

HEALTH BILL INFORMATION PAPER: MEDICINES AND PHARMACIES: MAKING THE BEST USE OF THE PHARMACY WORKFORCE

INTRODUCTION

1. This paper provides information on the matters that may be included in the regulations made following changes to the Medicines Act 1968 and related NHS legislation in the Health Bill. The legal framework surrounding the sale and supply of medicines by pharmacists from pharmacies is complex and the intention of this paper is to give a fuller picture of the possible exercise of the new provisions within the Health Bill. Further discussion and consultation with key stakeholders will inform the development of the detailed provisions in these regulations.

Background

2. The Government has a long-standing commitment to provide for greater flexibility in the working arrangements for health professionals. For pharmacy, this is set out in plans for improving NHS pharmacy services issued by the four UK Health Departments (see below).

3. Pharmacists have extensive training in the actions, uses and side effects of medicines and they have an important role and contribution to make in improving services for patients in hospitals and in the community. Pharmacists and their staff can also help tackle health inequalities and help people live healthier lives. In particular, pharmacists have a long tradition of providing the public with readily accessible, professional, advice in the community – for example, on the high street and in shopping centres.

4. Community pharmacies can offer more than the safe and efficient dispensing of NHS prescriptions and the sale of medicines. Other services might include, for example, providing clinical advice to patients experiencing problems in using their medicines, diagnostic testing (eg ensuring the right dose of a medicine to slow the clotting rate of blood) and advice on healthier lifestyles such as stopping smoking. Improving the range of services offered from pharmacies requires the effective use of all staff working in pharmacies – pharmacists, pharmacy technicians, dispensing assistants, counter assistants and others.

Plans for improving and modernising NHS pharmacy services

5. The four UK Health Departments continue to develop and update plans for improving NHS pharmacy services, including how best to develop the potential for pharmacists to expand the range of services available to patients.

6. In September 2002, the Department of Health published a paper *Pharmacy Workforce in the new NHS*, which set out options (also adopted by the Welsh Assembly Government) for making better use of pharmacy staff. In July 2003, the Department of Health paper, *A Vision for Pharmacy in the new NHS*, stated that it was consistent with the need to safeguard the public for the pharmacist to retain responsibility for ensuring that procedures for the safe sale and supply of medicines are in place in the pharmacy. However, it also put forward the view that the pharmacist did not need at all times to

supervise, personally, registered pharmacy technicians undertaking these activities. In December 2003, a further paper (*Building on the Best – Choice, Responsiveness and Equality in the NHS*) drew attention to the expanding role of pharmacists in providing services other than the dispensing of prescriptions and the retail sale of medicines.

7. In 2000, *Our National Health: a Plan for Action, a Plan for Change* was published in Scotland, followed in 2002 by *The Right Medicine: A Strategy for Pharmaceutical Care in Scotland* which set out plans for modernising pharmacy services. The 2002 paper made a specific commitment to review the provision of community pharmacy services in Scotland to examine how more effective use could be made of the skills and training of pharmacy technicians, dispensers and pharmacy assistants.

8. In January 2001, the National Assembly for Wales published plans for the future development of NHS services in Wales – *Improving Health in Wales: a Plan for the NHS with its Partners*. Amongst other things, the Plan highlighted the need to develop more responsive and flexible community pharmacy services, better integrated with other primary care and community health services. In 2002, the paper, *Remedies for Success: a Strategy for Pharmacy in Wales* outlined the need to make better use of the complementary skills of those working in pharmacies, developing their role and contribution to support improvements in services for patients.

9. In 2004, the Department of Health, Social Services and Public Safety (DHSSPSNI) published *Investing for Health – a plan for improving health in Northern Ireland*. In 2004, a further paper, *Making It Better – a Strategy for Pharmacy in the Community*, set out a strategy for pharmacy that builds on its traditional role whilst making better use of the pharmacist's clinical skills and training, including his contribution as a member of the wider community health team. *A Healthier Future* (2005) examined new demands and opportunities for the provision of modern, integrated services in Northern Ireland over the next twenty years. Following this paper, the DHSSPSNI published, in October 2005, a strategic framework for developing primary health and social care, including emphasis on a team approach that made better use of professional skills in meeting the needs of the population.

Public Consultation on Making Better Use of Pharmacists and Others working in Pharmacies

10. Detailed proposals for the better use of staff working in pharmacies are set out in the consultation paper, *Making the Best Use of the Pharmacy Workforce*, published on 13 December 2004 in England, on 2 February 2005 in Scotland and on 1 April 2005 in Northern Ireland. The paper published in England also formed the basis of consultation by the National Assembly for Wales.

11. The responses to consultation demonstrated strong and clear support for changes to the Medicines Act 1968 and related NHS legislation to allow pharmacies and pharmacists to make better use of the skills and training of those working in pharmacies. Some 75% of respondents called for greater clarity on the Medicines Act requirement that each pharmacy must be under the personal control of a pharmacist insofar as this concerns the sale and supply of medicines. On the supervision requirements in the Medicines Act and NHS legislation, 80% of respondents felt there was a need for change - to reflect modern pharmacy practice and the increasing availability of modern

technologies, and to remove constraints on pharmacists in offering services other than the dispensing and sale of medicines.

12. The changes to the Medicines Act 1968 and related NHS legislation, which form part of the Health Bill, reflect the response to consultation across the four parts of the United Kingdom.

WHY CHANGE?

13. Changes to the Medicines Act requirement for a pharmacist to be in personal control of the pharmacy and for pharmacist supervision of the preparation, sale and dispensing of medicines, and related supervision requirements in NHS legislation, will

- continue to support the safe, efficient sale and supply of medicines to the public – public safety remains paramount
- update current legislation to reflect modern pharmacy practice (eg less preparation of medicines in the pharmacy) and the increasing availability of new technologies that can be used to support safe dispensing (eg electronic prescribing, barcodes and the use of robotics in selecting prescribed medicines)
- free up the pharmacist from the dispensing bench allowing him to use his clinical skills to offer other services to patients and the public
- allow more effective use of other staff working in the pharmacy – for example, an enhanced role for pharmacy technicians
- clarify the role of the pharmacist (“the responsible pharmacist”) in charge of the pharmacy by setting out his responsibilities for the safe and effective running of the pharmacy
- support plans for improving and modernising NHS pharmacy services, including through the introduction of the new contract for pharmacy services (from 1 April 2005 in England and Wales, from 1 April 2006 in Scotland and in the future in Northern Ireland)
- improve patient access to professional advice on the high street and to a wider range of services available in community pharmacies

14. An electronic copy of the Health Bill, introduced in the House of Commons on 27 October 2005, is available, together with Explanatory Notes prepared by the Department of Health to assist readers of the Bill, at

<http://www.publications.parliament.uk/pa/cm200506/cmbills/069/2006069.pdf>

or

<http://www.publications.parliament.uk/pa/cm200506/cmbills/069/2006069.htm>

or

<http://www.dh.gov.uk/PublicationsAndStatistics/Legislation/ActsAndBills/fs/en>

WHAT WILL CHANGE?

The Responsible Pharmacist

15. The Health Bill removes the requirement in Sections 70 to 72 of the Medicines Act 1968 for each pharmacy to be under the personal control of a pharmacist and replaces this with a new requirement for each set of pharmacy premises to have a “responsible pharmacist” in charge of the business of the retail sale or supply of medicines. In addition, the Bill will insert a new section into the Act, which places a statutory duty on the responsible pharmacist to secure the safe and effective running of the pharmacy.

The Duty on the Responsible Pharmacist

16. The Medicines Act 1968 does not define “personal control” nor does it set out how the pharmacist is to exercise control. In response to public consultation, 75% of respondents wished to see greater clarity as to how the pharmacist in charge of the pharmacy is to exercise his responsibilities. It is felt that the current “personal control” requirement is too open to differences in interpretation. In addition, it is felt that the common interpretation of this requirement, that the pharmacist must be physically present in the pharmacy at all times in order to exercise control, constrains the pharmacist in his ability to offer services away from the pharmacy – for example, in GP practices and clinics.

17. The requirement for a responsible pharmacist continues to ensure that the responsible pharmacist is legally responsible for everything that goes on in the pharmacy through a duty to secure the safe and effective running of the pharmacy. In exercising that duty, it is proposed that the responsible pharmacist

- May not be responsible for more than one pharmacy at any one time except in specified circumstances
- Must establish, maintain and review procedures (eg Standing Operating Procedures (SOPs)) that determine how activities are to be carried out in the pharmacy
- Must keep and maintain a record, at the pharmacy premises, of the responsible pharmacist for that pharmacy on any day and at any time.

One Pharmacy, One Responsible Pharmacist

18. Generally, the Government believes that the “rule” should be that a pharmacist should only be the responsible pharmacist for one registered pharmacy at any one time so that he is able to discharge these important duties fully and effectively to secure a safe service to the public. However, the Government recognises that, in the future, circumstances may arise where it may be sensible to make an exception to this general “rule”. Although exceptional, the Government believes that there should be sufficient flexibility to allow such circumstances to be considered and, where necessary, a response to be made if and as these arise.

19. For example, in the future, a responsible pharmacist might control a vending machine that supplies certain medicines in another location. This type of vending system is already available in parts of Australia, particularly remote areas. It enables

pharmacy customers to have their prescriptions dispensed or to purchase pharmacy medicines, and for these transactions to be controlled by the pharmacist. Such a vending machine will need to be located in premises that are registered as a pharmacy. Another example might be the provision of over the counter medicines to members of the public attending a large event that extends over several days. Such events already take place each summer. Pharmacy technicians and other pharmacy staff might provide this limited service, working in accordance with procedures for safe working set down by the pharmacist responsible for a pharmacy in a nearby village or town – who would also be responsible for the pharmacy service on the event site. The intention is that regulations will make clear to pharmacy owners, the responsible pharmacist, and others the circumstances and the conditions that must be met to permit a responsible pharmacist to take on responsibility for another pharmacy at the same time.

Exception to One Pharmacy, One Responsible Pharmacist

20. Importantly, the Government believes that the circumstances and conditions that might permit a responsible pharmacist to be responsible for more than one pharmacy at any one time must continue to ensure the safe sale and supply of medicines to the public from each registered pharmacy for which the pharmacist is responsible. It is also the Government's view that there is a need to ensure that these do not over stretch the responsible pharmacist's ability to exercise his duty for the safe and effective running of each pharmacy.

21. For example, these circumstances and conditions might include

- The ability of the responsible pharmacist to exercise his duties effectively in relation to each set of premises for which he is responsible – that is, in maintaining the safe sale and supply of medicines to the public.
- The extent to which the responsible pharmacist may be engaged in the provision of a range of other services from the pharmacies, other than the sale and supply of medicines, and the possible impact on his capacity/ability to exercise his responsibilities effectively in more than one pharmacy.
- Whether there is a need to limit the period for which a pharmacist may exercise responsibility for more than one pharmacy at any one time.
- That where a pharmacist is responsible for more than one pharmacy, whether the pharmacies concerned should be owned and managed by the same partnership or company
- That where a pharmacist is responsible for more than one pharmacy, each pharmacy should employ certain registered and suitably trained pharmacy staff – for example, a pharmacy technician or other specified health professional
- That a pharmacist might be limited as to the number of pharmacies for which he may be responsible at any one time to, say, two pharmacies.

22. If such circumstances arise, and subject to requirements to meet specified conditions set out in regulations, there is also a need to consider arrangements that allow a pharmacist responsible for one pharmacy to assume responsibility for another pharmacy at the same time. For example, one option might be that the pharmacy owner could be required to give notice that the pharmacist responsible for one pharmacy is to assume responsibility for another pharmacy at the same time. And that such notice may be given to the Royal Pharmaceutical Society of Great Britain Inspectorate or, in Northern Ireland, to the Pharmaceutical Inspectorate so arrangements can be made to ensure these circumstances meet the required conditions. As now, any failure to notify these circumstances or action by a pharmacy owner to appoint a responsible pharmacist for more than one pharmacy in circumstances not meeting these tightly drawn conditions could result in the removal of the pharmacy premises from the register.

23. The Government intends to discuss and consult further with key stakeholders on these and other proposals to ensure that the specified circumstances and conditions, allowing a responsible pharmacist to be responsible for more than one pharmacy, included in the regulations strike the right balance.

General Sale List (GSL) Medicines

24. The lack of clarity in the current “personal control” requirement in the Medicines Act 1968 has led to the common interpretation that the exercise of control in relation to the sale and supply of medicines from the pharmacy requires a pharmacist to be physically present in the pharmacy at all times. There is no specific requirement in the Medicines Act 1968 relating to pharmacist supervision of the sale of general sale list medicines. However, the current uncertainty about the exercise of the personal control requirement means that pharmacies allow sale of general sale list (GSL) medicines only when the pharmacist is present in the pharmacy. This has led to an anomaly as the public may purchase these medicines from other retail outlets (such as a newsagent or garage shop) without the need for a pharmacist to be present.

25. The new requirement for each pharmacy to have a responsible pharmacist and the greater clarity in how he is to exercise his responsibilities will end such uncertainty. It will be for the responsible pharmacist to decide whether general sale list medicines may be sold from the pharmacy when he is not present but we anticipate that most responsible pharmacists will decide to permit this. Thus, when the pharmacist is not present, someone wishing to buy general sale list medicines will no longer have to visit another pharmacy. This greater clarity will place pharmacies on a more equal footing with other retail outlets selling GSL medicines.

26. However, in choosing to buy general sale list medicines from a pharmacy, the public expects advice to be available on the use of these medicines and it is the Government’s view that the responsible pharmacist should include arrangements for the sale of GSL medicines in the procedures for the safe running of the pharmacy. For example, procedures that guide pharmacy staff as to the way in which they should offer advice to pharmacy customers and when they may need to seek further advice from the pharmacist.

The Conditions Applying to the Responsible Pharmacist

Qualifications and Experience

27. The Health Bill sets out that one of the conditions supporting the responsible pharmacist requirement might relate to the qualifications and experience needed to be a responsible pharmacist. For example, this might mean someone who has been qualified as a registered pharmacist for a number of years and for a community pharmacy someone who has experience of working in a registered pharmacy in that setting. The Government recognises that it would be helpful to consider the timing of introducing such regulations to allow the professional regulatory bodies, pharmacy owners, and others to put in place arrangements that ensure that those wishing to become responsible pharmacists have the experience and training to take on this important role. The intention is to consult with stakeholders on these regulations, including discussion of training requirements.

Absence from the Pharmacy

28. The aim of changes to the “personal control” requirement in the Medicines Act is to clarify the pharmacist’s ability to leave the pharmacy premises – that the safe and effective running of the pharmacy is not wholly dependent on his physical presence in the pharmacy at all times. Thus, the pharmacist in charge of the pharmacy – the responsible pharmacist – will be able to offer pharmacy services away from the pharmacy, including in patients’ homes, and to work with other health professionals in providing health services in the community.

29. The Government recognises concerns that allowing the pharmacist to be absent may lead to circumstances where a pharmacy is operating for unreasonable periods without a pharmacist present. The Government intends to set out in regulations the conditions that must be met to allow the pharmacist to be absent from the pharmacy. It is the Government’s view that the responsible pharmacist should consider the pharmacy to be his main place of work and he should spend the majority of his time there if he is to exercise his responsibilities as required. Therefore, the Government believes the regulations relating to the responsible pharmacist’s absence need to be tightly drawn. At the same time, these should ensure that there is a balance between allowing the responsible pharmacist sufficient time and flexibility to offer other services away from the pharmacy and the exercise of his statutory duty for safe and effective working in the pharmacy.

30. Many of those responding to public consultation on this issue recognised the need for this balance. Therefore, the Government believes that, to some extent, the responsible pharmacist must be able to judge when and for how long he may be absent from the pharmacy on any working day, in the light of his statutory duty as the responsible pharmacist and his knowledge of the pharmacy business. However, the Government also believes that there is a need for clarity on the conditions that might support absence and intends to consult with the pharmacy profession and other interested parties as to what these might be. For example, these might include limitations on the length of time that the responsible pharmacist may be absent from the pharmacy and arrangements for the responsible pharmacist to remain contactable by pharmacy staff in order to provide advice, as required.

Pharmacy Procedures

31. In exercising his responsibilities, the responsible pharmacist is required to establish, maintain and review procedures for the safe and effective running of the pharmacy. Whilst allowing the responsible pharmacist sufficient flexibility to address the operational needs of the individual pharmacy in such procedures, the Government believes that some consistency in their format will be helpful to those consulting them. For example, an incoming responsible pharmacist wishing to assess the content and comprehensiveness of the procedures in the pharmacy or those with responsibilities for standards of pharmacy practice who wish to inspect these procedures.

32. Generally, it is the Government's view that pharmacy procedures should reflect guidance issued by the UK professional regulatory bodies (for example, the Royal Pharmaceutical Society's guidance on the development of Standard Operating Procedures (SOPs) to support safe working in the pharmacy) and guidance and other information provided by the superintendent pharmacist or pharmacy owner. It would be reasonable to expect such procedures to include matters relating to operational systems that support safe working in the pharmacy and the provision of services from the pharmacy (for example, where a pharmacy delivers prescriptions to patients' homes). These might also include the activities in the pharmacy that may be undertaken by specified staff working in the pharmacy, who have particular levels of training and competence, and the arrangements for contacting the responsible pharmacist when he is absent from the pharmacy.

33. There is recognition that the pharmacist responsible for a pharmacy may change during the working day, when the pharmacy is open to the public. For example, where a pharmacy is open for extended hours, the pharmacist responsible for the pharmacy may handover to another responsible pharmacist at some time – using a shift pattern of working. Or a locum pharmacist might take on responsibility for the pharmacy for the whole or part of a working day. However, the Government believes that when a pharmacist becomes the responsible pharmacist for a pharmacy, he should consider the appropriateness of the pharmacy procedures and the need for any changes, taking into account his knowledge of the pharmacy business in question and the skills and experience of pharmacy staff working in the pharmacy. If the incoming responsible pharmacist considers changes are required to the pharmacy procedures, the Government view is that he should note the changes in the written procedures and should keep pharmacy staff informed of these - in particular, where these affect the activities and responsibilities of individual staff working in the pharmacy.

34. The Government intends to consult all those with an interest as to the matters that might be included in the pharmacy procedures and the requirements that might support the establishment, maintenance and review of these procedures.

Pharmacy Record

35. In exercising his duty, the responsible pharmacist is required to keep a record of the responsible pharmacist for the pharmacy in question on any day and at any time. The Government believes the pharmacy record will be an important document. For example, it will support clarification as to the pharmacist in charge of the pharmacy where there has been an adverse incident in the pharmacy or where there is a complaint about

services provided by the pharmacy or the safe and effective running of the pharmacy. Here, too, the Government is of the view that a consistent format for the record will help support the responsible pharmacist in keeping the record and those consulting the record so that they can readily assess information noted in the record. The Government intends to consult on the matters that might be included in the record. For example, these might include the name and registration number of the responsible pharmacist, the date and time that the responsible pharmacist assumed responsibility for the safe and effective running of the pharmacy, the date and time when the responsible pharmacist ceased to be the responsible pharmacist and information relating to the inspection of the record.

36. The Health Bill also introduces a requirement on the pharmacy owner to ensure that the responsible pharmacist properly maintains and preserves the record held in each pharmacy and for regulations to specify the length of time in which the record is to be preserved. The Government's present view is that preservation of the record for a period of five years should allow sufficient time to consult the record when considering any failure to meet this requirement. For example, where the responsible pharmacist has failed to exercise his statutory duty or where the pharmacy owner has not complied with the requirement to ensure proper maintenance of the record.

Identifying the Responsible Pharmacist

37. Changes to the "personal control" requirement also provide an opportunity to change the requirement on the pharmacist in personal control of the pharmacy to display his registration certificate, conspicuously, in the pharmacy. In practice, although not required to do so, most – if not all - pharmacists display their registration certificates in the pharmacy even when they are not the pharmacist in charge. Where more than one pharmacist is working in the pharmacy, it may be particularly difficult for the public and others, to identify the responsible pharmacist. Therefore, this requirement will change. Instead, the Health Bill makes provision for the responsible pharmacist to be required to display a notice, conspicuously, in the pharmacy stating that he is the pharmacist in charge of the pharmacy on that particular day and time, together with details of his registration number.

Pharmacist Supervision of the Preparation, Sale and Supply of Medicines from the Pharmacy

38. Good practice guidelines are already available to support pharmacists in meeting the supervision requirements in the Medicines Act 1968 and NHS legislation. The Health Bill will introduce regulation making powers to enable the Secretary of State to clarify what a pharmacist must do in order to discharge the requirements in section 10 and section 52 of the Medicines Act – that is, the pharmacist's obligation to supervise the preparation, assembly, sale and supply of medicines. The intention is that regulations, following the changes in the Medicine Act and related NHS legislation, will also make clear the circumstances and the conditions that will enable the pharmacist to delegate to staff working in the pharmacy certain activities supporting the preparation, assembly, dispensing and sale of medicines acting under the pharmacist's general supervision. This will clarify the law, ensuring that the pharmacist will have greater flexibility to use his time and clinical expertise to offer other services (for example, professional advice to patients on the most effective use of their prescribed medicines) whilst maintaining a safe, effective and efficient dispensing service to the public.

39. The Government believes that it remains important for the pharmacist to undertake the clinical assessment of each new prescription and to approve the formulation or specification of a medicinal product to be prepared in the pharmacy. However, the Government also believes that the pharmacist should be able to utilise fully the skills and experience of pharmacy staff to supervise or undertake other elements of dispensing activity without the need for his personal supervision at all times. This might include, for example, such activities as the selection of medicines from pharmacy shelves and the printing and labelling of prescribed medicines. In this way, the pharmacist will be able to make use of his time to offer other services from the pharmacy, including where this is in partnership with other health professionals, such as GPs and community nurses.

40. It is the Government's view that certain conditions should be in place in the pharmacy to support the responsible pharmacist's decision to allocate certain activities relating to the preparation, assembly, sale and supply of medicines to pharmacy staff. The responsible pharmacist will be required to establish (if these are not already available) procedures in the pharmacy to secure the safe and effective working of the pharmacy. There is also to be a requirement to maintain and review pharmacy procedures to reflect any changes in the pharmacy. (For example, changes in the availability of suitably trained pharmacy staff). Generally, the Government believes that these conditions, set out in regulations, should include requirements that pharmacy staff work in accordance with written pharmacy procedures and that the responsible pharmacist is satisfied that pharmacy staff are trained and competent to take on the tasks allocated to them. It may be that the responsible pharmacist chooses to limit the types of activity undertaken by pharmacy staff. For example, he may wish to set out in his written procedures that only named pharmacy staff may be involved in arrangements within the pharmacy for the safe and effective handling of certain controlled drugs.

Activities reserved for the Pharmacist

41. It is the Government's present intention that the pharmacist should continue to undertake certain activities in the pharmacy, including

- The clinical assessment of a new prescription or a repeat prescription where there has been a change to one or more of the patient's medicines or the patient's condition has materially changed in some way – for example, where a patient reports that an asthma inhaler is not controlling his wheezing as well as before
- The approval of any formulation/specification of a medicinal product before allocating preparation to a suitably trained member of pharmacy staff, such as a pharmacy technician.

Remote Supervision by the Pharmacist

42. There are uncertainties about the current "personal control" requirement. The Medicines Act says nothing as to the exercise of this requirement, but the common interpretation is that the pharmacist in charge of the pharmacy must be physically present in the pharmacy in order to maintain control. This ties the pharmacist to the pharmacy premises. The intention is to replace this with a requirement that each pharmacy should have a responsible pharmacist and to clarify how he may exercise his

duty to secure the safe and effective running of the pharmacy, including where he is absent from the pharmacy.

43. In the case of *Roberts v Littlewoods* (1943), the judge commented that a pharmacist might supervise the sale of a medicine “without being bodily present” and that this would be possible with the mechanical assistance of a telephone or “something of that sort”. Given the judge’s comments in this case and the changes put forward in the Health Bill to clarify the pharmacist’s ability to leave the pharmacy, the Government believes there is a need to consider the range of modern technology that is available now – and in the future - which pharmacists might use to support supervision from another location – ie remotely. It is the Government’s view that, in most cases, use of a telephone alone would be inappropriate in meeting the supervision requirements. The pharmacist will be unable to see the product being dispensed and will be reliant on pharmacy staff to provide details over the telephone which he is unable to check.

44. It is likely that the development of appropriate new technologies (such as bar coding, robotics and video links) will continue to advance at a rapid pace and that these will be increasingly used in pharmacies to support the safe and efficient dispensing of medicines. Additionally, pharmacists will make use of electronic access to prescriptions and other systems that are becoming available in pharmacies to support the delivery of improved services to patients. These developments can support the pharmacist in exercising his supervision responsibilities where he is not located in the pharmacy. It is the Government’s view that it seems sensible to make provision now to set out the circumstances and conditions for use of modern technologies. For example, allowing a pharmacist to supervise activities in a limited number of pharmacies from a remote location and setting out use of appropriate technologies, which allow face-to-face contact with pharmacy staff and patients where necessary. The Government is also of the view that setting these out in regulations (rather than on the face of the Bill) will allow these to take into account the rapid pace of change in this area. However, the Government intends to consult all those with an interest on the conditions supporting remote supervision.

45. The Government believes that the ability to supervise activities in the pharmacy from another location should be for the pharmacist only. That the time is not yet right to consider whether other health professionals working in a pharmacy may undertake remote supervision. There needs to be time to allow pharmacists to make use of the new provisions relating to supervision and for pharmacy staff to develop any enhanced role they take on in the pharmacy. There is also a need to take account of the continuing development of new technologies that support supervision in this way.

Delegation of Supervision to Suitably Trained and Registered Health Professionals working in the Pharmacy

46. In conjunction with the changes introduced by the Health Bill, it is also proposed to utilise existing powers in the Medicines Act 1968, to allow the responsible pharmacist to delegate the supervision of certain activities to suitably trained and registered health professionals, such as suitably trained and registered pharmacy technicians, without the personal supervision of a pharmacist. For example, supervision of the dispensing of a repeat prescription, where there has been no change to the patient’s medicines or material change to the patient’s condition, could be delegated to a suitably trained and

registered pharmacy technician. It is the intention to enable these staff to supervise activities in the pharmacy, subject to certain conditions set out in regulations.

47. It is the Government's view that it is for the pharmacist in charge of the pharmacy, within the limits set out in regulations, to decide where suitably trained and registered health professionals may supervise activities in the pharmacy, in the light of the written procedures he has set down for the safe and effective running of the pharmacy. The Government is also of the view that the responsible pharmacist will need to be satisfied as to the training and experience of staff carrying out this task. However, in addition, the responsible pharmacist may wish to exercise other options. For example, he may wish to limit the extent to which he gives authority to a registered health professional working in the pharmacy to supervise or undertake certain activities in the pharmacy. This may be where he gives authority only to the extent that the health professional carries out the specific activity personally and does not delegate this to another person. However, regulations may set out that only a suitably trained and experienced pharmacy technician may undertake the preparation of a medicinal product in the pharmacy without the supervision of a pharmacist.

48. The responsible pharmacist may also wish to limit the types of activity undertaken by other pharmacy staff, when supervised by a suitably trained and registered health professional. For example, he may wish to set out in his written procedures that only named pharmacy staff may sell certain pharmacy medicines to the public and that the sale is subject to these staff posing appropriate and relevant questions to the customer to establish that the medicines are not resulting in ill effects.

49. The Government intends to consult with all interested parties on what conditions may be set out in regulations, including for example

- Where the pharmacist, personally, is to undertake certain activities
- The extent to which a pharmacist may delegate to pharmacy staff aspects of activities carried out under his supervision
- Where suitably trained and registered health professionals, such as pharmacy technicians, working in the pharmacy may supervise certain activities involving the preparation, sale and supply of medicines from the pharmacy, in place of the pharmacist.

NHS Legislation

50. The NHS Act 1977 (England and Wales) requires all medicines supplied on NHS prescriptions through pharmacies to be dispensed either by or under the direct supervision of a pharmacist. The Health Bill provides for the removal of the word "direct" bringing the supervision requirements in the 1977 Act into line with the Medicines Act 1968. In addition, the regulation making powers under the NHS Act 1977 will be modified to make clear that exceptions might be created in these regulations to the requirement for supervision of dispensing by a registered pharmacist. This will allow the NHS legislation to reflect the changes in the Medicines Act that will enable the responsible pharmacist to allocate supervision of the sale and supply of medicines to a suitably trained and registered health professional. However, it is the Government's view that the dispensing of general sale list medicines on an NHS

prescription will need to continue, as now, to be supervised on the same basis as Pharmacy (P) medicines and Prescription Only Medicines (POMs). The Government believes that it is important that the pharmacist's clinical assessment include the appropriateness of the whole prescription that a patient is receiving – not just part of the treatment – to ensure, for example, there are no interactions between the different medicines.

51. There is also provision in the Health Bill for changes to the National Health Service (Scotland) Act 1978 to enable Scottish Ministers to set out, in regulations, the circumstances and conditions in relation to the supervision of dispensing by pharmacists in Scotland who provide NHS services under a Pharmaceutical Care Services (PCS) contract and exceptions to these requirements.

52. No changes are required to primary NHS legislation in Northern Ireland as currently there is no specific requirement in that legislation for NHS prescriptions to be dispensed under the supervision of a registered pharmacist. However, there will be changes to secondary legislation in line with the changes outlined above.

CONSULTATION

53. The Medicines Act 1968 requires there to be consultation on the provision of or changes to regulation and order making powers. Subject to Parliament's scrutiny of the provisions in the Health Bill relating to pharmacy, pharmacists and the sale and supply of medicines, the Government intends to consult with interested parties on the details within regulations. At this stage, the Government recognises that it would be helpful to set out what might be included in the regulations relating to the responsible pharmacist and the supervision of the preparation, sale and supply of medicines by someone other than a pharmacist or remotely by the pharmacist. This information paper outlines the matters that may be included in regulations as a starting point for further work and discussion on how these might be developed.