EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) (AMENDMENT) REGULATIONS 2018

2018 No. 1255

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 seeks to control the costs of branded health service medicines through two schemes:—

(a) a statutory scheme currently set out in the Branded Health Service Medicines (Costs) Regulations 2018 ("the 2018 Regulations"); and

(b) a separate voluntary scheme that may be agreed between the industry body that represents manufacturers and suppliers of branded health service medicines and the Secretary of State.

2.2 The main purpose of these amendment Regulations is to amend the 2018 Regulations so that:

(a) certain manufacturers and suppliers of branded health service medicines pay to the Secretary of State 9.9% (in 2019), 14.7% (in 2020) and 20.5% (in 2021) of their net sales income received for the supply of those medicines;

(b) sales of branded health service medicines which are either sold under contracts with a contracting authority based on a framework agreement or supplied under a public contract (both referred to in the remainder of this document as "Agreements"), where this is agreed (i.e. entered into following an invitation to tender that closed ("entered into")) on or after 1 January 2019 will be subject to the prevailing payment percentages set out in 2.2 (a) or the payment percentage as amended (see further explanation of this provision in particular, at paragraph 7.7). However any Agreements entered into before 1 April 2018 will retain the exemption from payment. Those entered into on or after 1 April 2018 but prior to 1 January 2019 will be fixed at the payment percentage that was in force at the time they entered into the Agreements, namely 7.8%; and

(c) all biological medicinal products are included in the definition of a relevant medicine for the purposes of the payment mechanism, price controls, information requirements and enforcement provisions which widens the current scope of the 2018 Regulations to include any biosimilar marketed under a combination of International Nonprorietary Name (INN) and a company name.

2.3 In making these changes the Government's intention is to ensure that sufficient NHS savings are delivered, as the overall branded medicines bill to the NHS is unlikely to be appropriately limited by the payment percentage implemented in April 2018. We have sought to do this in a manner consistent with the supply of clinically- and cost-effective medicines to patients and supporting the UK life sciences sector and the broader economy, bearing in mind in particular the need for medicinal products to be

available for the health service on reasonable terms, and the costs of research and development.

2.4 The Government has recently concluded Heads of Agreement on a voluntary scheme for branded medicines pricing and access, with the intention that it operates from 1 January 2019. Should agreement on the details of the voluntary scheme be achieved and should the voluntary scheme commence on 1 January 2019, the 2018 Regulations will not apply to companies that choose to join that voluntary scheme.

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 These Regulations apply to the United Kingdom.

4.2 With respect to application in Northern Ireland, given that medicines pricing is transferred to Northern Ireland, the former Northern Ireland Executive had agreed that the NI Assembly's endorsement should be sought for a LCM relating to the Health Service Medical Supplies (Costs) Act 2017 ("the 2017 Act"). A Legislative Consent Motion ("LCM") had been laid in the NI Assembly but it was not possible to schedule a debate in advance of the Assembly being dissolved. The 2017 Act provided for separate commencement in Northern Ireland, on the understanding that a reformed Northern Ireland Executive may bring forward an LCM at a later stage. However, the Government decided that it was in the public interest that Northern Ireland be included in the commencement order for the 2017 Act. Due to the continued absence of a Northern Ireland Executive it has not been possible to bring forward an LCM. Following consultation and consideration of responses the Government implemented the 2018 Regulations on a UK-wide basis. The Government has committed that when a Northern Ireland Executive has been restored the UK Government will write to the Northern Ireland Health Minister to confirm that they are content for the commenced 2017 Act to remain in place. We have restated that this commitment still applies in the process of consulting on these amendment Regulations.

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 2018 Regulations revoked previous statutory scheme Regulations, including reversing a 15% price cut which had historically been the mechanism to limit branded health service medicine costs.

6.2 The 2018 Regulations replaced the 15% price cut with a requirement that certain manufacturers and suppliers of branded health service medicines pay to the Secretary of State 7.8% of their net sales income received from the supply of individual packs of branded health service medicines.

6.3 These Regulations amend the 2018 Regulations.

6.4 The power to require payments to be made to the Secretary of State was added to the National Health Service Act 2006 ("the 2006 Act") by an amendment made by the 2017 Act. The 2018 Regulations were the first use of that power.

6.5 The following statement relevant to these amendment Regulations were made by the Government during the passage of the 2017 Act through Parliament:

- That, subject to consultation, the Government was, at that time, intending to exempt branded health service medicines procured under framework agreements extant at the time the 2018 Regulations came into force from the price control and payment mechanism provisions in the statutory scheme (Lords Hansard, volume 778, column 89 and 1656). For the purposes of the payment mechanism, the Government is retaining the exemption from payment for branded health service medicines supplied under Agreements entered into before 1 April 2018, whilst clarifying the position for Agreements entered into after 1 April 2018 as set out at paragraph 2.2 (b).

7. Policy background

What is being done and why?

7.1 The voluntary scheme (as agreed between the Secretary of State and the industry body representing manufacturers and suppliers of branded health service medicines) and the statutory scheme (as set out under the 2018 Regulations) together control the costs of branded health service medicines. The statutory scheme applies to manufacturers and suppliers of branded health service medicines that are not members of the voluntary scheme.

7.2 Within the 2014 Pharmaceutical Price Regulation Scheme ("2014 PPRS") – the voluntary scheme agreed in 2014 – it was agreed that in the event that sales of branded health service medicines exceeded a certain predetermined level of growth, members of the 2014 PPRS would make payments to the Department.

7.3 The 2017 Act and 2018 Regulations were introduced, in large part, to enable the statutory scheme to be brought into broad commercial alignment with the 2014 PPRS. This is because the savings produced by controls on the maximum price were not producing relative to the number of sales, the level of savings produced by the 2014 PPRS.

7.4 In order to deliver this broad commercial alignment the payment percentage to be paid by certain manufacturers or suppliers of branded health service medicines, to the Secretary of State, was set in the 2018 Regulations as 7.8% of net sales income received for the supply of each individual pack of branded health service medicines. This payment percentage was aligned to the payment percentage operating in the 2014 PPRS in the calendar year 2018. This was unless the particular type of branded health service medicine is exempt from the calculation of net sales income as described in paragraph 7.9.

7.5 The 2014 PPRS expires on 31 December 2018, ending the rationale supporting the current payment level of 7.8%. The Department has sought to establish what an appropriate measure is to limit the growth of branded health service medicines to a level that secures the financial position of the NHS in the coming years and balances the Government's overall objectives for the statutory scheme.

7.6 The payment percentages implemented reflect an allowed growth rate of 1.1% nominal per annum growth from the baseline of relevant sales in 2018. The payment percentages are determined to recover a payment equivalent to the value of the gap in relevant sales expected between our forecast for overall relevant sales and sales growth at the allowed rate. This results in payment percentages of 9.9% in 2019, 14.7% in 2020 and 20.5% in 2021. There will be an annual review of the 2018 Regulations, including the payment percentages, 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. This means that the payment percentages for the years 2019, 2020 and 2021 as set out in the 2018 Regulations, may increase or decrease following further consultation on any such proposals.

7.7 These Regulations also amend the treatment of sales made under Agreements. An exemption for payment was in place for the duration of any Agreements that were entered into before the 2018 Regulations came into force on 1 April 2018, as manufacturers and suppliers at the time they entered into the Agreements could not have taken into account the payment when the tender was agreed. Agreements entered into after 1 April 2018 were completed in full knowledge of the 7.8% payment under the 2018 Regulations, and were therefore not exempt from the payment percentage. These amendment Regulations fix the payment percentage applied to sales made under any Agreements entered into between 1 April 2018 and 1 January 2019 at 7.8% for the duration of that Agreement. Again, this is because manufacturers and suppliers had not been put on notice that the payment percentage could change at the time that they entered into the Agreement. Manufacturers or suppliers making sales under Agreements entered into after 1 January 2019 will be subject to the payment percentages set out at paragraph 7.6, including any future variability. This is because manufacturers or suppliers entering into tenders will now be doing so with full knowledge of the proposed payment percentages for the years 2019, 2020 and 2021 as well as their potential variability. These Regulations make clear that where a manufacturer or supplier has entered into an Agreement on or after 1 January 2019, and the payment percentage for the applicable period is amended, the manufacturer or supplier will, with respect to the supply of the medicines under those Agreements, be subject to the amended payment percentage for the applicable period.

7.8 Separately, these amendment Regulations propose to include biological medicinal products within the scope of the payment mechanism, price controls, information requirements and enforcement provisions in the 2018 Regulations. This is because in the vast majority of circumstances biological medicinal products are branded health service medicines, and already within scope of the payment mechanism. However, in 2017 one biosimilar medicine was launched (by a voluntary scheme member) under a different naming convention, specifically under an International Nonproprietary Name (INN) combined with the company name. As drafted, the 2018 Regulations would not have captured this as within the scope of the definition of a relevant medicine for the purposes of the payment mechanism, price controls, information requirements and enforcement provisions, despite the fact that there is no difference in the way that such

a product operates in the market when compared to other biosimilar medicines. Therefore, to ensure a level playing field between such medicines, a technical change has been made by these amendment Regulations to the definition of "relevant medicines" to bring them into scope.

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 six weeks between August and September 2018. The six week consultation period was considered sufficient as the changes to the 2018 Regulations consulted on were limited in scope, and a consultation on the main elements of the 2018 Regulations had already been conducted within the past year. The consultation document set out 10 questions for respondents covering the three proposals. Additionally, they sought views on the Department's approach to forecasting future medicines expenditure, as this underwrote the calculation of payment percentages. 48 responses to the consultation were received. The Department additionally held meetings with 2 interested pharmaceutical trade bodies upon request. Of the responses, 3 were from health service bodies, 2 from individuals and the remainder from companies and industry representatives.

10.2 As some respondents requested further details on underlying modelling calculations, the Department issued a clarification note in October over a period of two weeks, allowing additional comments, with 11 responses received. Overall, respondents were split on the merits of changes regarding Agreements and biological medicinal products. Regarding the payment percentage, health service bodies supported the measure, arguing it supported frontline efforts to allocate limited financial resource to activities offering the greatest health gain per pound. However industry respondents were opposed to an increase in the payment percentage, on the grounds that it is lower than the agreed increase in the overall NHS budget and would be detrimental to profitable supply of medicines in the UK. A more detailed analysis of how the Department considered consultation responses is available on the Department of Health and Social Care website.

11. Guidance

11.1 Operational guidance will be made available to companies before 1 January 2019 to enable them to understand the operational requirements of the scheme. DHSC will be retaining the operational platform used to administer the current statutory scheme.

12. Impact

12.1 The impact on business is a reduction in pharmaceutical company revenues of £152m by 2021, with consequent loss of profits for UK shareholders valued at £22.6m over the same period. Reduced revenue for pharmaceutical companies is expected to result

in reduced investment in research and development, including £5.5m by 2021 in the UK, with consequent loss of spill-over benefits for the UK economy valued at £2.4m. There is no impact on charities and voluntary bodies.

12.2 The impact on the public sector is that the policy is expected to reduce NHS costs by £152m by 2021, enabling the provision of additional treatments and services estimated to provide NHS patients with an additional 10,123 Quality-Adjusted Life Years (QALYs, the general unit of health), valued at £950m over the period.

12.3 Improved patient health is expected to lead to wider economic benefits, for example through increased productivity and reduced need for informal and formal care, valued at £220m over the period.

12.4 An Impact Assessment is submitted with this memorandum and will be published on the legislation.gov.uk website.

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, companies with qualifying sales or estimated sales of branded health service medicines of less than £5m will not be required to make payments and different reporting requirements will apply.

13.3 This exemption was introduced by the 2018 Regulations, based on responses to that consultation and Impact Assessment. The Department has determined it is appropriate to continue it.

14. Monitoring & review

14.1 The 2018 Regulations will 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.

15. Contact

15.1 Samuel Jackson at the Department of Health and Social Care. Telephone: 02079726082 or email: Samuel.Jackson@dhsc.gov.uk.

15.2 Robert Kettell, 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 Lord O'Shaughnessy at the Department of Health of Social Care can confirm that this Explanatory Memorandum meets the required standard.