

## CHAPTER FOURTEEN

### The Discussion Paper and the Seminars: Conclusions

#### Introduction

- 14.1 In July 2003, the Inquiry issued a Discussion Paper, entitled 'The Use and Monitoring of Controlled Drugs in the Community'. Its purpose was to provide a focus and stimulus for written responses and for discussion at a series of seminars held by the Inquiry over three days in January 2004. Issues arising under the following general topics were discussed:
- (a) prescribing controlled drugs and prescriptions for controlled drugs
  - (b) arrangements for security and record keeping for controlled drugs in doctors' surgeries
  - (c) arrangements for security and record keeping for controlled drugs in community pharmacies
  - (d) computerised record keeping
  - (e) inspection and monitoring of community pharmacies and surgeries
  - (f) collection and delivery of controlled drugs in the community
  - (g) controlled drugs in the community and record keeping
  - (h) administration, return and destruction of controlled drugs in the community.
- 14.2 The Inquiry received written responses to the Discussion Paper from 126 individuals and organisations. A list of respondents appears at Appendix E to this Report.
- 14.3 The first day of the seminars comprised two presentations, which explained the arrangements for the prescribing and monitoring of the use of controlled drugs in British Columbia and the inspection and monitoring arrangements in Northern Ireland. This seminar has been summarised in the previous Chapter. The second and third days of the seminars were taken up by a discussion of the various topics raised in the Discussion Paper.
- 14.4 Each of the organisations and individuals taking part in the seminars had an interest in, or involvement with, controlled drugs. The organisations were the Department of Health (DoH), the Prescription Pricing Authority (PPA), the Royal Pharmaceutical Society of Great Britain (RPSGB), the National Pharmaceutical Association (NPA), Macmillan Cancer Relief, the British Medical Association (BMA), the Royal College of General Practitioners (RCGP), the Association of Chief Police Officers (ACPO) and the National Association of Chemist Inspection Officers (NACIO). Those who attended in an individual capacity included Mr Alan Macfarlane, Chief Inspector of the Home Office Drugs Inspectorate (HODI), Professor Richard Baker, Director of the Clinical Governance Research and Development Unit, University of Leicester, and Mrs Kay Roberts, Lead Pharmacist for the RCGP National Drug Misuse Training Programme and pharmacist member of the Advisory Council on the Misuse of Drugs (ACMD). A complete list of participants appears at Appendix F to this Report.

- 14.5 Participants submitted written responses to the Discussion Paper in advance of the seminars and expanded on those responses in the course of discussions, which were led by Senior Counsel to the Inquiry. Others attending the seminars as observers were able to raise points with members of the Inquiry team and their contributions were passed on to Counsel. The seminars followed the same outline as the Discussion Paper and I shall adopt a similar framework in this Chapter.
- 14.6 I found the seminars extremely valuable. Participants were familiar with the background to Shipman's misuse of controlled drugs and were very well informed about the issues under discussion. They recognised the potential for the abuse of controlled drugs by healthcare professionals. All participants brought to the discussion their own particular knowledge and expertise and, where applicable, the concerns of those whom they represented. All recognised the need to improve the existing systems of control, while safeguarding the interests of patients. None was over-protective of his/her sectional interest. There were bound to be differences of view on some issues but the argument was always constructive. On occasions, some participants were prepared to express a change of view after hearing the debate.
- 14.7 In this Chapter, I shall summarise the views expressed by respondents and participants. I shall then express my own views, which will form the basis of my recommendations. However, I stress that my views have been informed not only by the responses to the Discussion Paper and the discussion at the seminars but also by all the evidence I have received, both oral and written. In Chapter Three, I mentioned the principle behind the recommendations in the Duthie Report in 1988. This was that the regulation of the use of controlled drugs should be based upon the **'three Rs'**: reconciliation, record keeping and responsibility. I too have sought to base my recommendations on those requirements.

### Should the Freedom to Prescribe Controlled Drugs Extend only to Practitioners in Actual Clinical Practice in a Relevant Field?

- 14.8 At present, every registered medical practitioner is entitled to prescribe prescription only drugs, including controlled drugs, unless s/he is subject to some specific restriction. It had come to the Inquiry's attention that some doctors prescribe controlled drugs on an occasional basis although they have no list of patients. They may be employed in, or even retired from, a purely administrative post. Such doctors have no professional need to prescribe controlled drugs. They are unlikely to have a good up to date knowledge of the properties and effects of controlled drugs and are therefore at increased risk of making prescribing errors or poor prescribing decisions. Such doctors will not have the benefit of the framework of clinical governance that now exists for all those practising doctors working in the NHS. Any errors of judgement they might make will be unlikely to be noticed. Moreover, if such a doctor were to abuse the privilege of prescribing by feeding his/her own addiction or that of the occasional 'unofficial' patient, the conduct might go undetected. There is much to be said for limiting the right to prescribe controlled drugs to those who need to do so in the course of their professional practice. As I explained in Chapter Three, the value of restricting the freedom to prescribe controlled drugs to those doctors **'in actual practice'** was recognised by the Home Office in the 1920s, but the attempt to enact such a restriction was abandoned.

- 14.9 Among respondents to the Discussion Paper, there was general support for the idea that some restriction should be imposed on the general freedom of all doctors to prescribe controlled drugs. Dr John Grenville, for the BMA, Professor Baker, and Mr Alaster Rutherford, Head of Medicines Management, Bristol North Primary Care Trust (PCT), all supported the idea in principle. They saw the prescribing of controlled drugs as an integral part of a doctor's practice. They expressed the view that, if a doctor wishes to practise as such, s/he must be able to do so competently and with an awareness of current thinking in his/her chosen field. For them, the fundamental issue was whether a doctor was clinically competent to practise in his/her field; if s/he was, then it would be wrong to curb his/her freedom to prescribe controlled drugs. If s/he was not, then s/he should enjoy none of the privileges of the status of doctor, including the freedom to prescribe controlled drugs.
- 14.10 Dr Clare Gerada, representing the RCGP, said that it would be necessary to provide a clear definition of what was meant by a term such as 'actual clinical practice'. She thought there were some situations in which it might not be clear whether the doctor was in 'actual clinical practice'. She cited the example of a retired general practitioner (GP) who kept on a few private patients, seeing them only occasionally. Such a doctor has genuine patients and might be said to be in 'actual clinical practice'; even if the prescribing of controlled drugs were restricted to those in 'actual clinical practice', such a doctor would not fall foul of the restriction. Dr Gerada felt that this was not acceptable and she questioned from where such a doctor would obtain his/her clinical support and clinical governance structure. I recognise the force of that point, which, as Professor Baker and Dr Grenville said, is not limited to the prescribing of controlled drugs.
- 14.11 A second point was raised in the Discussion Paper, as an alternative issue to that of whether the right to prescribe controlled drugs should be limited to those doctors in 'actual clinical practice'. The Inquiry also asked whether, in future, when licensing is brought in, only licensed doctors should be permitted to prescribe controlled drugs. What the Inquiry had in mind was whether the requirement for revalidation, to be imposed by the General Medical Council (GMC) in the near future, would provide a sufficient safeguard for patients and the public. If only those doctors who were in 'actual clinical practice' were to be revalidated, there would be no need to impose the kind of restriction that the Inquiry was considering. Unfortunately, the question was misunderstood by some respondents, who thought that the Inquiry had in mind a special licence for the prescribing of controlled drugs. For example, the Royal College of Nursing (RCN) and Macmillan Cancer Relief expressed a concern that limiting the right to prescribe controlled drugs to doctors holding a licence might compromise patient care if licensed doctors were to fall into the minority. I had never envisaged the need for a special licence, such as exists now for doctors prescribing certain drugs for the treatment of addiction. I think the misunderstanding arose from the Inquiry's use of the word 'licence' instead of 'revalidation'. In any event, now that the Inquiry has a greater understanding of the GMC's revalidation proposals (which I shall discuss in detail in the Fifth Report), it is clear that doctors who are not in 'actual clinical practice', such as those in administrative positions, will be eligible to apply for revalidation. They might well be revalidated and yet not be competent to prescribe controlled drugs, particularly without clinical support and outside

a structure of clinical governance. The introduction of revalidation might, however, resolve the problem, envisaged by Dr Gerada, of the doctor who sees a few private patients in retirement. Such a doctor may well decide not to apply for revalidation and would then be obliged to give up his/her vestigial practice.

- 14.12 The Association of the British Pharmaceutical Industry made the point that pharmaceutical physicians employed in industry, who will have to undergo revalidation in order to remain in post, would probably not be in 'actual clinical practice'. It seems to me that the position of such doctors is a good example of the problem under discussion. I think it is inappropriate for pharmaceutical physicians employed in industry to have the power to prescribe controlled drugs for a patient or indeed for themselves or any member of their families.
- 14.13 A small number of respondents made the point that doctors might be reluctant to take up administrative posts if re-entry into clinical practice were difficult to achieve. The answer to that point must surely be that, provided they have kept up their relevant skills and knowledge, they should be allowed to re-enter clinical practice; if they have not kept up their skills, then it would hardly be reasonable for them to acquire full prescribing powers and to be 'let loose' on patients without further training and assessment of their competency.

## Conclusion

- 14.14 In my view, it is not right that a doctor should retain the privilege of prescribing controlled drugs from the time s/he is registered as a doctor until death, even when s/he spends a lifetime in administrative posts and never sees a 'real' patient. Doctors not engaged in 'actual clinical practice' are, in my view, far more likely to fall into poor prescribing practice than their actively engaged colleagues. A doctor should be entitled to prescribe or administer controlled drugs (and possibly any drugs) only if s/he needs to do so for the purposes of the 'actual clinical practice' in which s/he is engaged. I think that the concept of 'actual clinical practice' must connote the existence of a direct professional relationship between the doctor and his/her patients. This would mean that a doctor working solely in the area of public health or as an officer of a PCT, for example, should not prescribe or administer controlled drugs. Nor should a GP who has completely retired from practice. A GP who has retired from full-time practice but still undertakes locum work should be entitled to prescribe controlled drugs while s/he remains on the list of a PCT and undergoes whatever requirements are imposed for continuing education, clinical governance and revalidation.
- 14.15 Within the NHS, I do not think that the imposition of such a restriction should cause practical difficulties. Usually, it will be obvious from the nature of the post held or from the contractual relationship with a PCT whether there will be a legitimate need to prescribe controlled drugs. For a doctor operating wholly in the private sector, the position may be more difficult and it may be necessary for such a doctor to apply for authorisation to an appropriate body, explaining the nature of his/her practice and justifying the need to prescribe controlled drugs. This system operates satisfactorily in British Columbia, where physicians have to apply to the College of Physicians and Surgeons of British Columbia

before they are issued with the special prescription forms that are used there for controlled drugs. In this country, the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission) might be an appropriate body to make such decisions. The Healthcare Commission is the body now responsible for the inspection and monitoring of private medicine. Alternatively, if a controlled drugs inspectorate were to be set up, that body would be well placed to fulfil this function.

- 14.16 A prohibition against the prescribing of controlled drugs by those doctors not required to do so in the course of 'actual clinical practice' should not compromise patient care. It should have the opposite effect. I recognise that such a prohibition would mean that some doctors would not be able to provide appropriate treatment to a patient *in extremis* whom they might encounter in an emergency situation. However, such situations, which would have to involve a retired GP (for example) happening upon the emergency, close to a pharmacy which had no suitable 'non-controlled' alternatives to the controlled drug required, would occur very rarely indeed. Moreover, the Medical Adviser to the Inquiry, Dr Aneez Esmail, has advised me that few lives are saved by emergency treatment such as this and a doctor who is not in 'actual clinical practice' may inadvertently harm or even kill a patient by ill-informed or careless administration of controlled drugs. Shipman, it will be remembered, more than once, diverted diamorphine obtained on this 'emergency' pretext.
- 14.17 I also recognise that Government policy is moving towards extending, rather than restricting, the categories of healthcare professionals who are allowed to prescribe and administer controlled drugs. What I propose is not inconsistent with this extension. It is envisaged that only properly qualified nurse prescribers, acting in the course of their duties in a specified post, should be allowed to prescribe controlled drugs. It cannot be envisaged that, once having gained their qualification, such nurses should retain their prescribing powers until death.

### **Should There Be Some Control on Doctors' Prescribing of Controlled Drugs for Themselves, Their Families or Friends?**

- 14.18 There is currently no prohibition against, or restriction on, doctors prescribing controlled drugs for themselves, their families or friends although, broadly speaking, it is regarded as poor practice. There are two main reasons why it is so regarded. First, a doctor who prescribes outside a true professional relationship may lack the objectivity needed for the proper care of the patient. Second, it is by no means unknown for doctors to prescribe for themselves or their families or friends to feed a concealed addiction.
- 14.19 The Discussion Paper raised the question whether such practice ought to be prohibited and, if not, whether there might be a way of ensuring that such prescribing is more readily detectable. It queried whether a doctor issuing a controlled drug prescription should be required to state on the prescription whether s/he is the patient and whether s/he is in other than an 'arm's length' relationship with the patient. It queried whether a requirement should be introduced that such prescriptions be approved and countersigned by an 'uninvolved' prescriber.

- 14.20 Among the responses from pharmacists, healthcare professionals other than doctors, and primary care organisations, there was strong support for an absolute prohibition against such prescribing. The Council of the Independent Doctors Forum supported an absolute prohibition.
- 14.21 Perhaps not surprisingly, the idea received less support from the medical profession generally. The main reason given was that such prescribing might be unavoidable in certain circumstances. The geographical isolation of some practices was felt to be a key factor. In its response to the Discussion Paper, Macmillan Cancer Relief said that, in rural communities, GPs might be called upon to prescribe for terminally ill 'friends'. Restrictions on prescribing controlled drugs in these situations could be medically and ethically unacceptable. The RCGP made the same point. The GMC, which generally regards such prescribing as poor practice and advises that doctors should not have family members on their lists, said that, while a total prohibition against the self-prescribing of controlled drugs might be unobjectionable, a prohibition against prescribing for family and friends might cause significant problems in small communities, where doctors necessarily have social lives, and sometimes extended families, in the communities they serve. These responses highlight the difficulty of defining what is meant by 'family' and 'friends', which would be necessary if any legal restriction were to be applied. The real mischief at which this suggestion was aimed is prescribing outside a professional doctor/patient relationship. It was never intended to suggest that a doctor could never have a friend or relative on his/her list of patients. Most doctors recognise that it is inadvisable to give professional services to those with whom they are closely connected but, in small communities, this will sometimes be unavoidable.
- 14.22 In its written response, the NPA supported the idea of an absolute prohibition but, at the seminars, its Chief Executive, Mr John D'Arcy, said that the Association had not really taken account of the situation in which a doctor might be called upon to prescribe for a relative in an emergency, which he thought should be permitted.
- 14.23 The initial view of the BMA was that such prescribing should not be limited, because it is rarely abused (in fact, the extent of the abuse is unknown) and, in rural and remote areas, there will be no alternative. I should point out that such cases of prescribing for family members of which the Inquiry has heard did not occur either in an emergency or in a remote area. At the seminars, Dr Grenville, speaking on behalf of the BMA, explained that attitudes among members of the medical profession to such prescribing were changing and it was increasingly being regarded as a serious matter. Instead of an absolute prohibition, the BMA favoured an approach that placed greater emphasis on the correct and open recording of such prescribing.
- 14.24 Miss Mandie Lavin, representing the RPSGB, advocated the idea of a special endorsement on a prescription to the effect that the patient was known to the doctor other than in a professional capacity. Mr D'Arcy felt that the NPA would support the idea of a special endorsement on the prescription stating that it had been issued in an emergency. Dr Grenville thought that the idea of a special endorsement might be attractive but had concerns about how such a requirement would be phrased.

- 14.25 There was broad support for the suggestion that there should be some safeguards to ensure that the prescribing of controlled drugs by doctors for themselves or their families and friends should be monitored. Miss Lavin advocated a requirement whereby a doctor would report to his/her PCT in the event that such a prescription was issued, although she acknowledged that this would leave a *lacuna* with regard to non-NHS prescriptions.

## Conclusion

- 14.26 In my view, it should be a criminal offence for a doctor to prescribe a controlled drug for him/herself, subject to a statutory defence available where the doctor acted in an emergency. Such circumstances would be most exceptional and would arise if, for example, a doctor were in severe acute pain and needed analgesia to provide relief until s/he could receive independent professional medical care. It is, in my view, quite wrong for a doctor to prescribe a controlled drug for him/herself for any non-acute condition. Many doctors who have become addicted to a controlled drug say that the abuse began with unwise self-prescribing for chronic pain, depression, insomnia or anxiety. That may be true. The rule that I propose should greatly reduce the risk of such addiction. In my view, the same rule should apply to the self-administration of a controlled drug taken from a doctor's own or practice stock; it should be unlawful, subject to the statutory defence. The practical effect of this rule would be that a doctor would be able to self-prescribe only a very limited number of controlled drugs, namely the Schedule 2 analgesics, and then only in exceptional circumstances. He or she would, of course, be able to self-administer any drug prescribed by another doctor.
- 14.27 In my view, it is also highly undesirable for a doctor to prescribe controlled drugs for a member of his/her immediate family or to administer to such a person a controlled drug from personal or practice stock. There are particular risks to the patient when controlled drugs are prescribed by a doctor who cannot exercise full professional objectivity. The prescribing of controlled drugs is but one aspect of the treatment a GP provides. It is generally accepted that everyone should have a GP with whom they have a professional – rather than a personal – relationship. The need for this professional independence is well illustrated by consideration of the example of the woman whose GP husband advises that her back pain or depression should be treated with a controlled drug. He may or may not be right but his objectivity must be questionable. In my view, GPs should not normally treat members of their immediate families and should ensure that they are on the list of another GP. I do accept, however, that, in exceptional circumstances, for example in very remote areas, it may be necessary for a GP to have members of his/her immediate family on his/her list. This is not ideal but, where it is unavoidable, at least there should be the potential for supervision through clinical governance, in particular by the monitoring of controlled drugs prescribing. To facilitate such supervision, I think PCTs should require a doctor who has a member of his/her immediate family on his/her list to inform the PCT of the position. The need for such an arrangement to continue might well be questioned, for example, by a medical adviser or at appraisal. Leaving aside the very limited circumstances where it is unavoidable that a GP has immediate family members on his/her list, it should be regarded as unacceptable for any doctor to prescribe a controlled drug for an immediate family member, save in the type of emergency I mentioned above.

I accept that such emergencies might arise more often for those living in remote areas than for those living within easy reach of a hospital or health centre. The GMC and PCTs should make the position clear.

- 14.28 Thus, I do not favour an absolute prohibition against the prescribing of controlled drugs for immediate family members. However, I regard it as essential that, when a doctor prescribes a controlled drug for him/herself or for a member of his/her immediate family, the position is clearly acknowledged. I would define the immediate family as comprising a spouse, family partner, children, grandchildren, stepchildren (including the children of family partners), parents and grandparents. A doctor issuing a prescription (whether on the NHS or privately) for a controlled drug within Schedules 2–4 to the Misuse of Drugs Regulations 2001 (MDR 2001) should be required to declare on the prescription, if it be the case, that s/he is prescribing for him/herself or for a member of his/her immediate family. He or she should also be required to state, if it be the case, that s/he is prescribing in an emergency. Administration to anyone, including a family member, of a Schedule 2 drug from personal or practice stock should always, in any event, be recorded in the doctor's controlled drugs register (CDR) as well as in that person's medical records.
- 14.29 If prescriptions containing such a declaration were likely to come to the attention of someone in authority, a doctor in two minds about prescribing benzodiazepines for his/her spouse or partner, or Ritalin for his/her child, might, I think, decide not to do so. A false declaration or the failure to make a declaration where one was called for would, at the least, be professional misconduct, which in my view the GMC should regard as a serious matter. The presence or absence of such a declaration would also be of relevance in the context of a criminal trial such as that in the case of R v Dunbar<sup>1</sup>, to which I referred in Chapter Four, if an issue arose as to whether the doctor was genuinely prescribing in his/her capacity as such.
- 14.30 I shall recommend that all controlled drug prescriptions, both NHS and private, should be sent to the PPA for processing. Prescriptions with a declaration such as I have described above should be readily identifiable. They could be analysed and monitored by the relevant PCT or the Healthcare Commission or the controlled drugs inspectorate, if one were to be created.
- 14.31 Although I recognise that it will usually be unwise for a doctor to prescribe controlled drugs for a friend and that such prescribing might conceal diversion of the drug for improper purposes, I do not think it would be practicable to institute any rules designed to curb such a practice. It is almost impossible to draw the line between who is a 'friend' and who is not. In my view, the GMC should make plain that it is bad practice for a doctor to prescribe a controlled drug for anyone with whom s/he does not have a genuine professional relationship. Although it would be difficult to define where the line should be drawn, it will usually be quite easy to recognise cases in which a doctor has crossed the line and prescribed outside a professional relationship. In my view, such cases should be regarded as professional misconduct.

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<sup>1</sup> [1982] 1 All ER 188



14.32 I do not regard the countersigning of a prescription by a second doctor to be viable or worthwhile. A doctor who is in a position to countersign would be able to prescribe in his/her own name.

### **Should the Freedom to Prescribe Controlled Drugs for a Patient in the Community Extend only to a Patient's 'Nominated' General Practitioner?**

14.33 It is recognised that some patients (almost always addicts) will try to obtain supplies of controlled drugs from more than one prescriber concurrently, a practice known as 'double scripting'. This practice might be carried out with or without the knowledge and connivance of the prescribers. One or both prescriptions might be private prescriptions. The evidence to the Inquiry suggests that double scripting is a significant problem. To counter this problem, the suggestion was made that a patient should be issued with controlled drug prescriptions only by his/her nominated general practitioner.

14.34 There was a general recognition of the advantages that accrue where one doctor has special responsibility for the prescribing of controlled drugs to a patient, whether in the context of palliative care or in that of the treatment of addiction. Dr Gerada, whose special interest is the treatment of addiction, explained that, as a means of reducing diversion of controlled drugs, DoH guidelines require that there should be a named GP for the care of all patients receiving treatment for addiction. She supported this principle even though the requirement can give rise to practical problems.

14.35 Notwithstanding the recognition of these advantages, the concept of such a restriction received very little support from those who responded to the Discussion Paper. The main objection was that its introduction would lead to practical problems. Under the new General Medical Services Contract, which came into effect in April 2004, patients are registered with a practice rather than with individual doctors. It would create real difficulties if only one member of the practice could prescribe any controlled drug for the therapeutic care of a patient. Attention was also drawn to the difficulties such a restriction would create for patients needing palliative care out of hours or while visiting relatives or friends away from their home area. It was also pointed out that a restriction would cause problems for GPs working in collaboration with other doctors in substance misuse clinics.

### **Conclusion**

14.36 I recognise that the nomination of one GP to be responsible for the care of a patient receiving controlled drugs would assist in the prevention and detection of double scripting. However, the imposition of a rule to that effect could have a direct adverse impact upon patient care. There are other ways in which double scripting might be better policed. One would be a system whereby all controlled drugs prescriptions carry a unique patient identifier (as they do in British Columbia) so that patient-specific information can be processed by the PPA and will come to the attention of the monitoring organisation. Another would be the introduction of electronic patient care records, available to all

doctors and pharmacists at the time of prescribing and dispensing, about which I shall say more later in this Chapter.

### Should Section 12 of the Misuse of Drugs Act 1971 Be Repealed?

- 14.37 As I have explained in earlier Chapters, the power conferred by section 12 of the Misuse of Drugs Act 1971 (MDA 1971) has fallen into disuse. It has not been used to curtail the freedom of an individual doctor to prescribe, possess, supply or administer controlled drugs since 1986.
- 14.38 There was a general consensus that some power to restrict the prescribing rights of doctors convicted of controlled drugs offences should exist. Most respondents to the Discussion Paper thought that the power under section 12 should be retained. However, it appeared to me that many of those expressing that view were under the mistaken impression that it was still being actively used.
- 14.39 Mr Macfarlane was of the view that the power to restrict a doctor's right to prescribe controlled drugs is more appropriately exercised by the GMC or by the doctor's employer or contracting authority, usually a NHS body, rather than by the Home Office. At the present time, the HODI has neither the resources nor the expertise to deal satisfactorily with the issues to be taken into consideration when deciding whether to recommend exercise of such a power.
- 14.40 Mrs Roberts was concerned that, if section 12 were to be repealed, it should be replaced with something else that would be robust and could be implemented quickly, for the protection of patients. Many respondents echoed these sentiments. Mrs Roberts was not happy with the way in which the GMC dealt with such cases. She referred to one case, of which she knew, in which it took six years for the GMC to remove from the register a practitioner found to have been prescribing irresponsibly. On the other hand, Dr Grenville described a case that illustrated prompt and effective action taken by the medical authorities.
- 14.41 PCTs and the GMC have the power to take prompt action. The GMC can refer a case to its Interim Orders Committee, which can impose conditions on the right of a doctor to continue in practice pending the full hearing of the case against him/her. Those conditions can include a restriction on prescribing rights. Miss Lavin thought that a doctor's prescribing rights should be automatically suspended following a conviction or caution for controlled drugs offences. Mr Rutherford agreed. He said that, although PCTs can now suspend a doctor from the medical list, thereby preventing him/her from practising in the area of that PCT, the doctor was still free to prescribe in a non-NHS setting. Dr Gerada did not disagree fundamentally with the idea of an automatic suspension following conviction but expressed concern that the immediate withdrawal of a young doctor's right to prescribe controlled drugs, perhaps following weekend recreational drug abuse outside the work setting, might be inappropriate and disproportionate.
- 14.42 Miss Lavin stressed that, once a restriction has been imposed, there must be a satisfactory method of informing pharmacists of the restriction and of enabling them to confirm the status of a prescriber at any time of the day or night.

## Conclusion

- 14.43 I accept that the Home Office has never been well placed to make decisions about the withdrawal of prescribing rights. It lacks the necessary medical expertise. The GMC and PCTs have the power to restrict the rights of GPs to prescribe controlled drugs, and have ready access to the necessary expertise. I have no means of knowing whether they always use those powers satisfactorily so as to protect the interests of patients and the public. In my view, it would be wrong for Government to remove section 12 from the statute book unless and until satisfied, after an independent review and audit of recent cases, that the GMC and PCTs were taking prompt, sufficient and effective measures in such cases. The Inquiry has examined a number of cases in which the GMC has dealt with doctors convicted of controlled drugs offences. These will be described in the Fifth Report. However, I cannot claim to have carried out a thorough audit. Many of these cases involve a doctor who has become addicted to a controlled drug. My impression is that the GMC focusses mainly upon the treatment of the doctor's addiction. Dishonest conduct is treated as being 'part of the illness' and the assumption is made that, once the illness is treated and under control, prescribing rights should be restored, subject to a period of monitoring. There is limited, if any, investigation into the effect which the doctor's addiction has had or is likely to have on the quality of care given to patients. On the basis of the necessarily limited exercise carried out by the Inquiry, I could not say that I was satisfied that the GMC always strikes the right balance between the rehabilitation of the doctor and the need to protect patients and the public. I have little information about how PCTs deal with such cases. If, on conducting a more complete audit of all the recent cases, the view is formed that the current position is not satisfactory, I think that the Government should retain section 12 and ensure that it can be effectively operated.
- 14.44 At present, doctors on a PCT list are required to inform the PCT whenever they accept a police caution, are bound over or are convicted of a criminal offence. They are also under a duty to tell the PCT when they become the subject of any criminal proceedings. For the present, my view is that, as soon as a GP is cautioned or convicted in connection with a controlled drugs offence, it should be incumbent upon him/her and on the police to report the caution or conviction to the GMC, which should promptly decide whether, and if so what, action is necessary. In my view, the GMC should also inform the doctor's employer or PCT of the action it intends to take, if any.
- 14.45 Whenever a curb is placed on a doctor's prescribing powers, the information must promptly be made available, at all times of day, to those who need to know of it, namely the doctor's employer or PCT and, above all, the pharmacists who will give it practical effect. This should not be too difficult to achieve in this electronic age.
- 14.46 For the sake of completeness, I add that I can well understand why the Government has no intention of using section 13 of the MDA 1971 again. The use of a tribunal to make findings of fact and to advise the Home Secretary in respect of irresponsible prescribing proved unsatisfactory. Such matters must be dealt with by the GMC and/or, in the case of a doctor working in the NHS, by the relevant NHS body. In future, it may be thought appropriate for the Healthcare Commission to exercise similar powers over doctors practising in the private sector.

## Should There Be a Policy Shift towards Encouraging the Provision of Community Pharmacies in Rural Areas so as to Reduce the Need for Doctors to Provide Dispensing Services?

- 14.47 In Chapter Five, I referred to the position of GPs practising in rural areas who provide dispensing services to NHS patients in addition to the usual range of medical services. In the UK, there is a well-established differentiation between the prescribing and dispensing functions; usually, doctors prescribe and pharmacists dispense. The Inquiry raised the issue of whether the present arrangements for determining when and where doctors, rather than pharmacists, provide pharmaceutical services operate in the best interests of patients.
- 14.48 It is generally accepted that the involvement of a pharmacist in the process of providing medication to a patient acts as a safety check against error. Many respondents to the Discussion Paper, including Dr Jim Smith, Chief Pharmaceutical Officer for England at the DoH, emphasised the importance of the check inherent in the differentiation of functions. Second, it is obvious that, where both prescribing and dispensing functions are carried out by the same person or within the same commercial or professional entity, there is a potential for the loss of professional objectivity or even abuse. Moreover, at present, the arrangements for the inspection of the dispensaries of dispensing doctors appear to be virtually non-existent.
- 14.49 Several respondents pointed to the benefits of the dispensing doctors' service. The DoH reported that many patients find the arrangement very convenient. That will often be the case as, by definition, the service should be offered only in an area in which pharmacy services are not readily accessible. Dr Smith said that the Office of Fair Trading had recently produced a report on the competition issues raised by the existing legislation and had recommended that any person who met the professional requirements of the RPSGB should be free to set up a pharmacy anywhere. The Government had not accepted that recommendation but was shortly to produce a position paper setting out its proposals for the future.
- 14.50 Turning to the more practical concerns that arise from the lack of pharmacy expertise available when dispensing doctors dispense as well as prescribe, Dr Malcolm Ward, Chairman of the Dispensing Doctors' Association (DDA), pointed out that a dispensing doctor frequently has a dispenser working in his/her practice. He argued that a trained dispenser can provide an independent safety check. That I accept, although I find it hard to believe that a dispenser who has undergone a brief practical course can do so as well as a pharmacist with five years' professional training. But, in any event, there is no obligation on the dispensing doctor to employ a trained dispenser and my understanding is that many do not. In a post-seminar response, Dr Ward said that the DDA was fully aware of the need to improve the availability and accessibility of dispenser training. He described the provision of such training as a '**huge logistic exercise**'.
- 14.51 It was pointed out by Dr Grenville that any doctor can supply drugs by personal administration and that this amounts, in effect, to prescribing and dispensing as one process. That is also true, although personal administration of the medication by a doctor occurs relatively rarely when compared with the usual procedure of the prescribing of the

medication by a doctor, dispensing by a pharmacist and self-administration by the patient.

- 14.52 As I mentioned in Chapter Nine, chemist inspection officers (CIOs) do not have the power to inspect the premises of dispensing doctors and their visits to such premises are rare. Detective Constable (DC) Duncan White, Secretary of the NACIO, told the Inquiry that visits to dispensing doctors' premises usually take place only when the doctor invites the CIO to attend because s/he wishes to dispose of 'out of date' controlled drugs. The CIO may then be permitted to look at the records kept and the safe custody arrangements. However, the CIO has no power to require any shortcomings to be remedied. He also said that his colleagues reported to him that, in general, record keeping by dispensing doctors was less than satisfactory, although there were some whose standards of record keeping were 'superb'. In the absence of any system of routine inspection, such evidence is bound to be anecdotal. Mr Macfarlane said that the HODI (whose inspectors do have the power to inspect such premises) does not routinely inspect dispensing surgeries. However, on occasions when its inspectors have viewed the records kept in such establishments, they too have found evidence of poor record keeping.
- 14.53 Mr D'Arcy spoke of the disparity that exists, in terms of inspections, between pharmacists and dispensing doctors and advocated parity in those arrangements. His views were echoed by Dr Grenville, speaking on behalf of the BMA, who said that all doctors' premises should be inspected as regularly and as rigorously as pharmacies are. This would, he said, be beneficial for doctors and for public confidence in them. Both dispensing doctors and prescribing doctors should be subject to the same rules and regulations as their pharmacist colleagues.

## **Conclusion**

- 14.54 It is not part of my remit to explore the merits of the 'competition' issues that divide the dispensing doctors and pharmacists. Nor am I inclined to recommend that there should be a policy shift towards encouraging the provision of community pharmacies in rural areas. I cannot fail to observe, however, that, when a doctor both prescribes and dispenses controlled drugs, not only is the opportunity for independent professional scrutiny of the prescription lost but the opportunity for diversion and abuse is far greater.
- 14.55 Proper inspection of dispensing doctors' arrangements for controlled drugs is, in my view, an imperative. CIOs should have the power and the resources to inspect dispensing doctors' surgeries in the same way that they currently inspect pharmacies. If, in the future, there were to be a controlled drugs inspectorate such powers of inspection should be exercised by that body.

## **Prescriptions**

### **Should It Be Permissible and/or Encouraged for Controlled Drug Prescriptions to Be Generated by Computer?**

- 14.56 In Chapter Six, I described the special handwriting requirement imposed by the MDR 2001 for the issue of prescriptions for all controlled drugs in Schedule 2 and some in

Schedule 3. I discussed some of the advantages and disadvantages of the current requirement. When the question was raised in the Discussion Paper as to whether this requirement should be removed, there was widespread support for the suggestion that it should be permissible for prescriptions for all controlled drugs to be computer generated.

- 14.57 It is now Home Office policy that such a change should be introduced. At the seminars, Mr Macfarlane outlined, with some enthusiasm, the many advantages which he believes will accrue from computer generated prescriptions, integrated with computerised systems of record keeping for producers, wholesalers and pharmacists. The HODI has encouraged the experimental development of computerised systems alongside the paper-based records that are currently required. Mr Macfarlane sees real advantages in such an arrangement and believes that any security problems can be resolved, if not perfectly, at least to an acceptable degree.
- 14.58 Dr Grenville and Professor Baker strongly supported the suggestion for change to computer generated controlled drug prescriptions. In common with many others, they felt that the ability of software systems to alert prescribers to clinical or technical prescribing errors would lead to fewer errors being made. Dr Smith agreed. He said that handwriting problems are responsible for a very large proportion of medication errors, including fatal errors. Moreover, the electronic creation of prescriptions would allow much more efficient transfer and analysis of prescribing data.
- 14.59 Despite the general support for the proposal, a number of respondents sounded a note of caution. The substance misuse steering group of Kensington & Chelsea and Westminster PCTs said in its written response that writing a prescription by hand acts as a mechanism for doctors to double check the strength and the dose of the drug. Mr Ian Rudd, Macmillan Cancer Relief Principal Pharmacist at the Raigmore Hospital, Inverness, agreed that handwriting brought some advantages. He said that his team runs an electronic prescribing system for patients receiving cytotoxic chemotherapy. He added that, under the new system, prescribing had improved, in that fewer technical errors were being made, but it had been found that prescribers could become careless when using the computer. So, although the system had eliminated technical errors (e.g. a failure to write the word 'tablets'), it had not eliminated clinical errors.
- 14.60 A number of other respondents did not support computer generation. The ACPO Drugs Sub-Committee was worried that computer generated prescriptions would be easier to forge. The Kensington & Chelsea and Westminster PCTs steering group and others shared this concern. Conversely, some contributors felt that computer generated prescriptions offered greater security against forgery and theft, particularly if allied (as they could be in future) with electronic transmission and some centralised 'real time' system of authentication. Mr Macfarlane said that the Government hopes to introduce provisions for electronic signatures. Manual systems had not, he said, provided 'a perfect insurance against fraud'. The Inquiry received some post-seminar responses suggesting a number of novel and sophisticated methods of ensuring that computer entries are made only by those who are supposed to make them. I am unable to comment on the feasibility of these suggestions.

## **Conclusion**

- 14.61 The introduction of computer generated prescriptions for all controlled drugs would bring significant advantages by reducing errors and facilitating monitoring. I do, however, think that the change might bring security problems. I am concerned that a dishonest member of staff or a computer hacker might be able to create a controlled drug prescription which cannot be challenged by the pharmacist, when presented, because it appears in all respects to be correct and legitimate. Computer generation of prescriptions for non-controlled drugs, and for controlled drugs in Schedule 4, has been commonplace for some years and I have not been told that these have given rise to any security problems. However, there is probably less incentive to forge such prescriptions than to do so for drugs in Schedule 2. The extent of the security problem which would arise from the computer generation of all controlled drug prescriptions is unknown. Although it appears to be Home Office policy to make this change, it seems to me that the security implications should first be tested in a pilot scheme. As the DoH is currently involved in the development of other computerised systems, including the electronic transmission of prescriptions, to which I shall shortly come, it might be sensible to test the security arrangements of the whole package rather than doing it piecemeal. This would necessarily take some time.
- 14.62 In the meantime, I shall recommend that the solution, mentioned in Chapter Six, of printing the prescribing information onto the prescription form and then writing it again in the space between the lines, should be adopted more widely, not as a legal requirement but as a matter of good practice. The practice complies with the existing legislative requirement for handwriting. Yet it also provides the advantage of the use of software to provide prompts and alerts and the use of a printer to ensure legibility. The prescription would not take any longer to prepare than at present because the doctor has to enter the prescribing information into the surgery computer in any event, for entry into the patient's medical records.

## **The Electronic Transmission of Prescriptions and the NHS Care Record**

- 14.63 At the seminars, Dr Smith said that it is now Government policy that, in the future, all prescriptions should be electronically transmitted from the doctor's surgery to the community pharmacy. He said that this is an important aspect of the Government's IT strategy and that there is a firm commitment to it. Successful pilot projects have been carried out, although, because of the current handwriting requirement, these have not included controlled drug prescriptions. The target is for half of all prescriptions to be transferred electronically by the end of 2005 and for all to be so transferred by the end of 2007.
- 14.64 The electronic transmission of prescriptions is closely related to the Government's plans to introduce a system of electronic healthcare records. Dr Smith explained that the DoH intends that, by the end of 2004, there will exist the beginnings of a national electronic patient record system (the NHS Care Record). Every person in England will have a personal health record on what is described as a 'common spine'. The common spine will contain a record of the patient's significant health events, including prescriptions, arising

from both GP and hospital treatment. This record will be accessible to any healthcare professional with the necessary authorisation. Accordingly, once a GP has written a prescription electronically, the prescription will rest on the common spine of the electronic record. The patient will then be able to collect the medication from any pharmacy in the country. Some means of allowing the chosen pharmacist to access the patient's prescription from the common spine is envisaged, although the precise mechanics of this have not yet been decided. The pharmacist would then be able to access a summary of the patient's medical records and would know for what condition the prescription had been issued. It is envisaged that the system will eventually be 'paper free'. Dr Smith said that this system would have all the advantages of the PharmaNet system currently operating in British Columbia, and more besides. However, he stressed that the system was designed not to facilitate the monitoring of prescribing but to improve health care. He said that the DoH was aware that the proposal gave rise to difficult issues of patient confidentiality and consent. He added that, if I was minded to recommend that information from the NHS Care Record should be made available for the purpose of monitoring the use of controlled drugs, I should say so sooner rather than later, because the system specifications and contractual arrangements are already well advanced.

- 14.65 There was some support from respondents to the Discussion Paper for the electronic transmission of controlled drug prescriptions. Many respondents could see the advantages but some expressed reservations about the security aspects of the proposal. Some felt that it would be a very long time before such systems could be put into practice, either because the funding would not be available to install the equipment or because the systems would not, in the foreseeable future, be sufficiently secure.

## Conclusion

- 14.66 It seems to me that there are a number of potential advantages to be derived from the Government's current proposals, provided the system can be made sufficiently secure. For one thing, as I have said, pharmacists would be able to access information from patients' medical records. Provided that adequate means of identification were required before a patient file was started (so that one patient could not have two files in different names) and provided that all prescriptions, both private and NHS, were recorded on the common spine, there could be greatly improved regulation of controlled drugs. For example, the system would allow the detection of double scripting. A doctor who was asked to prescribe a controlled drug would quickly be able to see when the patient had last received a supply of the drug and in what quantity. He or she would be able to judge whether or not a new prescription was justified and would have 'ammunition' to support his/her refusal if it was not. If a doctor chose to prescribe notwithstanding the fact that the patient had recently received a supply from another source, the pharmacist who was asked to dispense the second prescription should notice the anomaly. Apart from the detection of double scripting, other benefits would accrue. A dishonest doctor would be unable to prescribe for a wholly fictitious patient; there would be no NHS Care Record for the patient. A prescription could not be stolen or lost. Prescribing and dispensing information could be sent automatically to the PPA, saving a great deal of time and money. It would be possible to place an alert on the system so as to prevent a doctor whose right



to prescribe controlled drugs had been withdrawn from creating or transmitting a prescription for that type of drug.

- 14.67 These are real advantages. However, I understand and share the concerns expressed about the security of the computer networks to be used. Not only must secure systems be put in place, but doctors and their staff must be persuaded to use them properly. Shipman's computer system at the Market Street Surgery was password protected. However, all members of staff used the same password and had full access to the patients' records. If access to a GP's computer system were to include the ability to create and transmit prescriptions electronically, and if security were slack, the risk of diversion of controlled drugs would be grave. However, if an 'extra' security measure were introduced into the system for use when a doctor wished to prescribe a controlled drug and this could be accessed only by him/her personally, using a confidential code, then I would have thought that the system would be reasonably secure. Of course, a dishonest or foolish doctor could undermine such a system by deliberately or carelessly sharing his/her code with others. However, if all prescriptions and requisitions for controlled drugs, including those issued privately, could be analysed by the PPA and scrutinised by an appropriate monitoring organisation, then I think that the advantages of the proposed system would outweigh any security problems.
- 14.68 In any event, it will be some time before the NHS Care Record system with electronic transmission of prescriptions is in general use. In the meantime, it is necessary to consider how a paper-based system should operate for the prescription of controlled drugs. When I speak of a paper-based system, I am referring to prescriptions that are either handwritten on paper or computer generated, printed on paper and signed by the doctor.

### **NHS and Private Prescriptions**

- 14.69 I explained in Chapter Six that a NHS prescription form is printed in a standard format on special paper. There is no standard format or special paper for private prescriptions. A controlled drug prescription, whether NHS or private, must comply with the requirements of the MDA 1971 and MDR 2001. Under the Dangerous Drugs Regulations 1921, the Home Secretary was granted the power to issue an '**official form**' for the writing of controlled drug prescriptions but this power was never exercised. The Inquiry invited responses to the question whether a special form should now be introduced for all prescriptions for controlled drugs.
- 14.70 There was a good deal of support for the suggestion that private prescriptions should have the same degree of formality as NHS prescriptions. For example, in its written submission, the Boots Pharmacists' Association suggested that a special controlled drug prescription form, carrying a unique identification number, should be introduced and should be in such a format as could be used for both NHS and private prescriptions.
- 14.71 Respondents and contributors mentioned a number of potential advantages which would accrue from the use of a special form for controlled drug prescriptions. I note that the Council of the Independent Doctors Forum supported the auditing of controlled drugs prescriptions. The use of a special form would make it possible to put out an alert if a prescription pad were stolen. It would also make forgery of private prescriptions more

difficult. If the form were different from the existing FP10, it would be possible to ensure that a doctor who was not entitled to prescribe controlled drugs was not in possession of a pad of forms. It would also be possible to analyse and monitor the prescribing practice of all doctors, both on the NHS and privately, and a much more complete and reliable picture would be obtained. As Dr Smith pointed out, it makes sense for private prescribing information, indeed for private healthcare information generally, to be included on the NHS Care Record; if the object is to improve patient safety, it is desirable that the complete picture, rather than a partial one, be available.

- 14.72 In Chapter Thirteen, I described the system of prescription forms used for narcotic drugs in British Columbia. Until the introduction of the PharmaNet computer system in 1995, a triplicate form, printed on special paper, was used. One copy was kept at the prescribing doctor's surgery, and two were given to the patient for presentation at the pharmacy. After dispensing, one of those two copies was sent to the Provincial Government's office for entry onto a database. Since the introduction of PharmaNet, the third copy is redundant as the prescribing information is recorded in the computer system. Prescribers have to use a prescription pad which carries their own identification number. Also, the patient is identified by a code number. This means that the data entered into the PharmaNet system can be analysed by reference to individual patients as well as to individual physicians and to particular drugs or groups of drugs.
- 14.73 Some seminar participants advocated adopting this system in England. Mr Macfarlane was strongly in favour of the idea of the triplicate form system, at least for private (non-NHS) controlled drug prescriptions. He foresees that it will not be possible to ensure that all doctors who prescribe controlled drugs for non-NHS purposes will use a computer. He would think it most helpful if the HODI were to receive a copy of every non-NHS controlled drug prescription.

## Conclusion

- 14.74 I am sure that it would be desirable to introduce a special form for the private prescribing of controlled drugs. The precise practical details would require consideration. It would be possible to adapt the existing FP10 so as to be suitable for private as well as NHS use; tick boxes could be used to indicate whether or not the form was being used for a controlled drug and whether the prescription was being issued under the NHS or privately. Another possibility would be that there should be a special controlled drug prescription form for both NHS and private prescribing, printed on paper of a distinctive colour, with a layout similar to the existing FP10 and with a tick box to indicate whether the form is being used for NHS or private purposes. A further option would be to keep the FP10 for all NHS prescriptions and to introduce a different form for private controlled drug prescriptions. Any of these options would allow for monitoring and analysis of all controlled drug prescribing, not just NHS prescribing. Each prescription would have its own unique identification number. The choice between the various options I have outlined would depend upon several matters. One issue for consideration would be whether to devise a system that would readily be capable of adaptation to the computerised system discussed in the previous section. Another issue is whether the authorities consider that it would be beneficial to have all private prescriptions, not only those for controlled drugs,

written on a special form. That is an issue which goes beyond the Inquiry's Terms of Reference and I express no view upon it.

- 14.75 My preference would be for there to be a special form to be used for all controlled drug prescriptions whether NHS or private. This should be similar to the FP10 but should be printed on paper of a different colour. It should have a tick box to show whether the drugs are being prescribed on the NHS or privately. It should also have space for the declarations I have recommended in paragraphs 14.27–14.29 above. I shall deal with the related question of requisitions in paragraphs 14.127 and 14.133.
- 14.76 I mentioned in paragraph 14.36 that the inclusion of a patient-specific number on the prescription form, as happens in British Columbia, would assist in the detection of double scripting. The Inquiry has not consulted about the inclusion of such information. Plainly it has potential for monitoring purposes but the proposal raises issues of privacy which would require careful consideration. I shall recommend that the inclusion of a patient-specific number, such as the patient's NHS number, should be considered in the light of the Government's proposals for introduction of the NHS Care Record.
- 14.77 If a special form capable of being scanned into the PPA system is to be used for all controlled drug prescriptions, I do not think it would be necessary to introduce a triplicate, or even a duplicate, prescription pad such as is used in British Columbia. There, one copy of the prescription is retained at the doctor's surgery. I can see that such an arrangement might help in the monitoring of the doctor's prescribing practice and in the investigation of individual prescriptions if the need arose. However, if a record of the prescription exists at the PPA, the need for this is limited. In British Columbia, the third copy was sent for entry into a central monitoring database. That would not be necessary in the UK if all controlled drug prescriptions, both NHS and private, were sent to the PPA. However, if the HODI were of the view that it would be of real benefit for it to receive a copy of every prescription or requisition for a controlled drug, a duplicate pad would be appropriate.
- 14.78 Whichever form is chosen, some arrangement will have to be made for the distribution of the stationery. At present, this is done by PCTs but, if prescription pads also have to be issued to doctors practising solely in the private sector, some other means of distribution will have to be found. The DoH or the Healthcare Commission are possibilities. If, in the future, there were to be a controlled drugs inspectorate, that would be the appropriate body to issue the forms. Only doctors who need to prescribe controlled drugs for clinical practice would be entitled to receive such pads. A controlled drugs inspectorate would be best placed to ensure that that occurred. I will recommend that the information on private prescriptions for controlled drugs should be received by the PPA so that it can be processed by them and thereafter monitored locally by PCTs, regionally by the controlled drugs inspectorate, and/or nationally by the Healthcare Commission.
- 14.79 Recognising that systems will allow for all information recorded on a prescription to be read and analysed, the question then arises as to what extra information, not already mentioned above, should appear on a controlled drug prescription form and does not currently appear.

### **Should a Prescription for a Controlled Drug Bear the Time as well as the Date of Issue?**

- 14.80 The idea that a controlled drug prescription should bear the time of issue as well as the date arose because Shipman was able to prescribe controlled drugs in the names of certain patients after those patients had died. If the time of issue of the prescription had been recorded, it would have been relatively easy to establish that he knew that the patient was already dead at the time he issued or presented the prescription. Such information would aid the detection of dishonest practice and might also act as a deterrent.
- 14.81 While many respondents were unsure as to what such a requirement would achieve, the written response of Boots the Chemists (Boots) recognised the potential benefit of such a requirement, stating that it would assist in any investigation of what was thought to be suspicious practice. Boots did, however, also point out that, for handwritten prescriptions, such a requirement might prove detrimental if accidental omission at the time of issue delayed the pharmacist in dispensing the prescription. Boots suggested that a solution might be to permit dispensing if a prescription was clinically correct and to make it the responsibility of the PCT to deal with any administrative errors.

### **Conclusion**

- 14.82 I do not think it necessary to require the time of prescribing to be entered on handwritten prescriptions. This would add to the doctor's burden without producing any great benefit save in a tiny minority of cases. However, since computer systems have an in-built clock, I think it would be sensible if, when generation by computer is permitted, the time of issue were to be printed on all computer generated controlled drug prescriptions. In a fully computerised system, it would also be possible to record the time at which a prescription for a controlled drug was dispensed at the pharmacy. The computerised recording of information such as this would not add to the burden on the doctor or pharmacist and would serve as a useful investigative tool for the police and HODI inspectors in investigating cases of illicit obtaining of controlled drugs. It would, for example, have been invaluable in the investigation of Shipman's offences.

### **What Information about the Prescriber Should Appear on the Prescription Form?**

- 14.83 At present, a prescription has to contain the full name and address (within the UK) of the prescriber. As I mentioned in Chapter Six, a NHS prescription also carries the individual prescriber code of the doctor to whom the pad of prescriptions has been issued, as well as details of the PCT within whose area the doctor practises. The individual prescriber code is an identifying number, which allows the PPA's computer system to allocate the prescription to a particular prescriber. It is not the prescriber's GMC registration number. A private prescription does not require a prescribing number and need not contain the doctor's GMC registration number. The question asked in the Discussion Paper was whether all private and NHS prescriptions for controlled drugs should contain the professional registration number of the prescriber.
- 14.84 There was very strong support for this suggestion among the respondents to the Discussion Paper. Many felt that there should be parity between the requirements for prescribing within the NHS and privately.

- 14.85 During the seminars, I was reminded that the doctor who signs a NHS prescription is not necessarily the doctor whose details, which include the individual prescriber code, are printed on the prescription. Sometimes, doctors working within the same practice will use each other's prescription pads. Some doctors working in general practice do not have a pad of their own. For example, a GP registrar (trainee) does not have his/her own pad and uses the pad of one of the principals in the practice. Similarly, a locum or salaried GP assistant does not have a personal pad. Prescriptions issued by deputising doctors bear the individual prescriber code of the doctor with whom the patient is registered. There are three significant consequences of these arrangements, which, I understand, may soon change. A doctor with a portfolio practice, who works as a locum and possibly for a deputising service, cannot audit his/her own personal prescribing; nor can s/he produce his/her personal data for the purposes of appraisal. Of greater importance perhaps is that, if such a doctor were a 'rogue' prescriber of a certain drug, this could not be identified by prescribing analysis and cost (PACT) data. Third, the prescribing data of the GP principal whose pad is used by a locum or registrar does not accurately reflect his/her prescribing practice; the data is 'blurred' by the inclusion of prescriptions issued by other doctors. This latter point is of some importance as the scrutiny of prescribing data is now an important aspect of the clinical governance of GPs, a topic I shall discuss in greater detail in the Fifth Report.
- 14.86 Dr Gerada mentioned that, when she issues a prescription for a patient registered with another doctor, it comes out of the printer, not in her name but in the name of the doctor with whom the patient is registered. The result is that her personal PACT data and those of her partners are inaccurate. Later in the discussion, she was told that it would be possible to adjust the computer to correct this situation. However, if this is happening in Dr Gerada's practice, it may well be happening in others. Dr Gerada and Dr James Robertson, a GP and a member of the ACMD, both stressed that the real usefulness of PACT data was to focus on the prescribing of the group of doctors in a practice rather than of individuals. Once the group saw its collective figures, its members would examine the position internally and correct any anomalies. That is all very well and I am sure that this happens in many practices. However, there are two reasons why it is not satisfactory to rely on internal control. First, abnormal prescribing practice by one member of a group of, say, six doctors may well be concealed within the global figures; if only one member of the group is prescribing abnormal amounts of diamorphine and the rest are prescribing slightly less than average, the collective data may appear quite normal. Second, collective data may have been perfectly adequate to monitor the spending habits of a practice but it cannot be of value where one of the main objectives is to monitor an individual doctor's clinical practice.
- 14.87 During the discussion, I pointed out that, if prescribing data were to be used for the purposes of clinical governance and/or revalidation, it would have to be prepared on an individual basis to be of any use at all. Everyone seemed to recognise that, at present, the individual data is not at all accurate. Apart from the reasons I have already mentioned, there is another. In many practices, the doctors will take turns to be the 'duty' doctor for the signing of large numbers of repeat prescriptions. He or she will sign these possibly on his/her own pad or possibly on the pad of another doctor and, often, without having any

real clinical input into the choice of medication. He or she will check to make sure the prescription seems reasonable but that is all. Such an arrangement means that the individual prescribing data of the doctors concerned are inaccurate. The data shows only the collective picture.

- 14.88 The participants recognised the potential importance of accurate personal prescribing data for the purposes of clinical governance, including the monitoring of the use of controlled drugs. I have learned of two ways in which the problems of inaccurate data might be tackled. At the seminars, Dr Smith explained that a new system of dealing with repeat prescriptions had been successfully piloted in several areas and would soon be put into general operation. Under this system, a doctor who wishes to prescribe medication on a long-term basis will write a prescription to provide for periodic consignments over a period of up to a year. The patient will leave the prescription at the pharmacy of his/her choice, will collect the drugs every few weeks and need not return to the surgery until the expiry of the prescription. The pharmacist will be responsible for reviewing the appropriateness of the continuing supplies dispensed under the prescription during its currency. Not only will this system save a great deal of time for GPs, it will, as Dr Smith pointed out, allow greater accuracy of the prescribing data because the whole quantity supplied under the prescription will be attributed to the doctor who made the original decision. Dr Esmail has told me that, in his practice, the doctors have adopted a system whereby a doctor who wishes to prescribe a drug for a substantial period will issue a prescription for, say, a month's supply and will, at the same time, authorise the issue of repeat prescriptions for a further period of up to six months. Any repeat prescriptions issued under that authority will be assigned to the doctor who issued the initial prescription. When the authority expires, if the patient seeks further supplies, a doctor ought to give full consideration to the appropriateness and dosage of the drug s/he is to prescribe, which may cover the next six months. If this is done, the accuracy of the prescribing data is ensured.
- 14.89 After listening to the discussion about the inaccuracy of individual prescribing data, Professor Baker expressed the view that the best solution might be to ensure that all prescribers had their own prescription pads and that they contained their unique GMC (or other professional registration) number. The professional registration number could also be applied to private prescriptions.
- 14.90 Ms Christine Dalton, Director of Pharmaceutical Policy and Services at the PPA, supported the idea that, for the sake of accuracy, prescribers should not use each other's pads or each other's individual prescriber code. Initially, she said that the PPA would not welcome the use of a GMC registration number. There are more digits in a GMC number than in an individual prescriber code. As all data has to be keyed in by hand, any increase in the number of keystrokes to be made has a significant financial impact. However, this will not matter for long, as the PPA is installing a system whereby prescription forms will be scanned into the computer. When that comes about, as it is intended to do between 2005 and 2007, the additional digits will present no problem. Evidence received earlier from the PPA was to the effect that it would be quite practicable for the PPA to process private prescriptions provided they were on a form that was similar in size, weight and layout to the existing FP10.

## Conclusion

- 14.91 The discussion I have just described related to prescriptions for all prescription only medicines, not just controlled drugs. From the point of view of the Inquiry, whose interest is at present focussed mainly on the latter, it seems to me to be vital that all controlled drug prescriptions, whether NHS or private, should be accurately attributable to the prescriber who made the decision to issue. Without that, any attempt at monitoring for abnormal prescribing is likely to have limited success. In my view, the best means of achieving this is by ensuring that all prescribers use their own prescription pad, marked with their professional registration number.
- 14.92 For the wider issues of clinical governance, it is also, in my view, important to collect accurate individual prescribing data relating to all prescription only drugs. I shall recommend that all prescribers should use only their own pads marked with their own professional registration numbers. Once long-term prescriptions have taken the place of frequent repeat prescriptions, individual prescribing data should then be much more accurate. When electronic prescribing becomes a reality, as I am sure it eventually will, some means must be found of applying an electronic signature, associated with the prescriber's registration number. I do not think that will be difficult.

### **Should the Number of Days' Treatment or the Amount of Controlled Drugs Covered by a Single Prescription Be Limited?**

- 14.93 The possibility of introducing a limitation on the amount of a controlled drug that may be prescribed on a single prescription was raised as a potential mechanism for reducing the risk of diversion. The Prescribing Support Unit report entitled 'Audit of Controlled Drugs Prescribing in England for the Financial Year 2002/03' identified the routine prescribing of abnormally high quantities of controlled drugs on individual prescription forms.
- 14.94 There was broad consensus among respondents to the Discussion Paper that it would be appropriate to limit the period of time covered by a single prescription for controlled drugs to a supply sufficient to last for 28 days.
- 14.95 At the seminars, Dr Grenville, for the BMA, said that he would be very loath to prescribe amounts of a controlled drug intended for a long period. He recognised that they might be traded. Dr Gerada and Dr Grenville drew attention to the fact that many patients holiday abroad for long periods and some even go abroad to die. They felt that flexibility was required. However, Mr Macfarlane pointed out that to take a substantial quantity of controlled drugs abroad would breach UK export controls, unless a licence was obtained; it might also breach the law of the receiving country. It would be acceptable to take, say, two weeks' personal supply abroad without a licence but to take three months' supply would be unlawful.
- 14.96 Dr Smith said that, subject to the problem of patients going overseas, the DoH would support the idea of a 28 day limit. To restrict supplies to any greater extent might impinge on patient care and cause unacceptable inconvenience. In the view of the DoH, however, it was also very important to distinguish between the drugs listed in the various Schedules; so, for example, while 28 days should be the norm for Schedule 2 drugs, the DoH would

not want to see the period restricted to 28 days in the case of Schedule 5 products. Dr Smith said that, although some people question the utility of a lot of Schedule 5 products, there is no doubt that many people find them beneficial for chronic mild to moderate pain. To limit the period of time covered by prescriptions for such products would put unwarranted burdens on patients, prescribers and pharmacists.

- 14.97 Some respondents involved in palliative care were opposed to the proposal that a limit should be placed on the amount of a drug, such as diamorphine, that can be prescribed on one prescription. However, Mr Rudd, from Macmillan Cancer Relief, who had consulted quite widely on the issue, said that the consensus among those to whom he had spoken was that a limit of 28 days' supply was a reasonable compromise between the competing interests of convenience and security.

## Conclusion

- 14.98 I see the force of Dr Smith's observation about Schedule 5 products and do not think that there is any reason why the amounts to be supplied on a single prescription need be limited. These are, by definition, products which are relatively unlikely to be abused or diverted. With controlled drugs from Schedules 2–4, I think that it would be appropriate to limit the period of time to be covered by a single prescription to 28 days. The evidence suggests that there is a substantial leakage of drugs such as the benzodiazepines onto the illicit market from patients for whom the drugs have been prescribed, presumably in greater quantities than they actually needed. Although doctors are urged to prescribe modest amounts and not to allow patients to take such drugs on a long-term basis, it appears that many doctors continue to prescribe quite large amounts.
- 14.99 As for patients who wish to spend the winter abroad and take a personal supply of controlled drugs in any of Schedules 2–4 with them, it would appear that it would be unlawful for them to do so without obtaining a licence. If such patients are granted a licence, they can obtain the appropriate quantity under the terms of the licence and export it lawfully. Presumably, the supply would have to be purchased from a wholesaler and paid for; it would not be available under the NHS. Alternatively, the patient might have to make arrangements to receive a supply on prescription in the country in which s/he wished to stay.

## Should the Period of Validity of a Controlled Drug Prescription Be Further Limited?

- 14.100 At present, a pharmacist may not supply a controlled drug in Schedule 2 or 3 to the MDR 2001 on a prescription later than 13 weeks after the date specified in the prescription. The Discussion Paper asked whether this period should be reduced.
- 14.101 There was broad agreement among respondents and participants at the seminars that 13 weeks is far too long for a controlled drug prescription to be held by the patient before presentation. There is a risk that the prescription will fall into the wrong hands. If a patient really needs a controlled drug, s/he will present the prescription long before 13 weeks have passed. In British Columbia, the period has been reduced to five days and Dr Brian Taylor said that this has not given rise to any problems. Many respondents and some



participants were in favour of reducing the period to 7 or 14 days but the majority favoured a period of 28 days, as a compromise between the interests of security on the one hand and convenience to patients on the other.

## **Conclusion**

14.102 I agree with the general view that 13 weeks is far too long for a controlled drug prescription to remain valid before presentation. Although I see the advantage of reducing the period of validity to 7 days, I have come, in the end, to see 28 days as a reasonable compromise.

## **Relaxation of the Rule Prohibiting Pharmacists from Dispensing other than in Direct Accordance with the Prescription**

14.103 At present, the effect of the rules for the form and content of many controlled drug prescriptions is that a pharmacist is not permitted to dispense other than in strict accordance with the prescription. Any alteration must be effected by the prescriber in his/her own handwriting. The Discussion Paper asked whether this rule should be relaxed in the case of handwritten prescriptions and, if so, to what extent and with what alternative safeguards in place.

14.104 The question was raised because of concern expressed by pharmacists. Miss Lavin said that community pharmacists often receive prescriptions which are technically defective but where the intention of the prescriber is clear. In such circumstances, the pharmacist will usually try to speak to the doctor to arrange for an amended prescription to be provided. However, it is not always possible to make contact and, even when it is, doctors are sometimes unwilling to co-operate in the correction of a technical error. The RPSGB advises pharmacists that they should act in the best interests of the patient. In such circumstances, they should adopt a pragmatic approach. If the patient needs the medication without delay and if the pharmacist is not in doubt about the prescriber's intention, the RPSGB advises that s/he should dispense the prescription and ask the prescriber to amend it retrospectively. Miss Lavin acknowledged that the RPSGB may thereby be advising pharmacists to break the law. The Society would like to see some official relaxation of the rule so that pharmacists could amend a defective prescription themselves, where they were certain of the prescriber's intent, possibly without the need to ask the prescriber to ratify the amendment afterwards. Mrs Roberts would also welcome such a relaxation of the existing rule.

14.105 Mr D'Arcy, for the NPA, supported the position of the RPSGB. He emphasised that pharmacists face a real, not just a theoretical, risk of prosecution if they dispense prescriptions that do not comply with the MDR 2001.

14.106 Mrs Roberts described another kind of situation in which a pharmacist may have a genuine need to disobey the instructions given on a prescription. A drug dependent patient might arrive at a pharmacy to take an instalment dose of methadone which has been validly prescribed. The pharmacist might realise that the patient is not in a fit state to take the drug. He or she is then in a dilemma. If s/he gives the drug, s/he might harm the patient; if s/he refuses, arguably s/he is in breach of his/her duty to dispense the drug.

Similarly, a drug dependent patient, receiving a certain quantity of methadone every day, might fail to attend for several days. If s/he then turns up, demanding the usual dose, the pharmacist might be concerned that the amount prescribed is too great, given the break in treatment. Mrs Roberts said that, in such cases, the pharmacist should be able to make a clinical judgement as to what to do and should not be bound to dispense in accordance with the terms of the prescription.

## Conclusion

- 14.107 In my view, there should be some relaxation of the law so as to allow a pharmacist to exercise his/her discretion whether to dispense a defective prescription for controlled drugs, where the intention of the prescriber is clear. In such a case, the pharmacist should be able to amend the prescription so that it complies with the MDR 2001. I do not see why there should be any need for the pharmacist to send the prescription back to the prescriber for ratification. Miss Lavin said that some doctors are unwilling to co-operate with pharmacists by correcting errors; certainly, to do so increases their workload. In my view, provided that the pharmacist is satisfied that the intention of the prescriber is clear, that the defect is only technical and that the pharmacist is content to make the correction and take professional responsibility for dispensing the drug, that should be sufficient. The exercise of such discretion is appropriate, given the professional status of pharmacists. I envisage that the increased use of computer generated prescriptions would reduce the incidence of technical prescribing errors.
- 14.108 Mrs Roberts raised the more general issue of whether a pharmacist should be able to exercise his/her discretion to refuse to dispense a prescription either in strict accordance with the terms of the prescription or at all. I am not sure that the legal position is entirely clear, where a pharmacist refuses to dispense a prescription or declines to administer an instalment dose. It seems to me that it should be a usual part of a pharmacist's professional duty to refuse to dispense or administer any controlled drug if, in the pharmacist's professional judgement, refusal to do so would be in the patient's best interests.

## Should the Prescription Record the Condition for Which a Drug is Prescribed? To What Information about the Patient Should a Pharmacist Have Access?

- 14.109 At the moment, there is no requirement for a prescription to carry an indication of the medical condition for which the medication is prescribed. The only place where that is recorded is in the patient's GP records. Pharmacists do not have access to those records at present. In Chapter Seven, I explained why pharmacists are of the view that they ought to know the nature of the condition for which a drug has been prescribed. Only then can they apply their expertise to the issues of whether the prescribed drug and its dosage are appropriate.
- 14.110 The question was raised for discussion at the seminars. Mr D'Arcy, for the NPA, favoured the suggestion that pharmacists should know for what condition a drug has been prescribed. He emphasised that pharmacists are increasingly assuming an enhanced role in patient care. They try to ensure that patients get the best from the medicines

they take. Mr D'Arcy said that understanding why a patient is taking a medicine (not just a controlled drug) can help in that process. Understanding the purpose of the drug would help the pharmacist to decide whether the drug and dosage prescribed were appropriate and would operate as a check against the inappropriate use of controlled drugs. Mr D'Arcy acknowledged that a requirement to state the nature of the patient's condition on the prescription would give rise to issues of patient confidentiality but said that the NPA was, nonetheless, supportive of such a requirement. Issues of confidentiality also arise in the context of the NHS Care Record at present proposed by the DoH. Mr D'Arcy said that, when such electronic records are brought into use, pharmacists should have access to them for the purpose of finding out for what condition medication has been prescribed.

- 14.111 For similar reasons to those given by Mr D'Arcy, Mr Rutherford, Head of Medicines Management at Bristol North PCT, was also in favour of the idea that the patient's condition should appear on a prescription. He considered that pharmacists need to know the nature of the patient's condition in all cases, and particularly when the prescription is issued privately.
- 14.112 Miss Lavin, for the RPSGB, supported the idea but raised a practical concern. She said the Society would not wish pharmacists to be compelled to require such information before a prescription could be dispensed. In other words, the Society would not want another requirement to be introduced if it was unlikely to be met by doctors, resulting in yet more prescriptions that might have to be queried or returned by pharmacists.
- 14.113 There was a good deal of opposition to the proposal, mainly because of perceived problems of patient confidentiality. Dr Smith said that there had been a spread of views within the DoH team, but they had come down against the proposal because, while paper prescriptions remain in use, there would be a danger that the patient's medical condition would become known to anyone who saw a prescription. However, Dr Smith pointed out that, when the NHS Care Record is introduced, the patient's diagnosis will be available to pharmacists who have access to the record. He did not doubt the value of the information to the pharmacist and the contribution that could be made to patient safety by providing it.
- 14.114 Mr Rudd, for Macmillan Cancer Relief, had canvassed the views of a number of patients and frontline carers to discover their reaction to the suggestion. One patient who suffered from ovarian cancer did not want her condition to be known to the young part-time assistant in the pharmacy in the village in which she lived, because the assistant was in the same class at school as the patient's daughter. However, she would have been quite happy for the information to be passed direct to the pharmacist via a computer connection.
- 14.115 Dr Grenville, for the BMA, supported the idea that the pharmacist should know the nature of the patient's condition, but he said that this should happen only if the patient had been told what the diagnosis was and had consented to the disclosure of that information to the pharmacist. He thought that many patients would consent if the reason was explained to them. Dr Taylor told me that, although the facility to provide this information is available in British Columbia, it is rarely used by doctors there.

## Conclusion

- 14.116 The potential benefit that could accrue to a patient if a community pharmacist had access to information about the patient's condition is well recognised. The main objection arises on the ground of patient confidentiality. I discussed some of the issues in Chapter Seven. I noted that a patient's GP records are seen by the staff at his/her GP's surgery and the patient's consent is not sought for that disclosure. GPs could not operate effectively unless their staff were allowed to see patient records. Similarly, hospital records are seen by all members of the clinical team, including nurses and pharmacists (and inevitably some administrative staff), without reference to the patient. These groups of people who have access to the records are under a duty not to disclose confidential matters but they are allowed to exchange information within the group for the purpose of providing clinical care. I cannot see any reason why a community pharmacist should be in any less favourable a position to advise the patient than a hospital pharmacist. However, I can understand why some patients might feel unhappy about a particular member of staff in a community pharmacy seeing a prescription that described the nature of their condition. I understand that it might be difficult for some patients to use a different pharmacy where they are not known.
- 14.117 In my view, if it were explained to patients why it was for their benefit that the pharmacist should know for what condition their medication had been prescribed, most would consent to the pharmacist being given the information on the prescription. I see no reason why there should not be a space on the prescription form for a brief description of the patient's condition which should be completed if the patient consents. In other words, I agree with Dr Grenville. I would add that, because completion of the box would not be compulsory, a pharmacist would not be prevented from dispensing the medication just because it had not been completed. When the NHS Care Record is introduced, I hope that pharmacists will be given access to the common spine so that they will be able to find out the nature of the condition for which any medication has been prescribed.
- 14.118 I mention in passing that, if the patient's condition had appeared on prescriptions in the past, it would have been much more difficult for Shipman to obtain 30mg ampoules of diamorphine, as he did in 1993. He repeatedly prescribed 30mg diamorphine as a single dose for patients who were apparently opioid-naïve and for whom such a dose would have been fatal. He would have been discouraged from obtaining the drug in this way had he been required to record a diagnosis that was either inconsistent with what he had written in the patient's medical records, inconsistent with the patient's true condition or inappropriate for the administration of diamorphine. However, I would not have made any recommendation for change for that reason alone. I make it because I believe that information which helps a pharmacist to assess the correctness of a prescription is of benefit to patients.

## General Practitioners' Controlled Drugs Registers

### Should General Practitioners Have to Keep a Controlled Drugs Register? If So, What Should the Requirements Be?

- 14.119 In Chapter Five, I explained that the MDR 2001 require a GP who keeps a stock of Schedule 2 controlled drugs to maintain a CDR. At present, the CDR must comply with the

requirements of Schedule 6; it must be in paper form and must record all transactions by which controlled drugs are obtained or supplied. I also explained that, nowadays, many GPs have a poor understanding of their duties with regard to the CDR and regret the lack of any advice on the subject. Police CIOs do not inspect GPs' CDRs. Until 1991, regional medical officers (RMOs) used to inspect GPs' CDRs but many GPs have not had their CDRs examined since then. As there has been virtually no inspection of GPs' arrangements for the keeping of controlled drugs and their CDRs for some years now, the Discussion Paper questioned whether it was necessary or appropriate for GPs to be under a continuing obligation to keep a CDR. At paragraph 5.31, I mentioned that the requirement to keep a CDR would not deter a dishonest doctor from keeping an illicit supply of a controlled drug; nor would inspection of the CDR of a dishonest doctor necessarily reveal the existence of illicit supplies.

- 14.120 Respondents to the Discussion Paper were almost universally of the view that GPs should be required to keep a CDR if they kept a stock of controlled drugs. No one doubted its usefulness. The view was that there should be a common format for paper CDRs and it should be permissible for a GP to keep an electronic CDR. Some GP respondents mentioned the lack of inspection of their CDRs. The Council of the Independent Doctors Forum reported that, at a meeting of members, all members present said that they had maintained a CDR for many years but not one had ever had his/her CDR inspected.
- 14.121 Among respondents, there was also strong support for the suggestion that GPs within the same practice who shared the use of an emergency bag should be allowed to keep one CDR which identified who administered or otherwise disposed of the drugs.
- 14.122 At the seminars, there was universal acceptance that a CDR must be kept. Again, no one doubted its usefulness. Some participants felt that the requirements as to how the CDR should be kept should be flexible, so as to meet the needs of individual practices. Dr Grenville suggested that each GP practice should propose a standard operating procedure (SOP) for the use of controlled drugs, which would be adopted subject to the approval of the PCT or other body responsible for clinical governance. In some practices, doctors might wish to keep their own stocks, in which case they would have to keep their own CDRs; other practices might prefer to have a common stock and to share the use of an emergency bag. In such cases, a common CDR would be appropriate.
- 14.123 Mr Macfarlane said that, although in a group practice it seemed logical to keep a common stock of controlled drugs, he felt it was of paramount importance that each doctor in the practice should be personally accountable for the controlled drugs administered by him/her. The RPSGB agreed.
- 14.124 Dr Gerada, who has made a study of the use of controlled drugs in general practice, considered that, if a group practice were to maintain a central stock of controlled drugs, there should be a CDR for the central stock and each individual doctor's bag should have its own CDR. When a doctor took a drug from the central stock, that should be entered, presumably as a 'drug supplied' in the central CDR and as a 'drug obtained' in the CDR for the individual doctor's bag. Dr Grenville said that the practice where he had worked for much of his professional life had had such a system for over 20 years. Dr Gerada said that someone had to be responsible for physically checking the contents of the central stock

periodically. This should be done weekly if controlled drugs were not often used but daily in the case of a busy out of hours service, where usage would be very frequent.

- 14.125 Professor Baker expressed the hope that an electronic system could be developed whereby a record would be made at each stage when a doctor removed a controlled drug from the surgery cabinet, placed it into his bag and administered it to a patient. Professor Baker acknowledged that there had to be a human element to such a system in that the drug stock had to be regularly checked against the electronic record.
- 14.126 Mr Macfarlane explained that, at present, commercial organisations providing out of hours services were licensed to hold controlled drugs and could supply them to the doctors employed by them. Proper records have to be kept and should be inspected by the HODI. Mr Macfarlane said that, in future, it was likely that the distinction between deputising services and co-operatives might become blurred. I think he must have had in mind the change by which, as from January 2005, PCTs will become responsible for the provision of out of hours services in their area and may choose to provide these services in a variety of different ways. Dr Grenville was asked to explain what happened at present, where GPs banded together into a co-operative to provide out of hours services. He said that the position was variable. In the co-operative for which he sometimes works, each doctor is expected to bring with him/her any Schedule 2 drugs that might be required and to be responsible for maintaining the necessary CDR.
- 14.127 On a slightly different but related topic, Dr Grenville suggested that a doctor should be required to obtain his/her stocks of controlled drugs from a nominated pharmacist or wholesaler. He was concerned that a doctor who intended to abuse controlled drugs could present requisitions at any number of pharmacies and this might well not be noticed by a CIO. Mrs Roberts and Dr Robertson explained that, in Scotland, there is a special form, a GP10A, on which GPs order controlled drugs for their bags for use within the NHS. This makes it possible for such requisitions to be monitored.

## Conclusion

- 14.128 Despite the fact that the duty to keep a CDR will not deter a dishonest doctor from secreting an illicit supply of controlled drugs as Shipman did, it seems to me that the duty should be retained. Given the different practical arrangements that doctors may wish to make with regard to their individual and collective use of controlled drugs, I do not think it is sensible to suggest a 'one size fits all' procedure for the keeping of CDRs. Instead, a number of suitable SOPs should be drawn up from which an individual practice should be able to select the model most appropriate for its arrangements. Adherence to such SOPs should be mandatory and should be inspected on a regular basis.
- 14.129 I agree with Dr Gerada's view that, if a practice chooses to keep a joint stock of controlled drugs and to allow members of the practice to withdraw drugs for their personal bags, there must be a central CDR and a 'satellite' CDR for each bag. Any doctor working as a locum for a practice should be expected either to comply with the practice SOP or to make his/her personal arrangements to provide Schedule 2 drugs and to accept responsibility for keeping the necessary CDR. Whichever arrangement is adopted, all parties should be clear about where responsibility lies.

- 14.130 In my view, a doctor or practice should be able to choose whether to keep CDRs in paper or electronic form. In either event, the CDR should contain a running balance. All SOPs should specify the frequency with which the actual stock must be checked against the balance. In my view, it is desirable that responsibility for making such a physical check should be shared between all members of a practice, the practice manager and any registered nurses. It should certainly not be a duty assigned to any one person.
- 14.131 Advice as to compliance and best practice should be issued nationally and should also be available from PCT officers in the course of the annual clinical governance visit or review or at other times.
- 14.132 It is essential that, when new arrangements for the provision of out of hours services are made, there is complete clarity as to who is responsible for the provision of Schedule 2 drugs and for the keeping of the appropriate CDR. Here again, there should be an approved SOP and the capacity to monitor and enforce its provisions. I suggest that the Healthcare Commission (or, if it comes into being, the controlled drugs inspectorate) should be responsible for approving SOPs for GPs in private practice and for ensuring compliance.
- 14.133 I agree with the suggestion that the obtaining of controlled drugs on requisition should be better regulated. I think that requisitions should be written on the special form that I have suggested should be used for controlled drug prescriptions. The doctor could write on the prescription form that the drugs were required 'for practice use'. The requisition would be sent to the PPA and entered onto the database. The acquisition of the drugs would then show up in PACT data. Some doctors apparently buy their supplies direct from a wholesaler rather than a retail pharmacy. If that practice were to continue, wholesalers would have to be required to send the requisition forms to the PPA. Dr Grenville suggested that GPs or practices should purchase all controlled drugs stocks from a nominated pharmacist or wholesaler. Although, in itself, that is a sensible suggestion, I do not think such a restriction is necessary provided that all requisitions go to the PPA for analysis and that the doctors' complete controlled drugs data will be available for monitoring. Those monitoring the usage of controlled drugs will have to take account of the fact that some GPs order supplies for the use of all members of the practice.

### **Should the Dispensing of Controlled Drugs Be Confined to Specialist Pharmacies?**

- 14.134 The question of whether the dispensing of controlled drugs should be confined to specialist pharmacies arose because there was some evidence before the Inquiry that many pharmacies were only rarely required to dispense controlled drugs in Schedule 2 and kept very few in stock. Accordingly, their staff had little experience of such drugs. There was a clear preponderance of opinion from respondents that all pharmacies should continue to be allowed to dispense all controlled drugs. The view of Macmillan Cancer Relief, expressed at the seminars by Mr Rudd, was that any reduction in the number of pharmacies allowed to supply controlled drugs would restrict patient choice. However, his organisation recognised the advantage to patients of the service of pharmacists with particular expertise in palliative care or the treatment of chronic degenerative diseases.

- 14.135 Dr Gerada said that she could see advantages in pharmacists developing special expertise in particular areas of work, such as the use of controlled drugs in the treatment of addiction or chronic pain. However, she was not suggesting that pharmacies or pharmacists without such special expertise should be prevented from dispensing controlled drugs. She thought it would cause problems for patients if there were to be any such restriction.
- 14.136 Mr Rutherford expressed a similar view, pointing out that, although the number of pharmacies specialising in palliative care was likely to grow, there would be a continuing need for patients to access controlled drugs from all NHS pharmacies. Dr Smith said that, although the DoH envisaged that pharmacies would become increasingly specialised, this would not be directed from the centre through regulation but would arise as the result of contractual arrangements made at local level.
- 14.137 Mr D'Arcy said that the NPA did not see the benefit of restricting the number of pharmacies able to dispense controlled drugs. He also envisaged problems if specialist pharmacies were created. He referred to the example of a pharmacy in north London which specialised in providing services for patients addicted to drugs. Mr D'Arcy commented that this had created substantial disruption to the pharmacy concerned and also to the local neighbourhood. Mr D'Arcy also highlighted the security issues that can arise if a pharmacy is known to be dealing with large quantities of controlled drugs.

## Conclusion

- 14.138 It is clear, in my view, that the development of specialist expertise in the use of controlled drugs by some pharmacies will bring benefits to patients. However, the existence of pharmacies where specialist expertise is available is quite consistent with the continuing freedom of all pharmacies to dispense controlled drugs when called upon to do so. I accept that to restrict the right to dispense controlled drugs to a limited number of pharmacies would have an undesirable effect on patients' access to the drugs they need.

## Pharmacy Controlled Drugs Registers

### What Record Should Be Kept of the Identity of the Person Collecting Controlled Drugs from the Pharmacy?

- 14.139 Examination of the CDRs in which Shipman's prescriptions for diamorphine were recorded reveals no clue as to who had collected the drugs or as to whether that person was the patient, a relative or friend of the patient, a district nurse or Shipman himself. Under the present law, a person who collects certain poisons from a pharmacy has to sign the poisons book. A person who collects a controlled drug on requisition from a pharmacy on behalf of the doctor who has ordered it has to produce the signed authority of that doctor. My experience of trying to collect a parcel from a Royal Mail delivery office is that it will not be handed over without the production of some form of identification and the provision of a signature. By contrast, a person who collects a controlled drug which has



been prescribed for a patient need produce no authority from the patient and no identification; nor is s/he required to sign any record.

- 14.140 The Discussion Paper posed the question whether a pharmacist should be required to obtain some proof of the identity of a person collecting a controlled drug dispensed on a prescription and/or to record the name of that person. If so, what type of identification would be appropriate? Where should the information be recorded?
- 14.141 A majority of respondents favoured a requirement that the pharmacist should obtain some proof of the identity of the person collecting controlled drugs and record the details. However, some concerns were expressed, mainly by pharmacists. Very few suggested that it would be unreasonable to expect the pharmacist to record the name of the collector or that it would be unreasonable to expect the collector to provide his/her name and address.
- 14.142 The main concern expressed by pharmacists was that many patients and their representatives do not carry any form of identification. It would be undesirable if a pharmacist were unable to supply a controlled drug urgently needed just because identification was not available. The Pharmaceutical Advisers Group said that it would not like to see pharmacists being held legally responsible for verifying a collector's identity. The RCN drew attention to the problem of 'rough sleepers' who may have no identification papers and whose signature or mark acknowledging receipt may have no practical value. A number of respondents said that a strict rule would be impracticable but that a requirement that pharmacists should use their discretion would be desirable.
- 14.143 Many respondents and participants took the view that doctors and other healthcare professionals collecting a controlled drug on behalf of a patient should be required, unless personally known to the pharmacist (as they often would be), to provide some form of photographic identification.
- 14.144 At the seminars, Mr Rutherford emphasised the need for some form of identification to be provided before a controlled drug was handed over. He stressed that the need for this was increasing because so many pharmacies were now being run by locums who could not be expected to have personal knowledge of their clientele, not even the doctors practising in the area. He thought that nowadays most people carried a driving licence with a photograph. He recognised that there would be some patients who could not provide any identification. In their case, he advocated the keeping of a photographic record of the patient in the pharmacy computer.
- 14.145 Mr Rudd supported the suggestion that some form of identification should be provided and that a record should be made of the name of the person who collected the drug and the nature of the identification provided. Mr D'Arcy agreed that identification was desirable but expressed concern that a pharmacist might not be able to dispense the drugs if no identification was forthcoming. Miss Lavin agreed with that but thought that, if the pharmacist could exercise discretion to dispense the drugs even though no identification had been produced, that concern would be allayed. It was generally accepted that, in many cases, the person collecting would be known to the pharmacist and the pharmacist would not need to see identification but would record in the CDR that the collector was 'known to me'.

## Conclusion

- 14.146 In my view, it is wholly unsatisfactory that a person who is not known to a pharmacist should be able to collect a controlled drug without providing, at least, his/her name and address. Possession of a controlled drug without proper authority is a criminal offence. A requirement that a person collecting such a drug should produce some form of identification seems to me to be a valuable deterrent to wrongful collection. The recording of the name and address of a collector would be a valuable investigative tool if and when it appeared that a controlled drug had been diverted.
- 14.147 In the case of a controlled drug supply that has to be recorded in the CDR (i.e. the supply of a drug within Schedule 2), the pharmacist should be required, before agreeing to supply the drug, to ask the name and address of the person seeking to collect it. If the patient is collecting the drug him/herself, the pharmacist should record that fact in the CDR. If the collector is not the patient, the pharmacist should record his/her name and address in the CDR. The pharmacist should also be required to ask to see some form of identification, unless the person attending is personally known to him/her. The pharmacist should record the form of identification provided or should note that the person attending is personally known to him/her. If no identification is forthcoming, the pharmacist should have discretion to supply or withhold the drugs but, if the drugs are supplied, the pharmacist should record that no identification has been produced. Pharmacists should be very cautious about supplying a controlled drug to a person who is not known to them and has not produced identification. I recognise the possibility that a pharmacist who refuses to supply a controlled drug to a person who does not or cannot produce evidence of identity might be subjected to a threat of violence. In such circumstances, the pharmacist should not risk injury but should report the circumstances to the police.
- 14.148 Any person presenting a prescription or requisition for a controlled drug who claims to be a doctor or other healthcare professional, acting in his/her professional capacity and seeking to collect controlled drugs, should, if not known to the pharmacist, be required to produce identification, preferably his/her professional registration card. This might arise when a healthcare professional collects drugs for practice use purchased on requisition and also drugs prescribed for patients. The relevant information should be recorded in the CDR.
- 14.149 The discussion at the seminars related to drugs the supply of which has to be recorded in the CDR. However, there is a danger of diversion of other controlled drugs, particularly benzodiazepines. I think it would be too onerous to expect a pharmacist to demand identification in every case where drugs in Schedules 3 and 4 are dispensed. However, I see no reason why a collector should not be required to write and sign his/her name on the back of a FP10 or the new official form which I hope will soon be provided for controlled drug prescriptions. I do not think this would be too much to ask. At present, pharmacists have to ask persons presenting a NHS prescription to provide information about the patient's prescription charge exemption. If, as is usual, the same person presents the prescription and collects the drugs, only one signature will be needed. If a different person attends to collect the drugs, a further signature would be required but this would not take long.

## **Electronic Controlled Drugs Registers**

- 14.150 In Chapter Seven, I explained some of the disadvantages arising from the CDR currently used in most pharmacies. One of these is that the CDR must be kept in hard copy form. The process of entering data is time consuming. To a large extent, the time is wasted because much of the same information is keyed into the computerised patient medication records (PMRs). If it were permissible to keep an electronic CDR, the CDR could be connected to the PMR. Time and effort would be saved.
- 14.151 In the Discussion Paper, the Inquiry asked whether pharmacists should be permitted to keep an electronic CDR in preference to one in hard copy. There was very wide support for that idea.
- 14.152 The question also arose whether an electronic pharmacy CDR might usefully be linked to a wholesaler's records so as to ensure that all controlled drugs which appear in the wholesaler's records as being delivered to the pharmacy were automatically entered into the 'drugs obtained' side of the pharmacy CDR. At present, a dishonest pharmacist can order and receive drugs and avoid entering them into the CDR. Mr Macfarlane expressed the hope that this linkage could be made. Several respondents to the Discussion Paper, however, including the RPSGB, expressed concern about the possible confidentiality implications a system such as this system might entail. At the seminars, Miss Lavin said that the RPSGB could support such a system provided that adequate safeguards were inserted to ensure that patients' details were not being shared with wholesalers. I do not see that that will present a problem, as the linkage would be between the wholesaler's records and the 'drugs obtained' section of the CDR.
- 14.153 The Discussion Paper also raised a number of other issues related to more sophisticated methods of connected electronic record keeping. I have mentioned earlier the DoH's proposals for a NHS Care Record and for the electronic transmission of prescriptions between surgeries and pharmacies. At the seminars, great enthusiasm was expressed about these proposals. I have already said that it seems to me that many benefits would accrue from such a system. Mr Macfarlane also described the benefits of electronic linkage of controlled drugs prescribing information held by doctors with that held by pharmacies, wholesalers and producers. I observe only that I can see real benefits in a system which, at a stroke, allows the simultaneous sending of dispensing information back to the prescriber's surgery, to the PPA, into the CDR and to the pharmacy's stock ordering system.

## **Conclusion**

- 14.154 I think that the use of electronic CDRs should be permitted. Their use would save much time and would facilitate inspection and monitoring. I also think it would be useful if pharmacy CDRs were linked to the electronic systems of wholesale suppliers of controlled drugs in order to minimise the risk of diversion.

## **Should the Controlled Drugs Register Contain Details of Drugs other than Those in Schedule 2?**

- 14.155 At present, only transactions involving drugs in Schedule 2 are required to be recorded in the CDR. The Discussion Paper invited views as to whether, if and when electronic CDRs

were in general use, this requirement could usefully be extended to controlled drugs in other Schedules. The Inquiry had recognised that it would be far too onerous to expect a pharmacist to record in handwriting the very large number of supplies of drugs within Schedules 3 and 4.

- 14.156 Responses to these questions were very mixed. Several respondents questioned the value of such a requirement. Others acknowledged that many controlled drugs within Schedules 3 and 4, such as the benzodiazepines, are commonly abused and thought that improved auditing of the use of such drugs would be of benefit.
- 14.157 At the seminar, Mr D’Arcy explained that the issue was one of balancing the importance of improved audit of the drugs in Schedules 3 and 4 against the increased work the requirement would impose on pharmacists and those charged with auditing the information collected. However, he accepted that, if, in future, there were to be a fully integrated electronic network, which included a CDR, there would be no additional work for the pharmacist if transactions in drugs within Schedules 3 and 4 had to be entered in the CDR. I think he also accepted that, even before the fully integrated network is in place, if a pharmacy had a computerised CDR linked to its PMRs, there would not be much additional work if the CDR requirements were extended to drugs in Schedules 3 and 4. Underlying his contribution was the point that the information is worth collecting only if it is going to be used.
- 14.158 Mr Macfarlane supported the idea with enthusiasm. He looks forward to the introduction of a fully integrated computerised system, including a CDR, because this will allow greatly improved audit and control; it will also make it easier to detect theft or diversion of controlled drugs by pharmacy staff. Mr Macfarlane also explained that the Home Office hopes to be able to simplify the categorisation of controlled drugs into Schedules and thereby to streamline the application of the Regulations. In a post-seminar response, Miss Lavin said that the RPSGB would welcome reorganisation of the Schedules so as to reflect more accurately the degree of risk associated with each controlled drug and to group each drug logically with its prescription, recording and storage requirements.

## Conclusion

- 14.159 For the time being, it would not be feasible to extend the CDR requirements beyond their present scope. However, if and when electronic CDRs come into general use, it plainly would be feasible for all controlled drugs transactions to be subject to recording requirements. Whether it would be worthwhile collecting and analysing this data is, as Mr D’Arcy said, a balancing exercise. Plainly the cost of analysis would be considerable. I cannot express a view. However, it can be worth collecting data even if it is not analysed because the information can be useful in an investigation if the need arises. I can understand why Mr Macfarlane considers that the process would be worthwhile.
- 14.160 It is beyond the scope of this Inquiry to make recommendations relating to the rationalisation of the categorisation of controlled drugs into Schedules. However, I confess that I was delighted to hear from Mr Macfarlane that there exists a proposal to simplify the categorisation and to streamline the regulatory framework. I have personally found it difficult to grasp the intricacies of the Regulations. I recognise that pharmacists,

who deal with them on a daily basis, do have a full understanding. But I am sure there must be many people, such as doctors and police officers, who need some knowledge of the Regulations, who find them very complicated to digest and difficult to remember. I think there is scope for simplification and, in a post-seminar response, the RPSGB has indicated that it would welcome a more logical grouping of controlled drugs. In my view, the essential criterion should be, 'How great a social evil is the misuse of this drug?' If great, strong regulatory measures are needed. If modest, less regulation is required.

### **Should the Controlled Drugs Register Contain a Running Balance?**

- 14.161 During the oral evidence, I had been told that some pharmacists took the view that, under the existing Regulations, it was not permissible to include a running balance in the CDR. Others, such as those in charge of pharmacies in the ASDA stores, consider themselves free to use a form of register that includes the provision of a running balance. Among respondents to the Discussion Paper, there was strong support for the proposal that a running balance should be included in a pharmacy CDR. For example, CIOs supported the proposal; such a record would make the task of inspection easier and more effective.
- 14.162 There was, however, some resistance to the suggestion, particularly from the NPA. In its written response, the NPA said that a requirement to record a running balance would be of only limited value. Moreover, if the keeping of a running balance of controlled drug stocks were a legal or professional requirement on pharmacy owners and pharmacists, this would impose a disproportionate burden. The balance would have to be adjusted for every receipt and every supply, doubling the number of entries to be made.
- 14.163 Concern was also expressed by some respondents about the possibility that minor inaccuracies in the recording of stock might lead to prosecution of the pharmacist involved for technical breaches of the Regulations where the pharmacist was not at fault. Others raised concerns about the difficulty of keeping an accurate record of the stock of viscous fluids, which are not easily measured with accuracy. It appears that it is usual practice for manufacturers or wholesale suppliers to supply slightly more of a liquid preparation than the bottle officially contains. This is described as 'overage'. It was suggested that a pharmacist might find him/herself in difficulty if left with 'overage'.
- 14.164 At the seminars, Mr Macfarlane expressed strong support for the proposal that a running balance should be kept. He recognised some practical problems, particularly those to be encountered when the balance was first introduced, but felt that these could be overcome. He felt that the benefits would far outweigh any difficulties. It was clear, however, that he envisaged that a running balance would be a feature of an electronic CDR, rather than one kept on hard copy.
- 14.165 Miss Lavin said that the RPSGB fully supported the inclusion of a running balance in all CDRs, whether kept on paper or electronically. She spoke of the advantages to the audit process. She had personal experience of working in a hospital and said that running balances are always kept in hospital pharmacies. She had been amazed to discover that this was not so in community pharmacies. She said that the practical problems relating to overage and the measuring of viscous fluids were very minor and pragmatic solutions

could be found. For example, in hospital pharmacies, any overage was written off and the register countersigned.

- 14.166 Mr D'Arcy raised another concern of the NPA, that, for registers kept in paper form, the keeping of a running balance would be extremely complicated because pharmacists would have to have a separate page for every form or size of ampoule of every controlled drug. So, for example, a pharmacist might have to keep as many as 36 separate sections for morphine sulphate products alone. However, Miss Lavin made the point that this problem was more theoretical than real. Most pharmacists stocked only the drugs that the local doctors regularly prescribed and she did not think that the number of separate sections to be used would present a problem. Mr D'Arcy accepted that his example had been extreme but he remained concerned about the practicalities of keeping a running balance in a paper CDR. He was more sanguine about its introduction onto an electronic register.
- 14.167 Mrs Roberts, who has had some years' experience of keeping a running balance in a hard copy CDR, and is enthusiastic about the usefulness of such a balance, gave a number of examples of the ways in which minor practical difficulties can be overcome.
- 14.168 Mr Macfarlane concluded by saying that it would be a simple matter to amend the existing legislation to make it clear that it would be permissible to keep a running balance in the CDR. Then, as an interim measure, it could be made plain that it would be regarded as good practice to keep such a balance. When electronic CDRs are in general use, it could then become a requirement to keep a running balance.
- 14.169 In a post-seminar response, the NPA raised another objection to the introduction of running balances and reiterated several of the points already discussed. The new point related to the burdensome nature of the procedures that would have to be gone through every time there was a change in the pharmacist on duty. It was said that there would have to be a full audit of all controlled drugs. Following receipt of that response, the Inquiry invited ASDA to comment on the experience of its pharmacies operating a CDR with a running balance. ASDA said that the current version of its CDR, which has been in use for about a year, has caused very few problems. It provides a running balance and a column to record the name of the person collecting the drugs. ASDA pharmacies do not carry out an audit every time there is a change of pharmacist 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.
- 14.170 In a post-seminar response, Miss Lavin answered some of the objections raised by the NPA. She said that the keeping of a running balance is not found to be unduly onerous by the many pharmacies who do this on a voluntary basis. These include all hospital pharmacies and many 'multiples'. She said that, in New Zealand, the keeping of a running balance is standard practice. She expressed the view that the keeping of a running balance should be a statutory requirement, and not just a professional obligation on doctors and pharmacists. She also said that, in her view, it was not unduly onerous to

conduct an audit each time there was a change of pharmacist on duty. Such an audit should be regarded as best practice.

### **Conclusion**

14.171 There is general agreement that the maintenance of a running balance is a valuable tool in the audit of controlled drugs. The experience of those who have kept a running balance suggests that the practical difficulties that some respondents foresee are not as great as is feared. I do not think that the introduction of a requirement to keep running balances for Schedule 2 controlled drugs would be unduly burdensome, even while paper CDRs are still being used. However, it would seem to me that a sensible way to proceed would be for the Home Office to make it plain that, far from there being any official objection to the keeping of a running balance, such a procedure should be regarded as good practice. The RPSGB should publicise the new position. When electronic CDRs have come into general use, the keeping of such a balance should become compulsory. By then, as Mr Macfarlane observed, pharmacists would be prepared for the change.

### **Should the Controlled Drugs Register Contain the Professional Registration Number of the Prescriber?**

14.172 At present, the name of the person prescribing a controlled drug is recorded in the CDR. If the prescriber is a local doctor and if the pharmacist's writing is clear, it will usually be easy to identify the prescriber. However, if the doctor is not a local practitioner or if his/her name is a common one or if the pharmacist's writing is not easy to decipher, it might not be possible subsequently to identify the prescriber of a controlled drug from the entry in the CDR. It is important for inspection and investigation purposes that prescribers should be readily identifiable. The Discussion Paper raised the question whether the prescriber's professional registration number should be recorded in the CDR.

14.173 From respondents, there was almost unanimous support for the suggestion. Although the NPA initially questioned whether recording this information would be of any benefit, at the seminar, Mr D'Arcy accepted that it would be. Mr Macfarlane and Dr Smith both supported the idea. DC White, of the NACIO, said that such a requirement would be of value to CIOs.

### **Conclusion**

14.174 In my view, the recording of a prescriber's professional registration number in the CDR would be a valuable tool in the monitoring of controlled drug prescribing and in the investigation of cases of suspected diversion or irresponsible prescribing. This requirement would be more practicable if all controlled drug prescriptions carried the prescriber's registration number, as I think they should. I recognise that, while CDRs are manually kept, the recording of this number would be an additional burden upon the pharmacist. However, it may be that this burden could be reduced by the compilation of a list of names and professional registration numbers of the doctors whose names frequently appear in the CDR. Then it would be necessary only for the pharmacist to write the registration number of any prescriber who was not on the list. The introduction of an

integrated electronic system could result in the automatic recording of the registration number.

### **Should the Controlled Drugs Register Identify the Pharmacist Responsible for Dispensing the Drug?**

- 14.175 At the present time, there is no requirement that a pharmacist should identify him/herself when making an entry in the CDR. In a pharmacy where only regular staff are employed, the pharmacists all recognise each other's handwriting and there is little difficulty in identifying who was responsible for which transactions. However, where locum pharmacists are used, difficulty might arise. When electronic CDRs are introduced, there will be no handwriting to recognise. The Discussion Paper raised the question whether the pharmacist responsible for the transaction should be identified in the CDR.
- 14.176 Among respondents, there was strong support for this proposal. It was suggested that the pharmacist's RPSGB number should be provided. The RPSGB raised the question of whose name or number should be recorded if two pharmacists were responsible for the transaction.
- 14.177 At the seminar, Miss Lavin explained that sometimes one pharmacist will be responsible for approving the prescription and allowing it to be assembled and labelled. By the time the drugs are collected, that pharmacist may have gone off duty and another pharmacist might be responsible for handing over the drugs. After some discussion, she agreed that the pharmacist who handed the drugs over took responsibility for the supply and for the making of an entry in the CDR; accordingly it was that pharmacist's number that should be recorded.

### **Conclusion**

- 14.178 In my view, it is imperative that the pharmacist responsible for a supply of controlled drugs should be positively identifiable from the CDR. This should not depend on the recognition of handwriting. I have no doubt that, when computerised registers are in use, a simple means of automatic identification of the pharmacist will be possible.

### **Should the Current Two-Year Time Limit for the Retention of a Controlled Drugs Register Be Extended? If So, to What Period?**

- 14.179 At present, a CDR must be kept for two years from the date of the last recorded transaction. The inadequacy of this arrangement can be demonstrated by the Shipman case. Fortunately, the CDR at 23 Market Street went back to 1991. It was possible to examine Shipman's prescribing of diamorphine between 1991 and 1998. It would have been useful to the Inquiry if a register covering the 1980s had been available. However, if the register had become full in, say, 1996, and had been destroyed in 1998, it would have been impossible to trace his prescribing of the drug or to find out when he had appropriated it, and in what quantity. There must be many investigations of diversion of drugs or irresponsible prescribing where the period under investigation is longer than two years.



14.180 The DoH and some other respondents to the Discussion Paper felt that it would be appropriate for the CDR to be retained for a period of seven years after the date of the last entry, and all the participants at the seminars thought that this requirement would be satisfactory. Miss Lavin pointed out, however, that some controlled drugs have a very long shelf life. She would not wish a CDR to be destroyed if it contained a record of the purchase of a drug that remained in stock. She said that this would be only an occasional problem.

## **Conclusion**

14.181 In my view, retention of a CDR for two years after the date of the last entry is not long enough. I would think that retention for seven years would be reasonable for the purposes of investigation of past practices. If it is thought that the problem mentioned by Miss Lavin could be resolved by extending the period to, say, ten years, I would be in favour of a general rule to that effect. I do not think it desirable that a pharmacy should have to examine the date of purchase and remaining shelf life of its stock before deciding whether it is entitled to destroy a CDR. When electronic records are used, it should be possible for them to be kept almost indefinitely.

## **Inspection Arrangements**

14.182 In Chapter Five, I explained that at present the controlled drugs arrangements in GPs' surgeries are not routinely inspected and that there is an unfortunate paucity of advice available to them on such topics. In Chapter Nine, I outlined the current practice for the inspection of the arrangements for controlled drugs in community pharmacies. The HODI has an overarching responsibility for the enforcement of the legislation but, in most areas, the function of routine inspection is carried out by police CIOs. In a few areas, there is no routine CIO inspection. I also explained that the present arrangements are not ideal and that some chief constables do not regard the function as an appropriate use of police resources.

14.183 The Discussion Paper raised the question whether CIOs should continue to inspect CDRs and the safe custody arrangements for controlled drugs in pharmacies. It also asked whether CIOs should continue to be under a duty to look out for signs of irresponsible prescribing of controlled drugs. If not, should this duty be assigned to others and, if so, to whom? The question was also raised as to who should inspect the controlled drugs arrangements in GPs' surgeries and provide any necessary advice. How should dispensing doctors be treated? A wide variety of views was expressed by respondents and the issues were discussed at some length at the seminars. In the event, a remarkable degree of consensus was eventually reached.

14.184 Before describing the discussion, it may be helpful to recapitulate the main functions of CIO inspection. Pharmacy inspection is designed to ensure compliance with the MDR 2001 by the pharmacy staff. The CIO should look out for signs of illegal or improper practice by the pharmacy staff. Inspection should give the police access to valuable intelligence about the possible misuse of controlled drugs in the area. Finally, the CIO is expected to look out for signs of irresponsible prescribing by doctors and for signs of diversion, particularly by healthcare professionals. If it existed, a system of routine

inspection of GPs' CDRs, SOPs and safe custody arrangements might be expected to improve compliance with the relevant regulations.

- 14.185 DC White, of the NACIO, has six years' practical experience as a CIO. He first sought to impress upon me the need for pharmacy inspections to take place. No one dissented from that proposition and I accept it without reserve. DC White confirmed that, despite attempts to improve the coverage and quality of police inspections, they remain unsatisfactory in some places and non-existent in others. However, he had no doubt that the inspection of registers and safe custody arrangements is properly a police function and that a background in general police work is of great value to a CIO. He accepted that a police background was not essential and that, given appropriate training and experience, persons from other backgrounds could do the work well. It was necessary for whoever did the job to spend a considerable time in the post to gain the experience necessary to be effective. He pointed out that, at present, civilian personnel do not have the legal powers to enter pharmacies, inspect arrangements and demand the production of records; special authorisation has to be obtained from the Home Secretary when a civilian is appointed as an inspector.
- 14.186 Mr Macfarlane expressed the view that, if adequate resources were dedicated to the CIO service, it would operate well. In particular, he saw positive advantages in the deterrent effect of a police officer performing the task. He thought that the involvement of the police strengthened the hand of a pharmacist who might otherwise have difficulty in dealing with addicts. Police expertise in investigation was also invaluable. He was not opposed to the idea that civilian police personnel might carry out inspections and thought that it would be useful if the process of authorising them to do this were simplified.
- 14.187 Assistant Chief Constable (ACC) David Francis, representing ACPO, said that his organisation accepted that CIOs must continue to carry out inspection duties for the present. However, the ACPO view was that, in the longer term, the police should be relieved of their responsibility for routine inspections but should retain involvement in intelligence work and in the investigation of offences that came to light.
- 14.188 Mrs Roberts pointed out that there are two forms of inspection of pharmacies, one by the police and one by the RPSGB, and that the two types of inspector have quite different forms of expertise. The police have knowledge of the law, and the RPSGB inspectors have clinical knowledge and experience. The job of pharmacy inspection requires both forms of expertise. This function, she suggested, should be carried out by an independent inspectorate which should employ personnel with both forms of expertise.
- 14.189 A particular concern lay behind Mrs Roberts' suggestion. She said that prescribers, social workers and patients, particularly drug misusers, had voiced concern to her about the use made by the police of the information contained in CDRs. They felt that it was wrong for the police to have access to confidential medical information. For that reason, she would prefer to see inspections carried out by an independent body. Later in the discussion, DC White explained how he resolves the difficulty mentioned by Mrs Roberts; he is scrupulously careful to ensure that any intelligence passed on to colleagues does not identify patients by name unless such disclosure is justified on public interest grounds by

reason, for example, of the very serious nature of a criminal offence under investigation. He said that the NACIO is trying to ensure the adoption of a similar approach by all forces.

- 14.190 Dr Robertson said that he shared Mrs Roberts' concerns about the fragmentation of the current inspection arrangements. He, like Mrs Roberts, saw the solution in the formation of an integrated team. He considered that the role of inspection required significant medical expertise. Inspection of pharmacies and GPs' surgeries should be a local health function, according to Dr Robertson. Those carrying it out should have an advisory role but should also have access to police expertise, in case of need. He envisaged inspection being carried out at PCT level, to nationally set standards. The inspectors would report back to a central agency.
- 14.191 ACC Francis very much liked the idea of a national model for inspection. However, he did not think it appropriate that the inspection function should operate at a local (PCT) level. He thought a regional level would be more appropriate. Nor did he agree with Dr Robertson's emphasis on the medical and advisory aspects of inspection. He said that what was needed was more robust inspection and improved investigation; the motivation should be better law enforcement.
- 14.192 The discussion then moved on to the detection of irresponsible prescribing and whether police CIOs were best placed to carry out this task. Dr Grenville immediately picked up the idea of an integrated team. What was needed, he said, was a multidisciplinary team comprising people with the necessary skills and expertise to spot and investigate fairly any signs of abnormal prescribing. He said that the approach should be partly by analysis of statistical information and partly through investigation of apparent abnormalities. Local knowledge would also be necessary. He thought that, if the team had the necessary expertise, it would command the support and respect of the medical profession. Dr Gerada agreed with Dr Grenville. She felt that, if the right expertise were brought to bear on the PACT data, most prescribing abuses would be rapidly uncovered. She stressed that the processes of monitoring and investigation must cover private as well as NHS prescribing.
- 14.193 The discussion then turned to the question of how an inspectorate employing multidisciplinary teams might be organised. Dr Smith, for the DoH, strongly supported the general aim of improving and integrating the inspection and monitoring of controlled drugs by means of such teams. However, he said that it would not be appropriate for such an inspectorate to be driven from the centre by the DoH. The DoH's policy, he said, is to retrench from operational functions and to concentrate on policy issues. He suggested that, if a regional structure were sought, the inspectorate might be operated at strategic health authority (SHA) level or possibly by groups of SHAs. Alternatively, he suggested that the inspectorate might be located in regional Government offices, where there was already a Home Office and DoH presence. He said that there were eight such regional offices in the country, which he thought was about the right number for a regional inspectorate, and he thought that these organisations were accustomed to multi-agency work. A further possibility would be the Healthcare Commission, which is expected to have a regional presence in future. He also expressed the view that, if there were to be an inspectorate, the RPSGB's inspectorate should be part of the new framework. Miss Lavin

was enthusiastic about the idea of a multidisciplinary inspectorate. She thought that the RPSGB would be anxious to share its experience and expertise with a new controlled drugs inspectorate but would not wish an inspectorate to be seated within its organisation.

- 14.194 Mr Macfarlane said that, if there were to be a new inspectorate, it would have to take on responsibility not only for pharmacies but also for doctors, dentists and veterinary surgeons. He agreed that it should fulfil the whole range of responsibility for monitoring and inspection in connection with controlled drugs. However, he said that, in recent years, the HODI had been moving away from involvement with the medical profession. It has focussed on its licensing and investigative functions. If the HODI were to take responsibility for a new inspectorate with a wider remit, this would be a 'new ball game'. He agreed that an inspectorate with a wide remit would require a multidisciplinary team.
- 14.195 Dr Grenville found the idea of a regional structure attractive. He said that he thought many doctors would welcome the kind of inspection visits that used to be made by the RMOs. Although many doctors found any inspection to be an intrusion, they recognised that it had to be done. He thought that there should be no artificial distinction between the way in which prescribing and dispensing GPs were treated, although there might need to be a difference of emphasis.
- 14.196 Dr Grenville then went on to expand upon the view, expressed earlier by Dr Robertson, that a multidisciplinary inspectorate should be firmly based within an organisation that was primarily concerned with health, as opposed to law enforcement. He favoured an emphasis on medical expertise and the advisory aspects of inspection. He said that it would be a mistake to base an inspectorate on the foundation that people who misused drugs were criminals. He said that criminal activity connected with controlled drugs was driven by addiction, which is an illness. He said that, if a controlled drugs inspectorate were based within a 'health' organisation, the approach would be one of 'learning and improving and preventing', whereas if it were based in the Home Office or with the police, the approach would be one of 'blaming and shaming'. ACC Francis and DC White emphasised the need for an inspectorate to tackle the criminality aspect and the leakage of controlled drugs into the criminal world. I expressed the view, with which ACC Francis agreed, that there must be an element of both approaches and, for that reason, the organisation should, if possible, be based on neutral ground. Dr Robertson thought that the work to be done by the inspectorate would be 'largely medical' and that the criminal justice element would be 'pretty minimal', although essential. His view was that local knowledge was necessary, so the organisation should be run at PCT level. Dr Gerada thought that a 'bigger picture' was needed and that a regional organisation would be preferable to one located at PCT level. Mr Rutherford agreed with Dr Gerada and reminded the Inquiry that primary care organisations had changed a great deal in recent years and that it might be dangerous to set up an organisation that would depend on the continuance of the PCTs. He thought that a regionally based organisation could have links with PCTs so that local knowledge would be available.
- 14.197 Professor Baker spoke in favour of a regional organisation which could make use of medical and law enforcement expertise. He would like to see such a body taking responsibility for services other than GPs and pharmacies, including hospices and

nursing homes. He thought that PCTs might have a role to play in that they might undertake the analysis of PACT data, possibly in accordance with instructions given by the regional body.

- 14.198 Dr Michael Mawhinney, Misuse of Drugs Inspector for the Department of Health, Social Services and Public Safety, Northern Ireland, thought that a local structure would be inappropriate for England, with its large population, and said that his organisation, which covers the whole of the province, has good relations with local NHS bodies.
- 14.199 ACC Francis did not think that the creation of multidisciplinary inspection teams would adversely affect the enforcement of the law relating to controlled drugs provided that the new organisation had clearly defined objectives and accountability. DC White expressed concern about the view held by some of the 'health agencies' that their own people could investigate their own members; he did not think this was 'safe'. I think his concern was that there might be a lack of independence if doctors were allowed to investigate doctors. He also stressed the usefulness of the intelligence gathered from pharmacy inspections, particularly in the detection of double scripting and leakage of controlled drugs onto the illicit market.

## **Conclusion**

- 14.200 I found this part of the seminars most helpful. A general consensus emerged that there must be a proper system of inspection of the controlled drugs arrangements and of CDRs kept by pharmacists, GPs and dispensing doctors. Inspections should be co-ordinated with the monitoring of prescribing practice. There must be the facility to investigate expertly any concerns discovered.
- 14.201 It seems to me that the ideal solution would be the creation of an inspectorate comprising small multidisciplinary teams, operating regionally but co-ordinated nationally. For this purpose, I think that England could sensibly be divided into about six to eight regions. As I indicated earlier, I think that the inspectorate should be based 'on neutral ground' so that it cannot be dominated by either the medical or the law enforcement ethos. As it happens, neither the DoH nor the Home Office would be willing to provide a base for such an inspectorate, but I see no reason why both Departments should not co-operate closely with it, as the Home Office does with the Inspectorate in Northern Ireland. The Home Office would be free to concentrate on licensing, importation and exportation and the inspection of businesses licensed to manufacture controlled drugs.
- 14.202 Each regional team would include pharmacists, doctors, inspectors and investigators, at least some of whom would have a law enforcement background. The team would be responsible for inspecting the arrangements in pharmacies, dispensaries and surgeries, as to both the safe keeping of stocks and the maintenance of CDRs and other records. In principle, prescribing and dispensing doctors should be inspected, just as pharmacies are at present. It might sometimes be thought necessary for an inspection to be carried out by a doctor or pharmacist and an investigator with a law enforcement background. The need for independence and an arm's length approach is one reason why a regional structure would be preferable to a local one. The inspectorate could also be responsible for the supervised destruction of controlled drugs.

- 14.203 It should also be responsible for the monitoring of the prescribing of controlled drugs by means of analysis of PACT data. At present, monitoring of all prescribing is carried out at PCT level and there is no reason why that should not continue. However, in my view, the monitoring of controlled drugs should also be done by the inspectorate. First, the inspectors will have or will soon acquire considerable expertise in controlled drugs. Second, they will develop a broader view of trends and practices than would be possible for an individual PCT. Third, they will be better placed to detect diversion of controlled drugs by peripatetic healthcare professionals. It is, in my view, imperative that the inspectorate should have access to all prescribing information, whether the prescriptions were issued on the NHS or privately. Inspectors and investigators would require access to background information about the doctor or pharmacist under scrutiny and, in some cases, might even require access to patient records. Potentially, this might give rise to problems of patient confidentiality. However, it appears that computer technology might provide a solution to such problems by allowing access to anonymised information from healthcare records. If that is not possible or sufficient, the investigators would have to seek the consent of patients as the HODI and the police do at present.
- 14.204 I share the view of ACC Francis that the inspectorate should have clearly defined objectives. I would wish the inspectorate to provide advice and assistance to those who are trying to comply with the law, even though not always fully successfully. However, I would expect it to be rigorous in the investigation of anyone suspected of acting unprofessionally and of anyone thought to be breaking the law deliberately. Investigations could be assigned to suitable members of the team. If it appeared that a criminal offence had been committed, the case could be passed to the police or the Crown Prosecution Service for further process. If less serious matters were discovered, the inspectorate might administer informal warnings or refer a complaint to the GMC, the RPSGB or the RCN.
- 14.205 The police would cease to carry out routine inspections of pharmacy CDRs. They would be able to undertake such work as they wished for the purpose of intelligence gathering and would probably wish to maintain close links with the inspectorate and, in some cases, with pharmacists.

## Collecting Controlled Drugs from the Pharmacy

### Should Healthcare Professionals Continue to Collect Controlled Drugs from Pharmacies?

- 14.206 In earlier Chapters, I have described how Shipman collected controlled drugs from the pharmacy, ostensibly on behalf of patients but keeping them for his own purposes. The Discussion Paper raised the question of whether such a practice should be prohibited. The vast majority of respondents to the Discussion Paper and all seminar participants were in favour of allowing healthcare professionals to continue to collect drugs from pharmacies, provided that the identity of the collector of controlled drugs was recorded in the CDR.

### Conclusion

- 14.207 I do not think that healthcare professionals should be prohibited from collecting controlled drugs on behalf of patients. I have already said that the collector of any Schedule 2

controlled drug should be identified in the CDR and the collector of drugs in Schedules 3 and 4 should be asked to sign the prescription. Any collector not known to the pharmacist should be asked to produce identification. Any collector unknown to the pharmacist who claims to be a healthcare professional should be required to produce identification and his/her professional registration number.

- 14.208 Individual NHS trusts providing district nursing services may wish to impose additional requirements, for example, requiring district nurses to notify their managers when they intend to collect controlled drugs on behalf of patients. That is a matter for them.

### **Information about Controlled Drugs Provided by the Pharmacist for the Patient**

- 14.209 There is a sharp contrast between the strict regulations governing the arrangements for controlled drugs before they are handed over the pharmacist's counter and the virtual absence of any such regulation thereafter. When a controlled drug is handed to the patient or his/her representative, it is quite usual for no greater warning to be given (about safe custody or the risk of diversion) than is given in respect of any medicines. Often, the patient will be unaware of the existence of any special legal rules relating to the drug, for example, that possession of the drug without the authority of the patient would be a criminal offence.
- 14.210 The Discussion Paper, therefore, raised the question whether an explanatory leaflet should be handed out by the pharmacist with each controlled drug prescription (or possibly only with each new prescription), explaining the key issues relating to controlled drugs and emphasising the need for safe storage and disposal. It raised the connected question whether the pharmacist should be under a professional duty to explain to whoever collects the controlled drugs the potential for abuse of the drugs and the need to keep them safe.
- 14.211 There was strong support for the idea of an explanatory leaflet among the respondents to the Discussion Paper. However, several respondents, among them Boots and Lloyds Pharmacy Limited, were concerned that such a leaflet might frighten patients into not taking their medication, thereby compromising their treatment. One respondent said that a GP should explain the function of all drugs and should advise the patient (or the patient's representative if appropriate) of the special need for caution with regard to controlled drugs.
- 14.212 At the seminars, Mrs Roberts said that leaflets on the safe storage of medicines should refer to all medicines and not specifically to controlled drugs. She felt that special reference to controlled drugs might deter patients from taking their medication. Mr D'Arcy, for the NPA, confirmed that the labelling of drugs as 'controlled drugs' has a propensity to alarm. Mrs Roberts also highlighted the fact that some cytotoxic drugs which are not controlled drugs are more toxic than controlled drugs. Mrs Roberts' view was shared by the RPSGB which, in its written response, stated that it would not support any recommendation that singled out controlled drugs from other prescription only medicines, because by definition all prescription only medicines are potent medicines and capable of misuse.

- 14.213 Mr Rutherford said that he thought that the public should be educated about all dangerous medicines, not only controlled drugs. He mentioned that, every year, children in England die from taking iron tablets and tricyclic antidepressants. He said that patients have to be given information about the medicines they are taking if they are to understand their medical conditions. This educational process causes some problems. Patients can be worried by the information they receive and some even feel stigmatised when they go to pharmacies to collect controlled drugs because they fear that the counter staff will think they are drug addicts. Issues such as this must be resolved, he said.
- 14.214 In principle, the DoH supported the idea of a patient leaflet to accompany controlled drugs. Dr Smith said that the DoH had recently commissioned the National Prescribing Centre to draft an appropriate leaflet. The result was, however, to use Dr Smith's language, 'quite scary' and he thought that trying to find the right language to make the essential points is very difficult. He accepted the view, expressed by ACC Francis, that it is wrong for a patient or a patient's representative to be unaware of the legal implications of being in possession of a controlled drug.
- 14.215 Mr Rudd had informally discussed the issue of patient information with members of a small reference group. A minority expressed concern about causing alarm to patients but the majority view was that many people are more worried by their ignorance about what they have in their possession. Macmillan Cancer Relief was, therefore, supportive of improved patient information.
- 14.216 Dr Gerada said that the RCGP supported the idea of a patient leaflet and wanted it to contain information about storage of drugs and their disposal and return to the pharmacy. Although she understood it was important that patients should not be frightened into not taking their medicine, she thought that, in fact, patients are better informed than they are given credit for. She said that some computers allowed doctors to print off extracts from the British National Formulary and it was quite common practice to give this detailed information to patients.

## Conclusion

- 14.217 As I understand it, the modern approach to medical treatment is that the patient should be helped to understand the nature of his/her condition and the treatment to be provided. When a drug is prescribed by a GP, the doctor will usually explain its nature and purpose. However, I think it is not always possible for a patient to take in everything that s/he is told and that many patients would benefit from having the oral information provided confirmed in written form. When a doctor is prescribing a controlled drug, s/he will wish to explain the purpose of the drug and the way in which it is to be taken, rather than having to deal with practical issues such as safe keeping. In my view, those practical issues would be more appropriately dealt with by a pharmacist than by a GP. But, again, I think it would be helpful if the messages were to be reinforced in writing. As I observed during the seminars, more could be done, by posting notices in pharmacies, to educate the public about the need to keep drugs safe and to return leftovers for destruction.
- 14.218 Dealing specifically with controlled drugs, I am very sceptical of the suggestion that patients will be afraid to take their medication if they are told about its properties and



the risk of diversion. I sense that Dr Gerada is right when she says that patients know and understand more than they are given credit for. I think that the attitude that patients in general cannot be told about their controlled drugs is patronising. I can accept that some very elderly people might be confused by too much information and might also be alarmed if told that the drugs they are taking would be attractive to a drug addict. However, I think that it should be a general rule that pharmacists should give to patients or their representatives a proper and accurate description of the controlled drugs prescribed, warn them of the particular need to keep the drugs safe because of the risk of diversion and advise them that arrangements must be made for the safe disposal of any drugs left over. This advice should be given orally and should also be available in leaflet form. I can see that some care must be taken in the preparation of the leaflet and that pharmacists will need some guidance about how best to convey the advice to patients. I would accept that pharmacists should have discretion to give only limited information to those patients who they believe would be alarmed to receive the usual advice. The RPSGB should formulate guidance for pharmacists as to what should be said and could provide a helpful lead in the preparation of the information leaflets.

## **The Audit of Controlled Drugs in the Community**

### **Creating an Audit Trail by the Use of Bar Coding**

14.219 At paragraph 7.67, I discussed the possibility of creating an audit trail by recording the batch numbers of controlled drugs in the pharmacy CDR. I concluded that the idea was not practicable. However, the possibility of identifying the drugs dispensed using bar coding also arose for consideration. Everyone is now familiar with bar coded products. Supermarkets use this technology, both to charge customers at the checkout and as a means of stock control. The Discussion Paper asked whether bar coding might be used as a means of providing an audit trail of controlled drugs.

14.220 A substantial number of respondents considered that bar coding would be a useful innovation. At the seminars, the RPSGB fully supported its introduction, saying that it would provide several advantages. Dr Smith explained that, at present, the DoH had no firm commitment to bar coding. However, it recognised its potential usefulness for audit purposes, by permitting the tracking of products through the supply chain. He also said that bar coding is now quite old technology and mentioned that a newer technology, radio frequency tagging, might provide even greater benefits. Mr Macfarlane said that development work was in progress on a radio frequency tracking system for all medications. Although the purpose behind these developments was not improved compliance with Home Office controls, he was confident that it could be used to that end. Moreover, the system could be applied to individual ampoules of a controlled drug. The system would comprise a database which recorded every single pack of medication at the point of manufacture and could track it through every stage of the distribution process. It is beyond the scope of the Inquiry to consider such developments in detail. It is not clear to me whether the use of modern technology will allow there to be an audit trail of controlled drugs beyond the pharmacist and into the hands of an individual patient. If so, the

opportunity for the police or a controlled drugs inspectorate to detect improper diversion of controlled drugs would be much improved.

### **Should a Continuing Record Be Kept of the Transfer, Administration and Disposal of Controlled Drugs Once They Have Been Dispensed by the Pharmacist?**

- 14.221 I have mentioned that, once controlled drugs leave the pharmacy, there are no legal requirements as to the conditions in which they are stored; nor is there any requirement that a record should be kept of their administration or destruction. Above any other single factor, it was this absence of control after dispensing that enabled Shipman to obtain diamorphine illicitly and to avoid notice. It would be highly desirable to tighten the MDR 2001 in this respect. The problem is how to do it.
- 14.222 In Chapter Eight, I described the system by which district nurses keep a patient drug record card (PDRC) to record the administration of diamorphine in syringe drivers. They do so, not because there is any legal requirement to do so but as a matter of good professional practice. Such records provide a valuable measure of audit and control. Desirable as it might be to require a record of consumption of all controlled drugs, it is obvious that it would be impractical to expect patients who take controlled drugs at home to keep such a record. However, where a healthcare professional is involved in the administration of the drug, as is usual with opiate drugs in injectable form, it plainly is practicable for records to be maintained. If the keeping of such a record were a legal requirement rather than a professional one, it would be possible to require doctors as well as nurses to comply.
- 14.223 At present, the district nurse creates the record when the controlled drug (usually diamorphine) arrives at the patient's home. The district nurse would not necessarily know how much of the drug had been prescribed by the doctor or dispensed by the pharmacist. Shipman was able to divert supplies of diamorphine to his own use by presenting a prescription he had issued, collecting the drugs and removing part of the consignment before delivering it to the patient's home. Also, because there is no legal requirement for the return or destruction of unused drugs to be recorded, Shipman was able to claim that he had taken leftover diamorphine for destruction when, in fact, he had taken it for himself.
- 14.224 The Discussion Paper raised the question whether, in the case of controlled drugs to be administered by a healthcare professional, a continuing record should be kept of the transfer, administration and disposal of the drugs after dispensing. This would take the form of a PDRC, which would be opened by the pharmacist and sent to the patient's home with the drugs. As the drugs were administered, the card would be completed by the district nurse or other administering healthcare professional. When the drugs had all been used, the card could be returned to the GP to become part of the patient's medical record. If any drugs remained unused, their destruction could be recorded on the card, which could then be returned to the GP.
- 14.225 The idea of such a continuous record card received support from the majority of respondents to the Discussion Paper. It was recognised to have the potential at least to extend, and possibly to complete, the audit trail. However, some pharmacists expressed concern about the practicalities of such a scheme.

- 14.226 At the seminars, there was general agreement that a record should be kept of controlled drugs which were to be administered by healthcare professionals. It was agreed that it would not be unduly onerous to ask pharmacists to issue the card. It was suggested that the card should record, not only the amount dispensed, but also the dosage ordered on the prescription.
- 14.227 Concerns were expressed about what should happen to the card when it was complete. At present, the PDRCs kept by district nurses are kept with the patient records maintained by the nurses' employers and are not married up with the patients' GP records. Nor, in most areas, are the cards audited; in Tameside, samples of completed PDRCs are now 'reviewed'.
- 14.228 Mr D'Arcy said that there would be difficulties if the cards had to be returned to the pharmacy when the drugs had been used. He thought that cards would be lost and that healthcare professionals would not always make entries on the right card. He thought the system sounded 'convoluted'.
- 14.229 Dr Grenville supported the idea in principle but thought that 'closing the audit loop' would be very resource intensive. He wondered whether the task of audit could be assigned to the new controlled drugs inspectorate that had been discussed earlier and said that it was for society to decide what resources should be spent on audit. He recognised that there would be some value in marrying the PDRCs with the patients' medical records, although he said that good practice already required that a doctor should keep a detailed record of the dosages ordered.
- 14.230 Professor Baker thought it would be of benefit if the information from the PDRC were kept with or entered into the patient medical records. Even if all records were not audited, they would be available for examination if an investigation had to be undertaken. Random reviews might be useful. Dr Gerada and Dr Robertson agreed. Mr Rutherford made a practical suggestion, which, he thought, would make the task of record keeping easier. He said that, if manufacturers had to apply 'peel-off' labels to controlled drugs containers, the person administering the drug would be able to stick the label onto the PDRC instead of writing an entry. Then if any drugs were unused, the labels could be removed from the container at the time of destruction (whether in the home or in the pharmacy) and a record kept of exactly what had been destroyed. In its response to the Discussion Paper, the RCGP suggested that small bung-topped bottles could be used for the supply of controlled drugs, instead of (as at present) closed ampoules which have to be broken in order to open them. Also, the bottles could be supplied in a divided box. When a bottle of drugs had been used, it could be replaced in the box, without its bung. When all the drugs had been used, the box of empty bottles could accompany the completed PDRC to its destination, to demonstrate that all the drugs had, in fact, been used or, if it were the case, destroyed.

## **Conclusion**

- 14.231 The evidence about Shipman suggests that a PDRC, if properly completed, would provide a valuable audit trail for the controlled drugs for which it could be used. In my view, there should be a statutory requirement on healthcare professionals to maintain such a record.

There may be several ways in which the practical arrangements could be made. One is that, when a Schedule 2 injectable drug left the pharmacy, for administration in the community, it would be accompanied by a PDRC which would record the form and amount prescribed, the form and amount dispensed and the dosage as ordered on the prescription. That would become the 'master' PDRC. The healthcare professionals would be required to record all administrations of the drugs on the master PDRC. The record would include a running balance. Every new supply would have its own PDRC. When a new supply (with its PDRC) was brought to the patient's home, the healthcare professional would enter the new stock onto the master PDRC, so that a running record would be maintained. All cards issued by a pharmacy would have to be kept with the master PDRC, to provide a means of checking that the entries in the 'drugs obtained' side of the card accurately reflected the amounts that had left the pharmacy. When the treatment was completed, or after the patient's death, all the PDRCs would be sent to the PCT, which would carry out a review and, possibly, check the PDRCs against the pharmacy records. If no cause for concern arose, the PCT would send the completed records to the patient's GP, to be married up with the other records. If and when there is a controlled drugs inspectorate, it might wish to carry out an occasional audit of PDRCs.

- 14.232 Another possibility would be for the pharmacy to issue, with the drugs, a peel-off label on which the amount prescribed, the amount dispensed and the dosage would all appear. The healthcare professionals involved would provide a blank PDRC, as they do now. They would apply the label to the PDRC as an opening entry and the labels from any subsequent supplies could be applied so as to provide the running record. In other respects, the system would work as described above.
- 14.233 The destruction of any unused drugs would be recorded on the card, wherever it took place, in the manner set out in paragraph 14.251 below. The card would then be sent to the PCT (or kept by the PCT if it had carried out the destruction) or controlled drugs inspectorate and from there, after audit or review, it would be sent to the patient's GP. If the patient had died in the meantime, it is likely that, by the time audit was complete, the GP records would have been sent to the PCT. The master PDRC would then be kept with those GP records, in case an investigation had to take place.
- 14.234 If implemented, these proposals would do much to deter and/or detect the obtaining of drugs by the methods deployed by Shipman. However, they would not detect a doctor who issued a prescription for a controlled drug, presented it at a different pharmacy from the one usually used by the patient's family, collected the drugs and kept the whole consignment for him/herself. That deficiency is not, in my view, a reason to reject the proposal. If a doctor collects drugs from the pharmacy, his/her name will (if another of my proposals is implemented) be recorded in the CDR and should come to the attention of the CIO or, if there is one, the controlled drugs inspectorate. The inspectorate could then cross check the CDR with the PDRC and would soon discover if a supply had not been delivered to the patient's home and entered on the PDRC.

#### **Should Two Healthcare Professionals Witness Every Administration of Injectable Controlled Drugs in the Community?**

- 14.235 The Inquiry heard evidence that, since the discovery of Shipman's crimes, a special rule has been introduced in Tameside, whereby controlled drugs are administered by two

district nurses or healthcare professionals rather than one. This practice was introduced in order to protect the nurses from unfounded allegations of diversion or other impropriety. The Discussion Paper raised the question of whether it should be introduced as a general requirement.

14.236 There was strong opposition to the idea from all groups responding to the Discussion Paper. The objections were that it would be administratively difficult to achieve and far too resource intensive. It would be impracticable to apply to doctors visiting patients out of hours. I was told that it would result in terminally and chronically ill patients being left in pain. The same concerns were voiced in the seminars.

14.237 The Inquiry had been interested in whether a requirement that controlled drugs be administered by two healthcare professionals would benefit patient safety. Dr Smith said that the DoH had researched the issue of double-checking and confirmed that there was no statistical evidence to prove that double-checking leads to error reduction. I can understand how the knowledge that a procedure will be checked may, in some instances, cause the person performing that procedure to become lax.

## **Conclusion**

14.238 I shall not recommend that controlled drugs should be administered by two healthcare professionals rather than one. The adverse resource implications would far outweigh any possible advantage in reducing the risk of diversion of the drugs. However, if any employer of district nurses considers that such a measure is practicable and useful, for the protection of its staff or the reduction of the risk of diversion, it should remain free to impose it, as happens at present in Tameside.

## **The Disposal of Unused Controlled Drugs in the Community**

14.239 In paragraph 7.71, I explained that out of date or contaminated Schedule 2 controlled drugs can be lawfully destroyed only in the presence of a person authorised by the Home Secretary. At paragraph 7.75, I explained that Schedule 2 'patient returns' can be supplied to a doctor or pharmacist for the purpose of destruction; the destruction can take place without formality. As I have said, Shipman was able to divert diamorphine by taking for himself amounts left over after the deaths of his terminally ill patients. It would have been lawful for him to take possession of the drugs to destroy them provided that the personal representative of the deceased patient consented. It was not, of course, lawful for him to keep the drugs for himself. As I explained in paragraphs 8.31 to 8.33, the legal position relating to controlled drugs left over after a patient's death is unsatisfactory; they are the property of the deceased's personal representative and only s/he can give authority for them to be destroyed.

14.240 The Discussion Paper raised a number of questions about the destruction of unused controlled drugs. Who should be empowered to dispose of unused controlled drugs? Should two healthcare professionals be required to witness every destruction of unused controlled drugs in the community? After a patient's death, is it desirable that controlled drugs, that were the patient's property, should pass to the patient's estate? What

arrangements should be introduced so as to enable unused drugs to be returned to safe custody after the patient's death? Should a PCT be empowered or required to take possession of leftover controlled drugs in such circumstances? Should there be a duty imposed on a 'responsible person' to ensure the safe return or disposal of those drugs?

### **Ownership after Death**

14.241 At present, controlled drugs dispensed at a community pharmacy belong to the patient for whom they are prescribed, even if s/he has been exempt from any prescription charge. Often, in cases where the patient has been nursed in the community, district nurses destroy Schedule 2 controlled drugs following a patient's death, relying on the consent of a relative in attendance. However, there must be many occasions when this practice is not strictly lawful, because the relative may not be the deceased's personal representative. I make this point, not because I wish to discourage district nurses from their present practice, which seems to me to be eminently sensible, but to underline the need for a change in the law.

14.242 The Inquiry heard evidence that the present legal position can sometimes give rise to problems. Mrs Roberts had heard of an occasion when the family of a deceased patient had refused to allow the removal of leftover controlled drugs. This type of problem could apply to all controlled drugs in Schedules 2–4. Of those who expressed a view, the overwhelming majority of respondents to the Discussion Paper and all participants in the seminar thought that ownership of controlled drugs should not pass to the patient's estate on death.

14.243 The Department of Constitutional Affairs (DCA) suggested that it would be far simpler if controlled drugs never became the property of the patient in the first place. They should remain the property of those who supplied them, usually a pharmacy. After the death, the deceased's personal representatives should be under a specific duty to account for any controlled drugs or to return them to the supplier.

### **Conclusion**

14.244 It is undesirable that any controlled drugs in Schedules 2–4, unused at the time of death, should pass to the patient's estate. The DCA has suggested one possible solution. Another, which I think would be more practicable, is that all controlled drugs should become the property of the Crown on the death of the owner. There may be other solutions. Whatever solution is adopted, no person should be able to assert a right to the ownership or possession of controlled drugs prescribed for a deceased patient when requested by an appropriately authorised person to allow their destruction in, or removal from, the patient's home.

### **Witnessing and Recording Destruction**

14.245 At present, a patient may lawfully destroy or authorise another person to destroy any controlled drugs lawfully in his/her possession. A patient may also supply or authorise another person to supply any controlled drugs to a pharmacist or doctor for the purpose

of destruction. Doctors and pharmacists, receiving such controlled drugs, are authorised by regulation 27 of the MDR 2001 to destroy them without formality; there is no legal requirement that the destruction should be witnessed by another person or recorded. As a matter of good practice, many pharmacists do make a record and ask a witness to sign it.

14.246 There was almost universal support for the proposal that the destruction of unused Schedule 2 controlled drugs should be accompanied by a degree of formality. Many thought that two professional persons (such as pharmacists or doctors) should be present to undertake and observe the destruction and to sign an appropriate record. A number suggested that pharmacy staff and coroners' officers could be included in the category of those authorised to observe and sign the record of destruction. Some respondents thought that a lay person should be able to observe and sign the record where destruction was undertaken by a healthcare professional. Others said that this would not provide a sufficient safeguard, as the lay person might not understand the significance of what was taking place and could easily be hoodwinked into approving a false record. Some expressed the view that it would be inappropriate to ask a relative to witness the destruction of drugs of a deceased patient soon after the death. In my view, it is not appropriate to involve a lay person as a witness to the destruction of unused drugs.

14.247 The discussion then turned to where the destruction of controlled drugs should take place. It was recognised that it is desirable that it should occur as soon as possible. Concern was expressed about the danger to relatives or district nurses if they were required to return drugs to a pharmacy or other place for destruction. It was said to be preferable for the drugs to be destroyed at the patient's home, even if that did mean that they had to be put into the sewage system. I feel bound to observe that there have been several campaigns to persuade patients to return all unwanted drugs to a pharmacy for destruction and no one seems to have been worried about the risks in connection with controlled drugs. Also, no one seems to be greatly concerned about the safety of relatives or healthcare professionals who collect controlled drugs from a pharmacy and take them to a patient's home. At that stage, the risks must be just as great as, if not greater than, when leftovers have to be dealt with. However, that is not a reason to ignore the risks of transporting controlled drugs. Mr Ian Hargreaves, on behalf of the RCN, opposed the idea that district nurses should have to transport such drugs as diamorphine in their vehicles.

14.248 Professor Baker thought that, if two healthcare professionals were present at the home, the best course was to destroy any unwanted drugs immediately. A record should be made. Dr Gerada said that the RCGP recommended that there should be a tamper-proof bin in the patient's home into which the unused drugs should be put. The bin could then be collected and the drugs incinerated.

14.249 Dr Smith said that the DoH had given much thought to the issue of disposal of controlled drugs and to the possibility of setting up return schemes within PCTs in England. One possibility might be for the DoH to impose a formal requirement on PCTs to implement schemes for the collection, return and safe disposal of all medicines in accordance with waste disposal regulations. Insofar as community pharmacists currently undertake the informal destruction of controlled drugs returned to them, Dr Smith said that the DoH was considering whether to impose contractual requirements of record keeping and safe

handling. However, it was not expected that the pharmacists would be obliged to provide a collection service from patients' homes. Mr D'Arcy said that the NPA would resist 'tooth and nail' any suggestion that pharmacists should be required to retrieve medicines from patients' homes.

## Conclusion

- 14.250 It seems to me that it would be desirable if PCTs were to provide a service whereby all controlled drugs in Schedules 2–4 were collected from the homes of deceased patients and taken away in safe conditions and disposed of appropriately. However, I recognise that this might be thought to be too resource intensive. In the absence of such an arrangement, I shall focus upon the issues of greatest concern. These seem to me to be, first, the safe, prompt and recorded destruction of Schedule 2 injectable drugs and, second, ensuring that healthcare professionals are aware of their obligations and the options available to them. In my view, PCTs should be under an obligation to ensure that suitable arrangements are in place for the disposal of controlled drugs and that the healthcare professionals in the area are aware of them.
- 14.251 In my view, it would be beneficial to formalise the arrangements for the destruction of all Schedule 2 controlled drugs at the home of a deceased patient. However, I think that it will be practicable to impose formal statutory requirements only in relation to injectable controlled drugs in Schedule 2 (for which a statutory PDRC will exist). I shall recommend that the destruction of such drugs takes place in the following approved manner. It should be undertaken by one person and witnessed by another. Full details should be recorded on the PDRC. These details should include the form and quantity of the drugs destroyed and the date, time, place and mode of destruction. Both persons present should enter their names and signatures on the PDRC. The classes of persons who I suggest should be entitled to undertake or witness such destruction would be doctors, pharmacists, registered nurses and suitably trained law enforcement officers (such as CIOs and coroner's officers), inspectors of any new controlled drugs inspectorate and officers of the local PCT. However, in practice, such destruction would almost always fall to district nurses and GPs. As I have made clear, destruction would normally be expected to take place in the patient's home but that might, exceptionally, not be possible or desirable. In such cases, the removal of such drugs from the home should be subject to the same recording and witnessing requirements as destruction. Transport, most commonly to a pharmacy, could be effected by one person, provided that a record had been made by two. Members of the public, including the patient's family, would not be allowed to remove or destroy the drugs.
- 14.252 Frequently, district nurses (and very occasionally GPs) will be asked to remove or destroy non-injectable Schedule 2 drugs when attending the home of a deceased patient. In order to minimise the risk of diversion of such drugs, I suggest that rules of professional conduct and/or an employer's protocol should require that the same degree of formality should apply to their removal or destruction by nurses or GPs as applies to injectable Schedule 2 drugs, albeit not on the same statutory footing. The PDRC could be used for making the relevant record, although the information could be recorded on some other suitable form if, for example, the patient's treatment had not involved the creation of a PDRC. Such



requirements, applicable to all Schedule 2 controlled drugs, would render it far more difficult for healthcare professionals to divert such drugs. The same degree of formality would not apply to removal by the families of deceased patients, who should be allowed and encouraged to return such non-injectable unused controlled drugs to the pharmacy.

14.253 When any unused Schedule 2 controlled drugs are returned to the pharmacy or doctor's surgery for destruction, their destruction should be carried out and witnessed in the approved manner as described in paragraph 14.251 above. When destruction takes place in the pharmacy or surgery, it should be recorded on the PDRC, if there is one, or otherwise in the pharmacy or surgery records, possibly in the CDR.

14.254 I do not think it appropriate that I should make any recommendations as to the precise means by which controlled drugs should be destroyed. I was shown one proprietary method by which the drugs were rendered unusable by being mixed with a liquid which later solidified. I have no doubt that there are many different ways of dealing with this problem, all perfectly effective.

## Summary

14.255 In this Chapter, I have considered a large number of possible changes to the regime for the regulation of controlled drugs. My conclusions, which form the basis of my recommendations for change, have been formulated as a result of the evidence I have received and the views expressed in the responses to the Discussion Paper and at the seminars. Some of the ideas discussed I have found to be useful and feasible; others I have rejected as ineffective or because they seem likely to place a disproportionate onus on those professionals who would be responsible for implementing them. Some of my recommendations are particularly designed to deter or detect unlawful conduct of the kind perpetrated by Shipman. Others are not directly related to him but are designed to improve the safety of patients in using controlled drugs and to deter and facilitate the detection of any kind of unlawful conduct. I have listed my recommendations in a section that appears immediately after the Summary at the beginning of this Report.

14.256 The implementation of many of my recommendations would require primary legislation and some would involve the reallocation of, and possibly an increase in, existing resources. For example, I have recommended the formation of a controlled drugs inspectorate to take over the role of the CIO in the inspection of pharmacies. It would also provide for the inspection of both the dispensaries of dispensing GPs and the arrangements made by GPs (including those operating in the private sector) for the safe custody of controlled drugs and for their CDRs. The inspectorate would also be responsible for monitoring the use of controlled drugs by means of data provided by the PPA. It could, in addition, provide advice to doctors and pharmacists on controlled drugs issues and, as happens in Northern Ireland, its members could be involved in education and training. I make this recommendation because, at present, the monitoring of the use of controlled drugs and the inspection of the records kept and the safe custody arrangements in place are patchy and fragmented. They are carried out by police officers who do not have the necessary pharmaceutical or medical expertise or by medical

advisers for whom controlled drugs are but one of many responsibilities. An inspectorate should provide expertise and cohesion.

- 14.257 One of the threads running through my recommendations is the need to apply the same degree of regulation and monitoring to the use of controlled drugs in the private sector as is applied within the NHS. My recommendations include the use of a special prescription pad (possibly in duplicate) for controlled drugs prescribed (or obtained on requisition) by doctors in the private sector as well as under the NHS. The controlled drugs inspectorate could be responsible for the issue of the special prescription pads or a special access code for use if and when electronic generation and transmission of prescriptions is introduced. The inspectorate could ensure that only those doctors with a clinical need to prescribe such drugs would be authorised to do so. The inspectorate would also be aware of the identity and professional address of all doctors authorised to keep controlled drugs, and could arrange appropriate inspections. No doubt, the inspectorate would maintain a list of those authorised. All controlled drug prescriptions should be sent to the PPA for entry into its database and subsequent analysis and monitoring by the inspectorate.
- 14.258 My recommendations have focussed mainly on devising provisions that will make it more difficult for healthcare professionals to obtain controlled drugs by illicit means and will help to detect their activities if they occur. However, these recommendations should be considered against the general background of the legislation relating to controlled drugs. The framework of controlled drugs legislation has remained virtually unchanged for more than 30 years. The requirements in relation to prescriptions and record keeping are out of date and require modernisation. The Schedules to the MDR have been amended in a piecemeal fashion so that they are now an almost incomprehensible maze of provisions. I earnestly hope that the recommendations in this Report will provide an opportunity for the framework to be looked at afresh. A simplified and principled structure for the regulation of controlled drugs should be developed. The Home Office is aware of the need for improvements in many areas. However, it seems that the impetus for modernisation is coming largely from the DoH through its development of IT systems which are designed primarily to improve patient care rather than to facilitate the regulation of controlled drugs or the monitoring of their use. It seems to me that a joint approach between the two departments is needed so that the legislative framework can be changed to allow for the use of computer technology with an eye on improved regulation and monitoring of controlled drugs as well as on improved patient care.