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

INTRODUCTION

1. This document seeks views on possible changes in the law to enable all those working in a pharmacy setting – pharmacists, pharmacy technicians, dispensing assistants, counter assistants and others – to contribute as fully and effectively as possible to patient care. It sets out proposals for change in the context of Government plans for the development of pharmacy services in England. Most of the proposals, however, relate to the Medicines Act 1968 whose scope is the United Kingdom as a whole.

2. For the most part, policy and planning for health and healthcare is a matter for the individual four countries of the United Kingdom. Devolution includes legislation relating to the provision of NHS pharmacy services (other than primary legislation affecting the NHS in Wales). The possible registration of new professions, such as pharmacy technicians, is also a devolved matter. The legislation can vary from one part of the United Kingdom to another – for example, the regulation of the pharmacy profession is different in Northern Ireland.

3. All the UK Health Departments wish to see the best possible use made of the available pharmacy workforce. They are committed to working together to develop a modern legal framework that provides the clarity and flexibility needed to ensure that patients benefit fully from the skills and expertise available in pharmacies

4. There is agreement between the Department of Health, the Scottish Executive Health Department, the Welsh Assembly Government, and the Northern Ireland Department of Health, Social Services and Public Safety on the principles underpinning the proposals in this document. However, there will be separate consultation in Wales, Scotland and Northern Ireland, setting out detailed proposals for these countries in the context of their own plans for developing pharmacy services.

5. The proposals set out in this document will not make any compulsory changes to pharmacy practice. The aim is to allow pharmacies greater choice and flexibility in

    - How pharmacists meet their professional and legal responsibilities and obligations

- Contributing to the delivery of a wider range of safe and high quality services for patients

- Meeting the development and training needs of pharmacy staff.

Regulatory Impact Assessment

6. As part of modernising government, the Department of Health – like other government departments – is committed to better regulations and the removal of unnecessary ones. A Regulatory Impact Assessment (RIA) helps assess proposals for change and the impact of various options identified. A partial RIA is required as part of the consultation process and this is enclosed at Annex A. The response to consultation will contribute to the final RIA, which is part of any Parliamentary process.

Timetable

7. This document looks at possible amendments to primary legislation. Amendments may be introduced as and when Parliamentary time allows and there can be no firm commitment on any timetable for implementing change.

8. Views and comments on the proposals set out in this paper are welcome by Friday 11 March 2005. These should be sent to:

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Confidentiality Disclaimer

9. The information you send us may need to be passed on to colleagues within the Department of Health or other UK Health Departments and/or published in a summary of responses to this consultation. We assume you are content for us to do this and, if you are replying by e-mail, that your consent overrides any confidentiality disclaimer generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission to us.

Compliance with Cabinet Office Code of Practice on Consultation

10. This consultation follows the Cabinet Office Code of Practice on consultation. This document is available in the consultations section of the Department of Health's website. In due course, a summary of views received to the

consultation will be available on the website, together with the Government's response and proposals for action.

11. Details of the six consultation criteria set out in the Code of Practice are set out in Annex B.

CHAPTER 1: SUPPORTING CHANGE THROUGH BETTER USE OF SKILL MIX

The Need for Change

1. Pharmacists have extensive training in the actions, uses and side effects of medicines. They have an important role and contribution to make as part of clinical teams caring for patients in hospitals and in the community.

2. For a number of reasons, there is a need to take stock of ways in which pharmacists and pharmacy staff can extend and enhance their roles in a modernised, integrated, NHS. These include

    - the time it will take to achieve the significant growth in the pharmacist workforce which will result from increases in the number of pharmacy school places and the number of pharmacists in training

    - shortages in the number of qualified pharmacists, placing continuing reliance on locum pharmacists and on pharmacists older than the normal retirement age; and a continuing trend towards flexible and part-time working

    - the development of extended roles for pharmacists in hospitals and in the community, drawing on their professional experience and expertise in areas such as medicines management, prescribing and public health

    - the development of an enhanced role for pharmacy technicians and other pharmacy staff in supporting pharmacists in the delivery of a wider range of pharmacy services in the community and as part of modern hospital services

    - hospital staff skill mix has developed at a pace not matched in the community

    - changes in the dispensing process – for example, advances in technology (such as robotics) and the proposals, announced in England in *A Vision for Pharmacy in the New NHS*, to look at rounding and prescribing in full patient packs.

Setting the Context

3. *Building on the Best – Choice, Responsiveness and Equity in the NHS* (issued in December 2003) noted that the services people can get from their community pharmacist are widening beyond the traditional roles of dispensing prescriptions and selling medicines. For example, community pharmacies can

    - provide easy access to emergency hormonal contraception and stop smoking services
    - provide advice on healthy eating, obesity and the benefits of regular exercise

- review the medicines patients are taking and check whether they are experiencing problems

4. Community pharmacists have a wider part to play in improving services for patients wherever they live. However, *Building on the Best* noted that pharmacists can play a particularly important role in inner city or rural areas where local populations may have more limited access to healthcare services. In September 2002, the Department issued a discussion paper on ways of creating a modern pharmacy workforce with the capacity to meet the changing needs of patients. The response to this paper informed *A Vision for Pharmacy in the New NHS,* issued in July 2003. *A Vision* highlighted the importance of making better use of the pharmacy workforce, noting that new emerging roles for pharmacists will increase the demand for pharmacist skills and expertise. In the light of the decision of the Royal Pharmaceutical Society of Great Britain (RPSGB) on the registration of all pharmacy technicians by January 2007, with voluntary registration from 2005, the time is right to consider the case for change in more detail.

A Vision for Pharmacy in the New NHS

5. Recognising that patient safety must remain paramount at all times, *A Vision for Pharmacy* proposed:

   - The pharmacist should retain overall responsibility for ensuring that appropriate procedures for the safe dispensing and sale of medicines are in place. These should include arrangements for checking the appropriateness of the prescription and for providing advice to patients or carers at the time that medicines are dispensed or supplied

   - That a pharmacist need not personally supervise a registered and appropriately qualified pharmacy technician at all times. However, there is a need for a pharmacist with responsibility for each pharmacy, who is contactable and able to provide advice at all times.

6. *A Vision for Pharmacy* committed the Department of Health to consult further on these proposals. This document fulfils that commitment and takes account of the responses to proposals outlined in *A Vision for Pharmacy*.

Response to Skill Mix Proposals in *A Vision for Pharmacy in the New NHS*

7. The majority of respondents to *A Vision for Pharmacy* acknowledged the importance of skill mix in freeing up pharmacists' time for patient care and in the recruitment and retention of skilled pharmacy support staff. Most welcomed a developing role for pharmacy technicians (including registration) and other pharmacy support staff. However, respondents also welcomed an opportunity for further discussion of the training and registration of pharmacy technicians and proposals on pharmacist supervision.

8. Many respondents expressed concern about a perceived plan to introduce "remote supervision" of pharmacy technicians and felt that the presence of a pharmacist on pharmacy premises is essential and required at all times to

   - maintain the safe operation of premises
   - ensure high standards of patient care and safety
   - support the pharmacist's legal and professional responsibilities
   - maintain easy public access to professional advice

Ways of Working in other European Countries

9. It is recognised that pharmacists play an important role in protecting the public and that this role should not be delegated lightly. However, experience in other countries suggests that there are other possible models of working within the pharmacy. For example

   - In Denmark, "pharmaconomists" can dispense prescriptions independently and without the supervision of a pharmacist. "Pharmaconomists" independently manage some pharmacy sub-branches although a pharmacist is always available for consultation by telephone

   - In the Netherlands, pharmacist's assistants can undertake the complete dispensing process and provide advice on the sale of over-the-counter (OTC) medicines.

   - In Sweden, "prescriptionists" carry out a similar range of tasks to pharmacists, and pharmacy technicians can sell OTC products

Conclusion

10. The Health Departments believe that the current arrangements limit the extent to which pharmacists, particularly those working in a community setting, are able to develop their professional role in a way that makes best use of their training, skills and expertise. As recognised by most respondents to *A Vision for Pharmacy*, there is a need for more effective use of the pharmacist workforce, particularly at a time when many community pharmacists are involved in developing innovative services locally and providing a wider range of services. The new contractual framework for community pharmacy in England and Wales has the flexibility to respond to new services and standards of provision. The Health Departments believe there is also a need for greater flexibility in the legal framework to support the widening range of pharmacy services within a modernised NHS.

11. Proposals for introducing greater flexibility into the current legal framework are set out in more detail in Chapter 2. Better use of the pharmacy workforce needs the support provided through the training and continuing education of pharmacists, pharmacy technicians and other pharmacy staff. Key aims must be to ensure professional standards and competencies and to maintain patient safety and confidence in the service provided. Chapter 3 explores these issues in more detail.

CHAPTER 2: A MORE FLEXIBLE LEGAL FRAMEWORK

INTRODUCTION

1. Patient safety is paramount. The Health Departments consider that the pharmacist should retain overall responsibility for ensuring that proper procedures are in place in each pharmacy for the dispensing and sale of medicines and that there is adherence to these procedures. These should include arrangements for checking the appropriateness of the prescription and for providing advice to patients or carers at the time of dispensing or sale of medicines.

2. These key principles underpin proposals for introducing changes in relation to personal control and the supervision of the dispensing and sale of medicines.

The Case for Change

3. Whilst recognising the vital need to maintain the safe dispensing and supply of pharmacy medicines, the Health Departments believe that there is scope to amend the current legal requirements to provide a more flexible basis for the development of pharmacy services in the 21st century.

4. There is a need to support pharmacies that want to extend the range of services they offer to the public and to support pharmacists who want to develop their clinical role. Many pharmacists feel that the current legal framework limits their ability to pursue a wider role, as this will, on occasion, take them outside the pharmacy. The proposals for change put forward in this document aim to give pharmacists greater flexibility and choice in how they manage their work and their own professional development. And the intention is to allow pharmacies and pharmacists more freedom in making the best use of available skills and experience whilst continuing to meet their professional and legal responsibilities for the safe and efficient dispensing and sale of medicines to the public.

Chapter Summary

5. Firstly, this chapter looks at the current requirement for each pharmacy to have a pharmacist in personal control in the context of the modern pharmacy environment. It then looks at pharmacist supervision of the supply of medicines, including whether the supervising pharmacist needs, in all circumstances, to be physically or "bodily" present in the pharmacy when sale or supply is taking place. Finally, it puts forward some options for change that will allow the pharmacist to be absent, where a registered and suitably qualified pharmacy technician or another suitably accredited member of the pharmacy staff is present in the pharmacy to supervise the sale and supply of Pharmacy only Medicines (POM) or Pharmacy (P) medicines. These options will require these pharmacy staff to work under Standard Operating

Procedures (SOPs), acceptable to the pharmacist responsible for the pharmacy at that time, and wider clinical governance arrangements to be in place in the pharmacy to maintain the safe and efficient dispensing and supply of medicines to patients and the public.

PHARMACIST RESPONSIBILITY FOR CONTROL OF BUSINESS CONDUCTED IN THE PHARMACY: "PERSONAL CONTROL".

The Legislation

6. Under sections 70 and 71 of the Medicines Act 1968, the business of the retail sale and supply of medicines in each pharmacy must be under the "personal control" of a pharmacist. The Act says nothing as to the concept of personal control in requiring the presence of a pharmacist. Nor does it specify the responsibilities of the pharmacist in exercising personal control. Neither does the RPSGB's Code of Ethics include a statement (in contrast, for example, with the responsibilities of the superintendent pharmacist).

7. The case of R v Logan, decided on 19 November 1981, indicates that some physical presence on the premises is required if a pharmacist is to be considered in personal control. However, the decision also indicates that sale of general sale list (GSL) medicines (that is, those medicines that may be sold from retail premises other than pharmacies) may lawfully take place when the pharmacist is away from the premises.

Decisions of the RPSGB Statutory Committee

8. The RPSGB's Statutory Committee has tended to take the view that a pharmacist's presence on the premises is required, at least for a "substantial part of the time" in order for the pharmacist to be in personal control. In a 1970 decision, the Committee Chairman stated: "The question is whether the attendance of the pharmacist at the premises is such as to give him substantial personal control over the business for a substantial part of the time" but that the pharmacist would not cease to be in personal control "because he slipped out for a few minutes".

9. On 19 July 2004, the current Chairman of the Statutory Committee said, in a decision, that it was difficult to rely on a vague rule whereby absence of personal control was normally a breach but was not if it was unexpected or temporary. In August 2004, the RPSGB's Fitness to Practise and Legal Affairs Directorate issued the following statement:

> "All supplies of prescription-only medicines (POMs) and pharmacy (P) medicines from registered retail pharmacy premises must be made under the supervision of a pharmacist. Sales of general sale list (GSL) medicines do not require supervision, but do require a pharmacist to be in personal control of the premises. Thus, if a pharmacist is not in personal control, for instance because he is late attending or he has left for the afternoon, no

sales of medicines can be made, and this includes general sale list medicines.

The Chairman's ruling was that if a pharmacist was not in personal control, the premises could remain open for trading as long as nothing requiring the presence of a pharmacist (ie, POMs, Ps and GSLs) is sold. However, pharmacists should also be aware that the use of restricted titles such as "chemist" and "pharmacy" can only be used in connection with retail sales of any goods where they are being sold from registered retail pharmacy premises under the personal control of a pharmacist. Therefore, if restricted titles are used and a pharmacist has to leave the premises, the safest option may be to close the pharmacy premises. Where the pharmacy is in contract with a primary care trust to provide NHS services, the PCT should be contacted for advice."

10. The original purpose of the concept of "personal control" is difficult to determine. The term derives from the Pharmacy and Poisons Act 1933, but Parliament did not debate these provisions at great length in relation to the 1933 Act or during the passage of the Medicines Act in 1968. It is unclear why in the 1930s it was felt that the sale of (as then known) "simple remedies" should be under the personal control of a pharmacist when sold from a pharmacy, even though these were available from other retail outlets. However, modern pharmacy practice is very different from practice and the nature of medicines in the 1930s.

11. Some pharmacists take the view that it appears unreasonable that a pharmacy, staffed by trained medicines counter assistants, is unable to sell GSL medicines in the absence of a pharmacist when these are available for sale in other retail premises. However, others may support the view that, when people visit a pharmacy, they expect a pharmacist to be present so that they may seek professional advice on the range of medicines available.

A fresh look at "personal control"

12. In the light of the continuing debate on personal control, it may be helpful to take a fresh look at this requirement.

13. The provisions relating to personal control do <u>not</u> appear to be about

- Being in a position to intervene in individual transactions – since that is covered by the supervision provision in section 52 of the Medicines Act

- Being responsible for the management of the business of keeping, preparing and dispensing medicines (other than GSL medicines) – since, where the pharmacy is owned by a body corporate, that is the responsibility of a superintendent pharmacist. However, this does not remove the requirement for a pharmacist to be in personal control of each set of premises.

14. In contrast with the provisions relating to the supervision of transactions and the responsibilities of superintendent pharmacies, personal control applies to the business of the retail sale of all medicines, including GSL medicines. But, given the advances made in modern medicines and changes in pharmacy practice, it may be difficult to see the continuing relevance of this requirement to the sale of GSL medicines in pharmacies when there is no such requirement where these medicines are available for sale in other retail premises. There is a case for addressing this anomaly and views are welcome on the need for change in relation to GSL medicines.

15. As noted above, superintendent pharmacist responsibilities do not remove the requirement for a pharmacist to be in control of each set of pharmacy premises. Clearly, it would be impossible for the superintendent pharmacist to exercise day-to-day control where his responsibilities cover a significant number of premises. Therefore, where a pharmacy is open to the public, a pharmacist must be clearly responsible for

- Ensuring that safe systems of work are operating in the pharmacy and to support services provided from the pharmacy (for example delivery services)
- Allocating tasks to staff in accordance with those systems and
- Ensuring that staff are aware of their personal responsibilities in carrying out allocated tasks
- Clinical governance and audit

16. However, the case for the "responsible pharmacist" must also address a number of other questions to avoid continuation of those issues of interpretation that have arisen around the concept of "personal control".

Absence from the Pharmacy

17. Pharmacists may be handicapped in carrying out other professional duties by requirements that tie them to pharmacy premises. Often, these can be undertaken only where there is a break in the service offered to the public – including closure of the pharmacy. To support the pharmacist in offering professional services off pharmacy premises, the law will make clear that the responsible pharmacist does not have to be physically present in the pharmacy at all times.

18. The changes will help facilitate arrangements by a pharmacy owner or superintendent pharmacist in maintaining services offered by each pharmacy, whilst extending the range of services than can be provided outside the pharmacy. For example, with the support of appropriate technologies and SOPs, transactions requiring pharmacist supervision might be undertaken remotely or the pharmacist might delegate these activities to pharmacy staff

that are suitably qualified and accredited to take on these tasks – as discussed later in this document.

Limiting a Pharmacist's Absence from the Pharmacy

19. Setting out when and in what circumstances the responsible pharmacist may be away from the pharmacy, yet still considered to be exercising his responsibility for the safe conduct of business on those premises, may require placing limits on such absences. These limits should not be arbitrary. Further, it is unlikely that it will be possible to set limits that take account of the arrangements in every pharmacy. These will vary – for example, differences in the number of trained staff employed or the range of services offered. Some may feel that setting limits on the pharmacist's absence is inconsistent with the overall aim of allowing pharmacists and pharmacies greater flexibility in managing the delivery of pharmacy services. Others may take the view that setting limits appears to constrain the exercise of a pharmacist's professional judgement as to the conduct of business in the pharmacy in his/her absence.

Activities undertaken by the pharmacist when absent from the pharmacy

20. Some may feel that any limits should make clear that absence from the pharmacy should only be where the pharmacist is undertaking professional or pharmacy business off pharmacy premises – for example, continuing professional development, the provision of services to care homes etc.

Time Limits on Absence

21. There is also a need to look at whether it is reasonable to set a limit on the period of time during which the responsible pharmacist is away from the pharmacy. One view might be that pharmacist absence should be limited to, say, a maximum of one session (half day) with longer periods of absence requiring alternative pharmacist cover. Another view may be that it is for the responsible pharmacist to ensure that safe systems of work are in place within the pharmacy and that these support the conduct of business whether or not the pharmacist is present. Such systems should include arrangements for the conduct of business in the pharmacist's absence, contacting the pharmacist, withdrawing a service that requires the intervention of the pharmacist, or closing the pharmacy, as necessary.

Pharmacy Opening Hours

22. There is also the question of whether there is a need for a requirement on the responsible pharmacist to be present at certain periods during pharmacy opening hours. For example, the responsible pharmacist might be required to be present each day when the pharmacy opens for business, in order to ensure there are sufficient staff available and that they are aware of their responsibilities. Or it may be felt that it is for the professional judgement of the responsible pharmacist to make decisions on whether opening the pharmacy for business may be safely delegated to a member of the pharmacy staff, in the light of operational systems in place within the pharmacy. In some

circumstances (for example, where the pharmacy is located in a sparsely populated rural area) it might not be practicable or the most effective use of a pharmacist's time for him/her to be present in the pharmacy at the start of each day.

Should a pharmacist be able to be responsible for more than one pharmacy?

23. We believe that patient safety, the complexity of modern medicines and the demands of modern pharmacy practice require that an individual pharmacist should be responsible for only one pharmacy at any one time. However, there is also a need to look at this issue in the light of proposals for changes to the pharmacist supervision requirement (discussed below) and the business needs of individual pharmacies. Again, the view might be that a pharmacist may be able to exercise responsibility for the conduct of pharmacy business in more than one pharmacy where supported by safe operational systems and robust clinical governance arrangements within each pharmacy. We welcome views on this question.

Identifying the pharmacist responsible for the conduct of business within the pharmacy

24. Finally, we believe that there needs to be greater clarity as to the pharmacist identified as having responsibility for the conduct of pharmacy business within the pharmacy at any one time. Currently, the pharmacist in personal control must display his/her registration certificate prominently in the pharmacy. However, the proposal is that each pharmacy should also be required to keep an accurate and up to date record of the pharmacist responsible for that pharmacy at any particular time. It is felt that this will avoid any doubt as to where professional responsibility for the activity of the pharmacy lies at any point in time, and that this will also support clinical governance arrangements within the pharmacy.

25. Views are welcome on the proposals discussed above, which include

- Setting limits on a pharmacist's absence from the pharmacy
- Time limits on the pharmacist's absence
- The pharmacist's presence when the pharmacy opens for business and/or during hours of opening
- Pharmacist responsibility for more than one pharmacy
- Record of the pharmacist responsible for a pharmacy at any one time

26. It may be worth repeating here that, in considering the need to set limits on the pharmacist's absence from the pharmacy, proposals for change aim to allow the pharmacist greater flexibility and choice rather than to impose unreasonable restrictions. It may also be useful to continue to bear in mind the extent to which the detail of any statutory provision relating to the responsible pharmacist may also support a case for leaving these matters to the pharmacist's professional judgement. This will allow pharmacy owners and superintendent pharmacists greater freedom to carry on their business as they

see fit, subject only to the supervision requirements in the Medicines Act 1968 and the RPSGB Code of Ethics.

The Superintendent Pharmacist

27. Paragraph 13 above raises the issue of personal control in relation to the superintendent pharmacist. The responsibilities of the superintendent pharmacist are set out in Section 71 of the Medicines Act 1968. The requirement on a corporate body conducting a pharmacy business to appoint a superintendent pharmacist will continue. However, views are welcome on whether there is a need, as part of proposals for change, to strengthen the current statutory requirements to ensure patient safety and quality of care.

PHARMACIST SUPERVISION

The Legislation

28. Section 52 of the Medicines Act requires the sale or supply of medicines (other than GSL medicines) to be carried out by or under the supervision of a pharmacist. The Act does not define "supervision". The interpretation taken is that "supervision" means that the pharmacist must be aware of the transaction and in a position to intervene. The Health Departments support this interpretation, which has stood the test of time.

29. Where a pharmacist is "bodily present" and within sight or hearing of the transaction, he or she is considered to be in a position to supervise the sale or supply of medicines. However, even in 1943, the High Court recognised that, supported by some form of mechanical assistance, it might be possible for a pharmacist to supervise a task or transaction where s/he is not on the spot. With the development of new technologies, it seems likely that the courts may decide that the physical presence of the pharmacist is no longer required within the vicinity of the dispensing counter in all circumstances. Therefore, it may be helpful to consider what action – if any – may be required in the light of modern pharmacy practice and advances in technology that support remote supervision.

Options for Change

30. One option is to do nothing. However, this will do little to address current uncertainties and may well lead to Statutory Committee decisions or court cases, testing the boundaries of what is permissible in a modern, technological, age.

31.Another option might be to amend the law on supervision in a way that the supply of POM or P medicines no longer requires the pharmacist's presence in the pharmacy at all times. Parliament will need to be convinced that the evidence is there to support this change.

Introducing new supervision arrangements

32. Any proposals for change will require clarification of the circumstances in which any new supervision arrangements may be put in place. This might be set out:

- In the RPSGB's Code of Ethics, although this may leave the legal position uncertain – for example, the courts may decide that the Code went beyond what is permitted by law, or that it interpreted the law in an unreasonably restrictive way

- In regulations - this would clarify the legal position but the challenge will be to regulate in a way that is sufficiently flexible to cover a range of circumstances (including future developments in the profession) yet precise enough to ensure that the intention and interpretation is clear. Regulations will also need to make clear a single standard for patient safety, recognising the existing important reasons for the supervision requirements.

- In a Code of Practice - this might be supported by a statutory framework in a similar way to the Code developed under the Disability Discrimination Act 1995. The Code might be drawn up either by the Health Departments (taking into account variations in practice in all parts of the United Kingdom) or by the RPSGB. Development of a Code will involve full consultation with all interested parties.

33. Views are welcome on the options put forward above, including the best way of setting out those circumstances for putting in place any new supervision arrangements. We also welcome details of further options that you may wish to put forward for consideration.

SUPERVISION BY SOMEONE OTHER THAN A PHARMACIST

34.The possible options for change set out above do not allow the supply of POM or P medicines to continue where the pharmacist is not in a position to supervise the transaction. For example, where the pharmacist is undertaking professional duties elsewhere on the premises, or is absent from the pharmacy. Thus, some may find these to be still insufficiently flexible to support those pharmacists wishing to develop a wider professional role whilst continuing to provide the public with access to medicines from their pharmacy.

Options for Change

35. The Health Departments have looked at possible options for changes to the law relating to supervision. The law relating to supervision of the supply of medicines (see Annex C) does not apply to GSL medicines. Therefore, all references to medicines in this context relate only to POM and P medicines.

36. One option put forward is that based on the presence in the pharmacy of a registered and suitably qualified pharmacy technician to supervise the sale and supply of medicines; another on the presence of other suitably accredited pharmacy staff. Both options will require Standard Operating Procedures and other clinical governance arrangements to be in place within the pharmacy to ensure patient safety.

A Registered and Suitably Qualified Pharmacy Technician

37. This option will allow a registered and suitably qualified pharmacy technician to dispense and supply medicines or to supervise these tasks under the standard operating procedures acceptable to the pharmacist responsible for the pharmacy at that time. It requires amendment of the Medicines Act relating to supervision requirements. It also requires the removal of the word “direct” from the NHS legislation so that both Acts refer simply to “supervision” by a pharmacist being required in any other circumstances.

38. These amendments will enable a pharmacy to remain open and carry on its normal business under the supervision of a registered and suitably qualified pharmacy technician, allowing the responsible pharmacist to undertake professional duties elsewhere in the pharmacy or away from the pharmacy. For example:

- the care and treatment of patients outside the pharmacy
- public health functions in the community
- continuing professional development
- education and training of pharmacist trainees and other pharmacy staff
- engaging with PCTs and NHS Trusts in the planning and development of local services

These will also enable the pharmacist to take a break away from the premises without the need to suspend the sale and supply of POM and P medicines.

Other Registered and Suitably Accredited Pharmacy Staff

39. With this option, other registered and suitably accredited pharmacy staff may undertake or supervise the dispensing and supply of medicines, where the pharmacy operates under clinical governance arrangements and standard operating procedures that are acceptable to the pharmacist responsible for the pharmacy at that time. For example, registered and suitably accredited pharmacy staff might include a pharmacy technician, a nurse or an NHS accredited healthcare assistant.

40. There are similarities between these options but some may see the latter (ie: registered and suitably accredited pharmacy staff) as offering greater potential for the flexible use of staff within the pharmacy. For example, a nurse and a pharmacist might work together in a pharmacy to provide a range of services that make the best use of their combined professional skills and experience.

41. However, some may consider there are limitations on the range of activities that registered and suitably accredited pharmacy staff may carry out under standard operating procedures and clinical governance arrangements in place in the pharmacy. A registered and suitably qualified pharmacy technician will have undertaken extensive training and many will feel that this is particularly relevant to the section 10 exemptions (dispensing activities involving some preparation of the product).

Activities that may be undertaken by a registered and suitably qualified pharmacy technician or other registered and suitably accredited pharmacy staff

42. In relation to the tasks undertaken by a registered and suitably qualified pharmacy technician or other suitably accredited pharmacy staff, there may be arguments for setting national standards. For example, such standards may help to provide greater clarity both for pharmacies as employers and for pharmacy staff and help support the freer movement of registered and suitably qualified or accredited staff between postings.

43. However, once again it is important to bear in mind the clear aim to allow greater flexibility in the use of the available pharmacy workforce. These proposals for change will not be mandatory. The Health Departments recognise that pharmacies and pharmacists may wish to use such flexibilities in a way that supports the development of services locally. Therefore, we feel that setting centrally determined standards may not be the best way of achieving these aims. For example, initially, some pharmacists may wish to phase in supervision by a registered and suitably qualified pharmacy technician or other registered and suitably accredited pharmacy staff. Or the view may be taken that any central standards that may be set do not sufficiently match the needs of the pharmacy or their own professional needs. On balance, therefore, our provisional view is that, with the possible exceptions set out below, this should be a matter for the professional judgement of the pharmacist approving arrangements within the pharmacy, subject to guidance on professional and ethical standards issued by the RPSGB.

Remote Supervision by Someone other than a Pharmacist

44. We are not proposing that anyone other than a pharmacist should be able to supervise the supply of medicines remotely. Our view is that there is a risk to patient safety in moving from supervision by a pharmacist who is physically present in the pharmacy towards supervision by someone, other than a pharmacist, who is not required to be physically present in the pharmacy.

OPTIONS PUT FORWARD: SUMMARY

45. Proposals put forward in this chapter suggest there is a need to clarify the personal control requirement and to bring this up to date with modern pharmacy practice. The pharmacist does not need to be always physically present in the pharmacy to exercise his/her responsibility for the safe conduct of business. Changes in the supervision requirements will support remote supervision by the

pharmacist or allow the pharmacist to delegate certain activities to registered and suitably qualified staff in the pharmacy - provided there are robust SOP and clinical governance arrangements in place within the pharmacy. Thus, the pharmacy can continue to supply POM and P medicines where the responsible pharmacist

- is present in the pharmacy (ie is “bodily present)

- is present in the pharmacy but has delegated the supervision and sale of POM and P medicines to a registered and suitably qualified pharmacy technician or another member of pharmacy staff accredited to take on these activities. This will allow the pharmacist to provide services elsewhere on the premises (for example, in a consulting room)

- is not physically present in the pharmacy but is able to meet his supervision responsibilities remotely – ie with the aid of modern technologies and supported by clinical governance arrangements and SOPs within the pharmacy

- is not physically present in the pharmacy and has delegated the supervision and sale of POM and P medicines to a registered and suitably qualified pharmacy technician or another member of pharmacy staff accredited to take on these activities. This will allow the pharmacist to provide services off pharmacy premises; undertake continuing professional development; contribute to the development of local health strategies etc.

46. Under these proposed arrangements, there will – as now – be three levels of legal control applied to the sale and supply of medicines in pharmacies. These are shown in the box.

SUPERVISION

Supervision of the sale and supply of all medicines, other than GSL medicines, will continue where the person supervising these activities is aware of what is taking place and is in a position to intervene, as necessary, to ensure that these are undertaken safely and properly.

Supervision may be exercised through the physical presence of a pharmacist or a registered and suitably qualified pharmacy technician, or other suitably accredited member of pharmacy staff.

Supervision may also be exercised remotely by a pharmacist where appropriate information technology ensures that s/he is aware of transactions and is able to intervene.

THE RESPONSIBLE PHARMACIST

At all times, there will need to be a pharmacist who is responsible for ensuring that defined clinical governance arrangements, safe systems of working and standard operating procedures are in place in the pharmacy and that these are followed by all pharmacy staff. Exercising this responsibility does not require the physical presence of the pharmacist in the pharmacy at all times.

The responsible pharmacist should allocate tasks in accordance with these systems and ensure pharmacy staff are aware of their personal responsibilities in carrying out these tasks. This responsibility should be fulfilled through regular personal inspection, through reports and checks undertaken as part of standing operating procedures and through audit.

THE SUPERINTENDENT PHARMACIST

The requirement on a corporate body conducting a pharmacy business to appoint a superintendent pharmacist will continue. The responsibilities of the superintendent pharmacist are set out in Section 71 of the Medicines Act 1968

OTHER ISSUES

47. The following paragraphs look at a number of other issues arising under these options.

Controlled Drugs

48. We welcome views on whether the proposals put forward in relation to supervision should also apply to the supply of controlled drugs.

Preparation, Dispensing and Sale of Certain Medicines

49. There may be a need to put in place other legal restrictions on the circumstances in which the dispensing and sale of certain medicines may or may not be undertaken or supervised by a registered and suitably qualified pharmacy technician or other registered and suitably accredited pharmacy staff. For example, these might include the initial sale of pharmacy only medicines intended for long-term use (e.g. statins) or the supply of emergency hormonal contraception. Views are welcome on this.

50. Views are also welcome on whether these proposals should also apply to activity covered by exemptions under section 10 exemptions of the Medicines Act 1968. For example, extemporaneous dispensing and those technicians working within pharmacy technical services might be accredited to perform final release checks on aseptically dispensed item where they can demonstrate experience and a thorough understanding of the dispensing process and the underlying technical issues.

51. We welcome views on these proposals. It would be helpful if, when responding, you make clear, as necessary, whether your views are put forward in relation to

a) the first (pharmacy technicians) or second (other accredited staff) option set out above, or both

b) activities covered by section 52 of the Medicines Act 1968 (supply), those covered by the section 10 exemptions (dispensing activities involving some preparation of the product), or both.

Clinical Governance within the Pharmacy

52. Reviews of activity undertaken by a registered and suitably qualified pharmacy technician or other registered and suitably accredited pharmacy staff should form part of clinical governance arrangements within the pharmacy to assure the quality and safety of services. In *Pharmacy in the Future – Implementing the NHS Plan,* (September 2000) the Department of Health made clear the need for progress in putting in place local frameworks. In addition, the new contractual framework for community pharmacy in England and Wales requires pharmacies to put clinical governance arrangements in place, which will be monitored by Primary Care Trusts (PCTs). Therefore, the Health Departments' provisional view is that there is unlikely to be a need for any additional legal requirements to support local review arrangements. However, we welcome any views on this – for example, on strengthening the accountability of the superintendent pharmacist or the pharmacist responsible for a pharmacy in ensuring that clinical governance supports the delivery of quality care.

Information for Patients and the Public

53. The Health Departments believe that where there are restrictions on the dispensing and sale of medicines (because a pharmacist is unable to supervise supply), this information should be clearly and prominently displayed by the pharmacy during the period in question. Where there are planned periods when the pharmacy operates without pharmacist supervision, it is good practice for the pharmacy to set out the dates and times of any restrictions on the dispensing and sale of medicines. This will ensure that patients are aware of the service available during these periods and when the pharmacist is available for professional advice and consultation.

54. Patients, and the wider public, will need access to timely and accurate information about the services offered by the pharmacy. This is a matter of good professional practice and most pharmacies will consider that meeting public information needs forms part of the operating procedures for the conduct of business during the pharmacist's absence. Therefore, it is felt that this should not be a mandatory requirement on pharmacies. However, we welcome views on whether or not there is a need to place any legal requirement on pharmacies to ensure that the public is aware of services provided by the pharmacy, including NHS services and the availability of a pharmacist for consultation, and any periods during which there may be restrictions in the supply and sale of medicines.

CHAPTER 3: TRAINING AND EDUCATION

1. This chapter looks at the possible additional training requirements for registered pharmacy technicians or other pharmacy staff undertaking activities without the supervision of a pharmacist. It also considers possible arrangements to ensure that only registered and suitably qualified or accredited staff will be able to work in the pharmacy in this way.

Pharmacy Technicians

2. Changes in the role of pharmacy technicians are already under way in response to the need to recruit and retain a range of suitably qualified staff to support the development of clinical pharmacy services. The role of technicians within pharmacies varies but includes

    - carrying out final checks on dispensed items
    - clinical and medicines management
    - dispensing using new technologies
    - service management
    - procurement
    - quality control
    - stores distribution
    - manufacturing, including aseptic preparation.

3. Within hospitals, many pharmacy technicians have an enhanced role in managing and delivering hospital pharmacy services, including in-patient dispensaries. And in many areas, pharmacy technicians receive additional training beyond the Pharmacy Services Level 3 Scottish or National Vocational Qualification (S/NVQ) to take on tasks previously undertaken by a pharmacist. Within community pharmacy, their role is less well developed but here, too, the use of qualified pharmacy technicians is increasing as part of developing local services and freeing up the pharmacist's time for patient care.

4. The Health Departments believe that a more clearly defined and enhanced role for pharmacy technicians could support pharmacists in taking opportunities to fulfil their responsibilities for continuing professional development or to undertake additional training for specific clinical roles (for example, as supplementary or independent prescribers). In addition, a clearer pharmacy technician role can support more flexible use of the pharmacist's time, allowing, for example, increased pharmacist contribution to the planning of local health services.

Registration with the Royal Pharmaceutical Society of Great Britain

5. *A Vision for Pharmacy* reaffirmed the Department of Health's support for the RPSGB's intention to register all pharmacy technicians from 2007, with voluntary registration by 2005. This means that the safeguards provided through professional regulation, including continuing professional development, will apply to pharmacy technicians as well as pharmacists. It is

also an important step towards developing a career pathway for pharmacy technicians and enabling pharmacists to concentrate on their clinical role in hospitals and in the community.

6. Following a transitional period during which there will be recognition of a range of other pharmacy technician qualifications, the RPSGB has decided that the pharmacy technicians' education and training standard will be based on Level 3 of the Pharmacy Services S/NVQ. This will involve a training requirement that includes an underpinning accredited knowledge programme and the completion of work experience in a pharmacy. The work experience requirement has been set as two years of consecutive, recently completed, work-based experience in a pharmacy of 14 hours per week or equivalent.

7. The RPSGB has stated its intention to support moves towards the registration of pharmacy technicians with a requirement on all pharmacies to put in place Standing Operating Procedures (i.e. specifying what should be done when, where, and by whom) for dispensing activities.

8. We believe that progress in these areas will contribute much to support the greater freedoms proposed for pharmacy practice in this document. We welcome the RPSGB's work to support continuing confidence in pharmacy practice. This will do much to reassure the public that the safe supply and sale of medicines will continue without supervision by a pharmacist where registered and suitably qualified pharmacy technicians are working under clear standard operating procedures.

Other Registered and Suitably Accredited Pharmacy Staff

9. Chapter 2 outlines an argument that there may be greater potential to make better use of the available workforce where there are also opportunities for other pharmacy staff to achieve suitable accreditation. This would allow staff other than pharmacy technicians (for example nurses or NHS accredited healthcare assistants) to undertake activities within the pharmacy without the supervision of a pharmacist. Their knowledge and understanding of medicines-related issues will vary, though it is unlikely that any will have training in the technical aspects of dispensing – for example, extemporaneous dispensing – and some will require additional training to ensure that they are able to operate safe systems of work in a pharmacy setting.

10. Some pharmacy staff may not be associated or registered with a professional body, and may be working at differing levels of training and education. Others, such as nurses, will be registered with a professional body and have training and experience in the use of medicines – some nurses will be trained nurse prescribers or extended formulary nurse prescribers.

The Dispensing, Sale and Supply of Medicines not supervised by a Pharmacist

11. The essential requirement for practice is that it should be safe. Patients and the public – and pharmacists themselves - need reassurance that where pharmacy staff are not supervised by pharmacists that they are suitably qualified and competent to take on the tasks required.

12. Both options put forward to support a relaxation in pharmacy supervision requirements emphasise the need for robust standard operating procedures and clinical governance arrangements to be in place in the pharmacy. These must be acceptable to the pharmacist responsible for the pharmacy at the time. Procedures must also make clear the extent to which registered and suitably qualified pharmacy staff (ie pharmacy technicians or other suitably accredited staff) may carry out activities unsupervised. Without such procedures, our view is that practice would be unsafe. Therefore, where these procedures are absent, the current arrangements should remain in place.

13. In putting forward options for change, the Health Departments recognise that there will be differences of view on the qualifications required to support the safe and effective use of standard operating procedures where activities are not under the supervision of a pharmacist.

Pharmacy Technicians

14. The proposals for pharmacy technicians working under standard operating procedures, rather than under the supervision of a pharmacist, represent a significant extension of their current and planned future role (though there may be circumstances where a pharmacy technician is working without the supervision of a pharmacist, for example if they work within a dispensing doctor practice). This view suggests that, in a pharmacy setting, pharmacy technicians should demonstrate successful completion of training over and above the minimum Society requirements for registration to undertake those activities not supervised by a pharmacist. That is, before engaging in dispensing activities or in the sale or supply of medicines other than under the supervision of a pharmacist, a pharmacy technician should be required to complete a period of training that demonstrates their competence in taking on this role. That period of training, accredited by the RPSGB, might include theoretical and practical training and assessment, including practice experience, under the supervision of a pharmacist.

15. Pharmacy technicians who successfully complete this further training might have their additional qualifications identified within their entry in the register. Like other technicians, those attaining further qualification will be required to maintain these additional competencies as part of their continuing professional development.

Other Suitably Accredited Pharmacy Staff

16. The other option reflects a view that other pharmacy staff, as well as pharmacy technicians, could take on tasks in community pharmacies. Where staff are not supervised by the pharmacist, tasks must be carried out with the support of standard operating procedures and clinical governance arrangements within the pharmacy. Better use can be made of any necessary training and accreditation acquired by these staff to alleviate pressures on key staff groups such as pharmacists and pharmacy technicians. It may also help pharmacies to focus staff training on meeting business needs. For example, staff will not require training if they are not expected to undertake dispensing activities involving the preparation of products. Similarly, staff will not require training in dispensing prescriptions where they are involved only in the sale of P medicines.

17. The Health Departments believe that those undertaking dispensing activities and the sale and supply of medicines must be competent to undertake these tasks in a way that ensures safe practice. This means the accreditation of pharmacy staff working in this way. Views are welcome on where the responsibility should lie for the accreditation of pharmacy staff. Our provisional view is that it may be insufficient for pharmacists to rely solely on the RPSGB's Code of Ethics to ensure that patient safety and standards of pharmacy practice are uncompromised by the inadequate training of pharmacy staff.

18. One possibility might be for the RPSGB to be responsible, including the compilation of a national list of accredited people. Any such list should make clear where accreditation has been accorded to a specific standard or where those listed have achieved the required competency only in particular areas. If pharmacy staff training is to meet pharmacy business needs, such a list will need to reflect and respond to the particular skills requirements of individual workplaces.

19. Another possible approach might be for an NHS organisation to be responsible for accreditation – for example, the NHS University. (The Department of Health published an implementation framework for the reconfiguration of its Arms Length Bodies (ALBs) on 30 November 2004. This stated that the NHSU is currently the subject of more detailed study, within the overall ALB review. This will be completed shortly.)

Training and Accreditation Implications

20. The options put forward in this document have many similarities. However, a key difference may be the extent of discretion that might be available to suitably qualified technicians or to suitably accredited persons respectively. For example, the view might be that standard operating procedures, together with basic training, are sufficient to meet most safe pharmacy practice requirements. But there is also a need to consider whether these arrangements meet patient needs – for example the need for information and

advice at the time of sale or dispensing or medicines when the pharmacist is absent.

21. In addition, it may be possible to draw a distinction between activities requiring some technical expertise and those without a technical component. It may be argued that the case for suitably accredited persons (as distinct from suitably qualified pharmacy technicians) undertaking unsupervised activity is weaker in relation to activity under section 10 than to activity under section 52 of the Medicines Act.

22. Views are welcome on the discretion that might be extended to suitably qualified pharmacy technicians and/or other suitably accredited staff, taking into account training requirements and plans for the registration of pharmacy technicians.

Clinical Governance in Pharmacy

23. There is also a need to bear in mind the important contribution of clinical governance in ensuring continuous improvement in the provision of high quality standards of care to patients. All organisations providing NHS services are required to put clinical governance arrangements in place. This is a specific element in the new contractual framework for community pharmacy. The regulation and training of pharmacy support staff will play an important part in the further development of clinical governance within pharmacy. And it will help assure patients and the public that all those working within pharmacy are competent, well trained, and are subject to clear professional and ethical standards of care and treatment.

CHAPTER 4: CONCLUSION

Please let us have your views on the proposals set out in this consultation document. We also welcome other options for change that you may wish to put forward.

In particular, we welcome a response to the following questions:

Personal Control

- 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?

- 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?

- 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? Do you think there is a need to limit the time that a pharmacist may be away from the pharmacy and still considered to be fulfilling his/her responsibilities? If so, what might be a considered to be a reasonable period of absence?

- 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?

- 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?

- 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?

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

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 present in the pharmacy at all times for the supply of Pharmacy only Medicines (POM) or Prescription (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?

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?

- 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?

- 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?

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

- 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?

- 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?

- 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?

Training and Education

- 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 or a pharmacist?

- 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?

- 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?

- 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?

- 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?

ANNEX B

PARTIAL REGULATORY IMPACT ASSESSMENT: PHARMACIST CONTROL AND PHARMACIST SUPERVISION OF THE DISPENSING, SALE AND SUPPLY OF PRESCRIBED MEDICINES

Objective

1. To support the development of NHS community pharmacy services by allowing pharmacies and pharmacists greater freedom and flexibility in conducting pharmacy business, including better use of the pharmacy workforce.

Devolution

2. These proposals involve changes to the Medicines Act 1968, which is UK wide. These are enabling measures and in keeping with plans for pharmacy issued separately by all four parts of the UK.

Background

3. The Medicines Act 1968 requires

- The business of the retail sale and supply of medicines at every pharmacy to be under the "personal control" of a pharmacist

- Medicines – other than general sale list (GSL) medicines – may only be supplied under the supervision of a pharmacist

The intended effect of the first of these provisions is unclear but in the past has been taken to mean that a pharmacist may only be briefly absent from a pharmacy if the pharmacy is to remain open for business. During summer 2004, debate has cast doubt on that interpretation with the suggestion that a pharmacy cannot sell any medicines in the absence of a pharmacist. The second provision requires a pharmacist to be aware of transactions in the pharmacy and to be in a position to intervene. The courts have interpreted it as requiring the "bodily presence" of the pharmacist in the pharmacy. However, as far back as 1943 the suggestion has been that, given the right technology, this interpretation might change. The concept of "personal control" needs clarification. In addition, this requirement relates to GSL medicines but the sale of these medicines in other retail outlets does not require a pharmacist to be in "personal" control to achieve public safety. Over the past 40 years, the number and range of medicines on the GSL list has increased without a review of the legal requirement on pharmacies

4. The UK Health Departments believe that the current legal requirements limit the extent to which pharmacists, particularly those working within the community pharmacy sector, are able to develop their clinical professional role to make best use of their training, skills and experience. These requirements also limit the more effective use of the wider community pharmacy workforce, particularly at a time when many community pharmacies are developing innovative services locally and providing a wider range of NHS services. In July 2003, the Department set

out a continuing programme for improving pharmacy services in *A Vision for Pharmacy in the New NHS*. Greater freedom in providing community pharmacy services, including the more flexible use of the pharmacy workforce, is an important part of supporting pharmacists to deliver that programme and the implementation in England and Wales of the new contractual framework for community pharmacy from 2005.

Risk Assessment

5. Amongst other things, the intention of the Medicines Act 1968 is to minimise the risk to patients from the supply of potentially harmful or inappropriate medicines. However, the legislation is nearly 40 years old and, in parts, is possibly too restrictive when applied in the light of advances in technology and modern pharmacy practice. As such, it acts as a barrier to achieving further improvements in pharmacy services. These proposals aim to clarify and relax the requirements relating to pharmacist control and pharmacist supervision. That is, to free up community pharmacy from unnecessary regulatory burdens to allow pharmacies to make better use of the available pharmacy workforce to expand and improve their services to the public.

6. The following assessment has been made of risks in relation to these proposals:

- **Impact on retail pharmacies:** The aim is to allow community pharmacies greater freedom in how they plan and manage their business. Pharmacies will be free to make use of these proposed relaxations in the requirements on pharmacists – take up will not be mandatory**.** Where they do so, this is will enable the more cost effective use of pharmacy staff and allow increased income to be derived from an expanded range of pharmacy services offered to the NHS (Primary Care Trusts), patients and the public under the new pharmacy contractual framework. Current restrictions stifle innovation and competition. Retail pharmacies will be freer to develop competitive services based on quality and choice – to meet the needs of their customers and the local health community (eg GPs, Primary Care Trusts). And pharmacies will not be restricted in competing with other shops in the sale of GSL medicines

- **Patient safety**: Patient safety is paramount and the pharmacist will continue to have a legal responsibility for everything that goes on in the pharmacy. However, there is scope for relaxing the current “rules.” Changes in pharmacy practice (for example, less preparation of medicines on pharmacy premises) have reduced the potential for risk in the dispensing of medicines. On the other hand, freeing up the pharmacist from the supervision of dispensing will improve patient and public safety by extending their access to the clinical advice and expertise s/he can offer. This can include advice on minor ailments and managing long-term conditions such as diabetes; getting the best from prescribed and other medicines; and public health services such as reducing obesity and sexual health.

- **Dispensing error:** Some 80% of prescriptions are for repeat medication. The pharmacist does not always need to make a clinical check on dispensing each time. A relaxation of the supervision requirement will allow a pharmacist greater freedom to decide operational systems in the pharmacy in the light of the availability of trained pharmacy staff (such as pharmacy technicians) to undertake the dispensing, sale and supply of medicines. The Royal Pharmaceutical Society of Great Britain (RPSGB) proposes to require the registration of all pharmacy technicians from 2007 (with voluntary registration from 2005). Discussions are taking place with the RPSGB and other organisations on the training requirements for pharmacy staff taking on these tasks. In addition, new technologies (such as video links) offer pharmacists the potential to supervise transactions without the need to be "bodily present" in the pharmacy.

- **Improving skill mix in the pharmacy workforce:** *Pharmacy Workforce in the New NHS* (published in 2002) quoted figures of 8,000 technicians with a recognised qualification (1998 figures); and an estimated 16,000 dispensing assistants and 40,000 medicines counter assistants. In *A Vision for Pharmacy in the New NHS (July 2003),* it was recognised that there is scope to develop and make better use of these and other staff employed in community pharmacies and to alleviate workforce pressures arising from restrictions on pharmacists working within the community pharmacy sector. Relaxing these restrictions will allow pharmacies greater freedom to use non-pharmacist staff for dispensing tasks with pharmacists providing a wider range of clinical services to patients and the public. Pharmacies will be free to choose whether they take advantage of these flexibilities. Where they do so, it will provide pharmacists with opportunities to develop and practice their clinical skills; and provide other pharmacy staff with greater opportunities to enhance their role. These opportunities are likely to encourage entry into the pharmacy profession and the development of a clearer career pathway for other pharmacy staff.

- **Effective use of pharmacy staff:** Ineffective use of pharmacy staff can result in poor quality care or limit public/patient access to a range of healthcare – for example, in inner city or rural areas. And public access to medicines may be limited by the need for the pharmacist to be present to supervise transactions – these are currently unavailable if the pharmacist is absent. The current supervision requirements on pharmacists limit their ability to develop new services and take up opportunities to work with other healthcare professionals (for example, in reducing pressures on GP services), away from the pharmacy.

Options

8. Option 1: **Do Nothing**: Uncertainty over the extent to which a pharmacist must be present on pharmacy premises will continue. Pharmacies will remain restricted in how they conduct their business, limiting their potential to expand the range of services offered (eg stopping smoking, medication reviews for people with long-term conditions, such as diabetes etc) as much pharmacist time is devoted to the

dispensing of NHS prescriptions. Pharmacists will continue to face restrictions in developing their clinical skills. This option does nothing to support pharmacies in making best use of the available workforce to deliver improved NHS pharmacy services under the new community pharmacy contractual framework. Nor does it support making best use of the lengthy and expensive clinical training of pharmacists or the recruitment, training and retention of other pharmacy staff, such as pharmacy technicians. In addition, it does not encourage pharmacies to invest in the cost effective use of new technologies to support modern pharmacy practice.

9. Option 2: **Clarify legal requirements on "personal control" and relax requirements relating to pharmacist supervision:** Under this option, the pharmacist continues to have legal responsibility for everything that goes on in the pharmacy. However, there will be greater flexibility allowed to pharmacists on the personal supervision of the dispensing, sale and supply of medicines and the requirement to remain on pharmacy premises at all times. This will support pharmacies in planning the best use of pharmacists' time in the clinical care of patients; in providing more time and opportunities for further pharmacist training; and in delivering a wider range of NHS services. And it will promote better use of the skills of other pharmacy staff.

10. Patients and the public will see increased efficiency in the dispensing of prescriptions and a wider range of services on offer at their local pharmacy, including improved access to pharmacist clinical advice and treatment.

11. This option supports more competition between retail pharmacies on service quality and removes restrictions on pharmacies in competing with other shops on the sale of GSL medicines.

12. **Benefits**

Economic:

NHS community pharmacy costs are £862.5 million (2003/04 England & Wales figures). These costs are largely volume driven (ie the number of prescriptions dispensed – in 2003/04, 659.4 million prescription items were dispensed in the community in England). The new contractual framework for community pharmacy places greater emphasis on the cost effective provision of a wider range of quality services within and outside the pharmacy. Pharmacists will need to work in different ways to deliver these services, supported by improvements in the availability and mix of other pharmacy staff. This will be difficult for them to achieve without a relaxation in the rules to allow them to leave pharmacy premises and to allow them to make use of other suitably trained pharmacy staff and modern technologies in the supervision of the dispensing, sale and supply of medicines.

More generally, opportunities will continue to be lost in developing the pharmacy workforce. It takes five years, including a one-year pre-registration placement, to train a pharmacist. Yet supervision requirements

mean that many pharmacists spend much of their time on routine dispensing rather than the direct clinical care of patients. These requirements also limit opportunities for the recruitment and training of others to undertake the technical aspects of dispensing in a more cost effective way.

Overall, these changes can help secure improvements in NHS value for money in the provision of community pharmacy services. For example, better pharmacy services can help relieve burdens on GPs, freeing up their time to concentrate on the healthcare services that only they can deliver and enabling them to take on more work in the community that otherwise is provided in hospitals.

Average pharmacist salary costs are in the order of £40,000 pa**;** for an appropriately trained pharmacy technician, these are around £25,000 pa. Where pharmacies take opportunities to use other pharmacy staff to support dispensing services, significant economic benefits can be realised with the more cost effective use of pharmacists in developing business needs.

Environmental: Nil.

Social:

Allowing pharmacists greater flexibility in the requirement to remain on pharmacy premises to supervise the dispensing, sale and supply of prescribed medicines will support improvements in the provision of NHS services. Patients (particularly those receiving repeat prescriptions), carers and others will not have to await the return of the pharmacist if s/he is not present or go elsewhere for their medicines. Patients will have wider choice in the services offered by individual pharmacies. Patients can continue to look to the strengths of community pharmacy – the availability and improved accessibility of professional healthcare services – thus reducing pressures on GP and other community healthcare services.

Pharmacists will be encouraged to enter and remain in the profession in the light of greater opportunities to develop their clinical skills and expertise within community pharmacy (where 73% of active pharmacists work).

Other pharmacy staff, such as pharmacy technicians, can develop an enhanced role and responsibilities within the pharmacy team, supported by registration and training based on NVQ qualifications. This will encourage entry into the workforce and provide additional job opportunities within local employment markets.

Pharmacies will be encouraged to expand their businesses in a way that stimulates competition and rewards in providing the NHS, patients and the public with both quality and choice in the services offered.

13. Costs:

Economic

Greater flexibility offered to pharmacists on the personal supervision requirements will support pharmacists in providing the range of services within the new pharmacy contractual framework – securing high quality pharmacy services for the NHS, patients and the public. From April 2005, community pharmacy is expected to receive funding to deliver a wider range of services (a total investment of £1.7b for nationally specified services, with additional investment in England).

Relaxing the current requirements on community pharmacists does not impose additional costs on retail pharmacies. Rather it allows pharmacies greater flexibility to use the pharmacy workforce in a more cost effective way.

Environmental: Nil

Social: The social cost of continuing with the current legal framework on pharmacist supervision and dispensing as prescribed will increase, as these limit community pharmacy's ability to respond to changing health needs and their contribution in developing NHS public health and community healthcare services – particularly for older people and those with long-term medical conditions such as diabetes.

A Vision for Pharmacy in the new NHS, published in July 2003, sets out a programme to engage community pharmacists in working with other healthcare professionals, particularly GPs. For example, pharmacists have much to offer in developing accessible public health advice, clinical support for monitoring patients on long-term medication, and in reducing the burdens on GPs through repeat dispensing and the provision of advice and support in the treatment of minor ailments. To meet changing healthcare needs, pharmacy services need to be as flexible and diverse as the communities they serve.

Pharmacists also have an important role in supporting responsible self-care and encouraging people to take up healthier lifestyles – eg stopping smoking.

Currently, community pharmacy relies heavily on locum staff and pharmacists approaching retirement age. Failure to allow pharmacies to respond to modern pharmacy practice and make best use of pharmacist skills may result in fewer people entering the profession with increased pressures on the ability of pharmacies to recruit the professional staff they need to maintain their healthcare presence in the majority of communities.

Business Sectors Affected:

14. **Retail pharmacies:** There are 9,748 pharmacies in England providing NHS pharmaceutical services. There are also a small number of retail pharmacies not providing NHS services. Some of these are owned by large companies providing community pharmacy services as part of other retail services (eg Boots plc, Tesco plc, Asda etc), others by multiple chain retail pharmacy companies (eg Lloyds, Moss) and small retail pharmacy businesses owned by independent pharmacists.

Issues of Equity and Fairness

15. Retail pharmacies are not required to take up the proposed flexibilities on pharmacy supervision of the dispensing, sale and supply of prescribed medicines. Pharmacies will be free to use these in a way that best suits their business needs in providing NHS or private pharmaceutical services. Where pharmacies choose to do so, these flexibilities will support them in extending the range of pharmacy services offered under the new contractual framework for community pharmacists introduced from 2005.

16. An estimated 30% (around 2,800) of pharmacies have ethnic minority owners, with a substantial proportion of these pharmacies classified as small businesses. These pharmacy owners will be free – like other pharmacy businesses - to choose to take up the proposed regulatory changes at a time and pace that best suits their needs.

17. The changes will clarify the legal requirements relating to GSL medicines, placing pharmacies on an equal footing with other retail outlets.

Consultation with smaller businesses

18. Smaller retail pharmacy businesses were included in initial consultation on these proposals outlined in *A Vision for Pharmacy in the New NHS* – issued in July 2003. They will be included in further consultation on the detail of these proposals in December 2004.

19. Small retail pharmacy businesses (identified as independent pharmacies and chains with five or fewer pharmacies) are critical to the supply of NHS pharmaceutical services in England. In 1991, small businesses accounted for two thirds of all pharmacy contractors. By March 2002, this had fallen to under 50% - representing a trend towards greater market concentration due to mergers and takeovers and entry into the market of new low cost retailers and the expansion of supermarket pharmacies. By 2011, if this trend continues, some two thirds of pharmacies will be part of chains of 6 or more pharmacies. However, there is a view that smaller pharmacies can maintain business through stronger links with communities (particularly in deprived and rural areas) and the provision of pharmacist advice.

Competition Assessment:

20. The proposals to relax the legal requirements on pharmacist supervision and the dispensing of NHS prescriptions support the implementation of plans for NHS pharmacy services set out in *A Vision for Pharmacy in the New NHS*. Take up of these changes will not be mandatory but all pharmacies will be free to take advantage of these. Allowing pharmacists greater freedom in the supervision of other pharmacy staff and to be absent from pharmacy premises will help stimulate and support competition between pharmacies in competing for business from consumers, NHS patients and NHS organisations on the basis of the range and quality of services offered.

21. Generally, the retail pharmacy market is characterised by low levels of concentration and market power. There are many competing firms – both large and small – the top three chains are Boots the Chemist, Lloydspharmacy Ltd and Moss Pharmacy holding 27.8% of market share. There is little scope for competition on price, as NHS services account for the majority of business (dispensing NHS prescriptions accounts for around 80% of the turnover of the average, traditional, community pharmacy). The nature of demand means that consumers, patients and their carers expect to be able to access a range of suppliers speedily and conveniently – thus markets are likely to be localised. Retail pharmacies have competed for business mainly on location of pharmacy premises and, to a lesser extent, on service quality. In 2003, the Department of Health consulted on a range of measures to reform the current NHS (Pharmaceutical Services) Regulations 1992 and arrangements for "control of entry" to NHS lists of pharmaceutical service providers, as part of the Government response to the Office of Fair Trading (OFT) report on retail pharmacy. Although the OFT recommended full deregulation, in its response (published on 18 August 2003) the Government took the view that change needed to be look at in the broader context of the Government's plans for the NHS, including proposals for improving the range and quality of community pharmacy services set out in *A Vision for Pharmacy in the new NHS.*

22. There is unlikely to be an impact on other markets or other elements of the supply chain.

Enforcement and Sanctions:

23. Take up of the greater freedoms on supervision requirements will not be mandatory on pharmacies. Further consultation will seek views on other possible safeguards that may need to be in place to meet safety and quality assurance standards where pharmacy staff (other than pharmacists) dispense, sell and supply medicines and where the pharmacist is away from pharmacy premises. For example, the training requirements and qualifications for pharmacy staff taking on this work. Consultation will also seek views on the need to strengthen arrangements supporting remote supervision by a pharmacist (ie where a pharmacist is not physically present in the pharmacy but is able to maintain contact through links such as video). Such arrangements might include developing the current RPSGB Code of Ethics or a Code of Practice supported by a statutory framework.

24. RPSGB inspectors visit all pharmacies to ensure compliance with its professional code of ethics and guidance. Where necessary, the RPSGB takes disciplinary action against pharmacists and pharmacy owners who do not meet these requirements.

Monitoring and Review

25. The RPSGB will monitor and review take up of the proposed flexibilities in pharmacist supervision as part of its registration and inspection responsibilities. RPSGB inspectors undertake a rolling programme of visits to pharmacies. There is also scope for Primary Care Trusts to undertake a monitoring role as part of their responsibilities for commissioning healthcare services and in working with pharmacy contractors to ensure that NHS clinical governance arrangements are in place to assure the quality of NHS services. The Healthcare Commission also undertakes a rolling programme to assess clinical governance arrangements in the NHS.

Consultation:

26. The Department of Health is working with the Medicines and Healthcare products Regulatory Agency (which has statutory responsibilities under the Medicines Act 1968) and the UK Health Departments on the detailed proposals for consultation.

Summary and Recommendations

27. Option 2 is recommended, as this

- Removes unnecessary and outdated restrictions and burdens on pharmacy businesses
- Retains the legal and professional responsibilities of pharmacists in relation to the safe dispensing and sale of medicines
- Allows pharmacists and the NHS to make the best use of the skills and expertise acquired in lengthy and expensive training and encourages entry into the pharmacy profession
- Frees up pharmacist time from repetitive dispensing tasks to develop their clinical skills and to provide a wider range of services to patients and the public (eg public health advice, medicines management)
- Supports better and more effective use of other pharmacy staff, such as pharmacy technicians, including an enhanced role and responsibilities supported by recognised training qualification.
- Supports the development of high quality NHS community pharmacy services with improved access and choice to healthcare services for patients and the public
- Provides more and better job opportunities for local employment markets
- Encourages greater competition amongst pharmacies on the basis of the quality and range of services offered to the NHS, patients and the public
- Enable pharmacies to compete more freely with other retailers on the sale of GSL medicines

Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed:
Date:
Ministers Name, Title
Department of Health

Contact Point: Dr Jim Smith: Chief Pharmaceutical Officer: Department of Health. Jim.Smith@dh.gsi.gov.uk

CODE OF PRACTICE ON CONSULTATION **ANNEX B**

This further consultation follows earlier consultation in *Pharmacy Workforce in the New NHS* (September 2002) and *A Vision for Pharmacy in the New NHS* (July 2003) on making the best use of the pharmacy workforce. The Department of Health published a summary of the responses to *A Vision for Pharmacy* on 2 March 2004. This is available on the Department of Health Website at:

www.dh.gov.uk/Consultations/ResponsestoConsultations/fs/en

The paper takes account of the responses received to earlier consultation.

Any complaint about aspects of this consultation should be sent to:

Steve Wells
Consultations Co-ordinator
Department of Health
Skipton House
80 London Road
LONDON SE1 6LH

e-mail: Steve.Wells@dh.gsi.gov.uk

Below are the six criteria set out in the Cabinet Office Good Practice Guide on Consultation:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.

2. Be clear about your proposals, who may be affected, what questions are being asked, and the timescale for responses.

3. Ensure that your consultation is clear, concise and widely accessible.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.

5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

THE LAW RELATING TO SUPERVISION ANNEX C

1. Section 7 of the Medicines Act 1968 set out requirements for medicinal products to have product licences. Section 8 requires a licence to be held for the manufacture of medicines and for licences to be held by medicines wholesalers. Section 10 sets out exemptions to these requirements and, broadly, these are relevant to dispensing (including extemporaneous dispensing) which involves some element of preparation of the product and which is carried out in pharmacies, hospitals or health centres by or under the supervision of a pharmacist.

2. Section 52 of the Medicines Act 1968 provides for the supply of medicines (other than general sale list medicines) only from pharmacies, by or under the supervision of a registered pharmacist. (Section 52 does not apply to hospital dispensing, and in some circumstances to health professionals such as doctors, dentists and vets, but it applies to the sale of pharmacy only medicines from hospital pharmacies.)

3. Section 43(2) of the National Health Service Act 1977 (which applies to England and Wales) requires, amongst other things, that the dispensing of NHS prescriptions in community pharmacies to be carried out either by or under the direct supervision of a pharmacist.

THE LAW RELATING TO PERSONAL CONTROL

4. Section 70 of the Medicines Act 1968 states that a retail pharmacy business, as far as the sale or supply of medicinal products (whether or not these are on the general sales list) is concerned, must be under the personal control of the pharmacist carrying on the business or another pharmacist. Further, the name and registration certificate of the pharmacist in personal control must be conspicuously displayed in the pharmacy.

   Section 71 of the Act provides that where retail pharmacy business relating to the sale or supply of medicinal products (whether or not these are on the general sales list) is concerned, is not under the personal control of a superintendent pharmacist, it may be carried out under the personal control of a manager or assistant who is a pharmacist.