EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE MEDICINES (CONTROL OF PRICES AND SUPPLY OF INFORMATION) (AMENDMENT) REGULATIONS 2015

2015 No. 233

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. **Information requirements** – To require certain manufacturers and suppliers that supply branded medicines used for the purposes of the National Health Service to record and keep information of the actual amount they received for each transaction of each medicine so that if the Department reasonably considers that the manufacturer or supplier may have breached the statutory scheme regulations (which provides for a statutory scheme to control prices), the Department may request this information from the manufacturer or supplier.

2.2. **Relevant Medicines –** To clarify that the limit on price in the statutory scheme regulations only applies to medicines that are prescription only branded medicines used for the purposes of the health services.

2.3. **Application of Price Control** – To clarify that the current 15% price cut in the statutory scheme regulations does not apply to medicines that were procured for use in the National Health Service under EU and UK procurement law prior to the implementation of the price cut.

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

3.1. None.

4. Legislative Context

4.1. The Secretary of State has the power to limit the prices of, or profits accrued from, medicines used for the purposes of the National Health Service.

4.2. This is done via the voluntary scheme (currently the Pharmaceutical Price Regulation Scheme 2014 ["the PPRS 2014"], as negotiated between the Department of Health and the Industry Body, the Association of the British Pharmaceutical Industry ["ABPI"]), and the statutory scheme, as set out in specific Regulations. Manufacturers and suppliers that choose not to become members of the PPRS 2014 will by default become subject to the statutory scheme regulations.

4.3. There are two principal sets of regulations which provide for the statutory scheme:

- 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"].

4.4. These two sets of Regulations govern different aspects of the scheme. The 2008 Regulations deal with price control and the enforcement of that control and the 2007 Regulations deal with the information needed to determine whether a manufacturer or supplier has been selling the relevant medicines at a price above the maximum provided for under the 2008 Regulations.

4.5. This instrument – The Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2015 ["the 2015 Regulations"] – amends both these statutory scheme regulations.

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 England NHS spends approximately £10billion a year on branded prescription medicines. The statutory scheme regulations and the voluntary PPRS 2014 work together to limit the overall spend on branded medicines and thereby contribute to safeguarding the financial position of the NHS.

7.2. Under the PPRS 2014, it was agreed that, for the duration of the agreement, the vast majority of branded health service medicine spend will remain flat for two years, followed by small increases of less than two per cent for three years. If branded medicines spend is higher than the agreed level, companies that are members of the scheme will make payments to the Department of Health. The payment is a percentage of a company's health service sales, subject to agreed exclusions and net of discounts, and is paid quarterly in arrears.

7.3. With regards to the statutory scheme, the 2008 Regulations set out the provisions for enforcement of the limit on maximum price for branded health service medicines. Accordingly, a manufacturer or supplier who supplies a prescription only, branded health service medicine at a price in excess of the maximum price permitted in the regulations is liable to pay on demand a recoverable sum as set out in the Schedule to the Regulations. The recoverable sum is the difference between the amount the manufacturer actually received and the amount they would have received if the medicine had been supplied at the maximum permitted price.

7.4. The amendments to the 2007 Regulations introduce new information requirements to require manufacturers or suppliers to record and keep information on the actual amount received for the medicine and to provide this information to the Department when the Department considers there may have been a breach of the price limits. This will enable the Department when necessary to confirm whether or not a breach of the price limit has occurred and to calculate accurately the amount that the manufacturer or supplier actually received in order to improve the Department's ability to determine the recoverable sum and to apply existing penalties.

7.5. The Department considers that there is generally good compliance with the Regulations and it is therefore expected that numbers of affected companies will be low. However, in order to safeguard the financial position of the NHS, it is important that the Department can take effective enforcement action, if the need for this arises.

- ***Consolidation***

7.6. The Department recognises that the regulations are complex and that due to several amendments over a number of years to both the 2007 and 2008 Regulations there is a need not only to consolidate the amendments but also to consolidate the two sets of Regulations together. The Department therefore expects to fully consolidate the amendments as well as the two sets of regulations themselves in the next Parliament, but wanted to ensure that the information required for enforcement was available in the meantime.

8. Consultation outcome

8.1. Industry stakeholders, in particular companies that are affected by the regulations and their industry representatives, as required, were consulted as part of the consultation. This included a roundtable meeting hosted by the Department.

8.2. The consultation concerned options for i) a further limit to the maximum price (i.e. a price cut) of prescription only, branded health service medicines with reference to the price at which the presentation was on sale for health service purposes on 1 December 2013 and ii) strengthening the information requirements for enforcement to enable fair and consistent application of the limit on price.

8.3. The consultation was conducted from 10 October 2014 to 7 November 2014. While, as a general principle, the Department recognises that it is desirable to consult for a period of up to 12 weeks in line with relevant guidance, the timing of this consultation needed to be aligned with the availability of branded health service medicines sales data under the 2014 PPRS. This data was necessary to inform consultation proposals on a potential further price adjustment in the statutory scheme. The Department's aim is to keep the two schemes broadly aligned and the Department consulted on a further price cut as soon as possible after the relevant data became available and had been considered fully. The end date for the consultation was set so as to ensure that if a further price limit had been imposed under the statutory scheme it could be aligned, as close as possible, to the increased payments that would be due by members of the PPRS 2014.

8.4. A total of 29 responses were received, of these 21 were received from pharmaceutical companies and their trade associations, or consultants advising industry. Other respondents included NHS organisations, one patient support group, one research charity and one private individual.

8.5. The Department has analysed the responses to the consultation and has published its response at https://www.gov.uk/government/consultations/branded-medicines-controlling-prices

8.6. Taking into account the responses to the consultation, as well as a range of other factors, the Department decided not to implement a price cut at this time but to keep this issue under review.

8.7. Just under half of all respondents, and the majority of industry respondents, supported the proposal that companies should be required to record and keep information on actual selling prices. Of those that were not in favour, the most common concern was the impact of the new information requirement on small businesses.

8.8. In its response, the Department confirmed that it is not its intention to require the information to be supplied regularly – the information would only be requested from a company in cases (which we expect to be rare) where the Department reasonably believes that a breach in the regulations has occurred.

9. Guidance

9.1. The Department will issue guidance on the implementation of these revised regulations directly to those companies covered by the regulations and will make that guidance available to the representative industry bodies.

10. Impact

10.1. The final impact assessment is attached to this memorandum and will be published alongside it.

10.2. There may be increased costs to business through a greater requirement for administration. However it is expected that these costs will be negligible, because the collection and retention of the information that will be requested is already required for other purposes not connected to pharmaceutical price control. Additional costs will only be incurred if and when the Department requests that the information is reported to the Department.

10.3. The Department considers that there is generally good compliance with the Regulations and it is therefore expected that numbers of affected companies will be low. The impact on the public sector is therefore expected to be minimal. The processing of any requests for information from companies regarding actual price will be covered by the Department's existing Medicines Pricing Operations Team.

11. Regulating small business

11.1. The legislation applies to small businesses.

11.2. To minimise the impact of the requirements on small firms, manufacturers and suppliers with UK sales income of less than £5 million (in the most recent complete calendar year) for branded health service medicines will be exempt from the new information requirements.

11.3. The consultation document specifically asked for comments of the impact that the new information requirements may have on small businesses. Following the consultation, the Department took the view that as the new information requirements would only apply in very rare circumstances where the Department considers that there may have been a breach of the regulations, and as companies are already required to keep information on sales transactions in their accounts, it is proportionate to apply the new requirements on firms whose UK sales income derived from branded health service medicines was above the £5million threshold. In addition, 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.

12. Monitoring and Review

12.1. There will be further review in due course as part of an ongoing assessment of the branded medicines pricing system and as part of a planned consolidation of these regulations. There is already generally good compliance with the regulations and the Department would only request the information in very rare circumstances where it considers that there may have been a breach of the regulations.

13. Contact

13.1 Cathleen Schulte at the Department of Health, Tel: 020 7972 6539 or email: cathleen.schulte@dh.gsi.gov.uk can answer any queries regarding the instrument.