EXPLANATORY MEMORANDUM TO

THE MEDICINES (PHARMACIES) (APPLICATIONS FOR REGISTRATION AND FEES –AMENDMENT) REGULATIONS 2009

2009 No. 2502

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 The Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland ("the Societies") hold registers of pharmacy premises. This Instrument allows the Societies' registrars to accept applications from existing pharmacy businesses for registration of additional pharmacy premises during an influenza pandemic, without the need to provide all the information that is usually required with applications for registration in their Societies' registers. In addition, it allows the registrars to waive all or part of the prescribed registration fee.

3. Matters of Special Interest to the Joint Committee on Statutory Instruments

3.1 Yes. These Regulations breach the '21 day rule'. Originally, the measures included in these Regulations were to be included with a set of pandemic influenza changes to the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 (S.I. 2008/2789 – "the 2008 Regulations"), and consideration was also given to delaying the coming into force of the 2008 Regulations because their introduction would coincide with the next expected wave of cases of pandemic influenza, which may peak in the middle of October 2009 (the 2008 Regulations come into force on 1st October 2009). In the event, it was decided to continue with the current implementation arrangements for the 2008 Regulations and not to amend the 2008 Regulations. Once these decisions had been taken, the Department was concerned nevertheless to bring these Regulations into force as soon as practicable so that they would be in force before the projected peak of the next expected wave of pandemic influenza cases. As a consequence, it set a tighter timetable for obtaining the two signatures necessary for these Regulations than would normally have been the case. In the event, it did not prove possible to obtain the signatures and lay the instrument before Parliament within the required timetable. The Department apologises for what has happened. It should have split the package of legislative changes earlier.

4. Legislative Context

4.1 The registrars of the Societies are required by section 75 of the Medicines Act 1968 to keep registers of pharmacy businesses carrying on the retail sale (or supply in circumstances corresponding to retail sale) of medicinal products. By virtue of section 75(2) of that Act, applications for registration have to be made in the prescribed manner, and by virtue of section 75(1) entries will only be made in the register on payment of the prescribed fee.

4.2 The prescribed particulars that applications must contain are set out in The Medicines (Pharmacies)(Applications for Registration and Fees) Regulations 1973 (S.I. 1973/1822), which also contain the prescribed fees. At the moment, the fee payable for registration of premises in Great Britain is £529, and in Northern Ireland is £102. These fees were last uprated as from 1st January 2008.

5. Territorial Extent and Application

5.1 This instrument applies to 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. These Regulations are a further set of measures in response to the pandemic of influenza caused by a new virus subtype that was first identified earlier this year in Mexico.

7.2 The flexibilities that have been introduced in these Regulations all only apply in circumstances where, for the purposes of mitigating the effects of an outbreak of pandemic influenza, the NHS bodies that are responsible for commissioning NHS pharmaceutical services (that is, the sorts of NHS services provided by retail pharmacy businesses) have agreed with pharmaceutical services contractors to open temporary pharmacy premises. For example, it may be necessary to provide additional capacity in order to secure adequate provision of pharmaceutical services in the commissioning body's area. In these circumstances, NHS commissioning bodies may wish to authorise contractors to acquire new, temporary, premises from which to provide pharmaceutical services.

7.3. The acquisition of new, temporary premises will require pharmacy businesses to apply to the registrar of one of the Societies (depending on the location of the premises) for registration of these additional premises and pay the prescribed fee. The registrars will be able to accept applications for registration, which do not include all of the prescribed information, and this will enable registered additional premises to be available as soon as possible, thus helping to maintain adequate provision of pharmaceutical services. The ability to waive all or part of the fee for these applications will also help to streamline processes and reflects the essentially co-operative nature of any necessary emergency registrations.

7.4 The flexibilities will only apply to registration of temporary premises, and acceptance of an application for registration without all the prescribed information and any decision to waive all or part of the registration fee will be at the discretion of the registrar.

8. Consultation outcome

8.1 The Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland, together with other pharmacy organisations (including those representative of pharmaceutical services contractors and those owning pharmacy businesses) have been consulted on these provisions. None of the organisations consulted is opposed to these proposals.

8.2 The proposals in paragraphs 7.1. to 7.4 build on a wider consultation led by the Medicines and Healthcare products Regulatory Agency (MHRA), which took place in 2008 on a series of measures to ease requirements in both medicines and NHS legislation regarding the supply of medicines across the UK during a pandemic. Respondents to that consultation were in favour of introducing amendments aimed at enabling the more flexible provision of pharmaceutical services in a pandemic situation.

9. Guidance

9.1 Guidance on legislative amendments to mitigate the effect of an influenza pandemic is scheduled for publication in September 2009.

10. Impact

10.1 The Department considers these amendments are largely technical in effect. The original consultation in 2008 did not identify any significant impact on business nor on the NHS from these regulatory amendments. An Impact Assessment (IA) has therefore not been prepared.

10.2 There is no negative impact on equality issues.

11. Regulating Small Business

11.1 The Regulations apply to small businesses, including firms employing up to 20 people. As the Regulations concern the provision of NHS 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 universal standards and practices in the provision of such services.

11.2 However, it is anticipated that the flexibilities being introduced to help contractors deal with an emergency such as pandemic flu will be of particular help to smaller contractors who may not have access to the same staffing reserves and resources of larger contractors.

12. Monitoring and Review

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

13. Contact

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