

CHAPTER THREE

A Brief History of the Regulation of Controlled Drugs

Introduction

- 3.1 In this Chapter, I shall examine the historical development of the regulation of controlled drugs in England and Wales. Some features of this development concern measures taken to deal with the problem of addiction to controlled drugs, a subject lying on the periphery of the Inquiry's remit. I have included them for the better understanding of the system as a whole.

The Origins of the Royal Pharmaceutical Society of Great Britain and the Passage of the Pharmacy Act 1868

- 3.2 From as early as the sixteenth century, the importance of maintaining standards in the supply of medicines was recognised. A body of physicians, later to become the Royal College of Physicians, received letters patent from King Henry VIII, entitling them to inspect the premises of apothecaries, i.e. persons who prepared and sold medicines. The inspectors were known as 'censors' and their role was to identify defective or impure medicines and to destroy them. Responsibility for fulfilling this role remained with the College until 1856. From the seventeenth century, the Society of Apothecaries also undertook inspections and paid particular attention to preparations containing opium, which were used for a wide variety of purposes.
- 3.3 Until the second half of the nineteenth century, medicinal drugs were supplied by apothecaries, chemists and druggists, as well as medical practitioners. They could also be sold by any general dealer and there were many 'quack' dispensers of potions and remedies. In due course, the chemists, druggists and apothecaries joined forces in an attempt to impose restrictions on the sale of drugs and to oppose the activities of the 'quacks'. The Pharmaceutical Society of Great Britain was established in 1841. It was granted a Royal Charter in 1843 and became the Royal Pharmaceutical Society of Great Britain (RPSGB) in 1988. Soon after the original formation of the Society, there were calls to restrict the right to practise pharmacy to those who were specially licensed, to promote professional standards of training and to establish controls on the sale of drugs.
- 3.4 These calls led to the passing of the Pharmacy Act 1868, which introduced a list of drugs, including opium, which could be sold only by 'pharmaceutical chemists'. Apart from the restrictions imposed by the 1868 Act, there was no legislative control of opiate drugs in the UK until 1916.

The Dangerous Drugs Act 1920

- 3.5 In 1916, a Regulation was introduced, under the Defence of the Realm Act, to curb the use of cocaine by soldiers in London on leave from war service. As the Government Department responsible for the Act, the Home Office acquired the custodianship of drug control legislation. The Regulation initially gave authority to an official of the Home Office

to inspect retail pharmacists' premises and records. In 1917, this authority was extended to police officers not below the rank of inspector.

- 3.6 The UK had earlier become committed to a more extensive system of domestic control over narcotic drugs when it signed the International Opium Convention at The Hague in 1912 (the 1912 Convention). The 1912 Convention obliged the Government to take effective measures for the prevention of the traffic in, and abuse of, dangerous drugs. The term 'dangerous drugs' was used in all relevant domestic legislation until the Misuse of Drugs Act 1971 (MDA 1971), after which time such drugs were usually described as 'controlled drugs'. It was not until after the First World War that the Government was able to give effect to its obligations under the 1912 Convention (and, by then, also Article 29 of the Treaty of Peace) by the passage of the Dangerous Drugs Act 1920 (the 1920 Act).
- 3.7 The 1920 Act prohibited the importation and exportation of certain dangerous drugs (which included opium, cocaine, morphine and diamorphine) save under licence granted by the Secretary of State (in practice, the Home Secretary). It allowed for secondary legislation to provide for a licensing and regulatory framework governing the manufacture, sale, prescription, possession and distribution of dangerous drugs. The drugs to which the Act applied could be extended in future, by Order in Council, where such drugs were considered **'likely to be productive, if improperly used, of ill effects ... analogous to those produced by morphine or cocaine'**. Breaches of the Act or any regulation made under it would be criminal offences. The Act conferred on police officers and other authorised persons powers (but not duties) of inspection of the premises of producers, manufacturers, sellers and distributors of such drugs. It did not confer a power to inspect doctors' surgeries.

The Dangerous Drugs Regulations 1921

- 3.8 The secondary legislation was contained in the Dangerous Drugs Regulations 1921 (the 1921 Regulations). The production, supply, prescription and possession of dangerous drugs was made unlawful unless the person dealing with the drugs had a licence or was a medical practitioner, dentist or veterinary surgeon. Others were allowed to possess the drugs only when prescribed by a medical practitioner. This was the first statutory expression of the particular privileges of the medical practitioner in relation to dangerous drugs.
- 3.9 The 1921 Regulations laid down the formal obligations of doctors and pharmacists with regard to the prescribing and dispensing of dangerous drugs. Many of these obligations still exist today. The Regulations introduced the requirement that dangerous drugs be dispensed only on written prescription. Any person, authorised under the 1920 Act to manufacture, possess or supply a dangerous drug, who was convicted of any offence under the Act or Regulations might have that authorisation withdrawn by the Home Secretary.
- 3.10 Regulation 5 of the 1921 Regulations conferred on the Home Secretary the power to prescribe and issue an **'official form'** to be used by doctors when prescribing dangerous drugs. The intention was that the new **'official form'** would be used for the private

prescribing of dangerous drugs. When issuing publicly funded prescriptions for dangerous drugs, doctors would use the same prescription form as for other medicines available on prescription. In the event, no **'official form'** for the private prescribing of dangerous drugs was ever introduced. It is perhaps of interest that, more than 80 years later, the Inquiry should be discussing this and other ideas that were current at the time that the 1921 Regulations came into effect.

- 3.11 The 1921 Regulations required all suppliers of dangerous drugs to record relevant transactions in a register, the form of which was prescribed by the Regulations. They also imposed an obligation of record keeping on a doctor supplying dangerous drugs to a patient. That duty was different from, and less onerous than, that imposed upon pharmacists. A doctor was required only to keep a daybook, which was less detailed than the pharmacist's register. This concession was removed in 1926, from which time a doctor was required to keep a dangerous drugs register.
- 3.12 It is interesting to note that a regulation, proposed in 1922, that doctors should not be permitted to prescribe a controlled drug for their own use was withdrawn by the Home Office following objections from the British Medical Association. A further proposal by the Home Office in 1923 to limit the right of a medical practitioner to possess, prescribe or administer dangerous drugs to those medical practitioners **'in actual practice'** (i.e. not retired or working in a non-clinical capacity) was also abandoned¹. When similar proposals were raised in 2003 in the Inquiry's Discussion Paper, 'The Use and Monitoring of Controlled Drugs in the Community', they received support from a wide variety of organisations, including the Royal Colleges of Physicians of London and Edinburgh. The Royal College of General Practitioners supported the latter, though not the former, proposal.

Establishing Regular Police Inspection of Retail Pharmacies

- 3.13 In 1921, the police powers of inspection of retail pharmacies were extended to officers below the rank of inspector. A Home Office Circular issued to Chief Officers of Police explained the police role in ensuring compliance by pharmacists with the statutory requirements under the 1921 Regulations. The scheme was that the police would inspect pharmacies, the Home Office was to inspect the arrangements of pharmaceutical wholesalers and those licensed to manufacture or produce dangerous drugs, and the Ministry of Health was to be responsible for the inspection of the arrangements made by medical practitioners. The Ministry of Health assigned the duty of inspecting the arrangements of general practitioners (GPs) to the Regional Medical Service (RMS), which continued to perform this function until 1991.
- 3.14 In July 1922, the Commissioner of the Metropolitan Police wrote to the Home Office, questioning whether the inspection of pharmacies was a proper and worthwhile role for police officers and suggesting that these responsibilities might be better fulfilled by persons having some practical knowledge of the retail pharmacy business. (It is interesting to note that the Greater Manchester Police made exactly the same point to the

¹ Spear, Bing and Mott, Joy, *Heroin Addiction, Care and Control: The British System*, London: Drugscope, September 2002

Inquiry in 2003.) The Home Office response in 1922 was that the police were not expected to undertake elaborate examinations of the pharmacists' records. Their inspections would be a valuable stimulus to retail chemists, who might otherwise become slack, to maintain strict compliance with legislative requirements. Similar views about the value of a police inspection were expressed to the Inquiry in 2003.

The Rolleston Report 1926

The Appointment of the Rolleston Committee

- 3.15 From 1921 at the latest, the Home Office was concerned about the practice of prescribing dangerous drugs to addicts. It opposed the treatment of addiction to a dangerous drug by the prescribing of 'maintenance' doses, i.e. the continued prescribing of the quantity of the drug to which the patient had become accustomed, with the intention of maintaining the patient's stability. It did not approve even of the use of gradually reducing doses of the drug of addiction. Its position was that abrupt withdrawal from drug dependence was possible and that any other form of treatment was improper. For its part, in the years following the passing of the 1920 Act, the medical profession had become concerned about what it perceived as official intrusion into the sanctity of the doctor/patient relationship.
- 3.16 In 1924, as a result of its concerns, the Home Office approached the Ministry of Health, querying the propriety of the practice, followed by many doctors, of treating drug addiction by the gradual reduction of dosage. Following that approach, on 30th September 1924, a Departmental Committee was appointed, under the chairmanship of Sir Humphry Rolleston, to report on the problem. The Rolleston Committee, which was composed mainly of doctors, was required by its Terms of Reference:

'... to consider and advise as to the circumstances, if any, in which the supply of morphine and heroin (including preparations containing morphine and heroin) to persons suffering from addiction to those drugs may be regarded as medically advisable, and as to the precautions which it is desirable that medical practitioners administering or prescribing morphine or heroin should adopt for the avoidance of abuse, and to suggest any administrative measures that seem expedient for securing observance of such precautions'.

The Main Findings of the Committee

- 3.17 On the main issue before it, the Committee found that the method of treatment favoured by the Home Office, namely sudden and complete withdrawal of the drug of addiction, was not practicable in the case of most addicts. They recommended that, in most cases, the steady reduction of the dosage of the drug of addiction was the method of treatment most likely to result in eventual withdrawal. Doctors had to be free to prescribe for the purpose of such treatment. There would be a few cases in which it would prove impossible to wean a patient from a longstanding addiction and in which it would be appropriate for the doctor to prescribe a small maintenance dose of the drug of addiction. The Committee

stated that doctors must also remain free to prescribe controlled drugs for the treatment of organic disease.

A Useful Perspective on the Problems of the Day

- 3.18 The Report of the Rolleston Committee (the Rolleston Report) provides a useful perspective on the problems of the day. The Committee reported that the inspection of wholesale pharmaceutical suppliers and pharmacies had revealed cases in which very large quantities of dangerous drugs had been supplied to particular doctors and where individual patients had received unusually large quantities on prescription. Further enquiries had revealed a number of specific problems. Some doctors were prescribing dangerous drugs for addicts on a maintenance basis, without any attempt to reduce dependence. Some doctors had issued supplies of, or prescriptions for, large quantities of dangerous drugs to patients whom they saw only infrequently; in some cases, the drugs or prescriptions had been sent by post. Some doctors had supplied dangerous drugs or had issued prescriptions to persons previously unknown to them and without making any effort to communicate with those persons' usual medical advisers. There were cases in which persons had obtained supplies of dangerous drugs from several practitioners concurrently. Finally, it had been found that, in some cases, large supplies had been purchased or prescribed by practitioners for self-administration. I interpose to say that the same problems still exist today. These practices would now be described collectively as 'irresponsible prescribing' and some would involve the commission of criminal offences.
- 3.19 The Committee noted that cases of addiction to morphine or heroin were more prevalent in the '**great urban centres**', among persons who had to handle those drugs for professional or business reasons and among persons especially liable to nervous or mental strain. Facility of access was said to be an important factor in the onset of addiction. Again, this observation would not be out of place if the Committee had reported 70 years later.
- 3.20 Even the ways in which the doctors' behaviour was addressed are familiar to those involved in monitoring the conduct of doctors today. It was said that an informal approach to the doctor, seeking to persuade him/her to pay due regard to the requirements of the legislation, had in many cases been followed by beneficial results. Some doctors might be prosecuted. In other cases, the Home Office might bring the case to the notice of the General Medical Council (GMC) if it appeared that the doctor's conduct had been such as might be regarded by the GMC as '**infamous in a professional respect**'.

Restricting Prescribing Powers

- 3.21 The Rolleston Report noted that the general authority to supply and possess dangerous drugs could, at the discretion of the Home Secretary, be withdrawn from individual practitioners who had been convicted of offences under the 1920 Act. As the Regulations stood at that time, withdrawal of authority had to be preceded by conviction in a police court. As a means of dealing with those problems of irresponsible prescribing which did not involve the commission of a criminal offence, the Committee recommended that the Home Secretary should have the power to withdraw the authority of a practitioner to

possess, prescribe and supply dangerous drugs, if advised to do so by a suitably constituted medical tribunal. The question for the tribunal would be whether dangerous drugs had been supplied, administered or prescribed by the practitioner for purposes other than legitimate medical purposes. The tribunal would comprise three medical members and a legal assessor.

- 3.22 Some of the Rolleston Committee's recommendations were accepted by the Home Office and were introduced in the Dangerous Drugs Regulations 1926. However, although the statutory power to create the medical tribunal system was provided by those Regulations, the machinery for such a system was introduced only by the MDA 1971, almost half a century later.

The Evolution of the Chemist Inspection Officer's Role

- 3.23 In 1935, the League of Nations placed on national governments a duty to provide statistics about known drug addicts. In 1939, police forces were given the task of informing the Home Office about persons who were receiving regular supplies of dangerous drugs. It was the job of the chemist inspection officer (CIO) to gather this information during his/her inspections. This instruction was apparently contained in a Home Office booklet entitled 'Notes for the Guidance of Police Officers', published in 1939. No copies were available to the Inquiry.
- 3.24 In this way, the role of the CIO evolved from that described in the 1921 Circular (see paragraph 3.13), which focussed primarily upon compliance with the 1921 Regulations by pharmacists. Now, the police were also instructed to look at what individual patients were receiving and were seeking to identify addicts.

Continuing Problems with Diversion

- 3.25 The Dangerous Drugs Act 1951 consolidated the previous legislation and the Dangerous Drugs Regulations 1953 consolidated and updated previous Regulations.
- 3.26 In February 1956, the Home Office issued a publication giving guidance to doctors and dentists about dangerous drugs. Doctors were reminded of their obligations and of the limitation of their authority to possess and supply dangerous drugs. A practitioner could do so only **'so far as may be necessary for the practice or exercise of his profession'**. The publication warned that there had been cases in which doctors and dentists had been convicted of offences under the dangerous drugs legislation for having obtained drugs, ostensibly for use in their practices, and having subsequently diverted them **'to the gratification of their own addiction'**.

United Nations Conventions

- 3.27 Beginning with the 1912 Convention, successive international treaties had modified the systems of international control and the list of drugs controlled, notably by the addition of synthetic opiates and cannabis and cannabis resin. Whenever necessary, domestic law was amended to accommodate those changes. The 1961 United Nations Single

Convention on Narcotic Drugs (the 1961 Convention) replaced all the earlier international agreements governing the control of narcotic substances, including opiates, cocaine, cannabis and cannabis resin (but not lysergide (LSD) or amphetamines). It required national governments to place restrictions on particular narcotic drugs (including heroin, morphine, cocaine and cannabis), limiting their use to medical and scientific purposes. The UK ratified this Convention on 2nd September 1964 and the Dangerous Drugs Act 1964 enacted the provisions necessary for compliance. The Dangerous Drugs Act 1965 consolidated the Acts of 1951 and 1964.

- 3.28 Mr Alan Macfarlane is the current Chief Inspector of the Home Office Drugs Inspectorate. In evidence to the Inquiry, he explained that the 1961 Convention led very quickly to a much more organised approach to the licensing of the manufacture and wholesale supply of dangerous drugs and to improved compilation of statistical data for transmission to the United Nations (UN). The intention was for the UN to be in a position to monitor the use of dangerous drugs worldwide.
- 3.29 The problems arising from the misuse of LSD, amphetamines and other hallucinogens, which were outside the ambit of the 1961 Convention, were addressed domestically by the Drugs (Prevention of Misuse) Act 1964 (the 1964 Act). The 1964 Act provided a measure of control by rendering unlawful the possession of amphetamines and certain other drugs, although it did not impose any regulatory controls on their prescribing or storage. Restrictions similar to those contained in the 1961 Convention were required by the 1971 United Nations Convention on Psychotropic Substances. The UK ratified this Convention in 1986.

The Work of the Brain Committee

The Appointment of the Brain Committee

- 3.30 In the late 1950s, new synthetic opiates were being manufactured. Doctors began to use them for therapeutic purposes but it was soon found that they were capable of producing addiction. Accordingly, in 1958, again at the instigation of the Home Office, the Department of Health and Social Security (DHSS) set up an Interdepartmental Committee to review the policy of using dangerous drugs for the treatment of addiction.
- 3.31 Sir Russell Brain was appointed as Chairman of the Interdepartmental Committee on Drug Addiction. Its Terms of Reference required it to:

'... review, in the light of more recent developments, the advice given by the Departmental Committee (*i.e. the Rolleston Committee*) on Morphine and Heroin Addiction in 1926; to consider whether any revised advice should also cover other drugs liable to produce addiction or to be habit-forming; to consider whether there is a medical need to provide special, including institutional, treatment outside the resources already available, for persons addicted to drugs; and to make recommendations, including proposals for any administrative measures that seem expedient, to the Minister of Health and the Secretary of State for Scotland'.

The First Brain Report

- 3.32 The Committee's Report (the first Brain Report) was published in 1961. Its conclusions effectively endorsed the main conclusions of the Rolleston Report and supported the principle that all doctors should be allowed to continue to prescribe addictive drugs as part of treatment for dependence. The Chairman reported that there was no need for any change in the British approach. Specifically, the Report concluded that the incidence of addiction to controlled drugs in Great Britain was still very small and traffic in illicit supplies (with the exception of traffic in cannabis) was almost negligible. Irregular prescribing of dangerous drugs by doctors was an infrequent occurrence and further statutory controls were not justified. There was no need for a medical tribunal system (such as that suggested by the Rolleston Report) to be set up to consider cases of improper use of dangerous drugs by doctors. Instead, the Report concluded, it would be sufficient for doctors to obtain a second medical opinion before embarking on the regular prescribing of dangerous drugs to a patient. No advantage would arise from the use of distinctive prescription forms for dangerous drugs. The Report was publicly criticised for failing to recognise the extent of the problems of addiction in Great Britain.

The Second Brain Report

- 3.33 In fact, by the beginning of the 1960s, heroin addiction in the UK had begun to increase and the pattern of use was changing. For the first time, CIOs reported that there were more people addicted to heroin than to morphine. Most of the 'new' addicts lived in London. The heroin used was pharmaceutically pure and was thought to be coming from the prescribing practices of a small number of doctors. It appears that the failings of a few weak, elderly, incompetent or dishonest doctors were being exploited by addicts. There was also concern that some doctors were exhibiting little or no inclination to make any attempt at a cure when prescribing for addiction.
- 3.34 In July 1964, the Brain Committee was reconvened to consider whether, in the light of recent experience, the advice given in its first Report required revision and, if so, to make recommendations. In 1965, the second Brain Report gave advice that was materially different from that contained in the Committee's first Report. The Committee concluded that there was a major problem with addiction to heroin and cocaine, that the main source of supply of these two drugs was over-prescribing by a small number of doctors and that further measures were required to deal with this problem. Evidence was cited in the Report that, in 1962, one doctor alone had prescribed almost 600,000 tablets (i.e. 6kg) of heroin for addicts. On one occasion, that doctor had prescribed 900 tablets to an addict and then, three days later, had prescribed another 600 tablets for the same patient **'to replace pills lost in an accident'**. The Committee commented that the evidence showed that the doctors who had over-prescribed in this way had acted **'within the law and according to their professional judgement'**. It might well have been right that the actions of the doctors did not contravene the letter of the law. However, if the Committee thought that doctors who over-prescribed in this way had done so **'according to their professional judgement'**, its members must have thought that doctors had a very wide professional discretion. To modern eyes, it seems surprising that the Committee did not attempt to lay down any standards as to how a responsible doctor should act. Instead, it recommended

a drastic curtailment of the power of doctors to prescribe heroin and cocaine for the treatment of addiction.

- 3.35 The Committee recommended that the right to prescribe heroin and cocaine (but not other drugs) to addicts should be limited to doctors on the staff of special treatment centres. It should be a statutory offence for other doctors to prescribe these drugs to an addict for the treatment of addiction. Disciplinary measures against doctors alleged to have prescribed these drugs irregularly should be the responsibility of the GMC. All addicts should be formally notified to a central authority which would keep a register of addicts. Doctors should be under a statutory duty to notify the authority responsible for keeping the register of any addict with whom s/he had come into a professional relationship. There was still no need, in the opinion of the Committee, to introduce a different prescription form for dangerous drugs but, when prescribing dangerous drugs, a doctor should indicate the quantities by words as well as figures. An advisory committee should be set up to keep under review the whole problem of drug addiction, which was acknowledged to be a **'changing problem'**.

The Dangerous Drugs Legislation of 1967 and 1968

- 3.36 The Dangerous Drugs Act 1967, the Dangerous Drugs (Supply to Addicts) Regulations 1968 and the Dangerous Drugs (Notification of Addicts) Regulations 1968 implemented some of the recommendations of the second Brain Report.
- 3.37 Under the Dangerous Drugs (Supply to Addicts) Regulations 1968, practitioners were prohibited from prescribing, supplying or administering heroin or cocaine to addicts, except in the treatment of organic disease or injury, unless they were specially authorised to do so by the Home Secretary. In practice, authorisation was given only to doctors working in special treatment clinics. Doctors who contravened these rules might have their right to prescribe these drugs removed by direction of the Home Secretary.
- 3.38 The Addicts Index was set up and doctors were required to report to the Home Office any person whom they considered to be addicted to any dangerous drug. A person was to be regarded as addicted to a drug if, as a result of repeated administration, s/he had become so dependent upon it that s/he had an overpowering desire for its administration to be continued. The Addicts Index remained in operation until 1997, when the Regulations requiring notification were revoked.
- 3.39 The Dangerous Drugs Act 1967 gave the Home Secretary the power to make a direction restricting the right of a doctor to prescribe, supply, possess or administer any controlled drug if s/he were found, by a tribunal, to be in breach of certain regulations governing the handling of controlled drugs or the terms of a licence. However, this power could not be exercised until a tribunal had been set up to investigate the allegations and make the necessary findings. It appears that the tribunal system was not set up until the early 1970s.

The Medicines Act 1968

- 3.40 The Medicines Act 1968 was introduced by the DHSS following a review of legislation relating to medicines prompted by the thalidomide tragedy in the 1960s. It brought

together most of the previous legislation on medicines and introduced a number of other legal provisions for the control of medicines. It did not deal specifically with dangerous drugs but many of the requirements of the Act applied to dangerous drugs.

- 3.41 The Act divided medicinal drugs into three categories, depending mainly on the dangers they posed and the risk of misuse. The categories are:
- (a) prescription only medicines, which may be sold or supplied to the public only on a practitioner's prescription. They may be administered only by or in accordance with directions from an appropriate practitioner, which term includes a medical practitioner. With the exception of controlled drug preparations below a certain strength set out in Schedule 5 to the Misuse of Drugs Regulations (MDR) 2001, all controlled drugs are prescription only medicines.
 - (b) pharmacy medicines, which, subject to certain exceptions, may be sold or supplied only from registered premises by, or under the supervision of, a pharmacist. Most products listed within Schedule 5 are pharmacy medicines.
 - (c) general sales list medicines, which may be sold or supplied direct to the public in an unopened manufacturer's pack from any lockable premises. No controlled drugs are general sales lists medicines.

The Legislation of 1971 and 1973

- 3.42 The MDA 1971 and the Regulations made under it in 1973 provided a new statutory framework for the control and regulation of **'dangerous or otherwise harmful'** drugs which, from this time, usually became known as 'controlled' drugs. The new legislation came into force in July 1973. The Act remains in force today. It repealed almost all the previous legislation and re-enacted many of its substantive provisions. The Regulations relating to addiction, which had come into force in 1968, were retained. The MDR 1973 were amended on many occasions and were replaced by the MDR 1985, which were in turn amended several times before being replaced by the Regulations currently in force, the MDR 2001.
- 3.43 Essentially, the MDA 1971 made it unlawful to possess or supply a controlled drug unless an exception or exemption applied. A number of specific offences were created, such as unlawful possession of a controlled drug and unlawful possession of a controlled drug with intent to supply it to another. A controlled drug was defined as any drug listed in Schedule 2 to the Act. Under Schedule 2, controlled drugs were divided into Classes A, B and C. Upon this classification depended the severity of the penalties that could be imposed under the criminal law for an infringement of the Act. Drugs such as heroin and cocaine were in Class A and the penalty imposed for committing, say, an offence of unlawful possession of heroin was more severe than that which could be imposed for unlawful possession of a drug from Class B or Class C. Class B contained such drugs as amphetamines and cannabis and Class C contained such drugs as benzodiazepines.
- 3.44 Section 10 of the Act empowered the Home Secretary to make regulations to prevent the misuse of controlled drugs with particular reference to safe custody, documentation,

record keeping, furnishing information, packaging and labelling, transportation, destruction or disposal, prescribing, dispensing, and notification of and prescribing for addicts. Section 18 of the Act made it a criminal offence to breach any of the Regulations made under the Act or the terms of a licence granted under the Act.

- 3.45 Section 7 of the MDA 1971 allowed the Home Secretary to authorise activities that would otherwise be unlawful under the Act. It specifically required him to make regulations to **‘secure . . . that it is not unlawful’** for a doctor, acting as such, to possess, prescribe, administer or supply controlled drugs or for a pharmacist or person conducting a pharmacy business to supply controlled drugs. Without such regulations, doctors and pharmacists would not be able to deal with controlled drugs in any way.
- 3.46 Section 13(2) of the MDA 1971 gave the Home Secretary a new power to prohibit a practitioner from dealing with controlled drugs where s/he had been **‘prescribing, administering or supplying ... any controlled drugs in an irresponsible manner’**. Section 14 provided for the setting up of a tribunal system by which cases of alleged irresponsible prescribing could be investigated and a recommendation made to the Home Secretary with a view to possible curtailment of a doctor’s powers to possess or prescribe controlled drugs. The power of the Home Secretary to withdraw the authority of a doctor who had been convicted of offences under the relevant legislation was preserved by section 12. As I explained in paragraph 3.21, this power had been introduced in the 1921 Regulations.
- 3.47 The Act also provided for the setting up of a statutory Advisory Council on the Misuse of Drugs (ACMD) to replace a non-statutory Interdepartmental Advisory Committee on Drug Dependence, which had provided advice since 1968. The main duty of the ACMD was to keep under review the situation in the UK in relation to drugs liable to misuse and to advise on measures to deal with any social problems caused by such misuse.
- 3.48 The MDR 1973 provided a code of Regulations governing the conduct of those people who were permitted to possess, prescribe, supply or administer a controlled drug under an exception to or exemption from the main provisions of the Act. The Regulations divided controlled drugs into categories according to the degree to which their use was to be regulated. Somewhat confusingly, instead of utilising the three Classes A, B and C under Schedule 2 to the MDA 1971, the Regulations divided all controlled drugs into four Schedules. Schedule 1 contained drugs that required little regulation. Schedule 2 contained such drugs as heroin and cocaine, which could be held and prescribed by doctors, dentists and veterinary surgeons; they were subject to quite stringent regulation. Schedule 3 contained very few drugs, which, somewhat illogically, were less regulated than those in Schedule 2. Schedule 4 contained the drugs to be most closely regulated. They could be dealt with only by persons specifically licensed to do so by the Home Office.
- 3.49 The MDR 1973 contained many provisions, most of which remain in force today, albeit after some amendment and consolidation in the MDR of 1985 and 2001. I shall mention only those of particular interest to the Inquiry. Pharmacists and doctors, acting in their capacity as such, were authorised to possess any controlled drug, save those in Schedule 4, and supply it to anyone who might lawfully possess it. Regulation 6 authorised persons such as police officers, customs officers, post office employees and carriers, acting as

such, to be in lawful possession of controlled drugs and to supply them to anyone who might lawfully possess them. Any person lawfully in possession of a controlled drug was authorised to supply it to the person for whom it was obtained. The Regulations laid down formal requirements for prescriptions for controlled drugs, save those in Schedule 1. These included the requirement that the information on the prescription should be written in the prescriber's own hand. A controlled drug prescription was to be valid for only 13 weeks after the date of issue. Any person with authority to supply to another a controlled drug from Schedule 2 or 4 was under a duty to keep a chronological record of all such transactions in a controlled drugs register (CDR). The specifications relating to CDRs were also laid down. Records relating to controlled drugs, such as CDRs, were to be kept for at least two years from the date on which the last entry was made. Regulation 24 provided that controlled drugs from Schedules 2 and 4 could be lawfully destroyed by doctors and pharmacists only in the presence of a person authorised by the Home Secretary and that a record of such destruction should be kept. In practice, Home Office inspectors, CIOs and inspectors appointed by the RPSGB were authorised to witness the destruction of controlled drugs.

- 3.50 The Misuse of Drugs (Safe Custody) Regulations 1973, which, with some amendment, remain in force today, prescribe the arrangements for the physical security of controlled drugs held by any person entitled to hold a stock. The requirements apply only to drugs within Schedule 2 (apart from quinalbarbitone and some other liquid preparations), and a few from Schedule 3, to the MDR 2001. The occupiers of pharmacies, nursing homes and private hospitals must, so far as circumstances permit, keep the relevant controlled drugs in a **'locked safe, cabinet or room which is so constructed as to prevent unauthorised access to the drugs'**. The Regulations also provide a specification for the type of cabinet in which controlled drugs are to be stored. The duty of a GP who keeps a stock of controlled drugs is provided by regulation 5. Any person keeping a stock of controlled drugs must ensure that, if the drugs are not kept in a locked safe, cabinet or room so constructed as to prevent unauthorised access to the drugs, they are, so far as circumstances permit, kept in a locked receptacle which can be opened only by that person or by someone acting with his/her authority.

Amendment of the Misuse of Drugs Regulations between 1973 and 2001

- 3.51 The MDR 1973 were the subject of minor modifications on eight occasions between 1973 and 1984. Most of these changes brought further drugs under control. In 1984, dipipanone was included with heroin and cocaine on the list of drugs for which a special authority was required for a doctor to prescribe to addicts.
- 3.52 The first major revision resulted in the MDR 1985. The main substantive change was the introduction of a specific authority to patients to return prescribed controlled drugs to a medical practitioner or pharmacist for the purpose of destruction. The practitioner or pharmacist was allowed to destroy the drugs without formality, i.e. without their destruction being formally recorded or witnessed. This was designed to achieve the safe removal from the community of controlled drugs that might otherwise be diverted to the illicit market. The change had been recommended by the ACMD in its 1983 Report entitled 'Security of Controlled Drugs'.

- 3.53 The Schedules to the MDR were also extended and re-organised. The number of Schedules was increased from four to five and the 'order of precedence' was rationalised. Schedule 1 drugs were those for which a licence was required. Schedule 2 contained such drugs as heroin, morphine and cocaine, which were strictly regulated. Schedules 3, 4 and 5 contained drugs which were progressively less regulated. Schedule 5 drugs included 'weak' preparations containing a controlled drug that could be sold over the counter.
- 3.54 Subsequent amendments to the MDR 1985 comprised the addition of various drugs to one or other of the Schedules. In 1996, controls were extended to 48 anabolic and androgenic steroids and to six similar products, all liable to misuse by sportsmen and sportswomen. Temazepam and flunitrazepam were transferred from Schedule 4 to Schedule 3 in 1996 and 1998 respectively. In 2001, 36 additional substances were brought within the controls for the first time. 'Ecstasy' became a Schedule 1 drug.

The Duthie Report

- 3.55 In 1988, the Joint Sub-Committee of the Standing Medical, Nursing and Midwifery and Pharmaceutical Advisory Committees published a report entitled 'Guidelines for the Safe and Secure Handling of Medicines: A Report to the Secretary of State for Social Services'. The Sub-Committee was chaired by Professor Robert Duthie. It was set up following advice from the ACMD that current guidelines on the security of controlled drugs in hospitals should be updated and consolidated.
- 3.56 The Sub-Committee's Report, known as the Duthie Report, suggested guidelines for the procedures governing controlled drugs in the hospital sector. They were adopted and are still in use today. Their premise is that the need for the **'three Rs'** (reconciliation, record keeping and responsibility) applies to controlled drugs as it applies to all medicines. It seems to me that the 'three Rs' are very sound principles on which to base the rules and systems which should govern the use of controlled drugs in the community as well as in hospitals.

Inspection Arrangements

- 3.57 I mentioned earlier that, since the 1920s, police CIOs have been responsible for the inspection of controlled drugs arrangements and CDRs in pharmacies. This continues to be the case, although there are some police areas in which there is no CIO in post. I also said that the RMS of the Ministry of Health (later the DHSS, then the Department of Health) was responsible for visiting GPs' surgeries and for examining, among other things, the arrangements made by GPs in connection with controlled drugs. The RMS ceased to make such visits in 1991. Since that time, many GPs have not had their controlled drugs arrangements inspected. Many primary care organisations arrange for a medical adviser or a clinical governance lead to carry out an annual practice visit, although this has not been universal practice. In the past, such visits have not focussed on the arrangements for controlled drugs. In a few areas, police CIOs visit the premises of GPs who also provide a dispensing service. They have no statutory power to do so and it appears that such visits

occur mainly by invitation, when the practice wants a CIO to witness the destruction of 'out of date' controlled drugs.

Ideas for Improvement

- 3.58 No further significant changes had been made to the legislative framework relating to controlled drugs by the time Shipman's crimes came to light in August 1998. Since the extent to which he used and abused diamorphine has been understood, there has been much discussion about how the systems of control should be improved. There has also been much debate about ways to modernise the present systems. I shall describe those ideas and proposals later in this Report.
- 3.59 For the moment, I say only that this brief summary of the historical development of the regulation of controlled drugs has revealed several matters that are of particular relevance to the issues facing the Inquiry in 2004. The danger attaching to the freedom of medical practitioners to prescribe, supply and administer controlled drugs for therapeutic purposes has been recognised for more than 80 years. If that freedom is to remain, as it must, it should be circumscribed in ways that minimise the risk of diversion without compromising patient care. Two particular ways in which the risk might be reduced were recognised in the 1920s but not implemented, namely the suggestions that doctors should not be allowed to prescribe dangerous drugs for themselves and that they should be able to prescribe only while **'in actual practice'**.
- 3.60 Also, certain specific practical arrangements have been considered in the past, but rejected or abandoned. For the time being, I shall highlight only two. The provision in the 1921 Regulations, that all private controlled drug prescriptions should be written on special forms, was not implemented, possibly because it was thought that the advantage accruing would be slight. This proposal is worthy of reconsideration now, with the advent of the computerised analysis of prescribing data.
- 3.61 Second, from the very beginning of the routine police inspection of pharmacies, it was suggested by the police that it might not be a suitable body to carry out the task. As the nature of pharmacy practice has become more refined, it may be said that there is an even greater need now for some specialist expertise to be introduced into pharmacy inspection.
- 3.62 I shall return to all these issues in Chapter Fourteen of this Report.