

Briefing Note – Responsible Pharmacist Obligations February 2021

The purpose of this note is to consider the legal and ethical obligations on responsible pharmacists, including responsibility for activities that may be carried out in the absence of the responsible pharmacist.

Statutory Background

The Medicines Act 1968 (“the Act”)¹ requires a responsible pharmacist to be in charge of the retail pharmacy business carried on at pharmacy premises. The Act² sets out the responsible pharmacist’s duties, which include:

- To secure the safe and effective running of the pharmacy business at the premises in question so far as concerns the retail sale at those premises of medicinal products (whether they are on a general sale list or not) and the supply at those premises of such products in circumstances corresponding to retail sale.
- To establish (if they are not already established), maintain and keep under review procedures designed to secure the safe and effective running of the business.
- To make a record of who is the responsible pharmacist in relation to the premises on any day and at any time.

On the 1 October 2009, the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 (“the Regulations”) came into force.

The Regulations and Act together set out the obligations upon pharmacy owners and responsible pharmacists, which are summarised below

Pharmacy procedures

The Regulations set out the matters which must be covered by pharmacy procedures as follows:

- 1 The arrangements to secure that medicinal products are ordered, stored, prepared, sold by retail, supplied in circumstances corresponding to retail sale, delivered outside the pharmacy, and disposed of in a safe and effective manner
- 2 The circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products
- 3 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
- 4 The keeping of records about the arrangements mentioned in paragraph 1
- 5 The arrangements which are to apply during the absence of the responsible pharmacist from the premises
- 6 Steps to be taken when there is a change of responsible pharmacist at the premises
- 7 The procedure which is to be followed if a complaint is made about the pharmacy business
- 8 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

¹ Sections 70 and 71 of the Medicines Act 1968

² Section 72A of the Medicines Act 1968

9 The manner in which changes to the pharmacy procedures are to be notified to pharmacy staff.

Pharmacy procedures must be recorded either in writing or in electronic form and must be available for inspection by the pharmacy owner and staff.

Responsible pharmacist record

The responsible pharmacist record must include the following particulars:

- 1 The responsible pharmacist's name
- 2 The responsible pharmacist's GPhC registration number
- 3 The date and time at which the responsible pharmacist became the responsible pharmacist
- 4 The date and time at which the responsible pharmacist ceased to be the responsible pharmacist
- 5 In relation to any absence of the responsible pharmacist from the premises on a day on which they were the responsible pharmacist, the date of the absence, the time at which the absence commenced and the time at which the responsible pharmacist returned to the premises.

Absence of the responsible pharmacist

The Regulations provide that the responsible pharmacist may be absent from the premises for a maximum period of two hours during the pharmacy's business hours.

The responsible pharmacist must not be absent from the premises unless the following arrangements have been put in place:

- 1 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 be contacted by other pharmacy staff and 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.
- 2 For any period of absence where it is not reasonably practicable to put in place the arrangements above, arrangements must ensure that another pharmacist is both available and contactable to provide advice to other pharmacy staff.

During the absence of the responsible pharmacist, the retail sale of medicinal products on a general sale list from the premises may continue.

Display of a notice

The Act requires the responsible pharmacist to display a notice, conspicuously, in the pharmacy stating that he or she is the responsible pharmacist.

Department of Health Guidance

When the Regulations were introduced, the Department of Health issued guidance on the responsible pharmacist regulations and the legal duties on the responsible pharmacist. ("the Guidance").

The Guidance makes the following clear:

"1.23 throughout the time s/he is in charge of the pharmacy, the responsible pharmacist is accountable for any failure to comply with the legal duty and the requirements set out in the Regulations. The pharmacy record will provide details of the pharmacist in charge of the pharmacy on any date and at any time, including when the

pharmacist took on responsibility for the pharmacy, when s/he is absent from the pharmacy and when he or she ceased to have responsibility.

1.24 all pharmacists are professionally accountable for the exercise of their professional judgement and adherence to the professional Code of Ethics. Where a pharmacist is in charge of a pharmacy, s/he also has a legal responsibility to secure safe and effective working in the pharmacy. In complying with the legal duty, the responsible pharmacist is required to set out procedures for safe and effective working in the pharmacy. This supports the professional requirement on pharmacists to ensure there are Standard Operating Procedures (SOPs). Thus, the responsible pharmacist is legally and professionally accountable for the pharmacy procedures.

1.25 pharmacy staff (including other pharmacists working in the pharmacy) should work within the procedures set down by the responsible pharmacist. If another registered pharmacist working in the pharmacy, who is not the responsible pharmacist, exercises his/her professional judgment as to divergence from the procedures set down by the responsible pharmacist, he or she will be professionally accountable for that decision and for working in that way. This also applies to registered pharmacy technicians.“

In terms of the responsible pharmacist's absence from the pharmacy, the Guidance provides that “the responsible pharmacist must comply with the requirements in section 72A and the Regulations throughout the time s/he is responsible for the pharmacy - that is, whether or not s/he is present on the registered pharmacy premises.”

Guidance from the General Pharmaceutical Council and Royal Pharmaceutical Society

The General Pharmaceutical Council has not issued specific guidance in relation to obligations under the Regulations. The GPhC's Standards apply to the conduct of pharmacists whilst acting in a professional capacity, which would include whilst signed in as responsible pharmacist even where absent.

Guidance has been issued by the Royal Pharmaceutical Society (www.rpharms.com/resources/toolkits/responsible-pharmacist-rp#activities).

Matters to be considered when signed in as responsible pharmacist but absent from the pharmacy

As summarised above, the responsible pharmacist has a number of legal obligations when becoming responsible pharmacist.

Consideration should be given by pharmacists to those legal obligations in circumstances where the responsible pharmacist is to be absent from the pharmacy, including where the absence occurs before the pharmacist arrives at the pharmacy to being work. These include:

- 1 The pharmacist themselves has the legal obligation to complete the responsible pharmacist register accurately. This includes recording any periods of absence. The Regulations do not explicitly state whether the RP record can be completed by another member of staff on behalf of the pharmacist, or whether it can be completed remotely by the responsible pharmacist. It is a criminal offence by the pharmacist to fail to comply with the responsible pharmacist recording requirements.
- 2 A pharmacist is legally responsible for the safe and effective supply of medicinal products (including GSL products) whilst signed in as responsible pharmacist. Although GSL products may be supplied in the absence of the responsible pharmacist, the pharmacist remains legally responsible for the safe and effective supply of those products at all times whilst signed in as responsible pharmacist even when absent from the pharmacy.
- 3 Certain activities may be carried out in the absence of the responsible pharmacist but where the responsible pharmacist is signed in to the RP register. Where activities, such as the assembly of medicinal products, must be carried out under the supervision of a pharmacist, this may not necessarily

require the physical presence of the responsible pharmacist whilst assembly is taking place. Guidance from the Royal Pharmaceutical Society provides that “*supervision in this context may not require the physical presence of a pharmacist. The level of supervision required of suitably trained staff who undertake this work will depend on what is regarded as good practice within the pharmacy profession*”. The responsible pharmacist must therefore satisfy himself or herself that assembly can safely take place in his or her absence.

- 4 The responsible pharmacist is required to display a notice in the pharmacy that he or she is the responsible pharmacist at that moment. The obligation to display a notice rests on the pharmacist, who must therefore be satisfied that the notice will be displayed in his or her absence whilst signed in as the responsible pharmacist.
- 5 The responsible pharmacist must be satisfied that there are appropriate procedures in place dealing with the matters set out in the Regulations (and summarised above).
- 6 The responsible pharmacist must be satisfied that there are suitably competent and sufficiently trained members of staff to carry out the activities which will take place during the absence of the responsible pharmacist.
- 7 The responsible pharmacist must be contactable during any period of absence and must be able to return to the pharmacy if appropriate or necessary, or alternative arrangements must be made with another pharmacist to attend the pharmacy if required.

Summary

A responsible pharmacist should not be absent from the pharmacy unless he or she can be satisfied that he or she has complied, and will comply, with his/her legal obligations in respect of the pharmacy premises during his or her absence.

The responsible pharmacist remains professionally accountable for the services provided at the pharmacy during his or her absence in the same way that the responsible pharmacist is accountable for activities which take place during his or her presence in the pharmacy.

If any inappropriate or unprofessional activities were to take place during the absence of the responsible pharmacist (for example a dispensing error or the supply of a non-GSL medicinal product) the General Pharmaceutical Council may require the pharmacist to demonstrate how he or she had complied with his or her legal obligations during the period of absence.

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