EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE PRODUCTS (PROVISION AND DISCLOSURE OF INFORMATION) REGULATIONS 2018

2018 No. 677

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 main purpose of these Regulations is to require persons who manufacture, distribute or supply any UK health service products to record, keep and provide information to the Secretary of State about the purchase or supply of those products. The Regulations also make provision in connection with the disclosure of such information and the purpose for which any information disclosed may be used.

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 As this instrument is subject to negative resolution procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

3.3 The pricing of medicines and medical supplies used for the purposes of the health service is transferred to Northern Ireland. These Regulations will enable information to be collected which is relevant to the pricing of those medicines and supplies. 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 The National Health Service Act 2006 ("the 2006 Act") was amended by section 8 of the 2017 Act to give the Secretary of State the power, by regulations, to require UK producers to record, keep and provide information about the supply of UK health service products and which the Secretary of State requires for the statutory purpose. A "UK producer" is a person who manufactures, distributes or supplies any UK health service products (section 264A(1) of the 2006 Act). "UK health service products" are medicinal products, medical supplies and other related products used for any of the purposes of any of the health services in England, Wales, Scotland or Northern Ireland (section 264A(14) of the 2006 Act).

4.2 The "statutory purpose" is set out in section 264A(3) of the 2006 Act. It includes: enabling or facilitating the determination of remuneration for NHS chemists and primary medical service providers (such as GPs), the assessment of whether there are adequate supplies of UK health service products available or supporting the cost control provision in the 2006 Act.

4.3 The 2006 Act was also amended to make provision for the disclosure of information provided to the Secretary of State under such Regulations. Section 264B of the 2006 Act (as inserted by section 8 of the 2017 Act) sets out the persons to whom that information may be disclosed. Those persons include bodies prescribed, in regulations, by the Secretary of State ("prescribed persons"). Section 264B also sets out the statutory purpose for which confidential or commercially sensitive information disclosed under this section may be used. The Secretary of State may, by regulations, prescribe the statutory purpose for which prescribed persons may use confidential or commercially sensitive information disclosed to them under section 264B of the 2006 Act.

4.4 These Regulations will set out the new information requirements for manufacturers, distributers and suppliers of any UK health service products. These Regulations will replace various existing voluntary arrangements for the provision of information about the supply of health service medicines to the Secretary of State. The requirements in these Regulations are in addition to those in the Branded Health Service Medicines (Costs) Regulations 2018 (S.I. 2018/345).

4.5 The following statements were made by the Government during the passage of the 2017 Act through Parliament:

- That there will be an annual review of the Regulations to review the objectives of the Regulations and 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 (see regulation 36).
- That there will be provisions in the regulations for small companies (Lords Hansard, Volume 778, column 93). Provisions allowing small producers to provide some information by means of pre-existing information such as invoices have been included in these Regulations (see regulations 24 and 31).
- That there will be rights of appeal in relation to enforcement decisions by the Secretary of State (Lord Hansard, volume 778, column 152). Provisions for the appeal of enforcement decision have been included in these Regulations (see regulation 33).

5. Extent and Territorial Application

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

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

5.3 Medicines and medical supplies pricing is reserved matter with respect to Wales and Scotland and transferred matter with respect to Northern Ireland. These Regulations make provision for the recording, keeping and provision of information which relate to medicines and medical supplies pricing in 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 2017 Act amended the 2006 Act to give the Secretary of State the power to make regulations requiring anyone manufacturing, distributing or supplying UK health service products to record, keep and provide information about those products. Such information may be collected for the purpose of enabling or facilitating:

- The remuneration/payment of NHS chemists and primary medical service providers in, or in any part of, the UK;
- The availability of products in, or in any part of, the UK and the assessment of whether the products represent value for money;
- The cost control powers in the 2006 Act.

7.2 NHS chemists and primary services providers are reimbursed for the costs of every medicine they dispense. Reimbursement prices are published in the monthly Drug Tariff. There are three Drug Tariffs in the UK: one for England and Wales (made by the Secretary of State and the Welsh Government), and one each for Scotland and Northern Ireland. All three are constructed in a similar way, drawing where appropriate on similar market intelligence.

7.3 Under the current community pharmacy reimbursement arrangements in England, supporting information about sales and purchases of unbranded generic medicines and (manufactured) special medicinal products[1] is provided on a voluntary basis by some manufacturers/suppliers and wholesalers. Whilst these voluntary arrangements have worked well, under these arrangements the information is provided only by those manufacturers and wholesalers of unbranded generic medicines and special medicinal products that have signed up to the voluntary arrangements and the purpose for which the information can be used is restricted to informing reimbursing arrangements.

7.4 These Regulations therefore require all manufacturers, importers and wholesalers of unbranded generic medicines (Part 2 of the Regulations) and special medicinal products (Part 3 of the Regulations) to provide the Department with information about their sales and/or purchases of such medicines. This information must be provided to the Secretary of State every quarter. This information will enable the Department and to improve the robustness of their reimbursement arrangements. In England,

[1] Special medicinal products are unlicensed medicines which have been specially manufactured or imported for the treatment of an individual patient after being ordered by a healthcare professional.

reimbursement prices could be based on information from the whole market instead of only part of the market. Also, the Department could, subject to consultation with the Pharmaceutical Services Negotiating Committee (PSNC), use the information to consider basing more reimbursement prices on actual sales and purchase information including for example imported special medicinal products. The Department will disclose the information obtained from industry to the Welsh Ministers, Scottish Ministers and, in future, the Northern Ireland Executive who may use it to inform the reimbursement prices in their own Drug Tariffs.

7.5 The Regulations also support the process for setting concessionary prices in England when NHS chemists cannot source a medicine at or below the reimbursement price for that medicine which is set in the Drug Tariff (regulation 27). The Regulations require manufacturers, importers, distributers and wholesalers to provide information within two working days about available volumes and prices of the medicine (including information about branded equivalents) when requested. This will replace current arrangements where the Department asks manufacturers and suppliers to provide the information voluntarily and will make the concessionary price setting process more robust.

7.6 Furthermore, the Regulations require all manufacturers, importers and wholesalers, and anyone supplying to patients otherwise than by sale, to record and keep information about their sales and/or purchases medicines used for the purposes of the health service in England, Wales, Scotland or Northern Ireland, as well as certain appliances (including chemical reagents) and borderline substances which are used for the purposes of any of those health services (Part 4 of the Regulations). This information must be kept for a period of 4 years. The Department can request that a UK producer provides it with any of this information for the statutory purpose set out in section 264A(3) of the 2006 Act(see paragraph 7.1).

7.7 The Regulations also enable the Secretary of State to require UK producers to provide information about costs incurred in the manufacturing, distribution or supply of health service products (Part 5 of the Regulations). The information requested is information that a UK producer can reasonably be expected to record and keep for the purpose of understanding their own relevant costs. Where this information is in connection with a particular presentation or appliance (as opposed to overall costs) the Secretary of State must issue an information notice requesting that information. The notice must state the statutory purpose for which the information is requested. A producer can appeal such a notice. An information notice would be used, for example, if the Secretary of State investigated a potentially unwarranted price of an unbranded generic medicine and would like to understand whether the cost of manufacturing that medicine bears any relation to the price that it is sold at. Any request for information about overall costs information must be made in writing to the relevant producer.

7.8 Finally, the Regulations include provisions which will support the Secretary of State, the Welsh Ministers, the Scottish Ministers and the Northern Ireland Executive to manage supply shortages and mitigate any potential impact on patients (Part 6 of the Regulations). A manufacturer or marketing authorisation holder must notify the Secretary of State of their plans to discontinue the manufacture of any health service medicine and of any anticipated supply shortages of health service medicines (regulation 29). The information that must be provided to the Secretary of State includes information about the quantity of the presentation which the producer has available for supply. These requirements will replace current voluntary guidelines

under which the Department estimates only about half of all supply shortages are notified. The Secretary of State can also require manufacturers, importers and wholesalers to provide information about available volumes when the Secretary of State considers there is a supply shortage (regulation 28). Currently, this information is obtained on a voluntary basis and the legal requirement will ensure that the information about availability of supply will be more robust.

7.9 The Regulations also contain provisions to enable the Secretary of State to confirm how UK producers have calculated reasonable estimates (regulation 30), as well as to enable the Secretary of State to take enforcement action if a UK producer does not provide information as required by the Regulations (regulations 31 and 32). Provision is also made for appeals in connection with various decisions made under the Regulations (regulation 33). Part 9 makes provision to prescribe various bodies to which information obtained under the Regulations may be disclosed, as well as the purposes for which that information may be used by those bodies. Relevant industry bodies, representing producers impacted by these Regulations, have been prescribed. And, foundations trusts and other relevant health service bodies have been prescribed to ensure that the Department can disclose information about supply shortages to the NHS. Part 10 of the Regulations makes transitional provision and provides for an annual review of the Regulations.

8. Consultation outcome

8.1 A public consultation was held between August and November 2017. The consultation document set out 37 questions for respondents covering all aspects of how the Department proposed the Regulations should work. During the consultation period workshops were held for representatives from across the supply chain for health service products as well as meetings with individual representative bodies. 60 responses to the consultation were received. Respondents made suggestions for how the Regulations could be improved. The Department has amended the regulations in the light of the feedback received. In particular:

- Transitional provisions have been made for those UK producers who currently provide currently provide information on a voluntary basis under Schemes M and W and the Specials MoU. Those producers may continue to provide information under the relevant scheme or the MoU, rather than under Parts 2 and 3 of the Regulations, until the Scheme or MoU is ended (regulation 35(2) and Schedule 5);
- Restriction of the requirement to provide quarterly information about unbranded generic health service medicines and special health service medicines to those medicines which have a reimbursement price in a Drug Tariff and which are sold to primary medical service providers, NHS chemists or wholesalers (Parts 2 and 3 of the Regulations);
- Reduction of the period for which information has to be kept under Part 4 of the Regulations from six years to four years;
- Restriction of the definition of medical supplies to appliances (including chemical reagents) and certain borderline substances listed in a Drug Tariff;
- Restriction of power to request cost information for a particular branded medicine to information about distribution and supply costs (regulation 25);
- Entry into force of the provisions for notification of supply shortages and discontinuations on 1 January 2019 (regulation 1(4));
- Introduction of a more proportionate penalties regime reflecting the different size companies impacted by the Regulations (regulation 32 and Schedule 4).

8.2 A more detailed analysis of the consultation outcome is available on the Department of Health and Social Care website.

9. Guidance

9.1 For the quarterly provision of information under Parts 2 and 3, operational guidance will be made available to companies to enable them to understand the operational requirements and workshops are planned for companies to discuss the operational requirements with the Department of Health and Social Care.

10. Impact

10.1 The impact on business, charities or voluntary bodies is the cost of complying with the new information requirements. In particular, UK suppliers of health service medicines, medical supplies or other related products will incur costs associated with collating and providing data to the Secretary of State. It is estimated that over a period of 10 years, the cost would be in the region of £19.6m.

10.2 The impact on the public sector is that there will be costs of developing additional systems to collect, process and analyse the data. There may also be some enforcement costs. It is anticipated that over a period of 10 years the cost would be in the region of £3m.

10.3 The information powers will also deliver benefits by providing greater visibility to the Department on the functioning of the supply chain for health service products, and ensuring greater value-for-money to the NHS and the tax payer. However these benefits remain unquantified.

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, provisions have been including for 'small producers' who can provide information under Part 4 by means of pre-existing information such as invoices, as well as for lower financial penalties in connection with failure to comply with the Regulations. 'Small producers' include:

(a) GP practices who are not wholesalers;

(b) NHS chemists who are not wholesalers and have an annual remuneration income of £5 million or less;

(c) NHS hospital purchasers who are not wholesalers and with a net annual NHS expenditure of £5 million or less;

(d) and certain UK producers with total net NHS sales of £5 million or less (regulations 27, 31 and 32 of and Schedule 2 to the Regulations).

12. Monitoring & review

12.1 The Regulations require the Secretary of State to carry out an annual review of the Regulations (regulation 36). The review must set out the objectives of the Regulations, assess the extent to which those objectives were achieved and whether those objectives remain appropriate

13. Contact

13.1 Sandor Beukers at the Department of Health and Social Care. Telephone: 020 7972 1152 or email: sandor.beukers@dh.gsi.gov.uk can answer any queries regarding the instrument.