EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2025

2025 No. 667

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 Karin Smyth, Minister of State for Health (Secondary Care) at DHSC confirms that this Explanatory Memorandum meets the required standard.

2.2 David Simmons, Director, Supply Resilience (acting 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: dh.brandedmedicines@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 pharmaceutical companies who are members of the statutory scheme for branded medicine pricing and introduce new data assurance requirements for presentation level data returns.

4.2 This amending instrument will update the 2018 Regulations so that:

(a) The headline 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 23.4% for 2025, 24.3% for 2026 and 26.0% for 2027;

(b) Where a manufacturer or supplier has made payments at 15.5% under the 2018 Regulations on their net sales income received for the supply of those medicines to the NHS in the first 6 months of 2025 (1 January 2025 to 30 June 2025), they will pay a higher rate of 31.3% for the remainder of 2025 (1 July 2025 to 31 December 2025); and

(c) In relation to the information contained in presentation reports, manufacturer or supplier must provide a statement that the report has been subject to procedures agreed upon with a qualified independent auditor in accordance with an applicable related service standard, and a report from the auditor produced in accordance with this standard. The timing for the delivery of that

statement and the report is to coincide with the delivery of audited sales reports.

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) 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, in a way 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 January 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 was for the first quarter in 2024. When figures for the second and third quarters became available, the payment rate calculated for VPAG for 2025 was significantly higher 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 revised headline payment percentages for 2025, 2026 and 2027.

5.6 The newer presentation payment percentages that will apply when this instrument comes into force are slightly lower than those consulted on as a result of a recalculation that takes account of sales data to the end of 2024. The overall policy aim of broad commercial equivalence between the two schemes has not changed.

5.7 The newer presentation payment percentage from 1 July 2025 will therefore be increased to 23.4%. Companies who made statutory scheme payments in the first half of 2025 at the lower rate of 15.5% will instead pay an uplifted rate of 31.3% from 1 July 2025 to 31 December 2025, so that these companies pay an average payment percentage of 23.4% across the whole year.

5.8 The statutory scheme headline payment percentage for the following years will be increased to 24.3% in 2026, and 26.0% in 2027 (proposed rates were 24.7% in 2026 and 26.4% in 2027).

5.9 The requirement for additional assurance on presentation reports was also consulted on, so as to mirror similar requirements being introduced into VPAG.

5.10 To provide additional assurance for presentation reports, a manufacturer or supplier must provide a statement that the report has been subject to procedures agreed upon with a qualified independent auditor in accordance with an applicable related service standard, and a report from the auditor produced in accordance with this standard.

What was the previous policy, how is this different?

5.11 The headline payment percentages for newer medicines, set in January 2025, were 15.5% in 2025, 17.9% in 2026 and 20.1% in 2027, intended to maintain broad commercial equivalence with VPAG. They are now 23.4% in 2025, 24.3% in 2026 and 26.0% in 2027. Companies who made statutory scheme payments in the first half of 2025 at the lower rate of 15.5% now pay the uplifted rate of 31.3% from 1 July 2025 to 31 December 2025, so that these companies pay an average payment percentage throughout 2025 of 23.4%.

5.12 To reach the proposed headline payment percentages, adjustments to the baseline will be made. Previous baseline adjustments were set at £150 million in 2025, £330 million in 2026, and £380 million in 2027. To achieve the updated headline payment percentages, two-thirds of the 2025 adjustment is now delayed to 2026 giving new values of £50 million in 2025, £430 million in 2026 and £380 million in 2027.

5.13 The importance of the information provided in presentation reports has increased under the statutory scheme. As a result, DHSC requires additional assurance of the accuracy of presentation reports in accordance with the applicable related services standard by a qualified independent accountant auditor. The required statement and copy of the relevant assurance document is to be provided to DHSC at the same time as the audit of the Annual Sales report.

5.14 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.

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 amended 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 again amended 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) 2023 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 (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 most recently 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 headline 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 This amendment updates the 2018 Regulations to increase the headline 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 headline payment percentage of 31.3% will apply to payments for the period 1 July 2025 to 31 December 2025.

6.9 This amendment also introduces a requirement for manufacturers and suppliers to carry out additional assurance procedures on their presentation reports. This requires such reports to be subject to a degree of scrutiny by a qualified independent auditor as agreed with the relevant manufacturer and supplier in accordance with a recognised standard, such as *the International Standard on Related Services (ISRS) 4400 (Revised)* published by the International Auditing and Assurance Standards Board and recognised by the Financial Reporting Council in the *International Standard on Quality Management (UK) 1*. Manufacturers and suppliers will also be required to provide a statement confirming the presentation report has been subject to an assurance procedure in accordance with the appropriate standard and a copy of the report produced by the qualified independent auditor to the Secretary of State.

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 6 weeks from 14 March to 25 April 2025. The consultation set out 6 questions for respondents, covering their views on the

consultation proposals. Questions focused on the level of allowed growth, the proposed new headline payment levels for newer medicines, the methodology for their calculation and the additional reassurance requirements.

7.2 DHSC received 23 responses. Most of the responses 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 2025 and can be found at the following link: https://www.gov.uk/government/consultations/proposed-review-of-the-statutory-scheme-for-branded-medicines-pricing

7.4 Responses from industry generally expressed dissatisfaction with both voluntary and statutory schemes and disagreed with the proposal to increase statutory scheme rates. Respondents emphasised that the ongoing VPAG review should lead to a mutually beneficial settlement for the Government and industry, moving away from high rates in both schemes. Most respondents were supportive of the proposal to introduce new data assurance requirements for presentation level data returns.

7.5 DHSC considers the proposed amendments to the statutory scheme to be necessary to maintain broad commercial equivalence, notwithstanding the ongoing VPAG review. Given the extended timeline required for implementation of these updates, these should be enacted as soon as possible to maintain broad commercial equivalence between the schemes within 2025, the rate for which in VPAG is not expected to be subject to change through the VPAG review. Rates set for the statutory scheme in 2026 and 2027 are therefore not to be considered indicative of the outcome of the VPAG review. Any change agreed to VPAG in these years would be considered in future consultations proposing to amend the statutory scheme.

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 rise to reflect the greater measured sales growth that was identified from the third quarter of 2024, compared with the first quarter of 2024. Compared with the counterfactual of doing nothing, as a result of the total fall in company profits by £31m from 2025 to 2027 under the best estimate, we expect there to be lower investment. This is likely to lead to lower spillovers than under BAU and therefore lower 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

has been interpreted to imply that only medium and large businesses are in scope of the proposals.

9.4 The impact on the public sector is through NHS finances. Under the best estimate, £31 million additional income to the NHS will be produced, compared with the do-nothing counterfactual, meaning benefits to patients. However, the consequence of this is £31 million lower profits to pharmaceutical company shareholders. Consequent lower investment could have detrimental consequences to the future pipeline of drugs developed in the UK, which might be detrimental to patients' health outcomes in the UK.

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 and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Karin Smyth 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 ("relevant European Union Acts").