EXPLANATORY MEMORANDUM TO

THE MEDICINES (PHARMACIES) (RESPONSIBLE PHARMACIST) REGULATIONS 2008

2008 No. 2789

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 prescribe how a responsible pharmacist – ie the pharmacist in charge of a registered pharmacy business – is to comply with his statutory duty relating to the business. The overriding duty is to secure the safe and effective running of the pharmacy where this concerns the retail sale or supply (eg on prescription) of medicines.

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

3.1. None

4. Legislative Context

4.1. The Medicines Act 1968 ("the 1968 Act") requires each registered pharmacy business to be under the personal control of a pharmacist where this concerns the sale and supply of medicines. Sections 27, 28 and 29 of the Health Act 2006 amend sections 70, 71 and 72 of the 1968 Act to remove the "personal control" requirement and to insert a new requirement that each pharmacy is to have a responsible pharmacist in charge of the business where this relates to the sale and supply of medicines.

4.2. Section 30 of the Health Act 2006 inserts a new section 72A in the 1968 Act that places a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy. These Regulations set out further how the responsible pharmacist is to comply with that statutory duty.

4.3. The Regulations are subject to the negative resolution procedure. These are made by both the Secretary of State for Health and the Minister for Health, Social Services and Public Safety in Northern Ireland.

5. Territorial Extent and Application

5.1. These Regulations apply 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 1968 Act does not define "personal control" or specify how the pharmacist in control of the pharmacy is to meet this requirement. There is also little case law on the

subject. In the absence of clarity on the personal control requirement, in 2004 the Chair of the Statutory Committee of the Royal Pharmaceutical Society of Great Britain advised that, to exercise personal control, the pharmacist must be present on the registered pharmacy premises. If the pharmacist is not present, he is not in personal control of the pharmacy and the sale and supply of medicines to the public may not continue. Pharmacy owners and pharmacists comply with the Statutory Committee's interpretation of "personal control". However, increasingly they raised questions in relation to

- the restrictions on the pharmacist's ability to leave the registered premises during business hours and the public's access to medicines they need – as the view is that medicines may not be sold or supplied unless the pharmacist is physically present in the pharmacy at all times when it is open for business. This interpretation of "personal control" means the pharmacy must close for the sale or supply of all medicines where the pharmacist is not present

- the creation of an anomaly relating to the sale of general sale list (GSL) medicines from pharmacies – that is, medicines (eg aspirin) which may be safely purchased in small quantities from other outlets as well as pharmacies. As the Statutory Committee's advice on the exercise of personal control relates to the sale of *all* medicines from a pharmacy, this has meant that the public may not buy a GSL medicine from a pharmacy if the pharmacist is not present. Yet, someone may purchase these medicines from a newsagents or corner shop where there is no requirement for a pharmacist to be present to permit sale.

- the need for greater clarity on the legal responsibilities of the pharmacist in "personal control" of the pharmacy – there is a view that the pharmacist's physical presence should not be the sole indicator that the pharmacy is operating safely and effectively

7.2. The Health Act 2006 amends the 1968 Act to remove the "personal control" requirement and to replace it with a new requirement that each pharmacy is to have a responsible pharmacist. These changes make clear that the responsible pharmacist

- is the pharmacist in charge of the pharmacy on any date and at any time and he must display a notice to that effect in the pharmacy, together with details of his registration number

- whilst responsible for a pharmacy, he has a statutory duty to secure the safe and effective running of the pharmacy

- generally, may be responsible for only one pharmacy at the same time save in prescribed circumstances

- must set down, maintain and review procedures that secure safe and effective working in the pharmacy

- must keep a record of the pharmacist responsible for the pharmacy on any date and at any time.

7.3. The Regulations provide further detail on how the responsible pharmacist is to comply with the statutory duty. These include restrictions on his absence from the pharmacy, the need for arrangements where the responsible pharmacist is absent from the pharmacy and the removal of the current anomaly relating to the sale of general sale list (GSL) medicines from pharmacies (Regulation 3); establishing and reviewing pharmacy procedures (Regulation 4); and maintaining and preserving the pharmacy record (Regulation 5).

8. Consultation outcome

8.1. In 2005, in responding to public consultation on ways of making better use of the pharmacy workforce to improve the delivery of pharmaceutical services, 75% of respondents called for changes to the "personal control" requirement in sections 70, 71 and 72 of the 1968 Act. They wished to see greater clarity on the role of the pharmacist in charge of the pharmacy, in terms of the pharmacist's professional accountability for safeguarding the public in relation to the sale and supply of medicines. The Health Act 2006 amends the 1968 Act to remove the "personal control" requirement and to replace it with a new requirement that each pharmacy is to have a responsible pharmacist.

8.2. In October 2007, the Department of Health published a further public consultation paper setting out proposals for the content of the Regulations. Consultation closed in January 2008. There were 311 responses.

8.3. In May 2008, the Department of Health published the outcome of the public consultation, details of those individuals and organisations who responded to proposals for the Regulations, together with the Government's response. This is available on the Department of Health website at
www.dh.gov.uk/en/consultations/responsestoconsultations/index/htm

8.4. Section 72A of the 1968 Act allows the responsible pharmacist to be absent from the pharmacy but no clear majority view emerged from the consultation on proposals for regulations relating to the responsible pharmacist's absence. During passage of the Health Act 2006, and in consultation on the Regulations, the Government made clear its view that to exercise the duty to secure the safe and effective running of the pharmacy, the responsible pharmacist should spend the majority of his time in the pharmacy. Additionally, the Government's view is limiting absence will avoid widely differing interpretations of absence that may result in the responsible pharmacist being away from the pharmacy for significant periods. Regulation 3 limits absence to a maximum of 2 hours during the pharmacy's business hours – in line with the views of the majority of those responding on the need to limit any period of absence. In addition, before he is absent from the pharmacy, the responsible pharmacist must put in place arrangements that will continue to support safe and effective working in the pharmacy throughout any period of absence.

8.5. The majority of those responding to public consultation supported the Regulations relating to the pharmacy procedures and the pharmacy record.

8.6. In accordance with custom and practice, informal consultation continued with key pharmacy organisations on the drafting of the Regulations. These organisations included

The Royal Pharmaceutical Society of Great Britain
The Pharmaceutical Society of Northern Ireland

The Company Chemists Association
The National Pharmacy Association
The Pharmaceutical Services Negotiating Committee
The Guild of Healthcare Pharmacists
The Association of Independent Multiple Pharmacies
The Medicines and Healthcare Products Regulatory Authority
Community Pharmacy, Scotland
Community Pharmacy, Wales

9. Guidance

9.1. In consultation with the professional regulatory bodies and other pharmacy organisations, the Government will provide guidance to users and stakeholders on changes to sections 70, 71 and 72 of the 1968 Act, the new section 72A inserted into that Act, and the Regulations. The Government is also working with the professional regulatory bodies (the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland) on the development of professional regulatory standards and guidance that reflect the changes to the 1968 Act.

10. Impact

10.1. An Impact Assessment has not been prepared for this instrument as it has only a negligible impact on business, charities or voluntary bodies. The legislative changes clarify the requirements in the 1968 Act relating to retail pharmacy businesses and underpin existing professional and ethical standards for pharmacists and safe pharmacy practice.

11. Regulating small business

11.1. The legislation applies to small business.

11.2. However, there is no change in how the Medicines Act 1968 applies to small business – that is an individual retail pharmacy business or a small chain of retail pharmacies, owned by a pharmacist. Like other retail pharmacy businesses, these must comply with the requirements that each pharmacy is to have a responsible pharmacist (formerly a pharmacist in personal control) to allow the sale and supply of medicines to the public. Like other retail pharmacy businesses, these smaller businesses comply with professional regulatory standards set for safe pharmacy practice (eg the use of pharmacy procedures). The removal of the current anomaly relating to the sale of GSL medicines (see paragraph 7.1 above) relates to all retail pharmacies, including small business, placing them on a more level footing with other retail outlets selling these medicines.

12. Monitoring & review

12.1. The Government has stated its intention to keep under review Regulation 3, which relates to the responsible pharmacist's absence from the pharmacy. This will be subject to the outcome of further public consultation on proposed changes to the requirement (in the Medicines Act 1968 and related NHS legislation) on pharmacists to supervise individual transactions involving the sale and dispensing of Pharmacy (P) medicines and Prescription only Medicines (POMs).

13. Contact

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