CHAPTER THIRTEEN

Controlled Drugs Regulation in British Columbia and Northern Ireland

Introduction

13.1 The Inquiry team considered the systems of controlled drugs regulation in several different jurisdictions and, on the basis of the information gathered, I decided that it would be helpful to hear presentations explaining the systems in operation in the Canadian province of British Columbia and in Northern Ireland. The system in British Columbia was chosen primarily because of its advanced computerised system of review and monitoring of the use of controlled drugs. Northern Ireland was chosen because of the distinctive inspection arrangements that operate there. The presentations were made, at a seminar held by the Inquiry on 12th January 2004, by Dr Brian Taylor, Deputy Registrar of the College of Physicians and Surgeons of British Columbia (CPSBC) and Dr Michael Mawhinney, Misuse of Drugs Inspector for the Department of Health, Social Services and Public Safety, Northern Ireland (the Department). I am grateful to both of them for their contributions.

British Columbia

13.2 British Columbia has approximately 9000 physicians and approximately 800 pharmacies, serving a population of 4.5 million. The CPSBC is responsible for licensing and regulating all physicians practising in British Columbia. It also has a mandate to oversee the quality of medical care provided in the province. Among its responsibilities are the review and monitoring of the use of 'narcotics' or 'narcotic drugs', the Canadian terms equivalent to 'controlled drugs'. In this Chapter, I shall describe only those aspects of Dr Taylor's presentation relating to narcotic drugs, which are of particular interest to the Inquiry.

The Triplicate Prescription Program

13.3 In 1990, the CPSBC introduced the 'Triplicate Prescription Program', for use by physicians when prescribing certain narcotic drugs (described by Dr Taylor as 'heavy duty opioids'). The programme was intended to assist in the prevention and detection of the diversion of such narcotics. It has recently been renamed the 'Control Prescription Program'.

13.4 Under the programme, a physician wishing to prescribe narcotics, other than in a hospital setting, may do so only on a special triplicate prescription pad issued for the purpose. This pad must be used whether the drug is to be paid for by the patient or where its cost is to be reimbursed to the patient under the Canadian system of state subsidised health insurance. Issue of the pads is controlled by the CPSBC. Any physician applying for the issue of a pad may be required to justify his/her application, if it appears that s/he practises in a field of medicine (e.g. radiology) in which it would not be usual to prescribe narcotics. The prescriptions in the pad may be used only by the physician in whose name the pad was issued.

13.5 The prescriptions are printed on special paper, similar to that used for banknotes, which is very difficult to reproduce. A separate prescription must be issued for each drug prescribed. This contrasts with the present position in the UK. The quantity of the drug prescribed must be written both in numbers and in words (as in the UK). The issuing physician must endorse the prescription with his/her unique CPSBC identifying number. The prescription also identifies the patient by name and by his/her unique patient identifying number.

13.6 When the programme was first introduced, each prescription was created in triplicate. The physician would retain one copy of the prescription for his/her own records and would provide two copies of the prescription to the patient for presentation at the pharmacy. After dispensing, the pharmacist would keep one copy and the other would be sent to the office of the Provincial Government, where the data would be manually entered into a central database. According to Dr Taylor, this method of data collection was not entirely satisfactory and about 20% of data was lost. In 1995, a computerised system for the central recording of all prescriptions issued in British Columbia, known as PharmaNet, was introduced. Since that time, the third copy of the prescription has been redundant, as the prescription information is automatically recorded in the central database. The collection of data is complete and the information it yields on analysis more reliable.

13.7 According to Dr Taylor, the programme has produced several benefits. First, the use of the special paper on which prescriptions are printed and the handwriting requirements have reduced the incidence of forgery. Second, each prescription specifically identifies both the prescribing doctor and the patient by their unique identifying numbers. This facilitates any monitoring or investigatory process. Third, according to Dr Taylor, the special prescribing requirements and the use of the distinctive pads cause the physician to pause and think before writing the prescription.

13.8 Under the programme, a prescription is valid for only five days. As I will explain in Chapter Fourteen, many in the UK would not welcome such a brief period of validity. However, according to Dr Taylor, this has not caused any difficulty in British Columbia, where experience has shown that, when narcotics for pain relief are prescribed, the patient normally wishes them to be dispensed immediately.

13.9 The central collection of prescribing data enabled the CPSBC to review the narcotics prescribing profiles of all physicians, so as to identify outliers and those with unusual prescribing practices. These could then be investigated individually. It was also possible to analyse the data by reference to individual patients, so as to reveal, for example, those who were receiving narcotics on prescription from more than one physician at the same time (a practice described in the UK as 'double scripting'). Since the inception of PharmaNet, the CPSBC has used software that enables it to carry out a far wider range of analyses than was possible before 1995.

PharmaNet

13.10 The benefits stemming from the Triplicate Prescription Program were significantly enhanced with the introduction of PharmaNet. PharmaNet is funded by the Provincial Government and was developed with advice and assistance from the CPSBC. A part of

the initial impetus for its development was a wish to understand more about the cost of state subsidised prescribing and, to that extent, its genesis can be likened to that of prescribing analysis and cost (PACT) data in England and Wales. There was also a desire to reduce the incidence of prescription fraud and inappropriate prescribing. According to Dr Taylor, PharmaNet also rapidly became a useful therapeutic tool.

13.11 PharmaNet contains the complete known history of drugs prescribed for every resident of British Columbia and, if a visitor to the province requires medication, a record will be created for him/her. At the time of dispensing any drug (not only narcotic drugs), the pharmacist enters the details of the prescription into the PharmaNet database. The previous 14 months' prescribing history for the patient is immediately shown on the pharmacist's computer screen, as is any history of, for example, allergy or adverse drug reaction. The pharmacist is under a professional obligation to consider this information and may, if s/he wishes, seek further details of the patient's prescribing history. It is possible to record on PharmaNet the condition for which medication has been prescribed, although I formed the impression that only limited use is made of that facility.

13.12 The system also provides a summary of information about the drug being prescribed; this is in a form suitable for giving to the patient at the time of dispensing. A 24 hour help desk is available to give further information to the pharmacist, if required, about the profile of the drug being dispensed.

13.13 An 'alert' can be attached to the name of a particular prescriber or patient. This warns the pharmacist not to dispense any prescriptions, which may be subsequently presented, issued by the named prescriber or in the name of the named patient.

13.14 Every community pharmacy in British Columbia has on-line access to PharmaNet. Access is also now mandatory for every hospital pharmacy and accident and emergency department in the province and it is used in the prison system. On payment of a licence fee, PharmaNet is also accessible to physicians. At the time of the seminar in January 2004, about 150 physicians had access but the cost of the licence was proving a disincentive for many.

13.15 Although prescriptions for all drugs, not only narcotics, are entered into PharmaNet, the system makes special provision for the monitoring of narcotics. Each time a prescription for a narcotic drug is entered, an automatic entry is also made in the electronic narcotics log kept by the CPSBC. If a physician receives a supply of a narcotic drug for practice use (or office use, as it is called), the supply will be entered into PharmaNet.

13.16 The CPSBC has a software program that allows it to analyse PharmaNet data by reference to patients, communities, physicians, groups of physicians or drug types. This flexibility enables the CPSBC to focus on particular prescribing issues. For example, it can keep a watch on individual physicians known to have a history of inappropriate narcotic prescribing. It can isolate high prescribers of a particular drug with a view to identifying outliers and problem prescribers. However, it does not monitor physicians by setting 'flags' at certain levels of prescribing. Given the wide scope of possible patient prescribing needs and the numbers of prescriptions involved, it was found that the setting of such flags would be unmanageable. The CPSBC can monitor the overall usage

(and the usage in a particular area) of specific drugs that are known to have a high value 'on the street'. It can monitor the prescriptions issued to patients known to be addicted to a narcotic. It can identify double scripting patients. It can look out for addicts who might trade one narcotic drug for another. Dr Taylor said that, without the facilities afforded by PharmaNet, the CPSBC would be 'groping in the dark' in its attempts to monitor the use of narcotic drugs.

13.17 Dr Taylor said that, since PharmaNet was introduced, it is not possible for a physician to prescribe for a patient who has died, because access to the patient's record is quickly stopped following the death. However, he agreed that access would remain open for a few hours after the death, during which time a dishonest physician, such as Shipman, might be able to prescribe in the patient's name and divert the drugs to his/her own use. It seems to me that the existence of an electronic record, in which transactions would be timed, would greatly improve the chances of detecting such dishonest practice if it occurred. Dr Taylor told the seminars that he thought that such prescribing would be likely to be picked up after the event.

13.18 Patients are allowed access to their PharmaNet record. They may also opt into a system whereby a key word (or password) has to be supplied by them before the pharmacist may access their record. Apparently, only about 1% of patients take up this option. In addition to any key word required, a pharmacist or physician wishing to access the system must use his/her user identification number. He or she and all members of his/her staff must sign a confidentiality undertaking before a user number will be issued. An electronic log is created every time the PharmaNet database is accessed so that browsing of the system can easily be detected.

13.19 The College of Pharmacists of British Columbia has prime responsibility for the security of the information in PharmaNet. Only that College and the CPSBC have unfettered access. The system contains information that is of great value to researchers and also to the Government. If the Government or a university research body seeks access, the permission of the College of Pharmacists must be obtained. The College has a committee which handles such applications. It has a duty to safeguard patient confidentiality. Information provided for research or Government purposes is anonymised before release.

Pharmacy Records and Inspection

13.20 Until the introduction of PharmaNet, community pharmacists in British Columbia had to keep a handwritten hard copy record of all transactions relating to narcotic drugs. This was known as the narcotic log and it appears to have been very similar to the controlled drugs register (CDR) still used in the UK. The arrangements for the safe keeping of narcotics and the narcotics log were inspected periodically by federal inspectors based in Ottawa. Since the introduction of PharmaNet, pharmacists can keep an electronic narcotics log and, in fact, the information required is automatically entered into the narcotics log as soon as the prescribing information is entered into the PharmaNet database. The pharmacist must be able to produce a hard copy of the log on request. Inspection of the arrangements for the safe keeping of narcotics and narcotic logs has now been transferred to the provincial Colleges of Pharmacists. In British Columbia, the

College of Pharmacists inspects pharmacy premises, safe keeping arrangements and narcotic logs.

Comment

13.21 I was very impressed by Dr Taylor's account of the systems in British Columbia. The need to keep strict control of narcotic drugs is given a high priority. The use of a special prescribing pad, issued only to doctors who can justify its use, seems to me to be a good idea. The requirement that this pad be used for all prescriptions for the relevant narcotic drugs, not only those to be paid for by the state, is very sensible and allows the monitoring of all usage, including the supplies obtained by a doctor for practice or personal stock. The use of individual prescriber numbers and an individual patient number greatly facilitates monitoring and analysis. The advantages of an integrated computerised system, such as PharmaNet, are obvious.

13.22 As Dr Taylor acknowledged, the demographic differences between the UK and British Columbia mean that some aspects of the British Columbia system could not be directly applied in the UK. I see the force of his suggestion that a UK body charged with the duty of monitoring the use of controlled drugs would have to be regionally based.

13.23 In Chapter Fourteen, I shall consider further the extent to which elements of the British Columbia system might be incorporated into the system in the UK.

Northern Ireland

13.24 Dr Mawhinney was accompanied at the seminar on 12th January by Dr Norman Morrow, the Chief Pharmaceutical Officer (CPO) for the Department. Dr Mawhinney gave a presentation outlining the system of monitoring and inspection of controlled drugs arrangements in Northern Ireland and both he and Dr Morrow answered questions raised by participants to the seminars.

13.25 Northern Ireland has a population of about 1.6 million and is served by approximately 1100 general practitioners (GPs), working in about 370 GP practices. The administration of primary care services is carried out by four health and social service boards and 15 local health and social care groups. The Misuse of Drugs Act 1971 and the Misuse of Drugs (Northern Ireland) Regulations 2001 (the Regulations), which are the same as the mainland Misuse of Drugs Regulations 2001, apply in the province.

The Inspectorate within the Department

13.26 The CPO is responsible for the development and implementation of an inspection and enforcement programme under the legislation covering medicines and pharmacies, including controlled drugs. An Inspectorate has been set up within the Department, comprising the CPO and a small professional group of staff, including a Medicines Inspector, a Misuse of Drugs Inspector (Dr Mawhinney), a Pharmacy Inspector and a Senior Enforcement Officer (with a police background) who can provide investigative support to all members of the team. The Inspectorate has close links with the police, who investigate suspected criminal offences, and with the Crown Prosecution Service (CPS),

which offers legal advice and prosecutes on the Department's behalf. It receives administrative support through the Health Protection Branch and professional assistance from the Medical College within the Department.

13.27 The Inspectorate is responsible for inspection and enforcement across a wide range of controlled drug regulation, not just in relation to community pharmacies. Dr Mawhinney explained that, in his capacity as Misuse of Drugs Inspector, he is responsible for the control of the manufacture and distribution of controlled drugs within the province. There is an overlap between his role and that of the Pharmacy Inspector. Dr Mawhinney meets the Pharmacy Inspector on a regular basis to discuss and decide upon strategy.

13.28 Inspectors participate in department-led training and inter-agency training. This covers such topics as the provisions of the Police and Criminal Evidence Act 1984, freedom of information and data protection. Inspectors also undergo continuing professional development. Recently, there has been an opportunity for inspectors to refresh their clinical knowledge. The provision of such training was under discussion at the time of the seminars.

13.29 The inspectors are also involved in the provision of education, which they regard as a key role. At undergraduate level, Dr Mawhinney assists in the design of the law and ethics element of the pharmacy degree at Queen's University, Belfast. The CPO and other members of the team are involved in postgraduate education. Members of the team provide advice and assistance to pharmacists and some undertake to talk to GPs about their responsibilities in connection with controlled drugs. Recently, GPs have been issued with CDRs, readily identifiable by a unique serial number, and have been 'bombarded' with advice about their responsibilities. Dr Mawhinney says that this appears to have resulted in improved compliance with the Regulations.

Inspection of Community Pharmacies

13.30 There are about 500 community pharmacists, who process in the region of 25 million prescriptions each year. This system of inspection is quite different from that operating in other parts of the UK. The Pharmaceutical Society of Northern Ireland, the province's equivalent of the Royal Pharmaceutical Society of Great Britain (RPSGB), does not carry out pharmacy inspections. The police have powers of entry to the business premises of producers and suppliers of controlled drugs, including community pharmacies, and can demand the production of records. They can search premises and seize property. However, they do not carry out routine inspections. For some time, in the 1980s, there was a police chemist inspection officer (CIO). It was found that this officer could not travel safely throughout the province without protection. The post was abandoned and the Police Service of Northern Ireland is not pressing for its reinstatement. It appears that there is no significant loss of useful intelligence about illicit drug use. This may be because, as Dr Mawhinney said, the problems of illicit drug usage are much less serious in Northern Ireland than in other parts of the UK. Although cannabis and 'Ecstasy' are quite widely used, there is far less illicit use of heroin, cocaine and methadone than elsewhere in the UK.

13.31 Legislation requires that all inspectors within the Inspectorate should be qualified pharmacists. Dr Mawhinney thinks this has significant advantages, particularly because the profession has a strong ethical core. He said, however, that he thought that a multidisciplinary team could perform the inspection function equally well.

13.32 Dr Mawhinney stressed that intelligence is vital to a successful system of inspection. The inspectors in Northern Ireland have access to intelligence from a wide range of sources, relating to such matters as, for example, the illicit use of controlled drugs, disciplinary proceedings taken by the General Medical Council and pharmacists suspected of fraud. An addicts register is still maintained in Northern Ireland. Perhaps the most important of these sources of intelligence is the Central Services Agency (CSA), the body performing the functions of the Prescription Pricing Authority (PPA) in the province. This body shares controlled drugs data with the Inspectorate.

13.33 Pharmacy inspections in the province combine the purposes and functions of those of CIOs and RPSGB inspectors on the mainland. They are unannounced. During the course of a routine inspection, the inspector will look at the whole operation of the pharmacy. He or she will also examine the CDR and will reconcile the entries with data obtained by the Department from controlled drug suppliers. This permits a check on the accuracy of entries in the 'drugs obtained' side of the CDR.

13.34 The inspector will also ask the pharmacist to produce the prescription forms for the latest prescriptions entered into the CDR. Such prescription forms are, as on the mainland, kept on the premises until they are sent for processing to the CSA. These prescription forms are checked for compliance with the Regulations and also against the entries in the CDR. The inspector will also examine the physical security of the controlled drugs cabinet. He or she might also gather intelligence.

13.35 The inspector also fulfils an educational role, comparable to that of the RPSGB inspectors on the mainland. He or she imparts news and information about recent developments in pharmacy and gives advice about good practice. Dr Mawhinney said that the combined educational and inspecting roles do not usually clash, provided that the inspectors 'tread carefully'.

13.36 There is only one Pharmacy Inspector for the whole province. He inspects about three pharmacies a day. He has good administrative support and spends only one day a week in the office. He manages to visit each pharmacy about once every 15 months. As he is also responsible for witnessing the destruction of 'out of date' or damaged controlled drugs, the infrequency of his visits can cause problems. These problems are not great, however, because the quantities accumulated are not excessive.

Inspection of Doctors' Surgeries

13.37 The Department has not the resources to carry out routine inspection of the controlled drugs arrangements in GPs' surgeries. However, the Department has arranged with the medical advisers of the health boards that, during their regular visits, known as 'probity visits', they will examine the CDRs held. Dr Mawhinney accepted that such examination is likely to be cursory but thinks that it serves a useful purpose, certainly as a 'stop-gap'. The

medical advisers report back any obvious cause for concern and Dr Mawhinney will then arrange a more formal inspection.

Inspection of Other Premises

13.38 The Inspectorate also inspects the premises of manufacturers and wholesalers, on behalf of the Home Office. It aims to inspect such premises at least once each year in the case of major wholesalers and at least once every two years in the case of minor wholesalers. It is also responsible for the inspection of the premises and arrangements made by veterinary practitioners and dentists, although these are not the subject of routine inspection.

13.39 The Inspectorate is also involved in the inspection of the arrangements made by secondary care providers. There are currently 21 hospital trusts in the province and the controlled drugs arrangements at their premises are inspected at least once every three years. The Inspectorate also has responsibility for a range of miscellaneous licensed authority holders including private hospitals, hospices, mountain rescue teams and forensic laboratories.

Monitoring of Prescriptions

13.40 The CSA is a public service body providing wide-ranging support to service deliverers. That support includes the provision of services analogous to those provided by the PPA on the mainland. By agreement with the Director of Pharmaceutical Services of the CSA, the Department's Inspectorate can, as I mentioned earlier, be provided with prescribing information.

13.41 The CSA and the Inspectorate jointly undertake both random and targeted analyses of controlled drug prescriptions. For its random analyses, every month, the CSA will select 12 pharmacies and will extract every Schedule 2 controlled drug prescription dispensed during a particular chosen month. The prescription forms are sent to the Inspectorate where they are examined to ensure that the prescriptions comply with the Regulations. The inspectors also look for trends that might reveal problems, either with particular practitioners or with particular types of drug. Just over 25% of pharmacies are examined annually in this way. Targeted analyses take place when the Department asks the CSA for the prescriptions relating to a particular pharmacy or prescriber or drug.

Private Prescriptions

13.42 Dr Mawhinney explained that far fewer private prescriptions are issued in Northern Ireland than on the mainland. The Department has an unofficial arrangement with community pharmacists whereby, if a private prescription is presented for a controlled drug, the Department will immediately be notified. This arrangement works well.

Enforcement

13.43 The Inspectorate has a flexible approach to enforcement, depending on the circumstances and, in particular, on the gravity of the breach discovered. Where it is found

that a doctor or pharmacist has been in technical breach of the Regulations, the initial approach is likely to be to give advice about future conduct, coupled with follow-up to ensure that the advice has been heeded. If the Inspectorate discovered that a GP was addicted to a controlled drug, the circumstances would be investigated by Dr Mawhinney and by the Department's Medical Officer. The relevant health board's medical adviser would also be involved. If it appeared that breaches of the criminal law had occurred, the doctor would be interviewed formally, and the advice of the CPS would be sought as to whether there should be a prosecution. Often, the decision is that the matter should be dealt with as a health problem. Where an investigation revealed more serious breaches of controlled drugs regulations, possibly including fraud, the circumstances would be fully examined by the Inspectorate and then referred to the CPS for prosecution on behalf of the Department.

Discussion at the Seminars

13.44 Dr Mawhinney said that he thought that the framework for inspection in Northern Ireland was very good, although the Inspectorate was under-resourced. He felt that the topic of controlled drugs was not given a great deal of prominence until something went wrong. The Inspectorate would be able to do a better job with only a modest increase in manpower.

13.45 Mr Alan Macfarlane, Chief Inspector of the Home Office Drugs Inspectorate (HODI), said that the Home Office found that co-operation between his department and the Northern Ireland Inspectorate worked well.

13.46 Dr Clare Gerada, Director and Chair of the Royal College of General Practitioners National Advisory Group for Drug Misuse, observed that those responsible for controlled drugs in Northern Ireland were fortunate in that there was very little private prescribing in the province. She said that in England, prescribing on the NHS could be closely monitored but there was no central monitoring or audit of private prescribing of controlled drugs. Private prescriptions were far more likely to be for amounts that fall outside national guidelines. She was of the view that private prescribing consequently gave rise to far greater risks of abuses, such as diversion, than did NHS prescribing. She felt that this was a 'big problem'.

13.47 Dr John Grenville, on behalf of the British Medical Association, said that it appeared to him that the size and location of the inspection operation in Northern Ireland was 'exactly right'. Its value, he accepted, is that it is 'small enough to know what is going on but big enough to have the expertise necessary'. Dr Morrow agreed that the size of the organisation in Northern Ireland did confer certain advantages but also emphasised that what is important is 'to allow the facility to have structures which suit a particular context' so that there is 'some freedom of operation'. He said that, in his view, it should be possible to transfer this situation into England. Dr Grenville suggested that, if this were to happen, then the best size would be something that covered an area equivalent to that covered by a strategic health authority. Dr Morrow agreed and added that a primary care trust (PCT) covers too small an area to allow for the operation of an effective controlled drugs inspectorate.

Comment

13.48 I was very impressed with the way in which the system of inspection of arrangements for controlled drugs operates in Northern Ireland. The centralised nature of the Inspectorate, and its integration with the Department, confer undoubted benefits. I agree with Dr Grenville that the size of the province makes it suitable for a centralised Inspectorate, whereas England would require a regional Inspectorate.

13.49 It seems to me that the main advantage of the system in Northern Ireland is that the Inspectorate covers all aspects of the use and abuse of controlled drugs. On the mainland, the arrangements for inspection are fragmented. Although the HODI has overarching responsibility for controlled drugs, its efforts are focussed mainly on import and export control, the inspection of manufacturers and large-scale suppliers and the issue of licences. With its present resources, it cannot be closely involved with the issues that arise in connection with pharmacies, doctors and poor prescribing practice. In any event, the HODI has no medical or pharmaceutical expertise; it is an investigative organisation with law enforcement functions. Pharmacy inspections are carried out by police CIOs who, individually, may be very interested in and focussed on controlled drugs but are part of an organisation that is not particularly interested in such matters. They too have no real medical or pharmaceutical expertise. There is no proper arrangement for the inspection of GPs' surgeries or dispensaries or for the provision of advice to GPs. PCTs have a great number of other responsibilties and cannot be expected to focus on controlled drugs. The PPA does an excellent job but has no clearly defined links with inspection systems. It seems to me that there is much to be said for an inspectorate, like that in Northern Ireland, which is focussed solely on its responsibility for the inspection and monitoring of all aspects of controlled drug use.