EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2023

2023 No. 239

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 This statutory instrument updates the payment percentage paid 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 (the "2018 Regulations") (known as the "Statutory Scheme"). These amendment Regulations update the 2018 Regulations so that:

- certain manufacturers and suppliers of branded health service medicines pay to the Secretary of State 27.5% of their 2023 net sales income received for the supply of those medicines to the NHS; and
- manufacturers and suppliers who have made payments at 24.4% under the 2018 Regulations on their net sales income received for the supply of those medicines to the NHS (during the period of 1 January 2023 to 31 March 2023), will pay 28.6% for the remainder of 2023 (1 April 2023 to 31 December 2023).

2.2 The change is a routine update to the payment percentage for the purpose of controlling growth within the Statutory Scheme at agreed levels and to maintain the Government's existing policy of ensuring broad commercial equivalence with the 2019 voluntary scheme for branded medicines pricing and access ("VPAS"), following the December 2022 publication of the VPAS payment percentage for 2023. This is intended to ensure NHS spending on branded medicines remains affordable in a way that is consistent with supporting the life sciences sector.

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 the 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 Health Service Medical Supplies (Costs) Act (the "2017 Act") amended the National Health Service Act 2006 (the "NHS Act") to clarify that the Secretary of State can 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.

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 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 (SI 2018/1255) which 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 (SI 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 (SI 2022/593), which updated the payment percentages for 2022, 2023 and subsequent years.

6.6 These regulations further amend the 2018 Regulations to update the payment percentage for 2023 and subsequent years, for the purpose of maintaining the current policy of controlling growth in the Statutory Scheme to agreed levels and maintaining broad commercial equivalence with VPAS.

7. Policy background

What is being done and why?

7.1 The Statutory Scheme is one of two schemes that control the prices of branded medicines to the NHS (the other scheme being VPAS). The Statutory Scheme was established in its current form in 2018 when, following consultation, it changed from operating as a price cut scheme to a payment scheme.

7.2 Any company that supplies licensed branded medicines to the NHS is subject to the Statutory Scheme unless they opt to join VPAS. Companies may move between the two schemes at the start of each year, provided they have given notice in line with scheme rules. The majority of companies supplying branded medicines to the NHS opted to join or remain in VPAS in 2023.

7.3 It is intended that both schemes work together 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 this end, the Government aims to maintain broad commercial equivalence between the two schemes.

7.4 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.

7.5 Since it took its current form in 2018, the allowed growth rate for the cost of medicine expenditure in the NHS for medicines subject to payments in the Statutory Scheme has been 1.1% per year (this is a nominal rate unadjusted for inflation). Sales growth is controlled through the application of a payment percentage, a percentage of eligible sales that manufacturers and suppliers subject to the Statutory Scheme pay back to the NHS.

7.6 Unlike VPAS, the payment percentage in the Statutory Scheme does not automatically adjust in response to observed growth. This means that Statutory Scheme payment percentages may need to be changed to keep them broadly equivalent with those in VPAS. Payment percentages are set in regulations at the level calculated to keep growth within the allowed level each year.

7.7 The payment percentage was last updated in 2022, following public consultation. In that update the payment percentage for 2022 was increased from 10.9% to 14.3% and the payment percentage in 2023 and subsequent years was set to 24.4%. The schemes work on a calendar year basis and, as the change was introduced partway through 2022, companies who had already made Statutory Scheme payments in Q1 and Q2 of 2022 at the lower rate of 10.9%, paid at an increased rate of 17.7% for the rest of 2022, so that these companies paid an average payment percentage of 14.3% across the whole year.

7.8 Continued high sales growth in 2022 has led to an increase in the payment percentage in VPAS from 15% in 2022 to 26.5% in 2023, which is higher than was projected at the time of the 2022 Statutory Scheme consultation. As a result, at a payment percentage of 24.4% the Statutory Scheme would not be broadly commercially equivalent with VPAS in 2023. A 2023 Statutory Scheme payment percentage of 24.4% is also lower than required to control growth in the Statutory Scheme at 1.1%.

7.9 As a result of this amendment, the payment percentage in the Statutory Scheme will be set for 2023 at 27.5%, a rate calculated to continue to control annual sales growth in the Statutory Scheme to 1.1%. As the updated payment percentage for 2023 does not take effect until 1 April 2023, we have set an adjusted payment percentage of 28.6% for any company that has made a payment in the first quarter of 2023 at the lower rate of 24.4%. This is intended to give an overall average payment percentage equivalent to 27.5% for all scheme members in 2023 regardless of when sales took place. The adjustment ensures that companies who made sales in the first quarter of 2023 do not have an unfair advantage over those who only made sales in the remaining three quarters of the year as a result of the lower payment percentage in place between 1 January and 31 March 2023.

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 need consolidation at present.

10. Consultation outcome

10.1 A public consultation was held for a period of 39 days between December 2022 and January 2023.

10.2 The consultation document set out five questions for respondents including whether they agreed with the reasons for updating the payment percentage; the proposed level of the payment percentage; the methodology for calculating the proposed payment percentage; the assessment of the impact of these Regulations, and the assessment of the impact of these Regulations specifically on the relevant statutory duties (which considered the Secretary of State's duties under the NHS Act 2006, the Public Sector Equalities Duties and the Family Test).

10.3 The Department received 33 responses to the consultation. Of these, 3 were from trade associations representing the pharmaceutical industry, 28 were from pharmaceutical companies and 2 from individuals. This is an increase compared to the consultation that was conducted in relation to the 2022 payment percentage amendment which received 18 responses. It is likely this rise in the number of responses reflects a stronger level of interest in the consultation from industry in advance of negotiations for a new voluntary scheme to succeed VPAS, which expires at the end of 2023.

10.4 Most of the respondents (30) to the consultation disagreed with the proposal to update the payment percentages in the scheme. Most responses were broad in scope and expressed dissatisfaction with the level of the payment percentages in VPAS as well as the Statutory Scheme.

10.5 Several respondents argued that increased payment percentages in both VPAS and the Statutory Scheme in 2023 would make it uneconomical for companies to supply or launch certain medicines in the UK, and that increased payments would lead to reduced investment in the life sciences sector in the UK. Respondents argued further that the 'signalling' effect of the change would negatively affect sentiment towards the UK by the pharmaceutical industry, and this would result in impacts on investment over and above those estimated by the Department's Impact Assessment. Several respondents also argued that the change would make an already challenging commercial environment for medicines in the UK more difficult, and that the UK would therefore not achieve the goals set out in the Life Sciences Vision or the objectives of the Statutory Scheme as they relate to the life sciences sector.

10.6 The Department has considered the responses and the further evidence provided by the respondents and did not conclude that this justified a change in policy, given the risks in failing to maintain broad equivalence with VPAS and the benefits of the policy. Most companies chose to join VPAS in 2023 and so are unaffected by this change. The Department has also established mitigations in both schemes so that the supply of medicines remains economically viable for industry in changing market conditions. Companies who joined VPAS also benefit from exemptions that provide a strong incentive for the launch of new products.

10.7 Regarding investment, while consultation respondents argued that the Department's Impact Assessment underestimated the impact of the change on investment, the Department's view remains the same as that given in previous consultations, that supply side factors, such as having a skilled scientific workforce, rather than local pricing policies on final products, are of greatest significance in decisions about the location of research and development activity. The Department acknowledges there remains uncertainty in the evidence on this issue and has considered additional

evidence and analysis in its Impact Assessment, but does not consider there is sufficient evidence to support a change in policy.

10.8 A detailed analysis of how the Department considered the consultation responses is available at https://www.gov.uk/government/consultations/proposed-update-to-the-2023-statutory-scheme-to-control-the-costs-of-branded-health-service-medicines.

11. Guidance

11.1 The current Operational Guidance will be amended and made available to companies to enable them to understand the requirements of the scheme. DHSC will continue to retain the operational platform used to administer the current Statutory Scheme.

12. Impact

12.1 The impact on business, charities or voluntary bodies is specific to the pharmaceutical industry: pharmaceuticals companies who are members of the schemes will make payments at the correct level in line with the policy objectives of the scheme. Government continues to support these objectives of the scheme, but higher than projected growth in medicines sales means that the current payment percentage in the Statutory Scheme is now too low to maintain broad commercial equivalence with VPAS or control growth at 1.1%.

12.2 Maintaining broad commercial equivalence with VPAS provides certainty for industry about the basis on which the schemes are run. It also ensures that companies who chose to join VPAS for 2023 are not unfairly disadvantaged as a result of Government failing to uphold its stated policy in respect of the schemes.

12.3 To ensure the objectives of the scheme continue to be met and broad commercial equivalence maintained in 2023, the payment percentage in the Statutory Scheme needs to be increased. This will reduce revenues for the small number of pharmaceutical companies who are members of the scheme in 2023 compared to not making any change. This may have some impacts on areas such as research and development investment, a proportion of which may be felt in the UK. While some consultation respondents believed that the Department had underestimated the 'signalling effect' of this change on such investment, the Department's view is that direct communications to industry about a successor voluntary scheme is likely to have a greater influence on sentiment toward the UK. For these reasons, no disproportionate negative impacts are expected from amending the payment percentages in these amendment Regulations, which will ensure that companies in the scheme continue to make payments at a level that is appropriate to the objectives of the scheme.

12.4 The impact on the public sector is that more income will be recovered for the NHS than would have been received had no change been made, providing increased funding for additional NHS treatments and services, estimated to be between £17m and £19m.

12.5 By making changes to the payment percentages, the Government is also ensuring good operation of the Statutory Scheme, so that the NHS continues to receive payments from companies while growth in sales under the scheme is controlled at 1.1% per year. This means the NHS will continue to use the funds realised in the best interest of patients.

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

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses. To minimise the impact on such businesses. Companies with qualifying sales of branded health service medicines of less than £5m, are not required to make payments and are subject to different reporting requirements.

14. Monitoring & review

14.1 The Department keeps the Statutory Scheme payment percentage under regular review to ensure it continues to meet the policy objectives of the scheme. If it is determined that the Statutory Scheme is no longer meeting these objectives the Department will consider consultation on further amendments to the Regulations.

14.2 Further consultation is likely be held following a wider review of the policy and operation of the Statutory Scheme to coincide with discussions on the successor to VPAS, which expires at the end of 2023.

15. Contact

15.1 Simon Roer at the Department of Health and Social Care Telephone: 0207 972 153 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 has confirmed that this Explanatory Memorandum meets the required standard.

15.3 Will Quince, 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.