EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE MEDICINES (PRICE CONTROL PENALTIES AND PRICE CONTROL APPEALS AMENDMENT) REGULATIONS 2018

2018 No. 384

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 Section 262(1)(a) of the National Health Service Act 2006 ("NHS Act 2006") provides the Secretary of State with the power to make a direction to limit the price charged by any manufacturer or supplier for the supply of any health service medicine. These Regulations make a manufacturer or supplier liable to the payment of a penalty where that manufacturer or supplier charges in excess of the limit specified in a direction given under section 262(1)(a) of the NHS Act 2006.

2.2 These Regulations also amend the Health Service Medicines (Price Control Appeals) Regulations 2000 ("the Appeals Regulations"). The Appeals Regulations make provision for the appeals process where a manufacturer, supplier or where relevant, other UK producer of health service medicines or health service products has a right of appeal in relation to an enforcement decision made by the Secretary of State or any other person. These Regulations amend the Appeals Regulations to remove reference to the Council of Tribunals, which no longer exists.

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.

4. Legislative Context

4.1 Section 262 of the NHS Act 2006 provides the Secretary of State with the power to limit prices of health service medicines and to provide for any amount representing sums charged for that medicine, in excess of the limit, to be paid to the Secretary of State.

4.2 Section 265(1) and (2) of the NHS Act 2006 enables the Secretary of State to make Regulations to apply a single penalty not exceeding £100,000 or a daily penalty not exceeding £10,000 for every day on which a contravention occurs.

4.3 These Regulations make a manufacturer or supplier liable to the payment of a penalty where that manufacturer or supplier charges in excess of the limit specified in a direction given under section 262(1)(a) of the NHS Act 2006.

4.4 Section 265(4) of the NHS Act 2006 provides the Secretary of State with the power to make Regulations to provide a right of appeal to manufacturers and suppliers, and UK producers of health service medicines. These Regulations provide a manufacturer or supplier who has been issued with a written notice demanding the payment of a penalty with the right of appeal.

4.5 The appeals process is set out in the Appeals Regulations and is based on the model provisions with respect to appeals under section 6 of the Deregulation and Contracting Out Act 1994.

4.6 These Regulations update the Appeals Regulations to remove the reference to Council of Tribunals as the Council of Tribunals has been abolished.

5. Extent and Territorial Application

5.1 The extent of this instrument is to England, Scotland, Wales and Northern Ireland.

5.2 The territorial application of this instrument is to England, Scotland, Wales and 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

Penalty Provisions – Section 262(1)(a) of the NHS Act 2006

7.1 The penalty provisions are being introduced because the Secretary of State intends to use the power in sections 262 to limit prices including, but not limited to, some unbranded generic health service medicines that have increased in price significantly. The penalty provisions in these Regulations ensure that where the Secretary of State, after consultation with the industry body, limits the price that may be charged for the supply of, for example, an unbranded generic health service medicine by a manufacturer or supplier, it can require the manufacturer or supplier to pay a daily penalty for charging in excess of the limit specified in the direction.

7.2 These Regulations make provision for a manufacturer or supplier to be liable to the payment of a penalty where that manufacturer or supplier charges in excess of the limit specified in a direction made under section 262(1)(a) of the NHS Act 2006.

7.3 The level of penalty varies according to the total annual turnover in the UK that a manufacturer or supplier makes according to their individual accounts submitted to Companies House. A manufacturer or supplier that has a total annual turnover below £100 million will be liable to a lower level of penalty than a manufacturer or supplier that has a total annual turnover of £100 million or above. A new manufacturer or supplier (i.e. a company that is within its first accounting reference period) may not have submitted its individual accounts at the point that they may become liable to pay a penalty under these Regulations. These Regulations therefore make clear that a new manufacturer or supplier will be assumed to have a total annual turnover below £100 million and therefore be liable to pay the lower level of penalty.

7.4 These Regulations also provide manufacturers and suppliers with a right of appeal, and ensure that the period during which an appeal is ongoing is discounted for the purposes of calculating daily penalties.

The Health Service Medicines (Price Control Appeals) Regulations 2000

7.5 As set out above these Regulations provide manufacturers and suppliers with a right of appeal in accordance with the Appeals Regulations in respect of a demand for a penalty. The Government has also recently consulted on a revised statutory scheme to control the cost of branded health service medicines. The Branded Health Service Medicines (Costs) Regulations 2018 ("the Statutory Scheme Regulations") were laid in Parliament on 9th March 2018 and provide manufacturers and suppliers with a right of appeal in accordance with the Appeals Regulations in relation to enforcement decisions made under the Statutory Scheme Regulations. The Department is therefore updating the Appeal Regulations by removing the reference to Council of Tribunals which no longer exists.

7.6 ***Consolidation***

These Regulations amend the Health Service Medicines (Price Control Appeals) Regulations 2000.

8. Consultation outcome

8.1 As part of the consultations on the Information Regulations (pertaining to the retention and provision of information relating to the sale and purchase of health service products) and on the Statutory Scheme Regulations the Department consulted on updating the Appeals Regulations. There was broad support for the proposed update (see Chapter 5 of the consultation response). We separately consulted the Association of the British Pharmaceutical Industry, the Association of Pharmaceutical Specials Manufacturers, the Bioindustry Association, the British Association of European Pharmaceutical Distributors, British Generic Manufacturers Association, the Ethical Medicines Industry Group, the Healthcare Distribution Association, the National Pharmaceutical Production Committee and the Proprietary Association of Great Britain on the addition of penalty provisions relating to section 262(1)(a) of the 2006 NHS Act to these Regulations between 13 and 28 November 2017. No responses were received.

9. Guidance

9.1 Operational guidance will be available to companies to enable them to understand the operational requirements of the appeals process and workshops are planned for companies to discuss the operational requirements with DHSC.

10. Impact

10.1 The impact on business, charities or voluntary bodies is the availability of an independent appeals tribunal should a manufacturer or supplier, or other UK producer wish to appeal an enforcement decision.

10.2 The impact on the public sector is the cost of providing an appeals tribunal (this will vary depending on the number of appeals heard), and the ability to enforce any limits placed on the price of a specific medicine.

10.3 An Impact Assessment for the Statutory Scheme Regulations is available on the legislation.gov.uk website. A draft Impact Assessment for the Information Regulations is available at the consultation page link above.

11. Regulating small business

11.1 The legislation applies to any enforcement decisions taken that affect a small business.

11.2 No specific action is proposed to minimise the regulatory impact on small businesses.

11.3 The basis for the final decision on what action to take to assist small businesses was based on the lack of concerns raised during consultation, and the need for small businesses against whom an enforcement decision was made to have access to the same provision for appeals as other businesses.

12. Monitoring & review

12.1 The Regulations include an annual review provision.

13. Contact

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