EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE BRANDED MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) AMENDMENT REGULATIONS 2012

2012 No. 2791

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 change the maximum prices of prescription-only, branded medicines supplied to the National Health Service. These regulations do not apply to any company that is a member of a voluntary scheme to control the prices of branded health service medicines.

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

3.1 None

4. Legislative Context

4.1 Sections 260 to 266 of the National Health Service Act 2006 enable the Secretary of State to control maximum prices of health service medicines and medical supplies. They also provide for voluntary schemes limiting the prices of NHS medicines and the profits of the manufacturer and suppliers of such medicines.

4.2 There is in existence a voluntary scheme, the Pharmaceutical Price Regulation Scheme (PPRS), made by the Department of Health and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI), to control 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.

4.3 These regulations are made under sections 262(1), 263(1), 266(1)(a) and 272(7) of the Act and will apply on expiry of the current PPRS or to any company which is not a member of the 2009 PPRS.

4.4 These regulations further amend the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008, which provided that, subject to certain exceptions, that prices of medicines should be reduced by 3.9% from 1 February 2009.

4.5 The Regulations comply with the requirements of Council Directive 89/105/EEC of 21st December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national insurance systems.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

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 National Health Service (NHS) spends about £10 billion a year on branded prescription medicines in the UK. The PPRS is the mechanism, which the Department of Health (on behalf of the UK Health Departments) uses to control the prices of these medicines by regulating the profits that companies can make on these sales. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the ABPI. The PPRS seeks to achieve a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry to enable it to research, develop and market new and improved medicines for the benefit of NHS patients.

7.2 The PPRS covers all licensed, branded, prescription medicines sold to the NHS. It does not cover products without a brand name (generics) nor branded products available without prescription (over the counter, OTC, medicines) except when prescribed. It is a UK wide scheme and covers around 80 percent by value (some £10 billion a year) of the medicines used in the NHS in both primary and secondary care.

7.3 The scheme, which has existed in various forms since 1957, is generally renegotiated every five or so years. The latest scheme agreed by the Department and the industry started in January 2009 and is intended to last for five years.

7.4 The Department is introducing these amending regulations to control the prices of prescription-only branded NHS medicines from 1st January 2013 at levels which mirror those in the 2009 PPRS and to safeguard the financial position of the NHS by ensuring that there is a statutory fall-back for the PPRS to cover any companies choosing not to be members of the voluntary scheme. These statutory measures do not apply to any company whilst it is a member of a voluntary scheme.

7.5 These Regulations protect NHS expenditure by providing that, subject to the exceptions set out below, from 1st January 2013, the maximum price which may be charged for medicines within scope of these regulations is 5.3% less than the price of that medicine on 1st December 2008. The requirement to reduce prices by 5.3% mirrors the price adjustment arrangements in the voluntary scheme.

7.6 There is an exemption from the requirement to reduce the price by 5.3% compared to the price on 1st December 2008 for low cost presentations. Low cost presentations are presentations which cost the NHS not more than £450,000 in a calendar year, or which have a reimbursement price of less than £2.00.

7.7 Products may also be exempted from the effect of regulation either on the election of the Secretary of State or in response to an application from the relevant manufacturer or supplier on the grounds that the supply of that medicine may be jeopardised. Similarly, the Secretary of State can provide for a price increase for products by means of a direction.

7.8 The information requirements to monitor the proposed price controls and their impact contained in the regulations which this instrument amends remain unchanged, as do the controls on the maximum price of new products and the rights of appeal against any enforcement decisions made by the Secretary of State.

7.9 There will be limited interest in these regulations outside the branded pharmaceutical industry.

8. Consultation outcome

8.1 The Department consulted with the ABPI as the appropriate body under the National Health Service Act 2006. The ABPI were content with the proposed amendments to mirror the effect of the 2009 PPRS from 1st January 2013.

9. Guidance

9.1 The Department has issued guidance on the implementation of these regulations directly to those companies affected and has made that guidance available to the ABPI.

10. Impact

10.1 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business. Companies with NHS sales of less than £25m are exempt from the information provisions

12. Monitoring & review

12.1 The Regulations will be reviewed annually, so as to ensure compliance with Council Directive 89/105/EEC, Article 4 of which requires that any price freeze be reviewed at least once a year.

13. Contact

13.1 Dani Lee at the Department of Health who may be reached by telephone on 020 79722983 or by e-mail at Dani.Lee@dh.gsi.gov.uk.