EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) (AMENDMENT) REGULATIONS 2013

2013 No. 2881

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1. These regulations amend the price controls and information provisions of the statutory pharmaceutical pricing scheme. The statutory scheme controls the prices of prescription only branded medicines supplied to the National Health Service by manufacturers or suppliers who are not members of a voluntary Pharmaceutical Price Regulation scheme.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None.

4. Legislative context

4.1. The National Health Service Act 2006 enables the Secretary of State to control maximum prices of health service medicines and medical supplies. It also provides for voluntary schemes which limit the prices of NHS medicines and the profits of the manufacturer and supplier of such medicines.

4.2. The Pharmaceutical Price Regulation Scheme ("PPRS") is a voluntary scheme , made by the Department of Health and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI), which controls NHS expenditure on branded medicines. The PPRS applies to those manufacturers and suppliers of branded medicines who elect to be scheme members. The latest agreement, the 2009 PPRS, started in January 2009. This will terminate on 31 December 2013, and negotiations are underway on a successor scheme.

4.3. These regulations are made under the National Health Service Act 2006 and will apply to any manufacturer or supplier of health service medicines which decides not to become a member of the voluntary scheme, or to all manufacturers and suppliers of health service medicines in the event that no voluntary scheme is agreed.

4.4. These regulations amend the Health Service Branded Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 and the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008, which established the statutory scheme.

5. Territorial Extent and Application

5.1. This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

7.1. The National Health Service (NHS) spends about £12 billion a year on branded prescription medicines in the UK. The PPRS is the main mechanism, through regulating the profits that companies can make on their sales, which the Department of Health (on behalf of the UK Health Departments) uses to control the prices of these branded medicines, and thereby safeguard the financial position of the NHS. This voluntary agreement has existed in various forms in the UK for over 50 years but has been renegotiated approximately every five years. The terms of the voluntary scheme have changed over time to reflect developments in the NHS and the pharmaceutical industry.

7.2. In August 2012 the Government confirmed its intention to negotiate new arrangements for the pricing of branded medicines to replace the current PPRS, with the intention that a new agreement will come into effect in January 2014.

7.3. Alongside new voluntary arrangements, the Government made plans to implement a revised statutory scheme that would apply to any manufacturer or supplier which chooses not to join the voluntary scheme.

7.4. The Government consulted on proposed changes to the statutory scheme in June and July 2013. The proposed changes were:

- To establish revised reference prices, so that price controls will apply to drugs that came onto the market after the period established by the existing regulations, i.e. those drugs that were on sale on 1st December 2008;
- To introduce a new price cut. This has been amended regularly to reflect changes in the PPRS. As negotiations on the new PPRS were still underway, and no

provisional agreement had been reached on price cut levels, views were sought on indicative cuts of 10%, 15% and 20%;

- To remove the exemptions to: the price cut established by the low cost presentation provision for drugs costing the NHS not more than £450,000 per year; and to the information requirements for companies with health service sales in England of less than £25 million. It was then proposed that this would be replaced by a new small firms exemption for the price cut and information provisions covering companies with UK health service sales of branded medicines of less than £5 million;
- To introduce price controls on average selling prices (ASPs) within hospitals, so that price cuts are on top of discounts already negotiated by hospitals; and
- To make specific provisions for the pricing of line extensions of existing drugs.

7.5. The Government is still considering some of the above proposals in light of the consultation responses, and intends to consult next year on further changes arising from the negotiations on the voluntary scheme. Consequently, the Government intends to consolidate these regulations when these further changes are taken forward.

8. Consultation outcome

8.1. The Government published its proposals in 'Consultation on Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines' (https://www.gov.uk/government/consultations/revisions-to-statutory-scheme-for-pricing-branded-nhs-medicines) , and the consultation ran from 20th June to 31st July 2013.

8.2. A total of 79 responses were received, with 62 of these from pharmaceutical companies and their representative bodies. The remainder were from pharmacy trade bodies, NHS and other organisations, a charity organisation and an individual response.

8.3. The key messages emerging from the consultation responses were:

- Objections mainly by pharmaceutical companies to the suggested levels of the downward price adjustment;
- Some concern, mainly from pharmaceutical companies, about the proposal to apply the price adjustment to ASPs to medicines purchased by hospitals;
- Some concern about the line extensions proposal, as the suggested approach would not always reflect the amount of additional investment a company had made;
- Some support for retention of the £450,000 low cost presentation provision;

- Many objections to the proposed removal of the £25m threshold for the information provision exemption. There was support for the proposed small firms' exemption, but a number thought that the £5m threshold was too low and should be increased; and
- Some perceived the information requirement as a result of proposals in the consultation to be unnecessarily burdensome.

8.4. On the level of the price cut, as well as inviting views, the consultation also made specific statements about alignment to the level agreed in the voluntary scheme negotiations. The 15% cut which is being introduced is roughly comparable to the level in the new PPRS, with an uplift to reflect the relative lack of certainty which the price cut will provide, as opposed to the new approach adopted in the PPRS.

8.5. The Government acknowledges the concerns raised about ASPs and line extensions, and recognises the need for further consideration on these issues. Consequently, these proposals are not being introduced at this time. However, because any possible future application of price controls on ASPs will require historical reference data, the Government is proceeding with the full changes to the information requirements.

8.6. Concerns were raised about risks to supply with the removal of the £450,000 low cost presentation exemption. However, under the existing regulations the Secretary of State is able to exempt a drug from price controls to ensure continuity of supply, and to set out a mechanism for a company to apply for a price increase. The Government is therefore proceeding as planned on the exemption provisions.

8.7. On the information provisions, it is notable that companies in the PPRS submit this data as a matter of course, and it is the Government's view that the administrative cost burden is proportionate. The introduction of the small firms exemption, for which there was significant support in the consultation, will ensure that small firms are protected from the additional burden, and the price cut. The responses did suggest that the proposed £5 million level should be higher, in line with commonly used definitions of small and medium sized enterprises. However, these definitions generally relate to total sales and this exemption uses UK health service sales only. Additionally, the Government made clear that a level of alignment between the statutory and voluntary scheme would be sought, and this level is consistent with the exemption agreed with industry and set out in the new PPRS Heads of Agreement.

8.8. The full Government response to the consultation is available at www.gov.uk.

9. Guidance

9.1. The Department will issue guidance on the implementation of these revised regulations directly to those companies affected and will make that guidance available to the ABPI.

10. Impact

10.1. An Impact Assessment is attached to this memorandum.

10.2. The main benefit is an improvement in patient health as costs of drugs are reduced, freeing up NHS resources to spend on other services and treatments, which provide additional health benefits to patients. The estimated health gain over 5 years is valued at £738m.

10.3. The main cost is a loss of profits to shareholders in the pharmaceutical industry. The estimated total loss of profits over 5 years is valued at £124m. As the pharmaceutical industry is global, with an estimated 90% of shares under overseas ownership, the cost to UK shareholders is accordingly estimated to be £12m.

10.4. The net benefit of the proposal (including lost profits to UK and overseas shareholders) is estimated to be £613m over the 5 year period evaluated.

11. Regulating small business

11.1. The legislation applies to small business. However, companies with UK health service sales of branded medicines of less than £5 million will be exempt from the price cut and the information provisions.

11.2. The Regulatory Policy Committee, commenting on a statutory scheme Impact Assessment in 2012, accepted that ‘One-in, two-out’" does not apply to the statutory scheme because its effect is akin to procurement in a market in which there is no downward pressure on prices from external market forces.

11.3. The amended regulations will be subject to review – see section 12.

12. Monitoring and Review

12.1. The amended regulations will expire at the end of December 2020 unless they are renewed. The Secretary of State for Health will also undertake a review, and publish a report of the review findings, before the end of a 7 year period. The amended regulations will also be reviewed annually for the purposes of Council Directive 89/105/EEC.

13. Contact

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