

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

RESPONSE TO MAKING THE BEST USE OF THE PHARMACY WORKFORCE: A CONSULTATION PAPER

1. INTRODUCTION

The Royal Pharmaceutical Society of Great Britain welcomes the opportunity to respond to this important consultation and looks forward to responding to the equivalent documents in Scotland and Wales. The RPSGB has a long-standing policy position that recognises the need for changes to pharmacy working practices in order to allow pharmacists to make best use of their skills and expertise, maximise the pharmacy profession's contribution to public health and ensure that patients and the public have comprehensive access to medicines and professional advice. The RPSGB believes that the current legislative requirements restrict the development of the role and working practices of pharmacists and prevent community pharmacists fulfilling the breadth of service provision framed by the new pharmacy NHS services contract.

It is paramount that public safety is the prime consideration in any change in professional practice. Reform must enhance the culture of personal professional accountability not detract from it. The RPSGB is currently working to improve and modernise its professional regulatory framework, which together with the exercise of appropriate clinical and corporate governance would support the safe implementation and appropriate oversight of any new arrangements.

Personal control and supervision cannot be addressed alone, there needs to be a consolidated analysis of other key provisions of the Medicines Act 1968 such as restricted titles, corporate jurisdiction and the role of superintendent pharmacists. Any new legislative framework will need to be underpinned by guidance to the profession that will afford flexibility and proportionality while prioritising patient safety and consistent standards of care. It will be necessary to ensure that such professional guidance is enforceable and does not fall foul of other legislation such as the Competition Act 1998 and Enterprise Act 2002. The RPSGB believes that this can be best achieved either by a code of practice that is supported by a statutory framework and professional guidance; or by giving the RPSGB Code of Ethics and Standards the same legal status as a code of practice. The RPSGB would wish to be involved in the drafting of legislative changes and development of a code of practice.

The consultation document's comparison of the ways of working in other European countries does not detail the level of training that pharmacy support staff in these countries have undertaken before dispensing prescriptions and selling over the counter medicines (OTC) unsupervised, for example some staff are trained to degree level. In addition, no reference is made to the IT framework or supply chain systems such as barcoding or radio frequency identification that have provided additional controls and influenced the way in which pharmacists in other countries discharge their responsibilities. Consideration of these factors would be essential if a

comparable assessment of the impact of document's proposals on patient safety and pharmacy practice in this country is to be made.

Pharmacy skill mix has been successfully developed in secondary care and much can be learned from this experience. The enhanced role of pharmacy technicians and other pharmacy staff has been important in supporting hospital pharmacists deliver a wider range of pharmacy services. However, the secondary care model is not automatically transferable to primary care and due consideration must be given to the differing skills, expertise and work pressures of primary and secondary care support staff and to the level of support available from the wider healthcare team.

It is essential that reform does not inhibit access to pharmaceutical services. The public expects pharmacists to be readily available to provide advice and support and successful initiatives such as the 'Ask your pharmacist' campaign and minor ailment schemes have relied upon the pharmacist's presence in the pharmacy. Whatever new arrangements are adopted, people going into a pharmacy need to be clear whether the pharmacist is available and whether the person they are consulting is a pharmacist, a registered technician or other trained individual. The RPSGB believes that any changes must be supported by a major public awareness campaign to inform patients of the new arrangements and provide assurance that pharmacies will continue to provide high standards of professional care.

1.1 Summary of General Principles

The RPSGB propose that the underlying principles that must support the sale and supply of medicines and provision of professional services from registered retail pharmacies are professional accountability, accessibility and safety. To ensure patient safety and the adequate provision of professional services, each pharmacy must have a pharmacist with personal, professional accountability for all processes in the pharmacy. The RPSGB does not believe that the professionally accountable pharmacist should be acting in a similar capacity for any other registered pharmacy.

Subject to appropriate safeguards and protocols outlined in section 2.3, the professionally accountable pharmacist should be able to be absent from the pharmacy for short periods of time, for example to have a rest break or to undertake professional activities. However, steps must be taken to ensure that patient access to pharmaceutical services is not unduly compromised. Pharmacies should not operate for prolonged periods without the presence of a pharmacist and the professionally accountable pharmacist must be contactable and must be able to justify any absence from the pharmacy.

Pharmacists should, in accordance with defined criteria, be able to delegate the provision and supervision of certain services to appropriately trained members of staff. Robust protocols must clearly define who tasks could be delegated to and stipulate when a pharmacist's personal intervention is required. There are a number of areas of practice that could not be delegated to other pharmacy staff including;

- Aspects of dispensing process (e.g. professional assessment of prescriptions, supply of controlled drugs)
- Sale of certain pharmacy medicines e.g. newly deregulated classes of medicines, medicines of potential abuse.
- Oversight of public health interventions

- Elements of enhanced and advanced level services in the community pharmacy NHS services contract.
- Advice to other healthcare professionals

These are discussed in more detail in section 3.2.2.

Each pharmacy would need to have a defined scheme of delegation and pharmacy staff undertaking delegated activities would need to meet the requirements of a specified competency framework. Regular risk assessments would need to be carried out and an appropriate audit trail developed to monitor activities undertaken in the absence of a pharmacist.

Corporate and clinical governance, together with professional regulation will each have a role to play in ensuring the safe implementation and appropriate oversight of any of the new arrangements. A balance between legislative requirements and professional guidance will be crucial to the success of the changes. The RPSGB has indicated a number of requirements in this response that it believes need to be defined in a code of practice that is supported by a statutory framework. The RPSGB would also support these requirements forming part of its own Code of Ethics and Standards, provided the Code gains the same legal status as a code of practice. Both of these options would provide the statutory support necessary to ensure consistency of arrangements and appropriate oversight, while providing the necessary flexibility for change to allow the continued best use of the pharmacy workforce in the future.

2 PERSONAL CONTROL

2.1 Personal Control Requirements

- **Do you think there is a continuing need for the requirement that a pharmacist be in personal control of the business of the retail sale and supply of medicines, including GSL medicines?**
- **Is there a case for change in relation to GSL medicines?**
- **Is there a need for a pharmacist to be clearly responsible for each pharmacy at all times when it is open for business? If so, do you think this should be set out in law? Or might it be sufficient to set this out in the RPSGB's Code of Ethics?**

The RPSGB believe that patient safety dictates the need for a pharmacist to have overall responsibility for the sale and supply of medicines and provision of other professional services from a particular pharmacy. However, the current arrangements may restrict the development of the role and working practices of pharmacists and may prevent community pharmacists fulfilling the breadth of service provision framed in the community pharmacy contract for England and Wales. Additionally, the continued use of the term 'personal control' is misleading and unhelpful due to the current interpretation that the pharmacist needs to be physically present in the pharmacy. It is proposed that 'personal professional accountability' and 'responsibility' may be more suitable terms.

The RPSGB proposes that legislation should require that each registered retail pharmacy must have an accountable pharmacist. The accountable pharmacist will be responsible for the sale or supply medicines and the provision of other professional pharmacy services such as blood pressure/ cholesterol testing, medication reviews, advice on long-term conditions etc.

A pharmacist should only be professionally accountable for one pharmacy at any given time and professional accountability should be maintained while a registered pharmacy is open for business. However, subject to appropriate safeguards such as standard operating procedures and the presence of an adequate number of appropriately trained staff, professional accountability should not require a pharmacist to be physically present in a pharmacy at all times.

If there is no professionally accountable pharmacist the sale or supply of medicines and the provision of professional services from that pharmacy should be precluded and the safest option would be for the pharmacy to close.

In the public interest, the requirement for each registered retail pharmacy to have a professionally accountable pharmacist must be laid down in primary legislation. The term 'professionally accountable' will need to be clearly defined.

2.1.1 GSL Medicines

The RPSGB supports the view that patients and the public expect high standards of care and professional advice when purchasing any medicines from a registered pharmacy. There is concern that the public perceive GSL medicines to be inherently 'safe' and as more medicines become available for general sale, the role of the pharmacist in overseeing the safe effective use of GSL medicines should be deemed as important as the appropriate professional oversight of the sale and supply of pharmacy and prescription only medicines. However, the current anomaly of an appropriately trained member of pharmacy staff being unable to sell GSL medicines in accordance with protocols during the temporary absence of a pharmacist, when such medicines are available for sale in other retail premises, is recognised.

A pharmacist's ability to be professionally accountable for a registered pharmacy premises without being physically present in the pharmacy at all times, would remove the need to amend the Medicines Act 1968 requirements for the sale of GSL medicines from registered pharmacy premises. Subject to appropriate protocols and the presence of appropriately trained staff, GSL medicines could be sold when the pharmacist was temporarily absent from the pharmacy, for example, to have a rest break or undertake professional related activities. This would ensure that patients are able to access the GSL medicines they require while continuing be assured that there is appropriate professional oversight.

2.1.2 Restricted Titles

There are implications for the Medicines Act restrictions on the use of certain titles, descriptions and emblems. The current restrictions are linked with the definition of personal control. To ensure that the public is not misled, the RPSGB believes legislation should require that titles such as 'Pharmacy' and 'Chemist' only be used in connection with the retail sale or supply of goods if the business is a lawfully conducted retail pharmacy i.e. a registered pharmacy for which there is an professionally accountable pharmacist; and in respect of the title 'pharmacy', a pharmacy department in a hospital or health centre.

2.2 Levels of Accountability

- **Is there a need for greater clarity on the role of the pharmacist responsible for the conduct of business in each pharmacy? What should these responsibilities include? In your view, how might these responsibilities be more clearly defined?**

When assuming professional accountability for a registered retail pharmacy, a pharmacist has a professional duty to verify that safe systems are operating within the pharmacy and take account of the resources, support systems and workflow within that particular pharmacy.

The professionally accountable pharmacist must establish sufficient information to be satisfied that

- The requisite facilities, equipment and materials are available to enable the safe provision of professional services
- Systems and procedures allow them to comply with the key responsibilities of a pharmacist and observe all legal and professional requirements.
- Tasks are delegated to suitably trained, competent staff who are working within clearly defined SOPs.
- Support staff are aware of their personal responsibilities and limits of competency.
- There are clear protocols in place defining the circumstances for which a pharmacist needs to have personal involvement or direct oversight.
- Incident reporting and complaints procedures are in place.

Pharmacy owners and superintendent pharmacists should have responsibility to

- Ensure safe systems of working and SOPs are in place
- Ensure systems are in place so that staff are suitably trained and competent to undertake tasks in accordance with SOPs
- Ensure the continued presence of an adequate number of appropriately trained staff.
- Ensure staff are aware of personal responsibilities and limits of competence and authority.
- Ensure staffing arrangements can deliver a safe service.
- Define delegation arrangements.
- Define both the circumstances and provide the means by which the professionally accountable pharmacist is to be contacted (and what action is to be taken if they cannot be contacted)
- Ensure clinical governance and audit arrangements are in place which provide appropriate risk assessment and adequate records etc.

Professional indemnity arrangements will need to cover a pharmacist's absence from the pharmacy and any delegation arrangements that are in place.

These responsibilities should be defined in a Code of Practice that is supported by a statutory framework (i.e. similar to the Code of Practice developed under the Disability Discrimination Act 1995). This would promote patient safety and reflect the statutory duty of quality assurance that currently exists in NHS trusts.

(NB- The RPSGB has indicated a number of requirements that it believes need to be defined in a code of practice that is supported by a statutory framework. The RPSGB

would also support these requirements forming part of its own Code of Ethics and Standards, provided the Code gains the same legal status as a code of practice)

2.3 Absence from the pharmacy

- **What are your views on allowing the pharmacist to be absent from the pharmacy whilst continuing to meet his/her responsibilities? Should the pharmacist's absence be limited – for example to undertake professional or pharmacy business away from pharmacy premises?**
- **If absent from the pharmacy, is there a need to limit the period of time during which the pharmacist responsible for the pharmacy is away? If so, what do you consider is a reasonable period?**
- **What are your views on requiring the pharmacist to be present at certain periods during pharmacy opening hours - for example, when the pharmacy opens for business?**
- **In your view, can decisions on the time and circumstances in which the pharmacist responsible for the pharmacy might be absent be left to his/her individual professional judgement, supported by standing operating procedures and clinical governance arrangements?**

To ensure the provision of safe, accurate and effective professional services, pharmacists must be able to have adequate rest breaks. A pharmacist taking a break should remain professionally accountable for a designated registered pharmacy.

The RPSGB suggest that professional accountability could also be maintained when a pharmacist is absent from the pharmacy for a short period of time to undertake professionally related activities (e.g. patient medication review, meeting with other health professionals). The sale or supply of pharmacy and prescription only medicines should still be subject to supervisory requirements and there will be times when the professionally accountable pharmacist will have an absolute requirement to be present (see 3.2.2 *Areas of practice that should not be delegated to other pharmacy staff*). Boundaries need to be defined in a Code of Practice and patients need to be clearly informed that the pharmacist is absent from the pharmacy.

The onus should be on both the professionally accountable pharmacist and employer to consider the possible consequences of unavailability, however temporary, and be satisfied that the necessary steps have been taken to minimise potential risks to patients and the public. For example there should be the continued presence of a sufficient number of appropriately trained staff, relevant SOPs and an ability to contact the pharmacist if urgently required etc. There may be circumstances where the adequate provision of professional services will require the physical presence of an additional pharmacist(s).

The RPSGB believes that in order to meet public expectations for ready access to a full range of pharmaceutical services and to ensure appropriate oversight of services, the professionally accountable pharmacist should only be absent from the pharmacy for a limited time. The professionally accountable pharmacist should still be contactable and be able to return to the pharmacy without undue delay. If a pharmacist is to be absent from the pharmacy for a prolonged period of time another pharmacist should be required to assume professional accountability. An audit trail of

the pharmacist's absence and reasons for absence needs to be maintained. RPSGB inspectors should be able to compel disclosure of such records.

These proposals represent a fundamental change in pharmacy practice and a widespread implementation with no assessment of practical experiences would be extremely risky. The RPSGB is also concerned about how these changes will be implemented and how we can ensure that patient care is not being compromised. To allow appropriate evaluation of the impact of these changes on pharmacy practice, patient safety and patient care and determine whether appropriate regulatory safeguards are in place, an early review of the new working practices should be undertaken by the Department of Health.

2.3.1 Limits on absence

Without adequate safeguards and procedures, patient care and access to pharmaceutical services could potentially be compromised irrespective of the length of time a pharmacist is absent from 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 professionally accountable pharmacist.

Time limits on absence will be very difficult to regulate and enforce. A more effective way of ensuring that the professionally accountable pharmacist is only absent from the pharmacy for a limited time may be to link the absence with adherence to professional requirements that necessitate

- patients must be able to access a full range of pharmaceutical services without undue delay
- there must be a continued presence of adequate numbers of appropriately trained staff
- the professionally accountable pharmacist must only be absent from the pharmacy when having a break or undertaking professional services
- the professionally accountable pharmacist must be satisfied adequate systems are in place to deliver a safe service to the public and that all legal and professional requirements will be adhered to
- the professionally accountable pharmacist must be able to justify any absence from the pharmacy
- the professionally accountable pharmacist must be contactable and able to return to the pharmacy without undue delay, should they be required.

These requirements would need to be defined in a Code of Practice that is supported by a statutory framework. Terms such as 'undue delay' would need to be clearly defined.

As stated above an audit trail of the pharmacist's absence and reasons for absence should be maintained and be available for inspection by RPSGB inspectors.

Staff must be clear and able to inform patients

- Who the professionally accountable pharmacist is at any time
- Whether the professionally accountable pharmacist is immediately available
- Who is managerially responsible for pharmacy staff
- How the pharmacist can be contacted
- What services are not available when the pharmacist is absent from the pharmacy

Patients and the public must be able to easily identify whether they are receiving advice from the pharmacist or other appropriately trained members of staff.

Professional accountability should be maintained while the pharmacy is open for business and there will be a variety of times when the pharmacist will have an absolute requirement to be present, such as for the supply of controlled drugs. Consideration will need to be given to the implications of absence for a pharmacy's NHS services contract. Would a pharmacist's absence from the pharmacy during contracted hours to undertake non NHS activities constitute a breach of the NHS contract, and if so, how would this be effectively monitored and enforced by the primary care organisation?

There may be times when a pharmacist could assume professional accountability before physically arriving at the pharmacy, for example, if the pharmacist is familiar with the pharmacy and has knowledge of the systems in place. However, this is an area of potential risk and a pharmacist who is not familiar with the pharmacy (e.g. a locum pharmacist) would need to be physically present when the pharmacy opens for business in order to assume professional accountability for that pharmacy. There would need to be a notification and recording process to demonstrate that the pharmacist had assumed professional accountability.

There are clear dangers to the public and patients if the time and circumstances that the professionally accountable pharmacist may be absent were to be left to individual judgement. Any restrictions would need to be defined in a Code of Practice that is supported by a statutory framework. It may be that a progressive approach can be taken, with greater restrictions and monitoring of absence during the initial stages until the impact of the changes on patient safety and pharmacy practice can be fully assessed.

2.4 Professional accountability for more than one pharmacy

- **What are your views on allowing an individual pharmacist to be responsible for more than one pharmacy at any one time? If pharmacists are able to be responsible for more than one pharmacy, do you think there should be a limit on the number of pharmacies?**
- **If a pharmacist is able to exercise responsibility for more than one pharmacy, do you have a view on how s/he might display his/her registration certificate in each pharmacy?**

Accountability needs to be considered on a number of levels. Pharmacy owners and superintendent pharmacists will have an overarching accountability for all their pharmacies. Corporate owners may then decide to delegate responsibility for overseeing the day to day running of a specific number of pharmacies to, for example, an area manager who may not always be a pharmacist.

However legislation must require each individual pharmacy to have a specific pharmacist who is solely accountable for that pharmacy while it is trading. Professional accountability for more than one pharmacy at this level would risk endangering the public and would cause a high level of professional concern.

While the RPSGB would not support a pharmacist being able to exercise responsibility for more than one pharmacy, there will still be a need to revise Sections 70 and 71 of the Medicines Act 1968 (display of registration certificates) to take account of circumstances where a pharmacist could assume professional accountability remotely i.e. if pharmacist can satisfy themselves of the systems and procedures in place without arriving at the pharmacy. The RPSGB proposes that there be a statutory duty for the name and registration number of the professionally accountable pharmacist, and details of the person assuming managerial responsibility (if different) to be conspicuously displayed in the pharmacy.

2.5 Records of the Professionally Accountable Pharmacist

- **Is there a need for other requirements to ensure that the responsible pharmacist is clearly identifiable? What are your views on the proposed requirement that an accurate, up to date, record of the responsible pharmacist at a particular time should also be available in each pharmacy?**

The RPSGB supports this requirement. The professionally accountable pharmacist needs to be clearly identifiable and an accurate, up to date record of the professionally accountable pharmacist should be available in each pharmacy. Currently the RPSGB's Code of Ethics and Standards requires there to be a retrievable record of the pharmacist taking responsibility for the provision of each pharmacy service, but to ensure a verifiable audit trail this should be a requirement of a Code of Practice that has statutory support. RPSGB inspectors should be able to require disclosure of all relevant records.

2.6 Superintendent Pharmacists and Corporate Governance

- **Is there a need to strengthen the accountability of the superintendent pharmacist? If so, in what way?**

Pharmacy operates in a highly commercial environment where professional standards and judgement may sometimes compete with commercial imperatives. With a large number of registered pharmacies owned by bodies corporate, corporate governance will have an important role to play in any new arrangements.

The Medicines Act requires a body corporate to appoint a superintendent pharmacist to be responsible for the management of the business of preparing and dispensing medicines (except GSLs). The RPSGB would propose a strengthening of the collective accountability of the company's Board (including any subsidiary corporate structure to who the superintendent is managerially responsible). This should not be restricted to merely strengthening the accountability of the superintendent pharmacist, consideration must also be given to the need for the 'guiding minds' of bodies corporate to have responsibility for ensuring professional services are not compromised, or patient safety put at risk by their actions. Both the superintendent pharmacist and the members of the board of bodies corporate should have a statutory duty of care to patients for the pharmaceutical services provided by the business.

The RPSGB notes that in corporate dentistry and optometry there is no requirement for a superintendent, instead the majority of directors must be members of the professional body. While these professions do not operate in the same retail trading

environment as pharmacy, the RPSGB proposes that that a detailed review of bodies corporate acting within healthcare may be of value in determining an effective system that ensures appropriate levels of professional accountability, while allowing pharmacies to operate commercially. Further liaison with relevant stakeholders and interested parties would be of vital importance to this complex issue.

Patient safety must be pre-eminent, and a superintendent pharmacist's role as arbiter of good professional practice must not be capable of being overruled by non-pharmacist members of the Board for commercial reasons. Appropriate sanctions must be available if bodies corporate fail to take appropriate steps to ensure patient safety i.e. power to levy fines or prevent non pharmacist directors from operating a registered pharmacy business. It is important that any legislative requirements are applicable to both small bodies corporate and multinational corporations and that they encapsulate the various ways in which companies can structure themselves (i.e. Group Boards and subsidiary companies).

It is the superintendent pharmacist's duty to ensure that current defined statutory and professional requirements are delivered. To strengthen this accountability there could be a requirement for superintendent pharmacists to submit declarations of compliance in a range of professional domains to the RPSGB. In addition, the sanctions guidance and referral criteria for disciplinary matters could explicitly identify factors to be taken into account in assessing superintendent pharmacists exercise of their responsibilities and their wider impact on practice.

3. Supervision

3.1 Pharmacist Supervision

- **Do you think action is needed in relation to the remote supervision of the dispensing and supply of medicines - given the development of technologies that might better support this and the possibility that the courts might decide that this is acceptable under the terms of the Medicines Act 1968?**
- **What are your views on the proposal that a pharmacist may not need to be present in the pharmacy at all times for the supply of Prescription only Medicines (POM) or Pharmacy (P) medicines?**
- **Is there a need to clarify the circumstances in which a pharmacist can supervise the supply of POM or P medicines without being present in the pharmacy?**
- **What are your views on the options put forward for possible changes in the supervision requirement? Are there other options that you feel should also be considered? If so, what might these include?**

The proposed changes to the supervision requirement represent a fundamental change in pharmacy practice and the RPSGB is concerned how these changes can be effectively monitored and regulated. Steps must be taken to ensure appropriate oversight and establish the impact on patient care. The RPSGB has outlined below the requirements and safeguards that should be in place if pharmacy and prescription only medicines are to be supplied when the pharmacist is not physically present in the pharmacy. However, consideration should be given to the role that

accreditation and monitoring schemes have in ensuring that such pharmacies have appropriate systems in place to protect the public. It is essential that adequate steps are taken to prevent situations arising where the ability for a pharmacist to be absent from the pharmacy is abused. The RPSGB would be happy to discuss this proposal with the Department of Health and other pharmacy organisations.

Consideration needs to be given to the definition of 'supervision' of the dispensing and supply of medicines. There are currently many instances where a 'supervising' pharmacist may be aware that a sale or supply is taking place (i.e. bells and buzzer approach) but does not necessarily know what is being sold or have any meaningful involvement in the sale.

There may be little difference in circumstances between a pharmacist who is involved in a lengthy consultation with a patient in a private area (or room) of the pharmacy and a pharmacist who is temporarily absent from the pharmacy, but contactable. In each case the pharmacist cannot be aware of the sales taking place, or of the conversations between staff and patients.

The RPSGB would question the consultation documents continued support for the interpretation of supervision as 'the pharmacist being aware of the transaction and be in a position to intervene'. This interpretation places emphasis on the pharmacist having knowledge of every transaction, which is neither a viable nor realistic requirement in modern practice. It is the RPSGB's opinion that an effective system of supervision requires identification of circumstances where a pharmacist's intervention is required and provides for that intervention (either in person or remotely). Provided that such systems are in place the sale or supply of pharmacy and prescription only medicines should be able to proceed.

3.1.1 Prescribed Medicines

The RPSGB Code of Ethics and Standards requires that every prescription must be professionally assessed by a pharmacist to determine its suitability for the patient. A pharmacist must carry out this professional assessment on each occasion that a prescribed medicine is supplied. However, provided safe systems are in place and further professional intervention by the pharmacist is not deemed necessary, the prescribed item could then be supplied when the professionally accountable pharmacist is absent from the pharmacy. The pharmacist would still need to be contactable and provision would need to be made for subsequent counselling by the pharmacist if required.

Provided the pharmacist had access to PMR details and other necessary information sources the professional assessment could be carried out remotely. Standard operating procedures would need to detail the appropriately trained staff who have been delegated the authority to assemble prescriptions or issue dispensed medicines when the pharmacist is unavailable or absent from the pharmacy, as well as specify the circumstances in which supply would be precluded.

The RPSGB propose that prescriptions which have previously been dispensed and checked and are awaiting collection could be supplied by any specifically designated trained members of staff. However, when the pharmacist is not present the actual assembly and checking of prescriptions should be overseen by a suitably competent registered pharmacy technician. Two trained members of staff should be involved in the dispensing process and a retrievable record of such transactions should be maintained to ensure an adequate audit trail

In order to comply with the requirements of the Misuse of Drugs Regulations 2001, the pharmacist would need to be present in the pharmacy when controlled drugs are supplied.

3.1.2 Pharmacy Medicines

With regard to the sale of pharmacy medicines, the Code of Ethics currently requires systems to be in place to ensure the pharmacist's personal intervention where necessary. For sales of pharmacy medicines to take place when the pharmacist is not present, standard operating procedures should detail those circumstances that require the pharmacist to be contacted before the sale proceeds; and the staff who have delegated authority to sell pharmacy medicines when the pharmacist is absent or unavailable. There are certain supplies of pharmacy medicines for which the RPSGB propose the pharmacist must have oversight (*see 3.2.2 Areas of Practice that should not be delegated to other pharmacy staff*). The RPSGB would not wish any pharmacy only medicines to be sold when a pharmacist was not supervising (either in person or remotely) unless a suitably competent registered member of staff (i.e. a pharmacy technician) was present in the pharmacy.

3.1.3 Remote Supervision

While the RPSGB continues to strongly advocate the benefits of face-to-face consultation, it is recognised that a broader view of how patients can access information and pharmacy services is required. For some patients telephone access or on-line advice may be a practical alternative to a face-to-face encounter. Developing technologies, combined with the introduction of electronic prescriptions and electronic care records, may afford pharmacists the opportunity to supervise the dispensing and supply of medicines remotely. Additionally, automated dispensing systems not only have the potential to improve accuracy and efficiency, but will

cause the focus of professional activity to move away from the physical act of dispensing prescriptions allowing pharmacists to spend more time advising patients.

However, remote supervision must be subject to appropriate patient safeguards. The RPSGB does have reservations about the current ability of pharmacists to adequately supervise the sale and supply of POM and P medicines remotely i.e. video link and advises that caution be exercised until systems are proven to be robust and effective.

Appropriate technology would need to be in place and audit trail requirements would need to be fulfilled. The equipment and facilities must ensure adequate communication between pharmacy staff and the pharmacist and must be capable of providing rapid contact with the pharmacist, while ensuring confidentiality is maintained.

There will be circumstances where a pharmacist will not be able to supervise a sale or supply remotely e.g. supply of a controlled drug.

Pharmacists supervising remotely will need to ensure they have access to all the relevant information they need about a patient/customer (e.g. Patient Medication Records and prescription details), answers to specific questions such as WWHAM and access to technical information e.g. British National Formulary that they would have if they were present in the pharmacy. SOPs would need to cover;

- How the pharmacist can be contacted.
- How clarity of communication between pharmacy staff and the pharmacist is ensured.
- How patients/customers can obtain advice when a pharmacist is supervising remotely.
- What to do in an emergency.

Patients will need to be aware when the pharmacist is not available for face to face consultation and understand that their medication records may be accessed remotely.

Remote supervision will not remove the need for a professionally accountable pharmacist who adheres to the requirements defined in earlier questions, but would allow for the supply of Pharmacy and Prescription Only Medicines when the accountable pharmacist is unavailable (i.e. involved in a lengthy consultation) or absent from the pharmacy.

3.2 Supervision by pharmacy staff other than pharmacists

- **Do you think there is scope for suitably qualified pharmacy staff, other than pharmacists, to supervise the dispensing, sale and supply of medicines provided they work under clinical governance arrangements and standard operating procedures acceptable to the pharmacist responsible for the pharmacy at that time? If so, what do think are the most important issues to address to support working in this way?**

3.2.1 Registered pharmacy technicians

The voluntary register for pharmacy technicians is now open; from 2007, all pharmacy technicians will be required to register with the RPSGB. Registered

pharmacy technicians will be professionally accountable for their actions, are expected to adhere to accepted standards of professional and personal conduct and undertake continuing professional development relevant to their field of practice. Therefore, subject to appropriate safeguards, the RPSGB believes that there is scope for suitably competent registered pharmacy technicians to be delegated to supervise the sale of certain pharmacy medicines, the assembly of prescriptions and provision of defined professional services. The RPSGB would wish to discuss the definition of “suitably competent” with the Department of Health and other pharmacy organisations.

Legislation should make provision for pharmacists to delegate supervisory duties, but should not confer registered pharmacy technicians, or other pharmacy staff, the authority to supervise the dispensing, sale or supply of medicines unless they have been authorised to do so by the professionally accountable pharmacist. The pharmacy would still be required to have a professionally accountable pharmacist and the registered pharmacy technician could not assume responsibility for activities or transactions that are not deemed to be suitable for delegation (see - section 3.2.2 *Areas of practice that should not be delegated to other pharmacy staff*).

Currently, many pharmacy technicians have the necessary competencies to supervise the assembly and checking of prescriptions. However, supervision of the sale of pharmacy medicines will require additional competency based training to be undertaken. Competency must not only mean that the registered technician has the knowledge or skills to undertake the delegated tasks, but that they are able to recognise when input or guidance from another health professional is required.

Supervision by someone other than a pharmacist should require specific criteria to be met. To ensure consistency of patient care the criteria should be defined in a Code of Practice underpinned by a statutory framework. The setting of standards for activities that can be supervised by a suitably competent registered pharmacy technician should not be a matter solely left to the professional judgement of the pharmacist.

Code of practice requirements should include-;

- The professionally accountable pharmacist must be contactable and able to return to the pharmacy without undue delay, should they be required (this would enable provision of urgent services that require the pharmacist's physical presence i.e. supply of CDs in palliative care)
- The professionally accountable pharmacist must be satisfied of the SOPs, clinical governance arrangements and competence of staff before delegating the supervisory role. Procedures should clearly state the extent to which suitably competent registered pharmacy technicians can carry out activities without the pharmacist's intervention.
- Transactions or other professional services that require the intervention of the pharmacist must be defined.
- Patients must be clearly informed of what services will be restricted and offered alternative sources for that service
- Specific records must be kept and there must be additional audit of activities that are not supervised by the pharmacist

3.2.2 Areas of practice that should not be delegated to other pharmacy staff

There are a number of areas of practice that should not be delegated to other pharmacy staff, including-:

Dispensing

- The professional assessment of a prescription to determine its suitability for the patient. Suitably competent registered pharmacy technicians could supervise the assembly and accuracy check of prescriptions, but dispensed items must not be supplied unless a pharmacist has undertaken a clinical check.
- Supply of Controlled Drugs
- Aspects of repeat dispensing (the new community pharmacy contract for England and Wales requires pharmacists to '*check whether the patient's medication regimen has been altered since the prescriber authorised the repeatable medication and whether there have been any other changes in the patient's health since that time, which may indicate that the treatment needs to be reviewed by the prescriber*')
- Advising the patient about their medicines (the pharmacist will need to identify those patients they wish to personally counsel)
- Advising other health professionals on specific professional issues.

Sale of Pharmacy Medicines

The RPSGB Code of Ethics and Standards requires pharmacists to be personally involved in the sale of pharmacy medicines whenever this is necessary to provide an acceptable standard of pharmaceutical care. Protocols should be in place to clearly identify when the pharmacist must be involved in the sale of a pharmacy medicine.

Pharmacists would need to have appropriate involvement in medicine sales for patients who are taking other prescribed medicines or over the counter remedies to ensure a professional assessment of potential interactions is made and circumstances that require referral to a medical practitioner are identified. The RPSGB propose that a pharmacist must also have oversight of the supply of certain pharmacy medicines. These include, for example, newly deregulated classes of medicines, the initial supply of medicines intended for long-term use, or medicines of potential abuse. If the pharmacist were not supervising, either in person or remotely, the supply must not proceed. Currently such a restriction, even in the name of public safety, potentially conflicts with competition legislation. Therefore any restrictions of this nature would need to have statutory support rather than solely being set out in professional guidance. The RPSGB would wish to be involved in discussions about medicines that require the pharmacist's intervention.

Public Health Interventions

Pharmacists are expected to provide public health interventions as part of the new community pharmacy contract in England and Wales. While other pharmacy staff may be trained to help provide these services, the RPSGB would expect the pharmacist to be available to lead and oversee public health interventions.

Advanced and Enhanced level services

It is apparent that elements of advanced and enhanced level services under the new community pharmacy contract for England and Wales will require the

professional input of the pharmacist. Any contractual services expected to be undertaken by a pharmacist should not be delegated.

3.2.3 Other pharmacy staff

It would not be appropriate, or in the patient's best interests, for any pharmacy staff other than suitably competent registered pharmacy technicians to supervise the supply of pharmacy and prescription only medicines in the absence of the professionally accountable pharmacist. Other pharmacy staff are not bound by a professional code, or continuing professional development requirements relating to the provision of professional pharmacy services and their ability to practise cannot be restricted by the RPSGB. The term "NHS accredited healthcare assistants" is not defined in the consultation, but the underlying principle should be that any member of pharmacy staff taking on a supervision role must be registered and of equivalent competency to a suitably competent pharmacy technician.

Nurses may have some of the necessary skills and expertise to supervise certain activities, but are unlikely to fulfil all the competency requirements of a registered pharmacy technician. The RPSGB would be concerned if different standards were applied to nurses than to suitably competent registered pharmacy technicians. We would expect that anyone undertaking supervision of the supply of pharmacy and prescription only medicines in the absence of the accountable pharmacist to demonstrate the same competencies as a suitably competent registered pharmacy technician and to be registered with a healthcare professional regulatory body. We would also expect that any staff would abide by the same rules as a suitably competent registered pharmacy technician.

In the event that other pharmacy staff are to be regulated, the RPSGB would give consideration to broader regulatory responsibilities. However, this would not confer other staff the right to undertake supervisory duties of the nature described, unless they meet the required levels of competency.

3.2.4 Pre-Registration Pharmacists

The role of pre-registration pharmacists in supervising the sale or supply of pharmacy and prescription only medicines in the absence of a pharmacist is not specifically addressed in the consultation document, but is an area that requires careful consideration. The level of potential delegated responsibility will depend on the experience and competency of the individual pre-registration pharmacist and will be largely influenced by the stage the trainee is at in their training year. For example, a pre-registration pharmacist a few weeks from qualification could be delegated far greater supervisory duties than a pre-registration student at the beginning of their training programme. The RPSGB would wish to give this matter further attention and discuss with the Department of Health how delegation to pre-registration pharmacists could be incorporated into Code of Practice requirements and professional guidance.

3.3 Risks and benefits

- **What do you think are the main benefits and/or risks associated with the options put forward on supervision by a registered and suitably qualified pharmacy technician or other suitably accredited pharmacy staff?**

The supervision of the sale of certain pharmacy medicines, assembly of prescriptions and provision of specified pharmacy services by a registered and suitable qualified pharmacy technician will provide pharmacists with greater flexibility to develop new services and work with other healthcare professionals to improve services to the public. The proposed arrangements will allow pharmacists to use their expertise to undertake medication reviews, have greater involvement in public health initiatives and give more in depth advice on minor ailments and long term conditions. It will also allow patients to access many OTC and prescribed medicines in circumstances where the pharmacist is temporarily unavailable or absent from the pharmacy.

However, patient safety must remain paramount. Any change must ensure the public is not exposed to additional risks or lower standards of care. Patients expect to have ready access to advice from pharmacists. A pharmacist's absence from a pharmacy could restrict the level of professional advice the patient receives and may result in patients being unable to urgently obtain certain prescribed items e.g. controlled drugs.

Supervision of the supply of pharmacy and prescription only medicines by staff who are not regulated by the RPSGB poses a risk to patient and public safety. Such staff would not be bound by the same professional requirements as pharmacists and registered pharmacy technicians and their practice could not be restricted.

Consideration must be given to financial resource implications and workforce issues. Registered pharmacy technicians will be required to undergo additional competency based training in order to supervise the sale of pharmacy medicines or activities exempt under Section 10 of the Medicines Act 1968. This will require adequate numbers of assessors with appropriate expertise. At a local level, consideration will need to be given to whether there is a sufficient pool of individuals with the potential to fulfil the extended role of registered technicians. Steps must be taken to prevent a destabilisation of the secondary care workforce as demand for registered pharmacy technicians in primary care grows.

It is important to recognise that pharmacy technicians in secondary care are likely to have differing experiences and competencies to those currently working in primary care. Pharmacy technicians in secondary care work as part of a larger healthcare team and may have managerial responsibilities or experience in manufacturing and medicines information etc. In primary care, especially community pharmacy practice, many pharmacy technicians tend to work in a more isolated environment and do not have the support of a larger healthcare team. They operate under different work pressures and roles and responsibilities may often largely focus on the dispensing and checking process. Competency and experience in secondary care will not automatically equip a registered technician to work unsupervised in primary care or vice versa. Steps must be taken to ensure technicians working in primary and secondary care have the necessary competency and support for any new roles or enhanced responsibility and accountability.

3.4 Remote Supervision by Other Pharmacy Staff

- **What are your views on allowing pharmacy staff other than pharmacists to undertake remote supervision of the supply of POM or P medicines? Is there scope for this? If so, what are your views on the timing for introducing this further flexibility?**

The RPSGB would not support a move to allow pharmacy staff, other than pharmacists, to undertake remote supervision of the supply of pharmacy and prescription only medicines. If the professionally accountable pharmacist is unavailable or absent from the pharmacy, and there is no other pharmacist supervising (either in person or remotely) a registered pharmacy technician needs to be present to supervise the sale of pharmacy medicines and the assembly of prescriptions.

3.5 Controlled Drugs

- **What are your views on the supervision proposals in relation to the supply of controlled drugs?**

Registered pharmacy technicians and other pharmacy staff are not currently authorised to supply or supervise the supply of Controlled Drugs. To allow them to do so would require an amendment to Misuse of Drugs legislation and would be contrary to the additional safeguards being implemented as a result of the Shipman Inquiry.

The RPSGB is extremely concerned about the implications of the supervision proposals on a patient's ability to access controlled drugs, especially palliative care patients. As compliance with the Misuse of Drugs Regulations 2001 requires a pharmacist to be present in the pharmacy when controlled drugs are supplied, remote supervision or supervision by a registered pharmacy technician could result in unacceptable delays to patient care. Therefore, consideration would need to be given to how local arrangements could ensure patients have timely access to prescribed controlled drugs, particularly in more remote areas.

3.6 Section 10 Exemption

- **Do you think that a suitably qualified pharmacy technician or other suitably accredited pharmacy staff should be able to undertake or supervise activities covered by the Section 10 exemptions?**

A registered pharmacy technician could undertake or supervise activities covered by the Section 10 exemptions provided

- the activities were not deemed to require the pharmacist's intervention and
- the technician met a specified competency framework for Section 10 activities.

3.7 Additional safeguards

- **Do you think there is a need for other arrangements to be in place, in addition to clinical governance, to support review by a pharmacist of all or specific activity undertaken under the supervision of a suitably qualified pharmacy technician or other suitably accredited pharmacy staff?**

Regular risk assessments should be conducted and procedures put in place to minimise the risks associated with the pharmacist being unavailable or absent from the pharmacy.

A Code of Practice should specify the additional record keeping, audit and risk assessment that must be undertaken in pharmacies where remote supervision, or other supervision arrangements exist.

As a minimum, records should be kept of

- The professionally accountable pharmacist at any given time
- Each time the professionally accountable pharmacist is contacted, or contact is attempted
- The action taken as a result of any contact made between the pharmacy staff and the pharmacist
- When the pharmacist was unavailable or absent from the pharmacy and for how long
- Sales and supplies of medicines made in the absence of a pharmacist
- Complaints relating to pharmacist unavailability
- Errors or near misses occurring while the pharmacist is unavailable.

The professionally accountable pharmacist should be required to review what has happened in their absence and take any necessary action. All records should be subject to regular review and audit to identify how systems can be improved. RPSGB inspectors should be able to compel disclosure of all records, audits and risk assessments.

Effective auditing and monitoring will need to be underpinned by appropriate IT support and the RPSGB recommends that consideration be given to this in the context of the wider healthcare IT strategy.

3.8 Information for patients

- **Is there a need to place a requirement on pharmacies to display information on any restrictions in services where the pharmacist is unable to supervise the supply of medicines? If so, should this include the provision of advance information of specific future periods of time during which the pharmacist will be unavailable to supervise the supply of medicines or for consultation?**

Patients need to be informed when the pharmacist is not available for face to face consultation and when they will return. A Code of Practice, supported by a statutory framework should require pharmacies to display information about when the pharmacist is unavailable or absent and the resulting restrictions on services.

The duty on primary care organisations to ensure appropriate delivery of services should be a key part of contracting arrangements and should extend to maintaining patient safety.

Public awareness campaigns must not only inform the public about changes to the current arrangements, but should inform the patients what to do if they have any concerns about the service they have received. This will be an important factor in monitoring the impact of the arrangements on patient safety and access to pharmaceutical services.

4. TRAINING AND EDUCATION

4.1 Pharmacy Technicians

- **What are your views on the nature and extent of training that a pharmacy technician should be required to undertake before engaging (under clinical governance arrangements and standard operating procedures) in dispensing activities or the sale or supply of medicines other than under the supervision of a pharmacist?**

Registered pharmacy technicians should undertake competency-based training before being able to undertake supervisory responsibilities. It would seem prudent to review the current training programmes for registered pharmacy technicians to reflect the competencies required for pharmacy technicians to supervise the sale or supply of pharmacy and prescription only medicines.

Pharmacy technicians assuming responsibility for the dispensing or sale of medicines should have a programme of CPD relevant to their role and be subject to annual appraisal. Undertaking Section 10 activities unsupervised should require specialist competency based training.

The current NVQ training programme for pharmacy technicians needs to be reviewed to ensure that professional attitudes and values are fully incorporated into the training arrangements. From 2007, pharmacy technicians will be registered professionals. Education standards for pharmacy technicians must therefore reflect those of other healthcare professionals in respect of promoting professional responsibility, accountability and endorsing values that provide patient care and public protection.

4.2 Other Pharmacy Staff

- **Do you believe that similar training should be required of other pharmacy staff, other than pharmacy technicians, to achieve accreditation to engage in these activities?**

The RPSGB believes that the public interest demands that those persons who are engaged in professional activities should be regulated and be of a suitable competence. Only persons who are registered and accountable to the RPSGB should have supervisory responsibilities.

The RPSGB does not believe other pharmacy staff should undertake supervisory activities unless they have equivalent competence to that of a suitably competent registered pharmacy technician and are subject to the same regulatory controls as a registered pharmacy technician.

Any expansion of RPSGB powers to accredit and register individuals who have fulfilled specific competency based training requirements would require the appropriate authority and resources to deal with registration and fitness to practise issues. However, the RPSGB feel that individuals who achieve equivalent competence of a suitably competent registered technician, should register as pharmacy technicians.

4.3 Training Programmes

- **What are your views on structuring training programmes for pharmacy staff to focus on meeting pharmacy business needs? Are**

there any specific aspects of training or gaps that may benefit from this approach?

The RPSGB believes that training for pharmacy staff should balance the commercial realities of meeting business needs with providing a professional service to patients and the public. The greater responsibility must be to ensure that staff are aware of the legal and ethical requirements and understand the importance of dealing with potential problems or complaints in a professional manner.

- **Is there a distinction to be drawn in relation to the type of training required between preparation and dispensing activities under section 10 of the Medicines Act and the sale and supply of medicines under section 52 of the Medicines Act?**

Any person assuming supervisory responsibility will be required to have the necessary competencies for the activities that they are required to undertake. Supervision of activities under Section 10 of the Medicines Act will require a different competency framework to the competencies required for the sale or supply of medicines under Section 52 of the Medicines Act.

- **Which body or bodies do you consider might be best suited to take on responsibility for accreditation of staff wishing to undertake unsupervised activities within the pharmacy?**

The RPSGB would be the most appropriate body to regulate and define accreditation standards for suitably competent registered pharmacy technicians wishing to undertake unsupervised activities within a pharmacy. Additional regulatory responsibility for other pharmacy staff would require appropriate resources and the necessary powers to deal with registration or fitness to practise issues and place restrictions on practise.