EXPLANATORY MEMORANDUM TO

THE HEALTH SERVICE MEDICINES (INFORMATION RELATING TO SALES OF BRANDED MEDICINES ETC.) REGULATIONS 2007

2007 No.1320

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

2. Description

2.1 These Regulations require the major pharmaceutical companies to provide the Department of Health with quarterly information on their income from the sales, after discount, of each branded medicine supplied to the National Health Service (NHS).

2.2 These Regulations also revoke various regulations which no longer reflect the policy on statutory price controls of medicines supplied for NHS purposes.

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

3.1 None.

4. Legislative Background

4.1 The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement, between 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.

4.2 The scheme, which has existed in various forms since 1957, is generally renegotiated every five or six years. It is a UK-wide scheme. The current PPRS commenced on 1st January 2005 and is set to operate for at least five years from that date.

4.3 The PPRS applies to those manufacturers and suppliers of branded medicines who elect to be scheme members.

4.4 The Regulations require PPRS scheme members to supply information on the sales of each pack size and strength of branded medicines for NHS purposes. The Regulations do not apply to scheme members who voluntarily agree to supply to the Secretary of State information on the sales of branded medicines to the NHS under the 2005 PPRS.

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

7.1 The PPRS regulates the prices of branded prescription medicines and the profits that manufacturers are allowed to make on the sales of such medicines to the NHS. The objectives of the PPRS are to secure the provision of safe and effective medicines for the NHS at reasonable prices, to promote a strong and profitable pharmaceutical industry and to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets.

7.2 The PPRS covers some £8 billion by value of the medicines used in the NHS in both primary and secondary care.

7.3 The 2005 PPRS includes a seven per cent price reduction for branded prescription medicines, which delivered savings of £370 million in 2005 in primary care in England and it is estimated will save the NHS more than £1.8 billion over the five-year agreement.

7.4 Since the Department and the ABPI negotiated the 2005 scheme, several pharmaceutical companies have decided to change or are considering changing the arrangements for the distribution of their branded medicines to the NHS. Such changes could impact on the delivery of the seven per cent price reduction to the NHS.

7.5 The information on the extent of discounts given by PPRS members on sales of branded medicines, required by the Regulations, will allow the Department to assess whether it is achieving value for money for the NHS by ensuring the continued delivery of the seven per cent price reduction and by ensuring that the changes to distribution arrangements are at no extra cost to the NHS.

7.6 The Department consulted with the ABPI as the appropriate representative industry body under section 261(7) of the National Health Service Act 2006. The Department wrote to the ABPI with its proposals for regulations on 9 October 2006.

7.7 Following discussions, it was agreed that scheme members would be invited to supply information on sales of branded medicines under the 2005 PPRS i.e. on a voluntary basis. Those scheme members that were not prepared to agree to supply the information voluntarily would be subject to

regulations requiring the supply of information on the sales of branded medicines. The Regulations reflect this agreement.

7.8 There will be limited interest in these Regulations outside the branded pharmaceutical industry. The Department has prepared guidance, agreed with the ABPI, to be issued to pharmaceutical companies on the effect of the Regulations. The Regulations will come into force on 7th May 2007 with the obligation to provide information relating to the period beginning 1st May 2007. The Department will make arrangements to ensure that the Regulations are drawn to the attention of relevant scheme members from an early date.

7.9 The Regulations also revoke the following Regulations:
1) the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000 – these Regulations control the price of branded medicines sold for NHS purposes and apply to manufacturers who are not PPRS members. However, the price controls under the Regulations reflect the price controls imposed by the 1999 PPRS as the Regulations were intended to be the statutory equivalent of the 1999 PPRS. The 2005 PPRS imposes higher price controls than the 1999 PPRS and it is expected that any price controls on non-PPRS members would reflect the new higher price control under the 2005 PPRS. The Regulations therefore no longer reflect the policy on the extent of the price controls of medicines sold by non-PPRS members and are being revoked for that reason.
2) the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000 and 3) the Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2000 (the 2000 Regulations) - these Regulations respectively control the price of generic medicines sold for NHS purposes and require the provision of information in relation to the price of such medicines. They apply to manufacturers who are not members of a voluntary scheme. In September 2005 new long-term arrangements were introduced for reimbursement of generic medicines, namely voluntary Schemes M and W for manufacturers and wholesalers respectively. These arrangements are different to those made under the 2000 Regulations and it is expected that any price controls imposed on non-scheme members would reflect these arrangements rather than those under the 2000 Regulations. The 2000 Regulations therefore no longer reflect DH policy on generic pricing arrangements in respect of non-scheme members and are being revoked for that reason.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 There is no impact on the public sector.

9. Contact

9.1 Any enquiries should be addressed to: David Kullman at the Department of Health. Tel: 020 7972 2983 or email david.kullman@dh.gsi.gov.uk.

Full RIA

Title: Provision of Information in relation to the sales of branded medicines from suppliers to the NHS

The Department of Health (the Department) is introducing regulations to require the provision of quarterly information from the major pharmaceutical companies supplying branded prescription medicines to the National Health Service (NHS) on the net income and volume of each branded medicine sold.

Purpose and intended effect

Objective

The arrangements are designed to provide information on the extent of discount in the supply of branded medicines to the NHS. These regulations will not apply to a member of the 2005 Pharmaceutical Price Regulation Scheme (PPRS) who agrees as part of its obligation under a voluntary scheme to provide the information set out below and within the specific time limits set out below.

The policy covers the whole of the UK.

Background

The prices of branded prescription medicines and the profits that manufacturers are allowed to make on their sales to the NHS are regulated by the PPRS. The PPRS is a voluntary agreement made between the Department and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI) – under Section 33 of the Health Act 1999. A new five-year scheme commenced on 1 January 2005. It includes a seven per cent price reduction for branded prescription medicines, which delivered savings of £370 million in 2005 in primary care in England and it is estimated will save the NHS more than £1.8 billion over the five-year agreement. It is a UK wide scheme covering some £8 billion by value of the medicines used in the NHS in both primary and secondary care. A team in Medicines Pharmacy and Industry Group of the Department administer the scheme on behalf of the UK Health Departments.

The distribution margin in the current PPRS is nominally 12.5 per cent of the manufacturer's NHS list price although in practice some companies may be allowing higher or lower margins. Since the Department and the ABPI negotiated the 2005 scheme, several pharmaceutical companies have decided to change or are considering changing the arrangements for the distribution of their branded medicines to the NHS e.g. exclusive logistics arrangements with a sole wholesaler rather than supplying UK

wholesalers. The Department has an obligation to ensure that there is no extra cost to public expenditure arising from these changes to the medicines supply chain.

Rationale for Government Regulation

The information on the extent of discounts in the supply of branded medicines to the NHS will allow the Department to assess whether it is achieving value for money for the NHS by ensuring the continued delivery of the seven per cent price reduction and by ensuring that changes to distribution arrangements are at nil cost to the NHS.

There are no EU directives that necessitate this consultation.

Consultation

The Department consulted with the Association of the British Pharmaceutical Industry (ABPI) as the appropriate representative industry body under section 33(7) of the Health Act 1999. The Department wrote to the ABPI on 9 October 2006 with its proposals to introduce regulations requiring the provision of information. The consultation closed on 20 December and the Department held a series of meetings with the ABPI between October 2006 and March 2007. As a result of these discussions, the Department amended its original proposals. In particular, agreement was reached with the ABPI that those members of the 2005 PPRS who agree to supply the required information voluntarily and within the time limits would not be subject to the regulations.

Options

The Department identified a range of potential options:

Option 1: collect information, under powers in section 33 (7) of the Health Act 1999**1**, from the major manufacturers and suppliers of branded medicines to the NHS.

Members of the 2005 PPRS with sales of branded medicines of over £25 million a year (currently 40 companies) will be required to submit information in respect of each pack size and strength of each presentation of each medicine on the number of packs sold in any given quarter and the net income derived from those sales of each product. The information is required to be split into sales into six channels to wholesalers, retail pharmacists, hospitals, dispensing doctors, GMS**2** and PMS**3** contractors. Net income means income after discounts offered to customers. The value of any discount, which cannot be specifically attributed to specific products, is also required.

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1 *Section 33 (7) gives the Secretary of State power by regulations or direction to require any manufacturer or supplier to record and keep information, and to provide information to the Secretary of State.*

2 General Medical Services

3 Primary Medical Services

The information is required quarterly and is to be submitted to the department within one calendar month of each quarter.

Any company leaving the 2005 PPRS before or during the lifetime of the regulations would have the same information sought under section 35(3) of the Health Act 1999.

Option 2: invite the major manufacturers and suppliers of branded medicines to the NHS to provide the information below on a voluntary basis under the 2005 PPRS. Those members who do not agree to provide the information voluntarily will be required to provide the information set out in option 1 under regulations.

The information required on a voluntary basis is the net value of sales of branded medicines to the NHS quarterly by product and the gross value of the same sales i.e. NHS list price. Net value of sales means income from sales of branded products after deduction of all trade and other discounts (howsoever named) including settlement discounts, rebates and sales taxes. The information is required to be split into sales into three channels - wholesalers/retail pharmacists, NHS hospitals and other (which includes dispensing doctors and GMS/PMS contractors). Companies should also provide information about discounts given that cannot be specifically attributed to a specific branded product. The information is required quarterly and is to be submitted to the department within one calendar month of each quarter. The information will be required to be audited annually.

Option 3: invite major manufacturers and suppliers to supply the information (as set out in option 2 above) voluntarily.

There is a risk that not all the companies will supply information. The Department will have incomplete data and will be unable to assess whether it is achieving value for money. Those companies that choose to supply information will incur the costs of supplying the information and may be at a commercial disadvantage to those who choose not to provide information. The Department would need to make regulations to enforce any breach of the undertaking.

Option 4: Do nothing. In view of the media and parliamentary attention that the changes to the supply change have attracted and the risk to public expenditure, this is not a feasible option.

Costs and benefits

Sectors and groups affected

The business sector affected is the pharmaceutical industry, specifically the manufacturers and suppliers of branded medicines to the NHS. There are over 160 members of the 2005 PPRS, of which there are 40 major companies with sales of branded medicines to the NHS of £25 million a year or more and which would be required to submit this additional information relating to sales of their medicines. These 40 major companies account for over 90 per cent of NHS expenditure on branded medicines.

There are no identified racial equality impacts.

Benefits

Option 1: The information on the value and volumes of branded medicines sold to the NHS will allow the Department to calculate the extent of the discounts in the supply chain and to assess whether it is achieving value for money. NHS expenditure on branded medicines is £8 billion a year, so a one per cent increase in expenditure as a result of the changes in the supply chain will cost £80 million. The information will also ensure that companies continue to deliver savings to the NHS from the 7 per cent price reduction. This is worth £370 million a year (England, primary care) or some £450 million for the UK. In total, up to some £530 million of NHS expenditure is at risk.

Option 2: In addition to the benefits above, the provision of information on a voluntary basis would preserve the voluntary nature of the PPRS agreement. It would allow for discussion and flexibility e.g. less detailed information is required on a voluntary basis (by product rather than pack size and strength of each presentation and by sales split into three channels (wholesalers/retail pharmacists, NHS hospitals and other) rather than six channels under regulations). Light touch regulation.

Option 3: The voluntary provision of information would not require the introduction of regulations.

Option 4: The benefit to the manufacturers and suppliers is that they do not incur costs supplying the information. There would be no benefit to the Department if no information was provided.

Costs

Option 1: Information on sales of their products will be readily available to companies. Most companies are delivering the seven per cent price reduction by modulation and already provide some of the required information to the Department on an annual basis. However, companies will incur some administrative costs in providing additional information i.e. quarterly information on the value and volumes of each pack size and strength of branded medicines sold to the NHS split into six channels – wholesalers, retail pharmacists, NHS hospitals, dispensing doctors, GMS and PMS contractors. The additional costs will vary from company to company depending on the extent to which companies have to adjust and re-present the data available in their own accounts systems. Discussions with industry and the Department's experience of collecting similar information from suppliers of generic medicines give an estimated additional cost of supplying this information of an average of £1,000 a year. In total, £40,000 for the 40 major companies required to provide information.

There are no identified economic, environmental, social or rural impacts.
There are no additional policy or administrative costs to the Department from processing this information.

Options 2-3: Companies will incur some administrative costs in providing quarterly information on the value and volumes of branded medicines sold to the NHS to the Department. However, information on sales of their products will be readily available to companies. Most companies are delivering the seven per cent price reduction by modulation and already provide much of this information to the Department on an annual basis. The additional requirements are providing information quarterly and splitting sales of products into three channels – wholesalers/retail pharmacists, NHS hospitals and other. The additional costs will be affected by the degree to which companies have to adjust and re-present the data available in their own accounts systems. Discussions with industry and the Department's experience of collecting similar information from suppliers of generic medicines give an estimated additional cost of supplying this information of an average of £1,000 a year, mostly audit costs. In total, £40,000 for the 40 major companies required to provide information.

There are no identified economic, environmental, social or rural impacts.

There are no additional policy or administrative costs to the Department from processing this information.

Summary of costs and benefits

Options	**Costs**	**Benefits**
Option 1: Regulations	£40,000	Up to £530 million
Option 2: Voluntarily under PPRS with regulations as required	£40,000	Up to £530 million
Option 3: Voluntarily	£0 to £40,000	Up to £530 million
Option 4: Do nothing	£0	£0

Impact on small firms

None of the options would have an impact on small companies as information is only required from companies with sales of branded medicines to the NHS above £25 million.

Competition Assessment

The Office of Fair Trading's filter test has been applied, and the Department has been required to carry out only a simple competition assessment.

In aggregate, no company holds more than 10 per cent of market share[4] although as a percentage of the branded market, one company holds more than 10 per cent. However, the pharmaceutical sector consists of many sub markets, each of which treats specific conditions. In some markets, individual companies hold more than 10

4 As a share of total NIC of medicines dispensed in the community and in hospitals.

per cent or 20 per cent, or three companies hold more than 50 per cent of market share.

As a result, depending on the perspective, between one and four of the questions could be answered as yes. However, in either case the result is that less than half of the filter questions are answered as yes, so a full assessment is not required.

Enforcement, monitoring and sanctions

Option 1 would be enforced under section 33(7) of the Health Act 1999. Companies would have a right of appeal in accordance with regulations under section 37(5) of the Health Act 1999. Failure to provide the information sought will attract penalties as listed in the table below.

Sales recorded in the 2004 Annual Financial Return	*Daily penalty for first 14 days*	*Daily penalty for subsequent days*
Less than £100 million	£2,500	£5,000
Not less than £100 million	£5,000	£10,000

However, discussions with the ABPI indicate that most, if not all, of the companies are likely to agree to provide the information on a voluntary basis under the 2005 PPRS (option 2). All companies are complying with the current provisions of the scheme including submitting audited information on their delivery of the seven per cent price reduction. Companies will be required to submit information quarterly and an audit certificate annually. The existing PPRS team in Medicines Pharmacy and Industry Group of the Department will monitor and analyse the information. Companies and the Department may refer any unresolved issues to the existing arbitration panel set up under the 2005 PPRS.

The Department has no powers to enforce companies to provide information on a voluntary basis (option 3).

The Department consulted the ABPI on the design of the form for the information and of the audit certificate. The information is to be submitted electronically and the form is available for downloading as an Excel file from the Department's website.

Implementation and delivery plan

The Department has engaged in consultation with the ABPI since October 2006 and has jointly developed option 2 – the provision of information on a voluntary basis with companies not prepared to agree to this subject to regulations. This has included drafting a letter to companies with drafts of the form and the regulations. The information is required quarterly, the first quarter being the three months ending 30th June 2007. (In respect of the quarter commencing on 1st April 2007, the requirement to provide information under regulations applies in respect of the period 1st May 2007 to 30th June 2007). The information is to be submitted to the department within one calendar month of each quarter.

Post-implementation review

The provision of information on a voluntary basis will be reviewed as part of the 2005 PPRS, which will operate for not less than five years from 1 January 2005. There is provision for either party to the agreement to request a mid-term review from 1 July 2007.

Summary and recommendation

Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: economic, environmental, social; policy and administrative**
Option 1	£40,000	Up to £530 million
Option 2	£40,000	Up to £530 million
Option 3	£0 to £40,000	Up to £530 million
Option 4	£0	£0

The recommended option is option 2: to invite the major manufacturers and suppliers of branded medicines to the NHS to provide information on a voluntary basis. Those members who do not agree to provide the information voluntarily will be required to provide the information under regulations.

This option has been negotiated with the ABPI and is preferred to option 1 as it gives companies the choice of providing information voluntarily and is in keeping with the voluntary nature of the PPRS agreement. It allows for discussion and flexibility e.g. less detailed information is required on a voluntary basis than under regulation. We expect most, if not all, companies to agree to provide the information voluntarily rather than be subject to regulations. Under option 3 (the provision of information voluntarily), the Department would not be able to enforce any breaches of the undertaking without taking regulations. Option 4 (Do nothing) would not address the issue and risk over £500 million NHS expenditure.

Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed *Hunt*

Date 19th April 2007