CHAPTER SIX

Prescriptions and Requisitions

Introduction

6.1 In this Chapter, I shall examine the existing statutory rules and requirements governing the issue of prescriptions and requisitions for controlled drugs and the way in which they operate in practice. I will rehearse the evidence from various sources as to whether these rules should be changed. In Chapter Fourteen, I will weigh the competing arguments for and against change.

The Current Position

6.2 The current rules and requirements governing the issue and dispensing of prescriptions for prescription only medicines are laid down in the Medicines Act 1968 and secondary legislation made under the Act. Additional requirements exist for some but not all controlled drugs and these are set out in the Misuse of Drugs Regulations (MDR) 2001.

6.3 Regulation 15 of the Prescription Only Medicines (Human Use) Order 1997 lays down the requirements for a prescription for all prescription only medicines, including controlled drugs. The regulation requires that a prescription issued by a practitioner must bear the practitioner's signature in ink. The other parts of the prescription must be written in ink or otherwise so as to be indelible, although NHS prescriptions may be carbon-copied. The prescription must give the practitioner's name, address and profession and the date of issue. It must give the patient's name and address and age, if under 12. There is no legal limit to the volume or quantity of any drug that may be prescribed on one prescription. The drugs prescribed may not be dispensed more than six months after the date of issue of the prescription.

6.4 Regulation 15 of the MDR 2001 imposes additional requirements for all controlled drugs in Schedule 2 to the Regulations and for almost all those in Schedule 3. First, the prescription must specify the dose, the form, the strength (where appropriate) and either the total quantity (in both words and figures) or the number of dosage units (in both words and figures) to be dispensed. The Royal Pharmaceutical Society of Great Britain (RPSGB) advises its members on the interpretation of the statutory requirements affecting these controlled drugs. The advice is that dosage must be specifically stated and that a statement, for example, that medication is to be 'taken as directed' is unacceptable. Also, prescriptions for controlled drugs to be used in a syringe driver must specify the number of ampoules or the amount of controlled drug to be used over a specified period of time. The requirement to specify the form of the drug prescribed means that, even where only one form of the drug exists or where the form is implicit in the proprietary name (e.g. MST, which is the standard abbreviation for morphine sulphate tablets), the prescription must contain a specific direction as to the form in which the drug is to be dispensed (e.g. the words 'tablets' or 'tabs'). The use of abbreviations such as 'T' for tablets and 'C' for capsules is regarded by the RPSGB as unacceptable. The strength of the preparation must be specified if more than one strength of the drug is available. In the case of drugs

to be supplied in instalments, detailed instructions are required. Since 1998, it has been possible for a practitioner to issue a prescription for a controlled drug to be dispensed in instalments. Special rules apply to such prescriptions.

6.5 Second, except in the case of phenobarbitone, all this information must be entered in the prescriber's own handwriting. Doctors may not, therefore, issue typewritten or computer generated prescriptions for controlled drugs. Where a prescription requires amendment, the amendment must be made in indelible ink in the handwriting of the original prescriber. If that doctor is not available, a new prescription must be issued. Moreover, RPSGB guidance suggests that prescription details cannot be amended by a covering letter from the prescriber, purporting to give authorisation. Nor is a carbon copy or faxed amended prescription acceptable.

6.6 A doctor, such as one working on a community drugs team, who makes out a large number of Schedule 2 and 3 prescriptions can apply to the Home Office for exemption from the handwriting requirement. If exemption is granted, the doctor may use computer generated prescriptions. Each year many such exemptions are granted.

Changes in General Practice

6.7 The special handwriting requirements have not changed since 1973. In the intervening period, there has been a radical change in the administrative systems used in general practice. Until the late 1980s or early 1990s, all patient medical records were written on cards kept in an envelope or folder and named 'Lloyd George cards' (after the Rt Hon David Lloyd George who was Minister of Health in the early twentieth century). All NHS prescriptions were written, usually by hand, on a NHS prescription form. Starting in the late 1980s, most general practices installed computer systems on which patient records are kept. Most prescriptions are now drafted automatically when the doctor enters the prescribing information into the patient record; s/he then prints the prescription onto the NHS prescription form and signs it. Much time is saved by this method of creating a prescription but there are also other advantages that I shall refer to later. However, prescriptions for controlled drugs that attract the special handwriting provisions cannot be prepared in this way. The doctor must still make out the controlled drug prescription by hand although s/he will almost certainly have already entered the prescribing information into the patient's record on the computer. This makes the task of prescribing a controlled drug much more time-consuming for the doctor. Questions have arisen as to whether the special handwriting rules are now necessary or worthwhile.

6.8 It seems to be generally accepted that change is desirable. In 1997, the Advisory Council on the Misuse of Drugs (ACMD) gave its approval in principle to computer generated controlled drug prescriptions. The Home Office issued a consultation paper on this topic in May 2003. It now appears likely that the handwriting rules relating to controlled drug prescriptions will be relaxed in future. These potential changes are of interest to the Inquiry because it is charged with making recommendations for the future safety of patients. In order to form a view as to whether the relaxation of the existing requirements would compromise patient safety or make it easier for a dishonest doctor to obtain illicit supplies of controlled drugs, I must examine the purpose for which each restriction was intended

and the effect of its removal. I shall include an examination of the requirements relating to private (i.e. non-NHS) prescriptions for controlled drugs. So far as it is known, Shipman did not use private prescriptions and, to that extent, it might be said that consideration of them lies outside the Inquiry's remit. However, in my view, I should recommend changes that will improve the safety of all patients, not just those treated under the NHS.

The Advantages and Disadvantages of Handwritten Prescriptions for Controlled Drugs

6.9 The requirement that the essential information on a controlled drug prescription should be written by hand appears to have two purposes. First, it ensures that the doctor writes the whole prescription him/herself rather than delegating the task (save for signature) to a member of staff. This requires the doctor to apply his/her own mind to the details of the prescription. Second, it reduces the risk of forgery. The more handwriting there is, the more difficult it is for the forger to imitate and the greater the chance that a pharmacist will spot the forgery. The requirement that numbers should be written in words as well as figures must also be intended to reduce the risk of forgery and mistake.

6.10 It is impossible to judge the extent to which the handwriting requirement produces the desirable effects intended. However, it does appear that it gives rise to several problems. Mr Alan Macfarlane, Chief Inspector, Home Office Drugs Inspectorate, described the requirement as 'antediluvian' and told the Inquiry that it leads to all sorts of difficulties.

6.11 I have already mentioned one disadvantage, namely, that to write a controlled drug prescription by hand is time-consuming for the doctor. The simultaneous entry of the prescribing information onto the prescription and into the patient records saves much time for the doctor. Of course, I recognise that general practitioners (GPs) are very busy and any measure that saves time must have some attraction. However, if the handwriting requirement increases patient safety, I would say that the saving of time should not be a determinative factor.

6.12 The main disadvantage of the handwriting rule appears to be that the incidence of errors is far greater when prescriptions are handwritten than when they are generated by computer. In her evidence, Mrs Kay Roberts, Lead Pharmacist for the Royal College of General Practitioners National Drug Misuse Training Programme and pharmacist member of the ACMD, emphasised that many handwritten prescriptions are technically incorrect and do not comply with the Regulations. One advantage of computer generation is that the computer should ordinarily prompt the prescriber to comply with every technical requirement. Mrs Roberts explained that technical prescribing errors can give rise to great inconvenience, frustration and anger at the pharmacy. If an error is detected at the pharmacy, the pharmacist has to explain to the patient or his/her representative that s/he cannot dispense the prescription and that the prescription form must be returned to the prescriber for amendment and signature. This is so even where the prescriber's intention is clear, as, for example, on a prescription for MST, where the prescriber has forgotten to state that the 'form' of the drug is 'tablets'. On occasions, pharmacists will 'take a chance' and dispense a drug even though the technical requirements have not been complied with, because they know that a refusal to do so will cause distress and they are confident that the doctor will, on request, provide a correct prescription.

6.13 Errors on the prescription can also give rise to a risk that the patient might be given a drug that is contraindicated or that s/he might be directed to take the drug in too large a dose. If a computer is used to generate the prescription, the software should produce an 'alert' signal if the doctor tries to prescribe a drug that is contraindicated for a patient by reason of an allergy or on account of incompatibility with another drug that the patient is currently taking. There should also be an alert if the doctor seeks to prescribe a dosage that is outside the normal range. However, research published in May 2004[1], while this Report was being written, suggests that computer systems currently in operation do not satisfactorily draw attention to many contraindicated drugs or hazardous drug interactions. The authors have suggested ways in which such systems might be improved and this work is to be taken forward by the National Patient Safety Agency.

6.14 Mrs Roberts said that many prescribing errors made by GPs occur because the legal requirements are not fully understood; she would like to see improved training on these issues. Also, she is of the view that the incidence of errors would be much reduced if all prescriptions were generated by computer. These advantages present a strong argument in favour of computer generated prescriptions for controlled drugs.

6.15 Would the switch to computer generation make it easier for dishonest people, whether healthcare professionals, drug addicts or drug dealers, to obtain illicit supplies? The evidence presented to the Inquiry suggested that it would probably not make a great deal of difference, and it was pointed out that, with electronic transmission, there might be a reduced danger of the theft of prescription pads. However, these views were based on the assumption that GPs' computer systems could be made secure. It is beyond the scope of the Inquiry to examine whether secure systems can be achieved in practice. Two types of problem spring to mind. First, can the systems be protected from 'hackers'? That is a difficult question and is not for me to consider. Second, can access to the prescribing facility be limited to those doctors and nurses with prescribing rights, to the exclusion of other members of the practice staff and staff employed by the primary care trust (PCT) with which most GP computer systems are now linked? I know, of course, that it is technically possible to do these things; access to parts of a system can be restricted to authorised people. However, I do have some concern that, in reality, security might not be as tight as it should be. For example, in Shipman's practice, all the staff had access to all parts of the computer system; everyone used the same password.

6.16 It seems to me that there are sensible arguments both for and against permitting the computer generation of controlled drug prescriptions. I realise that it might be thought advisable to move to computer generated prescriptions on the grounds of patient safety even though this might give rise to an increased risk of forgery and fraud. There is, however, a way to get the best of both worlds. The Inquiry heard evidence about a general practice where the doctors have found a way of combining the advantages of computer generation with compliance with the handwriting requirement of the MDR. They print out the prescription in a format that allows space for the doctor to write, in his/her own hand, beneath the printed words. In this way, the computer provides the prompts that ensure compliance with all the technical requirements and the alerts that avoid contraindicated

[1] 'Prescribing Safety Features of General Practice Computer Systems: Evaluation Using Simulated Test Cases', *British Medical Journal* 2004; 328:1171

drugs or excessive dosages. The writing provides a safeguard against forgery and mistake. The prescription complies with the MDR. The whole process does not take longer than the present processes whereby the doctor types the prescribing information into the computer and then writes the prescription by hand. It seems to me that this idea is worthy of serious consideration.

6.17 Whether or not computer generated prescriptions are permitted for controlled drugs, there will, at least for the foreseeable future, be some circumstances, such as a home visit, in which it will not be possible to use a computer, or at least not one that complies with the necessary security arrangements. No witness suggested to the Inquiry that, for a controlled drug prescription generated without the assistance of a computer, the existing special requirements should be lifted.

The Monitoring of Controlled Drug Prescriptions Issued under the NHS

6.18 Most prescriptions written for a patient being treated on the NHS are written on a standard prescription form, known as a FP10. Pads of such forms are issued to GPs by the local PCT. The same form, printed on white paper with blue and green shading, is used for all drugs, including controlled drugs, unless the controlled drug is being prescribed for dispensing by instalments, in which case a different form is used. All the prescriptions in the pads bear the name of the issuing PCT. They also bear a serial number unique to each individual prescription printed. If a pad is stolen, a warning can be issued to pharmacists not to dispense prescriptions within the range of numbers covered by the pad. The prescription pad also bears the name of the GP to whom it is issued and the GP's individual prescriber code. This code is not the GP's General Medical Council (GMC) registration number. Not all doctors working in general practice currently have an individual prescriber code. For example, locums and GP registrars (trainees) use the prescription pad of the GP principal for whom they are working. Such doctors are required to endorse the prescription with the letter 'D' to indicate their status as deputies or 'T' as trainees. However, I understand that it is intended that, at some stage in the future, all doctors who are entitled to prescribe will be allocated an individual prescriber code and pad.

6.19 The reverse of the FP10 requires the patient or the patient's representative to provide certain information at the time the prescription is presented. The collection of this information is designed to combat prescription charge fraud.

The Prescription Pricing Authority

6.20 All NHS prescriptions are sent to the Prescription Pricing Authority (PPA), which is a special health authority established under the National Health Service Act 1977 (as amended). Its principal functions are to price NHS prescriptions, to reimburse dispensers (i.e. pharmacists and dispensing doctors) and to collect and analyse information derived from these activities. It records details of all NHS prescriptions.

6.21 Prescription forms are received in batches from pharmacists and reimbursement is calculated according to the applicable Regulations. In the year to September 2003, more than 600 million prescription items were reimbursed following the receipt and processing

of more than 350 million prescription forms. The process of entering data into the computer is currently performed manually by PPA employees but computer scanning and reading of the prescription forms is to be introduced between 2005 and 2007.

6.22 Because the details of individual drugs dispensed are recorded, the PPA is able to provide prescribing and cost analysis (PACT) data and related information to strategic health authorities, PCTs and a range of other NHS bodies. Information can also be provided to individual GPs and their practices. The PPA produces its information in paper and electronic format. The information is analysed by reference to the individual prescriber code on the FP10. In theory, this means that the prescribing habits of any doctor can be examined, down to the level of each individual drug. This is a very valuable tool. The doctor can audit his/her own prescribing habits. Also, a PCT can monitor the prescribing practice of any individual doctor or of the doctors within a particular practice. However, the accuracy of the prescribing data is limited as a result of three factors. First, as I indicated above, at present a locum or registrar does not have his/her own prescription pad and instead uses the pad of one of the principals in the practice. As I have said, this arrangement is set to end in the future. Each individual doctor will have his/her own individual prescriber code and will be permitted to prescribe only under that code. The second factor that has reduced the accuracy of individual prescribing data is the very common practice whereby doctors sign repeat prescriptions for medication initially prescribed by a colleague. They often do so without either seeing the patient concerned or giving much thought to the appropriateness of the choice of medication. If a doctor signs a lot of repeat prescriptions, using his/her own prescription pad, the PACT data will not accurately reflect his/her own prescribing practice nor that of the doctor(s) who initially prescribed the medication. Third, doctors working for a deputising service or co-operative use prescription forms on which the prescribing doctor's individual prescriber code does not appear, only the code for the practice with which the patient is registered. Thus, the cost of the drug is attributed to the right cost centre but, in the PACT data, the prescription is not attributed to the prescribing doctor. If these three problems can be resolved, it should be possible in future for accurate information about any GP's NHS prescribing practice to be provided.

6.23 The usefulness of prescribing data has recently been confirmed in a report entitled 'Audit of Controlled Drugs Prescribing in England for the Financial Year 2002/3', published by the Prescribing Support Unit (PSU) of the Department of Health. The PSU examined the prescribing of controlled drugs, based on the prescribing data from the PPA, and found a number of cases where GPs were repeatedly prescribing large quantities of controlled drugs. It appears that some of these had not been picked up by the routine surveillance carried out by PCTs. The circumstances of each case have now been investigated by the PCTs in whose areas these doctors practise. In most cases, a reasonable explanation has been provided but, in some, there has been cause for concern about the doctor's conduct or competence.

6.24 Prescription forms are normally kept by the PPA for 14 months 'post-pricing', although this period is flexible and may be extended in individual cases where, for example, irregularity is suspected. Police chemist inspection officers (CIOs) often request the production of old prescription forms for the purpose of their investigations. The PPA was able to provide

relevant 'in date' prescription forms issued by Shipman at the request of the prosecuting authorities. However, the PPA's inability (for reasons of lack of storage space) to keep prescription forms for a longer period limits the use that can be made of them in investigations. Mr Barry Lloyd, an independent prescribing information consultant, who provides training for PCT employees in the analysis of PACT data, expressed the hope that, in future, it will be possible to keep an electronic archive of prescriptions and prescribing data for much longer.

Private Prescriptions

6.25 The overwhelming majority of GPs in this country work within the NHS. However, many have a few private patients and a few work exclusively, or almost exclusively, in the private sector. All prescriptions, whether issued under the NHS or privately, have to comply with the statutory requirements that apply to the kind of drug being prescribed. Whereas NHS prescriptions must be written or printed on form FP10, there is no special form for a private prescription. Most private prescriptions are written on a sheet of the doctor's headed notepaper. However, a pharmacist is obliged to dispense drugs on a private prescription written on any paper, provided that s/he is satisfied that the document is genuine, that the signatory is entitled to prescribe and that the technical requirements are satisfied. A private prescription carries no individual prescriber code such as appears on NHS prescriptions, and the prescriber is not required, as a matter of course, to provide his/her unique GMC registration number. A doctor seeing a patient privately may charge the patient a prescription fee, in addition to any consultation fee, and the pharmacist may charge a dispensing fee.

6.26 When a private prescription for a controlled drug is dispensed at a pharmacy, the pharmacist must enter the particulars of the prescription in a private prescriptions book unless the drug in question is a Schedule 2 drug and its supply has already been entered in the controlled drugs register (CDR). Private prescriptions must be kept on the pharmacy premises for two years after dispensing, unlike NHS prescriptions, which are sent to the PPA at the end of each month. A CIO or RPSGB inspector is entitled to examine private prescriptions and the private prescriptions book during a periodic inspection. However, RPSGB inspectors rarely look at them. Their brief is to ensure that the pharmacy as a whole is being properly conducted. Most CIOs do examine private prescriptions, as well as the CDR, and, from time to time, they notice signs of unlawful or irresponsible prescribing. In particular, by visiting several pharmacies in a locality, a CIO might notice a pattern of prescribing by a particular doctor which had not been apparent to any individual pharmacist.

6.27 Because private prescriptions for controlled drugs are not sent to the PPA, there is no way, at present, whereby the totality of a doctor's prescribing of controlled drugs can be monitored or audited. His or her prescribing on NHS prescriptions can be analysed by the PPA and monitored by the PCT but his/her private prescribing cannot be included in that scrutiny. Dishonest doctors know that they can evade scrutiny by prescribing privately. The Inquiry heard evidence of a GP who had been prescribing large amounts of controlled drugs on the NHS and sending an agent to collect them from the pharmacy. When he realised that his activities had come under suspicion, he switched to private prescribing,

which did not show up on the PACT data received by the PCT. Accordingly, it appeared that he had heeded advice to reduce his prescribing of controlled drugs, although all he had in fact done was reduce his NHS prescribing. Mr Michael Siswick, Director of Human Resources for the PPA, told the Inquiry that it would be quite possible for the PPA to process information from private prescriptions, as well as NHS prescriptions, provided that the prescription was written on a form that could be 'read' by the new scanning equipment that will shortly be in use. In practice, the form and layout of the prescription would have to be very similar to the FP10 form used in the NHS. Mr Siswick said that a 'more holistic picture of prescribing' would be obtained if information about private prescriptions were provided to the PPA. He believed that the PPA would welcome any step that enhanced the level of prescribing information available to doctors and NHS bodies.

Requisitions or Signed Orders

6.28 At present, any doctor can obtain supplies of a controlled drug by presenting a signed order or requisition either to a pharmacy or to a wholesaler. In effect, a signed order is very similar to a private prescription, save that it is not made out in the name of an individual patient and will normally be endorsed by the doctor with words such as 'for practice use'. In England, there is no requirement that a signed order should be presented in any particular form. In Scotland, a signed order has to be made out on a special form, akin to but distinguishable from the FP10. In England, most doctors or practices order their supplies on headed paper but this is not compulsory. The transaction is a private one and the doctor or practice pays the commercial price for the drug. If the drug is administered to a patient under the NHS, the doctor or practice is entitled to be reimbursed the cost of the drug and an administration fee. If the treatment is given privately, the patient will pay the cost of the drug.

6.29 When a requisition is presented, the pharmacist makes an entry in the CDR (when necessary) and should keep the requisition for at least two years. The CIO might well inspect it. For the great majority of doctors, these arrangements are perfectly satisfactory. However, it is possible for a doctor who is addicted to drugs to obtain supplies on requisition from different pharmacies and for his diversion to escape the notice of a CIO. If a doctor repeatedly obtains controlled drugs on requisition from the same pharmacy or even from several pharmacies within the area of one CIO, a pattern of obtaining should be noticed. But, if the doctor obtains his/her supplies from pharmacies in different areas, the entries are unlikely to appear significant to the CIO. Such requisitions are not sent to the PPA and do not form part of its analysis of the doctor's usage of controlled drugs.

Conclusion

6.30 I mentioned in Chapter Three that, more than 80 years ago, the Dangerous Drugs Regulations 1921 conferred on the Home Secretary the power to prescribe and issue an official form for the private prescribing of controlled drugs. The proposal was never implemented. I can understand why it was not thought necessary. The abuse of controlled drugs was not such a grave problem then as it is today. In the 1960s, the Brain Committee twice decided against the introduction of such a form. It was thought that the additional

safeguard to be provided by the use of such a form would be slight. However, in modern times, the use of an official form for the private prescribing and/or requisitioning of controlled drugs would provide a significant safeguard against abuse, principally because it would allow the PPA to analyse the whole of a doctor's use of controlled drugs, both private and NHS. This is an issue to which I will return in Chapter Fourteen. I shall also consider the need for additional information, such as some means of identification more informative than just a signature, to be included on a private prescription.

6.31 In Chapter Fourteen, I shall also return to consider whether, in the light of the responses to the Discussion Paper and the views of participants in the seminars, I should recommend the abolition of the handwriting rule and the introduction of computer generated forms for the prescribing of controlled drugs.