EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2024

2024 No. 1277

1. Introduction

1.1 This Explanatory Memorandum (EM) 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 the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Noah Kidron-Style, Deputy Director for Medicines Pricing at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Eleanor Johnson at the Department of Health and Social Care Telephone: 020 7210 5189 or email: Eleanor.Johnson1@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 "Statutory Scheme Regulations"). The Statutory Scheme Regulations make a scheme requiring specific manufacturers and suppliers of branded medicines for health service use to pay certain amounts to the Secretary of State.

4.2 These Regulations update the payment percentages and introduce a new approach for calculating the amount of the net sales income manufacturers and suppliers subject to the Statutory Scheme Regulations will pay to the Secretary of State based on whether the supplies of the presentations (medicines) are newer or older. Newer medicines will pay a headline payment percentage, while older medicines will pay a basic payment percentage and an additional payment percentage based on the level of price decline of that medicine.

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) ("the 2024 VPAG"), and a statutory scheme, which is set out by the Statutory Scheme Regulations.

5.2 Any company that supplies licensed branded medicines to the NHS is subject to the statutory scheme unless they opt to join the 2024 VPAG. Both schemes control the cost of branded medicines to the NHS by requiring companies to pay back a set percentage of their sales of licensed branded medicines to the NHS to the Department of Health and Social Care.

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, the government aims 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 The 2024 VPAG was negotiated and agreed in 2023 and came into effect on 1 January 2024. In making these changes to the statutory scheme, the government intends to ensure that it is broadly commercially equivalent to the 2024 VPAG.

5.6 Specifically, this means introducing a differentiated approach to setting payment percentages for newer medicines and older medicines in the Statutory Scheme. The headline payment percentage applicable to net sales income from newer medicines will be set at 15.5% in 2025, 17.9% in 2026, and 20.1% in 2027 and for each subsequent calendar year thereafter. This is calculated according to a target level of allowed sales, with allowed growth of this target maintained at 2% per annum, and with a series of one-off adjustments made to the target level of allowed sales in 2025, 2026 and 2027.

5.7 A basic rate of 10.6% in 2025, 11% in 2026 and 10.9% in 2027 and for each calendar year thereafter will be applicable to eligible sales income from older medicines. Additionally, a top up rate of between 1 and 25% will be paid on supplies of older medicines, if applicable, based on the level of observed price decline against a reference price, subject to exemption

5.8 There will be an exemption to the top-up payment percentage for relevant plasma-derived medicinal products, as well as for sales of older medicines with annual measures sales of less than £1.5 million across one Virtual Therapeutic Moiety (VTM) by one scheme member. These exemptions are aligned with the exemptions in the 2024 VPAG.

5.9 The payment percentages referred to above differ to those quoted in the consultation document. This is due to the delay in bringing forward these changes as contemplated in the consultation document as a result of the 2024 general election and the Q1 2024 data becoming available (leading to revisions in forecasts for newer medicines and parallel imports). Additionally, these figures extend to 2027 to reflect scheme implementation from Q1 2025, rather than Q3 2024 as originally intended. The policy intent has not changed from that set out in the consultation document. More

information on these changes can be found in Annex G of the Impact Assessment that accompanied the Consultation Response document.

5.10 The threshold for an exemption from scheme payments for small companies will be uprated from companies with sales of less than £5 million to companies with sales of less than £6 million.

What was the previous policy, how is this different?

5.11 Previously, the Statutory Scheme Regulations did not distinguish medicines as being newer or older medicines and applied a single payment percentage to all supplies of medicines within the scope of the scheme. Small companies with sales of less than £5 million were exempt from making scheme payments.

5.12 Now, newer medicines pay a headline payment percentage, and older medicines pay a basic payment percentage plus an additional 'top-up' payment percentage if they have demonstrated less than 35% price decline compared to a reference price, which establishes a pre-loss of exclusivity benchmark against which price decline is measured. The threshold for the small company exemption is now £6 million. This, in conjunction with the continuation of certain exemptions and introduction of certain exemptions to the top-up payment, aims to ensure the scheme is broadly commercially equivalent to the 2024 VPAG.

6. Legislative and Legal Context

How has the law changed?

6.1 These Regulations update the statutory scheme to introduce a differentiated approach to setting payment percentages for newer and older medicines. Under the previous regulations, both newer and older medicines would have same the payment percentages applied to them under the scheme.

6.2 As a result of the amendments made by these regulations, newer medicines will be subject to a headline payment percentage set at 15.5% in 2025, 17.9% in 2026 and 20.1% in 2027. Older medicines will be subject to a basic payment percentage, and an additional payment percentage if they have demonstrated less than 35% price decline compared to a reference price. The Regulations also increase the exemption for small companies from covering companies with sales of less than £5 million to covering companies with sales of less than £6 million.

Why was this approach taken to change the law?

6.3 This is the only possible approach to make the necessary changes to achieve the policy intent of broad commercial equivalence with the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG).

7. Consultation

Summary of consultation outcome and methodology

7.1 A public consultation was held for 6 weeks from 18 March to 24 April 2024. The consultation document set out 14 questions for respondents covering their views on the consultation proposals. The majority of questions focused on the introduction of a differentiated approach to setting payment percentages for newer and older medicines.

7.2 DHSC received 30 responses to the consultation. Most of the responses were from pharmaceutical companies and industry representative organisations. A small number of responses were received from organisations representing patients and the public.

Publication of the Government response to the matters raised in the consultation was delayed following the announcement of a General Election.

7.3 The response document was published on the gov.uk website on 18 October 2024 and can be found here: https://www.gov.uk/government/consultations/proposed-update-to-the-statutory-scheme-to-control-the-cost-of-branded-health-service-medicines.

7.4 In summary, responses demonstrated continued support for the principle of maintaining broad commercial equivalence between the statutory scheme and the voluntary scheme.

7.5 Responses criticised retaining the allowed growth rate at 2%, arguing that this was below the rate of inflation, the growth in the NHS budget, and the growth in the life sciences sector, as well as it being inappropriate because of demographic changes such as an ageing population. Responses believed this allowed growth rate would lead to payment percentages which were not internationally competitive and discourage investment in the UK life sciences industry and lead to supply issues for some medicines.

7.6 Responses criticised the proposed definitions of newer and older medicines and argued that using the Supplementary Protection Certificate as the sole measure of intellectual property and ignoring other valid measures of intellectual property would risk undermining the UK's system of intellectual property protection.

7.7 Some responses called for a reconciliation system, similar to that which exists in the 2024 VPAG, to account for underpayments or overpayments due to actuals differing from forecasts used to set payment percentages.

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 EM on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The Net Present Social Value (NPSV) of this legislation is negative, due to the legislation lowering payment percentages on firms compared with retaining the previous legislation. More information on how society is estimated to benefit from greater firm profits can be found in Annex B and Annex C of the Impact Assessment. More information on how the benefit of greater revenue to the NHS is assessed can be found in Annex D of the Impact Assessment.

9.3 The legislation does not impact small or micro businesses because businesses with NHS sales of less than £6 million per annum 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. Income to the NHS of around £164 million to £183 million is forecast to be generated over the three-year

appraisal period. This equates to a reduction in income for the NHS of between £34 million and £49 million over the three-year appraisal period compared to the counterfactual of retaining the previous legislation.

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 the policy objectives of the scheme, 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 Minister Smyth MP has 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").