



Guidance on the “Remote Signing on” in the Pharmacy record by a pharmacist

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

Can you, as a locum, assume the role of a Responsible Pharmacist whilst you are not physically present in the registered premises by merely just ticking a box remotely ?

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

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.

*We consider that remote supervision has the potential to bring benefits to patients **but that it should be permitted only in carefully controlled circumstances** It would be up to the responsible pharmacist to determine whether to allow remote supervision of the activities in the pharmacy for which he is responsible, provided that the conditions within the regulations are met.*

Earl Howe :

*I realise that the Bill moves us away from the concept of personal control, **but I suggest that being in professional control of the business is still important.** The Minister was right to say that one can envisage a pharmacist delegating a range of tasks and duties to suitably competent staff; that already happens. Dispensing technicians are already regulated, albeit on a voluntary basis. The pharmacist himself does not need to do everything personally, nor does he need to be physically present on the premises at all times. He should be allowed to go out, provided that it is not for excessively long periods. **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 Medicines Act 1968 thus amended gave rise to the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 then specified certain conditions that had to be satisfied if a Pharmacist were to be absent from a registered premises:

Absence of the responsible pharmacist 3.—

(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.*

It is clear that Parliament intended absence to occur only after the pharmacist had arrived at the pharmacy, secured its safe operations, delegated certain activities to competent staff and then left the premises for professional reasons (and then only for a maximum of 2 hours). The word **return** is not a legislative error. It defines specific meaning to the intent of Parliament and it is done so to ensure patient safety.

The GPhC guidance issued in 2010 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 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.*

Lets look at 2 not uncommon scenarios to help crystallise the intent of Parliament when drafting the Health Act 2006 and the subsequent Responsible Pharmacy Regulations 2008 that underpin the Guidance issued by the Regulator in 2010.

Scenario 1

A Pharmacy Area Manager (for a large national multiple) asks you as a locum to assume the role of a Responsible Pharmacist to a pharmacy premises which are new to you and where you have never worked before.

You are not familiar with the specific premises but are informed that they are open from 9 am to 6 pm.

He specifies that it is a condition of the booking that you log on remotely at 7am so that staff can carry on with the preparation of dosette boxes. You will be required to sign off the dosette boxes that have been prepared in your absence.

You are further informed that you will not be paid for the 2 hour period between 7 am to 9 am as you are not on the premises.

Ask yourself:

Can I secure the safe and effective running of the pharmacy?

If not, should I accept the booking given the condition placed?

PS we will consider the obligations imposed by the RP regulations on owners and superintendents separately

Scenario 2

A Pharmacy Area Manager (for a large national multiple) asks you, as a locum, to assume the role of a Responsible Pharmacist to a pharmacy premises where you locum regularly and which are 5 minute drive from your house

The Head Office, as a cost cutting has created mini-hubs for dosette boxes to be prepared for all patients in the locality. This pharmacy will serve as a hub for its other 4 pharmacies in the locality where it has a monopoly.

You are familiar with the premises, the staff are known to you, but are informed that the premises is now a hub for dosette box preparation and staff will be working in the pharmacy before opening. The opening times to the public are still from 9 am to 6 pm.

The area manager specifies that it is a condition of the booking that you log on remotely at 7am so that staff can open the pharmacy and carry on with the preparation of dosette boxes. You will be required to sign off the dosette boxes that have been prepared in your absence.

You are further informed that you will not be payed for the 2 hour period between 7 am to 9 am as you will not be on the premises.

Ask yourself:

How can I secure the safe and effective running of the pharmacy, from 7am to satisfy the requirements of the Responsible Pharmacy regulations?

Should I accept the booking given the condition placed?