# CHAPTER NINE

# The Inspection and Monitoring of the Arrangements for Controlled Drugs

## Introduction

9.1 In this Chapter, I shall describe the ways in which various bodies inspect the storage arrangements and standards of record keeping for controlled drugs in community pharmacies. I shall also consider the extent to which the use of controlled drugs is monitored through the inspection of pharmacies. I have already explained, in Chapter Five, that there is very little inspection of the practical arrangements in general practitioners' (GPs') surgery premises. There is some monitoring of GPs' prescribing. This will be described more fully in the Fifth Report.

## The Legislation

9.2 Section 23 of the Misuse of Drugs Act 1971 (MDA 1971) provides the statutory basis for the inspection, by the Home Office Drugs Inspectorate (HODI) and police chemist inspection officers (CIOs), of the premises of those who carry on business as producers or suppliers of controlled drugs. The section permits CIOs and HODI inspectors to enter the premises of a pharmacist or manufacturer or wholesaler of controlled drugs and to inspect the arrangements for the keeping of the drugs and the records of controlled drugs transactions. This includes the power to inspect the controlled drugs register (CDR). Since the power extends only to 'business premises' it does not allow the routine inspection of GPs' surgeries.

9.3 Regulation 26 of the Misuse of Drugs Regulations (MDR) 2001 requires doctors and pharmacists to provide to authorised persons such particulars or documents as may be requested in respect of the production, obtaining or supplying of controlled drugs or of any stock of controlled drugs in their possession. Such doctors and pharmacists are also required to produce such stock for inspection when requested to do so. However, by regulation 26(3), this requirement does not extend to personal records held in confidence. It was in the exercise of powers conferred upon HODI inspectors by regulation 26 that Mr Graham Calder, a HODI inspector, accompanied by Detective Constable (DC) Michael Beard, the Greater Manchester Police (GMP) CIO for Tameside, visited Shipman at his surgery on 14th August 1998, asking to see his CDR. By this time, Shipman had come under suspicion of murdering Mrs Kathleen Grundy by administering an opiate drug. Shipman said that he did not keep a CDR.

## Home Office Inspections

9.4 The Home Office Drugs Branch is responsible for administering the statutory systems of control applicable to the production and distribution of controlled drugs. The role is performed by two units within the Drugs Branch, the HODI and the Licensing Section. Mr Alan Macfarlane is the Chief Inspector in charge of the HODI. He reports to the Head of the Drug Legislation Enforcement Unit. The role of the Drugs Branch is to implement

international convention obligations through the licensing of the manufacture and wholesale supply of controlled drugs. The Licensing Section issues the necessary licences and authorities to manufacture, possess and supply controlled drugs, together with licences to import and export such drugs. The main focus of activity of the HODI is the inspection of licensed manufacturers and wholesalers and the giving of advice to the Licensing Section on the grant of licences.

**The Organisation of the Home Office Drugs Inspectorate**

9.5 Apart from the Chief Inspector, the HODI has three senior inspectors and 11 inspectors. The HODI Headquarters and the South Eastern Regional Office are in London and there are two small regional offices located outside London. The Northern Regional Office, which was relocated from Bradford to Leeds in 1990, covers the North of England and Scotland. It is staffed by a senior inspector, three inspectors, a full-time clerk and a part-time administrative assistant. The Inquiry heard oral evidence from Mr Macfarlane and four inspectors from the Northern Regional Office. These were Mr Alan Stears (an inspector from 1972 and a senior inspector from 1987 until his retirement in May 2003), Mr Calder (an inspector since 1989, with responsibility for Greater Manchester since the late 1990s), Mr John Scullion (an inspector since 1985) and Mr Frank Eggleston (an inspector from 1969 and a senior inspector from 1974 until 1981).

**The Qualifications and Training of Inspectors**

9.6 HODI inspectors are not pharmacists or doctors and they have no specialist training in pharmacy or medicine. The inspectors who gave evidence to the Inquiry had all worked previously as Home Office immigration officers. Their initial training is provided 'on the job'. Understanding of such issues as irresponsible prescribing is gained in an *ad hoc* manner, by learning from the experience of colleagues, listening to them recount details of previous cases and reading old case files. It is, however, clear that, as they gain experience, they become knowledgeable about trends in the uses and abuses of controlled drugs. They have access to textbooks and use for reference the Department of Health (DoH) guidelines for doctors on the treatment of addiction, entitled 'Drug Misuse and Dependence – Guidelines on Clinical Management', to which I have referred in Chapter Four. They may also seek help from the Royal Pharmaceutical Society of Great Britain (RPSGB) inspectors or from primary care trust (PCT) medical or prescribing advisers. According to Mr Macfarlane, they also have access to advice from a Controlled Drug Adviser at the DoH. From time to time, HODI inspectors meet consultant psychiatrists or pharmacists who have a special interest in the treatment of drug addiction.

**The Types of Inspection Undertaken by the Home Office**

9.7 Apart from the core function of inspecting the arrangements of manufacturers and wholesalers of controlled drugs, a function which occupies about 80% to 90% of its inspectors' time, the HODI also carries out routine inspections of the arrangements in private hospitals and in other premises licensed to hold controlled drugs, such as drug treatment clinics and some care homes. NHS hospitals do not require a licence and are

not inspected by the HODI unless their pharmacies supply controlled drugs to other hospitals or units. The HODI also has overall responsibility for enforcing the statutory provisions relating to retail pharmacies and GPs' surgeries, but the routine inspection of retail pharmacies is delegated to the police. HODI inspectors examine the arrangements in GPs' surgeries and dispensaries only when a problem is brought to their attention.

9.8 As well as examining the safe custody arrangements made by manufacturers and wholesalers, HODI inspectors also routinely examine stock and stock records which, unlike those held at community pharmacies, are often kept electronically and include running balances. They also examine records of supply, such as invoices and delivery notes. As I mentioned in Chapter Seven, however, these records of supply, whether in electronic or paper form, are not routinely compared, even on a sample basis, with records (such as the CDR) held at community pharmacies or at GPs' practices.

**The Involvement of the Home Office Drugs Inspectorate with General Practitioners and Community Pharmacies**

9.9 Although it does not routinely inspect community pharmacies or GPs' surgeries, the HODI may become involved in the investigation of any problem or concern that arises in a retail pharmacy and which suggests that there might have been a breach of the MDA 1971 or of the MDR in force at the material time.

9.10 The HODI also issues detailed written guidance notes, called 'Notes for Chemist Inspection Officers', to CIOs for the purpose of informing their routine inspections of community pharmacies. HODI inspectors are sometimes involved in the training of CIOs and are available to give advice over the telephone on controlled drugs matters to CIOs, PCT prescribing advisers and others. According to its guidance notes, the HODI expects CIOs to report to it any supply of controlled drugs by a community pharmacy which appears to be unlawful or in breach of the Regulations or which suggests that a doctor might be prescribing irresponsibly, for example by over-prescribing in such a way as to give rise to the danger of leakage of drugs onto the illicit market. The same is true of cases where a doctor issues prescriptions for controlled drugs, naming him/herself as patient, or where a doctor regularly presents prescriptions for controlled drugs in the name of patients and collects the drugs him/herself. Mr Stears said, however, that the HODI would not necessarily expect CIOs to report all such cases. He suggested that if, for example, there was concern that the doctor was likely to move around the country, then the HODI might become involved so as to ensure that people were aware of his/her past history. Otherwise, he did not take the view that the HODI had to be informed about each and every criminal offence coming to the attention of the police or of a NHS authority involving the diversion or abuse of controlled drugs by a doctor.

9.11 The HODI inspectors also receive expressions of concern about unlawful or improper practice from RPSGB inspectors and, sometimes, from pharmacists and GPs. They liaise with PCT medical and prescribing advisers in the investigation of concerns about a GP's irresponsible prescribing. Until 1997, CIOs were expected to notify to the HODI the name of any drug addict of whom they had recently become aware, for incorporation into the Home Office Addicts Index. After 1997, the Index was no longer kept.

9.12 If, on investigation of a reported concern, it is found that a doctor has been prescribing irresponsibly or has breached one of the technical requirements of the MDR 2001, but has not apparently committed a serious crime, a HODI inspector will often issue a warning or advice to the doctor and enlist the help of the PCT prescribing adviser in re-educating the doctor or in monitoring the doctor's future conduct. If the doctor's conduct does not improve, the inspector may refer the case to the General Medical Council (GMC) with a view to disciplinary action. However, if, on investigation, the conduct in question appears to amount to an offence under the MDA 1971 or a serious or continuing breach of the MDR 2001, the case will be taken over by the police for further investigation and possible prosecution. As I explained in Chapter Four, the Home Secretary's powers (which used to be instigated by the HODI) to restrict a doctor's use of controlled drugs following a drugs-related conviction or a finding of irresponsible prescribing have fallen into disuse.

## Police Inspections

9.13 In Chapter Three, I explained that, in 1917, police officers not below the rank of inspector were given the power to inspect the arrangements made for controlled drugs in community pharmacies and that, in 1921, the power was extended to officers below the rank of inspector. A Home Office Circular, issued to Chief Officers of Police, described the role that the police were to fulfil. However, the police were not placed under a statutory duty to inspect community pharmacies. Police officers had the power to enter and inspect, but were under no duty to do so. The position remains the same today. As I said in Chapter Three, in 1922, the Commissioner of the Metropolitan Police queried whether the task of inspection could not more appropriately be performed by persons with practical knowledge of the retail pharmacy business. Today, although the Association of Chief Police Officers (ACPO) values the work of the CIO and encourages its members to ensure that the job is performed by properly trained officers, there remains a body of opinion among senior officers that pharmacy inspection is not 'police work'. Not all police areas employ a CIO and, in many areas where there is a CIO, the post is not accorded the prominence or resources that its incumbent might wish.

### The Changing Purpose of Police Inspections

9.14 In 1922, the object of a pharmacy inspection appears to have been to check that the safe custody and formal prescription requirements for controlled drugs were being complied with and that the relevant records were being properly kept. No special expertise was required for the work. It appears that, prior to 1939, the CIO was not expected to examine the contents of the records (then the dangerous drugs register) in detail, only to check that the pharmacist was complying with the Regulations. The CIO would not be expected to notice the names of the prescribing doctors or their patients; nor would s/he be expected to notice the quantities of controlled drugs prescribed or supplied. After 1939, however, it appears that the scope of the inspection widened. CIOs were then asked also to identify persons who were receiving regular supplies of dangerous drugs and to report back to the HODI. This information was required to enable the Government to comply with its international obligations.

9.15 During the 1960s and 1970s, the duties of the CIO increased again. Following the Brain Committee's second Report, the Government brought in measures designed to control irresponsible prescribing by doctors. Section 13 of the MDA 1971 permitted the Home Secretary to restrict the right of a doctor to deal with controlled drugs following tribunal proceedings at which irresponsible prescribing had been proved. Consequently, after the passing of the MDA 1971, CIOs were encouraged to report, not only supplies to known or suspected drug misusers, but also supplies that suggested irresponsible prescribing or diversion. That remains the position today, despite the fact that directions under section 13 of the MDA 1971 are no longer made.

**Home Office Guidance Notes for Chemist Inspection Officers**

9.16 The nature of the duties of a CIO and the types of knowledge and understanding required for the position can be inferred from an examination of the guidance notes for CIOs issued by the Home Office. The purpose of CIO inspections, as described in 'Notes for Chemist Inspection Officers', has remained essentially the same for more than 15 years. The 1988 edition of the guidance notes, which was still current in 1993, when the GMP CIO inspected the CDR held at the pharmacy at 23 Market Street, Hyde (which inspection I shall describe in Chapter Eleven), states:

> **'The inspections are intended to ensure that controlled drugs are not being supplied to unauthorised persons and that proper records are kept, and to bring suspicious supplies to the attention of the Home Office. The efficient supervision of the arrangements for storing and distributing controlled drugs from retail pharmacies is an essential part of the machinery of drugs control. The inspection of retail pharmacies can also provide valuable intelligence about overall drug abuse, especially in relation to the type of drugs being abused, the incidence of drug addiction, irresponsible prescribers and those practitioners who are failing to notify drug addicts to the Home Office.'**

9.17 That passage gives some indication of the wide scope of the duties of the modern CIO. He or she is not merely an examiner of records and safe custody arrangements and a witness to the destruction of 'out of date' controlled drugs (which would be fairly routine tasks), s/he is also an intelligence officer who is expected to sniff out all manner of wrongful practices which would not necessarily be apparent from a CDR. The duty to notify the Home Office of addicts no longer exists, as I have explained, although the current guidance notes still mention it.

9.18 The CIO is expected to look out for irresponsible prescribing. The 1988 guidance notes attempted to define this concept, which is not easy. There has never been either a statutory or a judicial definition. The 1988 guidance notes stated that a doctor would be guilty of irresponsible prescribing if s/he prescribed controlled drugs in a way that resulted in the recipient selling the drugs on the black market, or where there was a real risk of this happening or where there was a risk that the recipient was misusing the drugs. To help with the CIO's assessment of a particular prescription, a small table was annexed to the guidance notes, showing the levels of periodic supply of certain drugs which might suggest

that a doctor was prescribing irresponsibly. To make proper sense of this table and to apply it intelligently, the CIO needed knowledge of a range of controlled drugs, of the proper uses to which they were put and of the ways and means by which they were sometimes abused.

9.19 The 1988 guidance notes also contained advice on detecting signs of suspicious practice. For example, Note 9 said:

> **'Any large or regular supplies by doctors should be reported. Details of any instances where a doctor issues prescriptions for CDs naming himself as the patient, or where the doctor regularly presents prescriptions for controlled drugs in the names of patients and collects the drugs himself, should also be reported.'**

9.20 And again, Note 10 stated that:

> **'A practitioner may act as a patient's agent in cashing a prescription and taking the drugs to the person he has specified as the recipient on the prescription. ... This obviously enables the unscrupulous practitioner to obtain CDs by deception. He may do this rather than obtain CDs lawfully through written requisition in an attempt to conceal his own drug use or to avoid having to pay for drugs which he intends to use in his practice, and at the same time to claim reimbursement from his Family Practitioner Committee ....'**

9.21 This advice would certainly help a CIO to recognise the kind of features that might be present when a doctor was obtaining illicit supplies of a controlled drug. However, even armed with this advice, a CIO would not necessarily become aware of instances of a doctor collecting controlled drugs. As I said in Chapter Seven, the CDR provides for the name of the prescribing doctor to be recorded but not the name of the collector of the drugs. The CIO would, therefore, be dependent almost exclusively on information received from the pharmacist if s/he were to learn of cases where a doctor regularly presented prescriptions for controlled drugs in the names of patients and collected the drugs him/herself.

9.22 The most recent edition of the guidance notes, issued in June 2002, describes the obligations of doctors and pharmacists and the organisation of the Home Office Drugs Branch. It states that inspections should be carried out at least twice a year. The guidance notes advise how a routine inspection should be undertaken and recorded. Among other things, it is said that the CIO should check each section of the CDR for compliance with the Regulations and should then sign and date the last entry in each section. The CIO must be satisfied that all drugs that should be kept in the controlled drugs cabinet are in fact kept there. He or she must check for over-stocking and the presence of out of date stocks. Guidance is given about the destruction of out of date controlled drugs, which is an important part of the CIO's role.

9.23 CIOs are still required to report to the HODI any concerns that controlled drugs are being prescribed unlawfully or irresponsibly. A 'new' definition or description of irresponsible prescribing has been provided. The guidance notes say that the definition used by the HODI is that used by the then Home Secretary in the House of Commons debate on the

relevant provisions of the Misuse of Drugs Bill 1970, i.e. **'careless, negligent or unduly liberal prescribing ...'**. The guidance notes also suggest that experience has given the Home Office some understanding of the factors that a tribunal or the GMC will take into account when considering an allegation of irresponsible prescribing. The reference to a tribunal is puzzling, as the tribunal system instituted by the MDA 1971 has been defunct for about ten years. Also, I am unsure how the experience of the Home Office in respect of GMC proceedings will be of assistance to a CIO when examining a CDR. It may be intended that the CIO should telephone the HODI for advice if s/he sees something that might be suspicious. The current edition of the guidance notes repeats the warning about doctors who collect controlled drugs, ostensibly for their patients.

9.24 One aspect of the CIO's duty is to gather intelligence about drug addicts and the practice of those who prescribe for them. The guidance notes provide some advice on these issues. They quote extracts from the DoH guidelines for doctors on the treatment of addiction, entitled 'Drug Misuse and Dependence – Guidelines on Clinical Management', to which I referred in paragraph 9.6. To understand some of these guidelines, the CIO would need a considerable depth of knowledge of the subject. I suppose that any CIO will understand the point when told that doctors should avoid prescribing methadone tablets which, if crushed and injected, are dangerous. However, other advice contained in the guidelines, such as that recommending the use of long-acting rather than short-acting benzodiazepines when treating benzodiazepine dependence, may be beyond the understanding of many CIOs. CIOs will not, of course, be able to glean from the CDR for what condition the drugs have been prescribed and nor will pharmacists necessarily be in a position to tell them.

9.25 Annex A to the guidance notes contains a list of the controlled drug preparations commonly encountered on CIOs' inspections. This sets out the name of each drug, the proprietary or other preparations in which it is normally found and the purpose for which it is normally used. This information is obviously useful for the CIO. However, nothing is said about the normal dose or the quantities that should usually be prescribed. So the CIO must rely on his/her own experience when assessing whether it appears that the drug has been prescribed appropriately.

9.26 In short, to be done well, the duties of a CIO require a good working knowledge of the quite complex statutory requirements, the acquisition of considerable knowledge about the proper and improper usage of a wide variety of controlled drugs, the establishment of good confidential relations with pharmacists (while still maintaining an objective view of the pharmacists' own honesty, conduct and performance), a knowledge of what is happening on the 'drug scene' in the area and a sensitive 'nose' for detecting all manner of different types of illegal and unethical behaviour. Perhaps the most difficult aspect of the job is the detection of irresponsible prescribing. Where the CIO has to cover a large number of retail pharmacies, the job requires dedication and enthusiasm. However, as I shall later explain, some CIOs become very experienced in examining CDRs and develop a very sensitive 'nose' for bad prescribing practices of all kinds.

**The National Protocol**

9.27 The ACPO Drugs Sub-Committee's National Protocol for Chemist Inspecting (*sic*) Officers, published in 1997, describes the functions and responsibilities of CIOs. The

functions are summarised as inspection, investigation, intelligence gathering, crime prevention and liaison. According to the Protocol, the CIO's role **'is often viewed as esoteric and somehow standing apart from mainstream** *(police)* **activity'**. The general description of the investigative elements of the role correlates broadly with what is said in the Home Office guidance notes.

**Coverage by Chemist Inspection Officers**

9.28 All 43 police forces in England and Wales provided general information to the Inquiry about their CIO arrangements. The Inquiry obtained detailed information from the Metropolitan Police Force and from forces in West Yorkshire, Avon and Somerset, Lancashire, Merseyside, Northumbria, South Wales, North Wales and Northern Ireland, as well as from all the Scottish police forces. A number of forces which have no CIO coverage (or had none until recently), such as Cumbria, Essex, Cleveland, Warwickshire and North Yorkshire, also provided information. Chief Superintendent John Taylor, from Cumbria, and Detective Superintendent Wilson Kennedy, from Essex, gave oral evidence to the Inquiry, as did former or current CIOs, Detective Sergeant (DS) Raymond Humphreys and retired DS Arthur Kilner from the Metropolitan Police and DC Neville Hanley and retired DS William Barker from the West Yorkshire Police. Further material was provided by ACPO. DC Diane Cooper, a trainer involved in the course for CIOs at the West Yorkshire Police Training Centre, gave evidence, as did several GMP CIOs and Detective Chief Superintendent (DCS) Peter Stelfox. A witness statement was provided by DC Duncan White, a CIO and Secretary of the National Association of Chemist Inspection Officers (NACIO), who also participated in the Inquiry's seminars in that capacity.

9.29 Although police officers have been inspecting community pharmacies since 1917, coverage has never been universal across the country and, even now, there are several areas where there are no pharmacy inspections by police officers. This variability of coverage arises because the decision as to the appointment of a CIO is an operational matter for the chief constable for the area concerned. The Home Office and ACPO can only encourage such appointments. So, for example, the Warwickshire Police undertake no pharmacy inspections. They take the view that the appointment of a CIO would involve an inappropriate use of scarce police resources.

9.30 The practice of appointing a dedicated CIO began in some areas in the 1960s. However, more than half the current CIOs also perform other duties. In some areas, an officer will combine the duties of a CIO with that of a chemical liaison officer (CLO). A CLO's duty is to visit manufacturers of chemicals that are capable of being used in the production of controlled drugs. The purpose of such visits is to advise the management of the company about the illicit purposes to which its products might be put and to monitor the destinations of those products. The duties of a CLO fit well with those of the CIO. However, in many areas, the CIO has to combine his/her duties with quite unrelated work. In 2003, only about 11 police forces had an officer employed exclusively either on CIO duties or on CIO-related and CLO-related work. In other areas, the work was undertaken on a part-time basis. I heard evidence about CIOs being seconded to other criminal investigations and spending very little time on the duties of pharmacy inspection. Those senior police officers who regard the task as an inappropriate use of police time will readily

transfer the CIO to other duties when they are short-staffed. An officer in that position has little opportunity to acquire the necessary experience and expertise to carry out the job competently. However, I accept that it is better that there should be a part-time CIO in post than none at all. When Derbyshire Police reintroduced a dedicated CIO in 2001, DC Beard assumed a mentoring role towards the new appointee. He told the Inquiry that, on carrying out the first visits with the new CIO, he saw abysmally low standards of record keeping and security in pharmacies. This was, no doubt, a result of the lack of inspection previously.

9.31 The number of community pharmacies in each police area varies significantly. According to data obtained by the GMP in 2000, the Metropolitan Police area had the greatest number; the Metropolitan Police undertook the inspection of 1510 pharmacies. It now covers about 1900. The police in the other large conurbations have several hundred each; in 2000, the GMP area had 611, West Midlands had 650 and West Yorkshire had 480. Eleven police areas covered between 300 and 400 and six covered between 200 and 300. Fourteen areas contained fewer than 200, but more than 100, and five areas had fewer than 100. It appears that there is no obvious correlation between the number of CIOs in post and the number of pharmacies to be inspected. So, whereas, in 2000, County Durham had one CIO/CLO with 117 pharmacies to inspect, the sole CIO in Hampshire had 303 pharmacies to inspect and the CIO for Sussex had 358.

**The Quality of the Work of Chemist Inspection Officers**

9.32 It appears to me from the evidence before the Inquiry that, in many police forces, though not all, the work of a CIO is regarded as unimportant and unrewarding. The position is not seen as a useful part of an officer's career progression; rather the reverse, it is more likely to be seen as a backwater. The work does not fit closely with other police functions although in some forces there is an association between the CIO and the Drugs Squad. In general, the status accorded to a CIO is not high. According to DC Cooper, some senior police officers have the perception that the main responsibility of the CIO is the destruction of controlled drugs which can be done 'as and when needed'. As I have explained, the duties are far more complex and onerous than that, although the destruction of controlled drugs is an important function. In most forces, the position of CIO is occupied by a police or detective constable who rarely has the advantage of guidance or supervision by a senior officer with any real understanding of what the job entails. Another problem is that there is a tendency for an officer to be moved from his/her position as a CIO onto other work after only two or three years in post. If this happens, the valuable experience and specialised knowledge the officer has gained is lost for good.

9.33 The evidence suggested that the quality of CIOs' work was, at least in the past, very variable. Some CIOs were undoubtedly conscientious and enthusiastic about their duties and became extremely knowledgeable. Others appeared to regard the job as a 'soft option'. I heard that, on entering a pharmacy, some officers would ask the pharmacist whether 'everything was all right' and, on being told that it was, would ask to be shown where to sign the CDR. This was plainly unsatisfactory. Others would be less cavalier about their duties, but might still rely too heavily on what the pharmacist told them. From a conscientious pharmacist, no doubt the CIO would learn a great deal, but over-reliance

on a pharmacist is not satisfactory, as it is one of the CIO's duties to inspect the pharmacist's practice with respect to controlled drugs.

9.34 Until recently, there had been no organised form of training for a CIO. Until 1999, the usual arrangement in Greater Manchester was for a new appointee to spend a few weeks working alongside an experienced CIO and to learn by a brief 'apprenticeship'. The quality of an apprenticeship can only be as good as the individual officer providing it. No doubt some were good and some less good. A new CIO could also read the guidance notes provided by the Home Office, to which I have referred. If a CIO post was being created in a force for the first time, a CIO from a neighbouring force might provide the training. Some CIOs would take it upon themselves to spend time at a regional office of the HODI, to learn what was required.

9.35 In 1997, the need for a training course for CIOs was recognised. Since 1999, such a course has been provided at the West Yorkshire Police Training Centre, Wakefield, which is open to CIOs from all over the country. The course takes place annually and up to 16 students can attend. A distance learning pack, including a workbook, is sent out to students for completion in advance of the course. The course itself, which lasts for four and a half days, covers all the relevant topics, including a half day on basic pharmacology. DC Cooper said that, even with the benefit of the training course, it takes about two years for a CIO to build up a sufficient reservoir of knowledge to be competent in the job; she thinks that four to five years represents the minimum satisfactory period of tenure.

9.36 The evidence suggests that the existence of the training course has done much to improve the commitment and quality of work of many CIOs. Another improvement has been the formation, in 2000, of the NACIO. The NACIO was founded by a group of enthusiastic CIOs. It circulates advice as to best practice and makes possible the discussion of common problems. It provides peer support to newly appointed officers. The organisation has been very well received by CIOs and the Home Office.

9.37 Notwithstanding these improvements, I fear that, in police areas where there is no dedicated CIO, standards are not high. It must be tempting for an officer with other pressing work and a limited time in which to carry out inspections to rely entirely on what a pharmacist reports. Mr Calder said that, in the North of England, the area for which he is responsible, there is a wide divergence of commitment to the job even where there is a dedicated CIO. Much depends on the attitude of the police force and the enthusiasm of the individual post-holder. In two police areas of which he has detailed knowledge, there is a theoretical commitment to the provision of dedicated CIOs, but in practice this is very limited. In these two areas, pharmacies are not routinely inspected and the officers are not sure of what they are supposed to be inspecting. This does not surprise me. If officers are to perform well, most will need management and supervision. Even after attending a training course, it must be an exceptional police officer who can motivate him/herself without direction and support from above. That some CIOs are highly motivated and very successful is much to their individual credit.

**The Position of a Chemist Inspection Officer Seeking to Detect Irresponsible Prescribing**

9.38 Without training and experience, it must be very difficult for a CIO to detect irresponsible prescribing. Even with training and experience, it seems to me that the CIO is not ideally

placed for this particular aspect of the work. Recognition of irresponsible prescribing requires not only a good deal of knowledge about the uses and abuses of drugs, but also considerable medical knowledge. In order to assess the reasonableness of any prescription, the CIO needs to know the general properties and uses of the controlled drug and the dosage in which it is usually prescribed. Ideally, s/he should also know the condition for which it has been prescribed in the individual case, but that information is not available. When in need of advice or assistance, some CIOs liaise with the local PCT's medical or prescribing advisers or the regional RPSGB inspector. However, even with access to such advice, it seems to me that the CIO is not well equipped for this type of work. It appears to me that a person qualified in either medicine or pharmacy would be far better equipped to detect irresponsible prescribing than a CIO, however well trained and conscientious s/he may be.

### Should Chemist Inspection Officers Be Civilians?

9.39 I have mentioned that some chief constables of police are not prepared to expend resources on the work of pharmacy inspection. In some areas, the duties of a CIO are undertaken by police civilian workers. Such personnel do not have the powers of entry and inspection granted to a constable under the MDA 1971 but the Home Office can and does authorise named civilians to exercise those powers. One advantage is that the contractual arrangements for such personnel are more flexible than those of a police officer and the cost of employment is much less. Also, a civilian employee can concentrate on the specific duties of a CIO, possibly remaining in the same post for many years. This allows the development of experience and expertise. There are those who say that a civilian CIO does not have the same deterrent effect against slackness as does a police officer. Official ACPO policy is that the duties of CIOs should be carried out by police officers. However, it was clear from the evidence I heard, particularly from DCS Stelfox, that there is a view that, if the police are to continue to be responsible for pharmacy inspection, they will almost inevitably have to deploy civilian personnel for the purpose.

## Greater Manchester Police Inspections

### The Background

9.40 The first Manchester CIO was DC John Galt, who took up the post in 1967 when serving with what was then Manchester City Police. Upon the formation of the GMP in 1974, another detective constable was appointed to assist in covering the pharmacies in the enlarged police area. The target of the two CIOs was to inspect each pharmacy twice a year. This situation continued until the number of pharmacies had increased so that it became impossible for two officers to do the job. A third CIO was appointed in 2001. DC Galt was succeeded by DC Alan Jackson in 1988. DC Jackson was in turn succeeded by DC Patrick Kelly in 1993. He was succeeded by DC Stefan Bidolak in 1997. The second post, created in 1974, was occupied by a succession of four officers until 1987, when DC Robert Peers was appointed. DC Peers occupied the post until 1997, when he was succeeded by DC Beard. DC William Graham was appointed as the third GMP CIO in 2001.

9.41 The GMP developed the job description of the two officers in accordance with the terms of the ACPO National Protocol for Chemist Inspecting Officers. My overall impression, gathered from the evidence of GMP officers, is that the position of a CIO is not accorded much status or priority. I also suspect that the work has been regarded by some within the GMP as undemanding and easy. I do not think appointment as a CIO has been seen as a good career move. That is a pity, because the effectiveness of the role and the job satisfaction to be derived from it are dependent upon the effort and enthusiasm invested in it. However, some of the GMP CIOs have been diligent and enthusiastic about their work.

9.42 Prior to 1999, the training offered to GMP CIOs was, as I described in paragraph 9.34, limited to a short apprenticeship with an existing CIO. The training period was not always spent with the 'retiring' CIO and, therefore, did not always include a handover period in which the new CIO was introduced to at least some of the pharmacists on his/her patch. DC Kelly said that, when his training was complete, he felt ill equipped for the job and lacked the confidence necessary to discuss issues with the pharmacists he was visiting for fear of revealing his own lack of knowledge. He said that he gradually gained experience and confidence while working in the job. Nowadays, a new CIO will spend a short period with an experienced CIO and will attend the Wakefield course as soon as is practicable. This might be several months after s/he has taken up his/her duties. All three of the current GMP CIOs have now attended the course. CIOs are also able to discuss problems with their colleagues and with their Drug Squad supervisor if the need arises. That will often be of only limited value because the supervisor will rarely, if ever, have performed CIO duties. DCS Stelfox acknowledged that it is difficult to monitor the quality of the work of CIOs. Although they are asked to submit reports, he said that '... in terms of looking at the judgements they have made in individual cases and assessing whether they were ... the appropriate judgements, that does not go on'. He added that there is no one to whom DC Beard can report; no one within the GMP knows more than he does about pharmacy inspections.

**The Purpose and Form of Greater Manchester Police Inspections**

9.43 Inspections by GMP CIOs take place at intervals of approximately six months. They are unannounced and the CIOs attend in plain clothes. In recent years at least, the Force Instruction Book has contained directions very similar to the Home Office guidance notes. For example, in 1990, the Instruction Book said:

> **'47. Any irregularity by a pharmacist or doctor etc., or any suspicion that a doctor or any other person is purchasing large quantities of drugs, or is prescribing excessively either for himself or for a patient, or that an excessive stock is being carried having regard to the quantity dispensed and that kept by other pharmacists in the district, must be made the subject of a report to the Home Office Drugs Branch.'**

9.44 The CIOs are generally aware that, apart from ensuring that pharmacists comply with the requirements imposed upon them, it is also part of their responsibility to detect irresponsible prescribing or diversion of controlled drugs by prescribing doctors.

9.45 DC Beard described his role and a typical visit of inspection. He said that his main task was to keep the pharmacist interested in controlled drugs issues. My understanding of his evidence is that, if the pharmacist is encouraged to maintain an interest in these issues, s/he may (provided s/he is honest) achieve a high standard of personal compliance with the Regulations and may also become a very useful source of intelligence for the CIO. In order to foster this interest, DC Beard will spend the first part of any inspection, possibly up to an hour, listening to any concerns that the pharmacist may have. During that time, he will keep an eye open to ensure that the pharmacist is complying with his/her professional obligations and, if he suspects that the pharmacist is not, he may alert the RPSGB inspectors. He then empties the controlled drugs cabinet or safe and sorts out any drugs that are out of date. He will try to reconcile the stock with the CDR. However, this is difficult because there is usually no opening stock entry and no running balance. He will examine each section of the CDR and sign and date the last page of each section. He will look out for signs of unusual prescribing and other features such as the cessation of a previous pattern of prescribing. If he were to notice that a patient who used to receive methadone had not collected his/her supply for some time, he would enquire why; the failure to collect might signify that the patient had returned to the use of illicit drugs. He might ask the pharmacist for information about who had collected a particular supply of drugs. Together with the pharmacist, he will undertake the destruction of any out of date stock. After a visit, DC Beard will record on his laptop computer any information of significance, including any advice or warning he has given to the pharmacist.

9.46 Until about 1997, the CIOs recorded the results of their visits in writing. A leather-bound book was kept, in which to record the times and dates of inspections, whether drugs were destroyed and whether any particular problems had arisen. Space in this volume was limited, so it did not usually contain information about individual patients or doctors. More detailed records were kept on a series of cards, with one card or set of cards being kept for each pharmacy. This system was initiated in the 1970s and was designed to maintain a record of any supply of controlled drugs that might give rise to concern. The names of all patients to whom drugs were being prescribed for addiction were recorded; they had to be reported to the Home Office. The names of patients who began to receive diamorphine were also recorded. The CIOs would then follow the patient's prescribing history. Usually, patients on diamorphine would be terminally ill; their supplies would increase and then stop suddenly. That would be a normal pattern and would not give rise to concern. If that pattern was not seen and the supplies continued, suspicion might arise that the drugs were being diverted. The card system seems to have worked well. It enabled a CIO to refresh his/her memory when preparing for a visit. It would also enable him/her to make a cross-check if s/he noticed a name in the CDR of one pharmacy and suspected that s/he might have seen the name in the record of another. It would enable him/her to discuss the precise details of any odd features with colleagues. Unfortunately, the card system was abandoned in 1997 (possibly as a result of the removal of the requirement to notify the Home Office about addicts), and the cards and the leather-bound books have all been destroyed.

9.47 DCS Stelfox accepted that, at least until 1999, the training provided by the GMP for its CIOs had been unsatisfactory. He also accepted that the CIOs were not adequately

supervised and pointed out that it was almost impossible to find a more senior officer who had a real understanding of the work of a CIO. In essence, his view was that the police should not be involved at all in the routine inspection of retail pharmacies. He considers that this function is not appropriate for police forces. He would like to see the duty of routine inspection taken away from the police and given to a dedicated independent inspectorate which would benefit (in the way that CIOs do not) from inspecting the broad range of individuals and organisations involved in the production and supply of controlled drugs intended for therapeutic use. The police could then receive any complaints or concerns about possible criminality and could investigate them with a view to prosecution in the usual way. He was not impressed by the suggestion that regular contact with pharmacists through routine inspection provided a valuable source of intelligence to the police. He accepted that this contact was of some value, but considered that it did not justify the expenditure of police resources involved.

### Inspection by the Greater Manchester Police of the Controlled Drugs Registers in Hyde

9.48 Since about 1974, a CIO has inspected the pharmacies in the Hyde area on a regular basis. This is usually achieved twice yearly. In the CDRs available to the Inquiry, the signature of the CIO in each section of the CDR can be seen as evidence of these visits.

9.49 Mrs Ghislaine Brant, who, since October 1991, has been the pharmacist manager of the pharmacy at 23 Market Street, Hyde, where most of Shipman's controlled drug prescriptions were dispensed, confirmed that inspections took place regularly. The CIOs were entirely satisfied that Mrs Brant was efficient in her work and they had no complaints about her conduct of the pharmacy in any respect.

9.50 The CDR kept by the pharmacy was produced to the Inquiry. It dated from 1991. The earlier CDRs were no longer available. In the CDR, Shipman's name appears as prescriber rather more frequently than that of any other doctor. In the period between 1991 and 1998, 83 out of a total of 188 supplies of controlled drugs were made on prescriptions issued by Shipman. However, with the exception of a period in 1993, his prescribing does not stand out as unusual or remarkable. I would not have expected a CIO to notice Shipman's name particularly or to suspect that he was obtaining drugs from the pharmacy by illicit methods. Mrs Brant did not tell the CIO that Shipman used to collect diamorphine prescribed for patients. Without this additional information, the CIO would have had no reason to notice Shipman's name in the CDR.

9.51 I have already said that Shipman's prescribing of diamorphine in 1993 was unusual. I shall consider that prescribing and the actions of the pharmacist and CIO concerned in Chapter Eleven.

## Royal Pharmaceutical Society of Great Britain Inspections

### The Inspection Function

9.52 In Chapter Three and Chapter Seven, I described the origins and functions of the RPSGB. Mr Stephen Lutener, whose position as Head of Professional Conduct included

responsibility for the Inspectorate and Enforcement Division of the RPSGB, gave oral evidence to the Inquiry.

9.53 The RPSGB has no specific inspection or enforcement role under the Misuse of Drugs legislation, although its inspectors are authorised to possess and to witness the destruction of controlled drugs in the course of their duties. This position contrasts with the situation under the Medicines Act 1968, where (as I explained in Chapter Seven) the RPSGB has a statutory inspection and enforcement function with regard, for example, to offences relating to the adulteration or mis-labelling of medicines.

**The Inspectors**

9.54 The RPSGB employs 18 full-time inspectors who are all qualified pharmacists. They are based in different regions of the country and carry out periodic inspections of all retail pharmacies and of those hospital pharmacies that are registered with the RPSGB and have a retail pharmacy on the premises. However, they do not inspect doctors' surgeries or dispensing doctors' premises. The Society also employs eight inspectors who are not qualified pharmacists; their duties are to inspect the premises of distributors of agricultural pharmaceutical products. These inspectors also carry out test purchases in retail pharmacies because, unlike their pharmacist colleagues, they will not be recognised by the pharmacy staff.

9.55 The Inquiry received evidence from five RPSGB inspectors, Mr David Young, Mr Stanley Brandwood, Mr Graham Pickup, Mr David Slater and Mr Peter Greenwood. All save Mr Greenwood gave oral evidence. Mr Pickup and Mr Greenwood are now retired.

9.56 In Chapter Seven, I set out the educational and vocational requirements for qualification as a pharmacist. Pharmacists seeking appointment as a RPSGB inspector must have at least three years' experience as practising pharmacists. They must then undergo training as an inspector. There is no formal training course, although there is a structured training programme. The turnover of inspectors is low and the numbers to be trained are too small to justify a training course. Initially, a trainee spends two weeks at the RPSGB Headquarters in Lambeth, south London, where s/he is shown the workings of the governing body and the relevant committees and is introduced to office procedures. This is followed by two weeks spent accompanying one or two experienced inspectors on their rounds. Finally, trainees spend two further weeks with senior staff at Headquarters.

9.57 Inspectors also undergo continuing professional development. This focusses on such matters as interview technique, the gathering of evidence and personal safety. There are two inspectors' meetings each year. One lasts for three days and is devoted to training; the other comprises two days devoted to training and policy. There are also two one-day meetings each year, held at regional level, at which difficult or topical issues are discussed.

9.58 There is no continuing education on clinical pharmacy specifically focussed on controlled drugs, although inspectors are trained in the regulatory provisions of the MDA 1971 and the MDR 2001. Both Mr Brandwood and Mr Young told the Inquiry that they could not hold themselves out as being clinically up to date.

### The Nature and Purpose of Royal Pharmaceutical Society of Great Britain Inspections

9.59 RSPGB inspectors have two main functions. They carry out routine inspections of pharmacies and they investigate complaints against pharmacists. Mr Slater said that he investigates about 30 complaints a year and this occupies about half his time.

9.60 The purpose of routine inspections is the promotion of good and safe pharmaceutical practice. This is achieved by ensuring compliance with the legislative requirements and the professional Code of Ethics. In the main, compliance is achieved by the giving of advice although, in the case of serious shortcomings, an inspector will make a report to Headquarters, for consideration by the Infringements Committee, or even a report to the police. Such serious matters are found only rarely on routine inspection and, in recent years, there has been a shift in the emphasis of these visits towards an advisory or pastoral role. Mr Young said that the most valuable aspect of his work was the time he spent talking to pharmacists about their continuing professional development, the introduction of standard operating procedures and other developments in pharmacy. In effect, the inspectors supplement the guidance and direction given in the RPSGB publication 'Medicine, Ethics and Practice – A Guide for Pharmacists'.

9.61 In the 1980s, all visits were unannounced, but nowadays about 75% of visits are made by prior arrangement. Prior arrangement allows a pharmacist to ensure that the most appropriate persons are present in the pharmacy on the day in question and enables him/her to prepare in advance any questions s/he might wish to discuss. However, the inspectors acknowledged that a poorly performing pharmacist is more likely to be 'caught out' by an unannounced inspection and that is why a proportion of inspections are not arranged in advance. In general, a pharmacy will be inspected about every two years, although this could be more frequent if any cause for concern arose.

9.62 There is no set format to an inspection. The focus of the inspection and the time spent on particular aspects of pharmacy practice will vary from one pharmacy to the next. I was told, for example, that, in the case of a pharmacy which is a member of a large retail chain, there is often no need to check that the dispensary is being kept tidy; an area or regional manager will routinely ensure that the dispensary is in good order. Such pharmacies often provide pre-registration training for new graduates, so the inspector might spend more time checking on the quality and arrangements of the pre-registration training being given. A pharmacy with a poor track record will warrant a longer visit than will one that is obviously well run. Some visits take as long as three hours. The inspector might wish to observe the procedures for dispensing and for the sale of medicines over the counter.

### Controlled Drugs

9.63 It is implicit in what I have said that, in the course of a routine inspection, the RPSGB inspector is not expected to focus on the arrangements for controlled drugs. Not unreasonably, the inspectors regard this as the job of the CIO. However, an inspector would almost certainly notice if there did not appear to be proper arrangements for the safe custody of controlled drugs. He or she might also look at the CDR from time to time, not so as to study it, but in order to satisfy him/herself that it appeared to be properly kept.

He or she would not look at the entries in detail. He or she might notice if something were obviously wrong. For example, s/he might well notice a marked imbalance between the amounts of a controlled drug acquired and the amounts dispensed. As I have mentioned in Chapter Seven, a RPSGB inspector might also help out a pharmacist who could not find anyone to witness the destruction of out of date controlled drugs. Mr Lutener confirmed that the description given by the inspectors of their duties in relation to controlled drugs was as he would have expected. One of the inspectors described his role, in relation to controlled drugs, as providing 'an extra pair of hands and eyes'.

9.64 Thus, nowadays at least, RPSGB inspectors do not look at CDRs with a view to identifying prescribing patterns that might give rise to concern or might suggest irresponsible prescribing by a doctor. Under the present arrangements, I cannot see how they could be expected to perform such a task. However, it appears that, in the past, they did look out for cases of over-prescribing and, according to Mr Pickup, had a special form on which to report it. This practice seems to have fallen into disuse by about the end of the 1980s. Nowadays, the RPSGB inspectors are so busy that the various aspects of an inspection have been prioritised. Some tasks must be undertaken at every inspection; others are optional and should be undertaken only if time allows. The inspection of arrangements for controlled drugs is essentially optional. Broadly speaking, the inspectors said that, if they were unable to look at the CDR on one visit, they would make a point of doing so on the next or the one after that. In other words, six years might pass between inspections of the CDR. In general, the inspector would notice only problems that were gross and obvious; s/he would not notice that a pattern of prescribing was unusual.

9.65 According to the inspectors, they would expect pharmacists to raise any concerns they had about the prescribing practice of particular doctors. This would not be limited to the prescribing of controlled drugs. If a pharmacist raised a concern about excessive prescribing of a controlled drug, the inspector would look at the CDR and would advise the pharmacist what should be done.

9.66 The inspectors said that, if they came across evidence of improper prescribing by a doctor, they might liaise with the CIO or the HODI or with a PCT's medical or prescribing adviser. Thereafter, the matter would be reported, either to the police or to the GMC. If the case also gave rise to a potential breach of the Code of Ethics by the pharmacist (e.g. where the pharmacist had failed to report a case of obviously irresponsible or dangerous prescribing), the inspector would report the pharmacist to the RPSGB. I accept that RPSGB inspectors are not under a duty to look out for signs of irresponsible prescribing. However, in my view, this is a pity, as it seems to me that, by reason of their professional background, they are very much better equipped than CIOs to detect such signs.

9.67 The RPSGB inspector responsible for the Manchester area during the 1990s was Mr Young. He visited the pharmacy at 23 Market Street, Hyde, on a regular basis and formed the view that Mrs Brant was a competent and conscientious pharmacist. The CDR appeared to be well kept and he felt no concern about any aspect of the business or the practice of any prescribing doctor in the area. In Chapter Eleven, I shall consider the position of Mr Young, in relation to the CDR that reveals Shipman's unusual pattern of prescribing of diamorphine in 1993.

## Inspection of General Practitioners' Surgeries by NHS Bodies

9.68 In the Fifth Report, I shall deal fully with the monitoring of GPs and the inspection of their premises by NHS organisations. Here, I shall explain briefly the scope of such activities with specific reference to the keeping and prescribing of controlled drugs. I shall deal first with the position nationally and then with the position locally in Tameside.

### The Nationwide Position

9.69 As I explained in Chapter Three, prior to 1991, the officers of the Regional Medical Service (RMS) visited general practices periodically. The regional medical officer (RMO) would discuss the doctors' prescribing and would usually examine the practice's CDR and its arrangements for storing controlled drugs. Such visits were not regarded as inspections; rather they were an opportunity to advise the practice about good prescribing and the right methods of compliance with the requirements of the legislation. In 1991, the RMS ceased to undertake these visits. Responsibility for visiting GPs passed to the NHS body with responsibility for administering primary care services in the locality.

9.70 From 1991, family health services authorities (FHSAs), the NHS bodies responsible for the administration of primary care services, began to appoint medical advisers. These advisers were doctors; many had been in general practice; some were former RMOs. One of their roles was to inspect GPs' surgeries, including their equipment and facilities. Some medical advisers were given authority to inspect GPs' CDRs and their arrangements for the storage of controlled drugs. Inspection of CDRs and storage arrangements has been patchy ever since, and many GPs have not had their controlled drugs arrangements inspected for more than ten years.

9.71 Another function of the medical adviser was to monitor the prescribing practice of GPs and to promote rational and cost-effective prescribing. When appropriate, GPs were to be discouraged from prescribing expensive drugs of a proprietary brand and were to be encouraged to prescribe a cheaper generic equivalent. The medical advisers received prescribing data provided by the Prescription Pricing Authority (PPA) and used this to inform their discussions with GPs. Little attention was paid to controlled drugs; indeed, until fentanyl patches came into common use, controlled drugs were not of particular interest to the medical adviser as most are not expensive. According to Dr Jim Smith, Chief Pharmaceutical Officer for England at the DoH, controlled drugs were not regarded as presenting a problem and so were not given any special attention.

9.72 During the 1990s, there was a gradual change in the purpose and focus of the monitoring of prescribing. Instead of being concerned almost entirely with cost factors, FHSAs (and later the health authorities (HAs) that took over their responsibilities for general practice in 1996) sought to promote good and therapeutically effective prescribing practice. To this end, they began to appoint pharmaceutical advisers (usually part-time) to advise on the more technical aspects of prescribing. They also began to employ community pharmacists to go into general practices on a regular basis to advise the doctors on the prescribing needs of particular patients or groups of patients. The PPA provided FHSAs and HAs with increasingly sophisticated prescribing data. This data came in paper and, later, electronic form. From 1995, FHSAs were additionally able to send requests to

the PPA for more detailed data analysis. However, until 1999, it was difficult and time-consuming for a medical or pharmaceutical adviser to analyse prescribing practice in respect of a particular drug or class of drugs. Mr Peter Welsby, Pharmaceutical Adviser for the West Pennine Health Authority (WPHA) in the 1990s, said that this task would be undertaken only if a concern had been expressed. The process of analysis became easier when prescribing data became available on-line from June 1999.

9.73 Neither the pharmaceutical advisers nor the community pharmacists were intended to examine a doctor's prescribing practice critically; their role was advisory. Nor did they have the authority to inspect GPs' CDRs and controlled drugs stocks. Dr Smith said that, during the 1990s, it was thought that the routine inspection of community pharmacies by CIOs provided a sufficiently robust system of control in respect of controlled drugs. It was not until 1998 or 1999, when it became clear how Shipman had obtained and kept controlled drugs for his own purposes, that it was realised that the assumptions underlying the existing policy had been mistaken.

**The Position in Tameside**

9.74 The bodies successively responsible for organising primary care in Tameside were unaware until 1998 of the fact that Shipman had convictions associated with the misuse of controlled drugs. They were unaware that he presented any particular risk, either with regard to controlled drugs or at all.

9.75 The RMOs covering the Tameside area made regular visits to GPs between 1977 and 1990. The Inquiry received evidence from three former RMOs. It appears that prescribing was one of the topics that would be discussed at such visits, as was the question of whether the doctor kept a CDR. When Dr David Edwards, working as a RMO in the 1980s, visited Shipman at Donneybrook House, Shipman told him that he did not keep an emergency supply of controlled drugs and, therefore, did not keep a CDR. Such a claim would not have caused any surprise. It was rather more common in those days than now for doctors to keep controlled drugs for use in emergencies, but the practice was by no means universal. Shipman obtained his diamorphine supplies illicitly and kept them well hidden. No regular inspection of GPs' arrangements for keeping controlled drugs and CDRs could reasonably have been expected to detect Shipman's illicit supplies. The practice of a RMO inspecting a GP's patient records had ceased long before Shipman arrived in Hyde. In any case, the purpose of the inspection was to ensure that records were being kept, not to carry out any routine comparison of patient records with prescriptions or other records held at community pharmacies.

9.76 During the 1990s, Shipman's use of diamorphine increased. He had several patients who were terminally ill and required substantial amounts of diamorphine for pain relief. His theft of drugs from patients after dispensing and his retention of unused supplies after a patient's death went unnoticed. During a routine practice visit, he told Dr Roger Freedman, Medical Adviser to the Tameside FHSA from 1991 to 1993, that he kept neither an emergency supply of controlled drugs nor a CDR. He said that keeping controlled drugs gave rise to a risk of theft. He also said that, if a patient telephoned the surgery complaining of chest pain, it was his practice to admit the patient to hospital immediately

rather than go to the house himself. Thus, he had little need of emergency analgesia. In fact, this was quite untrue but Dr Freedman had no reason to disbelieve him.

9.77 The increasing use of diamorphine occasioned by the introduction of syringe drivers in 1993 would have shown up on the prescribing data provided by the PPA. However, this never gave cause for concern. Ms Carol Abdulezer, the pharmacy consultant employed by the Tameside Consortium (the GP fundholding Consortium of which Shipman was a member), told the Inquiry that, in 1995 or early 1996, she had occasion to speak to Shipman about his prescribing of diamorphine. She did so, not because diamorphine was a controlled drug or because Shipman was suspected of any wrongdoing. On examining the Consortium's prescribing data, she had noticed that his diamorphine prescribing for the relevant quarter was high. She spoke about it to Shipman, not to investigate the reason for his prescribing or to persuade him to reduce it, but to ascertain for how long the current level of need for diamorphine was likely to continue. She assumed that it was being used for the treatment of a terminally ill patient and wanted to know whether she should request special provision in the Consortium's prescribing budget. Shipman immediately identified the patient concerned, got out the medical records and showed Ms Abdulezer a letter from the consultant at the hospital where the patient was being treated. This confirmed that a high dosage of diamorphine was indeed necessary. Shipman told her that the drug would not be required for long, as the patient was in the terminal stages of illness. When Ms Abdulezer next came to review the prescribing data, she noticed that the diamorphine usage had returned to its previous level. She had no reason to doubt Shipman's explanation for the short-term increase.

9.78 I have mentioned that there was a period in 1993 when Shipman's prescribing of diamorphine was unusual in that, over a period of seven months, he prescribed 14 single 30mg ampoules of diamorphine in the names of 13 different patients. In Chapter Eleven, I shall consider whether this prescribing should have been identified as unusual by the dispensing pharmacist and by the local CIO. However, I am quite satisfied that these prescriptions would not have shown up as unusual on routine examination of prescribing data. Prescribing data was in its infancy in 1993 and it was less easy to analyse than it is now. Not even the most conscientious or suspicious pharmaceutical adviser could have been expected to notice this series of prescriptions from the prescribing data.

**Analysis after Shipman's Arrest**

9.79 In October 1998, following Shipman's arrest, Dr Alan Banks, then Medical Adviser to the WPHA, asked the PPA to analyse Shipman's prescribing of 100mg diamorphine injections during the two previous years. Data from further back was not available. The analysis revealed, first, that Shipman was only the sixth highest prescriber of diamorphine in the area of the WPHA. I am not sure whether, if diamorphine prescribing had been subject to analysis and monitoring at that time, a doctor in the sixth highest position would have been regarded as an outlier. Second, it was found that the pattern of Shipman's prescribing was not quite as would be expected. It is usual to find a sporadic pattern of prescribing of diamorphine. From time to time, the doctor will have a terminally ill cancer patient. Gradually increasing supplies of diamorphine will be needed but will cease abruptly on the death of the patient. There may then be a period when the doctor does not prescribe

diamorphine at all. Shipman's pattern of prescribing showed more frequent, relatively low level, prescribing than would be expected. However, examination of the other high volume prescribers also showed some unconventional patterns. Nevertheless, had the data been available earlier, the patterns revealed by the analysis would probably have given rise to some concern about Shipman's prescribing of diamorphine. I think it highly likely, however, that, had Shipman been questioned about his prescribing of diamorphine, he would have been able to offer plausible explanations, by reference to individual terminally ill patients, as to why he had prescribed as he did.

## Conclusion

9.80 At present, the inspection and monitoring of the use of, and the arrangements for, controlled drugs are spread between three agencies: the Home Office, the police and the PCTs. RPSGB inspectors are also involved. Each agency seeks to do a good professional job and each co-operates with the others when appropriate. However, the overall result is less than satisfactory. The HODI appears to function well, but it cannot and does not attempt to cover the inspection of retail pharmacies. Coverage by CIOs is patchy. In general, the work of the CIOs is under-resourced. Moreover, even where a dedicated CIO is in post and even now that some training is available, most CIOs are left to their own devices. To be done properly, the job requires enthusiasm and the development of knowledge and experience over a substantial period. It also requires proper management. Even the longest serving and most able CIOs are not ideally placed to recognise irresponsible prescribing of controlled drugs. The RPSGB inspectors appear to me to be well trained, highly motivated and effective. Their professional knowledge equips them well to detect signs of irresponsible prescribing, but they are so few in number that they can visit a pharmacy only about once every two years and often do not have time to pay much attention to controlled drugs issues. Primary care organisations have many other tasks and the monitoring of controlled drug usage is but a small part of their responsibility for promoting good prescribing practice. They have limited resources to devote to the inspection of GPs' surgeries; as a result, the controlled drugs arrangements of many GPs have not been inspected for many years. In Chapter Fourteen, I shall consider how the work done by these various agencies might be rationalised and co-ordinated.