EXPLANATORY MEMORANDUM TO

THE BRANDED HEALTH SERVICE MEDICINES (COSTS) REGULATIONS 2018

2018 No. 345

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 costs of branded health service medicines are currently controlled by the 2014 Pharmaceutical Price Regulation Scheme ("the 2014 PPRS"), a voluntary scheme as agreed between the industry body that represents manufacturers and suppliers of branded health service medicines and the Secretary of State, and by a separate statutory scheme.

2.2 The main purpose of these Regulations is to provide for a statutory scheme which –

(a) controls the maximum price which may be charged for the supply of branded health service medicines; and

(b) requires certain manufacturers and suppliers of branded health service medicines to pay to the Secretary of State 7.8% of their net sales income received for the supply of those medicines.

2.3 In making these changes the Government intends to better align the way the statutory scheme and voluntary 2014 Pharmaceutical Price Regulation Scheme work, to move towards a more level playing field between companies in the two schemes. Reforming the statutory scheme will also enable the Department to put more effective pricing and enforcement controls in place, whilst increasing the levels of savings of health service medicines covered by the scheme.

2.4 These Regulations do not apply to members of the 2014 PPRS.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 These Regulations apply to the United Kingdom.

3.3 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 to enable consultation on these Regulations to take place. Due to the continued absence of a Northern Ireland Executive it has not been possible to bring forward an LCM. However, the UK Government is of the view that it is in the interests of the people of Northern Ireland that they be included in these Regulations. Therefore following consultation and consideration of responses the Government has now decided to implement on a UK-wide basis. 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.

4. Legislative context

4.1 Provision for a statutory scheme is currently made under the following Regulations:

- The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 S.I. 2007/1320 ("the 2007 Regulations"); and
- The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 S.I. 2008/3258 ("the 2008 Regulations").

4.2 The 2007 Regulations require manufacturers and suppliers of branded health service medicines to provide specified information to the Secretary of State to support the operation of the statutory scheme.

4.3 The 2008 Regulations limit the maximum price which may be charged for the supply of branded health service medicines. On 1st January 2014 the 2008 Regulations were amended so as to impose a 15% price cut on the maximum price as at 1st December 2013 of branded health service medicines.

4.4 These Regulations will revoke the 2007 Regulations and include new information requirements for manufacturers and suppliers of branded health service medicines. The Regulations will also revoke the 2008 Regulations to reverse the 15% price cut.

4.5 These Regulations will continue to control the maximum price of branded health service medicines but will also require 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 individual packs of branded health service medicines.

4.6 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. These Regulations are the first use of that power.

4.7 The following statements were made by the Government during the passage of the 2017 Act through Parliament.

- The Secretary of State would consult on an exemption for branded health service medicines which were supplied below a certain cost (Lords Hansard volume 778, column 63). The proposal to include an exemption for individual packs of branded health service medicines supplied at a price below £2.00 was included in the consultation of these Regulations. Further to the consideration of the consultation responses this proposal is included as an exemption to the payment mechanism and maximum price controls in these Regulations.

- These Regulations would include a provision to allow for price increases and temporary exemptions from the price control provisions in order to ensure adequate supplies of branded health service medicines (Lords Hansard volume 778, column 64). These exemptions have been included in these Regulations.
- That there will be an annual review of the statutory scheme to address key issues arising during the year which might affect the operation of the scheme as well as reviewing scheme objectives, and the extent to which the scheme takes into account statutory duties relevant to it. That the annual review be published and put before Parliament. (Lords Hansard volume 778, column 66 and 1649). An annual review provision has been included in these Regulations.
- 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 these Regulations come into force be exempt from the price control and payment mechanism provisions in the statutory scheme (Lords Hansard, volume 778, column 89 and 1656). These Regulations exempt individual packs of branded health service medicines supplied by the manufacturer or supplier under a framework agreement or public contract extant at the time these Regulations come into force from the price control and payment mechanism provisions.
- That the statutory scheme exempt manufacturers and suppliers with sales of branded health service medicines of less than £5m from the price control and payment mechanism provisions in the statutory scheme (Lords Hansard, volume 778, column 93). These Regulations make provision to exempt small companies that have qualified sales or estimated sales below £5 million from the payment mechanism and the price control provisions.

5. Extent and territorial application

5.1 These Regulations extend to England, Scotland, Wales and Northern Ireland.

5.2 These Regulations apply to England, Scotland, Wales and Northern Ireland.

5.3 Medicines pricing is a reserved matter with respect to Wales and Scotland and a transferred matter with respect to Northern Ireland.

6. European Convention on Human Rights

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

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 together control the costs of branded health service medicines. The current statutory scheme applies to manufacturers and suppliers of branded health service medicines that are not members of the voluntary scheme.

7.2 Historically, the voluntary and statutory schemes have operated through controls on the maximum price that may be charged for the supply of branded health service medicines.

7.3 However, with respect to the 2014 PPRS, a new approach was agreed with the industry body, whereby in addition to controls on maximum prices, companies agreed to a payment system. For the purposes of the 2014 PPRS it was agreed that in the event that sales of branded health service medicines exceeded a certain predetermined level, members of the 2014 PPRS would make payments to the Department.

7.4 The 2017 Act was introduced, in large part, to enable the statutory scheme to be brought into broad alignment with the 2014 PPRS. This is because the savings produced by the current statutory scheme which imposes controls on the maximum price only does not produce, relative to the number of sales, the level of savings produced by the 2014 PPRS. In relation to the operation of the current statutory scheme, the actual prices of branded health service medicines after discounts are often below the maximum price in any event. Consequently, the savings generated by the current statutory scheme are limited. We estimate, as set out in the impact assessment published alongside this document, that the implementation of these Regulations (which will include a payment system) will generate savings of £33 million to the NHS between April 2018 and March 2019. This will also promote a more level playing field between the voluntary and statutory schemes.

7.5 These Regulations make provision for the continuation of maximum price controls and also makes provision for a payment system. These Regulations will also include information and enforcement provisions to support the operation of the statutory scheme.

7.6 Part 1 of these Regulations make provision for the payment scheme and in particular for the payment, by certain manufacturers or suppliers of branded health service medicines, to the Secretary of State of 7.8% of net sales income received for the supply of each individual pack of branded health service medicines (unless the particular type of branded health service medicine is exempt from the calculation of net sales income – see paragraph 7.12 below).

7.7 The policy intention is that the MA holder of an item of presentation should generally be responsible for paying the percentage payment on the net sales of eligible presentations, as is the case with the 2014 PPRS.

7.8 However, the difficulty of providing for such an approach in the statutory scheme is that the MA holder may be based outside of the UK, or if they are based within the UK, not be the company that supplies the item of presentation.

7.9 These Regulations therefore require the payment percentage to be paid on the first occasion that the item of presentation is supplied by a company in the UK to another person in the UK. There will be a requirement to pay 7.8% of the net sales income received in respect of the relevant presentations to the Secretary of State.

7.10 However there are certain challenges to this approach. In particular, the first supply may occasionally be made by a company, such as a manufacturer, to the MA holder. As a result these Regulations provide that where on the first occasion an item of presentation is supplied to the MA holder of that branded health service medicine or a company in the same group as the MA holder, the requirement to make the payment falls on the company responsible for the next occasion in the supply chain that the item of presentation is supplied. These Regulations also make clear that for these

purposes the supply of an item of presentation between two companies in the same group does not count as a form of supply. This is so that a company that is responsible for the first or next occasion on which the item of presentation is sold cannot avoid making the required level of payment by selling that pack to a company in their group at a low price.

7.11 Further provision to capture the circumstances where a manufacturer or supplier enters into arrangements to try to avoid making a payment or part of a payment is set out in regulation 4 of these Regulations. In such circumstances the Secretary of State may give a direction to a manufacturer or supplier of branded health service medicine with respect to a previous or future sale of that branded health service medicine.

7.12 Part 1 of these Regulations also sets out the type of branded health service medicines that will be exempt from the calculation of the manufacturer's or supplier's net sales income. This includes branded health service medicines covered by the voluntary scheme. It is important to make clear that such medicines are exempt because even though these Regulations do not apply to members of the voluntary scheme, a voluntary scheme member may have already made a payment percentage to the Secretary of State with respect to that presentation. This is because the voluntary scheme is not limited to circumstances where the supply of the presentations is between two persons in the United Kingdom. A member of the 2014 PPRS may for example, have supplied the presentation from outside of the United Kingdom to a manufacturer or supplier in the United Kingdom, and made a payment to the Secretary of State accordingly.

7.13 Part 1 also makes provision for a manufacturer or supplier that fails to make the required payment to be liable to interest on that payment and a daily penalty which the Secretary of State can demand by issuing a written notice to the manufacturer or supplier.

7.14 Part 2 of these Regulations sets out the price controls on branded health service medicines. The policy intention is that the maximum price should generally be the maximum price, as determined by the Secretary of State, of the medicine as at 1st December 2013 (that is, before the price cut imposed on 1st January 2014). This is so that the statutory scheme is more closely aligned to the 2014 PPRS which required a payment percentage but no price cut.

7.15 Where a price increase was agreed by the Secretary of State under the 2008 Regulations, the maximum price will be that increased price.

7.16 For branded health service medicines launched after 1st December 2013, the maximum price in most instances will have been determined by the Secretary of State under the 2008 Regulations, and it will be that maximum price which will generally apply under these Regulations. However, if an increase to the maximum price of any specific branded health service medicine launched after 1st December 2013 was agreed by the Secretary of State, it will be the increased price that will be the maximum price.

7.17 There is a risk that the Secretary of State may not have determined the maximum price of certain branded health service medicines launched after 1st December 2013. In these instances, these Regulations make provision for the Secretary of State to give a direction to the relevant manufacturer or supplier setting out the maximum price. These Regulations also set out other instances when the Secretary of State can give a direction specifying the maximum price. This includes, for example, where there are supply issues with respect to a particular branded health service medicine, and the

Secretary of State is satisfied that a new temporary maximum price needs to be provided to help resolve the supply issue.

7.18 Again part 2 of these Regulations makes provision for the enforcement of the maximum price. This includes requiring the difference between the amount charged and the amount that should have been charged had the maximum price provisions been complied with to be paid to the Secretary of State as a recoverable sum. These Regulations provide for this amount to be increased by a specified percentage over every month that the contravention continues. Provision is also made for interest to be applied to that recoverable sum. A manufacturer or supplier is also liable to pay a penalty for contravening the maximum price provisions, and the Regulations provide the Secretary of State with the power to issue a notice demanding payment of the recoverable sum, interest and penalty.

7.19 Part 3 of these Regulations sets out the information that is required for the purposes of the statutory scheme. Generally, a manufacturer or supplier will make a percentage payment of their net sales income received for each individual pack of branded health service medicines after each quarter in their Financial Year. The manufacturer or supplier must provide a sales report with respect to each of these quarters to enable the Department to verify that the correct payment has been made. The quarterly information is then further verified by additional information, including audited information provided on an annual basis.

7.20 Specific provision is made by these Regulations for new and small manufacturers and suppliers, including the provision of estimated information.

7.21 A small manufacturer or supplier is not required to make payments. In summary, when the payment percentage first begins to apply to a manufacturer or supplier, the manufacturer or supplier can provide estimated sales to the Secretary of State to demonstrate that it is likely to have sales of less than £5million in its current financial year. If the Secretary of State is satisfied that the manufacturer or supplier is likely to receive sales of less than £5million in its current financial year, the manufacturer or supplier will not have to make the payment percentage. After the first complete financial year, the manufacturer or supplier will need to provide sales information for its preceding financial year. If the sales information for the previous financial year shows sales of less than £5million, the manufacturer or supplier will be exempt from making payments in its current financial year.

7.22 Enforcement provisions in these Regulations make a manufacturer or supplier that contravenes any of the information requirements liable to a penalty. The Secretary of State can issue a written notice to demand payment of that penalty.

7.23 Part 4 of these Regulations makes general provision with respect to the statutory scheme. In particular, these Regulations provide for a right of appeal where the Secretary of State makes an enforcement decision with respect to the statutory scheme. An enforcement decision is defined in section 266(6) of the 2006 Act. These Regulations provide that where a manufacturer or supplier appeals an enforcement decision, the period during which that appeal is running will not be included in the calculation of the period of time used to calculate the recoverable sum, interest or penalty.

Consolidation

7.24 The Regulations revoke the 2007 Regulations and 2008 Regulations, save where a manufacturer or supplier breached the 2007 Regulations or the 2008 Regulations before these Regulations come into force.

8. Consultation outcome

8.1 A public consultation was held between August and October 2017. The consultation document set out 42 questions for respondents covering all aspects of how the Department proposed the scheme should operate. During the consultation period workshops were held for pharmaceutical industry companies and industry representatives to explain our proposals and hear their views. In addition to these workshops, 31 responses to the consultation were received. 5 were from health service bodies and the remainder from companies and industry representatives. Overall, respondents from industry were expecting the changes and made a number of suggestions for how the scheme design could be improved. The Department has amended the regulations in the light of the feedback received, although the key changes to the scheme remain as explained in Parliament during the passage of the 2017 Act. A more detailed analysis of the consultation outcome is available on the Department of Health and Social Care website.

9. Guidance

9.1 Operational guidance will be available to companies to enable them to understand the operational requirements of the scheme and workshops are planned for companies to discuss the operational requirements with Department of Health and Social Care.

10. Impact

10.1 The impact on business, charities or voluntary bodies is a reduction in pharmaceutical company revenues of £3m, with consequent loss of profits for UK shareholders valued at £0.7m. Reduced revenue for pharmaceutical companies is expected to result in reduced investment in research and development, including in the UK, with consequent loss of spill-over benefits for the UK economy valued at £0.4m.

10.2 The impact on the public sector is that the policy is expected to reduce NHS costs by £33m, enabling the provision of additional treatments and services estimated to provide NHS patients with an additional 2,213 Quality-Adjusted Life Years (QALYs, the general unit of health), valued at £133m.

10.3 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 £31m.

10.4 An Impact Assessment is submitted with this memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

11. Regulating small business

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

11.2 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.

11.3 The basis for the final decision on what action to take to assist small businesses was based on our impact assessment and on the consultation responses received.

12. Monitoring & review

12.1 The regulations will be reviewed annually against the duties in the 2017 Act that Government is required to consider when making a statutory scheme.

13. Contact

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