



# Guidance on the activities that can take place when there is no pharmacist present in a registered pharmacy

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.

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**In the total absence of a pharmacist, can the pharmacy “team” carry on with activities such as accessing the PMR, downloading prescriptions, labelling and assembling ready for checking or even dispensing and bagging a RD or an eRD?**

We need to establish some basic understanding of the Law and published Regulatory guidance before we can consider in detail the question above.

There are 2 sets of distinct issues that arise and the detail is quite complex.

Firstly, The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, deals with contractual issues between the NHS and a pharmacy owner, mandates that a pharmacist is present at all times during the pharmacy’s opening hours to provide **ALL** essential services that have been contractually agreed.

If there is any change to the providing of these NHS contracted essential services, the owner must inform the NHS that there is an impairment in providing the full services that the owner is being paid for.

This is not discretionary, the owners **MUST** inform the NHS regional teams of any changes that will effect the providing of all essential NHS services immediately so that alternative arrangements can be made.

Secondly, the Medicines Act 1968 and the provisions within The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 specifies that a Responsible Pharmacist **MUST** have secured the activities of the pharmacy before certain activities can take place. In the absence of the Responsible Pharmacist, no activities can take place as the pharmacy and its procedures have not been reviewed and mandated to be safe and effective.

Parliament had a clear vision for how the Responsible Pharmacist regulations would be used to allow the Pharmacist scope to be absent (for professional reasons) whilst safely leaving the Pharmacy for limited periods. This was clearly the intent of Parliament and is captured in the Parliamentary debate and reassurances given.

**22 May 2006 Lord Warner (For the Government):**

**The responsible pharmacist will, for the first time, have an explicit statutory duty to secure the safe and effective running of the pharmacy business.** They will be in charge of the pharmacy and responsible for ensuring that all activities involving the preparation, assembly, sale and supply of medicines are undertaken safely. The responsible pharmacist will need to set down procedures for these activities, allocating individual duties according to the competence of other members of the pharmacy staff. A record must be kept of the responsible pharmacist at all times.

**With these safeguards in place,** we do not believe it necessary for the responsible pharmacist to be physically present in the pharmacy at all times to maintain patient safety. But I stress that patient safety is a fundamental principle of the Medicines Act, and we would not seek to make changes that are not in keeping with that principle.

**Earl Howe:**

**But even if he is out at times, he is still in a meaningful sense in control of the pharmacy,** as well as being responsible for it, because he trusts those whom he has **left behind** to work competently within their delegated authority and not to exceed that authority while he is away.

The 2010 GPhC guidance issued to give practical interpretation for Responsible Pharmacists states:

**You must**

- 1.1 establish the scope of the role and responsibilities you will have as the responsible pharmacist and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacy owner, superintendent pharmacist or other delegated person.
- 1.2 only take on the role of the responsible pharmacist if this is within your professional competence.
- 1.3 only be the responsible pharmacist in charge of one registered pharmacy at any given time.
- 1.4 secure the safe and effective running of the of the pharmacy business at the registered pharmacy in question **before the pharmacy can undertake operational activities.** Only after you are personally satisfied that you have secured the safe and effective running of the pharmacy can any operational activities begin to take place\_(see appendix A).

The 2010 GPhC Responsible Pharmacist Guidance goes on to further clarify:

**You must**

- 3.5 *not become the responsible pharmacist **or make an entry in the pharmacy record until** you have secured the safe and effective running of the pharmacy business at the registered pharmacy in question.*

It is absolutely unambiguous that no operational activity can legally take place whilst there is no pharmacist logged into the statutory Pharmacy Record as a Responsible Pharmacist.

During the pandemic, the GPhC and PSNI has taken a pragmatic view to allow only some activities, which are strictly defined and for a limited period, to take place whilst there is no pharmacist present on the premises states:

*Even during highly challenging circumstances professionals quite rightly want to meet the legal requirements that apply. This includes the duty on the responsible pharmacist to secure the safe and effective running of the pharmacy in relation to the retail sale and supply of all medicines. 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.*

Lets look at 2 scenarios to help crystallise the intent of Parliament when drafting the Health Act 2006 and the subsequent Responsible Pharmacy Regulations 2008 that underpin the 2010 Guidance issued by the Regulator.

### **Scenario 1**

You are a locum pharmacist who works regularly at Pharmacy A. You arrive at Pharmacy A and assume the position of a Responsible Pharmacist.

You enter the time at which you assumed Responsibility in the Responsible Pharmacy Record.

Following lunch at around 2pm, you feel markedly unwell and need to urgently return home.

You ring the Area Manager and he advises that you should make an entry in the RP record of with a signing off time recorded at 7pm and it is OK to go home now (the time now is 2.30pm). He further advises that Pharmacy A will remain open until 7 pm and the staff will carry on downloading and assembling prescriptions for their employed pharmacist manager to check.

#### **Ask yourself:**

Should I follow the Area managers advise and make an entry in the RP record confirming that I was the Responsible Pharmacist until 7pm?

What time should the RP record state as the time of logging off as a RP?

Can the pharmacy carry on with the proposed activities without a responsible pharmacist logged on?

Who should inform the NHS Area team that the pharmacy will not be able to offer the full contracted services?

**Scenario 2**

You are a locum pharmacist who works regularly at Pharmacy A.

In the morning of your booking on waking you find you have a high temperature and as per Government guidelines you decide to self-isolate.

You ring the Area Manager and he says he will book someone else.

Half an hour later he rings back and says he cannot find anyone and could you log on remotely as the RP for the whole day. He states that the company will pay you in full for that day if you agree to sign on for the whole day and remain contactable by telephone for that day.

**Ask yourself:**

Is there such a shortage of pharmacists that no one else can be booked at short notice?

If I accept the booking on these revised terms, will I be able to secure the safe and effective running of the pharmacy by signing on remotely?

Can I be an absent responsible pharmacist for the whole day?

How will I perform a clinical check or supervise the sale of P medicines?

Whose responsibility is it to inform the NHS Area office that there is no pharmacist on the premises for the whole day?