Final stage impact assessment

Title: 2026 Statutory Scheme for Branded Medicines

Type of measure: Secondary Legislation

Stage: Final

Source of intervention: Domestic

Department or agency: Department of Health and Social Care

Other departments or agencies: NHS England

IA number: DHSCIA9721

Regulatory Policy Committee reference number: N/A

Contact for enquiries: Medicines.pricing@dhsc.gov.uk

Date: 03 June 2026

Summary: Intervention and Options

Cost of preferred (or more likely) option (base year = 2026)

Total net present social value (in £m): -£32.5m

Business net present value (in £m): £2.2m

Net cost to business per year (in £m): N/A

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

The 2026 headline payment percentage for the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) has been set at 14.5%[1] using the latest available actual data. Furthermore, a ceiling of 15% will be applied to the headline payment percentage in VPAG for 2026 to 2028[2]. Statutory Scheme headline payment percentages for 2026 and 2027 are currently set at 24.3% and 26.0%[3] as specified in The Branded Health Service Medicines (Costs) Regulations 2018 (the Regulations). A circa 10 percentage point differential between the headline payment percentage in VPAG versus the Statutory Scheme is not consistent with the longstanding principle of maintaining broad commercial equivalence (BCE) between the two. Intervention is required to update the Statutory Scheme headline payment percentage, reestablish broad commercial equivalence and support a stable branded medicines pricing system. Ensuring BCE is also necessary to adhere to the terms of the recent US-UK arrangement on pharmaceuticals. We also propose to

[1] The 2024 voluntary scheme for branded medicines pricing, access and growth: payment percentage for 2026 - GOV.UK

[2] U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing | United States Trade Representative

[3] The Branded Health Service Medicines (Costs) Regulations 2018 Part 1: Payment Scheme

simplify the Statutory Scheme headline payment percentage methodology to increase clarity for industry, and to make the consultation process leading to the amendment faster.

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

This proposed intervention will amend the Statutory Scheme headline payment percentage to deliver broad commercial equivalence with VPAG and better reflect the reality of branded medicines sales. The intended effect is to support the maintenance and stabilisation of the current branded medicines pricing system in the UK. At a high level, the objectives of the branded medicines pricing system are to support patient access to medicines, including those considered new and or innovative, support the UK pharmaceutical industry, and safeguard the financial position of the NHS. Furthermore, the proposal to streamline the process for setting the Statutory Scheme headline payment percentage is anticipated to increase clarity for businesses and reduce the burden of consultations.

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

This IA considered a "do nothing" business as usual (BAU) option where the current iteration of the Statutory Scheme continues, and a proposed option, where the Statutory Scheme headline payment percentage is updated and set in relation to the VPAG headline payment percentage.

- Business as Usual: The current regulations remain in force with a headline payment percentage of 24.3% in 2026, and 26.0% in 2027 and onwards[4] in the absence of further intervention.
- Proposed Option: Move to setting the Statutory Scheme headline payment percentage in relation to the VPAG headline payment percentage, at 16.5%. This equates to the 2026 VPAG headline payment percentage (14.5%), plus 1 percentage point (pp.) to reflect the 2026 Investment Programme payment percentage payable in VPAG, plus 1 further pp (rationale provided within evidence base). This results in a headline payment percentage of 16.5% for 2026 as a whole but as the regulation change will not take effect until 1st July 2026, companies that made payments between 1 January and 30 June 2026 at the higher rate of 24.3% will be subject to a lower rate of 8.7% between 1 July 2026 and 31 December 2026, to achieve an average rate of 16.5%.

Will the policy be reviewed? Statutory scheme payment percentages are kept under regular review to consider whether they continue to meet scheme objectives and maintain BCE. The Department will consult again if further changes are required to achieve this.

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 No	Medium Yes	Large Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		Traded: N/A	Non-traded: N/A	

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

Signed by the responsible Minister  Date: 9 June 2026

[4] The Branded Health Service Medicines (Costs) Regulations 2018

Summary: Analysis & Evidence

Policy Option 1

Description:

Full economic assessment

Price Base Year: **2026**	PV Base Year: **2026**	Time Period Years: **3**	Net Benefit (Present Value (PV)) (£m)		
			Low: -29.2	**High:** -35.7	**Best Estimate:** -32.5

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (exc. Transition, Constant Price)	Total Cost (Present Value)
Low	0.01	3	-10.6	-31.2
High	0.01		-12.9	-38.1
Best Estimate	0.01		-11.7	-34.6

Key monetised costs by 'main affected groups'

- **Industry transition costs**: Labour cost (office administrative, office support and other business support activities) per hour[1], multiplied by the assumed familiarisation time with proposal and any time taken to make administrative changes, multiplied by the number of firms in the Statutory Scheme.
- **Societal value QALY loss:** Reduction in Statutory Scheme income for Integrated Care Boards from reducing the headline payment percentage of the Statutory Scheme, converted into its QALY equivalent, and multiplied by the societal willingness to pay per QALY.

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

N/A

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition, constant price)	Total Benefit (Present Value)
Low	0		0.7	2.0
High	0		0.8	2.4
Best Estimate	0		0.8	2.2

Key monetised benefits by 'main affected groups'

- Increased profit accruing to UK shareholders of pharmaceutical firms as a result of reduced Statutory Scheme headline payment rates for pharmaceutical firms. Calculated by multiplying the reduction in Statutory Scheme payments given the proposed, reduced, headline payment percentage by the estimated proportion of pharmaceutical profits attributable to UK shareholders.

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

- Stabilising the branded medicines system, through maintaining broad commercial equivalence with VPAG.
- Provide clarity for firms with regards to the headline payment percentage of the Statutory Scheme in relation to VPAG.
- Future financial risk relating to over-payments may be mitigated for Statutory Scheme members.

Distributional impacts

This change will result in Integrated Care Boards receiving less income from the Statutory Scheme, which will reduce the proportion of their budget available for non-medicines spend. This will have adverse effects on spending in other areas, having distributional effects across patients.

Key assumptions/sensitivities/risks	Discount Rate: 1.5% / 3.5%[2]

[1] ONS - Earnings and hours worked, industry by four-digit SIC: ASHE Table 16 - Office for National Statistics

[2] Health effects are discounted at 1.5% per annum, all other figures are discounted at 3.50% as per the Green Book - The Green Book – UK government guidance on appraisal

This analysis uses actual sales data to Q4 2025 (the most recent data available), which we assume is correct, and forecast eligible sales thereafter. All income figures quoted relate to these forecasts, which are dynamic and may change over the course of the appraisal period. The analysis also assumes the rate will continue for the three-year appraisal period. In a scenario in which the VPAG rate changes significantly, the Statutory Scheme rate will be reviewed to confirm whether rates continue to achieve broad commercial equivalence.

Evidence Base

Background

1. The life sciences industry is one of the most important pillars of the UK economy, contributing over £146bn a year and 359,600 jobs across the country, of which the Biopharmaceuticals sector generated almost 67% of the turnover in 2023/24 and 45% of the employment[3].
2. When a new medicine is launched it will typically be under patent, with the suppliers of health services medicines holding these patents enjoying monopoly supply of products at high prices to the NHS. This high price enables the supplier to generate profits and provides an incentive to invest in research and development (R&D), as well as an opportunity to recoup R&D costs. These medicines will be sold under a brand name.
3. When a patent expires, competition can be driven by generic or biosimilar variants of medicines entering the market. This typically results in downwards pressure on market prices as new entrants seek to capture a proportion of the producer surplus previously enjoyed by the patent holder. Medicines can continue to be sold under a brand name when their patent expires, though typically in competition with new entrants.
4. In England, the 2024/25 spend on prescribed (generic and branded) medicines, appliances, and medical devices by the NHS was approximately £20.9bn, after £660m in central rebates[4]. Before central rebates, the cost to NHS commissioners was an estimated £21.6 billion.
5. In the UK, the costs of branded health service medicines measured sales made to the NHS are currently controlled within a voluntary and a statutory framework.

Voluntary Scheme

6. The UK Government needs a mechanism to control the NHS branded medicines bill to ensure the long-term financial stability of the NHS and protect patient access to medicines. A series of voluntary agreements between Government and Industry have existed since 1957 to do so. The latest of these is 2024-2028 Voluntary Scheme for branded medicines Pricing, Access and Growth (VPAG). VPAG is agreed between the Department of Health and Social Care (DHSC), on behalf of the UK Government (which includes the health departments of England, Wales, Scotland, and Northern Ireland), NHS England, and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI).
7. VPAG was introduced 1 January 2024 and brought in differentiated payment mechanisms for newer and older medicines from 1 April 2024. The headline payment percentage (HPP), which only relates to newer medicines, remains dynamic (i.e. will be amended for the start of each scheme year) and will be set to keep overall measured

[3] Office for Life Sciences, Department of Health and Social Care, Department of Business and Trade. 2025. Bioscience and health technology sector statistics 2023 to 2024. Bioscience and health technology sector statistics 2023 to 2024 - GOV.UK. All figures in 2023/24 prices.

[4] Prescribing Costs in Hospitals and the Community - England 2024/25 | NHSBSA Accessed 03/12/2025

sales within allowed sales given the risk sharing elements agreed under the updated VPAG[5]. From 2026 to 2028, the VPAG HPP will be capped at 15%[6].

8. For older medicines, a basic payment percentage of 10% will apply to all eligible sales. Where no exemption is applicable, older medicines will also be allocated a top-up payment percentage of between 0% and 25%, determined with respect to the level of price reduction observed from the Reference Price[7]. Finally, an Investment Programme payment percentage applies to all eligible sales of VPAG members (irrespective of whether they relate to older or newer medicines). Scheme members with annual NHS sales of branded health service medicines below £6 million will not be required to make payments.

Statutory Scheme

9. Operating alongside VPAG are statutory regulations set out in the Branded Health Service Medicines (Costs) Regulations 2018 (the Statutory Scheme). Companies that choose not to join VPAG are automatically subject to the Statutory Scheme. The Statutory Scheme generally makes up a small proportion of branded medicines sales; most recently the companies in the Statutory Scheme made up an estimated 1.7% of annual 2025 Voluntary and Statutory Scheme measured sales[8]. 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 introduced following the consultation launched in March 2024 took effect on 1st January 2025. This scheme update was designed to deliver a Statutory Scheme structure analogous to that of the updated VPAG to support BCE between the Voluntary and Statutory Schemes. Among other things, it implemented a differentiated approach to setting payment percentages for older and newer medicines, baseline adjustments to allowed sales, and matched VPAG's updated small sized company threshold. See here for further details.
11. Due to its statutory nature, the HPP for newer medicines in the Statutory Scheme is fixed in advance for the number of years specified in the legislation, following which the rate for the final year would continue in perpetuity in the absence of further secondary legislation.
12. Unlike VPAG, the terms of the Statutory Scheme include exemptions for sales of pharmacy medicines and general sale license medicines, and sales made under public contracts and framework agreements. The public contracts and frameworks exemption covers:
    - Full exclusion for sales of products which are sold under contracts which were extant at the date of coming into force of the 2018 Statutory Scheme regulations (i.e., entered into before 1st April 2018).
    - Agreements entered into on or after 1st April 2018, but before 1st January 2019, will qualify for a 7.8% payment percentage on sales.
    - For agreements entered into on or after the 1st of January 2019, the payment percentage laid out in the regulations will apply.
13. Previous Statutory Scheme IAs have taken framework agreement exemptions into account when calculating the income that is expected to be received from the scheme,

[5] For details on how the VPAG HPP is set, see "Affordability mechanism for newer medicines" section: 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth

[6] U.S. Government Announces Agreement in Principle with the United Kingdom on Pharmaceutical Pricing | United States Trade Representative

[7] Annexes to the 2024 voluntary scheme for branded medicines pricing, access and growth See Annex 4

[8] Aggregate net sales and payment information: November 2025 - GOV.UK

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.

Problem under consideration and rationale for intervention

14. The Statutory Scheme works alongside VPAG as part of the UK system on branded medicines. These two schemes work together to:
    - Safeguard the financial position of the NHS
    - Ensure medicines are available on reasonable terms
    - Support the UK life sciences sector
15. The newer medicines headline payment rate for VPAG is set dynamically. Each year, payment rates are recalculated to reflect the best and latest available data at the time of calculation. This includes resubmissions of historic company data and data up to quarter 3 of the calendar year prior to the year for which the VPAG HPP is being set. As specified in the VPAG documentation, year to date (YTD) growth in newer medicines measured sales to quarter 3 of the current year is assumed representative of growth for the full calendar year.[9] Beyond this, the at time of negotiation (ATON) forecast growth in newer medicine measured sales is applied to project future years' newer medicines measured sales.
16. The methodology also recalculates the level of under or overpayments incurred in previous scheme years and estimates this for the current year. These are then summed and the net value distributed across remaining scheme years via adjustment to the VPAG HPPs set and projected, such that under or over payments are projected to be zero by the end of the final VPAG year.
17. The Statutory Scheme, meanwhile, is static and the rate only changes from those specified in the most recent legislation through scheme amendments (requiring consultation and secondary legislation change).
18. The Statutory Scheme HPPs for 2026 and 2027 are currently set at 24.3% and 26.0% respectively. However, based on the latest data now available the newer medicines VPAG headline payment percentage for 2026, which is calculated dynamically, has been set at 14.5%. The static nature of the Statutory Scheme means that, without intervention, the current Statutory Scheme headline payment percentages for newer medicines are no longer considered to deliver its objective of BCE with VPAG and are set higher than supported by the latest available data. This could in turn threaten the stability of the UK's branded medicines pricing system.
19. We therefore consider intervention is required to set a Statutory Scheme HPP which will maintain BCE with VPAG and, in doing so, better reflect the latest available data. Further, the introduction of a 15% ceiling on the VPAG HPP suggests a new approach to setting the Statutory Scheme HPP could better deliver the objective of maintaining BCE. Without a change to the methodology, the newer medicines HPP in the two Schemes could diverge if the 15% VPAG HPP ceiling were to be triggered. As such, simplification of the process by which we set the Statutory Scheme HPP is considered beneficial.
20. By setting the 2026 Statutory Scheme HPP as equal to the combined 2026 VPAG HPP and investment programme rate, plus 1 percentage point (pp), the relationship between the Statutory Scheme HPP and the VPAG HPP is clearer. This provides benefits of maintaining BCE and stability, as well as simplifying the Statutory Scheme rate setting

[9] Annexes to the 2024 voluntary scheme for branded medicines pricing, access and growth Point 72

process and providing clarity to firms on future Statutory Scheme HPPs with respect to future VPAG HPPs.

Description of Options Considered

21. Only two options were considered for this consultation stage IA. These are a business as usual (BAU) option where the current iteration of the Statutory Scheme continues, and a proposed option, where the Statutory Scheme HPP is set at 16.5% in relation to the VPAG HPP.

22. Under the proposed option, only the Statutory Scheme HPP (relating to newer medicines) would be amended compared to the BAU option. The older medicines affordability mechanism, as well as exemptions that apply currently in the Statutory Scheme are not affected and therefore are not discussed in this impact assessment. More details regarding these aspects of the scheme can be found in the previous Statutory Scheme Impact Assessment here.

23. The two options are as follows:

    - **Business as Usual:** The current regulations remain in force with HPPs of 24.3% for 2026 and 26.0% for 2027. These payment rates were calculated from Q2-Q4 2024 data, with 2% per annum allowed growth rates (AGR) and baseline adjustments of £50m, £430m, and £380m for 2025, 2026 and 2027 respectively. This method of calculating the HPP through the use of AGRs and baseline adjustments has been the norm in previous Statutory Scheme amendments.
    - **Proposed Option:** Set a Statutory Scheme HPP calculated to deliver an average payment rate across 2026 as a whole of 16.5%, ensuring the continuation of BCE. The value of the Statutory Scheme HPP would be defined as the combined VPAG headline payment percentage and VPAG Investment Program payment rate for 2026, plus an additional uplift of 1 pp. We consider that this maintains broad commercial equivalence while reflecting the wider differences between the schemes. The 1 percentage point uplift supports stable VPAG membership and in doing so helps promote a clear and joined-up market access ecosystem that benefits patients and improves the health of the population. The choice is informed by precedent from previous years where the differential between voluntary and statutory scheme payment percentages has been at similar levels, including exactly 1% in 2023. For the avoidance of doubt, no Investment Programme exists in the Statutory Scheme, this is added solely to support BCE. The 2026 VPAG HPP has been set at 14.5%, plus an additional 1% to reflect the VPAG Investment Program payment rate, resulting in a proposed Statutory Scheme HPP of 16.5% over the course of the scheme. This is not only a change in the HPP, but a change in the methodology used, improving clarity and simplifying the calculation of the Statutory Scheme rate. Further changes to the approach include a more targeted consultation for interested parties and setting a single Statutory Scheme HPP from 2027 onwards, which will be assessed following publication of the VPAG headline payment percentage each year to ensure BCE is maintained.

24. To note, this change would come into effect on the 1st of July 2026. Therefore, for companies that made payments in quarters 1 and 2 of 2026, a payment rate of 8.7% would be applied to their sales in quarters 3 and 4 2026 to deliver an average payment rate across the whole year of 16.5%. From 2027 onwards, the HPP would be set at 16.5% for all companies.

25. This proposed option includes both the change to the methodology, as well as the change to the newer medicines HPP. These options are not considered individually e.g., setting a 16.5% HPP through the previous method (of baseline adjustments and AGR). Much of the benefits and costs of the proposed change relate to the HPP that is set,

rather than the way in which that rate is derived. Therefore, an option to set the rate at the same rate through a more complicated method is identical to our proposed option except it increases analytical and consultation burden and does not deliver the benefit of clarity to firms[10]. As such, this option would be strictly worse than our proposed option and therefore is not considered.

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

26. We have used the latest VPAG rate to set the rate for the proposed option. This is set using the best and latest available actual sales data, which we have also used to calculate the costs and benefits of the proposed option, combined with forecast newer medicines sales growth in the future. The availability of actual sales data is constrained by the timetable of companies submitting data returns under the terms of VPAG and the Statutory Scheme, and the latest currently available covers up to quarter four 2025.
27. The appraisal period is three calendar years. This reflects the inherent uncertainty surrounding forecasting medicines sales and is in line with precedent set in previous Statutory Scheme Impact Assessments. This three-year appraisal period also aligns with the remaining duration of VPAG. Since there will be a new iteration of the Voluntary Scheme after 2028, appraising costs and benefits beyond this point becomes increasingly difficult.
28. Where assumptions have been applied, these will be identified and described throughout at the point of use.

Policy objectives

29. The aim of this intervention is to ensure that BCE is maintained. Under the proposed option, this would be delivered via amending the current newer medicines Statutory Scheme rate in relation to the latest headline payment percentage set for VPAG (2026). This would also better reflect the reality of actual branded medicines sales, as well as streamlining the process of setting the Statutory Scheme headline rate, providing clarity to firms.
30. BCE is a stated objective of the branded medicines pricing schemes[11]. This has been an aim since 2015, where the Statutory Scheme was updated to provide equivalence with the Voluntary Scheme of the time. This was deemed “necessary to promote a more level playing field for companies in either scheme”.[12]
31. By maintaining BCE, this intervention can maintain and stabilise the current system of branded medicines in the UK. This system functions to aid UK population health, support the UK pharmaceutical industry, and safeguard the financial position of the NHS. Maintaining BCE between the Schemes supports their ability to work effectively together and thereby contribute to supporting the above objectives.
32. Whilst BCE has been a stated objective since 2015, under the terms of the recent arrangement between the United States of America and the UK on pharmaceutical pricing, the UK reiterated our commitment to updating the Statutory Scheme to ensure BCE with VPAG[13].

[10] Discussed later in Unquantified Benefits section

[11] EM The Branded Health Service Medicines (Costs) (Amendment) Regulations 2025 Paragraph 5.4

[12] Consultation on Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines Paragraph 2.10

[13] Arrangement between the United States of America and the United Kingdom on pharmaceutical pricing (HTML) - GOV.UK Section II.3

Summary and proposed option with description of implementation plan

33. The proposed option involves setting the Statutory Scheme newer medicines HPP with relation to the current VPAG HPP. This is set at 16.5% through the following process:
    - The VPAG HPP has been set at 14.5% for 2026; plus
    - The investment premium payment rate for 2026 is 1pp[14]; plus
    - A further uplift of 1 pp to maintain BCE while reflecting the wider differences between the schemes and our support for the important partnership and commitments between industry and government developed under the VPAG agreement. The choice of 1pp, representing a reasonable level of uplift to achieve this, is also informed by precedent from previous years where the VPAG/SS differential has been at similar levels, including the differential of exactly 1% set in 2023.
    - This gives the final HPP for the Statutory Scheme of 16.5% (14.5% 2026 VPAG HPP + 1pp VPAG 2026 investment programme payment rate + additional 1pp uplift).
34. The proposed changes to the Statutory Scheme would set a Statutory Scheme HPP of 16.5% in 2026. However, legislative timetables mean they would come into force on the 1st of July 2026. Therefore, companies that have made Statutory Scheme payments at the higher Statutory Scheme HPP of 24.3% in quarters 1 and 2 2026, would pay a Statutory Scheme HPP of 8.7% in quarters 3 and 4 of 2026, in order to deliver an effective whole of 2026 HPP of 16.5%.
35. From 1st of January 2027, the HPP would be set to 16.5%. Unless further intervention is deemed necessary based on future changes to the VPAG headline payment percentage and consequent impacts on BCE, this Statutory Scheme HPP would persist.
36. The proposed option is not just to change the rate, but to change the method by which the HPP for the Statutory Scheme is set such that this is in relation to VPAG headline payment percentages. Should the VPAG rate change in future years we would assess whether the Statutory Scheme HPP continues to achieve BCE with VPAG and, if not, propose an amendment to the Statutory Scheme HPP.
37. The proposed option will be given effect via secondary legislation and does not include the implementation of any transitional arrangements post the proposed coming into effect date of 1st July 2026.
38. The pricing schemes affect net expenditure on medicines by ICBs. While reducing the payment percentage relative to current levels reduces NHS and ICB revenue, the intervention is aimed to 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 the broader economy. DHSC will continue to be responsible for the ongoing operation and enforcement of the Statutory Scheme.
39. As has been the case with the current Statutory Scheme HPP, 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.
40. Please note that this proposal does not fall within the scope of the Better Regulation Framework and, as such, this assessment has not been scrutinised by the Regulatory Policy Committee (RPC). The regulation under consideration in this impact assessment only impacts companies that choose to sell to the NHS. The Department therefore

[14] 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth Section 5.3

considers the proposals to be in connection with procurement and, as such, the proposals sit outside the definition of Regulatory Provisions as set out within paragraph 2.3 of the Better Regulation Framework guidance[15]. This position has been confirmed previously by the Economic and Domestic Affairs Secretariat at the Cabinet Office.

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

41. The BAU option is the counterfactual against which the costs and benefits of the proposed option are measured. As such, by definition, the BAU option has no impacts and so does not feature in the following sections.

Quantified costs – proposed option

42. The transition costs of the proposed option have been identified as the administrative costs to industry in familiarising themselves with the updated Statutory Scheme terms and methodology, and the loss of income due to lowering the rate paid by medicines in the Statutory Scheme.
    - The transition costs are calculated by taking the cost per hour of administrative labour, the non-labour costs of work (e.g. National Insurance and pension contributions), the time taken for administration following a change in the rate of the Statutory Scheme, and the number of firms in the Statutory Scheme. This gives a total cost of £0.01m in low, high and central scenarios.

Impact on NHS finances

43. The primary quantified impact of the proposed option is a reduction in Statutory Scheme newer medicine income accruing to the UK NHS in the proposed option versus BAU. The proposed option is to reduce the Statutory Scheme HPP compared to BAU. Statutory Scheme newer medicine income is calculated as the Statutory Scheme HPP multiplied by Statutory Scheme newer medicines eligible sales. Therefore, a reduction in the Statutory Scheme HPP will, all other things being equal, drive a reduction in Statutory Scheme newer medicine income received by the UK NHS.
44. The monetised, direct loss of NHS income is calculated by multiplying forecast Statutory Scheme newer medicines eligible sales by the change in payment percentages between the proposed option and BAU. Statutory Scheme eligible sales of newer medicines are calculated by taking measured sales of newer medicines made by Statutory Scheme members and subtracting sales covered by the exemption from eligible sales applicable to New Active Substances (NAS).
45. Statutory Scheme forecasts of measured sales of newer medicines are calculated by taking the most recent total newer medicines measured sales (VPAG and Statutory Scheme) and growing this figure by the newer medicines measured sales growth. This is then multiplied by the proportion of newer medicines measured sales attributable to the Statutory Scheme. The newer medicines measured sales growth is either calculated using outturn data or is assumed to be the forecast determined at time of negotiation (ATON) of VPAG if outturn data is not available.
46. Table 1 demonstrates the estimated reduction in income from implementing the proposed option (compared to BAU) for the appraisal period, for central (calculated from the latest available Q4 2025 company returns data), low (central -10%) and high (central +10%) scenarios.

[15] Better regulation framework guidance 2023

Table 1: Impact on NHS finances

Impact on NHS Finances	2026	2027	2028	Total
Eligible Sales of Newer Medicines (£m) (Central)	26	28	30	84
Eligible Sales of Newer Medicines (£m) (Low)	24	25	27	76
Eligible Sales of Newer Medicines (£m) (High)	29	31	33	93
NHS Income under BAU HPP (£m) (Central)	6	7	8	21
NHS Income under proposed HPP (£m) (Central)	4	5	5	14
Difference in Income (£m) (Central)	**-2**	**-3**	**-3**	**-8**
NHS Income under BAU HPP (£m) (Low)	6	7	7	19
NHS Income under proposed HPP (£m) (Low)	4	4	4	12
Difference in Income (Low)	-2	-2	-3	-7
NHS Income under BAU HPP (£m) (High)	7	8	9	24
NHS Income under proposed HPP (£m) (High)	5	5	5	15
Difference in Income (£m) (High)	-2	-3	-3	-8

Impact on patients

47. The proposed option results in lower income associated with branded medicines to the UK NHS compared to the BAU counterfactual. In the context of a fixed NHS budget, this would require redistribution of funding from another area. We estimate the reduction in Statutory Scheme newer medicine income cumulatively equates to between 453 and 553 fewer undiscounted QALYs by 2028 compared to the BAU Option.

48. Conversely, patients will benefit from a scheme that sets payment rates to support the operation of the UK branded medicine pricing system as a whole, to support ongoing access to cost-effective medicines.

49. Ensuring the continued sustainability of the UK branded medicine pricing system 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.

50. Some groups are likely to be particularly affected by policies that may affect access to medicines. Previous consultations have noted specific groups where illness and use of medicines tend to be higher than in the rest of the population. These groups include those sharing protected characteristics, such as older people and those with long-term health conditions. NHS data[16] 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.

51. While the proposed option would result in a reduction in Statutory Scheme newer medicine income compared to BAU, resulting in decreased income to the NHS, 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 for 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 be used in the best interest of patients.

52. The reduction in Statutory Scheme newer medicine income can be translated into a quantified impact on patients using the established methodology set out in Annex C. The reduction in Statutory Scheme newer medicine income is converted into QALYs using the estimated £15,000 cost per additional QALY generated at the margin in the NHS. This

[16] healthcare-inequalities-nhs-prescribing-and-exemption-schemes

value is then multiplied by the societal willingness to pay value per QALY of £70,000[17]. This gives a net present societal value (NPSV) of -£34.6m in the central scenario (with ranges of -£31.2m to -£38.1) over the 3-year appraisal period. This is calculated using the 1.5% discount factor for QALYs[18].

Table 2: Quantified patient impacts

Impact on Patients	2026	2027	2028	Total
QALY loss (£15k per QALY) (Central)	-137	-177	-189	-503
Societal cost (£m) (£70k per QALY) (Central)	**-10**	**-12**	**-13**	**-35**
QALY loss (£15k per QALY) (Low)	-123	-159	-170	-453
Societal cost (£m) (£70k per QALY) (Low)	-9	-11	-12	-31
QALY loss (£15k per QALY) (High)	-151	-195	-208	-553
Societal cost (£m) (£70k per QALY) (High)	-11	-14	-15	-38
QALY NPV Multiplier (1.5% discount per year)	1.00	0.99	0.97	n/a
NPV Discounted Cost (£m) (Central)	**-10**	**-12**	**-13**	**-35**
NPV Discounted Cost (£m) (Low)	-9	-11	-12	-31
NPV Discounted Cost (£m) (High)	-11	-13	-14	-38

Quantified benefits

Impact on UK shareholder income

53. The monetised benefit for this change is the estimated impact on UK shareholders in pharmaceutical firms of increased profit generated by the proposed reduction in the Statutory Scheme HPP. This is calculated by first estimating the reduction in payments required from Statutory Scheme members driven by the reduced Statutory Scheme HPP in the proposed option versus BAU. This value is then multiplied by 29%, the estimated proportion of pharmaceutical firms' profits that may accrue to UK shareholders[19]. This gives an NPV over the appraisal period of 2026 to 2028 of £2.2m in the central scenario (with a range £2.0m to £2.4m) when discounted at 3.5%.

Table 3: Impact on UK Shareholders

	2026	2027	2028	Total
Difference in payments made (£m) (central)	-2	-3	-3	-8
Difference in payments made (£m) (low)	-2	-2	-3	-7
Difference in payments made (£m) (high)	-2	-3	-3	-8
Increased profit to UK shareholders (£m) (central)	**0.6**	**0.8**	**0.9**	**2.3**
Increased profit accrued by UK shareholders (£m) (low)	0.6	0.7	0.8	2.0
Increased profit accrued by UK shareholders (£m) (high)	0.7	0.9	0.9	2.5
NPV Multiplier (3.5% discount per year)	1.00	0.97	0.93	n/a
NPV Discounted Profit (central)	**0.6**	**0.8**	**0.8**	**2.2**
NPV Discounted Profit (low)	0.6	0.7	0.7	2.0
NPV Discounted Profit (high)	0.7	0.8	0.9	2.4

Unquantified benefits

54. **Industry will benefit from increased clarity for firms:** Firms will have increased clarity that the Statutory Scheme HPP has been set in relation to the VPAG headline payment

[17] See Annex C

[18] See Annex C

[19] Derived in Annex A

percentage. Whilst we have previously maintained a policy of BCE, the new methodology for setting the newer medicines rate further elucidates the process. This is intended to support firms making informed decisions about scheme membership via simplifying how the Statutory Scheme HPP is derived.

55. **The UK economy will benefit from reduced risk of a potential fall off in investment:** Whilst DHSC has maintained that other factors are the primary reason behind pharmaceutical investment choices, during the last consultation process, firms expressed concern that current headline payment rates are too high, and that we may have reached a “tipping point” around investment beyond which investment in the UK pharmaceuticals industry may reduce dramatically. Reducing the Statutory Scheme HPP, and thereby restoring BCE with VPAG, may support mitigating this risk. The wider impact on investment is further discussed in Annex B.

56. **Supports the UK-US pharmaceuticals arrangement:** The recently announced UK-US pharmaceuticals arrangement set out targets to increase investment in new medicines to 0.6% of GDP, with an interim target of 0.35% of GDP in 2028[20]. Reducing the HPP applicable to Statutory Scheme members' newer medicines eligible sales will contribute to increasing spend on newer medicines net of Voluntary and Statutory Scheme income. This change will thereby contribute towards meeting the interim target of 0.35% of GDP by 2028, as well supporting an improvement in the commercial environment, benefitting UK businesses through access to US markets, and UK patients through supporting access to innovative medicines.

57. **Delivers the goals of the Statutory Scheme:** Reducing the Statutory Scheme HPP for newer medicines to the rate indicated by the data will allow the Statutory Scheme to continue to function as intended. The rate is meant to be set at a rate which keeps medicines prices affordable and safeguards NHS finances, whilst also giving UK patients access to branded medicines and supporting investment in the UK pharmaceutical industry. By leaving the HPP far higher than where the current data indicates it should be, we risk adversely impacting on these objectives, particularly for access and investment.

58. **Supports the wider UK branded medicines system:** The Statutory Scheme, while only accounting for a small percentage of branded medicines sales, plays a large role in supporting the stability of the UK branded medicines system. BCE with VPAG is a core part of the two-scheme system, and having such a large difference in HPPs between the schemes does not achieve this. By changing the HPP and maintaining BCE, we can contribute towards the stability of the branded medicines systems and ensure that the VPAG aims are also met, benefiting industry, HMG and patients.

59. **Industry and HMG will benefit from accurately reflecting over and underpayments:** Under the previous methodology, the Statutory Scheme HPP was set using the latest data but did not account for previously set HPPs had been set. Due to the variable nature of newer medicines sales, it is often necessary for later years in VPAG to have higher or lower HPPs in order to reflect over or underpayments in previous years. The Statutory Scheme did not have a mechanism for accounting for this, but by linking the Statutory Scheme HPP to the VPAG HPP, this will now be reflected in the Statutory Scheme. Due to the 15% cap on the VPAG HPP, these under-over payments are more likely to be skewed towards correcting overpayments, which presents a further benefit for the UK pharmaceuticals industry.

[20] VPAG payment rate for newer medicines will be 14.5% in 2026

Risks and assumptions

60. The BAU Statutory Scheme option does not have an under-over payment mechanism, as the scheme is not time-bound. By tying the Statutory Scheme HPP to the VPAG HPP, the proposed option will better reflect under-over payments, as they are accounted for in the VPAG HPP. However, given the proximity of the 2026 VPAG HPP of 14.5% to the ceiling value of 15%, in the immediate term the scope for recouping underpayments is limited.

61. There are significant uncertainties associated with forecasting branded medicines sales growth, which increase as the forecast progresses over time. For this reason, the Statutory Scheme will be reviewed on a yearly basis to ensure it is consistent with VPAG and maintain BCE, and the Department will consult again if further changes are required to achieve this.

62. We present low, central, and high forecast scenarios for Statutory Scheme newer medicines measured sales post 2025. The central forecast applies the ATON VPAG forecast growth in newer medicines measured sales from 2026 onwards. As under VPAG, the latest available actuals data is used, up to quarter four 2025, and the year-to-date growth calculated for the first four quarters of 2025 is assumed to be representative of full year growth. The low and high scenarios reflect measured sales given in the central forecast +/- 10%.

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

    - Companies' annual sales reports are independently audited to give assurance that the sales and exclusions reported have been accurately extracted from a companies' information systems and reconcile with turnover in a company's statutory accounts.
    - The Branded Medicines Operations team undertakes validation, particularly of some sales exemptions, through detailed presentation level checks on separate presentation level reports that companies are required to provide, and which should reconcile with a company's high-level Sales Report.

64. The method of calculating low and high scenarios used in this impact assessment is a departure from the approach used in the previous Statutory Scheme impact assessment. Previously, low and high sensitivities were modelled by varying the proportion of measured sales, excluding parallel imports, attributable to the Statutory Scheme. In this impact assessment, we have instead varied the estimated value of Statutory Scheme newer medicines measured sales. This is due to the proposed simplification of the methodology for calculating the Statutory Scheme HPP, which sets the Statutory Scheme rate in relation to that set for the VPAG.

Table 4. Summary of assumptions used in the appraisal

Assumption	Used in	Source
Proposed option additional payment percentage uplift of 1pp	Proposed Option	Differential selected to reflect the partnership and commitment between the industry and HMG in VPAG, also informed by precedent from previous years where the VPAG/SS differential has been at similar levels, including the differential of exactly 1% set in 2023.
QALY cost of £15k		See Annex C

QALY social value of £70k	Monetised and non-monetised costs and benefits of each option	See Annex C
28.9% of pharmaceuticals savings going to British shareholders		Annex A
NPV discount rate for QALYs of 1.5%		HMT Green Book
NPV discount rate of 3.5%		HMT Green Book
Statutory Scheme newer medicines eligible sales forecast		Actual sales data to Q4 2025 and ATON newer medicine growth forecast thereafter plus estimated proportion of newer medicine eligible sales attributable to the Statutory Scheme in 2025, which we assume remains stable over time.
2025 price per hour labour cost		ONS - Earnings and hours worked, industry by four-digit SIC: ASHE Table 16.5 (2025)
Non-wage labour costs		RPC short guidance note – Implementation costs (August 2019, Updated 2025)
2026 price per hour labour cost		GDP deflators at market prices, and money GDP March 2026 (Quarterly National Accounts)

Distributional and wider impacts

65. The proposed option will result in the UK NHS receiving less income from newer medicines eligible sales made to the NHS by Statutory Scheme members. If we assume a fixed budget overall, this could drive a redistribution of funding from other areas towards branded medicines. This may result in reduced spending in other areas, with associated distributional effects across patients, as discussed in paragraphs 47-52 above.

Impact on small and micro businesses

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

Monitoring and Evaluation

67. The appraisal period for this change is 3 years, until 2028. Throughout this period, actual sales data will continue to be reported by firms, enabling monitoring of the actual impact on NHS income over time.

68. Many of the benefits of this option relate to maintaining BCE with VPAG and we will review whether the Statutory Scheme HPP under the proposed option continues to achieve this over time, given VPAG’s dynamic nature.

69. DHSC will continue to engage regularly with the Association for the British Pharmaceutical Industry (ABPI) and Medicines UK, who represent the interests of

pharmaceutical firms in the UK. Through regular engagement we can assess how the new HPP has been received by companies, and any impacts it is having on industry sales, new medicine launches and investment.

Consultation Responses

70. The consultation IA was published on the 10th of February 2026[21], and the consultation ran from the 10th of February 2026 until the 21st of April 2026.

71. We received a total of 16 responses to the consultation, mostly from the pharmaceutical industry. More detail is set out in the consultation response. A summary of responses is below:

- Respondents generally disagreed with the set payment percentage. The majority agreed with ABPI in that the payment percentage is too high and that the derivation of the additional 1 percentage point uplift, beyond the 14.5% VPAG rate and the 1pp investment programme payment, is unclear. DHSC will proceed with the 16.5% rate. This reflects DHSCs support for the important partnership and commitments between industry and government developed under VPAG. It also follows the precedent as to the level of the gap between the Statutory Scheme and VPAG payment percentages that has been considered to represent BCE in the past. DHSC will keep this rate under review in future years to ensure it continues to represent BCE.

- Most respondents expressed concern over the proposed changes to the consultation procedure, including the lack of an audit trail as a result of consultation through workshop. DHSC will proceed with the proposed approach to future consultations, but with an opportunity to submit written evidence to address concerns raised in consultation responses.

- The majority of respondents disagreed with the impact assessment analysis (75%), with some respondents arguing that the IA underestimates the impact on R&D and investment, as well as casting doubt on the NHS marginal productivity value of £15,000 per QALY. The department considers that investment decisions are based on an assessment of global returns, and therefore, we do not consider that the price paid for medicines and the level of investment are closely correlated. The department remains confident that the £15,000 per QALY figure is the best estimate of the opportunity cost per QALY in the NHS. The department will continue to use this figure, as the most recent re-assessment continues to support its use.

Conclusion

72. The proposed change to the Statutory Scheme HPP has a quantified NPSV of -£32.5m This negative NPSV is a result of the monetisable losses, primarily the loss in income due to lowering the HPP applied to Statutory Scheme newer medicines eligible sales and the associated reduction in QALYs generated by the NHS (assuming a fixed budget) as a result. The quantified benefits of value to UK shareholders of pharmaceutical firms is a far smaller value of £2.2m and does not offset the QALY impact of the loss of income.

73. These changes support the delivery of terms agreed in the UK-US pharmaceuticals arrangement, as well as reducing the industry identified risk of reaching a tipping point

[21] Proposed 2026 changes to the statutory scheme for branded medicines pricing - GOV.UK

where the commercial environment precludes UK pharmaceutical industry investment continuing at historic levels.

74. There are also substantial unquantified benefits identified in relation to the proposed option, accruing to HMG, industry and NHS patients, associated with supporting the continued operation of the UK’s branded medicine pricing system.

Annex A - Evidence underpinning industry revenue impacts accrue to UK shareholders

1. This section sets out the evidence underpinning the estimate of the proportion of industry revenue impacts that accrue to UK shareholders.
2. Assuming that profits are shared between the UK and overseas in the same proportion as total revenue, this implies that a corresponding proportion of the changes in profits will accrue to UK shareholders. As in the final stage Statutory Scheme impact assessment of 2025[22], we continue to assume that the proportion of UK consumption produced in the UK may be used as a proxy for the proportion of industry revenue impacts that accrue to UK shareholders. This is calculated as the UK production consumed domestically divided by total UK consumption of pharmaceuticals (UK production consumed domestically + Pharmaceutical imports).
3. We also used ONS Index of Production time series SIC 21, Manufacture of basic pharmaceutical products and pharmaceutical preparations, which provided a more accurate share of domestically consumed pharmaceuticals produced in the UK and the outturn growth of manufacturer turnover in 2022 and 2023.
4. Using Bioscience and health technology statistics 2021-22[23], we estimate that between 2017-18 and 2021-22, an average of 33% of life sciences turnover for companies with known ownership (excluding unknowns) was generated by companies with UK ownership. A similar estimate is found for the pharmaceutical sector more specifically. This corroborates our estimates for industry revenue impacts that accrue to UK shareholders, following assumptions in point 2, shown below.
5. According to section 8.3 of the Annual Business Survey technical report, the time series was classified as short-term indicators and should not represent absolute amounts or monetary values. The share of domestically consumed pharmaceuticals and outturn growth of manufactural turnovers were however applied to Annual Business Survey to provide a better and more recent estimate of UK consumption of pharmaceuticals.
6. Table 5 below shows the calculations of the assumption in paragraph 40 using preferred data sources.
7. Taking a five-year average to the estimate from 2020 to 2024, the latest estimate for the industry revenue impacts that accrue to UK shareholders is 28.9%.

Table 5: Estimated Proportion of UK consumption produced in the UK

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

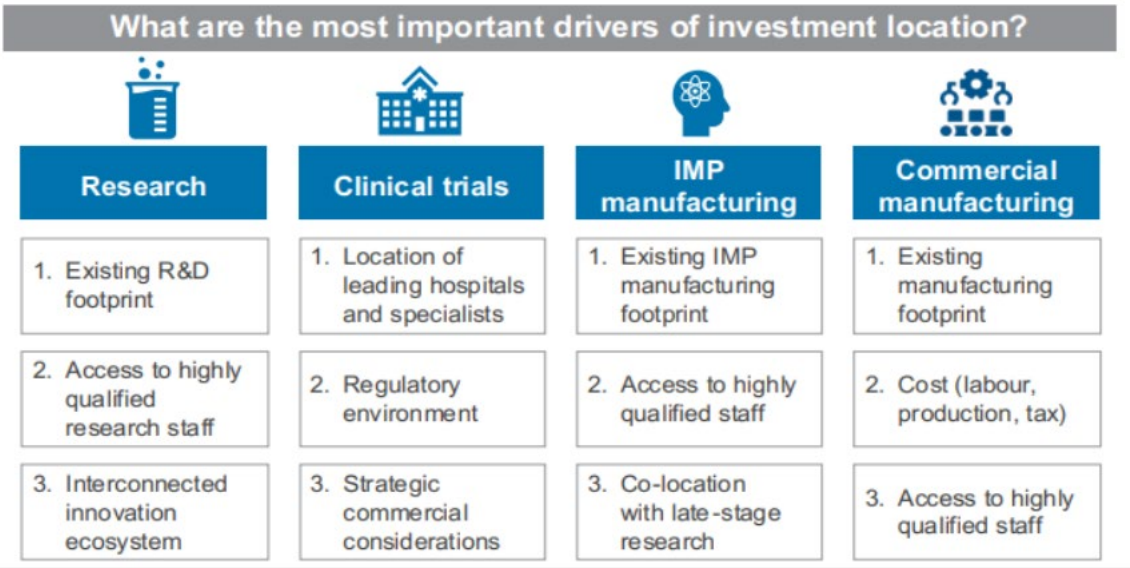
[22] Impact assessment: Statutory Scheme – Branded Medicines Pricing 2025

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

Annex B – Evidence underpinning wider economic impacts approach

1. This section sets out the evidence underpinning our approach to quantifying the potential wider economic impacts of the proposed option. Wider economic benefits are discussed in the IA as unquantified benefits in (54-59). This section also aims to assess the extent to which a change in pricing policy is likely to have wider economic impacts. Theoretically, decreased 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.
2. We use the same formulaic approach to estimate the potential impact of the change in payment percentages versus the counterfactual on UK investment as in previous impact assessments. This reflects the methodology set out for central government appraisal and evaluation in the Green Book, which notes at paragraphs 6.5 and 6.6 respectively:
3. “6.5 Green Book appraisal is not concerned with the macroeconomic effects of spending which is the concern of government when it makes macro spending decisions on the overall level of spending and taxation.”
4. “6.6 Therefore, changes to Gross Domestic Product (GDP), or Gross Value Added (GVA) or the use of Keynesian type multipliers arising from different options cannot provide useful information for choosing between options within a scheme and are therefore not part of the Green Book appraisal process. However, macro variables may well form part of the higher-level analytical research that informs identification of policy, and policy priorities.”
5. The drivers of pharmaceutical investment scale and location decisions are complicated, multifaceted and may differ for different types of investment, as demonstrated in the literature around the drivers for investment location decisions discussed below.
6. In their 2021 “Factors affecting the location of biopharmaceutical investments and implications for European policy priorities” report[24] 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 1).

Figure 1: Summary of factors driving the location of biopharmaceutical investments



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

7. Whilst cost and strategic commercial considerations feature in commercial manufacturing and clinical trials respectively, research and IMP (investigational medicinal product) manufacturing are focussed on existing footprint, access to highly qualified staff and connections with innovation and late-stage research.
8. With respect to clinical trials the report highlighted inconsistencies between statistical analyses and qualitative decision-maker interview findings. The former showed positive correlation between price regulation and location of clinical trials, whilst the latter suggested that, although important, price regulation is not a key driver of clinical trial location decisions. A possible explanation was suggested that in the short-term price regulation may not significantly impact location decisions but longer-term policies leading to a decline in the clinical standard of care may deter clinical trial investment if clinical guidelines do not provide a suitable comparator for an innovative clinical trial. Given the routes for innovative medicines to reach the UK market, including the Innovative Medicines Fund[25], Cancer Drugs Fund and provisions within VPAG we consider this risk to be relatively low.
9. Research has found that R&D investment strategy decisions of firms were strongly driven by firm effects and that exposure to price regulation had little effect.
10. The "Attracting life science investments in Europe" report published in June 2021[26] was an initiative of the Biomed alliance, Europabio and Johnson & Johnson. They assessed 14 European countries against 21 indicators to analyse the country's attractiveness for Life Sciences investments. The criteria selected were grouped into the four themes noted below, which demonstrate the breadth of factors involved in decision making.
    - Social and economic context.
    - Industrial context.
    - Life sciences innovation.
    - Healthcare environment.
11. The UK performed at or above the median on 16 of the indicators tested, with particularly high performance in life science publications and clinical trials. Only Germany had fewer than 5 below median indicators in the rest of the sample. The 5 indicators where the UK fell below the sample median were:
    - Political stability and absence of violence.
    - Labour productivity.
    - Life science trade balance (exports – imports).
    - Pharmaceutical spending.
    - Size of Med Tech market.
12. This provides another indication of the complexity and multi-factorial Life Science investment decision process and that, whilst the UK did not perform highly on pharmaceutical spending, it was strong in other areas.
13. Similarly, the 2021 EU R&D industrial investment scoreboard[27] 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

[25] 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/]

[26] 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]

[27] 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]

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.

14. More recently the "Startup Blink Global Ecosystem Report 2023"[28] cited the UK as having the second most innovative start-up ecosystem in the world (again behind the US), a position which has been consolidated since 2017.

15. The Life science competitiveness indicators 2026 found that amongst comparator countries, the UK ranked fourth in terms of estimated life science inward foreign direct investment (FDI) capital expenditure in 2024.The UK had one life science initial public offerings (IPOs) and raised £35m in 2024, this is an increase from 2023 when the UK had no IPOs however this is substantially lower than the 10 IPOs in 2021. The UK life science industry has seen generally increasing levels of equity finance raised since 2012 and continues to rank third globally at £4.5bn, behind only the USA and China.[29]

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

17. For illustrative purposes only, we have estimated the possible impact on investment of the increased industry revenue generated by the proposals versus the counterfactual. We used an estimate that the proportion of pharmaceutical company revenues devoted to R&D was 36%[30]. There are other sources that estimate the share of revenue devoted to R&D is closer to 25%[31], and Office for Life Sciences (OLS) analysis suggesting it may be nearer 15%[32]. Whilst it is likely that the proportion fluctuates over time and across different companies or parts of the sector, we have opted to update our assumption regarding the proportion of revenue that may be directed towards R&D investment to 25%.

18. This is the upper end of the 15% to 25% range recommended for use by the OLS. We then apply the latest identified estimate for the proportion of global pharmaceutical R&D that is in the UK to estimate possible additional UK investment. In 2023 we estimate the

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

[29] OLS competitiveness indicators 2026 https://www.gov.uk/government/publications/life-science-sector-data-2022/life-science-competitivenessindicators-2022#executive-summary-of-the-uks-performance-in-the-lscis

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

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

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

UK's share of global R&D came to 3.6%, with global pharmaceutical R&D at around £243 billion[33] and the UK's pharmaceutical R&D summing to approximately £8.7 billion[34].

19. We consider that R&D investment leads to "spillover" effects, for example through the generation of knowledge and human capital, which generate net societal benefits compared to other uses. We have updated the evidence base underpinning the level of spillover effects that might be reasonably expected from an increase in pharmaceutical investment. The results of 10 academic papers[35] were considered with a mean estimate of spillover effects being valued at 34% the value of the investment and the median at 32%.

20. Of the 10 papers, the two identified as having the highest relevance for use here related to the UK, were focused on investment in science and innovation[36] and biomedical research centres and units[37] and published in 2014 and 2020 respectively. Across these two papers, the lower estimate of investment spillover effects was 20% and the higher was 58%. We therefore concluded that continuing to use our assumption of spillover effects valuing 30% of the amount invested was reasonable and prudent. We remain open to receiving further evidence on this point.

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

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

Where proportion of revenue invested in R&D = 25%, UK share of global pharmaceutical investment = 3.6% and spillover impacts = 30%

22. Using the central forecast, this gives a wider economic impact of investment as:

$$£7.4m\ x\ 0.25\ x\ 0.036\ x\ 0.3 = £20{,}000$$

Please note that this purely formulaic approach does not account for wider factors noted previously around supporting an improvement in the UK's commercial environment.

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[33] World Preview 2024 – Pharma's Growth Boost - eBook | Evaluate. Figure sourced is $301bn in 2023, assumes average 2023 exchange rate of £1:$1.24 (accessed 29 January 2025)

[34] Business enterprise research and development, UK (designated as official statistics) - Office for National Statistics

[35] James Medhurst, Joel Marsden, Angina Jugnauth, Mark Peacock, Jonathan Lonsdale. 2014. An Economic Analysis of Spillovers from Programmes of Technological Innovation Support.
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[36] Frontier Economics. 2014. Rates of return to investment in science and innovation.
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[37] 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 £20k to £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[38]. 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. 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[39] 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'.
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

[38] 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/]

[39] 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]

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[40].
12. Note that the estimated social value of a QALY significantly exceeds the estimated cost of providing a QALY at the margin in the NHS. This implies that the value to society of NHS spending, at the margin, significantly exceeds its cost. Adding £15,000 to the NHS budget would provide 1 QALY, valued at £70,000, according to these estimates.

Example IA calculation

13. Suppose a project cost £15m – and these costs fall on the NHS budget. It is expected to generate health gains to patients amounting to 1,200 QALYs. The costs and benefits, and the overall net benefit of the project would be calculated as follows:
14. The <u>costs</u> of the project are the QALYs that would be gained if the funds were used elsewhere in the NHS, but which are foregone if the project is undertaken. Using the standard DH estimate that one QALY is gained elsewhere for every £15,000 of funding, this gives an 'opportunity' cost of **1,000 QALYs lost**. Monetising these costs at the DHSC estimate of the social value of a QALY gives a monetary equivalent of **<u>£70m</u>**.

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

15. The benefits of the project are simply the QALYs gained – that is 1,200 QALYs gained. Monetising these costs using the DH estimate of the social value of a QALY gives a monetary equivalent of £84m.
16. The net benefit of the project is therefore **200 QALYs**, or, expressed in monetary terms **£14m.**
17. In principle, costs and benefits in the above example can be expressed either in QALYs or in £ and give the same (correct) result. However, many projects have other impacts besides NHS costs and QALYs, and it is important to be able to express all the impacts in the same currency. For example, a project might generate cost savings to business, which are denominated in £s.
18. This is why standard DHSC practice is to convert all ultimate impacts into £, as recommended in the HMT Green Book. For costs falling on the NHS budget this means converting them first into QALYs (at £15,000 / QALY) and then monetising them (at £70,000 / QALY).

Annex D – Glossary

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

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

- **Baseline adjustment** – an amount of money added to the allowed sales baseline in a given year.
- **Exemptions from newer medicines eligible sales** – NAS sales
- **Exemptions from measured sales** - sales of scheme products by a scheme member relating to exceptional central procurements; sales of scheme products by a scheme member relating to centrally procured vaccines; small company sales; low value sales; sales of pharmacy medicines and general sale license medicines; and sales made under public contracts and framework agreements.