

Responsible Pharmacist – Then and Now

The issues	Pharmacist in Personal Control - Prior to 1 October 09	Responsible Pharmacist - From 1 October 09
How does the pharmacy show and document who is responsible for the provision of pharmacy services?		
Who is on duty?	The pharmacist must display their registration certificate.	The responsible pharmacist must conspicuously display a notice stating: (a) their name; (b) their registration number; and (c) that s/he is in charge of the pharmacy.
Record of who is on duty?	Principle 7.4 of the <i>Code of Ethics for Pharmacists and Pharmacy Technicians</i> and Standard 2 of the <i>Professional Standards for Pharmacists in Positions of Authority</i> requires that there must be in existence a retrievable audit trail of who is responsible for the pharmacy. There is no guidance on who should make this record or when it should be made.	The responsible pharmacist must personally make a record of the date and time of when they are the responsible pharmacist at the pharmacy premises. This record must be made contemporaneously (which means 'of the time').
What about the superintendent and /or the pharmacy owner?	Principle 7.4 of the <i>Code of Ethics</i> and Standard 2 of the <i>Professional Standards for Pharmacists in Positions of Authority</i> requires that there must be in existence a retrievable audit trail of who is responsible for the pharmacy.	There is a duty on the person carrying on the business to ensure that the record is properly maintained and preserved for five years.
Are there any criminal offences?	No.	Yes. Failure of the responsible pharmacist to make a record and failure of the owner to preserve the record is a criminal offence.
What will the	The focus of the regulator is the safety of service users	Whilst the Society is the enforcement authority for criminal

regulator do?	and effective and proportionate management of non-compliance.	<p>offences associated with the responsible pharmacist regulations, it is unlikely to consider criminal proceedings as this is not an effective use of resources and does not achieve the organisational objective of assuring patient safety and public confidence.</p> <p>However, it remains one of the options available for responding to those breaches within the legislation that are criminal offences.</p> <p>Many of the potential breaches of the responsible pharmacist requirements have been identified as suitable for management through the 'non-referral' process. Please see the following website links for the regulatory response to these specific breaches: www.rpsgb.org/pdfs/icothernonreferral.pdf www.rpsgb.org.uk/pdfs/rpresponinsp.pdf.</p>
Standard operating procedures (SOPs)		
What is an SOP?	It is a document which sets out how the pharmacy should operate.	It is a document which sets out how the pharmacy should operate.
What SOPs are needed?	Principle 7.4 of the <i>Code of Ethics</i> and Section 2 of the <i>Professional Standards for Pharmacists in Positions of Authority</i> requires that appropriate SOPs exist for the pharmacy service provided. There is no definitive list of what procedures are required.	<p>The responsible pharmacist regulations state that the pharmacy procedures must set out:</p> <p>(a) the arrangements to secure that medicinal products are:</p> <ul style="list-style-type: none"> (i) ordered; (ii) stored; (iii) prepared; (iv) sold by retail; (v) supplied in circumstances corresponding to retail sale; (vi) delivered outside the pharmacy; and (vii) disposed of in a safe and effective manner;

		<p>(b) the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;</p> <p>(c) 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;</p> <p>(d) the keeping of records about the arrangements mentioned in paragraph (a);</p> <p>(e) the arrangements which are to apply during the absence of the responsible pharmacist from the premises;</p> <p>(f) the steps to be taken when there is a change of responsible pharmacist at the premises;</p> <p>(g) the procedure which is to be followed if a complaint is made about the pharmacy business;</p> <p>(h) 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; and</p> <p>(i) the manner in which changes to the pharmacy procedures are to be notified to pharmacy staff.</p>
<p>Who is responsible for the SOPs?</p>	<p>Principle 7.4 of the <i>Code of Ethics</i> and Standard 2 of the <i>Professional Standards for Pharmacists in Positions of Authority</i> requires that pharmacists in a position of authority must ensure that there are adequate policies and SOPs to secure the safe and effective provision of pharmacy services.</p> <p>Superintendents / pharmacy owners are responsible for setting out standards and policies for the provision of</p>	<p>Section 72A of the Medicines Act 1968 requires that the responsible pharmacist must establish (if they are not already established) maintain and keep under review procedures designed to secure the safe and effective running of the business.</p>

	pharmacy services in their organisations.	
What about the superintendent / pharmacy owner?	<p>Standard 2 of the <i>Professional Standards for Pharmacists in Positions of Authority</i> requires that pharmacists in a position of authority must ensure that there are policies and SOPs in place to secure the safe and effective provision of pharmacy services.</p> <p>Standard 2 also says that superintendents / pharmacy owners are responsible for setting out standards and policies for the provision of pharmacy services in their organisations.</p>	<p>There is nothing specific in the new legislation for the superintendent / pharmacy owner with regards to SOPs.</p> <p>However, Standard 2 of the <i>Professional Standards for Pharmacists in Positions of Authority</i> requires that pharmacists in a position of authority must ensure that there are policies and SOPs to secure the safe and effective provision of pharmacy services.</p> <p>Standard 2 also says that superintendents / pharmacy owners are responsible for setting out standards and policies for the provision of pharmacy services in their organisations.</p>
Does the pharmacist in personal control / responsible pharmacist have to read all the SOPs?	<p>It is a matter of professional judgement. If the pharmacist in person control works in a pharmacy regularly then the premises and procedures will be familiar to them and there will be no need to read the SOPs every day.</p> <p>If the pharmacist is working in premises that are unfamiliar, they should read the SOPs so that s/he can be assured that the pharmacy can provide safe and effective services.</p>	<p>It is a matter of professional judgement. If the responsible pharmacist works in a pharmacy regularly then the premises and procedures will be familiar to them and there will be no need to read the SOPs every day.</p> <p>If the responsible pharmacist is working in premises that are unfamiliar, they should read the SOPs and accept (or amend) them as soon as possible. It is down to the responsible pharmacist's professional judgement as to whether this needs to occur before they are willing to assume responsibility as the responsible pharmacist.</p> <p>The responsible pharmacist must be assured that the SOPs are regularly reviewed.</p>
Does the pharmacist	Standard 2 of the <i>Professional Standards for Pharmacists</i>	If there are no SOPs the responsible pharmacist must establish

in personal control / responsible pharmacist have to write and/or change the SOPs?	<i>in Positions of Authority</i> requires that pharmacists in a position of authority must ensure that there are policies and SOPs to secure the safe and effective provision of pharmacy services.	the SOPs to secure the safe and effective running of the pharmacy. If the SOPs are not appropriate in a situation the responsible pharmacist should make the necessary amendments. The <i>Professional Standards and Guidance for Responsible Pharmacists</i> document provides further information on amending SOPs. See: www.rpsqb.org.uk/pdfs/coepsgrp.pdf .
Are there any criminal offences?	No.	No.
What will the regulator do?	The focus of the regulator is the safety of service users and effective and proportionate management of non-compliance.	The focus of the regulator is the safety of service users and effective and proportionate management of non-compliance. Many of the potential breaches of the responsible pharmacist requirements have been identified as suitable for management through the 'non-referral' process. Please see the following website links for the regulatory response to these specific breaches: www.rpsqb.org/pdfs/icothertonreferral.pdf www.rpsqb.org.uk/pdfs/rpresponinsp.pdf .
Absence		
What does absence mean?	The Medicines Act 1968 requires that a registered pharmacy has a pharmacist in personal control in order for it to be lawfully conducting its business. A pharmacist who leaves the registered pharmacy premises is no longer in personal control.	In this context absence means when the responsible pharmacist is no longer physically on the registered pharmacy premises but remains responsible for the safe and effective running of the pharmacy.
How long can the pharmacist in	N/A. If the pharmacist is no longer on the registered pharmacy premises they are no longer in personal	A maximum of two hours in every 24 hours (midnight to midnight).

personal control / responsible pharmacist be absent?	control.	
What can happen when the pharmacist in personal control / responsible pharmacist is absent?	Nothing. A pharmacist must be in personal control of a pharmacy in order for it to be lawfully conducting its business.	Detailed guidance on this issue has been published by the Society. Please see the <i>Responsible pharmacist requirements: What activities can be undertaken?</i> document at: www.rpsgb.org.uk/worldofpharmacy/currentdevelopmentsinpharmacy/skillmix .
What about the superintendent / pharmacy owner?	<p>The pharmacist in personal control is responsible for activities that take place when they are in charge of the registered pharmacy premises (they cannot be absent).</p> <p>The superintendent / pharmacy owner is responsible for the overarching governance framework.</p>	<p>The responsible pharmacist is responsible for activities that take place when they are in charge of a registered pharmacy premises (included during a period of absence).</p> <p>The superintendent / pharmacy owner is responsible for the overarching governance framework.</p>
Is there a criminal offence?	No.	No.
What will the regulator do?	The focus of the regulator is the safety of service users and effective and proportionate management of non-compliance.	<p>The focus of the regulator is the safety of service users and effective and proportionate management of non-compliance.</p> <p>Many of the potential breaches of the responsible pharmacist requirements have been identified as suitable for management through the 'non-referral' process. Please see the following links for the regulatory response to these specific breaches:</p> <p>www.rpsgb.org/pdfs/icothernonreferral.pdf www.rpsgb.org/pdfs/rpresponinsp.pdf.</p>