CHAPTER SEVEN

Pharmacists and Pharmacies

Legislation

7.1 The statutes governing the practice of pharmacy are the Pharmacy Act 1954, the Medicines Act 1968 and the Poisons Act 1972. The Misuse of Drugs Act 1971, the Misuse of Drugs Regulations (MDR) 2001 and the Misuse of Drugs (Safe Custody) Regulations 1973 (the Safe Custody Regulations) govern the way in which pharmacists deal with controlled drugs.

7.2 The legal basis for the provision of NHS pharmaceutical services in the community, including the dispensing of NHS prescriptions, is set out in sections 41 and 43 of Part II of the National Health Service Act 1977 (as amended), and in the NHS (Pharmaceutical Services) Regulations 1992, as amended. These Regulations require primary care organisations (then health authorities now primary care trusts (PCTs)) to provide NHS pharmaceutical services, mainly by contractual arrangements with pharmacists.

The Royal Pharmaceutical Society of Great Britain

7.3 The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for the pharmaceutical profession in Great Britain. As I said in Chapter Three, the RPSGB was originally granted a Royal Charter in 1843. In 1953, a Supplemental Charter was granted which still governs the Society today. The Council of the RPSGB has recently petitioned the Privy Council for the grant of a new Royal Charter. The objects of the RPSGB are to advance chemistry and pharmacy, to promote pharmaceutical education and the application of pharmaceutical knowledge, to maintain the honour and to safeguard and promote the interests of its members in their exercise of the profession of pharmacy and to provide relief for distressed persons in certain circumstances.

7.4 As a professional body, the RPSGB leads and develops the profession. As a regulator, it is responsible for maintaining the register of pharmacists, for assuring competence and fitness to practise, for setting standards for education and practice and for disciplining pharmacists who breach the standards set. It combines these functions with a statutory enforcement role, exercising law enforcement functions under the Medicines Act 1968 and the Poisons Act 1972.

7.5 Pharmacy is the only self-regulated profession with its own inspectorate. The RPSGB employs 18 full-time inspectors, who operate on a regional basis and carry out periodic inspections of all community pharmacies. I shall explain their role in the inspection of community pharmacies in Chapter Nine.

7.6 The Inquiry received valuable assistance from the RPSGB and, in particular, from two of its officers. Mr Stephen Lutener, who was Head of Professional Conduct when he left the Society in 2003, gave oral evidence and provided the Inquiry with much relevant material. Miss Mandie Lavin, Director of Fitness to Practise and Legal Affairs, represented the RPSGB at the seminars and I was greatly assisted by her contributions.

7.7 Most of the income of the RPSGB comes from membership subscriptions and the profits from its publications. The 2004 annual retention fee for a full-time pharmacist is £205 and for pharmacy premises is £125 per year. The Society receives a contribution from the Department of Health (DoH) towards the cost of enforcing certain provisions of the Medicines Act 1968.

The Register of Pharmaceutical Chemists

7.8 The Pharmacy Act 1954 imposes a duty on the RPSGB to maintain a register of pharmaceutical chemists, and to determine eligibility for admission to the register by setting examinations and determining the conditions and qualifications required for registration. A 'pharmacist' is defined in section 132(1) of the Medicines Act 1968 as a person being on the register maintained under the Pharmacy Act 1954. All pharmacists wishing to practise in Great Britain must, therefore, be on the register.

7.9 The RPSGB publishes on its website a list of all pharmacists on the register, with information about their professional status. Some 23,000 members work in community pharmacies, with about 6000 employed in hospital pharmacies and about 2000 in the pharmaceutical industry. All registered pharmacists have a registration certificate issued by the RPSGB, which must be displayed in the community pharmacy where the pharmacist is working. All registered pharmacists are subject to the RPSGB Code of Ethics, the standards of professional performance to be observed by its members and its disciplinary jurisdiction.

Training and Qualifications of Pharmacists

7.10 The educational and training requirements for pharmacists have increased significantly over the last three decades. Prior to 1970, many pharmacists gained their qualification by undertaking a period of apprenticeship and college training and by passing the RPSGB examinations. With the expansion of tertiary education in the 1960s, it became increasingly common for aspiring pharmacists to undertake a degree course in pharmacy. In 1970, the RPSGB made entry to the profession conditional upon such a qualification. After 1970, pharmacy graduates were additionally required to undertake 12 months' experience in a pharmacy prior to registration.

7.11 By the early 1980s, the RPSGB had begun to specify the content of the pre-registration training, and quarterly reporting by tutors on trainees' progress was introduced. Since 1993, all applicants have been required to pass a formal written examination on completion of their approved pre-registration training. In 1997, the total qualification requirement was increased from four to five years, achieved through a four-year Master of Pharmacy degree and one year's pre-registration training culminating in the registration examination.

7.12 The syllabus for the registration examination is practice-based. Candidates are required to demonstrate knowledge of a wide range of medicinal drugs, including their properties and uses, their manufacture, procurement and storage. They must show a working knowledge of the legal framework of the practice of pharmacy, including the requirements

in respect of controlled drugs. They must understand the ethics of the profession. One unit of the course deals with the supply of items against prescriptions and signed orders from practitioners. Trainees are required to demonstrate a thorough knowledge of the checks to be carried out before a prescription is dispensed. They learn how to assess a prescription, identifying any aspect that is unusual or clinically inappropriate and, if necessary, querying it with the prescriber. The trainee's skills, behaviour and knowledge are assessed in the workplace by an appointed tutor, as well as by examination. Once qualified, pharmacists are required to undergo continuing professional development.

Enforcement Functions of the Royal Pharmaceutical Society of Great Britain

7.13 The RPSGB has responsibility for the enforcement of certain provisions of the Medicines Act 1968 and of the Regulations made thereunder. Broadly speaking, these provisions deal with the adulteration and mis-labelling of medicines and the conditions under which some products may be sold.

7.14 The RPSGB also has enforcement duties under the Poisons Act 1972 relating to the sale of poisons. Certain poisons may be sold only on registered pharmacy premises under the supervision of a pharmacist. Moreover, before any lawful supply of certain poisons can be made, the seller must cause the purchaser to make an entry in the poisons book and sign it, giving particulars of the transaction. This requirement is more onerous than the requirements governing the supply of controlled drugs, which do not demand that any record be made of or by the person collecting the drugs. RPSGB inspectors routinely check pharmacy poisons books.

7.15 Breaches of the Medicines Act 1968 or the Poisons Act 1972 may result in prosecution in the courts. The RPSGB acts as prosecutor. However, the RPSGB has no power or duty to enforce any provision of the Medicines Act 1968 against a medical practitioner.

'Medicines, Ethics and Practice – A Guide for Pharmacists'

7.16 The professional standards to be observed by pharmacists are set out in the RPSGB booklet entitled 'Medicines, Ethics and Practice – A Guide for Pharmacists' (the MEP Guide). The MEP Guide, which is published annually, brings together the essential legal, professional and practical guidance needed by a pharmacist. In its current edition, it comprises four sections.

7.17 Section One describes the legal provisions relating to the sale or supply of medicinal products and poisons. It includes a subsection dealing with the requirements of the controlled drugs legislation.

7.18 Section Two is entitled **'Code of Ethics and Standards'**. Part 1 of this Section, entitled **'Pharmacists' ethics'**, highlights the pharmacist's ethical responsibility to act in the interests of patients and other members of the public, and to seek to provide the best possible health care for the community, in partnership with other healthcare professionals. It stresses the duty of a pharmacist to keep his/her knowledge up to date and emphasises that disreputable behaviour or breach of a professional responsibility or of a requirement identified in the Code of Ethics could form the basis of a complaint of professional

misconduct. Part 2 sets standards of professional performance under the headings **'Personal responsibilities'**, **'Professional competence'** and **'Confidentiality'**. Examples of the standards of **'Personal responsibilities'** include the pharmacist's duty to report to the prescriber and to the relevant authorities any adverse drug reaction experienced by a patient. Another example given is that, if a pharmacist becomes aware that anyone has received pharmaceutical care of a standard less than s/he had a right to expect, the pharmacist must, if possible, provide an explanation of what happened, whether or not the pharmacist is the person responsible for the substandard care. A pharmacist must report to the RPSGB any concerns s/he may have that **'a pharmacist's professional competence or ability to practise may be impaired and put the public at risk'**. The responsibilities of pharmacists, pharmacy owners and superintendent pharmacists in relation to the running of a pharmacy business are set out. I think that pharmacists must find it helpful that these important duties are pointed out in clear terms. Under the heading **'Professional competence'**, there is a requirement that a pharmacist should undergo at least 30 hours' continuing professional education each year. Under **'Confidentiality'**, the rules relating to the disclosure of confidential information without a patient's consent are clearly set out. Part 3 sets out Service Specifications on 23 aspects of the pharmacist's work, including dispensing procedures, patient medication records (PMRs) and prescription collection services.

7.19 Section Three provides practice guidance on a wide variety of topics, including, for example, the disposal of pharmaceutical waste, the provision of domiciliary oxygen services, and needle and syringe exchange schemes. This Section is a positive mine of information useful to pharmacists.

7.20 One topic of particular interest to the Inquiry was the advice given to pharmacists about their duties in relation to controlled drugs and other substances liable to misuse. Pharmacists are advised to be alert to the possibility of patients obtaining prescriptions for excessive quantities of controlled drugs and should question the prescriber where it appears that an inappropriate supply has been requested. Advice is given about the detection of forged or altered prescriptions. Since May 2000 there has been no specific warning to pharmacists of the need to be alert to the risk of drug dependency in healthcare professionals although such a warning did appear previously.

7.21 Section Four provides a telephone enquiry guide and a section providing advice for pharmacists in difficulty.

7.22 At the time of writing, the current edition of the MEP Guide is the 27th edition, which was published in July 2003. In considering Shipman's acquisition of controlled drugs in 1993, it was necessary for the Inquiry to look at the MEP Guide current at that time. The relevant provisions are examined in detail in Chapter Eleven and are not considered further here.

Disciplinary Function of the Royal Pharmaceutical Society of Great Britain

7.23 Breaches of the Code of Ethics and Standards contained in the MEP Guide, and disreputable behaviour generally, might lead to a complaint of professional misconduct to the RPSGB, resulting in disciplinary action. Such complaints are usually investigated initially by a local RPSGB inspector. When the investigation is complete, the investigator

submits a report to the RPSGB Directorate and, if it is decided that further action may be needed, the details of the case will be put before the Infringements Committee.

7.24 The Infringements Committee consists of pharmacists and lay members of the RPSGB Council. The Committee will receive a description of the case, in an anonymised form, on the basis of which its members will decide what action to take. The options are to take no action, to send an advice letter, to issue a formal warning, to order a prosecution or to refer the case to the Statutory Committee.

7.25 Allegations of professional misconduct are finally determined by the Statutory Committee, which also deals with pharmacists convicted of a criminal offence and with other matters related to the registration of pharmacists. The Statutory Committee sits as a formal tribunal. It may decide to take no further action, to admonish or reprimand the pharmacist or to direct that the pharmacist's name be removed from the register. Bodies corporate and partnerships may also be disqualified from operating a pharmacy. An appeal from a decision of the Statutory Committee lies to the High Court. The RPSGB is currently seeking statutory authority to widen its powers to include the imposition of a requirement that a pharmacist should practise only while under supervision.

The Operation of Community Pharmacies

7.26 There are more than 10,000 community pharmacies in England and Wales, of which about one half form part of a chain with four outlets or more. All community pharmacies must be registered in the RPSGB's register of pharmaceutical premises. Section 69(1) of the Medicines Act 1968 provides that the business of a community pharmacy may lawfully be conducted either by an individual pharmacist, by a partnership of pharmacists or by a 'body corporate'. Not all community pharmacies are contracted to provide NHS pharmaceutical services, although the great majority are.

Personal Control

7.27 Prescription only medicines and pharmacy medicines (see paragraph 3.41) can be dispensed in a community pharmacy only by registered pharmacists or by pharmacy technicians (also known as dispensers) working under the supervision of a registered pharmacist. Such medicines can be sold only from registered retail pharmacy premises, either by a pharmacist or by a person acting under the supervision of a pharmacist. At least one pharmacist should be on duty at all times when a community pharmacy is open. The RPSGB takes the view that temporary absence for about three quarters of an hour at lunchtime is regarded as acceptable, although no prescription only or pharmacy medicines can be supplied during such absence.

7.28 If a pharmacy is conducted by a body corporate, that part of the business concerned with the retail sale or supply of prescription only medicines and pharmacy medicines must be under the 'personal control' of a superintendent pharmacist, or of another pharmacist who is subject to the direction of the superintendent.

Locum Pharmacists

7.29 In its publication entitled 'A Vision for Pharmacy in the New NHS', issued in July 2003, the DoH stated that there is a shortage of pharmacists. This results in heavy reliance (especially in community pharmacies) on locum pharmacists and on pharmacists still working beyond the normal retirement age. Mr David Slater, an inspector employed by the RPSGB, told the Inquiry that, although many pharmacies are able to engage permanent staff, he and his colleagues encounter the increasing use of locum pharmacists. Locum work is quite well paid and, apparently, attractive to newly qualified pharmacists.

7.30 The availability of locum pharmacists is plainly important to the running of pharmacy businesses but some disadvantages are bound to accrue from their employment. A locum pharmacist cannot be expected to acquire the same degree of personal knowledge of customers or prescribers as is usually developed by permanent staff.

Keeping Records of Controlled Drugs Supplied by Pharmaceutical Wholesalers

7.31 Most community pharmacies purchase their supplies from wholesalers. Wholesalers of controlled drugs are required to keep records of all supplies to customers. When a sale is made, an invoice is prepared which records the quantity of each drug to be supplied and the name and address of the pharmacy to which the drug is to be delivered. The driver collects two copies of a delivery note with the drugs from the wholesaler's controlled drugs store. On receipt of the drugs, this document is signed by a representative at the community pharmacy and one copy is returned to the wholesaler as proof of delivery. The wholesaler will keep the signed delivery note for six months and a copy invoice for seven years. Wholesalers balance their actual stock of controlled drugs against book stocks following the completion of each shift, to check for discrepancies. All documentation relating to controlled drugs is subject to inspection by Home Office drugs inspectors.

7.32 Community pharmacies are required to keep invoices and copy delivery notes of all controlled drugs received. Pharmacists also have to enter a record of each drug received into the appropriate section of the pharmacy controlled drugs register (CDR), which, like its counterpart in the doctor's surgery, is intended to record receipts and supplies of controlled drugs. I shall discuss the CDR in detail later in this Chapter. As I will explain in Chapter Nine, the CDR should be inspected twice a year by a police chemist inspection officer (CIO), who also has the power to call for and inspect invoices and copy delivery notes. However, it seems that most CIOs do not routinely carry out a reconciliation of the quantities of controlled drugs arriving at the pharmacy with those entered into the pharmacy CDR. As a result, if a pharmacist were to order a greater amount of a controlled drug than was required by the business and keep part for him/herself, this would probably not be detected by a CIO, so long as the over-ordering was not immoderate and the CDR appeared to be technically in order. Nor would a CIO be likely to detect the activities of a pharmacist who diverted the whole of a supply obtained from a wholesaler but who made no corresponding entry in the CDR.

The Misuse of Drugs (Safe Custody) Regulations 1973

7.33 The Safe Custody Regulations regulate the conditions under which certain controlled drugs must be kept on certain types of premises. I have described their general

application in Chapter Three. The Safe Custody Regulations apply to a few drugs in Schedule 3, and all drugs in Schedule 2, save quinalbarbitone and some other liquid preparations. In short, these provisions are directed against the drugs most liable to misuse.

7.34 Regulation 3 of the Safe Custody Regulations requires pharmacists, so far as circumstances permit, to keep all relevant controlled drugs in a locked safe, cabinet or room, which should be so constructed as to prevent unauthorised access. Every such safe, cabinet or room must either comply with the various structural requirements set out in Schedule 2 to the Safe Custody Regulations or, in the case of a retail pharmacy, be covered by a current certificate of adequacy issued by a chief officer of police following an inspection.

Dispensing Controlled Drugs in the Community Pharmacy

The Legal Requirements

7.35 Regulation 16 of the MDR 2001, which does not apply to drugs in Schedules 4 or 5, sets out the conditions which must exist before a controlled drug can validly be dispensed on prescription by a pharmacist. The prescription must comply with the requirements of regulation 15 (which are set out in detail in Chapter Six). The issuer's address must be specified and must be in the UK. The dispensing pharmacist must either be acquainted with the prescriber's signature and have no reason to suspect that it is not genuine or must have taken reasonably sufficient steps to satisfy him/herself that it is genuine. The drug should not be dispensed prior to the date specified on the prescription. The supply (or the date of first supply in the case of instalment prescriptions) must not take place more than 13 weeks after the date specified in the prescription. The supplier of the drugs has to mark on the prescription the date of supply or, in the case of instalment prescriptions, the dates of supply.

7.36 According to the MEP Guide, where the signature of the prescriber is not known, the prescriber should be contacted by the pharmacist and asked to confirm that the prescription is genuine. The Inquiry was told that, with the increasing use of locum pharmacists and locum doctors, it was becoming more difficult for a pharmacist to recognise the signature of a prescriber. If a prescription is presented out of hours and the signature of the prescriber is not familiar to the pharmacist, s/he is unlikely to be able to contact the prescriber. In such circumstances, if the prescription is dispensed, the pharmacist may well be acting in breach of the strict letter of the law and of RPSGB guidance.

Patient Medication Records

7.37 Nowadays, although there is no obligation on them to do so, virtually all pharmacies keep a computerised record of the drugs dispensed to each individual patient. This record is known as a PMR. The pharmacy computer will store details of all items previously dispensed to the patient, identifying the drug prescribed, the date of the prescription and the name of the prescriber. The purpose is to provide as complete a medication history

as possible, in order to inform the future dispensing of drugs to the patient. In general, PMRs are kept by individual pharmacies and are not linked with other pharmacies. I understand that Boots the Chemists (Boots) has an integrated system connecting all its pharmacies. Because many people have their medication dispensed at a variety of different pharmacies, the PMR kept by any one pharmacy is likely to be an incomplete record of the patient's drug history.

The Usual Practice

7.38 The procedure for dispensing medicines varies to some extent from pharmacy to pharmacy. Mr Richard Aucott, the owner of Nupharm Chemist in Hyde, who is himself a pharmacist, described the procedures in operation at his pharmacy and I have no reason to think that they are atypical. The RPSGB intends to introduce, by 2005, a requirement for pharmacists to operate according to written standard operating procedures (SOPs). These will cover the dispensing process and the transfer of prescribed items to patients. Mr Aucott produced for the Inquiry the SOPs which have been in use at his pharmacy since 2003.

7.39 The essentials of dispensing a controlled drug are the same as for any prescription only medicine although there are some additional procedures to be completed. Usually, when the customer/patient presents a prescription for any medication, a pharmacy technician will assemble the medicine(s), packaging and labelling required. This process may involve the counting of tablets or the measuring of liquids. The preparation of a label, with instructions as to dosage, will, nowadays, entail the entry of the prescribing information into a computerised PMR; when the entry has been made, a label will be printed. Once the technician has assembled the medication, it is passed to the pharmacist on duty in its container, with the label and the prescription. The pharmacist will then check that the label and contents of the container correspond with the prescription. He or she will also consider the nature of the drug prescribed, the dosage, the age of the patient and the possibility of any interaction with any other drug being taken by the patient. This last consideration is possible only if the patient is a regular customer and all his/her recent prescriptions have been recorded in the PMR. If all is in order, the medication, suitably packaged and labelled, will then be handed to the customer/patient. The pharmacist must ensure that the patient receives sufficient information and advice to permit the safe and effective use of the medication. In that way, the pharmacist will have performed his/her duty, although the performance of much of the task will have been delegated.

7.40 On receipt of a prescription for a controlled drug, the pharmacist will first examine the prescription to assess its compliance with the MDR 2001. If all is in order, the pharmacist will give the technician the key to the safe, cabinet or room where the controlled drugs are stored, and the technician will assemble and label the medication in the usual way. At Nupharm Chemist, a second technician checks that the medication has been correctly dispensed, although this is not universal practice. The pharmacist will then make a final check in the way described above.

7.41 If satisfied, the pharmacist will then take the dispensed controlled drug to the counter and hand it over to the patient or the patient's representative. Mr Aucott said that he would give

an explanation to ensure that the patient knew the nature of the medication, that it is a 'strong drug', that it should not be used by anybody else, that it should be taken exactly as directed on the label and that it should be kept in a safe place. Mrs Ghislaine Brant, the pharmacist manager at 23 Market Street, Hyde, said that she would explain that it was a 'strong drug'. As a rule, she would give no warning as to the risk that the drug might be attractive to drug addicts or drug dealers; nor would she tell the patient or his/her representative that the drug was a 'controlled drug'. She was concerned that giving such warnings might worry patients.

7.42 At the time of supply or shortly afterwards, an entry recording the supply is made in the CDR. If no entry was required in the CDR (as would be the case with a Schedule 3 or 4 controlled drug, for example) and the prescription was a private prescription, an entry would be made in the private prescriptions book. I will explain the relevant requirements for an entry in a CDR in detail later in this Chapter.

Assessing the Appropriateness of the Prescription for the Patient's Needs

7.43 Nowadays, it is recognised that an important aspect of a pharmacist's duty is to assess every prescription in order to determine not only that it complies with any legal requirements but also that it is suitable for the patient. The SOPs to be introduced by the RPSGB will include a requirement that all prescriptions be assessed by pharmacists for safety and clinical appropriateness. The appropriateness of the drug for the patient's condition and the compatibility of the drug with other medication being taken will have to be considered.

7.44 This duty is alluded to in 'A Vision for Pharmacy in the New NHS', which I mentioned in paragraph 7.29. In that publication, the Chief Pharmaceutical Officer of the DoH identified, as a key role for pharmacists, the promotion of patient safety by **'preventing, detecting and reporting adverse drug reactions and medication errors'**. It seems to me that, with the growing complexity of the range of drugs available to doctors, pharmacists have an increasingly important role to play in the clinical treatment of patients. In general, they have a wider and more detailed knowledge of drugs, their properties, dosages and side effects than most general practitioners. That is their speciality. It must be in the interest of patients that pharmacists should be able to apply their expertise so as to carry out a proper assessment of the prescription issued by the doctor. Although it is the aim of all good pharmacists to carry out such an assessment, it appears that, at present, the extent to which this can be achieved is limited by the inadequacy of the information at the pharmacist's disposal. There are two aspects to the problem.

7.45 First, the pharmacist will probably not know for what condition the doctor has prescribed the medication. This does not appear on the prescription. Some drugs have such a specific application that the pharmacist can infer the condition for which a given drug has been prescribed. Some pharmacists know a lot about their regular customers and some customers will readily talk about their condition if given the opportunity. However, the customer is not necessarily a reliable source of information.

7.46 Mr Lutener said that pharmacists feel that the present situation is unsatisfactory. He stressed that the need for information is even greater in the case of controlled drugs than

with other medication. By way of example, he mentioned that benzodiazepines are very widely prescribed for a range of conditions. Without knowledge of the condition for which they are being prescribed, the pharmacist will not be able to tell whether they are being properly prescribed. If given on a long-term basis, they can easily lead to addiction. They should not be used in the long-term treatment of insomnia or for the relief of anxiety. However, if used in the control of epilepsy, long-term continuous treatment may be appropriate.

7.47 Second, for the reasons I have explained, the PMRs kept at a pharmacy may well not present a complete picture of the medication the patient is currently taking. Even if the PMRs are meticulously kept, they will be incomplete if the patient obtains medication from more than one pharmacy. Mr Lutener explained that, if the information is incomplete, it is difficult for the pharmacist to carry out an adequate assessment. The same point was made in written evidence submitted by the Oldham, Tameside and Glossop Local Pharmaceutical Committee.

How Could These Problems Be Overcome?

7.48 The problem of satisfying the pharmacist's need to know for what condition the medication has been prescribed was regarded by many witnesses to the Inquiry as virtually insoluble, at least for some time to come. Many regarded the idea that the patient's medical diagnosis should be recorded on the prescription as unacceptable, for reasons of patient confidentiality. It was, however, recognised that, if the NHS is soon to introduce a centralised electronic network of patient medical records (the NHS Case Record), to which all doctors could obtain access, pharmacists could also be given access to that network. In that way, both of the problems I have mentioned would be resolved. However, such a network may not be available for some time and, in any event, there are some who consider that access to such records by pharmacists would give rise to problems of patient confidentiality. This issue was raised for discussion at the Inquiry's seminars and I will return to consider it further in Chapter Fourteen.

The Controlled Drugs Register

Form and Format

7.49 Regulation 19 of the MDR 2001 requires pharmacists to maintain a chronological register (the CDR) detailing the quantities of every Schedule 2 controlled drug obtained or supplied. There is no such requirement for controlled drugs in Schedules 3–5. A separate CDR, or a separate part of the CDR, has to be used for each different Schedule 2 controlled drug. Regulation 27 provides that, when pharmacists destroy contaminated or 'out of date' stocks of such drugs, they should record in the CDR details of the date of destruction and of the quantity destroyed. The entry has to be signed by the authorised person in whose presence the drugs are destroyed. Unused drugs returned by a patient to a pharmacist for the purpose of destruction are specifically exempted from this provision.

7.50 The maintenance of a CDR is intended to permit the monitoring of stocks held at the pharmacy and to afford to CIOs the opportunity to identify prescribing or dispensing that gives cause for concern.

7.51 The format of the CDR is prescribed by the MDR 2001. Regulation 19 provides that each page of the register should take the form illustrated in Schedule 6 to the Regulations. However, the illustration which appears there is not at all detailed and shows only a number of unmarked columns (four in the case of the 'drugs obtained' pages and five in the case of the 'drugs supplied' pages). Regulation 20 requires that the class of drugs to which the entries on a given page relate should be specified at the head of that page. Every entry should be made on the day when the transaction takes place or, if that is not reasonably practicable, on the following day. Thus, entries do not have to be made contemporaneously with the transaction. Corrections must be indelible and made by a note in the margin or footnote; cancellations, obliterations or alterations are not allowed. All these requirements are designed to reduce the risk of forgery and diversion of drugs. The CDR is not to be used for any purpose other than the purpose of the Regulations. The CDR is specific to one set of premises only and has to be kept at those premises.

7.52 The physical form of the CDR is a matter for individual pharmacists. Many pharmacists use CDRs produced in a ring binder by the National Pharmaceutical Association (NPA). Some of the larger retail pharmacy chain stores and supermarkets, such as Boots and ASDA, have produced their own form of CDR for use in their pharmacies. The NPA ring binder contains a number of separately bound registers in the form of rectangular soft-backed stapled booklets, each designated for a different controlled drug. The first pages in each register contain records of drugs obtained and the remaining pages record drugs supplied. Coloured dividers separate the individual registers. The ring binders also contain a brief description of the drugs requiring an entry in the CDR.

7.53 At Appendix D, three sample pages from this CDR (which complies with the MDR 2001) are reproduced. The first page is the front cover of the diamorphine register, the second is a sample 'drugs obtained' page and the third is a sample 'drugs supplied' page. The record of 'drugs obtained' shows the date of receipt, the name and address of the person or firm from whom the drug was obtained and the amount and form in which it was obtained. The record of 'drugs supplied' shows the date of the relevant transaction, the name and address of the person or firm supplied and the amount and form supplied. The name and address of the patient, or (where the supply is on requisition) of the doctor or practice, are entered in the columns seeking details of the person or firm supplied. The next column requires the entry of **'Particulars as to licence or authority of person or firm supplied to be in possession'** and this is the column in which the prescriber's name is entered.

7.54 The entering of data into the CDR is a time-consuming business and the registers themselves are unwieldy. Some pharmacists may make as many as 200 entries in the CDR in a day, depending on the number of drug dependent patients they serve. At present, the Regulations do not permit the keeping of an electronic CDR. If pharmacists were permitted to keep their CDRs electronically, they could integrate the PMR with the CDR. Then, an entry could automatically be made in the CDR when the prescribing information was entered into the PMR. In this way, a great deal of time would be saved. The Home Office issued a Consultation Paper in May 2003, seeking views on a proposal that legislation be passed to allow the keeping of electronic CDRs and this met with the general approval of pharmacists. The Inquiry heard many other expressions of dissatisfaction

about the form of CDR currently in use. I shall now mention several of their perceived inadequacies.

Running Balances

7.55 The NPA has construed regulations 19 and 20 strictly, and has not provided space for the insertion of any additional information into the register besides that which is compulsory. Although many pharmacists have recognised that it would be advantageous to keep a running balance of the amount of each Schedule 2 controlled drug that is or should be in stock at any one time, most have felt unable to record this information in the CDR because there is no provision for it in the Regulations and no space in the NPA register.

7.56 In hospital pharmacies, the keeping of a running balance in CDRs is standard practice. According to the report entitled 'Reducing Leakage of Prescribed Drugs', to which I referred in Chapter Five, 80% of the community pharmacists surveyed in the study would support the maintenance of a running balance. The recording of such a balance is an elementary stock control measure. It would enable a pharmacist or superintendent pharmacist to make a regular check on stocks of controlled drugs and would act as a disincentive to diversion. It would be of great help to the CIO.

7.57 Some pharmacists have been so aware of the advantages of a running balance that they have devised a CDR which incorporates this feature. Mrs Kay Roberts, Lead Pharmacist for the Royal College of General Practitioners National Drug Misuse Training Programme and pharmacist member of the Advisory Council on the Misuse of Drugs (ACMD), devised one in the 1980s, while working in a community pharmacy in Harrow. She showed a draft to her local CIO and RPSGB inspector who were entirely content that it should be used. The CDR used by the ASDA chain of pharmacies is another case in point. It records all the information required by the Regulations and also requires a running balance to be recorded. It enables pharmacists to record the details of the drugs obtained alongside the corresponding record of drugs supplied. They can easily be cross-matched. An additional column to the right details the running balance. Pharmacists are instructed to calculate and enter the running balance after each transaction. At the end of each week, and before prescriptions are sent to the Prescription Pricing Authority (PPA), pharmacists are instructed to check the recorded balance against the quantities physically held in the controlled drugs cabinet. Thus, elementary stock control is achieved. This register was introduced with the knowledge and approval of one of the CIOs working in the Greater Manchester area, Detective Constable (DC) Michael Beard. He told the Inquiry that the feedback from pharmacists using this type of CDR was universally positive and the Home Office has not raised any objection. As I shall explain in Chapter Fourteen, ASDA has said that this CDR has caused very few problems. ASDA staff do not carry out an audit every time they change shift but check the running balance every week. In that way any discrepancy is discovered and corrected quickly. ASDA reported that the keeping of a running balance has resulted in the detection of a locum pharmacist who was manipulating the records and had stolen a large number of amphetamine tablets from a number of different ASDA pharmacies.

7.58 Historically, the RPSGB and the NPA have been reluctant to agree to a requirement that running balances be maintained. The proposal was rejected in 1990, when the Home

Office asked the RPSGB to consider the matter following discussion of the subject at the annual meeting of police CIOs. The RPSGB Community Pharmacy Sub-Committee noted that the keeping of running balances had been considered by the Council of the RPSGB on previous occasions and had been rejected. The fear had been expressed that an over-zealous CIO might take too strict a line with pharmacists for slight discrepancies beyond their control. This might occur, for example, where the container in which methadone (a liquid) is supplied to a community pharmacy is slightly overfilled, resulting in a small residue after the dispensing of a number of doses that would normally exhaust the supply. Mr Lutener, although supporting the introduction of running balances, was also concerned that failure to ensure an exact balance might be met with inappropriate criticism, or worse. I am puzzled by this concern. While I can understand that pharmacists might be concerned that an over-zealous CIO might seek to bring a prosecution for a trivial infringement, they might be equally concerned that that could happen in the event of an infringement of any of the existing requirements. In fact, the evidence I have heard suggests that CIOs do not prosecute for minor infringements. They see their role primarily as giving advice and support. Only if a pharmacist were doing something quite seriously wrong would they take legal action.

7.59 The NPA remains concerned about the burden on its members that would result from the keeping of a running balance. I shall discuss these concerns further in Chapter Fourteen.

Recording the Pharmacist's Name

7.60 There is no requirement under the MDR 2001 for the pharmacist responsible for a transaction to identify him/herself in the CDR. In a small pharmacy, using permanent staff, the handwriting of the individual pharmacists will be recognisable by other staff and by the local CIOs. However, this is not always the case in a large pharmacy or in a pharmacy where locum staff are used, some of them for only short periods. Although the Regulations do not provide for it, the ASDA CDR also records the name of the person responsible for entering each transaction. This may be vital information if it later becomes necessary to investigate a particular transaction.

Recording Who Collects Controlled Drugs

7.61 Regulation 14 of the MDR 2001, which does not apply to drugs in Schedules 4 or 5, is designed to prevent a controlled drug which has been ordered on requisition (as opposed to on prescription) from falling into unauthorised hands. If the drugs are to be collected by anyone other than the person who has ordered them, the pharmacist must be satisfied that the collector has been authorised in writing to collect the drugs. By contrast, there is no provision requiring a pharmacist who intends to supply a controlled drug, dispensed in accordance with a prescription, to a person other than the named patient to require the person collecting the drug to produce an authority signed by the patient. This proved to be a significant *lacuna* in Shipman's case. He was able to collect drugs, ostensibly on behalf of a patient, without the patient's knowledge.

7.62 Moreover, there is no requirement that the identity of the person who collects a controlled drug from the pharmacy should be recorded, either in the CDR or anywhere else. I have

already mentioned that anyone collecting certain poisons has to sign the poisons book. When a NHS prescription is presented, the person presenting it must sign the reverse side to state whether or not exemption from the prescription charge is claimed and whether any fee has been paid. However, the person presenting the prescription is not necessarily the same as the person who collects the drug. Moreover, no such statement is required in the case of private prescriptions. Thus, in the case of both private and NHS prescriptions, there is no formal record of the identity of the person who collects the drug.

7.63 Evidence before the Inquiry suggests that a record of who has collected a controlled drug would be useful. It also suggests that there are many other doctors, apart from Shipman, who have diverted controlled drugs by collecting them from community pharmacies, purportedly on behalf of their patients. Mrs Rose Smith, the niece of Mrs Lucy Virgin (who was unlawfully killed by Shipman in March 1995), was, until about two years ago, the manageress of Nupharm Chemist, Hyde. This pharmacy, like many others, runs a prescription collection and medication delivery service. Mrs Smith explained that, although it was a requirement that the person to whom the drugs were delivered should sign for the drugs, there was no corresponding requirement for those persons collecting drugs from the pharmacy to sign for them. She did not foresee any problem if patients or their representatives were required to produce identification and to sign their name when collecting controlled drugs.

7.64 If the identity of the person collecting a controlled drug were noted in the CDR, the pharmacist and the CIO would be likely to notice a name which occurred with any frequency. If the person were to use several pharmacies in the same area, the CIO might notice that. In 1993, when Shipman collected a series of 30mg ampoules of diamorphine from the pharmacy at 23 Market Street, it is likely that the CIO, DC Patrick Kelly, might have noticed the frequency with which Shipman's name appeared as a collector, even though he was not struck by the appearance of Shipman's name as the prescriber of the drugs. Certainly, in any later investigation, such entries would have been extremely useful in proving that Shipman had collected the drugs in question. Shipman might well have been discouraged from behaving as he did, had he known that his collection of the drugs would be recorded.

7.65 ASDA pharmacists are instructed to record the name of the person collecting controlled drugs and the ASDA CDR contains a column in which such entries should be made. This arrangement was adopted only shortly before the time when DC Beard attended to give evidence but he told the Inquiry that the feedback from one pharmacy where it was used was good. ASDA has since confirmed that it has caused very few problems.

Recording Batch Numbers in the Controlled Drugs Register

7.66 One of the ideas considered by the Inquiry in its quest to improve the recording of controlled drugs transactions was whether it would be possible to identify and record in the CDR the actual product supplied under each prescription. If a controlled drug were found in the hands of someone who appeared not to be entitled to possession of it, it would be of great value to the police or Home Office if its origin could be traced.

7.67 The Inquiry team had in mind the use of batch numbers. The standard labelling requirements for all medicinal products for human use, as prescribed by European Union Council Directive 92/27, also apply to controlled drugs. The manufacturer's batch number must appear on the label. However, when the Inquiry was considering the value of recording the batch number in the CDR, or using it as a part of any audit trail, it was discovered that the size of a production batch might be very large indeed, up to millions of unit doses. To record the batch number in the CDR would not, therefore, be very useful. Moreover, it would be time-consuming, particularly as the digits on the label can be very small or faint and difficult to read. If, in time, batch numbering or other coded information is applied to smaller numbers of unit doses or even to individual packets, or blister packs, this may become practicable and worthwhile. In Chapter Fourteen, I shall consider the possibility of creating an audit trail for controlled drugs by the use of bar coded products.

Bringing All Controlled Drugs within the Controlled Drugs Register

7.68 As I have explained, transactions involving controlled drugs in Schedule 2 have to be recorded in the pharmacy CDR. Pharmacists are also required to record details of the dispensing of all private (but not NHS) prescriptions of prescription only medicines, including prescriptions for controlled drugs, in a private prescriptions book, unless the transaction is recorded in the CDR. The RPSGB recommends that private prescriptions for Schedule 2 controlled drugs should be entered in both the private prescriptions book and the CDR.

7.69 It follows that all supplies of Schedule 2 controlled drugs will be recorded in the CDR; supplies relating to controlled drugs in Schedules 3–5 will be recorded in the private prescriptions book if they are dispensed on a private prescription. However, the great majority of supplies of controlled drugs in Schedules 3–5, which are dispensed under a NHS prescription, will not be recorded in any document or system that remains on the pharmacy premises and is available for inspection. It appears to me that this is not an ideal situation, if a serious attempt is to be made to monitor the use of controlled drugs through local inspection. A more satisfactory inspection could be achieved if transactions (whether private or NHS) in all controlled drugs in Schedules 2–4 were required to be recorded in the CDR. While CDRs are kept in paper form, this would be impracticable. If they were kept electronically, however, it might be feasible. I shall consider this further in Chapter Fourteen.

Retention of Records

7.70 Regulation 23 of the MDR 2001 provides that requisitions and private prescriptions for controlled drugs and CDRs must be retained for two years either from the date on which the last delivery under the prescription or requisition was made, or, in the case of CDRs, from the date on which the last entry was made. Insofar as private prescriptions are concerned, the provision under the MDR 2001 is otiose, as, under the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, all private prescriptions must be

retained by the pharmacist for two years. Regulation 23 does not apply to prescriptions issued under the NHS, which are sent to the PPA on a monthly basis.

Destruction of Controlled Drugs

Out of Date and Contaminated Drugs

7.71 All controlled drugs are marked with a date by which they should be used. A pharmacist is not permitted to dispense a drug which is out of date and nor, of course, should drugs that become contaminated in some way be dispensed. Because such drugs might be attractive to thieves, they must be kept secure until they can be destroyed. By virtue of regulation 27 of the MDR 2001, no pharmacist may destroy or cause to be destroyed any Schedule 2 controlled drugs except in the presence of, and in accordance with any directions given by, a person authorised by the Home Secretary to witness such destruction. Those authorised include Home Office inspectors, police constables (most commonly CIOs), RPSGB inspectors, Chief Executives of NHS Trusts, some PCT personnel and certain area managers of large pharmaceutical chain stores. The date of destruction, the quantity destroyed and the signature of the witness should all be recorded in the CDR. This provision applies to out of date and contaminated drugs but not to 'patient returns', which are exempt by virtue of regulation 6(2).

7.72 Problems arise when an opportunity for destruction does not occur for many months. At present, CIOs try to visit all pharmacies in their area twice yearly but this is often not achieved. In any event, there are some areas where there is no CIO in post. RPSGB inspectors are currently visiting each pharmacy about once every two years. Thus, opportunities for destruction are limited. The problems have become more acute in recent years as larger quantities of controlled drugs are being prescribed. The problems relate to security, storage capacity and the need to keep separate those drugs that are 'in date' from those that are out of date.

7.73 There is a degree of tension between the various bodies as to the allocation of resources to the task of destruction, which can be extremely time-consuming. The RPSGB, which receives no specific funding for the destruction of drugs, expects CIOs to perform this task, although, as I have said, CIO coverage is not universal. Standing instructions to RPSGB inspectors are that they should not carry out the destruction of controlled drugs as a matter of routine, although, if a pharmacist has accumulated a large volume of drugs and is obtaining no assistance from any other quarter, a special visit will be arranged for the purpose.

7.74 It is not within the remit of this Inquiry to make anything more than passing reference to such tensions, but they must be borne in mind when considering the alternatives for the safe and secure disposal of drugs which have been dispensed and have to be destroyed in the community.

Informal Destruction of Controlled Drugs: Patient Returns

7.75 It is generally recognised that the return and safe disposal of unwanted medicines is in the public interest and, in recent years, there have been several successful campaigns to

encourage the public to return them to community pharmacies. In 1983, the ACMD recommended that patient returns of controlled drugs should be allowed to be destroyed without formality. The thinking behind this relaxation of the legislation was that it was desirable to remove controlled drugs from the community in as swift and simple a way as possible. In consequence of this recommendation, regulation 6(2) of the MDR 1985 (now regulation 6(2) of the MDR 2001), permitting the informal destruction of patient returns by doctors and pharmacists, was passed.

7.76 Mrs Roberts drew to the attention of the Inquiry Government figures suggesting that more than 523 tonnes of unwanted medicines were returned to community pharmacies for disposal in 2003. This demonstrates the magnitude of the problem faced by pharmacists when they have to sift a large 'mixed bag' of drugs returned to them, some of which are controlled drugs and some of which are not.

7.77 All patient returns originally dispensed on NHS prescriptions must be destroyed. Drugs dispensed on private prescriptions can be put back into stock if they are still in date, although pharmacists are advised against this. RPSGB guidance to pharmacists with respect to the disposal of controlled drugs returned by patients is that they should be destroyed as soon as possible, for security reasons. NPA guidance suggests that the pharmacy should keep a record of destruction in the private prescriptions book and that destruction should be witnessed by a second member of staff who should sign the record.

7.78 The evidence from the pharmacists at 23 Market Street, Hyde, indicates that they did not follow this practice until after Shipman's arrest. Mrs Brant said that she usually destroyed patient returns by dissolving them in boiling water and flushing them down the lavatory. Mrs Brant did not ask anyone to witness this process, nor did she make a record. I think it likely that most pharmacists follow this type of procedure, which is not unlawful. However, I observe that pharmacists could very easily take such returned drugs for their own use with little, if any, risk of detection. According to Mr Lutener, many pharmacists feel uncomfortable about the informality of these arrangements. Consideration must be given to the issue of whether such destruction should be witnessed and recorded.

Conclusion

7.79 Many issues warranting further consideration have arisen in this Chapter. Pharmacists seek changes that would enable them better to carry out their important task of assessing the appropriateness of a prescription. There is a general view that CDRs should contain more information than at present. The destruction of controlled drugs gives rise to practical problems and there is a view that the destruction of patient returns should be witnessed and recorded. I will deal with these issues in Chapter Fourteen.