SUMMARY

Introduction

1. From my First Report, in which I found that, over a period of more than 20 years, Shipman had secretly obtained very large quantities of diamorphine and had used it to kill many of his patients, it was apparent that the regulatory framework governing the use of controlled drugs had not operated as it should. The purpose of regulation is to ensure accountability for the use of controlled drugs so as to avoid their diversion to improper use and to detect such diversion if it occurs. The Inquiry's Terms of Reference required me to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring the use of controlled drugs and to recommend what steps, if any, should be taken to protect patients in the future. The Inquiry's investigations into the reasons why Shipman's illicit acquisition of controlled drugs had not been detected for so long required an examination of the systems and rules relating to the prescribing, dispensing and keeping of controlled drugs. Also, the Inquiry considered the arrangements by which the use of controlled drugs in the community is monitored and the operation of the systems is inspected.

2. I was told that the scale of the problem of diversion of controlled drugs is unknown but that, quite apart from Shipman's activities, it is extensive enough to warrant attention. I found that the present systems of regulation and monitoring require improvement and modernisation. Because I did not wish to confine myself to making recommendations designed purely to 'catch another Shipman', I was also drawn into consideration of a number of issues, not directly related to Shipman, but concerned with the security of controlled drugs and with the safety and wellbeing of patients using such drugs.

The Legislative Framework

3. For more than 80 years, there has been legislation regulating the prescribing, possession and supply of certain medicinal drugs that are known to be addictive and to have a potential for abuse. The Home Office is the Government Department responsible for the legislation governing controlled drugs, which were formerly known as 'dangerous drugs'. The current legislative framework is the Misuse of Drugs Act 1971 (MDA 1971) and regulations made thereunder. The Regulations currently in force are the Misuse of Drugs Regulations (MDR) 2001, the Misuse of Drugs (Supply to Addicts) Regulations 1997 and the Misuse of Drugs (Safe Custody) Regulations 1973. The principles of regulation have not changed since 1973 when the MDA 1971 and the first set of Regulations made under it came into force. The basic principle is that it is unlawful to possess a controlled drug or to deal with one in any way without authority. Authority is provided by the issue of a licence by the Home Office or is conferred on certain classes of person by statute. For present purposes, the important classes of person who possess such authority are medical practitioners, pharmacists and patients. Medical practitioners, acting as such, are authorised to possess, prescribe, supply and administer any controlled drug for the treatment of organic disease. They may also prescribe some controlled drugs, such as methadone, for the treatment of addiction, although only specially authorised doctors are

allowed to prescribe diamorphine, cocaine and dipipanone for the treatment of addiction. Medical practitioners who keep a stock of certain types of controlled drug must keep them in a lockable receptacle and maintain a controlled drugs register (CDR), which is a chronological record of all purchases and supplies of the drugs in question. Pharmacists are authorised to deal with controlled drugs in the course of business, subject to compliance with the Regulations. These impose a duty to maintain a CDR and to keep some types of controlled drugs in a locked safe, cabinet or room. Patients are authorised to possess controlled drugs prescribed for them but cannot lawfully supply them to anyone who is not authorised to possess them.

4. All controlled drugs are listed in one of five Schedules to the MDR 2001, according to their therapeutic usefulness, their potential for abuse and the perceived need for control. Drugs within Schedule 1 have little or no therapeutic value, are addictive and have a high potential for abuse; they are the most strictly controlled and can be lawfully dealt with only under a Home Office licence. Schedule 2 contains opiate drugs such as diamorphine, morphine, methadone and pethidine, as well as stimulants such as amphetamines. These drugs have real therapeutic value but are highly addictive. Their use is quite strictly controlled. There are special prescription requirements, and Regulations relating to record keeping, safe storage and destruction apply. Schedule 3 comprises barbiturates and some benzodiazepines, such as temazepam. They are less rigorously controlled than drugs in Schedule 2. Schedule 4 Part 1 contains most of the benzodiazepines, such as diazepam and nitrazepam; Part 2 contains the anabolic and androgenic steroids which have a potential for abuse by athletes. These drugs are only lightly regulated. Schedule 5 includes preparations containing controlled drugs such as codeine or morphine, used in such low strength that they present little or no risk of abuse and can be sold over the counter.

5. Responsibility for inspecting and monitoring the operation of the controlled drugs regime in the community is divided between the Home Office, the police and primary care trusts (PCTs), the NHS bodies responsible for the provision of primary care. The Home Office Drugs Inspectorate (HODI) has overall responsibility for the regulatory system but undertakes routine inspections only of the premises and operations of those persons or organisations that have been licensed by the Home Office to deal with controlled drugs, such as private hospitals and drug treatment clinics. Police chemist inspection officers (CIOs) have a statutory power (but no statutory duty) to inspect the controlled drugs stocks and CDRs at pharmacies. Pharmacies are also inspected by inspectors of the Royal Pharmaceutical Society of Great Britain (RPSGB) but there is no requirement that these inspections should focus on the arrangements for controlled drugs and, in fact, they do not. The medical advisers of PCTs have the power (but no duty) to inspect the controlled drugs arrangements and CDRs at general practitioners' (GPs') surgeries and at the premises of GPs who also dispense medicines, as well as prescribing them.

6. Monitoring of the use of controlled drugs is carried out by PCTs, using prescribing data provided by the Prescription Pricing Authority (PPA), a special health authority whose primary duty is to pay pharmacists and dispensing doctors for the drugs, medicines and appliances they dispense under the NHS. However, the PPA also collects prescribing information on its database and processes it for monitoring purposes. This facility was

developed during the 1980s and 1990s and has gradually become more sophisticated, accurate and easy to use. However, the PPA does not collect information about drugs that are prescribed privately or purchased by doctors on requisition.

Pethidine and Diamorphine

7. The Inquiry has focussed mainly on diamorphine, the controlled drug used by Shipman to kill his patients, and pethidine, the controlled drug to which Shipman was addicted in the 1970s. Both drugs have a therapeutic use in the relief of pain. Both give rise to a sense of euphoria and are addictive. Both act as a respiratory depressant. Diamorphine, in particular, is dangerous for that reason. In overdose, respiration is slowed and eventually stops. The lack of oxygen to the brain leads to cardiac arrest and death. This was the means by which Shipman killed at least 214 patients.

8. In the 1970s, pethidine was widely used by GPs and midwives for the relief of pain in childbirth. Today, its use in general practice is limited, as more effective short-term analgesics are available. Diamorphine is widely used for the relief of severe pain in cases of terminal cancer. Since the early 1990s and the introduction into community medicine of the use of the syringe driver (a device which administers a continuous supply of a drug to the patient), the use of diamorphine has increased. The syringe driver allows greatly improved pain control, and more terminally ill patients can now be treated at home. Often, quite large quantities of the drug are required, as patients become habituated to it. Daily dosages of 1000mg or sometimes even substantially more can be needed. Some GPs also use small quantities of diamorphine for the relief of acute pain during a heart attack or following trauma. In such circumstances, the usual dosage is up to 5mg, although 10mg might be required. Many GPs keep a personal supply of 5mg ampoules for emergency use. Diamorphine is supplied in ampoules containing 5mg, 10mg, 30mg, 100mg and 500mg. The very large ampoules are only rarely used.

Shipman's Use of Pethidine in the 1970s

9. In March 1974, Shipman entered practice as a GP in Todmorden, West Yorkshire. Within a short time, he began obtaining large quantities of pethidine from Boots the Chemists (Boots) by presenting requisitions or signed orders for the drug. He told the pharmacist that the drugs were required for use in the practice. He also began to issue NHS prescriptions for pethidine in the name of an elderly patient who lived on the outskirts of Todmorden. Shipman presented these prescriptions and collected the drugs, saying that he would deliver them to the patient. In fact he kept the pethidine, or most of it, for himself. In early 1975, inspectors from the Northern Regional Office of the HODI, examining the records of a wholesale supplier, noticed unusually large deliveries of pethidine to Boots, Todmorden. The Boots CDR showed to whom it was being supplied. In July 1975, two HODI inspectors and an officer of the West Yorkshire Police (WYP) interviewed Shipman and inspected the practice's controlled drugs stock and CDR. There was no pethidine in stock. It was found that Shipman had entered the amounts of pethidine obtained into the CDR but had made no entries in the 'drugs supplied' pages and had not, therefore, accounted for the removal of the drug from stock. Shipman claimed that he did not know

that this was required. The HODI inspectors advised Shipman as to his duties and resolved to keep watch on his activities. Shipman continued to obtain pethidine on requisition and by collecting supplies dispensed against prescriptions issued by him in the names of patients. After a short while, his partners were informed; Shipman admitted that he had been using the pethidine himself. It emerged that, since the visit of the HODI inspectors in July, he had not made any entries at all in the practice CDR.

10. Shipman left the practice and, shortly afterwards, was admitted to a private hospital for treatment for addiction. While there, he was interviewed by a HODI inspector and the police. He admitted obtaining pethidine on requisition and by the improper use of prescriptions. He said that the patients for whom he had prescribed pethidine had received small amounts of the drug but that he had kept most of it himself. In fact, during a period of about 18 months, he had used over 83,000mg of pethidine. There is no evidence that Shipman used pethidine to kill patients, and I think it highly improbable that he did. In the First Report, I found that, while working in Todmorden, Shipman had killed one patient, probably using a strong opiate such as morphine or diamorphine. I was suspicious that he might have caused the deaths of six others.

11. At the end of 1975, Shipman left hospital and early the following year found employment with the Durham Area Health Authority (AHA) in the field of child development. In February 1976, he pleaded guilty at the Halifax Magistrates' Court to eight offences of unlawful possession of pethidine, obtaining pethidine by deception, and forgery. He asked to have 74 similar offences taken into consideration. He relied on two psychiatric reports from doctors who had treated him. These said that he had undergone treatment for addiction to pethidine and had responded well. He was fined and ordered to pay compensation and costs.

12. Shipman's convictions were notified to the General Medical Council (GMC), the doctors' regulatory body, so that it could consider disciplinary proceedings. The procedure at that time was for the circumstances to be considered by the Penal Cases Committee, which would decide whether the case warranted referral to the Disciplinary Committee on a charge of serious professional misconduct. If Shipman were to be found guilty of such misconduct, the GMC had the power to erase him from the register of medical practitioners or to suspend him for a period of up to a year. It had no power to impose conditions on his registration. The GMC obtained information about Shipman from the HODI and the WYP. Shipman's solicitors supplied copies of the two psychiatric reports prepared for the Magistrates' Court and an up to date report describing his recent progress. This expressed the view that it would be **'catastrophic'** if Shipman were not allowed to continue in practice. A letter from the Area Medical Officer of the Durham AHA reported that Shipman was doing well in his new post. On 28th April 1976, the Penal Cases Committee of the GMC decided not to refer his case to the Disciplinary Committee but concluded it with a warning to him against any repetition of his conduct. So far as the GMC was concerned, Shipman was free to practise medicine unrestricted. I shall consider the appropriateness of the GMC's decision in the Fifth Report.

13. Under section 12 of the MDA 1971, the Home Secretary had (and, in theory, still has) the power to make a direction restricting the right of any doctor convicted of offences under

the Act to possess, prescribe, supply or administer any controlled drug. Until 1976, this power was regularly used in cases such as Shipman's. Before deciding whether to invite the Home Secretary to make a direction, Home Office officials would consult with the GMC and with the Department of Health and Social Security (DHSS). They did so in Shipman's case. It is not clear whether the DHSS responded; if it did, its response has been lost. The GMC responded by telling the Home Office that Shipman's case had been concluded.

14. At about this time, it appears that there had been a change in policy within the Home Office as to the type of circumstances in which a direction under section 12 might be made. Previously, directions had been made in cases, such as Shipman's, where the doctor was addicted to a drug and had committed offences in the course of obtaining supplies for self-administration. For reasons that are now obscure, in about May or June 1976, it was decided that the Home Secretary would be invited to make a direction only where a doctor's offences involved supplying a controlled drug to someone else or allowing it to be so supplied. Shipman may have been the first doctor to benefit from this new policy. On 1st July 1976, Home Office officials decided not to invite the Home Secretary to consider making a decision in Shipman's case. His file was closed and he was free to practise medicine without restriction or supervision. I have concluded that no criticism should attach to the Home Office officials for this decision, which was made in accordance with the policy of the day. That policy did, however, leave a *lacuna* in the power of the authorities to protect patients from a drug-abusing doctor.

Shipman's Methods of Obtaining Diamorphine while Working in Hyde

15. In about July 1977, Shipman applied for a vacancy at one of the GP practices which operated from Donneybrook House, Hyde. At interview, he explained that he had had a problem with pethidine and had been convicted of controlled drugs offences. I have found that he probably understated the seriousness of his convictions. He said that, in future, he did not intend to keep a personal stock of controlled drugs for emergency use; non-controlled alternatives were available. After making enquiries of the Home Office and the GMC, the Donneybrook doctors were satisfied that Shipman was free to practise without restriction and offered him the position.

16. During the period of more than 14 years for which Shipman practised at Donneybrook House, he killed 71 patients, each time using an overdose of diamorphine. The deaths of 30 more patients give rise to suspicion. None of the other doctors in the practice had any reason to suspect him of misusing diamorphine. To all appearances, he kept to his word and did not maintain a stock of controlled drugs for emergency use.

17. Very few pharmacy records from this period survive and I am unable to say with certainty how Shipman obtained his supplies of diamorphine. However, I think it highly likely that he used the same methods as he was to use later, during the 1990s, a period for which records are available that allow a clear picture of his activities to emerge. In short, I think it likely that he stole diamorphine prescribed for cancer patients, by prescribing more than was needed for their treatment. He would take either the whole or part of a consignment for himself instead of delivering it to the patient and would remove and keep any supplies left over after the patient's death.

18. These methods of obtaining diamorphine would not have been likely to arouse suspicion. The prescriptions would have been properly made out. The amounts would have been recorded in the CDR of the pharmacy at which they were dispensed. They would not have appeared excessive for the needs of a patient suffering from terminal cancer. The fact that Shipman had collected the drugs from the pharmacy, ostensibly to save the patient or his/her relative the trouble of so doing, would have been attributed by the pharmacy staff to his caring nature. In any event, the fact that he collected the drugs would not have been recorded in the CDR. There was no requirement that this should be done. Accordingly, the visiting CIO would have been unaware of Shipman's practice of collecting drugs unless informed of it by the pharmacist. The appearance of Shipman's name as the prescriber of diamorphine for patients would have appeared to the CIO to be entirely normal. Nor would Shipman's removal of drugs left over after the patient's death have given rise to suspicion. Since 1985, the MDR have permitted a doctor or pharmacist to destroy unwanted or returned controlled drugs without any formality, i.e. without having the destruction witnessed or recorded. So, it would have appeared entirely acceptable for Shipman to take the drugs, saying that he would dispose of them.

19. In January 1992, Shipman left the Donneybrook practice and set up as a single-handed practitioner. In the August, he moved to new premises at 21 Market Street, Hyde. Immediately adjacent to his surgery, at number 23, was a pharmacy, which was used by many of Shipman's patients. In September 1991, it had changed hands and a new pharmacist manager, Mrs Ghislaine Brant, had been appointed. A new CDR had been opened; it survives and provides a clear picture of Shipman's diamorphine prescribing practice between October 1991 and July 1998. Between March 1992 and August 1993, Shipman obtained a total of sixteen 30mg ampoules of diamorphine on prescriptions issued in the names of patients who did not need the drug; indeed, in at least six cases, the patient was already dead at the time the prescription was written. I shall describe in greater detail at paragraphs 22–30 the events surrounding the dispensing of a sequence of 14 of these ampoules between February and August 1993.

20. From November 1993 onwards, Shipman obtained diamorphine supplies by prescribing in the names of patients who were suffering from cancer. Some of them were in actual need of the drug for pain relief; for them, Shipman would prescribe more than was necessary and would collect the drugs and keep the whole or part of the consignment for himself. He would also take drugs left over after the patient had died, on the pretext of disposing of them, but would keep them for himself. Sometimes, he would prescribe diamorphine in the name of a patient who, although suffering from cancer, was not in pain and had no need of the drug. He would collect the supply from the pharmacy and keep it for himself. These dishonest methods of obtaining the drug were not likely to arouse suspicion, for the reasons I outlined above. There was nothing unusual for the visiting CIO to notice.

21. Between 1992 and 1998, Shipman obtained more than 24,000mg diamorphine illicitly. During that time, he killed 143 patients and I am suspicious about a further nine deaths. Yet no concerns were aroused about his use of controlled drugs and, had it not been that, in 1998, he came under suspicion for forging the will of Mrs Kathleen Grundy and of killing her, his activities would, I believe, have continued undetected.

Shipman's Abnormal Prescribing of Diamorphine in 1993

22. Between February and August 1993, Shipman obtained for himself 14 single 30mg diamorphine ampoules by prescribing them in the names of 13 different patients. The question arose as to whether this pattern of prescribing was so abnormal that it should have aroused the concern of the pharmacist who dispensed them, Mrs Brant, and/or that of Detective Constable (DC) Patrick Kelly, the CIO for Hyde at the time.

23. Examination of a diamorphine CDR will usually show that the drug has been prescribed by a doctor for a single patient over a period of days or weeks; the amounts prescribed on each occasion will usually be increasingly large, often culminating in supplies of as much as ten 100mg ampoules. The supplies come to a sudden end with the death of the patient. Such groups of entries will be interspersed with entries recording supplies to practices or individual doctors 'for practice use' in emergencies. Such supplies will usually be of a box of five 5mg ampoules. There will also be entries relating to prescriptions issued by other doctors. A single 30mg ampoule is a very unusual amount of diamorphine to prescribe. It is far too much to administer to a patient who is suffering from the acute pain of a heart attack and too little to prescribe for a patient who has chronic pain caused by cancer. It is, as one witness observed, 'neither one thing nor the other'. As a single dose, given to a 'morphine-naïve' patient, it would be fatal. In fact, Shipman was using these ampoules to kill his patients. The appearance of the diamorphine CDR of the pharmacy at 23 Market Street was most unusual. On one page, there appeared 12 consecutive entries, made between February and May 1993, each recording the supply of a single 30mg ampoule, each prescribed by Shipman, each in the name of a different patient. On four days – two of them within the same week – Shipman had prescribed two single ampoules for different patients on the same day. All but one entry had been made by Mrs Brant. Copies of the relevant pages appear at Appendix A to this Report.

24. Mrs Brant told the Inquiry that Shipman had collected these 30mg diamorphine ampoules himself. At the time, she had not thought there was anything strange or suspicious about the prescriptions. She believed that, on the first occasion, he had prescribed a smaller ampoule, claiming it was required for the treatment of a patient suffering acute pain from a heart attack. She had had no small ampoules in stock and had supplied him with 30mg. Thereafter, he had prescribed 30mg ampoules. I rejected her evidence on this issue. I found that Shipman had prescribed 30mg ampoules from the start.

25. Exactly what explanations Shipman offered when presenting these prescriptions I cannot say. Whatever they were, Mrs Brant accepted them. She held him in very high regard. She should have been aware that this pattern of prescribing was most unusual and she should have been concerned that Shipman always collected the drugs himself. She was not concerned because, she said, she trusted him completely and because the amount of drugs collected was not so large as to give rise to the suspicion that Shipman might be addicted to diamorphine, a sign that she knew it was her duty to look out for.

26. Mrs Brant accepted that, in general, it was her duty, before dispensing a drug, to satisfy herself, so far as she could, that the drug and the dosage prescribed were appropriate for the patient. She had plainly not applied her mind to those issues in respect of the patients for whom Shipman had prescribed 30mg diamorphine although she had had the

opportunity to speak to Shipman on each occasion. However, she claimed that where, as here, she was supplying the drug directly to a doctor, it was reasonable for her to rely on the doctor's expertise. She said that she believed that, if 30mg was too much to give the patient, Shipman would use part of the ampoule and throw away the rest. I do not accept the distinction she drew; a pharmacist is under to a duty to ensure, so far as possible, that the doctor does not prescribe an excessive quantity of a controlled drug. The fact that the doctor is present when the drug is dispensed does not affect that duty.

27. Mrs Brant also suggested that it was possible that, in prescribing single 30mg ampoules, Shipman was, on each occasion, 'replenishing' his own stock of diamorphine which he had used in an emergency shortly beforehand. Such a practice would be improper but it appears that some doctors do 'replenish' (it is less cumbersome than following the correct procedures) and that some pharmacists turn a blind eye. It is possible that Shipman said or implied that that was what he was doing. If he did, Mrs Brant should have realised that emergencies had suddenly begun to occur with unusual frequency in Shipman's practice.

28. In my view, Mrs Brant should have realised that this course of prescribing was abnormal and should have at least discussed it with Mr Peter Rothman, the owner and superintendent of the pharmacy, or with the CIO or with an inspector from the RPSGB. She did not appreciate the unusual nature of these prescriptions because she had lost her professional objectivity when dealing with Shipman. My criticism of her is mitigated because I have no doubt that Shipman had deliberately set out to win her confidence and to deceive her.

29. When DC Kelly of the Greater Manchester Police (GMP) visited the pharmacy at 23 Market Street in July 1993, he examined and signed the diamorphine register. He did not notice anything unusual about the page of consecutive entries for single 30mg ampoules, all prescribed by the same doctor. He did not know that Shipman had collected the ampoules as well as prescribing them. That is not recorded in the CDR and Mrs Brant did not tell him. At the time, DC Kelly was very inexperienced. He had been appointed as a CIO only three months before. His training had been inadequate. It comprised a few weeks' apprenticeship with a CIO who worked only part-time in that role. When he began to work on his own, DC Kelly had little knowledge of the characteristics of controlled drugs and would not have known that a 30mg single ampoule of diamorphine was a very unusual amount to prescribe. Even so, by the time he examined this CDR, DC Kelly had seen at least 150 CDRs and, in my judgement, he should have recognised that the consecutive entries in this one were very unusual. He had no supervisor with knowledge of the CIO's role but he could have asked the advice of his colleague, DC Robert Peers, who had trained him. He could have asked for Mrs Brant's views. Had he done so, however, it is likely that she would have reassured him that Shipman was a very well respected doctor and that there was no cause for concern. My criticism of DC Kelly is mitigated by his inexperience, by the inadequacy of his training as a CIO and by the lack of supervision from a more senior GMP officer. Although the GMP was responsible for the inadequacy of DC Kelly's training and supervision, I recognise that it provided a better CIO service than many other police forces. Moreover, in 1993, no training course was available for CIOs, as it is now.

30. I have found that if Mrs Brant or DC Kelly had been concerned about these entries and had reported them to an appropriate authority, it is likely that the HODI would have investigated Shipman. The inspectors would have known of his previous convictions in relation to pethidine and this would have raised their level of suspicion about him. What the outcome of such an investigation would have been is uncertain but my considered view is that it is unlikely that the true nature of Shipman's activities would have been uncovered. However, I think it likely that the investigation itself would have had a salutary effect on Shipman, who would probably have ceased killing for a time. In that way, at least some lives would have been saved.

Other Types of Misconduct Connected with Controlled Drugs

31. The Inquiry learned that the misuse of drugs by doctors, nurses and pharmacists is not uncommon. The ready availability of such drugs appears to create an increased risk of dependence or addiction. Doctors addicted to a controlled drug tend to obtain their supplies in ways similar to those used by Shipman. Some doctors, not addicted themselves, supplement their income by selling controlled drugs or by selling prescriptions to addicts. Such activities are plainly unlawful but they are not easy to detect. Often the prescriptions are issued privately (i.e. not on the NHS) and, as I explained earlier, are not subject to the same monitoring processes as are NHS prescriptions. Some doctors, while not prescribing illegally, prescribe controlled drugs in an irresponsible and unethical way. For example, they might prescribe large quantities, turning a blind eye to the possibility that the patient might be an addict and might be selling part of his/her supply to purchase other drugs. Others might provide prescriptions to 'patients' whom they hardly know, without making any attempt to contact the patients' usual medical advisers. Drug addicts will often seek to obtain supplies from more than one doctor, a practice known as 'double scripting'. Doctors who are not alert to that possibility and are not willing to query such requests act irresponsibly. The Inquiry has also become aware that some doctors prescribe controlled drugs for themselves and for their friends and members of their families. Such prescribing is not unlawful, although the GMC regards it as poor practice. The scale of any of these problems is not known. Since the existing systems of monitoring are inadequate (and, in the case of private prescriptions, virtually non-existent), there is at present no means of knowing.

Systemic Shortcomings

Inspection and Monitoring

32. At paragraph 5 above, I described how the inspection of the arrangements made and records kept by the various people and businesses that handle controlled drugs and the monitoring of the use of controlled drugs are carried out by a variety of different bodies. The HODI is responsible for the investigation of certain breaches of the MDA 1971 or the MDR 2001. It undertakes routine inspections of the premises and records of producers and wholesalers of controlled drugs and other persons licensed to deal with such drugs. It has not the resources to undertake routine inspections of pharmacies or GPs' surgeries. The evidence received by the Inquiry suggested that the HODI carries out its duties effectively.

33. The routine inspection of pharmacies is carried out by police CIOs. The duties of a CIO are to inspect the CDR and the safe custody arrangements for the stock of controlled drugs. While inspecting the CDR and through discussion with the pharmacist, the CIO is expected to keep a lookout for signs of unlawful or irresponsible prescribing by doctors in the area. He or she must also witness the destruction of 'out of date' or contaminated stock. All these duties, except the detection of unlawful or irresponsible prescribing, are well within the capabilities of any trained police officer. However, the detection of unlawful or irresponsible prescribing requires a considerable depth of pharmaceutical knowledge. Some CIOs develop this knowledge but many do not.

34. In some police areas, there are no CIOs. Some chief constables do not consider that CIO work is a proper use of police resources. In some areas, there is a CIO, but s/he is expected to carry out other duties and has insufficient time for pharmacy inspections. Until recently, training for CIOs comprised a short apprenticeship to an experienced CIO. Inevitably, its quality was variable. A training course has now been established and standards should rise. However, coverage and standards remain patchy. Even where a dedicated CIO is in post, the position is less than ideal because the CIO does not have ready access to pharmaceutical expertise. In my view, some aspects of pharmacy inspection can be satisfactorily performed only by a qualified pharmacist.

35. Very few GPs have had their CDRs or surgery arrangements inspected during the last ten years or so. Many GPs do not understand the Regulations or know how to comply with their duties under them. It is likely that, in many practices, the safe custody and record keeping requirements are not observed. PCT medical advisers, who have the power to undertake such inspections and to witness the destruction of out of date or contaminated stock, have many other duties and little time to devote to controlled drugs. CIOs have no power to enter or inspect the premises of GPs. A particular concern is that many doctors in rural areas dispense medicines, including controlled drugs, from their surgery premises; yet CIOs have no power to inspect the arrangements made and records kept in their dispensaries. The lack of any regular visit by a medical adviser or a CIO means that many GPs rarely have an opportunity to have the destruction of old stocks of drugs properly witnessed.

36. Prescribing information collected and analysed by the PPA is monitored by PCTs. It is now possible to examine the prescribing practice of any doctor in respect of any drug, although the data is not as accurate as it might be because doctors use each other's prescription pads. There should be some improvement in this regard in the future, when all doctors will be provided with their own personal prescription pad, at least for NHS prescribing. PCT officers and advisers can and do analyse the usage of controlled drugs, although they have many other issues to consider, not least the cost of the prescriptions issued by a particular practice or doctor. The main weakness in the present system of monitoring the usage of controlled drugs is that it does not include private prescribing or the purchase of supplies for practice use.

37. In short, the inspection and monitoring of controlled drugs is fragmented and unsatisfactory. In my view, the ideal solution would be the creation of a controlled drugs inspectorate, on the lines of the one operated in Northern Ireland. It should be organised on a regional basis and should be staffed by a multidisciplinary team, comprising some

pharmacists, a few doctors and some investigators with law enforcement experience. This team could be responsible for the inspection of all premises on which controlled drugs are kept (save perhaps those that are inspected by the HODI) and could also monitor the use of controlled drugs.

38. In order that private prescribing can be monitored, it should be brought within the ambit of the PPA. For this to be achieved, it would be necessary for all private prescriptions for controlled drugs to be written on a special form, similar (although not identical) to the form currently used for NHS prescriptions. The prescribing information could then be scanned into the PPA database and analysed together with NHS prescribing information.

Post-Dispensing Regulation

39. I indicated earlier that the Regulations impose various safe custody and record keeping requirements in relation to controlled drugs. These duties are imposed on pharmacists and doctors who have controlled drugs in their possession. However, once a controlled drug has been dispensed and handed over to the patient or the patient's representative, no further attempt at regulation is attempted. Rather surprisingly, a patient who sends a representative to collect a controlled drug on his/her behalf is not expected to provide written authority to show to the pharmacist, and the pharmacist is not expected to ask the representative to identify him/herself. A requirement that the identity of any person collecting controlled drugs from a pharmacy should be recorded in the CDR might well have deterred Shipman from collecting controlled drugs, ostensibly on behalf of patients, as often as he did. It would also have made it easier to detect his activities if he had persisted in such a practice. It is uncommon for a doctor to collect controlled drugs for a patient and Shipman's name would have stood out. Certainly, in 1993, the fact that, within a short period, he had collected 14 single 30mg ampoules of diamorphine on behalf of 13 different patients should have been striking to any CIO, even one as inexperienced as DC Kelly.

40. Once the controlled drugs have left the pharmacy, the Regulations do not impose a duty on anyone to make a record of their use or of their destruction. In other words, there is no audit trail. Controlled drugs could be sold, given away or left lying around at the patient's home and no one in authority would have any means of knowing. It is impracticable to impose on patients the duty to keep records relating to the controlled drugs in their possession. However, some Schedule 2 controlled drugs used in the community have to be administered by healthcare professionals, usually district nurses, who are expected to maintain a proper record of their use and destruction.

41. I have said that, nowadays, diamorphine is usually administered by means of a syringe driver. Usually, the patient is terminally ill and in need of nursing care. A district nurse attends daily and recharges the syringe driver according to the GP's instructions. Nurses enter the arrival of all supplies of diamorphine and the administration of each daily dose onto a patient drug record card (PDRC). They do so as a matter of good professional practice, not because the law requires it. If any supplies are left over after the patient's death, it is common practice for the district nurses to destroy the drugs in the presence of a colleague (or sometimes a relative or neighbour of the deceased patient) and record the

destruction on the PDRC. This system provides a measure of control. However, the system is not entirely satisfactory. A dishonest nurse could destroy some of the leftover drugs and steal the rest. He or she could then ask a relative of the deceased to witness the destruction by signing the PDRC. The relative would be unlikely to count the number of ampoules actually destroyed. The nurse's deceit would not readily be detected. Similarly, a doctor visiting the patient's home shortly after the death could take all the remaining drugs with him/her and write on the PDRC that s/he had taken the drugs for disposal. Shipman used such a ploy on several occasions. On the face of it, his actions appeared lawful.

42. If the keeping of a PDRC for injectable Schedule 2 drugs were mandatory, and if the destruction of all such drugs had to be witnessed by a second healthcare professional or other authorised person and recorded on the PDRC, I believe that an additional useful safeguard would be provided. I also consider that the provision whereby all unwanted or 'returned' Schedule 2 controlled drugs can be destroyed without formality should be changed. A similar degree of formality should be required for 'returns' as is currently required for the destruction of out of date or contaminated stock.

Conclusion

43. The measures I have suggested above could not be guaranteed to prevent a dishonest doctor or healthcare professional from obtaining an illicit supply of a controlled drug. However, they would make it more difficult for him/her to do so and would also make it more likely that such an activity, if repeated, would be detected. The increase in the likelihood of detection would, I believe, have a powerful deterrent effect.

44. In paragraph 2, I said that I have considered a number of issues that are not directly intended to 'catch another Shipman' but are concerned more generally with issues of security and patient safety. I do not propose to include any discussion of those issues in this Summary. However, I have made a number of recommendations relating to these issues and these are included in the following section of this Report, together with the references at which a full discussion of the issues will be found.

45. The implementation of some of my recommendations would require primary legislation and some would also require the reallocation of, and possibly an increase in, existing resources. For example, the formation of a controlled drugs inspectorate would probably require both. However, I regard such an inspectorate as essential because, at present, the inspection and monitoring arrangements are fragmented and unsatisfactory.

46. One of the threads running through my recommendations is the need to apply the same degree of regulation and control to the use of controlled drugs in the private sector as is applied within the NHS. My recommendations include the use of a special form for the prescribing of controlled drugs in the private sector as well as under the NHS. The controlled drugs inspectorate could be responsible for the issue of the pads containing these special forms and would be able to ensure that they were supplied only to doctors who had a clinical need to prescribe controlled drugs.

47. Finally, there is, in my view, a need for modernisation and rationalisation of the system of regulating controlled drugs. There has been virtually no revision of the legislation relating

to controlled drugs since the early 1970s. The requirements relating to controlled drug prescriptions and record keeping are out of date. The Schedules to the MDR have been amended in a piecemeal fashion and are now almost incomprehensible. I hope that they will be looked at afresh and that a simplified and principled structure will be developed. A new framework must make provision for the use of computer technology. Above all, any new legislation must be based upon the dual objectives of improving the regulation and monitoring of controlled drugs as well as enhancing patient safety and care.