EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) (NO. 2) REGULATIONS 2023

2023 No. 1307

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 The costs of branded health service medicines are currently controlled by two schemes, a voluntary scheme known as the 2019 Voluntary Scheme for Branded Medicine Pricing and Access (VPAS) ("the 2019 VPAS"), and a statutory scheme, which is set out by the Branded Health Service Medicines (Costs) Regulations 2018 ("the 2018 Regulations") ("the statutory scheme").

2.2 This instrument updates the level of payments made to the Department of Health and Social Care by pharmaceutical companies who are members of the statutory scheme for branded medicine pricing (which is set out in the Branded Health Service Medicines (Costs) Regulations 2018) relating to their net sales of licensed branded medicines to the NHS. It also provides for additional exemptions from scheme payments on certain types of medicine sales.

2.3 Any company that supplies licensed branded medicines to the NHS is subject to the statutory scheme unless they opt to join the voluntary scheme. 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; this is known as the "payment percentage".

2.4 Where a voluntary scheme is in effect, the statutory scheme acts as an alternative and safeguard to commitments made under the voluntary scheme. In the event no voluntary scheme is in effect, the statutory scheme is intended to function as a standalone scheme to control the cost of medicines to the NHS and provide a framework for patients' access to those medicines.

2.5 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. To achieve this, the government aims to maintain broad commercial equivalence between the statutory and voluntary schemes.

2.6 The overarching objectives of the statutory scheme are: (1) to limit the growth in costs of branded health services medicines to safeguard the financial position of the NHS; (2) to ensure medicines are available on reasonable terms accounting for the costs of research and development; and (3) to deliver the first two objectives in a way that is consistent with supporting both the life sciences sector and broader economy.

2.7 The current voluntary scheme, the 2019 VPAS expires at the end of 2023. A successor voluntary scheme, to be known as the 2024 Voluntary Scheme for Branded Medicines Pricing, Access, and Growth ("VPAG") is intended to commence from the start of 2024. In making these changes to the statutory scheme, the government intends to set out a statutory scheme that can continue to meet its objectives from 2024 onwards whether this is alongside the 2024 VPAG or as a standalone scheme.

2.8 This statutory instrument specifically amends the 2018 Regulations so that the statutory scheme:

a) requires certain manufacturers and suppliers of branded health service medicines to pay to the Secretary of State 21.9%, 24.0% and 26.8% of their net sales income received for the supply of those medicines ("scheme payments") in 2024, 2025 and 2026 respectively;

b) provides for an exemption from scheme payments for sales of medicines containing a new active substance (NAS) and their line extensions for 36 months from the date of their first marketing authorisation in the United Kingdom of the NAS medicine;

c) provides for an exemption from scheme payments for sales of centrally procured vaccines (CPV) where certain criteria are met;

d) provides for an exemption from scheme payments for sales of medicines occurring as exceptional central procurements (ECP) where certain criteria are met.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

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

6. Legislative Context

6.1 The National Health Service Act 2006 (NHS Act) as amended by the Health Service Medical Supplies (Costs) Act ("the 2017 Act") includes provision for the Secretary of State to provide in 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 unless that manufacturer or supplier is a member of a voluntary scheme at the relevant time.

6.2 The 2018 Regulations then set out how the statutory scheme operates. The 2017 Act and the 2018 Regulations brought the statutory scheme closer in character to the 2019 VPAS arrangements of the voluntary scheme and set an initial scheme payment percentage.

6.3 The 2018 Regulations were further amended between January 2019 and July 2023 to:

a) update the payment percentages applicable to scheme payments during relevant periods of time; and

b) update the scope of products covered and update the payment percentage that applied for sales made under extant framework agreements or public contracts.

6.4 The purpose of the updates to the payment percentages was to maintain the policy of controlling growth in the cost of branded medicines to the NHS under the statutory scheme to agreed levels and continue to ensure broad commercial equivalence with the voluntary scheme during the relevant period. Broad commercial equivalence means that the government aims to set payment percentages in the statutory scheme that are comparable (but not necessarily identical) to those in the voluntary scheme.

6.5 These Regulations further update the payment percentages for 2024, 2025, 2026 and subsequent years. They also introduce exemptions for NAS, CPV and ECP from scheme payments, which were previously only available to companies who joined a voluntary scheme.

7. Policy background

What is being done and why?

7.1 These Regulations set updated payment percentages in the scheme. The updated payment percentages are calculated on the basis of an allowed growth rate of 2% nominal per annum, higher than that used to set payment percentages in the scheme between 2019 and 2023 (1.1%). The payment percentages have also been calculated on the basis of a starting point from which allowed growth is calculated ("baseline") that reflects the weighted average of allowed growth in both the statutory scheme and the 2019 VPAS since 2019 (1.1% and 2% respectively) in line with their relative proportions of scheme memberships as of this year. The effect is to reduce the payment percentage, and therefore the payment required from industry, when compared to continuing to control growth under the scheme at the current level.

7.2 Increasing the level of allowed growth used to calculate payment percentages from 1.1% to 2% ensures that companies can continue to access a broadly similar commercial environment to that available under the 2019 VPAS for the life sciences sector from 2024.

7.3 Setting payment percentages on the basis of an uprated baseline is to avoid unintended effects from different growth rates being in effect in the voluntary and statutory scheme over the last 5 years. Calculating payment percentages from the existing (lower) baseline in the statutory scheme would result in payment percentages that were set to recoup growth above 1.1% (i.e. the allowed growth between 2019 and 2023) for any companies that move into the statutory scheme, or existing statutory scheme members remaining in the scheme, from 2024. More information on this is contained in the impact assessment.

7.4 These Regulations also introduce exemptions from payment for certain types of sales. The change ensures that companies and patients can continue to benefit from the following exemptions even in the absence of a voluntary scheme:

a) Firstly, the Regulations provide exemption from statutory scheme payments for medicines containing a NAS for 36 months from the date of their first marketing authorisation. The method for determining if a medicine contains a NAS established in the statutory scheme currently (and used in the 2019 VPAS), whereby the Assessment Report produced by the Medicines and Healthcare products Regulation Agency (MHRA) or the European Public Assessment Report confirms the presence of a NAS will continue. Payment percentage for remaining sales in the scheme scaled to keep total net sales growth at 2%.

b) Secondly, the Regulations provide an exemption from scheme payments for sales of CPVs. This exemption would apply to sales of a vaccine that meets all of the following criteria: (1) it is for national immunisation programmes that have been recommended or advised by the Joint Committee on Vaccination and Immunisation (JCVI) (2) it is procured by a Secretary of State, meaning that purchases made by bodies such as Department for Health and Social Care but not the NHS, would meet this criteria (3) the UK Health Security Agency (UKHSA) manages the stockpiling and distribution, referring to the vaccines. The inclusion of this exemption helps to facilitate the supply of vaccines to the UK in the event there is no voluntary scheme.

c) Thirdly, the Regulations provide an exemption from scheme payments for sales of ECPs. This exemption would apply to sales of medicines which meet all of the following criteria: (1) they are procured for the purposes of emergency preparedness, such as national stockpiles for the security of the nation or pandemic preparation (2) it is procured by the Secretary of State (3) the UKHSA manages the stockpiling and distribution. The inclusion of this exemption helps facilitate the procurement of medicines for use in emergencies in the event there is no voluntary scheme.

7.5 These Regulations allow the Secretary of State discretion to disapply the requirement for UKHSA management of CPV and ECP sales. This discretion is intended to facilitate the procurement of ECPs and CPVs where UKHSA lacks the organisational capacity to conduct or manage such stockpiling and/or distribution (such as an emergency situation) and a third party has had to be engaged as a matter of necessity.

Explanations

What did any law do before the changes to be made by this instrument?

7.6 Prior to these Regulations, the statutory scheme provided for a payment percentage of 27.5%, calculated to control growth in the scheme to 1.1% nominal per annum. It also provided a more limited range of exemptions, for sales of pharmacy only (P) and general sales list (GSL) medicines, small companies with under £5 million sales to the NHS each year, sales of low-cost presentations with a list price of less than £2 and parallel imports. The existing exemptions in the statutory scheme are unaffected by the changes.

Why is it being changed?

7.7 Continuing to apply a payment percentage of 27.5% would not reflect the most recent data on branded medicines sales and would continue to reflect the impact of the one-off deferral of industry payments due in 2022 to 2023. It is therefore necessary to update the payment percentage in the scheme so that they continue to be set by reference to medicine sales, and to remove the effect of the one-off deferral of payments which is no longer required.

7.8 Revision of the terms of the statutory scheme is also considered necessary so that companies can continue to access a broadly similar commercial environment and set of exemptions to that available under the 2019 VPAS. Government considers that doing otherwise would risk not fully reflecting the objectives of the statutory scheme.

What will it now do?

7.9 Following the changes, the payment percentages under the scheme will be set to 21.9%, 24.0% and 26.8% in 2024, 2025 and 2026 respectively, as opposed to the current scheme which sets the payment percentage at 27.5% for all future years. The scheme will also incorporate additional exemptions from payment for medicines containing a NAS, and for sales of CPVs and ECPs.

7.10 The Government intends to maintain broad commercial equivalence between the statutory scheme and the 2024 VPAG.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 The amendments presented in this instrument do not consolidate any legislation.

10. Consultation outcome

10.1 A public consultation was held for 12 weeks from 18 July to 10 October 2023. Officials from devolved administrations were consulted in the course of policy development through their involvement in advisory groups overseeing negotiations for a successor voluntary scheme.

10.2 The consultation document set out 17 questions for respondents covering their views on the consultation proposals, including several questions about the proposals for lifecycle adjustment.

10.3 DHSC received 102 responses to the consultation. More than three quarters 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, and from individuals, mostly responding in a professional capacity. This is amongst the highest number of responses to a consultation on the statutory scheme since it was set up in its current form.

10.4 The high level of interest in the consultation is likely to be a reflection of the context in which it took place, that being alongside negotiations for a successor voluntary scheme and the interest in the proposals for lifecycle adjustment.

10.5 There was also strong criticism of the proposed allowed growth rate and resulting payment percentages, and of controlling medicines spending in general. Respondents argued that controlling growth in sales at 2% is too low, would damage the UK life sciences sector and signalled that government was not prepared to pay a fair price for medicines. Many stated that this would, in turn, negatively impact the launch of medicines and deter investment in the UK, and argued this effect had been underestimated by the impact assessment of the proposals.

10.6 There was strong support in principle for maintaining broad commercial equivalence between the statutory scheme and any voluntary scheme agreed, though many respondents stated their support for this principle was conditional on the terms of any voluntary scheme agreed.

10.7 On exemptions, respondents were generally supportive of the proposed exemptions for medicines containing a NAS, CPVs and ECPs. However, many argued that more generous or further exemptions were necessary.

10.8 Most respondents welcomed clarification of the status of unbranded biological medicines.

10.9 The Government has considered the responses to the consultation and the additional evidence provided. Following this consideration, the Government has decided to proceed to implement the proposals to increase the level of allowed growth in the scheme and to uprate the baseline from which allowed growth is controlled, and to introduce exemptions for medicines containing a NAS for 36 months after marketing authorisation, ECPs and CPVs into the statutory scheme. The Government also considers that it is appropriate to maintain the policy of broad equivalence with any voluntary scheme agreed.

10.10 Government does not consider there is a case to increase the rate of allowed growth used to set payment percentages in the statutory scheme beyond the rate consulted on as this is equal to the current maximum allowed growth rate of any scheme to date and represents an 80% rise in allowed growth compared to the current 1.1% per annum which has applied in the statutory scheme from 2019 to 2023. Controlling growth at this level results in a more favourable scheme for industry compared to the existing statutory scheme arrangements, whilst continuing to ensure that spend on branded medicines is affordable to the NHS.

10.11 The proposals for lifecycle adjustment received significant criticism in the consultation. Respondents raised concerns about the proposals on principled and practical grounds, though some respondents indicated support for the lifecycle adjustment in principle while expressing reservations about the specific proposals. The Government has decided not to implement the proposals for a lifecycle adjustment in the statutory scheme at this time. However, Government remains committed to the principle of ensuring sustainable spending on older medicines and is open to the future implementation within the statutory scheme and of policies designed to achieve similar objectives to the lifecycle adjustment – including those required to maintain broad commercial equivalence with any future voluntary scheme.

10.12 A detailed analysis of the consultation outcome and the government's response is available on the Department of Health and Social Care website[1].

11. Guidance

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

12. Impact

12.1 The impact on business, charities or voluntary bodies will depend on the proportion of current scheme members who choose to join the 2024 VPAG, since this will have a material impact on membership of the statutory scheme.

12.2 Were the statutory scheme to be the only scheme from 2024 all companies who are currently members of the 2019 VPAS would become members of the statutory scheme. When compared to continuing with the scheme unchanged, under such an outcome the main impact on business, charities or voluntary bodies is likely to be an increase in pharmaceutical companies' profits estimated at between £5,080m and £5,930m, of which £510m to £590m may accrue to UK shareholders by 2026. Theoretically, this could increase global pharmaceutical investment, such as research and development, a proportion of which may take place in the UK. However, in this case the changes would maintain similar commercial terms to the 2019 VPAS, which applies to the vast majority of pharmaceutical companies until the end of 2023. For this reason, spill-over benefits from any additional research and development investments as a result of these changes have not been quantified.

12.3 The impact on the public sector is that the policy is expected to have a net negative net present value (NPV) of between £22,260m and £25,980m as a result of reduced revenues, equating to between 338,460 and 395,470 fewer quality-adjusted life years (QALYs)[2] by 2026, compared to the counterfactual in which no change is made. However, when measured against the 2019 VPAS, the scheme that currently applies to the vast majority of pharmaceutical companies, these proposals will not result in any increase in the cost of medicines to the NHS or loss of QALYs. Moreover, patients will benefit from a scheme that sets payment rates to achieve predictable and sustainable growth in net sales of medicines so as to support ongoing access to cost-effective medicines.

12.4 Were the statutory scheme to operate alongside a new a voluntary scheme from 2024, we would expect to see the size of these impacts reduced significantly. This is because a large proportion of the membership of the statutory scheme would be expected to join a future voluntary scheme, reducing the proportion of sales and payments made under the statutory scheme.

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

[1] https://www.gov.uk/government/consultations/review-of-the-scheme-to-control-the-cost-of-branded-health-service-medicines/proposed-review-of-the-2023-scheme-to-control-the-cost-of-branded-health-service-medicines

[2] A QALY is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 To minimise the impact on such businesses, companies with qualifying sales or estimated sales of branded health service medicines of less than £5m, are not required to make payments and are subject to different reporting requirements. The regulations do not change the existing arrangements in the statutory scheme that minimise the impact of the scheme on, or are for the benefit of, small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is as follows: the 2018 Regulations required that a review was carried out within 12 months of them taking effect in 2018. This review was published in 2019. 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.

14.2 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 Andrew Stephenson 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. The Department will consider the operation of the additional exemptions as part of such reviews in future. It would therefore be disproportionate to carry out an additional review."

15. Contact

15.1 Simon Roer at the Department of Health and Social Care Telephone: 0207 972 1538 or email: simon.roer@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Stephen Hennigan, Deputy Director for Medicines Pricing at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Andrew Stephenson, Minister of State for Health and Secondary Care, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.