

THE RESPONSIBLE PHARMACIST AND THE 'RESPONSIBLE' INSPECTOR

By Andrew Smith, Professional Standards Inspector

As an Inspector on the ground I meet pharmacists on a daily basis. With the responsible pharmacist requirements coming into force on 1 October 2009 I am frequently asked what an Inspector will be looking for and what the Royal Pharmaceutical Society of Great Britain will do if we find non-compliance.

My answer to this question is simple. An Inspector will only visit a pharmacy periodically so satisfying the Inspector should not be the priority. It is more important that pharmacists focus on acting in the best interests of their patients; familiarising themselves with the new responsible pharmacist requirements and implementing the necessary changes. It is important that pharmacists are confident that they are working within the legislation and professional standards.

The role of the Inspector

Essentially Inspectors undertake two different roles; one of inspection and one of investigation.

Inspectors currently carry out monitoring visits of registered pharmacy premises. If, during a visit, an Inspector observes non-compliance with legislation and/or professional standards their primary objective is to help pharmacists comply and to seek to improve practice through giving advice and support. There are occasions when an Inspector has to instigate a formal regulatory response, for example, where there is clearly a risk to patient safety or where there is persistent non-compliance following repeated engagement.

Inspectors also investigate complaints and allegations involving registered pharmacists or registered pharmacy technicians.

Within the context of these two distinct roles, I will set out how the Inspectorate will respond to responsible pharmacist issues.

Monitoring visits

The Society has updated the Inspectorate checklist for monitoring visits, which is available on the Society's website: www.rpsgb.org/pdfs/inspvisitschecklist09.pdf. This checklist allows pharmacists, superintendents and owners to see what the Inspector may look for during a visit. We know that the responsible pharmacist requirements have caused anxiety within the profession so we have also published, within the checklist, what compliance with the responsible pharmacist requirements may look like. Pharmacists can now see what we will be looking for and what we expect to find.

If, during an inspection visit, an Inspector observes that a pharmacy is not compliant with the responsible pharmacist requirements the Inspector will seek to secure compliance by providing advice to the pharmacist and the superintendent/owner, as appropriate. For example, if a pharmacy is not displaying a notice to show who the Responsible Pharmacist is, the Inspector will give appropriate advice.

Complaints and allegations involving non-compliance with the responsible pharmacist requirements

Whenever the Society receives an allegation against a registered pharmacist or registered pharmacy technician it has a duty to investigate.

In order to maintain public confidence in the profession it is important that the Society discharges its regulatory functions in a proportionate and effective manner. With this in mind, the Society has put in place measures to deal with some allegations using the 'non-referral' process.

What is the 'non-referral' process?

The law allows the Society's Council to identify types of allegations that it considers would be more effectively and proportionately dealt with outside of a Fitness to Practise Committee¹, subject to the published threshold criteria. Put simply, because these types of allegations are not referred to a Fitness to Practise Committee we call this the 'non-referral' process.

¹ Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007

In order for a case to go through the 'non referral' process the pharmacist must accept a letter of advice from the Chief Inspector. A record is added to the pharmacist's fitness to practise history to show that s/he has accepted the advice given. In the event of further allegations, the Society will consider a matter dealt with by the 'non-referral' process in exactly the same way as it would consider a matter dealt with by a Fitness to Practise Committee.

More information on the Society's fitness to practise processes can be found on the website: www.rpsqb.org/protectingthepublic/fitnesstopractise.

The Society has examined the responsible pharmacist requirements and identified potential breaches. Some breaches are similar to case types that are currently considered suitable for the 'non-referral' process. Other potential breaches place patient safety at risk or directly undermine public confidence and would warrant referral to a Fitness to Practise Committee.

Panel 1 shows the case types suitable for the 'non-referral' process.

Panel 1: Responsible pharmacist case types considered suitable for the 'non-referral' process subject to the published threshold criteria.

Case Type	Examples	Proposed action	Mapping to existing case types and examples of cases suitable for the 'non-referral' process.
Responsible pharmacist	Display of notice Failure to conspicuously display notice to denote the responsible pharmacist in charge of the registered pharmacy premises.	Non-referral	Analogous to "failure to display registration certificate" case type.
	Pharmacy procedures <u>Example 1:</u>		

	<p>Failure of the responsible pharmacist at the material times to have adequate pharmacy procedures in place.</p> <p><u>Example 2:</u> Failure to regularly review pharmacy procedures at least once every two years or Failure to review the pharmacy procedures following an incident or event which indicates that the pharmacy is not running safely and effectively.²</p>	<p>Non-referral</p> <p>Non-referral</p>	<p>Analogous to “inadequate Standard Operating Procedures” case type.</p> <p>Analogous to “inadequate Standard Operating Procedures” case type.</p>
	<p>Pharmacy record</p> <p><u>Example 1:</u> Failure of the responsible pharmacist to complete the pharmacy record.</p>	<p>Non-referral</p>	<p>Analogous to “Simple book keeping cases” case type.</p>
	<p>Absence</p> <p><u>Example 1:</u> Responsible pharmacist is absent from the registered pharmacy premises for more than two hours during the pharmacy’s business hours because s/he was unavoidably delayed.</p>	<p>If, after consideration and investigation of the allegation made or the information calling the registrant’s fitness to practise into question, the Registrar’s opinion is that there is no (or insufficient) evidence that fitness to practise is impaired by</p>	<p>Does not map to existing case types</p>

² This is the act of ‘failing to update the procedures’ following an incident or event which indicates that the pharmacy is not running safely and effectively and not about the incident or event itself.

		<p>reason of the matters under consideration, no further action will be taken. This may be the case if the responsible pharmacist was unavoidably detained thereby making them absent for longer than two hours. The complainant will be signposted to alternative sources of assistance, where appropriate.</p>	
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As part of the process of examining the responsible pharmacist requirements the Society has also identified potential breaches that pose a significant risk to patient safety or undermine public confidence and are therefore not suitable for the 'non-referral' process.

Panel 2 shows the case types that would **not** be considered suitable for the 'non-referral' process.

Panel 2: Responsible Pharmacist case types **not** considered suitable for the 'non-referral' process.

Case Type	Examples	Proposed action
Responsible pharmacist	<p>Pharmacy record</p> <p>Failure of the person carrying on the pharmacy business to secure that the pharmacy record is preserved for a period of not less than five years.</p>	Referral to a Fitness to Practise Committee.
	<p>Absence</p> <p>Responsible pharmacist is absent from the registered pharmacy premises without the necessary arrangements in place.</p>	Referral to a Fitness to Practise Committee.

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Keeping and preserving the pharmacy record is very important. Patients must be confident that an organisation can properly identify who was responsible for the pharmacy when they received a service.

With regards to 'absence' the focus of the regulator will be on the safety of service users and the quality of service provision during the 'absence'. A pharmacist who is absent from the pharmacy premises without any procedures in place is putting patients at risk.

As you can see, this is very different from the regulatory approach to a pharmacist being absent from a pharmacy premises for more than two hours for reasons outside of their control but where there are clearly proper procedures in place. This is an example of the risk-based approach to regulation that the Society operates.

A full list of the case types that are currently considered suitable for the 'non-referral' process can be viewed on the Society's website:

www.rpsgb.org/protectingthepublic/investigatingcommittee/#case.

Please visit the Society's website www.rpsgb.org for more information or speak to your local Inspector.