EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2020

2020 No. 258

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 Her Majesty.

2. Purpose of the instrument

2.1 The Department controls the costs of branded health service medicines to the NHS through the 2019 Voluntary Scheme for Branded Health Service Medicine Pricing and Access (2019VS) and the Statutory Scheme. The Statutory Scheme is set out in the Branded Health Service Medicines (Costs) Regulations 2018 (2018 Regulations).

2.2 The 2019VS was agreed between the Department, NHS England, and the branded pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI). The 2019VS began on 1 January 2019 and will run until the end of 2023.

2.3 All pharmaceutical companies selling branded medicines to the NHS are automatically subject to the 2018 Regulations unless they opt to join the 2019VS.

2.4 These amendment Regulations will update the 2018 Regulations so that:

a) certain manufacturers and suppliers of branded health service medicines pay to the Secretary of State 7.4% in 2020 and 10.9% in 2021 of their net sales income received for the supply of those medicines to the NHS;

b) where manufacturers and suppliers have made payments at 14.7% under the 2018 Regulations in the first three months of 2020 (1 January 2020 to 31 March 2020), these manufacturers and suppliers will pay 5.0% for the remainder of 2020 (1 April 2020 to 31 December 2020).

2.5 In making these changes, the Government's intention is to support the NHS in providing a high-quality comprehensive health service to patients. These amended payment percentages will help to control allowed growth in the Government spend on branded health service medicines in the Statutory Scheme to 1.1% each year. This will assist in ensuring the continued affordability of medicines on reasonable terms, thereby avoiding potential cost pressures on the NHS of medicines not being available. This in turn will support the objectives of the Statutory Scheme around affordability, ensuring supply and having regard to 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

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is to the United Kingdom.

4.2 The territorial application of this instrument is to 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 (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. 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.

6.2 The 2018 Regulations revoked the previous Statutory Scheme Regulations, including reversing a 15% price cut which had been previously been established to control the costs of branded health service medicines.

6.3 The 2018 Regulations required certain manufacturers and suppliers of branded health service medicines to pay to the Secretary of State 7.8% of their net sales income received from the supply of branded health service medicines.

6.4 The 2018 Regulations were amended on 1 January 2019 by the Branded Health Service Medicines (Costs) (Amendment) Regulations 2018 – SI 2018 1255. These Regulations amended the payment percentages to 9.9% (2019), 14.7% (2020) and 20.5% (2021); included additional medicinal biological products the sales of which would be covered by the Statutory Scheme and changed the application of the payment percentage for sales of medicines supplied under a contract with a contracting authority based on a framework agreement or under a public contract.

6.5 These amendment Regulations amend the 2018 Regulations.

7. Policy background

What is being done and why?

7.1 The Statutory Scheme acts as one of the two mechanisms alongside the 2019VS to control the prices of branded medicines to the NHS. Companies that have opted not to join the 2019VS – a voluntary non-contractual agreement which replaced the previous Pharmaceutical Price Regulation Scheme (PPRS 2014) between Government and industry are automatically covered by the Statutory Scheme. Although there are clear distinctions between these two mechanisms, it is the overarching aim to ensure that

the Statutory Scheme maintains a broad level of commercial equivalence with the voluntary scheme arrangements.

7.2 The Statutory Scheme aims to facilitate an environment where clinically and cost-effective medicines are supplied at an affordable price, in a way consistent with supporting both the life sciences sector (including research and development) and the broader economy. This is achieved through seeking to limit the growth in allowed sales of branded medicines in the Statutory Scheme, which is currently at 1.1% (nominal) per year. Payment percentages, the rate at which companies pay back to the NHS are then set to try to ensure growth is controlled at that level each year.

7.3 In 2018, following consultation, the Department based the payment percentage on the one applied in the PPRS 2014, which was 7.8%. That payment percentage was then set out in the 2018 Regulations.

7.4 Section 29 of the 2018 Regulations provides an obligation to carry out an annual review of the Regulations to assess the extent to which the objectives of the Regulations are being achieved. The Department carried out the first review of the 2018 Regulations in 2019 and stated publicly in them our intention to continue to take into account broad commercial equivalence between the Voluntary and Statutory Schemes when considering amendments to the Regulations.

7.5 Subsequent to this, growth in NHS branded medicines sales for the first three quarters of 2019 was lower than forecast. The 2019VS included a mechanism to revise future payment percentages in line with actual growth, but the Statutory Scheme features fixed payment percentages.

7.6 The payment percentage for the 2019VS for 2020 is 5.9%. this payment percentage was arrived at using formulae set out in the 2019VS document and the financial data companies provide to the Department. To meet the objectives of the Statutory Scheme and ensure broad commercial equivalence with the 2019VS, the current payment percentages set out in the Regulations (14.7% for 2020 and 20.1% in 2021) are no longer appropriate and should be amended.

7.7 These amendment Regulations will set the payment percentages for 2020 and 2021 to 7.4% and 10.9% respectively. The Regulations also take into account the payments that will already have been made in 2020, by those companies that made payments at 14.7% under the 2018 Regulations in the first three months of the year. These companies will have a reduced payment percentage of 5.0% for the rest of the year (in order to achieve an average payment percentage of 7.4% over 2020).

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

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

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 four weeks between January and February 2020. This four-week consultation was considered sufficient as the changes

to the 2018 Regulations consulted on were minimal – changes were only being made to the payment percentages.

10.2 The consultation document set out seven questions for respondents including the impact of the proposed payment percentages; the methodologies used for calculations in the Impact Assessment; and 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 63 responses to the consultation. Of these responses, 9 were from health bodies and patient groups, 9 were from pharmaceutical companies, trade bodies and industry consultants and 45 were from individuals.

10.4 There was a general support for the proposals from respondents. However, some concerns were raised by industry representatives and a limited number of pharmaceutical companies regarding how the proposed payment percentages would be relatively less advantageous for some companies who have extant framework agreements or public contracts. Other industry concerns, which were not specific to the consultation and will be addressed as part of future policy considerations, related to biosimilars, branded generics and plasma derived products.

10.5 A more detailed analysis of how the Department considered the consultation responses is available on the Department of Health and Social Care website.

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 businesses is that the new payment percentage of 7.4% and 10.9%, for 2020 and 2021 respectively, would allow for increased revenue for pharmaceutical companies, which is a positive for the industry. The increased revenue may lead to increased investment in research and development (R&D) of which a proportion would be felt in the UK economy.

12.2 The Department considers that R&D investments leads to "spill-over" effects – for example, through the generation of knowledge and human capital – which generate net societal benefits. As such, we consider that these amendments will help support the life sciences sector, as well as protect the supply of medicines to the NHS at affordable levels, benefitting patients and the wider health system.

12.3 The impact on the public sector is that there will be benefits to patients through innovation. The Life Science Industrial Strategy sets out the importance of a clear, stable, and innovative medicines access and pricing system to the UK's position as global life sciences hub. The successful delivery of the Statutory Scheme is an essential part of a wider drive to improve collaboration with industry, ensuring the best innovations get to patients as fast as possible whilst ensuring affordability of medicines to the NHS

12.4 We do not believe there will be any disproportionately negative impacts from amending the payment percentages in these amendment Regulations. By making changes to the payment percentages, we will be ensuring good operation of the

Statutory Scheme, so that the NHS continues to receive payments from companies and 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 (IA) is submitted with this explanatory memorandum and will be published alongside this memorandum and the Amendment Regulations on the legislation.gov.uk website.

12.6 The IA shows that there is a small cost (of approximately - £20m in Net Present Value terms), however, this needs to be set against the unmonetised benefits of meeting the wider scheme objectives and mitigating concerns of industry.

13. Regulating small business

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

13.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken is that companies in the Statutory Scheme with qualifying sales or estimated sales of branded health service medicines of less than £5m, are not required to make payments. They are also subject to different reporting requirements.

13.3 The basis for the final decision on what action to take to assist small businesses in the form of this exemption was introduced by the 2018 Regulations based on responses to that consultation and the Impact Assessment. The Department has resolved to continue with this arrangement.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is that the 2018 Regulations will continue to be reviewed annually to assess the extent to which the objectives of the Statutory Scheme are achieved and to assess whether those objectives remain appropriate, and if so, the extent to which they could be achieved with a system that imposes less regulation.

14.2 A statutory review clause is included in the 2018 Regulations.

15. Contact

15.1 Eileen Ashamu at the Department of Health and Social Care Telephone: 0207 972 5772 or email: Eileen.ashamu@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Daniel Law, Deputy Director for Medicines and Pharmacy Analysis, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Secretary of State, Matt Hancock at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.