EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2022

2022 No. 593

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 Her Majesty.

2. Purpose of the instrument

2.1 This statutory instrument updates the payment percentages 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'). This amending instrument will update the 2018 Regulations so that:

a) certain manufacturers and suppliers of branded health service medicines pay to the Secretary of State 14.3%, in 2022 and 24.4%, in to 2023 of their net sales income received for the supply of those medicines to the NHS; and

b) where manufacturers and suppliers who have made payments at 10.9% 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 2022 (1 January 2022 to 30 June 2022), these manufacturers and suppliers will pay 17.7% for the remainder of 2022 (1 July 2022 to 31 December 2022).

2.2 The change is a routine update to control growth within the scheme at agreed levels and to maintain the Government's existing policy of ensuring broad commercial equivalence with the voluntary scheme for branded medicines pricing and access ('VPAS'), following the January 2022 update to the VPAS payment percentage. 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 territorial extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

5.1 As this 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 (NHS 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 VPAS 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). S.I. 2018/1255updated 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 These 2022 amendment Regulations further amend the 2018 Regulations to update the payment percentages for the years 2022-2023 and subsequent years, to maintain current policy of controlling growth in the 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, alongside VPAS, that control the prices of branded medicines to the NHS. It was established in its current form in 2018 when, following a consultation, it changed from operating as a price cut scheme to operating as 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.

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 in the Statutory Scheme has been 1.1% (nominal) per year. Sales growth is controlled through the application

of a payment percentage, a percentage of their eligible sales that companies 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 percentages were last updated in 2020, following public consultation. In those updates the payment percentage for 2020 was decreased from 14.7% to 7.4% and the payment percentage in 2021 and subsequent years was decreased from 20.5% to 10.9%. The schemes work on a calendar year basis and, as the change was introduced partway through the year, companies who had already made Statutory Scheme payments in Q1 of 2020 at the higher rate of 14.7%, paid at a lower rate of 5% for the rest of 2020, so that these companies paid an average payment percentage of 10.9% across the whole year.

7.8 Higher than expected growth in sales of medicines under the Statutory Scheme has meant that the 10.9% payment percentage set in 2020 is now lower than required to control growth at 1.1% in 2022 and 2023.

7.9 High sales growth in 2021 also led to an increase in the calculated payment percentage in VPAS from 5.1% in 2021 to 19.1% in 2022, although this was reduced by 4.1 percentage points by an agreed scheme amendment. The VPAS payment percentage for 2023 is currently projected to increase further to 23.7%, in part because of the deferral from 2022 to 2023 of the income forgone as result of the 4.1 percentage point reduction in the 2022 payment percentage.

7.10 As a result, at the pre-amendment payment percentage of 10.9%, the Statutory Scheme would not be broadly commercially equivalent with VPAS. The Statutory Scheme payment percentage would be meaningfully lower than VPAS in 2022 and likely substantially lower than VPAS in 2023.

7.11 The payment percentages will be set for 2022 and 2023 at 14.3% and 24.4% respectively. As the payment percentage for 2022 does not take effect until 1 July 2022, we have set an adjusted payment percentage (17.7%) for any company that has made a payment in the first half of the year at the lower rate. This is intended to give an overall average payment percentage equivalent to 14.3% for all scheme members in 2022 regardless of when sales took place. The adjustment ensures that companies who made sales in the first half of the year do not have an unfair advantage over those who only made sales in the second half of the year as a result of the lower payment percentage in place between 1 January and 30 June 2022.

7.12 These payment percentages have been calculated to control allowed growth in the Government spend on branded health service medicines in the Statutory Scheme to 1.1% each year. To maintain broad commercial equivalence with VPAS, the calculated Statutory Scheme payment percentage for 2022 was adjusted downwards by 4.1 percentage points, which was accounted for in the calculation of the 2023 payment percentage, so that forgone revenue is in effect deferred from 2022 to 2023 as with VPAS. Without this adjustment, the 2022 and 2023 Statutory Scheme payment percentages would have been set at 18.4% and 20.6% respectively.

7.13 In making this adjustment, the Government's intention is to maintain the broad equivalence between the two schemes, preventing companies who are members of

VPAS from benefitting from the 4.1 percentage point decrease in 2022 by moving to the Statutory Scheme in order to avoid payment of the consequent increase in 2023, resulting in substantial lost revenue for the NHS. This will assist in ensuring the continued affordability of medicines on reasonable terms, supporting the Statutory Scheme objectives in relation to affordability of medicines to the NHS.

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 a period of six weeks between March and April 2022. Although this update is virtually identical in scope to that made in 2020, a longer consultation period (six weeks) than the previous update (four weeks) was chosen to give interested parties additional time to respond.

10.2 The consultation document set out five questions for respondents including whether they agree with:

- our reasons for updating the payment percentages;
- the proposed level of the payment percentages;
- our methodology for calculating the proposed payment percentages;
- our assessment of the impact of this instrument generally; and
- our assessment of the impact of this instrument specifically on the 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 DHSC received 18 responses to the consultation. Of these responses, 8 were from pharmaceutical companies, three from pharmaceutical sector organisations and one from an organisation representing patients, the public or carers. The remaining responses were from individuals sharing personal or professional views. This is fewer than comparable consultations in 2018 and 2020, potentially because most companies were content to allow the industry position to be put forward by the three main UK trade associations that represent scheme member companies.

10.4 Most of the respondents (15) disagreed with the proposal to update the payment percentages. However, respondents, including those who disagreed with the proposal, were largely supportive of the principle of maintaining broad commercial equivalence between VPAS and the Statutory Scheme. Respondents proposed that the setting of the 2023 payment percentages in the Statutory Scheme be delayed while there was still 'uncertainty' about what the equivalent rate in VPAS would be. Industry also argued that the increase in payments could impact on the supply of medicine to, and on research and development investment in, the UK.

10.5 DHSC has considered the responses and any further evidence provided by the respondents but did not conclude there was evidence to justify a change to the consultation proposals given the substantial modelled benefit of this policy. It is standard practice for DHSC to use the best available projection to set payment

percentages for multiple years and commitments in the consultation minimise any remaining uncertainty and its impact. DHSC also has well established and effective processes to ensure the supply of medicines remains economically viable for industry in changing market conditions. Finally, the evidence presented in the consultation continues to indicate that supply side factors, such as availability of expert scientific labour, and not local pricing policies on final products, are of greatest significance in decisions about the location of research and development activity, though DHSC acknowledges that there is uncertainty in the available evidence.

10.6 A detailed analysis of how DHSC considered the consultation responses is available at https://www.gov.uk/government/consultations/update-to-the-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: pharmaceutical companies who are members of the schemes will make payments at the correct level in line with the policy objectives of the scheme. The 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 commercial equivalence with VPAS or control growth at 1.1%.

12.2 To ensure the objectives of the scheme continue to be met in 2022 and 2023, the payment percentage need to rise. This will reduce revenues for pharmaceutical companies in 2022 and 2023 compared to not making any change, which may have some impacts on areas such as research and development investment, a proportion of which may be felt in the UK. However, no disproportionate negative impacts are expected from amending the payment percentages in this amending instrument , which will ensure that companies in the scheme continue to make payments at a level that is appropriate to the objectives of the scheme.

12.3 The impact on the public sector is that substantially 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 £980m and £1,500m.

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

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

13. Regulating small business

13.1 This instrument 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.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is as follows: the 2018 Regulations require that an annual review is carried out within 12 months of them taking effect in 2018. This review was published in 2019. The 2018 Regulations do not require a further annual review and DHSC does not deem one to be necessary at this point: further consultation is likely be held representing 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.

14.2 However, DHSC 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 DHSC will consider consultation on further amendments to the 2018 Regulations.

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 can confirm that this explanatory memorandum meets the required standard.

15.3 The Secretary of State, Sajid Javid at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.