



Guidance to whether a Responsible Pharmacist can be in charge of more than one set of premises

April 2020



About the PDA

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. With more than 31,000 members, the PDA is the largest pharmacist membership organisation and trade union exclusively for pharmacists, in the UK.

As a Defence Association and Trades Union, the PDA often supports members in some kind of problem situation. This could be a conflict with their employer, a professional disciplinary episode where they are being investigated by the pharmacy regulator, a civil claim for compensation from a patient who alleges that they have been harmed by the error of the pharmacist or even a criminal prosecution. In this way, the PDA supports members in more than 5,000 cases per year and this provides a rich vein of valuable and comprehensive experience and a detailed knowledge of risk management and the kind of professional and operational environments that are likely to cause problems for both pharmacists and patients alike. It is this experience that drives the thrust of PDA's policy work as the PDA seeks to foster operational and professional environments that help to keep patients safe and in so doing keeping pharmacists out of harm's way.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.

Summary

This guidance is for use by members when deciding the scope of the Responsible Pharmacist Regulations for their particular working circumstance.

This guidance is not a substitute for a direct reference to the legislation and if in doubt please refer to the legislation or contact our support team for clarification.

April 2020

Does Legislation allow for a person to be the Responsible Pharmacist for more than one set of premises at the same time?

It was always clear that during Parliamentary debate prior to the Responsible Pharmacist Regulations being introduced that Ministers expected each set of premises to be under the direct supervision of one Responsible Pharmacist.

During Parliamentary debate, on 22nd May 2006, a Government minister explicitly stated:

Intention of Parliament during debate when introducing the Responsible Pharmacist Regulations

*Lord Warner: "It is the Government's view that, **in most cases, use of a telephone alone would be inappropriate in meeting the supervision requirements.**"*

*Lord Warner: "Let me begin by clearly stating the Government's position. We believe that the **general rule should be one responsible pharmacist for one pharmacy.** This will allow the pharmacist to exercise fully his or her important responsibility to secure the safe and effective running of the pharmacy."*

Section 72A of the Medicines Act 1968 requires a Responsible Pharmacist to secure the safe and effective running of a pharmacy business at the premises from which it is carried on as specified in regulations.

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, which came into force on the 1st of October 2009 specify the role and responsibilities of the Responsible Pharmacist in securing the safe and effective running of a pharmacy from those premises.

The Law

Specifically 72A (2) specifically states:

*72A (2) "A person may **not** be the responsible pharmacist in respect of more than one set of premises at the same time"*

This is the current legal position and there has been no change in this legal position in light of the Corona Virus Pandemic.

In order to clarify the new Responsible Pharmacist Regulations, Government issued specific guidance to ensure that the Regulations were followed as intended by Parliament:

Government Guidance issued to give operational meaning to legislation

*2.8. "Regulation 3(1) states that **two hours is the maximum time the responsible pharmacist may be absent** during the pharmacy's business hours. It is important to be clear that the maximum time allowed for absence includes the time needed to travel away from and return to the pharmacy. Regulation 3(7) defines business hours as a 24-hour period during which the pharmacy is operational on any day, beginning and ending at midnight."*

*2.15. "**The responsible pharmacist must first judge** whether s/he is able to comply with the conditions for absence in Regulation 3(4) and then consider the need to comply with Regulation 3(5). That is, to enable him/her, to be absent, the responsible pharmacist must arrange for another pharmacist to be available and contactable to provide advice throughout the period of absence, or any time during that absence that s/he will be unable to maintain contact with the pharmacy. There is no requirement in Regulation 3(5) for the other pharmacist to be a responsible pharmacist or to be present in the pharmacy in order to provide advice to pharmacy staff."*

The guidance is absolutely clear that if the Responsible Pharmacist has to be absent he must arrange for another pharmacist to be available and contactable during the period of his absence (and which can be no more than 2 hours in any 24 hour period)

Thus we can see that the intention of Parliament from the very beginning of the Parliamentary process that led to the Responsible Pharmacist legislation, and as explained in the Guidance, has always been that the legislation should only allow for one Responsible Pharmacist to supervise one set of premises.

Parliament allowed some room for absence, but only at the instigation of the Responsible Pharmacist and only to perform certain professional duties and only with specific measures in place.

We can clearly see that Parliament, like the profession as a whole, was rightly concerned that patient safety would be compromised if the Responsible Pharmacist was not available to supervise and secure the safe and effective running of the pharmacy.

In light of the exceptional circumstances of Covid 19, the regulators have allowed only for certain activities to take place in the unavoidable and unplanned absence of the Responsible Pharmacist.

The Regulatory statement is clear and unambiguous and is designed to allow for unplanned and exceptional absence whilst still protecting the public in these exceptional circumstances.

Regulatory approach in challenging circumstances - GPhC and PSNI joint statement

“We recognise there may be situations where the responsible pharmacist unavoidably has to leave the pharmacy at short notice part-way through the day, (e.g. if they are unwell and need to self-isolate).

Where no locum cover can be secured at the pharmacy, and recognising the potential effects of the current pandemic, it would be in the patient’s best interest for medicines already dispensed to be supplied from the pharmacy rather than not supplied at all, even though this may not be in strict accordance with the law as normally understood.

The pharmacy regulators will support pharmacy professionals in the front line making this judgement in patients’ best interests. In such circumstances we would expect there to be access to a pharmacist by phone or video link to provide direction for the remaining staff in the pharmacy.

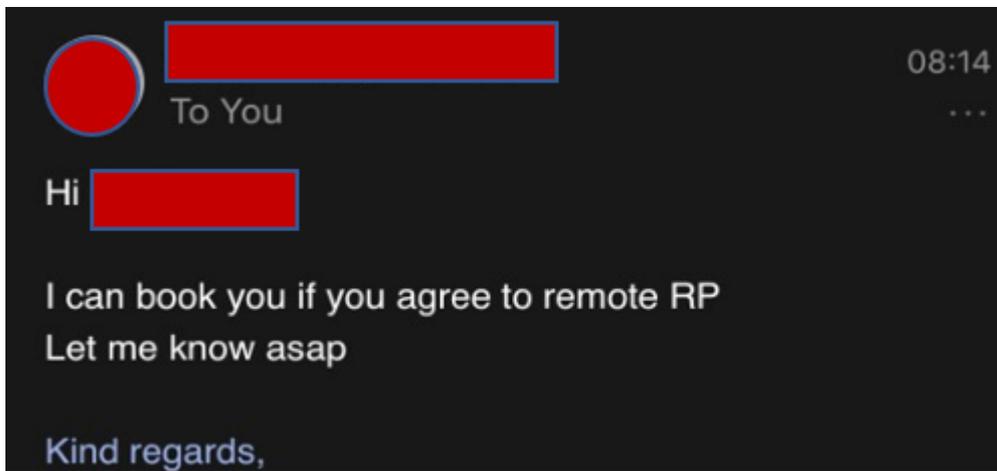
Such an approach should only be adopted for a short time period, where other options have been exhausted. Except in such exceptional circumstances, even in the current pandemic situation, arrangements must be made for a pharmacist to be at the pharmacy, including to undertake the responsible pharmacist role and supervise the sale and supply of POM and P medicines.”

It has been clear from feedback from members that:

- 1/ Certain companies have made it a condition of confirming a locum booking that the locum pharmacist must assume responsibility of more than one premises.
- 2/ Certain companies are using the challenging circumstances to misuse the special allowances made by regulators by offering poor locum rates so as not to fill vacancies.
- 3/ Certain companies and superintendents have a misunderstood the legal requirements of being a Superintendent Pharmacist or a Pharmacy Owner.

- 4/ Certain companies have cancelled locum shifts, en masse, agreed prior to the pandemic.
- 5/ Certain companies have misused local monopoly powers and blacklisted pharmacists who make sensible enquiries prior to accepting bookings.
- 6/ Certain companies have not abided by the GPhC and PSNI guidelines.

Examples of Illegal activities being proposed by certain multiples (redacted extracts are from contacts with pharmacists and corporate SOPs):



This guidance will help the pharmacy team during these times to establish an effective course of action to continue to provide the best possible service to our patients and customers depending upon each situation. At this time there may be two situations in which there is no RP physically present and we may need to have an RP supervising remotely.

An RP may be in one branch and may also be the remote RP for one or more additional sites. At all times the RP must only work in their area of competency and will need to be for a short period.

Following confirmation from the Resource Planning team that you will be without a pharmacist for the entire day, please refer to the guidance below: