EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2026

2026 No. 614

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Preet Kaur Gill, Parliamentary Under-Secretary of State at DHSC confirms that this Explanatory Memorandum meets the required standard.

2.2 David Simmons, Director, Supply Resilience and Interim Director, Medicines at DHSC confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Edward Evans at DHSC, telephone: 01132545030 or email: medicines.pricing@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 These Regulations amend the Branded Health Service Medicines (Costs) Regulations 2018 (S.I. 2018/345) (the "2018 Regulations") to update the payment percentages paid by manufacturers and suppliers subject to the statutory scheme for relevant supplies of newer presentations (as defined in 2018 Regulations) ("newer medicines").

4.2 This instrument will amend the 2018 Regulations so that:

a. The percentage payment rate, payable by manufacturers and suppliers subject to the 2018 Regulations, to the Secretary of State, for newer medicines will be adjusted to 16.5% for 2026 and each year thereafter; and

b. Where a manufacturer or supplier has made payments at 24.3% under the 2018 Regulations on their net sales income received for the supply of those newer medicines to the NHS in the first 6 months of 2026 (1 January 2026 to 30 June 2026), they will pay a lower rate of 8.7% for the remainder of 2026 (1 July 2026 to 31 December 2026).

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.

4.4 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the United Kingdom.

5. Policy Context

What is being done and why?

5.1 The costs of branded health service medicines are currently controlled by two schemes, a voluntary scheme known as the 2024 Voluntary Scheme for Branded Medicine Pricing, Access and Growth ("VPAG"), and the 2018 Regulations.

5.2 Any company that supplies licensed branded medicines to the NHS is subject to the 2018 Regulations unless they opt to join VPAG. Both schemes control the cost of branded medicines to the NHS by requiring companies to pay back a set percentage of their net sales income of certain branded medicines (known as the headline payment percentage in VPAG and payment percentage in the statutory scheme) to DHSC.

5.3 Government policy intends that the statutory and voluntary schemes should work together cohesively and in a complementary fashion to create an environment where medicines are supplied at an affordable price, enabling the NHS to continue investing in patients' access to new medicines and non-pharmaceutical services. This is consistent with supporting both the life sciences sector and the broader economy.

5.4 To achieve this, it is DHSC policy to maintain broad commercial equivalence between the statutory and voluntary schemes. Broad commercial equivalence means that government aims to set payment percentages in the statutory scheme that are comparable (but not necessarily identical) to those in the voluntary scheme.

5.5 When the 2018 Regulations were last amended in July 2025, payment percentages for 2025, 2026 and 2027 were set to values calculated to be broadly commercially equivalent to those forecast for VPAG, using the most up to date sales figures available at the time, which were data as of quarter 4 2024. When data up to and including quarter 3 2025 became available, the payment rate calculated for VPAG for 2026 was significantly lower than expected, creating an inconsistency between the equivalent payment percentages in the 2018 Regulations and the VPAG. In order to restore and maintain broad commercial equivalence, a new consultation was carried out proposing to introduce a revised payment percentage for newer medicines for 2026 onwards.

5.6 The payment percentage for newer medicines will therefore be lowered to 16.5% from 1 July 2026. Companies who made statutory scheme payments in the first half of 2026 at the higher rate of 24.3% will instead pay a reduced rate of 8.7% from 1 July 2026 to 31 December 2026, so that these companies pay an average payment percentage of 16.5% over the full year.

5.7 Adjusting the payment percentage to provide broad commercial equivalence with VPAG is expected to support the effective operation of both schemes in controlling the costs of branded medicines. If DHSC does not restore broad commercial equivalence with VPAG, there is a risk that the schemes may not work together effectively to control costs, exacerbating risks to the financial sustainability of the NHS and patient access to medicines. Implementing the change will, however, lead to a reduction in income to DHSC from payments. These risks are considered manageable because restoring broad commercial equivalence between the schemes is expected to support the control of NHS expenditure on branded medicines overall, thereby helping to maintain the financial stability of the NHS and supporting continued patient access to medicines.

5.8 At present, the statutory scheme applies to around 2% of branded medicine sales, resulting in £51 million in payments to DHSC in 2024 (excluding top-up payments for

older medicines). However, the statutory scheme provides an alternative for companies who have not consented to be part of VPAG, which led to over £2 billion in payments to DHSC in 2024. The legislation therefore has a significant effect on achieving value for money for the taxpayer and enabling the NHS to continue investing in patients' access to new medicines and non-pharmaceutical services.

What was the previous policy, how is this different?

5.9 The payment percentages for newer medicines, set in July 2025, were 23.4% in 2025, 24.3% in 2026, and 26.0% in 2027. The newer medicines payment percentage from 1 July 2026 will be lowered to 16.5%.

5.10 Companies who made statutory scheme payments in the first half of 2026 at the higher rate of 24.3% will pay a reduced rate of 8.7% from 1 July 2026 to 31 December 2026 so that these companies pay an average payment percentage throughout 2026 of 16.5%.

5.11 The new payment percentage has been calculated using a simplified methodology of setting the statutory scheme rate 1 percentage point above the combined 2026 VPAG headline payment percentage (14.5%) and the investment programme rate (1%). The statutory scheme rate being slightly higher than the VPAG reflects 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. This is a change to the previous methodology, which set the payment percentage rate for the statutory scheme with reference to a baseline adjustment and an allowed growth rate. The choice is informed by precedent from previous years where the differential between VPAG and statutory scheme payment percentages has been at similar levels, including exactly 1% in 2023. The methodology for calculating the statutory scheme payment percentage is a policy decision not reflected in the regulations and is not reflected in this amendment to the regulations.

5.12 The National Health Service Act 2006 ("the 2006 Act") requires the Secretary of State to carry out a consultation before laying a statutory instrument to amend the 2018 Regulations. This has previously been achieved through a full open consultation, using a survey on GOV.UK. The consultation approach for amending the statutory scheme is a policy decision not reflected in the regulations and is not reflected in this amendment to the regulations.

6. Legislative and Legal Context

How has the law changed?

6.1 The Health Service Medical Supplies (Costs) Act ("the 2017 Act") amended the 2006 Act. The amendment clarifies that the Secretary of State can provide for a statutory scheme for a manufacturer or supplier of any health service medicines to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of those medicines.

6.2 The 2018 Regulations then set out how the statutory scheme would operate. The 2017 Act and the 2018 Regulations brought the statutory scheme closer in character to the voluntary scheme for branded medicine pricing arrangements and set an initial scheme payment percentage.

6.3 The 2018 Regulations were amended on 1 January 2019 by the Branded Health Service Medicines (Costs) (Amendment) Regulations 2018 (S.I. 2018/1255). This

updated scheme payment percentages for the years 2019-2021 and subsequent years, updated the scope of products covered, and updated the payment percentage that applied for sales made under extant framework agreements or public contracts.

6.4 The 2018 Regulations were further amended on 1 April 2020 by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2020 (S.I. 2020/258), which updated the payment percentages for the years 2020-2021 and subsequent years.

6.5 The 2018 Regulations were amended again on 1 July 2022 by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2022 (S.I. 2022/593), which updated the payment percentages for the years 2022-2023. Further amendments to the payment percentage for 2023 and 2024 were made by The Branded Health Service Medicine (Costs) (Amendment) Regulations 2023 (S.I. 2023/239) which came into force on 1 April 2023.

6.6 The 2018 Regulations were amended by The Branded Health Service Medicine (Costs) (Amendment) (No. 2) Regulations 2023 (S.I. 2023/1307) which came into force on 1 January 2024. This amendment revised the payment percentages and introduced exemptions for certain health service medicines to be exempt from the payment percentages.

6.7 The 2018 Regulations were amended on 1 January 2025 by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2024 (S.I. 2024/1277), which updated the statutory scheme to introduce a differentiated approach to setting up payment percentages for newer and older medicines. Newer medicine sales would be subject to payment percentages set for 2025, 2026 and 2027, while older medicines would pay a basic payment percentage and an additional payment percentage if they demonstrated less than 35% price decline compared to a reference price. Additionally, the exemption threshold for small companies was increased from £5 million to £6 million.

6.8 The 2018 Regulations were most recently amended on 1 July 2025 by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2025 (S.I 2025/667) which updated the statutory scheme to increase the payment percentages for newer medicines to 23.4% in 2025, 24.3% in 2026 and 26.0% in 2027. Where a payment was payable during the period 1 January 2025 to 30 June 2025 at the lower payment percentage of 15.5%, an uplifted payment percentage of 31.3% applied to payments for the period 1 July 2025 to 31 December 2025. The amendment also introduced revisions to the audit and assurance arrangements for reporting aspects of the 2018 Regulations.

6.9 This amendment updates the 2018 Regulations to decrease the payment percentage for newer medicines to 16.5% from 2026 onwards. Where a payment was payable during the period 1 January 2026 to 30 June 2026 at the higher payment percentage of 24.3%, a reduced payment percentage of 8.7% will apply to payments for the period 1 July 2026 to 31 December 2026.

Why was this approach taken to change the law?

6.10 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 A public consultation was held for 10 weeks from 10 February to 21 April 2026. The consultation set out 4 questions for respondents, covering their views on the

consultation proposals. Questions focused on the new payment percentage, a direct engagement approach to future consultations on changing this percentage to restore broad commercial equivalence, the impact of the proposals and the Secretary of State for Health and Social Care's statutory duties. Engagement was proposed through workshops with industry and patient representatives, rather than through an open consultation survey on GOV.UK. This change of consultation approach does not require a change in the legislation.

7.2 DHSC received 16 responses. A majority of the responses (11) were from pharmaceutical companies and industry representative organisations. A small number of responses were received from public sector organisations and the public.

7.3 The response document was published on the GOV.UK website on 10 June 2026 and can be found at the following link: https://www.gov.uk/government/consultations/proposed-2026-changes-to-the-statutory-scheme-for-branded-medicines-pricing

7.4 Industrial respondents expressed dissatisfaction with the proposals arguing that, despite this being a significant reduction in payment percentage, rebate rates in the UK remain too high and are uncompetitive compared to other countries. They also raised concerns with the direct engagement approach, in particular that it prevented written evidence being submitted.

7.5 DHSC considers the proposed amendments to the statutory scheme payment percentage for new medicines to be necessary to maintain broad commercial equivalence with the VPAG, and the proposed rate is consistent with previous interpretations of broad commercial equivalence. DHSC will also proceed with the proposal for consultation through direct engagement. To address concerns raised by consultation respondents there will be an invitation to present written evidence, which will inform the engagement agenda, and the consultation response.

8. Applicable Guidance

8.1 Existing operational guidance will be updated to reflect the changes to the scheme.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is that the payment percentages will fall to reflect the lower measured sales growth that was identified from the fourth quarter of 2025, compared with the first quarter of 2025. As a result of the total increase in company profits by £2.2m from 2026 to 2028, when compared to the do nothing option, under the best estimate, we expect there to be greater investment in the UK pharmaceuticals industry. This is likely to lead to higher spillovers than under BAU and therefore higher net societal benefits.

9.3 The legislation does not impact small or micro businesses with NHS sales of less than £6 million per annum, who are excluded from the payment percentage mechanism in the statutory scheme, which represents the main likely impact of the proposals on small and micro companies. In terms of the classification of businesses, this exclusion

means that only medium and large businesses are specifically in scope of the proposals.

9.4 The impact on the public sector is through NHS finances. Under the best estimate, a reduction of £8 million in income to the NHS will be produced, compared with the do-nothing counterfactual, meaning a cost to patients. This will come with an associated present value cost, derived from the societal value of the Quality-Adjusted Life Year loss due a reduction in payment rates. This provides a best estimate of overall total net present social cost of £32.5m.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 DHSC keeps the statutory scheme payment percentage under regular review to ensure it continues to meet policy objectives, and the recent consultation is part of this process. If it is determined that the statutory scheme is no longer meeting these objectives, DHSC will consider consultation on further amendments to the 2018 Regulations.

10.2 The instrument does not include a statutory review clause, in line with the requirements of the Small Business, Enterprise and Employment Act 2015. In relation to this, Minister Preet Kaur Gill MP made the following statement:

"It is not appropriate to include a review provision within this instrument because the regulations setting out the statutory scheme for controlling the price of branded health service medicines are routinely reviewed each year to ensure the payment percentages set continue to meet the objectives of the scheme. It would therefore be disproportionate to carry out an additional review".

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023.