUSINESS ASSESSMENT (Option 1)

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 2

Description: Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2% allowed growth per annum, baseline adjustments of £150m, £150m and £330m in 2024, 2025 and 2026 respectively and increase the small company sales threshold from £5m to £6m.

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	**PV Base Year** 2024	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -£195m	**High:** -£120m	**Best Estimate:** -£160m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	£200m
High	Optional		Optional	£123m
Best Estimate				£163m

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

Depending on the level of sales growth between 2024 and 2026, there may be additional net costs to the NHS (UK) of between £27m to £44m by 2026. This equates to an estimated 1,789 to 2,910 fewer QALYs by 2026, valued at £123m to £200m in present value terms (before estimated benefits are netted off).

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

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	£4m
High	Optional		Optional	£3m
Best Estimate				£3m

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

Depending on the level of sales growth to 2026, pharmaceutical companies may see an increase in profits estimated at between £27m and £44m, of which circa £3m to £4m may accrue to UK shareholders by 2026.

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

The main non-monetised benefits of this option are bringing the statutory scheme in line with the structure of, and more in line with the financial elements agreed for VPAG, thereby better supporting Broad Commercial Equivalence. The differentiated approach to setting payment percentages is also considered to be supportive of both competition and innovation in the life sciences sector.

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

There is inherent uncertainty around future growth in branded medicines sales and therefore over the appropriate payment percentages. We assume that supply of products remains economically viable following application of these payment percentages given the options available relating to list and net price increase applications to mitigate supply issues, as well as the exemptions proposed from older medicines top-up payment percentages. A key source of data is company returns on NHS sales – we assume that this information is accurate.

BUSINESS ASSESSMENT (Option 2)

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	

Summary: Analysis & Evidence — Policy Option 3

Description: Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2%, 3.75% and 3.75% allowed growth per annum in 2024, 2025 and 2026 respectively and increase small company sales threshold from £5m to £6m.

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	**PV Base Year** 2024	**Time Period Years** 3	**Net Benefit (Present Value (PV)) (£m)**		
			Low: -£162m	**High:** -£87m	**Best Estimate:** -£126m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	£165m
High	Optional		Optional	£89m
Best Estimate				£129m

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

Depending on the level of sales growth between 2024 and 2026, there may be additional net costs to the NHS (UK) of between £19m to £36m by 2026. This equates to an estimated 1,290 to 2,410 fewer QALYs by 2026, valued at £89m to £165m in present value terms (i.e. before estimated benefits are netted off).

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

This option is considered to meet the objective of Broad Commercial Equivalence but does this using the allowed growth rate which is considered to have the risk of undermining the confidence of the NHS in its long-term spending position. So, achieving this through the baseline adjustments as option 2 is considered more favourable.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	£3m
High	Optional		Optional	£2m
Best Estimate				£3m

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

Depending on the level of sales growth to 2026, pharmaceutical companies may see an increase in profits estimated at between £19m and £36m, of which circa £2m to £4m may accrue to UK shareholders by 2026.

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

This option also has the benefit of bringing the statutory scheme in line with the structure of, and more in line with the financial elements agreed for VPAG, thereby better supporting Broad Commercial Equivalence. The differentiated approach to setting payment percentages is also considered to be supportive of both competition and innovation in the life sciences sector. However, this option does this through the allowed growth rate which is not the preferred mechanism for doing this because increasing growth in allowed sales within the statutory scheme risks undermining the confidence of the NHS in its long-term spending position. The Government consultation response from December 2023 set out why we consider 2% to be an appropriate long-term growth rate for branded medicines, noting that increasing allowed growth beyond this (outside of the context of a timebound negotiated voluntary agreement with mutual benefits for Government and industry) could increase the risk of unsustainable growth in spending on unbranded medicines.

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

There is inherent uncertainty around future growth in branded medicines sales and therefore over the appropriate payment percentages. We assume that supply of products remains economically viable following application of these payment percentages given the options available relating to list and net price increase applications to mitigate supply issues. A key source of data is company returns on NHS sales – we assume that this information is accurate. There is a further risk that increasing growth in allowed sales within the statutory scheme risks undermining the confidence of the NHS in its long-term spending position, while failing to increase short-term investment through baseline adjustment increases the risk that the statutory scheme cannot meet its objective of broad commercial equivalence by 2026.

BUSINESS ASSESSMENT (Option 3)

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	

Evidence Base

Background

1. The life sciences industry is one of the most important pillars of the UK economy, contributing over £108.1bn a year and 304,200 jobs across the country, of which the Biopharmaceuticals sector generated £73.9bn turnover in 2021/22 and employed 150,000 people[1].

2. When a newer medicine is launched it will typically be under patent, with the suppliers of health services medicines holding these patents enjoying monopoly supply of products at high prices to the NHS. This high price enables the supplier to generate profits and provides an incentive to invest in R&D, 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 variants of medicines entering the market. This typically results in downwards pressure on market prices as new entrant generics 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 generic competitors.

4. In England, the 2022/23 spend on prescribed medicines, appliances, and medical devices by the NHS was approximately £19.2bn[2], of which an estimated £14.0bn[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 £18.5bn[5].

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

Voluntary Scheme

6. Government needs a mechanism to control the NHS branded medicines bill in order 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 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. From 1 January 2024, VPAG was introduced which after a period of transition in Q1 (January-March) 2024 brings in differentiated payment mechanisms between newer and older medicines commencing 1 April 2024. The payment percentage for newer medicines will be dynamic (being amended for the start of each scheme year) and will be set to keep sales growth within allowed sales. 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 on a sliding scale with respect to the amount of

[1] Office for Life Sciences, Department for Business, Energy & Industrial Strategy and Department of Health and Social Care. 2023. Bioscience and health technology sector statistics 2021 to 2022. [https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021-to-2022]

[2] NHS Business Services Authority. 2023. Prescribing Costs in Hospitals and the Community - England 2018/19 to 2021/22. [https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122/prescribing-costs-hospitals-and-community-england-201819-202223]

[3] Based on updated DHSC estimates of share of medicine spend and share of branded spend. New approach estimates split of medicine and non-medicine spend in primary and secondary care from the published BSA spend data, and models estimate of branded spend within this.

[4] These are rebates from arrangements NHSE have agreed with pharmaceutical companies in negotiations to commission a variety of treatments both in the cancer drugs fund (CDF) and in routine commissioning. This includes treatments for both rare diseases and more common conditions

[5] NHS Business Services Authority. 2023. Prescribing Costs in Hospitals and the Community - England 2018/19 to 2021/22. [https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122/prescribing-costs-hospitals-and-community-england-201819-202223]

price reduction observed. Finally, an Investment Programme payment percentage will apply to all eligible sales of VPAG members (irrespective of whether they relate to older or newer medicines).

8. The previous (2019) VPAS scheme, 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 grows 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 in order to bring actual outturn growth in line with allowed growth. 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.

Statutory Scheme

9. 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 braded medicines sales, the companies that have opted to join the statutory scheme for 2024 made up 1.91% of sales in 2023 (as of latest data Q4 2023). 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.

10. The legislative changes we introduced following the consultation, which took effect on 1st January 2024, were necessary to ensure we had a robust, credible statutory scheme that could operate as a standalone medicines pricing scheme in the absence of an agreed successor to the 2019 voluntary scheme. We amended statutory scheme payment percentages for 2024 to 2026 on the basis of a higher allowed growth rate (moving from 1.1% to 2%), as well as introducing a number of exemptions from payment such as for medicines containing a new active substance for 36 months after Market Authorisation (MA).

11. We did not however introduce the VPAG older products adjustment mechanism as this was not possible due to dependencies on negotiations on VPAG which did not conclude until December. We noted in our consultation response and in communications with industry that Government would therefore consult in early 2024 on further amendments to the statutory scheme in order to maintain broad commercial equivalence with VPAG. More specifically, on the introduction of differentiated approach to setting payment percentages for older and newer medicines.

12. In practice, broad commercial equivalence (which does not require that the terms of the schemes are identical) was achieved between 2018 and 2023 by limiting the growth rate of branded health service medicines sales in the Statutory Scheme to 1.1% per annum (compared to 2% in VPAS).

13. 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.
    - Previous Statutory Scheme IAs have taken into account exemptions from payment due to sales under framework agreements when calculating the income that is expected to be received from the scheme, and subsequently the impacts of the policy option. There are now no relevant extant framework sales, so there is no impact on our conclusions or results from this category of sales.

Key concepts relevant in BAU and proposed policy options

14. There are a number of key concepts referred to in this IA that are relevant in both the BAU and proposed policy options. These are set out below, whereas key concepts relating to the differentiated approach to setting payment percentages proposed in the policy options are covered in the "differentiated approach to setting payment percentages for newer medicines and older medicines" section. A longer glossary of terms is included at Annex E.

- **Industry Measured Sales**: Overall measured sales of branded medicines to the NHS (defined as the sum of measured sales across VPAS, Statutory Scheme and Parallel Imports). Certain exemptions from measured sales exist under VPAG and the current Statutory Scheme.
- **Voluntary Scheme Measures Sales**: Overall sales of branded medicines to the NHS made by members of the voluntary scheme to which an exemption from measured sales does not apply under the terms of the scheme.
- **Statutory scheme Measured Sales**: Overall sales of branded medicines to the NHS made by members of the Statutory Scheme to which an exemption from measured sales does not apply under the terms of the scheme.
- **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 with the allowed growth rate applied.
- **Allowed Growth**: the amount that allowed sales is allowed to grow by each year.
- **Eligible sales**: Statutory Scheme measured sales which are subject to the payment percentage. In practice in the current Statutory Scheme and each of the proposed options this equates to Statutory Scheme measured sales less New Active Substance (NAS) sales.
- **Payment percentages**: The proportion applied to manufacturer's eligible sales value to calculate their required payment.

Simplified example of setting payment percentage under the BAU option

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

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

Problem under consideration and rationale for intervention

15. Since the statutory scheme was established as a payment scheme in 2018, we have sought to set payment rates in the scheme 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.

16. The statutory scheme was last updated to come into effect from 1st January 2024. While responses to that consultation supported the principle of BCE[6], negotiation timelines for VPAG precluded this update from bringing the statutory scheme into line with VPAG in all areas, so the statutory scheme currently mirrors the structure of VPAS with a single payment percentage applied to all eligible sales.

17. VPAG, agreed in November 2023, is significantly different to VPAS in that it contains separate approaches to setting payment percentages for newer medicines and older medicines. This approach was adopted to ensure that the scheme would be pro-innovation and pro-competition, as set out in the "background and rationale" section, by subsidising relatively lower payment rates for newer medicines and those in competitive markets through increased payments for older medicines that have not demonstrated significant price decay since the expiry of the relevant IP protection applying to the active substance. The introduction of this new approach reflects a concern by Government that for many older medicines, post-patent competition is not delivering the expected levels of savings.

18. Without separate payment percentages for newer and older medicines, the statutory scheme cannot be considered to be broadly commercially equivalent to VPAG, as companies face markedly different commercial conditions in each scheme. This creates significant risks to the operation of the schemes and the sustainability of medicines spending, including:

    - Leakage from the voluntary scheme to the statutory scheme of companies based on the mix of their products between newer and older medicines.
    - Perverse incentives for companies to set up subsidiaries in order to benefit from the different treatment of newer and older medicines in the two schemes.
    - A more complex commercial environment which is more costly to operate.

19. 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 bring it into broad commercial equivalence with VPAG, address the risks above, and ensuring the statutory scheme.

Policy objective

20. The objective of the policy options proposed in this update are to support achieving BCE between the Statutory Scheme and the recently agreed VPAG in order that the schemes should better support innovation and competition through the introduction of separate approaches to setting payment percentages for newer medicines and older medicines as defined in paragraph 29-31. In so doing, we also propose to incorporate the latest data now available in the calculations.

21. 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.

Description of options considered

22. To support BCE between the Statutory Scheme and VPAG, each of the proposed options include replicating several elements of VPAG, namely:

[6] Department of Health and Social Care. 2023. Review of the scheme to control the cost of branded health service medicines. [https://www.gov.uk/government/consultations/review-of-the-scheme-to-control-the-cost-of-branded-health-service-medicines]

- Differentiated approach to setting payment percentages for newer medicines and older medicines mirroring the design of VPAG (further detail provided subsequently in this section); and
- Uprating the threshold for an exemption from scheme payments for small companies with sales of less than £6m (up from £5m).
- The proposed options are differentiated by the level of Allowed Growth Rate (AGR) or Allowed Sales Baseline Adjustment ("baseline adjustments") proposed as set-out below.
- **Business as Usual (BAU)** – the current regulations remain in force with a payment percentage of 21.9%, 24.0% and 26.8% in each of the three years covered by this appraisal period and no change to exemptions.
- **Option 1** – Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2% allowed growth per annum and increase the small company sales threshold from £5m to £6m.
- **Option 2** – Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2% allowed growth per annum, baseline adjustments of £150m, £150m and £330m in 2024, 2025 and 2026 respectively and increase the small company sales threshold from £5m to £6m.
- **Option 3** – Introduce differentiated approach to setting payment percentages for newer medicines and older medicines with 2%, 3.75% and 3.75% allowed growth per annum in 2024, 2025 and 2026 respectively and increase small company sales threshold from £5m to £6m.

Affordability mechanisms for Newer Medicines and for Older Medicines

Background and rationale

23. The medicines market relies on the 'innovation paradigm', meaning that new medicines have higher prices at the start of their lifecycle, but lower ones towards the end of it. New innovations are awarded intellectual property (IP) protection that enables them to command prices that are typically above the opportunity cost to the NHS - meaning the NHS could produce more health gain if funds were allocated to alternative treatments instead of these new innovations. In return, older medicines are expected to face price competition from generics and biosimilars, resulting in prices falling towards the cost of supply, and below the opportunity cost to the NHS. When this occurs, the NHS can improve health with the innovation at a cost lower than alternative uses of the funds, enabling the NHS to achieve value and improve net health gain overall (over the whole product lifecycle) notwithstanding the loss of health gain in the early periods, while supporting innovation with higher prices early in the lifecycle.

24. While this system has been instrumental in enabling innovation in and patient access to medicines, it does not always operate exactly as intended due to the complexities of the medicines market. In particular, there is evidence that many older products are not facing competition sufficient to reduce prices and so are continuing to be sold at a high price even in the later stages of the product lifecycle. As an example, VPAS presentation level returns for 2021 show a large proportion of the sales of older products (those launched before 2009) appear to be in single supplier markets with no competition.

25. Of the total of £1.9 billion of sales of older biological products in 2021, 70% of the sales value was on single supplier products. Of the total of £1.2 billion of sales of older non-biological products required to be sold by brand name in 2021, 65% of the sales value was on single supplier products. This increases the cost of medicines to the NHS and so increases scheme payment percentages required to keep growth to 2% per annum.

26. To address this issue, VPAG introduced differentiated approaches to setting payment percentages for medicines defined as "older medicines" and "newer medicines". This is designed to support lower payment rates for newer medicines and for older medicines that have seen significant price reductions, subsidised by a top-up payment rate for older medicines that have not seen such price reductions. This is intended to support innovation and competition.

27. The current statutory scheme continues to operate with one approach to setting payment percentages for all medicines, with the same payment percentage charged regardless of how long a medicine has been on the market or whether that medicine is subject to competitive pressure on prices. Without changing this, the statutory scheme will diverge from broad commercial equivalence with VPAG, and we will fail to achieve the intended objectives of the new approach with respect to the innovation paradigm.

28. We propose that the Statutory Scheme also introduces separate approached to setting payment percentages for newer medicines and older medicines to maintain BCE between the schemes and support competition and innovation.

Defining newer and older medicines

29. The first stage of the differentiated approaches to setting payment percentages is to assign an "older medicine" or "newer medicine" classification to the current stock of scheme products. We propose to introduce an approach equivalent to that established in the 2024 VPAG[7].

30. Newer medicines will be 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 will be those where less than 12-years have elapsed from the date of the first marketing authorisation for the active substance. This will be taken from Market Authorisations data from MHRA and SPC data from the IPO (Intellectual Property Office).

31. Older medicines will be those that do not meet the definition of newer medicines, which will include all new entrants (branded generics and biosimilars) that are not licenced by an originator.

Approach to setting payment percentages for older medicines

32. All older medicines will pay a basic payment percentage. This will be applicable to all eligible sales of older medicines and will be set at 10.03%, 10.6% and 11.0% respectively in year 2024, 2025 and 2026. This represents the same level of payment as in VPAG, adjusted to reflect the VPAG investment programme payment, ensuring continued equivalence.

33. For older medicines that are not additionally subject to a top-up payment percentage (that is those that have demonstrated sufficient price decline or that qualify for a relevant exemption), such rates represent a significant reduction in the rebate compared to recent years (2022, 2023 and Q1-2 2024), responding to concerns articulated by manufacturers of branded generics and biosimilars that higher payment percentages could discourage competition. We consider that this level is appropriate, as it is within the range of rates that have been previously set within the statutory and voluntary schemes without causing issues for products operating in competitive markets.

34. Setting predictable payment percentages for older medicines has an additional benefit as it removes the requirement that companies include a future payment percentage risk premium when setting their prices on competitive multi-year tenders or framework agreements. Payments relating to the basic payment percentages will be made quarterly.

35. Certain older medicines, which have experienced a reduction in price on their relevant reference price of less than 35%, will additionally pay a top up payment percentage. The top up payment percentage which applies will be determined on a linear sliding scale up to a maximum on 25% based on the level of observed price decline (OPD) against a reference price: the greater the OPD, the lower the top up payment. For example, a medicine that experienced a price decline of 34% would pay a top up payment percentage of 1%, a medicine that experienced a price decline of 33% would pay a top up payment percentage of 2%, and so on. The maximum top up percentage of 25% will apply to older medicines with an observed price decline of 10% or less. The levels of OPD

[7] Department of Health and Social Care. 2023. 2024 voluntary scheme for branded medicines pricing, access and growth. [https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth]

and their associated top-up payment percentages proposed in each of the policy options mirror those negotiated and agreed for VPAG.

36. The top-up payment percentage applies to individual branded presentations of older medicines and will be calculated and paid following receipt of the annual Product Level Report data (PLR). For example, top-up payments relating to the 2024 calendar year will be calculated in April 2025.

37. The reference price is determined at a branded presentation level using either an observed average sales price or an adjusted list price as of 1 January in the year prior to a medicine becoming an older medicine. Where reference prices are determined based on average selling price this is taken from Presentation Level Returns data (PLRs) collected under the PPRS, VPAS, VPAG or the statutory scheme. Where reference prices are determined based on an adjusted list price, this will be subject to a downwards adjustment of 12.5%. As set out in the consultation document, where an exact match to a reference price is not possible, comparators will be identified with the aim of establishing and setting Reference Prices based on the closest match or matches to the relevant Branded Presentation, having consideration to factors including but not limited to pack size, strength, and mode of application. More detail on the proposed rules-based approach to setting a reference price is contained in the Consultation Document.

38. For 2024, the observed average selling price will be calculated across the last two quarters of 2024 only. For any given scheme year, where a branded presentation changes status between newer and older medicine mid-year, the observed average selling price for the year will be calculated across the remaining quarters following the branded presentation becoming an older medicine.

39. Where the observed average selling price is less than the reference price, this is denoted an observed price decline. The observed price decline for each branded presentation is expressed as a percentage and is calculated as one minus the observed average selling price divided by the reference price, rounded to the nearest whole percentage point. Table 1 below maps top-up payment percentages to levels of observed price decline.

Table 1: Top-up payment percentage and percentage of observed price decline

Observed price decline	**2024**	**2025**	**2026**
10% or less	25%	25%	25%
11%	24%	24%	24%
12%	23%	23%	23%
13%	22%	22%	22%
14%	21%	21%	21%
Each percentage point rise in observed price decline equates to a 1%-point reduction in the top-up payment percentage, until the observed price decline reaches 35%			
35% or more	0%	0%	0%

40. To ensure these rules are applied fairly, we propose that where a scheme member is selling a new entrant older medicine that is neither an originator or an originator licensee, the scheme member will be required to declare whether a commercial relationship exists between that product and the originator or originator licensee. Where a commercial relationship exists the top-up payment percentage applied shall be no lower than that of the originator product.

41. Where a scheme member fails to submit the annual PLR within required timelines without reasonable cause, the default top-up payment percentage to apply to that scheme member's eligible sales of older medicines will be 25%. The value of these sales would be derived by aggregating the quarterly reports received for the relevant year.

42. The proposals include the following exemptions from the top-up payment percentage:

- **Plasma derived medicinal products** (PDMPs), where they are considered older medicines, will be exempt from the top-up payment percentage applying to older medicines. They will be subject to the basic payment percentage only, regardless of the observed price decline calculated. The full list of VTMs included in the PDMP definition for this purpose is available in the consultation document. For the avoidance of doubt this does not include recombinant products. These are exempt in order to support the supply of these after sustained supply issues at a global level.
- **Lower sales value VTMs**, older medicines that sit within a VTM with annual measured sales of less than £1.5 million for a scheme member will be exempt from the top-up payment percentage due to proportionality. The eligible sales of older medicines through all branded presentations in that VTM will be subject to the basic payment percentage only for that Scheme member, regardless of the Observed Price Decline. This will not affect whether a top-up payment percentage applies to older medicines eligible sales of other scheme members within that same VTM.

43. The forecast payment from older medicines is derived by applying the distribution of older medicine eligible sales across basic plus top-up payment percentage values. For this consultation stage IA, we use the same distribution as published for VPAG 2024 and shown below for ease of reference.

Table 2: Payment percentages for older medicines and portion of older medicines sales in band

2024 basic plus top-up payment percentage	2025 basic plus top-up payment percentage	2026 basic plus top-up payment percentage	Proportion of older medicines sales in band
10.03%	10.6%	11%	30.4%
11.03%	11.6%	12%	0.2%
12.03%	12.6%	13%	0.2%
13.03%	13.6%	14%	0.3%
14.03%	14.6%	15%	0.1%
15.03%	15.6%	16%	0.1%
16.03%	16.6%	17%	0.0%
17.03%	17.6%	18%	0.1%
18.03%	18.6%	19%	0.9%
19.03%	19.6%	20%	0.4%
20.03%	20.6%	21%	0.9%
21.03%	21.6%	22%	0.1%
22.03%	22.6%	23%	0.1%
23.03%	23.6%	24%	0.1%
24.03%	24.6%	25%	1.7%
25.03%	25.6%	26%	0.5%
26.03%	26.6%	27%	2.2%
27.03%	27.6%	28%	0.4%
28.03%	28.6%	29%	1.4%
29.03%	29.6%	30%	0.3%
30.03%	30.6%	31%	1.0%
31.03%	31.6%	32%	1.0%
32.03%	32.6%	33%	0.6%
33.03%	33.6%	34%	0.2%
34.03%	34.6%	35%	0.6%
35.03%	35.6%	36%	56.5%

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

- 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.

45. For example, at individual top-up payment percentage band level, if in 2024 there were £10million 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 35.03% = just under £2 million.

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

Approach to setting payment percentages for newer medicines

47. 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 required payment from newer medicines, which itself is derived from the required total payment.

48. 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 as a share of industry measured sales.

49. Required payment from newer medicines is the required total payment minus the adjusted forecast payment from older medicines (calculation of this set out below). The headline payment percentage will equal the required payment from newer medicines divided by the eligible sales of newer medicines, rounded to one decimal place. Eligible sales of newer medicines are calculated as measured sales of newer medicines minus NAS Sales.

50. For the Statutory Scheme, the headline payment percentage will be calculated for 2024, 2025 and 2026. Ongoing monitoring will be undertaken to compare actuals data to forecast values at any future consultations.

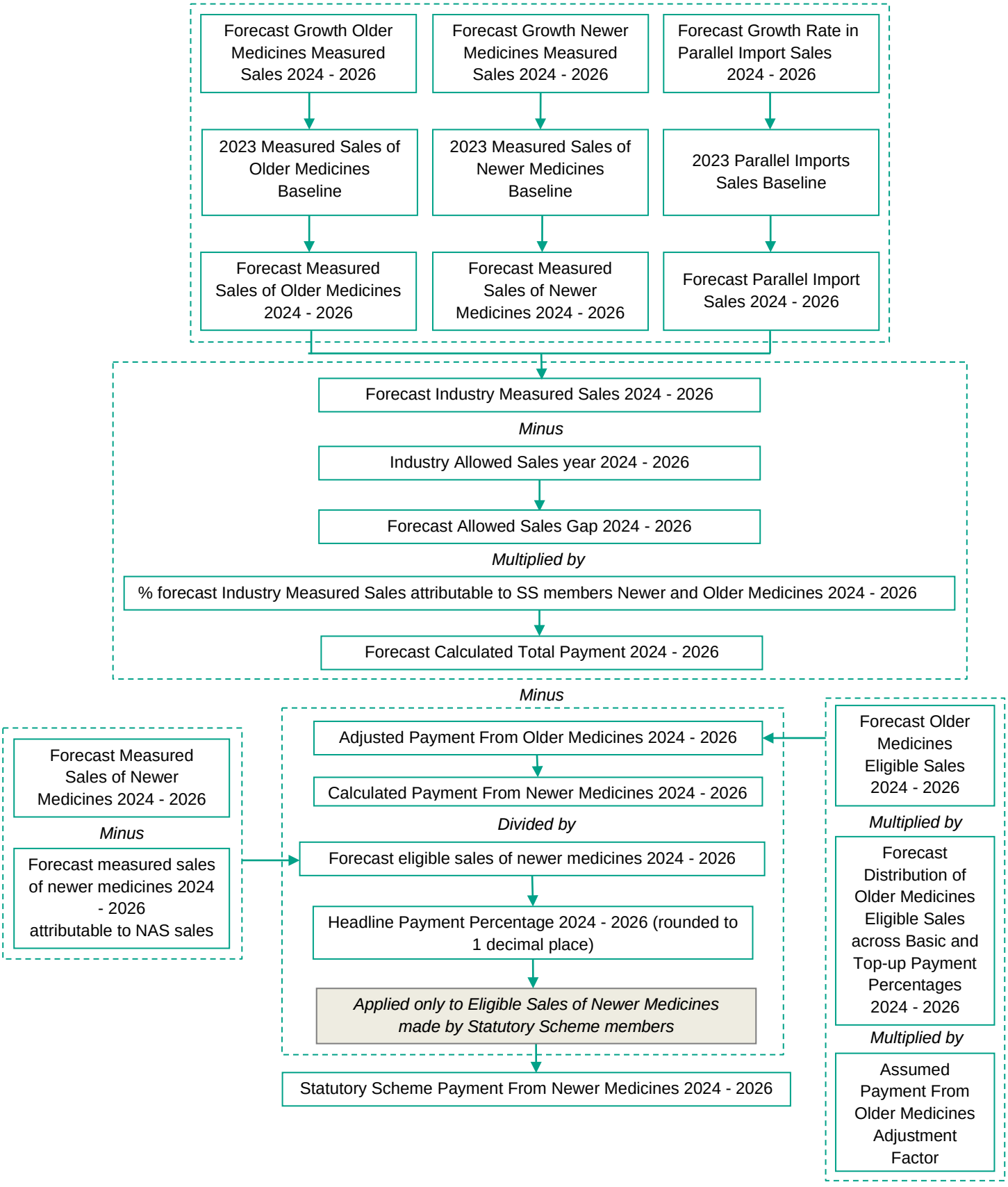
51. The adjusted forecast payment from older medicines that underpins the calculation of the forecast required payment from newer medicines is reached by applying a downwards adjustment factor to the forecast payment from older medicines. This is to reflect the inherent uncertainty regarding forecasting payments from older medicines over time and optimism bias.

52. It is applied as a proportional reduction per annum in the forecast payment from older medicines to reflect potential behavioural responses to the novel older medicines approach to setting payment percentages. As such, it increases over time and is pre-determined at the rates shown below.

Table 3: Forecast payment from older medicines adjustment factor

	2024	**2025**	**2026**
Forecast payment from older medicines adjustment factor	-3.1%	-5.8%	-8.3%

Figure 1: Calculation of the Newer Medicines Payment Percentage



Q1 and Q2 2024

53. To allow for respondents to have sufficient time to consider the proposals outlined in this IA and the accompanying consultation, as well as subsequent legislative timetables, the payment percentage for quarters one and two of 2024 will remain at 21.9% for all eligible sales. From 1 July 2024, the differentiated approach to setting payment percentages for newer medicines and older medicines will operate as described.

Summary and preferred option with description of implementation plan

54. The preferred option is option 2, i.e., to update the Statutory Scheme so that:

- Payment percentages are recalculated based on an allowed level of growth from the recalculated 2023 starting point;
- The threshold for an exemption from scheme payments for small companies is updated from sales of less than £5m to less than £6m;

55. Differentiated approach to setting payment percentages are introduced for newer medicines and older medicines reflecting the design of VPAG; and.

- The allowed growth in measured sales is equivalent to nominal 2% per annum with baseline adjustments of £150m, £150m, and £330m each in year 2024, 2025 and 2026.

56. 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 2024. The intervention would support the Statutory Scheme objectives of ensuring medicines are available on reasonable terms, accounting for the costs of research and development and to deliver cost control and value for money for the NHS in a way consistent with supporting both the life sciences sector and broader economy. DHSC would continue to be responsible for the ongoing operation and enforcement of the Statutory Scheme.

57. 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 which would be subject to consultation.

Summary of aggregate costs and benefits

58. As noted previously, the BAU option does not include differentiated approaches to setting payment percentages for newer and older medicines, nor does it reflect the increase in allowed growth rates per annum or the baseline adjustment values agreed as part of VPAG. Continuing to operate the schemes with such substantive differences in both structure and financial incentives is not considered to sufficiently deliver BCE between them and may therefore risk destabilising how the two schemes operate together. This could in-turn lead to increased costs for HMG and a less predictable commercial environment for companies. In addition, the support for competition and innovation in the life sciences sector that is considered a key benefit of the differentiated approaches to setting payment percentages would also not be generated.

59. It also does not reflect the latest available data which suggests the 2024, 2025 and 2026 Statutory Scheme payment percentage would be 19.8%, 22.1% and 25.3%. Furthermore, each of the three policy options propose to increase the threshold at which a company is defined as small, and therefore qualifies for the small company exemption from both measured and eligible sales, from £5m to £6m per annum. Whilst policy options 2 and 3 propose an increase in the allowed growth from 2% in the current Statutory Scheme to 3.75% in 2025 and 2026, and baseline adjustments to allowed sales reflecting those agreed in VPAG respectively.

60. The overall quantified impact of all the proposed policy options is therefore a net societal cost. That said, there are unquantified benefits in ensuring payment percentages are set according to a clear and justified methodology. Doing so supports achieving BCE between the Statutory Scheme and the recently agreed VPAG and therefore supports the long-term stability of both schemes and their ability to protect NHS budgets.

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

62. Rows from the summary table that feature in the overall NPV are flagged (NPV) in the "impact on" column and all figures are rounded to the nearest £1m in this high-level summary. More granular figures are provided in the assessment of specific options sections.

63. Note that the overall NPV becomes less negative in scenarios with higher forecast growth in branded medicines spend. This is because each of the options proposed sets payment percentages calibrated to an allowed nominal growth at 2% or higher with or without baseline adjustments, whereas the BAU option has a fixed payment percentage. In dynamic cap scenarios payment percentages, and therefore income generated, rise with higher rates of branded medicines spend growth to recoup all spend above the allowed level, whereas fixed payment percentages do not change.

Table 4: Summary of aggregate costs and benefits between BAU and option 2

Impact on	Description of impact	Cumulative low scenario	Cumulative mid scenario	Cumulative high scenario
NHS finances	Increased cost of branded medicines as reduced payment percentages increase costs	£44m	£36m	£27m
NHS patients (NPV)	Societal value QALYs foregone due to increased cost	£200m	£163m	£123m
NHS patients	Support to continuing/improving access to innovative branded medicines	Unquantified – patient benefits in supporting continued access to new and innovative medicines, via introduction of a NAS exemption		
NHS patients	Continue supporting patient access to cost-effective medicines	Unquantified – Patients will benefit from a scheme that sets payment rates to achieve predictable and sustainable growth in net sales of medicines so as to support ongoing access to cost-effective medicines.		
NHS patients	Ongoing support to vaccine supply and future emergency preparedness	Unquantified – patient benefits in terms of supporting access to vaccines generally and supporting future emergency preparedness		
Pharmaceutical / life sciences industry	Increased profit on UK sales of branded medicines driven by reduced payment percentages	£44m	£36m	£27m
Pharmaceutical / life sciences industry UK shareholders (NPV)	Increased profit on UK sales of branded medicines driven by reduced payment percentages accruing to UK shareholders	£4m	£3m	£3m
Overall quantified NPV		**-£195m**	**-£160m**	**-£120m**

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

Table 5: BAU expected income

		2024	2025	2026	Cumulative
Low Scenario	SS income forecast £m	56	64	75	195
Central Scenario	SS income forecast £m	56	64	76	196
High Scenario	SS income forecast £m	56	65	77	198

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

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

64. In line with Green Book guidance, the proposed option is assessed against the counterfactual BAU option of 21.9%, 24.0% and 26.8% payment percentages in 2024, 2025 and 2026 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.

65. We first describe establishing the 2023 allowed sales baseline and how measured sales are forecast to grow from this in each of our forecast scenarios. The aggregate cost and benefits appraisal is then presented followed by an assessment of option specific impacts.

Costs to business

66. There are potential familiarisation costs to business of understanding the design of the differentiated approach to setting payment percentages for newer medicines and older medicines as this is a newly introduced design for the statutory scheme. However, as the proposed options mirror the design of VPAG which was introduced for the start of 2024 and companies will have needed to be familiar with the design of this in order to opt-in to the Statutory scheme we consider these to be negligible.

67. Similarly, there is an additional data burden on businesses. We will require additional splits of the data to implement this, for situations where a product changes from being a newer medicine to an older medicine mid-year we will require them to provide the Presentation Level Returns data split into the part of the year the product was newer and the part of the year the product was older. This is additional reporting compared to previous schemes however the data burden on companies was a key consideration of in designing VPAG and so this was considered an acceptable additional ask.

Risks and assumptions

68. 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.

69. We are updating the Statutory Scheme in order to align with VPAG which is in place for 5 years. 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 and is consistent with the timeframe covered by the 2018 Statutory Scheme impact assessment[8] whilst also being the longest period we have consulted on. We have updated this annually over the last few years and have committed to doing so going forward. We present low, mid and high forecast scenarios, although the mid forecast is used for the “best estimate” presented, all three are considered similarly plausible.

70. Under the BAU counterfactual and the policy options, 2023 measured sales baseline is best available 2023 annual measured sales as of Q4 2023 sales data. According to the sales data, uprating the threshold for an exemption from scheme payments for small companies from £5m to £6m for the policy options is expected to have no impact to the 2023 measured sales baseline.

71. The share of Statutory Scheme measured sales within VPAG, and the Statutory Scheme measured sales is assumed to be 1.91% before taking in small company sales adjustment. This is estimated from the confirmed VPAG and the Statutory Scheme joiner profile with their full year

[8] 2018 Statutory Scheme – Branded Medicines Pricing. 2018. [https://assets.publishing.service.gov.uk/media/5c050d1440f0b67074ba8ce8/impact-assessment-2018-statutory-scheme-branded-medicines-pricing.pdf]

2023 measured sales. An estimate of measured sales from £825m to £846m in the appraisal period will be affected by the intervention.

72. The proposed option has a negative associated societal NPV. This partly reflects the fact that headline payment percentages are lower in all cases compared to the payment percentage for all medicines under BAU counterfactual. These lower headline payment percentages are driven in part by the latest data indicating a slowdown in branded medicines sales growth in Q4 2023, which was not available at the time the current Statutory Scheme payment percentage was calculated.

73. The proposed options also introduce baseline adjustments same or adjusted the allowed growth rate from 2% per annum to the currently level of VPAG. This is consistent with the approach to maintain broad commercial equivalence with VPAG.

74. The policy options also split the sales into sales of older medicines and sales of newer medicines, where according to the proposed differentiated payment mechanisms between newer and older medicines, a higher income from older medicines will be generated and will reduce the required income from newer medicines. The forecasted income from older products is projected with the percentage observed price decline where observed average selling price is less than the reference price from 2021 Annual Presentation Level Sales Report.

75. In view of the uprated threshold for an exemption from scheme payments for small companies under policy options, the allowed sales starting point in 2023 is adjusted accordingly. Calculation of the allowed sales starting point in 2023 is described in the later “Establishing a forecast allowed sales 2023 baseline” section.

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

77. 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.

78. We have modelled the Statutory scheme based on its current membership of companies that have joined for 2024 and their proportion of whole industry sales. We do not model assumed numbers of companies that joined VPAG in 2024 choosing to move to the Statutory Scheme in subsequent years. This reflects both the inherent uncertainties regarding the company level commercial incentives to do so. Whilst the proposed options make the Statutory scheme more generous than it previously was it is still considered less attractive to companies than the voluntary scheme largely due to the higher headline payment percentage. 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 this proposal will have minimal impact on companies’ incentives to move between schemes.

Table 6: Summary of assumptions used in appraisal

Assumption	Used in	Source
2023 outturn measured sales growth	2023 measured sales baseline forecast	• DHSC measured sales figures as of Q4 2023
Low forecast branded spend growth	2024-2026 measured sales forecast, required payment and payment percentage calculation	• DHSC medicines spend forecast
Central forecast branded spend growth		
High forecast branded spend growth		
10% of industry revenue impacts accrue to UK shareholders	Wider economic impacts	• Historic UK output from the ONS Annual Business Survey

		• Import/export data from UK overseas trade in goods statistics[9]
25% of industry revenue impacts invested globally*		• ONS Business Enterprise Research & Development (BERD) time series and upper end of OLS advised range
3.1% UK share of global investment*		• Literature review
30% spillover effects of investment*		• Literature review
Statutory scheme Sales make up 1.91% of industry sales	The proportion of industry measured and allowed sales we applied to the Statutory Scheme	• Q4 2023 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)

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

80. 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 2024, 2025 and 2026.

81. Where assumptions have been applied these will be identified and described throughout at the point of use. A key aspect of the analysis is DHSC's forecast of future growth in branded medicines spend. This is inherently uncertain and as a result we present low, mid and high scenario estimates of impacts. The High and low scenarios provided above demonstrate the payment percentages calculated for each forecast scenario and the associated income forecast. To demonstrate the scale of impact uncertainty regarding future growth in branded medicine sales may have on outcomes, below we have estimated the impact of sales being higher or lower than forecast whilst keeping the payment percentage unchanged versus the central scenario. We carried out this sensitivity test for each option compared to the central scenario, the difference in income is between -£1m and £1m so a proportional change of 0.4%.

82. 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[10]. 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 guidance. This position has been confirmed previously by the Economic and Domestic Affairs Secretariat at Cabinet Office.

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

[10] Small Business, Enterprise and Employment Act 2015. 2015. [https://www.legislation.gov.uk/ukpga/2015/26/section/22/enacted]

Forecast measured sales

83. 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.

84. Measured sales includes all sales of scheme products by companies in scope of the Statutory Scheme, the Voluntary Scheme, plus parallel import sales. According to the latest available sales data and current company joiners' profile, the share of Statutory Scheme among both the Statutory Scheme, the Voluntary Scheme is estimated to be 1.91%. 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.

85. Measured sales that are exempted in both the BAU counterfactual and the policy options but have different definitions are:

- **Small company sales** – sales by companies whose total sales of scheme products are less than £5m in the calendar year preceding the relevant calendar year (in the BAU counterfactual) / sales by companies whose total sales of scheme products are less than £6m in the calendar year preceding the relevant calendar year (in the policy options).

86. VPAG currently provides exemptions where sales by companies whose total sales of scheme products are less than £6m in the calendar year preceding the relevant calendar year. The current Statutory Scheme exempt sales by companies whose total sales of scheme products are less than £5m in the calendar year preceding the relevant calendar year and therefore neither does our BAU counterfactual.

87. This change would mean that sales by companies whose total sales of scheme products are between £5m to £6m in the calendar year would not count towards measured sales in the policy options for the Statutory Scheme. They would therefore not affect the level of measured growth in the scheme, which features in the payment percentage calculation, nor would Statutory Scheme members be required to make payments on their sales by companies whose total sales of scheme products are between £5m to £6m in the calendar year preceding the relevant calendar year.

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

89. The resulting forecast for measured sales in both the BAU counterfactual and under our proposed policy options is shown in the table below.

Table 7: Forecast SS measured sales

		2024	2025	2026
Low Scenario	Forecast SS measured sales £m	263	274	289
Central Scenario	Forecast SS measured sales £m	264	277	294
High Scenario	Forecast SS measured sales £m	265	281	301

Establishing a forecast allowed sales 2023 baseline

90. The forecast allowed sales 2023 baseline followed the same financial envelop equivalent to the previous consultation assuming all companies would be subject to the Statutory Scheme from 2024. However, because of the intervention of small company sales, the total allowed sales baseline in 2023 is adjusted at 99.65% at 2018 level of sales.

Table 8: Allowed sales 2023 baseline – BAU vs policy options

	2023
BAU Counterfactual allowed sales baseline £m	11,596
Policy options allowed sales baseline £m	11,554

Option 1

91. Under option 1, the structure of the Statutory Scheme would be updated to incorporate the differentiated approach to setting payment percentages for newer medicines and older medicines which mirrors VPAG. It would also uprate the threshold for an exemption from scheme payments for small companies with sales of less than £6m (up from £5m). The financial envelope of options remains the same as the previous consultation, which is equivalent to nominal allowed sales growth of 2% per annum from 2023. No allowed sales baseline adjustments are considered in this option.

Table 9: Option 1 Allowed sales

	2024	2025	2026
Allowed sales £m	11,786	12,021	12,262

92. The calculation of the headline payment percentages for newer medicines does not alter among options 1, 2 and 3, calculated as:

$$\frac{\left((Measured\ sales - Allowed\ sales) \times \frac{Statutory\ scheme\ sales}{Measured\ sales}\right) - Income\ from\ older\ medicines}{Statutory\ scheme\ eligible\ sales\ of\ newer\ medicines}$$

NHS finances

93. Under option 1 income to the NHS of around £170m to £190m is generated over the three year appraisal period. This equates to a reduction in income for the NHS of between £8m and £25m over the three year appraisal period compared to the counterfactual. This is driven by the latest data indicating a slowdown in branded medicines sales growth and also the uplift of small company sales exemption.

94. Assuming a fixed NHS budget, the increase in spend on branded medicines would need to be offset by reductions in spend elsewhere. 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 cost per QALY at the margin on the frontline estimate of £15k per QALY.

95. This is grounded in empirical literature[11] 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 2015/16 did not recommend an update be made[12].

96. Annex C provides more information around the correct interpretation of the £15,000 per QALY figure and how it differs from the cost-effective threshold of £30k per QALY used in NICE appraisals. Table 10 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).

Table 10: Option 1 Headline Payment percentage

	2024			2025	2026
	Q1-Q2	Q3-Q4	Average		
Low Scenario	21.9%	12.8%	17.2%	16.1%	21.2%
Central Scenario		13.7%	17.7%	18.1%	24.4%
High Scenario		14.7%	18.2%	20.3%	27.9%

Table 11: Option 1 Expected income

		2024			2025	2026	Cumulative
		Q1-Q2	Q3-Q4	Total			
Low Scenario	Older Medicines Income £m	12	16	28	32	33	94
	Newer Medicines Income £m	14	9	23	22	31	76
	Total Income £m	27	25	51	54	64	170
Central Scenario	Older Medicines Income £m	12	16	28	32	33	94
	Newer Medicines Income £m	14	9	24	25	37	86
	Total Income £m	27	25	52	57	70	179
High Scenario	Older Medicines Income £m	12	16	28	32	33	93
	Newer Medicines Income £m	14	10	25	29	43	97
	Total Income £m	27	26	53	61	76	190

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

[11] 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]

[12] 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.

Table 12: Monetising QALYs foregone option 1

	2024	2025	2026	Cumulative
Low Scenario				
Change in income vs BAU £m	-4	-9	-11	-25
QALYs foregone @ £15k/QALY	294	632	717	1,643
Nominal societal value @ £70k/QALY £m	21	44	50	115
Present value QALYs foregone £m	21	44	49	113
Central Scenario				
Change in income vs BAU £m	-4	-7	-6	-17
QALYs foregone @ £15k/QALY	254	453	411	1,118
Nominal societal value @ £70k/QALY £m	18	32	29	78
Present value QALYs foregone £m	18	31	28	77
High Scenario				
Change in income vs BAU £m	-3	-4	-1	-8
QALYs foregone @ £15k/QALY	209	252	56	517
Nominal societal value @ £70k/QALY £m	15	18	4	36
Present value QALYs foregone £m	15	17	4	36

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

Pharmaceutical industry and its shareholders plus wider economic impacts

97. The principal impact of the proposed option 1 in comparison to the BAU counterfactual is a decreased headline payment percentages due to the differentiated approach to setting payment percentages for newer medicines and older medicines, though the change in approach is cost neutral in nature.

98. The reduced payment percentages were also to reflect a lowered measured sales baseline than the BAU counterfactual, which also leads to a lower expected income across the three-year appraisal period.

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

100. Assuming that returns to capital are shared between the UK and overseas in the same proportion as total returns, this implies that a corresponding proportion of the changes in profits will accrue to UK shareholders.

101. Table 13 below sets out the estimated financial benefit to the pharmaceutical industry under option 1, our estimate of the UK shareholder element of this for inclusion in the NPV and its present value. These are all calculated as described in the “evidence underpinning wider economic impacts” annex.

Table 13: Pharmaceutical industry financial impacts option 1

	2024	2025	2026	Cumulative
Low Scenario				
Revenue benefit for industry £m	4	9	11	25
Of which accrues to UK shareholders £m	<1	1	1	2
Present value industry financial impacts £m	<1	1	1	2
Central Scenario				
Revenue benefit for industry £m	4	7	6	17
Of which accrues to UK shareholders £m	<1	1	1	2
Present value industry financial impacts £m	<1	1	1	2

High Scenario				
Revenue benefit for industry £m	3	4	1	8
Of which accrues to UK shareholders £m	<1	<1	<1	1
Present value industry financial impacts £m	<1	<1	<1	1

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

Impact on patients

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

Table 14: Overall NPV benefit option 1

	2024	2025	2026	Cumulative
Low scenario £m	-20	-43	-48	-111
Central scenario £m	-17	-31	-27	-75
High scenario £m	-14	-17	-4	-35

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

Option 2

103. The basic structure of option 2 is identical to option 1, in that it proposes a differentiated approach to setting payment percentages for newer medicines and older medicines.

104. The main difference from option 1 is the provision of allowed sales adjustment from 2024 to 2026 mirroring the current allowed sales adjustment in the Voluntary Scheme. Nominal allowed sales growth in option 2 remains at 2% per annum from 2023.

Table 15: Option 2 Allowed sales adjustment and allowed sales

	2024	2025	2026
Allowed sales adjustment £m	150	150	330
Allowed sales £m	11,939	12,330	12,914

NHS finances

105. Under option 2 income to the NHS of around £151m to £171m is generated over the three year appraisal period. This equates to a reduction in income for the NHS of between £27m and £44m over the three year appraisal period compared to the counterfactual.

106. The allowed sales adjustment in option 2 induced lower headline payment percentage and income than in option 1. The NPV of the cost of option 2 is calculated in the same manner as outlined previously in option 1.

Table 16: Option 2 Headline Payment percentage

	2024			2025	2026
	Q1-Q2	Q3-Q4	Average		
Low Scenario	21.9%	10.7%	16.1%	12.1%	13.0%
Central Scenario		11.6%	16.6%	14.1%	16.5%
High Scenario		12.6%	17.1%	16.3%	20.2%

Table 17: Option 2 Expected income

		2024			2025	2026	Cumulative
		Q1-Q2	Q3-Q4	Total			
Low Scenario	Older Medicines Income £m	12	16	28	32	33	94
	Newer Medicines Income £m	14	7	22	17	19	57
	Total Income £m	27	23	50	49	52	151
Central Scenario	Older Medicines Income £m	12	16	28	32	33	94
	Newer Medicines Income £m	14	8	22	20	25	67
	Total Income £m	27	24	51	52	58	161
High Scenario	Older Medicines Income £m	12	16	28	32	33	93
	Newer Medicines Income £m	14	9	23	23	31	78
	Total Income £m	27	25	51	55	64	171

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

Table 18: Monetising QALYs foregone option 2

	2024	2025	2026	Cumulative
Low Scenario				
Change in income vs BAU £m	-6	-15	-23	-44
QALYs foregone @ £15k/QALY	391	1,002	1,517	2,910
Nominal societal value @ £70k/QALY £m	27	70	106	204
Present value QALYs foregone £m	27	69	103	200
Central Scenario				
Change in income vs BAU £m	-5	-12	-18	-36
QALYs foregone @ £15k/QALY	350	828	1,201	2,379
Nominal societal value @ £70k/QALY £m	25	58	84	167
Present value QALYs foregone £m	25	57	82	163
High Scenario				
Change in income vs BAU £m	-5	-9	-13	-27
QALYs foregone @ £15k/QALY	306	633	850	1,789
Nominal societal value @ £70k/QALY £m	21	44	60	125
Present value QALYs foregone £m	21	44	58	123

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

Pharmaceutical industry and its shareholders plus wider economic impacts

107. The principal impact of the proposed option 2 for the pharmaceutical industry is that payment percentages reduce to reflect the baseline adjustments of £150m, £150m and £330m each in 2024, 2025 and 2026 and an allowed growth rate of 2% from a 2023 allowed sales baseline.

Table 19: Pharmaceutical industry financial impacts option 2

	2024	2025	2026	Cumulative
Low Scenario				
Revenue benefit for industry £m	6	15	23	44
Of which accrues to UK shareholders £m	1	2	2	4
Present value industry financial impacts £m	1	1	2	4
Central Scenario				
Revenue benefit for industry £m	5	12	18	36
Of which accrues to UK shareholders £m	1	1	2	4
Present value industry financial impacts £m	1	1	2	3

High Scenario				
Revenue benefit for industry £m	5	9	13	27
Of which accrues to UK shareholders £m	<1	1	1	3
Present value industry financial impacts £m	<1	1	1	3

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

Impact on patients

108. 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.

Table 20: Overall NPV benefit option 2

	2024	2025	2026	Cumulative
Low scenario £m	-27	-68	-101	-195
Central scenario £m	-24	-56	-80	-160
High scenario £m	-21	-43	-57	-120

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

Option 3

109. The basic structure of option 3 is identical to option 1 and 2, except the nominal allowed sales growth in option 3 increases from 2% to 3.75% per annum in 2024 and 2025. No allowed sales adjustment is considered in this option.

Table 21: Option 3 Allowed sales adjustment and allowed sales

	2024	2025	2026
Allowed growth rate	2%	3.75%	3.75%
Allowed sales £m	11,786	12,227	12,686

NHS finances

110. Under option 3 income to the NHS of around £159m to £178m is generated over the three year appraisal period. This equates to a reduction in income for the NHS of between £19m and £36m over the three year appraisal period compared to the counterfactual.

111. The uprated allowed sales growth from 2% to 3.75% in 2025 and 2026 in option 3 induced lower headline payment percentage and income than in option 1. The NPV of the cost of option 3 is calculated in the same manner as outlined previously in option 1.

Table 22: Option 3 Headline Payment percentage

	2024			2025	2026
	Q1-Q2	Q3-Q4	Average		
Low Scenario	21.9%	12.8%	17.2%	13.4%	15.9%
Central Scenario		13.7%	17.7%	15.4%	19.3%
High Scenario		14.7%	18.2%	17.6%	22.9%

Table 23: Option 3 Expected income

		2024			2025	2026	Cumulative
		Q1-Q2	Q3-Q4	Total			
Low Scenario	Older Medicines Income £m	12	16	28	32	33	94
	Newer Medicines Income £m	14	9	23	19	23	65
	Total Income £m	27	25	51	51	57	159
Central Scenario	Older Medicines Income £m	12	16	28	32	33	94
	Newer Medicines Income £m	14	9	24	22	29	74
	Total Income £m	27	25	52	54	62	168
High Scenario	Older Medicines Income £m	12	16	28	32	33	93
	Newer Medicines Income £m	14	10	25	25	35	85
	Total Income £m	27	26	53	57	69	178

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

Table 24: Monetising QALYs foregone option 3

	2024	2025	2026	Cumulative
Low Scenario				
Change in income vs BAU £m	-4	-13	-19	-36
QALYs foregone @ £15k/QALY	294	882	1,234	2,410
Nominal societal value @ £70k/QALY £m	21	62	86	169
Present value QALYs foregone £m	21	61	84	165
Central Scenario				
Change in income vs BAU £m	-4	-11	-14	-28
QALYs foregone @ £15k/QALY	253	706	921	1,880
Nominal societal value @ £70k/QALY £m	18	49	64	132
Present value QALYs foregone £m	18	49	63	129
High Scenario				
Change in income vs BAU £m	-3	-8	-9	-19
QALYs foregone @ £15k/QALY	209	509	572	1,290
Nominal societal value @ £70k/QALY £m	15	36	40	90
Present value QALYs foregone £m	15	35	39	89

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

Pharmaceutical industry and its shareholders plus wider economic impacts

112. The principal impact of the proposed option 3 for the pharmaceutical industry is that payment percentages reduce to reflect the allowed growth rate of 2%, 3.75% and 3.75% in 2024, 2025 and 2025. All companies and in-scope products would continue to pay the same payment percentage with the exception of uprated small company sales which would move to be exempt from the Statutory Scheme.

Table 25: Pharmaceutical industry financial impacts option 3

	2024	2025	2026	Cumulative
Low Scenario				
Revenue benefit for industry £m	4	13	19	36
Of which accrues to UK shareholders £m	<1	1	2	4
Present value industry financial impacts £m	<1	1	2	3
Central Scenario				
Revenue benefit for industry £m	4	11	14	28

Of which accrues to UK shareholders £m	<1	1	1	3
Present value industry financial impacts £m	<1	1	1	3
High Scenario				
Revenue benefit for industry £m	3	8	9	19
Of which accrues to UK shareholders £m	<1	1	1	2
Present value industry financial impacts £m	<1	1	1	2

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

Impact on patients

113. 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.

Table 26: Overall NPV benefit option 3

	2024	2025	2026	Cumulative
Low scenario £m	-20	-60	-82	-162
Central scenario £m	-17	-48	-61	-126
High scenario £m	-14	-34	-38	-87

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

Impact on small and micro businesses

114. Businesses with NHS sales of less than £5m per annum are excluded from the payment percentage mechanism in the Statutory Scheme under the BAU counterfactual and £6m per annum under policy options – which represents the main likely impact of the proposals on small and micro companies. In terms of the classification of businesses, this exclusion has been interpreted to imply that only “Medium” and “Large” businesses are in scope of the proposals.

Statutory requirements for consultation

115. 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.

116. 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.

117. 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, 2 and 3).

Economic consequences for the life sciences industry in the United Kingdom

118. As set out above, option 2 is expected to increase the gross revenues of pharmaceutical companies by between £27m and £44m compared to the business as usual option to 2026.

119. The pharmaceutical industry is global, with the majority of ownership, investment and production occurring overseas. The UK is estimated to represent not more than 10% of the global industry, so

impacts on UK interests are assumed to be commensurately affected, with a gross change in revenues of approximately £3m-£4m relative to the counterfactual over the period in question.

120. For illustrative purposes only, if we assume that the increased revenues under the proposed option are invested in the same proportion as companies typically invest in areas such as R&D, the change in revenue could translate to an increase in UK life sciences investment, including R&D of around £1m by 2026, with associated spill-overs worth less than £1m in the same period. Annex B notes the methodology behind this estimate.

The consequences for the economy of the United Kingdom

121. As set out above, theoretically, the proposed option could increase funding for global pharmaceutical investment, a proportion of which may located in the UK. For illustrative purposes only, if we assume this proportion would be in line with the UK's estimated share of global R&D it equates to investment worth around £1m, with associated spillover benefits to the UK worth less than £1m to 2026. We also identify potential increased returns to UK shareholders estimated to between £3m and £4m in the same period compared to the counterfactual.

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

122. The purpose of all options is to support NHS spending on medicines continuing to be affordable, enabling continued NHS investment in uptake of the most clinically and cost-effective medicines to the benefit of patients, and investment in other patient services. The main impact of this specific proposed update is to support the stability of the UK medicines pricing schemes; our assessment remains that ensuring the good operation of the schemes means the NHS can continue to use its funds in the best interest of patients.

123. The proposals result in higher net costs associated with branded medicines to the NHS compared to the counterfactual. In the context of a fixed NHS budget, this would require redistribution of funding from another area. We estimate the additional costs to equate to between 1,789 to 2,910 fewer QALYs by 2026. However, patients will benefit from a scheme that sets payment rates to achieve predictable and sustainable growth in net sales of medicines so as to support ongoing access to cost-effective medicines.

124. 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.

125. Some groups are likely to be particularly affected by policies that may affect access to medicines. The original consultation noted specific groups where illness and use of medicines tend to be higher than in the rest of the population. These groups include those sharing protected characteristics, such as older people and those with long-term health conditions. NHS data[13] 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.

126. 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.

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

127. 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.

128. While the proposals mean that the department will receive lower statutory scheme payments than currently set out in the regulations, 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 that will be apportioned to the NHS across the UK and will be used in the best interest of patients.

Monitoring the scheme

129. 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.

130. The current voluntary and statutory schemes are subject to a single programme of annual governance and operational review[14]. This includes quarterly publication of scheme metrics and six-monthly operational review with the industry body and observers.

131. Whilst the design of the scheme paid particular mind to 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.

132. 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. This exercise will be undertaken in conjunction with partners across other government organisations and industry stakeholders which this Consultation Stage IA does not preclude.

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

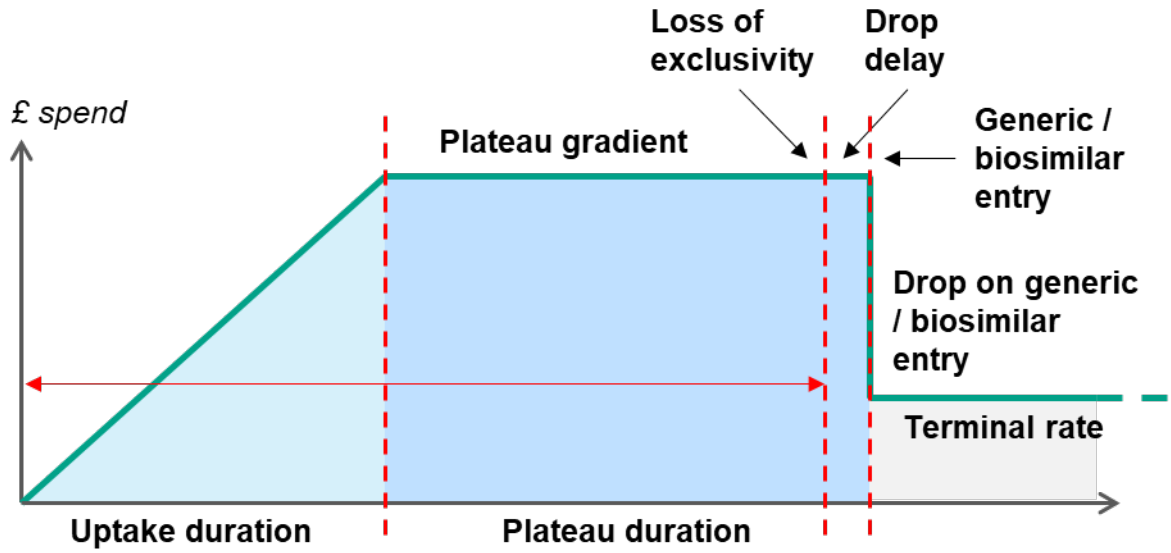
Annex A – medicines Spend Forecast

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

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

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

Figure 2: Stylised product lifecycle



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

5. Key parameters of the product lifecycle in the model are listed in Table 27.

Table 27: Parameter value overview

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

Uptake duration

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

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

Plateau duration

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

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

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

Plateau gradient

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

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

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

Gap between loss of exclusivity and generic entry

14. When a branded 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.

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

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

Drop on generic/biosimilar entry

17. This reflects the blended impact of price decay once a branded 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.

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

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

Terminal rate

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

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

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

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

Cohort growth rate

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

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

Parameter overview

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

27. The estimation of parameters was carried out using two spend data sources. For primary care medicines, NHS BSA prescribing data for the period January 2009 to March 2022 was used. For secondary care 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.

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

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

30. For products already on the market that were launched prior to 2018 (“established products”), we applied the set of parameters estimated for that particular category of 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.

31. The plateau gradient parameter captures a particularly complex market dynamic. This is because it is representing the stage of a lifecycle where there are most likely to be two counteracting effects on the trend for molecules in our historic dataset, which our methodology captures and incorporates into the forward projection. The first is competition within a therapeutic class, when the cannibalisation of a given product’s sales from new, branded competitors succeeds in capturing some of the market share of the 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.

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

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

Annex B – Evidence underpinning wider economic impacts approach

133. 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, reduced payment percentages versus the counterfactual may increase funding available for investment by the pharmaceutical industry at a global level, a portion of which may be in the UK. These impacts have not been included in the NPV calculations and are for illustrative purposes only.

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

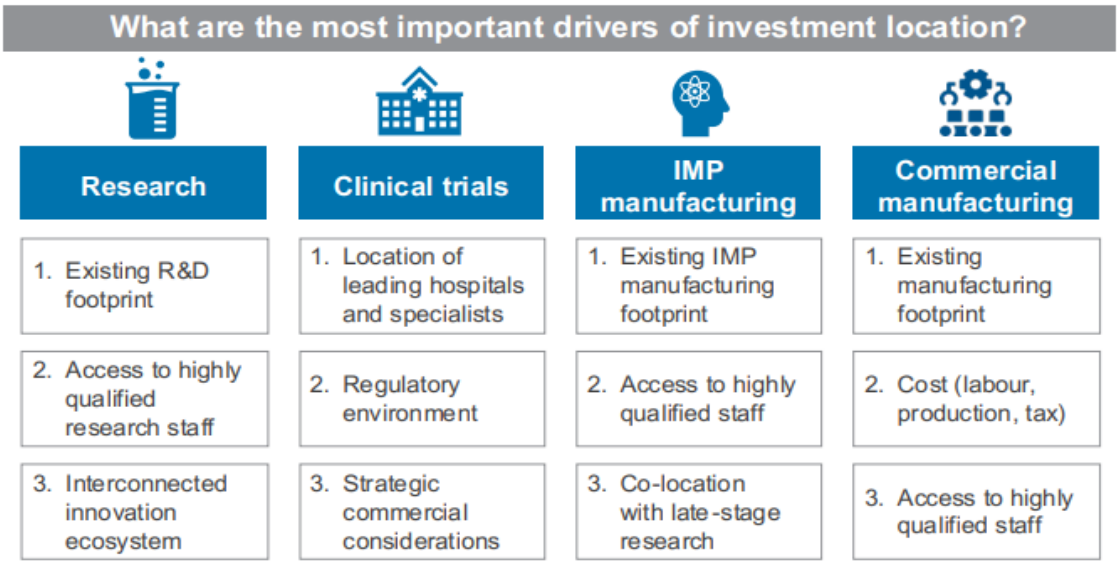
    "6.5 Green Book appraisal is not concerned with the macroeconomic effects of spending which is the concern of government when it makes macro spending decisions on the overall level of spending and taxation."

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

135. 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.

136. In their 2021 "Factors affecting the location of biopharmaceutical investments and implications for European policy priorities" report[15] 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



[15] 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]

137. 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.

138. 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[16], Cancer Drugs Fund and provisions within VPAS we consider this risk to be relatively low.

139. 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.

140. The "Attracting life science investments in Europe" report published in June 2021[17] 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.

141. 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.

142. 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.

143. Similarly, the 2021 EU R&D industrial investment scoreboard[18] 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.

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[16] 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/]

[17] 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]

[18] 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]

144. More recently the “Startup Blink Global Ecosystem Report 2023”[19] 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.

145. 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.[20]

146. 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.

147. 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%[21]. There are other sources that estimate the share of revenue devoted to R&D is closer to 25%[22], and OLS analysis suggesting it may be nearer 15%[23]. 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%.

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

[20] 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

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

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

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

148. This is the upper end of the 15% to 25% range recommended for use by the Office for Life Sciences (OLS). We then apply the latest identified estimate for the proportion of global pharmaceutical R&D that is located in the UK to estimate possible additional UK investment. In 2020 we estimate the UK's share of global R&D came to 3.1%, with global pharmaceutical R&D at £161 billion[24] and the UK's pharmaceutical R&D summing to just over £5 billion[25].

149. Note that investment in R&D is not, of itself, a net benefit (as it represents deployment of resources that would otherwise have found some other use). However, we consider that R&D investment leads to "spillover" effects, for example through the generation of knowledge and human capital, which generate net societal benefits compared to other uses. We have updated the evidence base underpinning the level of spillover effects that might be reasonably expected from an increase in pharmaceutical investment. The results of 10 academic papers[26] were considered with a mean estimate of spillover effects being valued at 34% the value of the investment and the median at 32%.

150. 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[27] and biomedical research centres and units[28] 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.

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

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

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

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

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

[26] 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];
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];
Jon Sussex, Yan Feng, Jorge Mestre-Ferrandiz, Michele Pistollato, Marco Hafner, Peter Burridge and Jonathan Grant. 2016. Quantifying the economic impact of government and charity funding of medical research on private research and development funding in the United Kingdom. BMC Medicine, 14, article no: 32;
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 Bull. 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 Reene. 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].

[27] 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]

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

Annex C – Estimates of the NHS cost of providing an additional QALY, and society's valuation of a QALY

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

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

3. The NHS budget is limited in any given time period. This means that there are potential activities or beneficial uses of funds which would generate QALYs, but which cannot be undertaken because the budget is fully employed. If additional funds were given to the NHS, additional QALYs would be generated by funding these activities. Similarly, if funds were taken from the NHS QALYs would be lost - as some activity "at the margin" could no longer be funded and would necessarily be discontinued.
4. The cost per QALY "at the margin" is an expression of how many QALYs are gained (or lost) if funds are added to (or taken from) the NHS budget. It has been estimated by a team led by York University, and funded by the Medical Research Council, to be £12,981[29]. 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[30] 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'.

[29] 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/]

[30] 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[31].

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:

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

[31] 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]

- The benefits of the project are simply the QALYs gained – that is **1,200 QALYs gained**. Monetising these costs using the DH estimate of the social value of a QALY gives a monetary equivalent of **£84m**.
- The net benefit of the project is therefore **200 QALYs**, or, expressed in monetary terms **£14m.**

14. In principle, costs and benefits in the above example can be expressed either in QALYs or in £ and give the same (correct) result. However, many projects have other impacts besides NHS costs and QALYs, and it is important to be able to express all the impacts in the same currency. For example, a project might generate cost savings to business, which are denominated in £s.

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

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

Business as Usual (BAU) Counterfactual

1. In line with the setting of the current Statutory Scheme, measured sales under BAU counterfactual will be calculated assuming there are no exemptions from payments also known as frameworks.
2. The 2024, 2025 and 2026 sales and payment has been calculated using data to Q4 2023 and DHSC's forecast of future growth in branded medicines spend.
3. Initially the Total Measured Sales is calculated using Q4 2023 data:

$$Total\ Measured\ Sales_{t,A,BAU} = SS\ Measured\ Sales_{t,A,BAU} + VS\ Measured\ Sales_{t,A} + Parallel\ Import\ Sales_{t,A}$$

Where *SS* refers to the Statutory Scheme, *VS* refers to the Voluntary Scheme, $_t$ refers to the calendar year, e.g., 2024, 2025 and 2026, $_A$ refers to Q4 2023 data and *BAU* refers to under BAU option.

4. Since small company sales in the Voluntary Scheme is adjusted to be sales by companies whose total sales of scheme products are less than £6m in the calendar year preceding the relevant calendar year, according to the full year 2023 sales data, the level of VPAS measured sales is projected to be 99.97% of the present level of measured sales of the Voluntary Scheme. In the BAU option, small company sales continue to be defined as sales by companies whose total sales of scheme products are less than £5m in the calendar year preceding the relevant calendar year for the Statutory Scheme.
5. According to the 2023 outturn sales data and current company joiners profile, Statutory Scheme measured sales are estimated to account for 1.91% of Statutory Scheme plus Voluntary Scheme measured sales adjusting small company sales.

$$SS\ Measured\ Sales_{t,A,BAU} = \left(Existing\ SS\ Measured\ Sales_{t,A} + Existing\ VPAS\ Measured\ Sales_{t,A} \times 99.97\%\right) \times 1.91\%$$

$$VS\ Measured\ Sales_{t,A} = \left(Existing\ SS\ Measured\ Sales_{t,A} + Existing\ VPAS\ Measured\ Sales_{t,A} \times 99.97\%\right) \times 98.09\%$$

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

$$SS\ Eligible\ Sales_{t,A,BAU} = SS\ Measured\ Sales_{t,A,BAU} - SS\ NAS\ Sales_{t,A,BAU}$$

7. Since the payment percentage is fixed at 21.9%, 24.0% and 26.8% from 2024 to 2026 in BAU, projected SS payment are as follows:

$$SS\ Actual\ Payment_{2024,A,BAU} = SS\ Eligible\ Sales_{2024,A,BAU} \times 21.9\%$$

$$SS\ Actual\ Payment_{2025,A,BAU} = SS\ Eligible\ Sales_{2025,A,BAU} \times 24.0\%$$

$$SS\ Actual\ Payment_{2026,A,BAU} = SS\ Eligible\ Sales_{2026,A,BAU} \times 26.8\%$$

Non-BAU Options

8. While all the remaining options introduces uprated small company sales, full year 2023 sales data suggested it will have no change to the SS measured sales.

$$Total\ Measured\ Sales_{t,A,nonBAU} = Total\ Measured\ Sales_{t,A,BAU}$$

$$SS\ Measured\ Sales_{t,A,nonBAU} = SS\ Measured\ Sales_{t,A,BAU}$$

Where *nonBAU* refers to non-BAU options.

9. Because of the intervention of small company sales, the total allowed sales baseline in 2023 is adjusted at 99.65% at 2018 as follows:

$$Total\ Allowed\ Sales_{2023,A} = (Total\ Measured\ Sales_{2018,A} - Payments_{2018,A}) \times 99.65\% \times (1 + 1.96\%)^5$$

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

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

$$Total\ Allowed\ Sales_{t,A,O} = \left(Total\ Allowed\ Sales_{t-1,A} + Baseline\ Adjustment_{t,O}\right) \times \left(1 + Allowed\ Growth_{t,O}\right)$$

Where O refers to the non-BAU options.

11. With the differentiated approach to setting payment percentages for newer medicines and older medicines, the Statutory Scheme measured sales is split into two types of product sales, namely newer medicines and older medicines.

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

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

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

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

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

$$Total\ Payment_{t,A,O} = Total\ Measured\ Sales_{t,A,O} - Total\ Allowed\ Sales_{t,A,O}$$

$$SS\ Required\ Payment_{t,A,O} = Total\ Payment_{t,A,O} \times \frac{SS\ Measured\ Sales_{t,A,O}}{Total\ Measured\ Sales_{t,A,O}}$$

14. According to the differentiated approach to setting payment percentages of older products, all eligible sales of older medicines will subject to the basic payment percentage and a top-up payment percentage from 0% to 25% based on the percentage of observed price decline of individual branded presentations.

$$SS\ Actual\ Payment\ (Older)_{t,A} = \sum_P SS\ Eligible\ Sales\ (Older)_{t,A,P} \times (basic\ payment\ percentage_t + top\ up\ payment\ percentage_P) \times Forecast\ payment\ from\ older\ medicines\ adjustment\ factor$$

Where *P* refers to the percentage of observed price decline of individual branded presentations.

15. Calculation of required Statutory Scheme payment from newer medicines:

$$SS\ Required\ Payment\ (Newer)_{t,A,O} = SS\ Required\ Payment_{t,A,O} - \ SS\ Actual\ Payment\ (Older)_{t,A}$$

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

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

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

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

Annex E – 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 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.
- **Low value sales** – Sales of any Scheme products by a scheme member where the NHS list price of such scheme product is less than £2.
- **Measured Sales** – overall sales of branded medicines to the NHS (measured by combining relevant sales across 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** – Scheme products that meet the definition set out at paragraphs 29 to 31.
- **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.
- **Payment percentage** – Payments are made based on a proportion of the manufacturer's eligible sales. This proportion is the payment percentage.
- **Small company sales** – sales by companies whose total sales of scheme products are less than £5m (in the BAU counterfactual) or £6m (in the policy options) in the calendar year preceding the relevant calendar year.
- **Basic payment percentage** – the base payment percentage for older products to which the top up rate is added. This is 10.03% in 2024, 10.6% in 2025 and 11.0% in 2026 respectively.
- **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.
- **Baseline adjustment** – an amount of money added to the allowed sales baseline.
- **Exemptions from eligible 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; NAS sales; small company sales; and low value 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; and low value sales.
- **Exemptions from 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).