EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (LOCAL PHARMACEUTICAL SERVICES) AMENDMENT REGULATIONS 2012

2012 No. 1467

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 framework Regulations which govern the arrangements for the provision of some NHS community pharmaceutical services in England. They amend contractors' terms of service with regard to the arrangements for dispensing in particular pack sizes.

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

3.1. None

4. Legislative Context

4.1. NHS community pharmaceutical services in England are provided primarily under arrangements governed by the National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641, as amended) ("the PS Regulations", but arrangements can also be made by Primary Care Trusts for the provision of "local pharmaceutical services" with contractors under the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (S.I. 2006/552, as amended) ("the LPS Regulations"). Whereas providers of pharmaceutical services under the PS Regulations do so on the basis of being included on a list of approved providers kept by their local Primary Care Trust, providers of local pharmaceutical services have a contract (an "LPS contract") with their Primary Care Trust to provide those services. Of the two schemes, the scheme governed by the PS Regulations is the more prescriptive, with the LPS Regulations allowing greater scope for local negotiation as regards the terms on which community pharmaceutical services are provided.

4.2. Contractors are required under paragraph 3 of Schedule 2 to the LPS Regulations to supply, with reasonable promptness, medicines that have been ordered on NHS prescription – subject to the provisions of the rest of that Schedule. Generally, a contractor is required to dispense the exact quantity ordered. However, there have been two exceptions to this rule – special containers and calendar packs.

4.3. These exceptions have been set out in paragraph 6 of Schedule 2 to the LPS Regulations. Paragraph 6(8) defines special containers and calendar packs, while paragraph 6(6) permits a contractor, in specified circumstances, to supply the special container or calendar pack whose quantity is nearest to the quantity ordered by the prescriber, where the drug is packaged in a calendar pack or a special container.

5. Territorial Extent and Application

5.1. This instrument applies to England.

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

What is being done and why

7.1 These Regulations will:

remove the provision concerning calendar packs from contractors' terms of service and require contractors instead to supply the exact quantity ordered by the prescriber in all cases, except when supplying (in the circumstances specified) medicines packed in special containers.

require contractors to supply medicines in the original packaging supplied by manufacturers unless they are unable to source packs in the appropriate size with reasonable promptness or it is not practicable for the contractor to supply such a pack or packs in response to the order from the prescriber.

7.2 The changes are linked to the reimbursement arrangements under the Drug Tariff: generally, LPS contracts provide that reimbursement for medicinal products provided under the contract is to be on the basis of the Drug Tariff reimbursement arrangements. Essentially, reimbursement for medicinal products under the Drug Tariff is relatively simple, with contractors being paid the manufacturer's list price minus a discount (where appropriate) for the quantity prescribed of the product – except for special containers and (until now) most dispensing of calendar packs, where the contractor has been required to supply (and so has been paid for) a quantity which is the pack size nearest to the quantity prescribed. Allowing these exceptions adds complexity to the reimbursement system and results in a lack of transparency to the prescriber as to the quantity dispensed to the patient.

7.3 Maintaining the exception for special containers is essentially for reasons of pragmatism, as in such cases it is generally not practical to dispense the exact quantity ordered. As regards calendar packs, removing the provisions requiring a contractor to supply a quantity other than that prescribed, when a calendar pack is available, and replacing it with a requirement to supply an original pack produced by a manufacturer, where possible and practicable, will require contractors to improve the efficiency of the dispensing process by reducing occasions on which they will be able to 'snip' blister packs and dispense split packs. In addition, dispensing original packs will ensure improved access to the approved patient information leaflets provided with authorised medicines in their original packaging.

Consolidation

7.4 These Regulations only amend a small proportion of contractors' statutory terms which are set out in the LPS Regulations, so the Department did not consider it appropriate to consolidate the LPS Regulations on this occasion, but keeps this matter under regular review.

8 Consultation outcome

8.1 The changes for contractors are part of a wider package of changes to reimbursement arrangements for providers of community pharmaceutical services as negotiated and agreed between DH and the Pharmaceutical Services Negotiating Committee (PSNC), which represents community pharmacy contractors. They have not been subject to public consultation.

8.2 Parallel changes have already been made to the PS Regulations to change the equivalent terms of service of providers included on pharmaceutical lists, and it was an oversight on the part of the Department which led to the two sets of amendments not featuring in a single instrument.

9 Guidance

9.1 DH and PSNC have developed guidance about the changes for providers of community pharmaceutical services under both the PS Regulations and the LPS Regulations, which is expected to be published shortly after these Regulations are made.

10 Impact

10.1 An Impact Assessment has not been prepared for this instrument.

10.2 The impact of the changes is intended to be cost neutral

11 Regulating small business

11.1 The legislation applies to small businesses, including firms employing up to 10 people. As the LPS Regulations concern the provision of NHS community pharmaceutical services, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed national standards and practices in the provision of such services as part of the nationally determined contractual framework.

12 Monitoring & review

12.1 The Department monitors the operation of the LPS Regulations and has regular discussions with interested parties, including the NHS and contractors' representatives, on any problems identified in their operation.

13 Contact

Susan Grieve at the Department of Health Telephone: 020 797 22969 email: Susan.Grieve@dh.gsi.gov.uk can answer any queries regarding the instrument.