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## The RPSGB Response to the content of the Responsible Pharmacist Regulations

### Introduction

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, a role that is expected to become statutory under new legislation soon. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB welcomes the opportunity to comment on the Governments proposals on the content of the responsible pharmacist Regulations.

The RPSGB recognises the importance of enabling pharmacists to undertake more clinical roles and agrees that these provisions will serve the public and increase their access to pharmaceutical services. It is also of paramount importance that patient safety is maintained. The RPSGB believes that a pharmacist must only be responsible for one pharmacy at any one time. A unique selling point of pharmacies is that members of the public can seek expert advice about their medicines and health without the need for appointment. It would be of concern to the RPSGB if this important quality service were to be lost. There is a need for a balance to be struck, and there are, and will be in the future, other clinical services that pharmacists can provide away from the pharmacy premises, which will be of benefit to both patients and the wider public. Hospital, PCT and practice pharmacists are already undertaking a wide range of clinical activities outside the dispensary and these have been shown to be of benefit to patients. It is important that provisions are drafted in the regulations to enable pharmacists to undertake these activities.

The RPSGB proposes that in periods of absence under two hours (the RPSGB proposes a maximum absence of two hours), the responsible pharmacist has the option of being absent and continuing to be the responsible pharmacist, or handing responsibility to a second pharmacist, if they are available. Where a responsible pharmacist is absent for periods of more than two hours, the RPSGB proposes that another pharmacist must become the responsible pharmacist. The RPSGB also recommends that the pharmacy record must contain the reason for absence, in order to maintain an appropriate audit trail.

When considering the provisions of the responsible pharmacist Regulations the RPSGB has sought to ensure that the current quality framework that is in place in all registered pharmacy premises is not lost. It is important that the responsible pharmacist regulations do not detract from the personal professional accountability that every pharmacist has, whether they are the responsible pharmacist or a supervising pharmacist.

The RPSGB strongly opposes any attempt to make the responsible pharmacist Regulations overly burdensome, but recognises the need for certain important safeguards that need to be put in to place to assure the quality and safety of service provision. In addition, the RPSGB would be concerned if breaches of the Regulations surrounding the responsible pharmacist provisions were to result in the potential for criminal prosecution. The Society believes that it has an effective regulatory machinery to deal with breaches where it is necessary to do so in the public interest. With the proposed formation of the General Pharmaceutical Council (GPhC), the Government are in a unique position to ensure that the new regulator is equipped

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with adequate powers and resources to ensure that the regulatory machinery continues to be effective. .

The RPSGB completed a fundamental review of its Code of Ethics in 2007, and launched a new Code of Ethics on 1<sup>st</sup> August 2007. The new Code of Ethics is based on set of overarching principles that informs the conduct, performance and practice of pharmacists and pharmacy technicians. The Code of Ethics encourages pharmacists to exercise their professional judgement and the RPSGB would seek to ensure that any new regulations would not undermine the ability of pharmacist to do this. In moving to a principle based code, the RPSGB recognised that there will be specific professional requirements and areas of practice that will require more detailed guidance than will be provided in the code. The RPSGB has produced seven supporting standards and guidance documents to the Code of Ethics. Each of these sets out those standards that are mandatory and those that are good practice. The RPSGB envisages that any further professional guidance, whether mandatory or good practice should be provided by the RPSGB in the form of standards and guidance documents and potentially the Code of Ethics. The RPSGB welcomes the opportunity to work closely with the Department of Health and other pharmacy bodies in drafting the content of any such documents.

The RPSGB has a well trained and expert team of inspectors who routinely visit registered pharmacies for the purposes of ensuring compliance and offering support and guidance on compliance issues to ensure that a high quality service provision is provided from pharmacies. The RPSGB would expect that if there were any enforcement requirements' the RPSGB (and in the future GPhC) would be the specified enforcement authority. The RPSGB would also seek to ensure that the inspectors were equipped with adequate powers in order to ensure compliance with the legislation.

When considering the changes necessary to bring into effect the provisions surrounding the responsible pharmacist, the RPSGB would also wish to ensure that the Government took into account the unintended consequences that the absence of a pharmacist in a pharmacy could potentially have on service provision. Current Home Office interpretation of the Misuse of Drugs Regulations 2001 indicates that in the absence of a pharmacist there may be no possession of Schedule 1, 2, 3 , 4 Part 1 Controlled Drugs by any other member of the pharmacy staff. This could potentially limit the service provided from the pharmacy when there is no pharmacist present and undermine the intention of the responsible pharmacist Regulations. The RPSGB would not wish to see patients' access to medicines to be restricted as this would be an unintended consequence of the provisions. Consideration should be given to ensuring other relevant legislation is amended appropriately, where necessary, to give effect to the policy intention behind these changes.

The RPSGB is aware that many pharmacies supply veterinary medicines from their premises. The supplies of these medicines are controlled under the Veterinary Medicines Regulations 2007. For certain categories of veterinary medicines the supply is restricted to the pharmacist e.g. Prescription Only Medicine – Veterinarian (POM – V) and Prescription Only Medicine – Veterinarian, Pharmacist and Suitably Qualified Person (POM – VPS) categories of medicines. The RPSGB would wish to ensure that the impact on other legislation relating to the sale and supply of medicines is considered carefully and wherever possible necessary legislative amendments are made to ensure that potential obstacles to progress are removed. The RPSGB believes that in the majority of circumstances, the superintendent pharmacist in the hospital is the Chief Pharmacist.

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### The Pharmacy Procedures: Chapter 3

The Government believes there is a need for a balance to achieve some consistency in the content of the pharmacy procedures whilst allowing the responsible pharmacist sufficient flexibility to ensure these meet the operational needs of the individual pharmacy

***Q. Do you agree with this approach? If not, what are your reasons for this and what do you propose instead?***

Pharmacy procedures will form a core part of the infrastructure underpinning the quality framework operating within the pharmacy. This is already recognised in Principle 7 of the RPSGB Code of Ethics for pharmacists and pharmacy technicians '**Take responsibility for your working practices**' which states that you must take responsibility for all work done by you or under your supervision. Ensure that individuals to whom you delegate tasks are competent and fit to practise and have undertaken, or are in the process of undertaking, the training required for their duties.

The RPSGB agrees that the approach to pharmacy procedures must be balanced. Whilst there is a need to achieve some consistency in the content of pharmacy procedures there must still be flexibility in their application. Ensuring consistency of content will be of particular importance for those pharmacists working in the locum sector. The RPSGB believes that core areas to be covered in pharmacy procedures could be identified, but the detail surrounding each area should be left flexible. The types of pharmacy operations are many and diverse. It is important that pharmacy procedures allow operational flexibility within the total quality framework and the current Code of Ethics supports this.

It is important that the flexibility allows an incoming responsible pharmacist to amend the pharmacy procedures to comply with their statutory duty to secure the safe and effective running of the pharmacy. The RPSGB does not believe that the flexibility should result in the responsible pharmacist changing procedures unless it is necessary to adhere to their statutory duty and therefore secure patient safety. In these circumstances, such changes need to be documented. The RPSGB would be concerned if procedures were amended on a daily basis for no obvious need, therefore causing confusion to pharmacy staff and potentially placing patient safety at risk. The boundary issues around the responsibilities of the superintendent pharmacist and responsible pharmacist would need to be considered and clarified. However, this should not detract from the personal professional accountability of each and every pharmacist and the requirement to adhere to the Code of Ethics.

The RPSGB would be concerned if regulations were overly restrictive and compromised operational flexibility and if pharmacists were unnecessarily inhibited from exercising their professional judgement.

The RPSGB's current guidance in relation to Standard Operating Procedures (SOPs) states that there is no single template that can be applied to all pharmacies and the Society welcomes the Government's recognition of the need for the responsible pharmacist to use and exercise their professional judgement when establishing and maintaining pharmacy procedures.

The Hospital Pharmacist Group (HPG) would not expect a responsible pharmacist within the hospital setting to change agreed procedures on a day to day basis without reference to the

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Chief Pharmacist (or appropriate deputy). They see the need to change procedures only happening in exceptional situations and it might be useful to consider recording of non-compliance with procedures.

The proposal is the procedures cover, as a minimum requirement, the areas specified in the regulations. Chapter 3 sets out what these minimum areas might be.

- Q. Do you think the proposed minimum areas are the right areas?***
- Q. Are there any other areas that you feel the regulations should specify be covered in the procedures? If so, what are these and why should these be covered?***
- Q. Do you agree the pharmacy procedures should include arrangements for the sale of GSL medicines?***
- Q. Do you agree that the inclusion of areas, over and above the specified minimum areas, should be a matter for the pharmacy owner/superintendent pharmacist and the responsible pharmacist? If not, what do you propose and what are your reasons for this?***

The RPSGB agrees with the minimum areas as outlined in the consultation. These areas are considered to be key to the safe and effective running of the pharmacy. The RPSGB considers that dispensing is usually defined as the process from receipt of prescription through to the supply of the dispensed medicine to the patient. Therefore; there is a need to ensure pharmacy procedures cover all aspects of the dispensing process as a minimum. Procedures covering record keeping and absence will ensure that a verifiable audit trail is maintained, and are important when considering the enforcement functions of the RPSGB.

The RPSGB welcomes the changes that will enable a General Sale List (GSL) medicine to be sold from the pharmacy when the pharmacist is absent, therefore bringing pharmacies into line with other retail outlets. The RPSGB agrees that pharmacy procedures should include arrangements for GSL medicines; this will ensure that patients are able to access the GSL medicines they require while continuing to be assured there is appropriate professional oversight. The RPSGB welcomes the Government's recognition that patients purchasing GSL medicines expect high standards of care and professional advice when purchasing medicines from a registered pharmacy. There is a need to ensure that the public perception of purchasing medicines from a pharmacy is maintained and therefore the sale and supply of GSL medicines must be included in pharmacy procedures. The RPSGB believes that where possible all members of the public should be encouraged to purchase their medicines from a registered pharmacy.

The RPSGB does not believe the Regulations must specify any other areas that pharmacy procedures must cover. There must be flexibility in the approach to pharmacy procedures, and the RPSGB believes that it should be for the pharmacist owner, superintendent and responsible pharmacist to use their judgement when considering if there are any other areas that require pharmacy procedures.

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The proposal is that pharmacy procedures may be set out on paper or electronically, provided these are readily available and accessible to those needing to consult them.

***Q. Do you agree with this approach? Are there any other requirements (other than readily available and accessible) that you consider should be set out in the regulations? If so, what are these and your reasons for putting them forward?***

The RPSGB agrees with the approach that pharmacy procedures should be maintained either electronically or on paper.

As with any electronic records, safeguards will be required to ensure the pharmacy procedures are not lost as a result of a systems failure. Adequate back-ups must be made and arrangements will need to be in place so that RPSGB inspectors can examine, and potentially retrieve, the procedures with minimal disruption to the dispensing process. The RPSGB does not seek for regulations to specify that adequate back-ups must be kept, and believes that this information would be best placed in mandatory guidance from the RPSGB. Guidance could also advise of the need for version control systems so that the most recent versions are in use.

The RPSGB believes strongly that pharmacy procedures must be readily available and accessible. It is important that all pharmacy staff have access to the procedures as these will form an important basis for the running of the pharmacy. The RPSGB believes that where pharmacy procedures are not available to all staff, confusion may arise and disruption to the running of the pharmacy may occur.

The proposal is that regulations do not specify the format used for setting out the pharmacy procedures

***Q. Do you agree with this approach? If not, what do you propose and what are your reasons for this?***

***Q. Do you agree with the view, set out in the consultation paper, on requiring the format used to allow the responsible pharmacist to “sign off” that s/he has checked the procedures and is content these support safe working in the pharmacy? If so, what are your reasons for supporting that view?***

***Q. Are there other matters that you feel should be included in the regulations in relation to the format of the pharmacy procedures?***

The RPSGB would not seek for the Regulations to be overly burdensome or prescriptive in respect of pharmacy procedures, and does not agree with the Regulations specifying the format used for setting out pharmacy procedures, given the diversity of possible approaches. The RPSGB would stress the need for clear procedures capable of being followed; overly cumbersome procedures could result in non compliance and introduce risk.

The RPSGB does not agree that a responsible pharmacist must sign off to say they have checked and are content with the pharmacy procedures. In complying with their statutory duty

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a responsible pharmacist will need to establish (where not already established), maintain and review pharmacy procedures. In a situation where a responsible pharmacist is the responsible pharmacist for consecutive days, the requirement to sign off procedures may cause unnecessary burden and delay the responsible pharmacist in undertaking other more relevant tasks.

In addition, most Hospital Trusts have robust systems to around approval of procedures and would not want them altered based on an individual responsible pharmacist without suitable discussion, consultation and in line with trust procedure.

The Government's view is the responsible pharmacist should check the procedures on taking on responsibility for the pharmacy and assess the need for review and/or amendment as appropriate.

***Q. Do you agree with this approach? If not, what do you propose and what are your reasons for this?***

Principle 7 of the RPSGB Code of Ethics for pharmacists and pharmacy technicians '**Take responsibility for your working practices**' states that you must ensure that you are able to comply with your legal and professional obligations and that your workload or working conditions do not compromise patient care or public safety. The RPSGB believes this requirement supports the need for the pharmacy procedures to be checked as appropriate.

The RPSGB agrees that on taking responsibility for a pharmacy, the responsible pharmacist must assess the need for the procedures to be reviewed and amend the procedures where necessary. The RPSGB believes that this process must be undertaken in order for a responsible pharmacist to be satisfied that safe systems are in place in the pharmacy.

The RPSGB would not seek for this requirement to be written in Regulations; instead this requirement should be placed in good practice guidance.

The RPSGB introduced a requirement for registered pharmacy premises to have Standard Operating Procedures as of 1<sup>st</sup> Jan 2005. The RPSGB therefore believes that pharmacists and pharmacy staff are familiar with the way in which registered pharmacy premises procedures should be implemented, and reviewed.

The Government is seeking views on the review and/or amendment of the pharmacy procedures

***Q. Do you agree that guidance may be a more appropriate means of providing information and advice on the review of procedures? If so, what are your reasons for supporting that view?***

***Q. Are there proposal(s) that you wish to put forward in relation to the review of procedures? What are the reasons supporting your proposals?***

The RPSGB agrees that guidance is a more appropriate means of providing information and advice on the review of procedures. Principle 7 of the Code of Ethics '**take responsibility for your working practices**' states that pharmacists and pharmacy technicians must be satisfied that appropriate standard operating procedures exist and are adhered to, and that clear lines

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of accountability and verifiable audit trails are in place. In addition, the RPSGB introduced the requirement for pharmacy premises to have SOPs in place from 1<sup>st</sup> Jan 2005. The concept of maintaining, reviewing and amending pharmacy procedures is not new to pharmacists and therefore the RPSGB believes that it would be unnecessary for Regulations to stipulate requirements. It is believed that procedures should be robust, yet flexible enough to cover most possible scenarios.

The RPSGB believes that professional guidance should require procedures to be reviewed at least annually and that procedures should be signed and dated to indicate that they have been reviewed. Procedures must also be appropriately reviewed in response to changes or incidents within the pharmacy that occur between annual reviews and systems should be in place to ensure that relevant staff are made aware of any changes to existing procedures. The requirement for procedures to be reviewed annually must not detract from the need for them to be reviewed in response to changes or incidents.

The RPSGB also believes that the Superintendent or Pharmacy Owner should sign a yearly declaration to state that appropriate procedures are in place. A declaration (similar to the CD declaration – which we have power to require under the Controlled Drugs (Supervision of Management and Use) Regulations 2006) could be added to the premises fee retention form with a requirement that it is completed by the superintendent pharmacist or owner of the pharmacy (as for CDs). Consideration could be given to targeted inspection where declarations are not made. Associated guidance about completing the forms can give the background to the declaration being sought. The Society has taken similar steps as part of the implementation of the new arrangements for Controlled Drugs and it has worked well with high compliance.

The RPSGB would also seek, in guidance, a requirement for any amendment made to the pharmacy procedure to be recorded, with the reason for the amendment. This will provide a verifiable audit trail and will be of importance during the monitoring and inspection visits undertaken by the RPSGB Professional Standards Inspectorate. In addition, these records will need to be sufficiently robust to be used as evidential material. Whilst, the RPSGB believes that a proper audit trail must be maintained, record keeping requirements should be proportionate and records need to remain fit for purpose. In conclusion pharmacy procedures need to be clear and definitive and should only detail current requirements' with a record of the archive of changes to be kept separately.

The RPSGB believes that the presence of pharmacy procedures does not in itself improve quality of service delivery unless the procedures are followed, reviewed and improved in light of experience. Pharmacy procedures must be audited and capable of being followed as failure to follow up-to-date procedures is a risk to the public.

The RPSGB also believes that any record of amendments to or non-compliance with the pharmacy procedures will enable the Superintendent or pharmacy owner who may have issued templates to review these as necessary. Pharmacy procedures play an integral part in the way in which pharmacists and pharmacy staff can improve working practices in the interests of the public and patients.

The consultation paper looks at the role of the responsible pharmacist, the pharmacy owner, the superintendent pharmacist, and the professional regulatory bodies in relation to the pharmacy procedures.

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***Q. What is your view of their role and what are your reasons for taking that view?***

Pharmacy owners and superintendent pharmacists have responsibility for setting out the overarching standards and policies for the pharmacy business. The responsible pharmacist has responsibility for ensuring that policies and procedures are appropriate for the particular pharmacy for which they are responsible. Where model procedures have been agreed by the pharmacy owner or superintendent pharmacist, the responsible pharmacist should ensure that these are implemented and adapted where necessary within the pharmacy for which they are assuming responsibility. Changes to existing pharmacy procedures should be justifiable, for example, in response to patient safety issues or staffing changes, and should normally be made in conjunction with the pharmacy owner or superintendent pharmacist.

The pharmacy owner or superintendent pharmacist must ensure that overarching safe systems of working and SOPs are in place, as well as ensure that there is a continued presence of an adequate number of appropriately trained staff and that staffing arrangements can deliver a safe service. The pharmacy owner and superintendent have responsibility to ensure that staff are aware of personal responsibilities and limits of competence and authority. The RPSGB views the role of the pharmacy owner or superintendent pharmacist as ensuring that pharmacies are provided with adequate resources (staff, equipment, etc) to ensure that the responsible pharmacist can carry out their responsibilities and ensure a safe, effective and efficient service delivery from the pharmacy. In addition, the RPSGB believes the superintendent/pharmacy owner should ensure clinical governance and audit arrangements provide appropriate risk assessment and adequate records etc and define delegation arrangements.

The superintendent/pharmacy owner should also define both the circumstances and provide the means by which the responsible pharmacist is to be contacted.

The responsible pharmacist should be satisfied that tasks are delegated to suitably trained, competent staff who are working within clearly defined SOPs. The responsible pharmacist must also be satisfied that support staff are aware of their personal responsibilities and limits of competency. The responsible pharmacist should ensure that incident reporting and complaints procedures are in place and must be satisfied that there are clear protocols defining the circumstances for which a pharmacist needs to have personal involvement, or direct oversight.

The RPSGB believes these responsibilities should be detailed in guidance.

The Hospital Pharmacist Group supports the view that the hospital Chief Pharmacist is regarded as having the roles and responsibility of the superintendent Pharmacist. The application of the role of responsible Pharmacist is likely to be complex in the hospital setting and local procedures should clearly define the roles and responsibilities of the responsible Pharmacist .

In most Trusts the Chief Pharmacist (Superintendent Pharmacist) would be responsible for policy, governance, service quality, professional standards. As such the Chief Pharmacist must have overall control of the contents of procedural documents. This would be for the whole department (not just the 'registered premises'). They would also be responsible for ensuring e.g. processes are in place for incident reporting / complaints etc. The role of the responsible Pharmacist in the hospital setting would need to be clarified in guidance.

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The regulations need to be flexible enough to allow for hospital practice and specific guidance should be written for the hospital setting.

#### **The Pharmacy Record: Chapter 4**

The Government proposes the regulations require the responsible pharmacist to include minimum specified information in the pharmacy record. Other information for inclusion in the record would be a matter for the pharmacy owner/ the superintendent pharmacist

***Q. Do you agree with this approach and the proposed minimum information requirements?***

***Q. What are your views on proposals set out in the consultation paper for other information requirements in relation to the pharmacy record?***

***Q. Do you think there is a need for other information requirements in relation to the record? If so, what are these and your reasons for putting these forward?***

The RPSGB supports the proposed minimum fields of information required for the pharmacy record. The responsible pharmacist needs to be clearly identifiable and an accurate, up-to-date record of the responsible pharmacist must be available in the pharmacy. Appropriate security measures must be in place to ensure records cannot be falsified.

The RPSGB believes that pharmacy records must be available in the pharmacy. Records could be held at another location provided the record is identifiable to the pharmacy and can be readily accessed for inspection and monitoring purposes.

RPSGB Inspectors should be able to require disclosure of all relevant records and Regulations should support this.

The RPSGB does not agree that the pharmacy record should contain details of the responsible pharmacist's registration date. This information can be easily located on the RPSGB website, and could be held in a pharmacy's resource file. The RPSGB agrees that this would result in duplication of records and is unnecessary.

The RPSGB believes that an audit trail of pharmacist's absence and reasons for absence needs to be maintained. The RPSGB proposes the reason for absence must be recorded.

The RPSGB does not agree that the Regulations should contain a requirement for the pharmacy record to include any amendment to the record and the reason for this. The amending of a pharmacy record, for example due to error, is accepted practice and the inclusion of this within regulation would be overly cumbersome.

The RPSGB does not agree the record should include information on pharmacists (other than the responsible pharmacist) and other staff working in the pharmacy (including the date and hours of working).

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The standards and guidance for pharmacists and pharmacy technicians in positions of authority, which supports the Code of Ethics for Pharmacists and Pharmacy Technicians, requires that you must ensure *'clear lines of accountability exist and a retrievable audit trail of the health professional taking responsibility for the provision of each pharmacy service is maintained'*. Therefore, the RPSGB believes that any requirement for the record to contain this information will result in a duplication of work and information.

The RPSGB does not support proposals that would result in the duplication of record keeping or regulation that is burdensome and provides no further protection against risk to the public. The RPSGB believes that with every duplication of work or record keeping there is an increased opportunity for error. Audit trails and clear lines of accountability are important; however the maintenance of records must not result in a pharmacist being unnecessarily burdened such that they are unable to concentrate on their role in providing patients with safe and timely access to medicines, information and advice.

The proposal is the pharmacy record may be kept electronically or on paper, provided it is readily accessible and available to those who need to consult it. The Government does not propose that regulations specify the format for the record – instead the regulations will specify the fields of information to be included in the record.

***Q. Do you agree with this approach? If not, what do you propose and what are your reasons for putting your proposals forward?***

The RPSGB supports the proposal that records should be capable of being maintained either electronically or on paper.

As with any electronic records, safeguards will be required to ensure data are not lost as a result of a systems failure. Adequate back-ups must be made and arrangements will need to be in place so that RPSGB inspectors can examine the records with minimal disruption to the dispensing process. The RPSGB does not seek for regulations to specify that adequate back-ups must be kept, and believes that this information would be best placed in guidance. Principle 1 of the Code of Ethics supports the need to keep records appropriately by stating that pharmacists must **'maintain timely, accurate and adequate records and include all relevant information in a clear and legible form'**.

The RPSGB welcomes the proposal that the Regulations should not specify the format of the pharmacy record, but should specify the minimum fields of information to be included in the record. The RPSGB believes that this will provide the necessary flexibility whilst still ensuring the consistency of information recorded and enable effective monitoring of record keeping requirements.

The Government proposes the regulations set out the minimum period that the pharmacy owner is required to preserve the pharmacy record and that the minimum period should be 5 years from the date of the last entry to the record.

***Q. Do you agree? If not, what do you propose? What do you think should be the minimum period specified in the regulations and why?***

The RPSGB supports the proposal that records should be preserved for a minimum period of five years.

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The RPSGB would seek clarification on the requirement to maintain records for a period of five years from the date of last entry. The RPSGB views the pharmacy record as a rolling record, particularly where a record is kept electronically and may never end. Therefore, the RPSGB proposes that records should be maintained for five years from the date of entry (the requirement for five years from the last entry in the record should only be applicable to paper based records).

The RPSGB would therefore seek that the regulations require the pharmacy record to be kept for a minimum of 5 years from the date on which an entry is made, or in line with other Regulations appropriate to the sector of practice.

### **Absence from the Pharmacy: Chapter 5**

The Government has stated the regulations specify the minimum proportion of time that the responsible pharmacist should spend in the pharmacy and this should be the majority of his/her time (ie more than 50% of each period when s/he is the responsible pharmacist and the pharmacy is operational).

*Q. Do you support this view? What are your reasons for this?*

*Q. What do you think should be the minimum proportion of time that the responsible pharmacist should be required to be present in the pharmacy? What are your reasons for this?*

*Q. If you do not agree, what do you propose and why?*

A unique selling point of pharmacies is that members of the public can seek expert advice about their medicines without the need for an appointment. It would be of concern to the RPSGB if this important quality service provision were to be lost. However, there is a need for a balance to be struck, and there are and will be in the future, other professional services that pharmacists can provide away from the pharmacy premises, which will be of benefit to both patients and the wider public. It is important that provisions are drafted in the regulations to enable pharmacists to undertake these activities; however there needs a balance between when activities can be conducted in a pharmacy without a pharmacist on-site and when there is a need for two pharmacists.

The RPSGB supports the concept of absence but strongly believes that length of absence must be proportional, and for no more or no less than is necessary, and for no longer than will compromise patient safety.

The RPSGB strongly opposes the government recommendation that the minimum amount of time the responsible pharmacist must be present in the pharmacy is 50%. Instead, the RPSGB proposes that the responsible pharmacist should spend **substantially more than half** of their time in the pharmacy. The RPSGB would be extremely concerned about a registered pharmacy continuing to operate for prolonged periods of time in the absence of a responsible pharmacist.

The RPSGB believes there should be provision for the responsible pharmacist to be absent for **short periods** of time, where the absence can be justified and provided specified

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conditions are met, but a responsible pharmacist must be present in the pharmacy for **substantially more than half** of the time the pharmacy is open.

The RPSGB believes that placing exact time limits on absence will be very difficult to regulate and enforce. The Society does not agree with the proposal that the regulations should specify a percentage of time the responsible pharmacist should spend in the pharmacy. The RPSGB believes it would be arbitrary to specify the limits on absence as a percentage of the day. Instead, the RPSGB would seek for guidance supporting the regulations to issue advice in relation to length of absence from the pharmacy.

If however, the Government decides that a percentage must be specified in regulation, the RPSGB believes that this should be 75% of the hours for which the pharmacy is open. The RPSGB would not support breaches of the Regulations being automatically defined as a criminal offence.

The RPSGB believes that absence of the responsible pharmacist should be linked with adherence to professional requirements that necessitate the pharmacist to only be absent from the pharmacy when having a break or undertaking professional services. In addition, Regulations should specify the need for the Responsible Pharmacist to be able to justify their absence, but professional guidance should exemplify what is justifiable

Within the hospital setting, the regulations need to be flexible enough to allow efficient systems on hospital (with suitable safeguards) and specific guidance would be needed for the hospital setting. In the hospital setting it is envisaged that the responsible pharmacist is likely to change frequently through the day limiting the need for absence.

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The Government proposes the maximum time during any one period of absence that the responsible pharmacist may be away from the pharmacy should be three hours. The Government seeks views on whether this period might vary in certain circumstances

*Q. Do you agree the regulations should specify a maximum time? If so, should this be set at three hours?*

*Q. Do you think the maximum time might vary, subject to meeting conditions set out in the regulations? Eg where another pharmacist or a suitably trained and registered pharmacy technician remain present in the pharmacy? If so, how might this vary and what are your reasons for putting that view forward?*

*Q. If you do not agree, what do you propose and why?*

The RPSGB agrees the regulations should specify a maximum time for which a pharmacist may be absent.

The RPSGB believes the regulations should enable the responsible pharmacist to be absent for **short periods** of time of up to two hours per day per pharmacy. There are clear dangers to the public and patients if the time and circumstances that the responsible pharmacist may be absent were left to individual judgement. The RPSGB proposes that in a single day a pharmacy must not operate for more than two hours without a responsible pharmacist.

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The RPSGB strongly believes that pharmacies must not be without pharmacists for prolonged periods of time. If the government's proposal for each responsible pharmacist to be able to absent for a maximum period (as set in regulation) were to be accepted, then based on the RPSGB maximum of two hours, a pharmacy that has two responsible pharmacists through the day would be able to operate for 4 hours without a responsible pharmacist. The RPSGB does not believe that this is appropriate. Therefore it is important that any reference, in regulation, to limits on absence should be clear i.e. x hours per day per pharmacy rather than per responsible pharmacist shift.

The RPSGB does not support the proposal that the presence of a second pharmacist should increase the maximum length of absence. Instead the RPSGB proposes that where a responsible pharmacist is to be absent for longer than regulations permit, another pharmacist must become the responsible pharmacist.

This would allow the pharmacy to continue to operate as normal. This simplifies the process and avoids confusion.

The proposal is the regulations specify the responsible pharmacist must be able to return to the pharmacy with reasonable promptness.

***Q. Do you agree? If not, what do you propose and what are your reasons for this?***

The RPSGB believes that when absent the responsible pharmacist must be able to return to the pharmacy with reasonable promptness. The RPSGB agrees that the requirement to return with reasonable promptness should be written in regulation.

The RPSGB does not however, believe that the regulations should define the term 'reasonable promptness'. It is the belief of the RPSGB that professional guidance supporting the regulations could advise more generally on the need to return with reasonable promptness; however pharmacists must be encouraged to exercise their professional judgement based on the circumstances of their absence.

The RPSGB strongly disagrees with a breach of the regulations automatically being defined as a criminal offence and therefore resulting in prosecution of the pharmacist.

The proposal is the regulations require the responsible pharmacist to be readily contactable by pharmacy staff during any period of absence but do not specify the arrangements to be made – however, it may be appropriate to provide advice on this in guidance.

***Q. Do you agree with this approach, including that guidance may be a more appropriate way of providing advice on arrangements for being readily contactable by pharmacy staff?***

***Q. If you do not agree, what do you propose and what are your reasons for this?***

The RPSGB supports the view that regulations require the responsible pharmacist to be readily contactable.

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The way in which contactability is maintained may vary depending on the circumstances surrounding absence and the responsible pharmacist must be able to use their professional discretion when considering how they should remain contactable. In addition, it is important that the Regulations are not overly cumbersome. Therefore, the RPSGB agrees that it is more appropriate for guidance to provide advice on the manner in which the responsible pharmacist maintains contact.

The RPSGB and ultimately the GPhC, as enforcement authorities would wish to minimise the use of the criminal courts to achieve compliance with the responsible pharmacist regulations. The preference is for existing fitness to practise procedures to be mobilised. The RPSGB strongly disagrees with a breach of the regulations automatically being defined as a criminal offence and therefore resulting in potential prosecution of the pharmacist.

The proposal is that the responsible pharmacist is required to arrange for another pharmacist to be available to provide advice when s/he is absent from the pharmacy and is unable to be contacted by pharmacy staff. The Government is also seeking views on whether the other pharmacist should also be a responsible pharmacist or eligible to take on that role

***Q. Do you think that the regulations should require the responsible pharmacist to arrange for another pharmacist to provide advice where s/he is unable to maintain contact with the pharmacy? If so, should the other pharmacist also be a responsible pharmacist or eligible to take on this role?***

***Q. If you do not agree, you propose and why?***

The RPSGB supports the proposal for another pharmacist to provide advice where the responsible pharmacist cannot be contacted. The RPSGB believes that all pharmacists must be eligible to be a responsible pharmacist at the point of registration, in so far as securing the safe and effective running of the pharmacy. Therefore all pharmacists must be able to provide advice in this situation.

The RPSGB believes that arrangements for a second pharmacist to provide advice must be arranged in advance. As all pharmacists are required by the Code of Ethics to only undertake activities within their competence the RPSGB does not believe that guidance or regulation should specify any further who can undertake the role of providing advice in this situation.

The criteria for the pharmacist who is being contacted in the responsible pharmacist's absence will be influenced by various factors' such as whether the pharmacist is present or remote from the pharmacy or whether the pharmacist is also responsible for/supervising activities in another pharmacy.

The regulations should not set out how the responsible pharmacist is to arrange for another pharmacist to provide advice during his/her absence. However, this might be a matter to be included in guidance.

***Q. Do you agree with this approach? If not, what do you propose and why?***

The RPSGB agrees with the approach for guidance to be issued rather than for this to be written in regulations. The RPSGB does believe that arrangements for the provision of advice should be made in advance but not set in Regulations.

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Due to the varying circumstances that may cause a pharmacist to be absent, it would not be appropriate for Regulation to stipulate this information. Pharmacists must exercise their professional judgement in this situation. The issuing of professional guidance will provide suitable advice for pharmacists instead.

The RPSGB believes that consideration must be given to the way in which independent pharmacies will comply with this requirement, and this could be seen to have regulatory impact on sole traders.

### Qualifications and Experience: Chapter 6

The Government is seeking views on an annotation to the registrar against those pharmacists with sufficient length of registration and experience to be a responsible pharmacist.

*Q. What is your view and your reasons for this?*

*Q. Do you think there are other matters to consider in addition to those outlined in chapter 6? If so what are these and your reasons for putting them forward?*

When considering the qualifications and experience required by a pharmacist to undertake the role of the responsible pharmacist, the RPSGB has sought to ensure that a quality framework is in place. Principle 1 of the Code of Ethics for pharmacists and pharmacy technicians states that they must **'Make the care of their patients their first concern'**. In addition, Principle 5 of the Code of Ethics states that they must recognise the limits of their competence and to practise only in those areas in which they are competent to do so.

The responsible pharmacist must secure the safe and effective running of the pharmacy, and they must do this to ensure patient safety. In complying with this statutory duty, there are a number of tasks over and above the current ones that newly qualified pharmacists will need to undertake. The RPSGB believes that some of these tasks will require extra competencies or experience over and above the undergraduate course and pre-registration year. The RPSGB proposes that all pharmacists should be capable of becoming a responsible pharmacist at the point of joining the Register. The RPSGB believes that, as currently, a newly qualified pharmacist is competent to be in sole charge of a pharmacy, which is the current position. However, the RPSGB believes that in order for a responsible pharmacist to be absent or to be responsible for more than one pharmacy, extra competencies are required. Confirmation of the additional competencies will have to be part of the consideration of the changes to supervision.

The RPSGB believes that there are leadership and management competencies that will be required by the responsible pharmacist to determine whether absence or being responsible for more than one pharmacy is appropriate. For example within management competencies there will be a need to consider staff training and delegation of tasks. The RPSGB does not believe these competencies can be acquired by education alone but instead experience is fundamental to this.

The RPSGB strongly opposes determining the ability of a pharmacist to undertake the role of the responsible pharmacist based on specific lengths of time on the Register. It is not the length of time a pharmacist has been on the register that is of importance, but the

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pharmacist's competence (demonstrated through their skills, knowledge, and experience) that is relevant. The ability to be absent or be responsible for more than one pharmacy must be based on competence.

The RPSGB believes that the necessary competencies can be achieved in a variety of ways, such as through mentorship or through peer support coupled with professional guidance or distance learning. The RPSGB is not suggesting that the acquisition of these competencies requires constant contact or supervision. By providing a number of different ways in which these competencies can be achieved, the RPSGB does not believe it will be onerous or difficult to achieve the requisite competencies to become a responsible pharmacist who can be absent from the pharmacy or be responsible for more than one pharmacy.

It is proposed that the RPSGB, and in the future the professional leadership body would facilitate the way in which competencies are achieved to enable pharmacists to become the responsible pharmacist to leave the pharmacy or be responsible for more than one pharmacy.

The RPSGB strongly opposes any changes in qualifications or experience that will result in extra years of qualifications that will lead to a tiered level of pharmacists.

Annotation to the register – The RPSGB believes that as a result of requiring extra competencies to be absent or be responsible for more than one pharmacy, there may be a need to annotate the register to show that a pharmacist has the requisite skills to be able to be absent.

The RPSGB believes that as the supervision provisions are considered in the future, it will be important to look at the requisite competencies that will be needed by support staff remaining in the pharmacy. Any decision about annotation of the register needs to consider transferability between sectors.

Should there be a requirement that a pharmacist have a minimum period of experience following registration before taking on the role of the responsible pharmacist? In addition, could the period vary in specified circumstances?

***Q. What is your view on a requirement for a minimum period of experience following registration before becoming a responsible pharmacist?***

***Q. Do you think the period could vary in certain circumstances? If so, what might these circumstances be and what is your reason for putting these forward?***

There should not be a requirement for a minimum period of experience following registration to be a responsible pharmacist.

There should be a competency based assessment in order for the responsible pharmacist to be able to be absent or be responsible for more than one pharmacy. The time needed for different pharmacists to be able to gain the knowledge, skills and behaviours for the responsible pharmacist to be able to be absent or be responsible for more than one pharmacy may vary. It is proposed that the RPSGB assesses competency.

The proposal is that regulations could specify a minimum period of experience in the *relevant* pharmacy sector and this, eg, could be expressed as 'x' period of experience in the last 'y' years.

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*Q. Do you agree with this approach? If so, what are your reasons for doing so?*

*Q. What do you think should be the minimum period and how should this be defined?*

*Q. If you do not agree, what do you propose instead and what are your reasons for this alternative approach?*

Principle 1 of the Code of Ethics states that pharmacists must **'Make the care of their patients their first concern'**. In addition, Principle 5 of the Code of Ethics states that pharmacists and pharmacy technicians should recognise the limits of their competence and to practise only in those areas in which they are competent to do so.

The RPSGB does not support the proposal for regulations to specify a minimum period of experience in the relevant sector. The number of roles that a pharmacist could undertake in their career is large and varied. Currently, pharmacists are able to move from one sector of practice to another. When considering such a move, pharmacists must consider their competency and the requirements of the Code of Ethics. The new status of 'responsible pharmacist' however does require a pharmacist working in a specific sector of practice to be competent in that sector. This would require the pharmacist to address any gaps in their competence. It is proposed that the RPSGB, and in the future the professional leadership body would facilitate the way in which competencies are achieved to enable pharmacists to become the responsible pharmacist and to leave the pharmacy.

The RPSGB believes that any decision to specify a minimum period of relevant experience would be detrimental to both patients and the pharmacy profession. Currently hospital pharmacists often undertake locum activities within the community sector, and their secondary care clinical knowledge is of benefit to patients accessing pharmaceutical services in primary care. The proposal for minimum cross sector experience could potentially restrict pharmacists from sharing knowledge and experience that is of benefit to the public.

In addition, the RPSGB strongly opposes the suggestion that time periods of experience should be specified. The regulations must be more flexible and should not be time or sector based. Instead a more flexible approach should be taken, and pharmacists must exercise their professional judgement to determine which tasks or responsibilities they accept and undertake.

The RPSGB also believes that, in addition to the pharmacist's duty to work within their professional competence, the role of the superintendent pharmacist or pharmacy owner is of importance. The standards for pharmacists and pharmacy technicians in positions of authority states that individuals who are employed or engaged to provide pharmacy services, including temporary staff and locums, must have achieved the requisite standard to undertake their role. Therefore, the superintendent or pharmacy owner has an important role in determining the ability of a pharmacist to undertake the role of the responsible pharmacist.

We believe that, just as a new pharmacist will need to acquire specific competences to fulfil the complete role of a responsible pharmacist, every pharmacist who is registered when the regulations take effect will need to assess their competence to be a responsible pharmacist. This duty will also apply to pharmacists who wish to return to the practising register. Provision

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for regulating this requirement is included in the draft CPD rules which were submitted to the Department of Health in March 2007.

Views are also sought on a proposal for a required minimum period of experience before taking on the role of the responsible pharmacist where a pharmacist has not practised for three years or more.

***Q. Do you agree that a minimum period of experience might differ where a pharmacist is returning to practise following an absence of three years or more? If so, what are your reasons for this? If you do not agree, what do you propose instead?***

Please see response above.

#### **One Pharmacy/One Responsible Pharmacist: Chapter 7**

The consultation paper sets out two examples of possible exceptional circumstances that might support allowing a pharmacist to be responsible for more than one pharmacy at the same time.

***Q. What are your views on the examples given?***

***Q. Are there any other exceptional circumstances that you think should be considered?***

The RPSGB believes that a pharmacist must only be responsible for one pharmacy at any one time. If however, regulations were to be drafted to permit a responsible pharmacist to be responsible for more than one pharmacy this should only be in truly exceptional circumstances, or where the responsible pharmacist is responsible for the pharmacy in which they are based and for one automated machine.

The RPSGB believes that patient safety would be placed at risk if a responsible pharmacist were to be responsible for more than one pharmacy.

The automated machine to which the RPSGB refers is a machine which has been seen by the RPSGB on a previous occasion. The RPSGB would seek to ensure that appropriate standards and systems are in place. Automated machines must be capable of enabling a pharmacist to comply with their legal and professional duties in respect of dispensing and counselling to patients.

The RPSGB does not support the proposal that a temporary pharmacy, for example at a festival, is an appropriate exceptional circumstance to enable a responsible pharmacist to be responsible for more than one pharmacy.

There are a large variety of temporary pharmacies that apply for registration, ranging from pharmacies at events such as Wimbledon and Glastonbury to temporary premises required to be registered when a pharmacy burns down e.g. Portacabins. For the majority of the temporary pharmacies registered it can be strongly argued that the presence of a pharmacist is wholly necessary to ensure adequate patient and public safety.

The RPSGB process for registering a temporary pharmacy currently takes 6-8 weeks. There is no evidence to suggest that this process is onerous and therefore the need for temporary pharmacies to be classed as an exceptional circumstance is unnecessary.

The RPSGB has not developed an exhaustive list of exceptional circumstances; however we agree that these should be clearly defined and that safeguards must be in place to ensure that these exceptions are not abused and do not become an everyday occurrence. Regulations must be tightly worded to prevent abuse of this provision. The RPSGB must be involved in any discussions to extend this exception.

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The RPSGB believes that truly exceptional circumstances should be described in guidance. The truly exceptional circumstances should only be used where there is an over-riding reason of patient safety.

To permit a pharmacist to be responsible for more than one pharmacy at the same time, there will need to be compliance with exceptional circumstances and certain specified conditions. The Government is seeking views on what these conditions might be

***Q. What are your views on each of the proposed conditions set out in chapter 6 and what are your reasons for supporting these views?***

***Q. Do you think the regulations should specify all or only some of the proposed conditions? What are your reasons for putting these forward?***

***Q. Do you think there is a need to specify other conditions? If so, what are these and what are your reasons for putting these forward?***

The RPSGB believes that a pharmacist must only be responsible for one pharmacy at any one time, but, when considering the criteria outlined below, the RPSGB believes there is a distinction to be drawn between an automated machine and any other future exceptional circumstances. The RPSGB believes that the automated machine scenario should be considered separately to other truly exceptional circumstances.

Capacity to exercise their statutory duty – the RPSGB agrees that a responsible pharmacist must be capable of exercising their statutory duties in both registered premises for which they are responsible. However the RPSGB does not agree that the regulations should specify their ‘capacity to exercise their statutory duty’. It is already clearly stipulated in the Health Act 2006 that a responsible pharmacist has a statutory duty to secure the safe and effective running of the pharmacy. This statutory duty applies to all pharmacies that a responsible pharmacist is responsible for. The RPSGB believes that including this as a condition is a duplication of requirements.

Staff employed in the pharmacies – The RPSGB does not agree with the proposal that certain staff (for example a registered pharmacy technician) must be in place in order for a responsible pharmacist to be responsible for more than one pharmacy. If regulations permit a responsible pharmacist to be responsible for more than one pharmacy this must only be in truly exceptional circumstances. In such circumstances (for example during the floods in the South West of England), there must not be constraints that will prevent patients accessing the urgent [pharmaceutical service they require.

The period for which a responsible pharmacist may be responsible for more than one pharmacy – The RPSGB believes that any time period must be proportionate to the risk associated with this. The RPSGB believes that the time period for which a responsible pharmacist can be responsible for more than one pharmacy should be the same as the time limits on absence. The RPSGB believes that the risk to the public in enabling a responsible pharmacist to be responsible for more than one pharmacy is greater than enabling absence from the pharmacy, therefore, as a minimum, the time period must be the same as that provided for in respect of absence. In the case of an automated machine, the RPSGB does not believe a time limit needs to be specified.

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Notification to the RPSGB – the RPSGB agrees with the proposal that the RPSGB should be notified where a responsible pharmacist is responsible for more than one premises. As a responsible pharmacist should only be responsible for more than one pharmacy in truly exceptional circumstances it is important that these circumstances are monitored. Patient safety must not be compromised, and there is increased risk associated with enabling this, therefore appropriate monitoring and inspection must be undertaken. The RPSGB will need to build procedures for monitoring these exceptional circumstances into its current inspection and monitoring systems.

The RPSGB believes it should be the duty of the responsible pharmacist to notify the RPSGB, however the RPSGB does not believe that the RPSGB must be notified prior to a responsible pharmacist being responsible for more than one pharmacy i.e. the notification could be retrospective. The RPSGB believes that guidance should provide information in relation to how the RPSGB is notified and within what time period notification must take place. The RPSGB believes that guidance should also provide information relating to the role of the superintendent pharmacist/pharmacy owner. The RPSGB believes that other relevant authorities such as local Primary Care Organisations may also need to be informed.

Each pharmacy concerned must be owned/managed by the same company – The RPSGB does not support the view that each pharmacy must be owned by the same company. There are a large number of independent pharmacies on the RPSGB register, and we would be concerned if regulations prevented responsible pharmacists working in the independent sector could not make use of this provision. The RPSGB cannot find any reason why the two registered premises must be owned by the same company. A responsible pharmacist would need to exercise their professional judgement based on the individual situation to determine whether they should take responsibility for a second pharmacy.

The number of pharmacies for which a pharmacist may be responsible – This should be one. If however, regulations were to be drafted to permit a responsible pharmacist to be responsible for more than one pharmacy this should only be in truly exceptional circumstances, or where the responsible pharmacist is responsible for the pharmacy in which they are based and for one automated machine. In this circumstance the limit should be two. The RPSGB strongly opposes any intention by the Government to enable a responsible pharmacist to be responsible for more than two pharmacies as a maximum. The RPSGB believes that patient safety will be placed at risk if regulations are drafted to enable a responsible pharmacist to be responsible for more than two pharmacies.

#### **Supervision by the Responsible Pharmacist in a Pharmacy where s/he is not the Responsible Pharmacist: Chapter 8**

The Government is seeking views on possible conditions supporting a responsible pharmacist's ability to supervising activities in another pharmacy where s/he is not the responsible pharmacist. Eg, such conditions (in addition to conditions set for the pharmacist's absence) might include that one or both pharmacies should employ certain staff (eg a registered pharmacy technician) and that both pharmacies have the same owner

***Q. What are your views on conditions supporting supervision by a responsible pharmacist in a pharmacy where s/he is not the responsible pharmacist and the possible conditions set out in chapter 8?***

***Q. Are there other conditions that you feel need to be specified in the regulations?***

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***Q. If you do not agree this approach, what do you propose instead?***

The RPSGB believes that this should not be a routine activity, and should only occur for temporary periods in clearly defined circumstances. An audit trail and clear lines of accountability must exist and there must be a limit on the number of pharmacies a responsible pharmacist can supervise. A pharmacist can only supervise activities in one pharmacy at any one time. Therefore, when a responsible pharmacist supervises the activities undertaken at another pharmacy, only activities that do not require their personal supervision may continue in the pharmacy they are responsible for. We do not believe that there should be a specific time limit on how long this supervision can last but a responsible pharmacist should not be supervising another pharmacy for prolonged periods of time. The two pharmacies do not need to be part of the same company.

### **Introducing the Responsible Pharmacist Regulations: Preparing for Change: Chapter 9**

The Government is seeking views on the time needed to prepare for the introduction of the responsible pharmacist regulations. Firstly, the Government proposes to introduce the regulations that provide a statutory framework supporting the safe and effective running of the pharmacy. That is, the regulations relating to

- The pharmacy procedures
- The pharmacy record
- Absence from the pharmacy
- Requirements relating to recent and relevant experience

***Q. What are your views on this proposal and your reasons for putting these forward?***

***Q. How long do you think that pharmacy owners, pharmacists and others need to prepare for the introduction of these regulations? What are your reasons for this?***

The RPSGB proposes that a 12 month time period is necessary to prepare for the introduction of the responsible pharmacist regulations. The RPSGB believes that whilst the requirements for SOPs and record keeping requirements are currently in place, an adequate lead-in time to prepare for the regulations is still necessary. In particular there are some proposed minimum areas for pharmacy procedures that are not currently required, for example in relation to absence.

It is important that the Government recognises the fundamental change in the way in which pharmacies will be able to operate. Whilst some of these, for example, absence and being responsible for more than one pharmacy, may not fully develop until a later change, there is still a need to ensure the quality framework to support these changes is in place from the outset of the introduction of the responsible pharmacist regulations.

When considering absence, the RPSGB believes the training and experience of the staff remaining in the pharmacy also needs to be considered. These staff will need to be prepared for the new level of responsibility they will take on.

In relation to experience, the time period required to prepare for these changes will ultimately depend on what changes are agreed. The RPSGB does not consider it necessary to set a minimum period following registration for a responsible pharmacist [to be able to secure the](#)

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safe and effective running of the pharmacy. However, any requirements for a minimum period post registration to become a responsible pharmacist would need to take account of workforce and education issues, for example these should not be implemented until the changes to supervision have been planned.

In considering the implementation of these regulations, consideration must be given to any possible changes that may need to occur to indemnity insurance arrangements.

Finally, the RPSGB would give support to the profession and the Government to implement these arrangements in the public interest.

There is a view more time is needed to prepare for introduction of other responsible pharmacist regulations - in particular, those linked to the pharmacist supervision regulations. In chapter 9, the Government is seeking views on a phased approach to introducing these regulations.

***Q. Do you think it would be helpful to take a phased approach to introducing further responsible pharmacist regulations? If so, what are your reasons for your view?***

***Q. What are your views on the option outlined in chapter 9 and your reasons for putting forward these views?***

***Q. If you not agree with the approach outlined, what do you propose instead?***

The RPSGB supports the proposal that a phased approach to the provisions Health Act 2006 should be taken.

It is important that the quality framework is put in place prior to making changes to the current supervision requirements. The RPSGB believes this quality framework will support the introduction of the supervision requirements.

Whilst the RPSGB supports the proposed phased approach, there are some areas such as absence and those topics covered in Chapter 8 that cannot be fully considered without considering the proposed changes to supervision. From a hospital perspective in particular, the potential benefits of absence are unlikely to be realised before the supervision changes are made.

The Government welcomes views on the need for guidance to support introduction of the responsible pharmacist regulations

***Q. Do you think there is a need for guidance? If so, what matters should this cover?***

***Q. Who should provide this guidance? For example, is there scope for a joint approach to developing guidance by the Government and the regulatory bodies?***

The RPSGB fully supports the proposal that further guidance to support the introduction of the responsible pharmacist regulations is needed. These are complex and fundamental changes that must be managed and supported so that pharmacists feel able to make use of the provisions in the Regulations.

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The RPSGB is the professional and regulatory body for pharmacists in England, Scotland and Wales. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy. In addition, the RPSGB completed a fundamental review of its Code of Ethics in 2007, and launched the new Code of Ethics on 1<sup>st</sup> August 2007. The new Code of Ethics is based on set of over-arching principles that informs the conduct, performance and practice of pharmacists and pharmacy technicians. In moving to a principle based code, the RPSGB recognised that there will be specific professional requirements and areas of practice that will require more detailed guidance than will be provided in the code. The RPSGB has produced seven supporting standards and guidance documents to the Code of Ethics. Each of these sets out those standards that are mandatory and those that are good practice. The RPSGB envisages that any further professional guidance, whether mandatory or good practice should be provided by the RPSGB in the form of standards and guidance documents. The RPSGB welcomes the opportunity to work closely with the Department of Health and other pharmacy bodies in drafting the content of any such documents.