STATUTORY INSTRUMENTS

2008 No. 2789

MEDICINES

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008

Made - - - -	*24th October 2008*
Laid before Parliament	*29th October 2008*
Coming into force - -	*1st October 2009*

The Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations, in the case of the Secretary of State, in exercise of the powers conferred by sections 72A(4)(b), (5)(b), (6) and (7)(b), (e) and (f) and 129(1) and (5) of the Medicines Act 1968(**1**), and, in the case of the Minister, the powers conferred by those provisions and now vested in him(**2**).

In accordance with section 129(6) of that Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations.

Citation and commencement

1. These Regulations may be cited as the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 and come into force on 1st October 2009.

Interpretation

2. In these Regulations—

"the Act" means the Medicines Act 1968;

"pharmacy business" means the business in respect of which the responsible pharmacist has a duty under section 72A(1) of the Act;

"pharmacy staff" means any pharmacist(**3**) or any other person who is working at the premises in question in a role connected to the pharmacy business;

(**1**) 1968 c.67. The expression "the Ministers" is defined in section 1 of the Act, as amended paragraph 1(1) of the Schedule to S.I. 1999/3142 and paragraph 2 of Schedule 8 to S.I. 2006/2407. Section 72A was inserted by section 30 of the Health Act 2006 (c.28).

(**2**) By virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47). The Department for which the Minister is responsible was renamed by Article 3(6) of S.I. 1999/283 (N.I.1).

(**3**) "Pharmacist" is defined in section 132(1) of the Act, as amended by article 26(6) of, and paragraph 7 of Schedule 5 to, S.I. 1976/1213 and by article 67 of, and paragraph 2(1) and (16) of Schedule 1 to, S.I. 2007/289.

"premises" means the premises from which the pharmacy business is carried on.

Absence of the responsible pharmacist

3.—(1) The maximum period for which the responsible pharmacist may be absent from the premises is two hours during the pharmacy's business hours.

(2) If there is more than one responsible pharmacist during the pharmacy's business hours, the maximum period in paragraph (1) relates to the total period of absence for all of them.

(3) The responsible pharmacist must not be absent from the premises unless the arrangements in paragraph (4) or (5) have been put in place.

(4) Where it is reasonably practicable for the responsible pharmacist to be contactable throughout the period of absence, arrangements must ensure that the responsible pharmacist can—

(a) be contacted by other pharmacy staff throughout the period of absence; and

(b) return to the premises with reasonable promptness if, in the opinion of the responsible pharmacist, this is necessary to secure the safe and effective running of the pharmacy business.

(5) For any period of absence where it is not reasonably practicable to put in place the arrangements specified in paragraph (4), arrangements must ensure that another pharmacist is both available and contactable to provide advice to other pharmacy staff.

(6) The retail sale of medicinal products(**4**) on a general sale list(**5**) from the premises may continue during the period of absence of the responsible pharmacist.

(7) In this regulation—

"business hours" means the period during which the pharmacy business is operational on any day;

"day" means the 24-hour period beginning and ending at midnight.

Pharmacy procedures

4.—(1) The matters which must be covered by pharmacy procedures are—

(a) the arrangements to secure that medicinal products are—

(i) ordered;

(ii) stored;

(iii) prepared;

(iv) sold by retail(**6**);

(v) supplied in circumstances corresponding to retail sale(**7**);

(vi) delivered outside the pharmacy; and

(vii) disposed of

in a safe and effective manner;

(b) the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;

(**4**) "Medicinal products" is defined in section 130 of the Act, as amended by sections 13(2) and 16 of, and paragraph 3 of Schedule 1 and Schedule 2 to, the Animal Health and Welfare Act 1984, regulation 2(a) and (b) of S.I. 1994/3119, regulations 1(2) and 25(1)(c) and (d) of S.I. 2005/50 and regulations 1 and 44(2) of, and paragraphs 1 and 66 of Schedule 8 to, S.I. 2006/2407.

(**5**) "Medicinal product on a general sale list" is defined in section 51(2) of the Act.

(**6**) *See* section 131(3) of the Act for the meaning of "sold by retail".

(**7**) *See* section 131(4) of the Act for the meaning of "supplied in circumstances corresponding to retail sale".

(c) the identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform certain tasks relating to the pharmacy business;

(d) the keeping of records about the arrangements mentioned in paragraph (a);

(e) the arrangements which are to apply during the absence of the responsible pharmacist from the premises;

(f) the steps to be taken when there is a change of responsible pharmacist at the premises;

(g) the procedure which is to be followed if a complaint is made about the pharmacy business;

(h) the procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner; and

(i) the manner in which changes to the pharmacy procedures are to be notified to pharmacy staff.

(2) Pharmacy procedures must be recorded—

(a) in writing;

(b) in electronic form; or

(c) in both forms.

(3) Pharmacy procedures must be available at the premises for inspection by—

(a) the person carrying on the pharmacy business;

(b) the superintendent, if any(**8**);

(c) the responsible pharmacist; and

(d) pharmacy staff.

(4) Pharmacy procedures must be reviewed regularly.

(5) In this regulation, "pharmacy procedures" means the procedures referred to in section 72A(3) of the Act.

The pharmacy record

5.—(1) The particulars which must be included in the pharmacy record are—

(a) the responsible pharmacist's name;

(b) any number associated with the responsible pharmacist's registration in the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007(**9**) or in the register of pharmaceutical chemists maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**10**);

(c) the date and time at which the responsible pharmacist became the responsible pharmacist;

(d) the date and time at which the responsible pharmacist ceased to be the responsible pharmacist; and

(e) in relation to any absence of the responsible pharmacist from the premises on a day on which they were the responsible pharmacist—

(i) the date of the absence;

(ii) the time at which the absence commenced; and

(iii) the time at which the responsible pharmacist returned to the premises.

(**8**) Section 71 is substituted by the Health Act 2006, section 28(1). Subsection (1)(a) of section 71 requires that a business which is carried on by a body corporate is under the management of a superintendent pharmacist.
(**9**) S.I. 2007/289.
(**10**) S.I. 1976/1213.

(2) The pharmacy record must be kept—

(a) in writing;

(b) in electronic form; or

(c) in both forms.

(3) The pharmacy record must be available at the premises for inspection by—

(a) the person carrying on the pharmacy business;

(b) the superintendent, if any;

(c) the responsible pharmacist; and

(d) pharmacy staff.

(4) The person carrying on the pharmacy business must secure that the pharmacy record is preserved for a period of not less than five years commencing on—

(a) in the case of a record in electronic form, the day on which it is created;

(b) in the case of a written record, the last day to which the record relates.

(5) In this regulation, "pharmacy record" means the record referred to in section 72A(4) of the Act.

Signed by authority of the Secretary of State for Health.

Dawn Primarolo
Minister of State,
Department of Health

14th October 2008

Michael McGimpsey
Minister,
Department of Health, Social Services and Public Safety

24th October 2008

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision about the duties of responsible pharmacists who are required, by virtue of section 72A of the Medicines Act 1968 (c.68), to secure the safe and effective running of a pharmacy business at the premises from which it is carried on.

Regulation 3(1) and (2) specifies the maximum permitted period that a responsible pharmacist may be absent from the premises during the pharmacy's business hours. Paragraph (3) provides that certain arrangements must be made in the event of the responsible pharmacist's absence. Paragraph (4) provides that where it is reasonably practicable for the responsible pharmacist to be contactable throughout the period of absence, arrangements must cover both being contactable during the period of absence and return to the premises with reasonable promptness if necessary. Paragraph (5) then provides that arrangements must cover another pharmacist being available and contactable if it is not practicable to make arrangements under paragraph (4). Paragraph (6) provides expressly that the retail sale of medicinal products on a general sale list may continue from the premises during the period of absence.

Regulation 4 specifies the procedures which the responsible pharmacist must establish (if they are not already established), maintain and keep under review and which persons must be allowed to inspect those procedures.

Regulation 5 specifies the record which the responsible pharmacist must make and keep, which persons must be allowed to inspect the record and the period for which the person carrying on the pharmacy business must keep the record.

An impact assessment has not been produced for this instrument as only a negligible impact on the private or voluntary sectors is foreseen.