

**THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN**

**RESPONSE TO THE RECOMMENDATIONS OF  
THE SHIPMAN INQUIRY FOURTH REPORT**

*The regulation of Controlled Drugs in the community*



**Royal  
Pharmaceutical  
Society  
of Great Britain**

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the regulatory and professional body for pharmacists in England, Scotland and Wales. The primary objective of the RPSGB is to lead, regulate and develop the pharmacy profession.

**November 2004**

# **THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN**

## **Response to the Recommendations of the Shipman Inquiry Fourth Report- 'The Regulation of Controlled Drugs in the Community'**

### **Introduction**

The Fourth Report of the Shipman Inquiry was published on 15th July 2004. The Report identifies systemic shortcomings which permitted Shipman to obtain the large quantities of controlled drugs used to kill his victims and makes 33 recommendations to provide better patient protection.

The Royal Pharmaceutical Society of Great Britain (RPSGB) strongly supports action to strengthen the safeguards that prevent poor practice and ensure that any health professional posing a risk to public safety is identified and appropriate action is taken promptly. The RPSGB advocates joint working between healthcare professional regulators, employers and inspection bodies to continuously improve practice.

The RPSGB welcomes the Report and in this paper makes suggestions to secure effective implementation of the recommendations.

### **The Royal Pharmaceutical Society of Great Britain**

The Royal Pharmaceutical Society of Great Britain performs various roles on behalf of both the public and its members. It is the regulatory and professional body for pharmacists in all aspects of pharmacy practice. It has a statutory duty to maintain the register of pharmacists and pharmacy premises; there are approximately 12,500 pharmacy premises in Great Britain, and around 48,000 member pharmacists working in all sectors of the profession.

The key duty of the RPSGB is safeguarding the public. It is responsible for enforcing the laws controlling the conduct of pharmacies and the sale of medicines and poisons.

The RPSGB also maintains the standards of the pharmacy profession through good practice advice, inspection, training and its disciplinary procedure. It oversees and regulates the training and professional accreditation of pharmacists, sets standards, regulates the inspection of pharmacy premises, and makes the profession's contribution to government, the media and other stakeholders. The RPSGB supports the development of the science and practice of pharmacy and promotes pharmacy as a career. It has a significant publishing division, producing both reference volumes and journals; possesses a unique library and museum and organises conferences and other events of international interest.

The RPSGB recognises that inspection and audit alone cannot prevent the kind of failings identified by the Inquiry and is working to modernise and reform its role, constitution and ways of working. The aim is to create a modern, effective and efficient regulatory and professional body for pharmacy, committed to quality and improvement and meeting its responsibilities to the public and the profession.

Although the Inquiry was informed about the systems in Scotland and Wales, the recommendations are confined to the systems in England. As the RPSGB is the regulatory and professional body for pharmacists in England, Scotland and Wales, it will need to ensure that any guidance or professional requirements are appropriate for all registered pharmacists practising in Great Britain.

### **The RPSGB Code of Ethics**

In addition to observing legal requirements, pharmacists are expected to adhere to the requirements of the RPSGB's Code of Ethics.<sup>1</sup> The Code of Ethics sets out the key professional responsibilities of pharmacists and details the professional requirements for the services they provide.

One of the key responsibilities of a pharmacist is to 'act in the best interests of patients and other members of the public'. Pharmacists can often be faced with situations where legal and ethical requirements conflict. In such circumstances pharmacists are required to use their professional judgement to decide the most appropriate action and must be able to justify the decision they make. The RPSGB provides pharmacists with advice and guidance on making such judgements.

### **The RPSGB Disciplinary Process**

The RPSGB has a well-developed disciplinary process to deal with complaints and concerns about pharmacists and pharmacies raised by members of the public, other pharmacists, or other health professionals.

A RPSGB inspector undertakes a formal investigation. If the inspector believes there are matters which warrant it, the RPSGB's Infringements Committee considers the case. The Infringements Committee consists of pharmacists and non-pharmacists and is chaired by a lay person appointed by the RPSGB Council. If the Committee finds infringements of standards, poor performance or a breach of the law, it has a number of sanctions available including: issuing a formal warning; ordering a prosecution; reference to the police or making a complaint to the Statutory Committee.

The Statutory Committee is the formal disciplinary committee of the RPSGB, established under the Pharmacy Act 1954<sup>2</sup>. It comprises a chairman appointed by the Privy Council, who is a lawyer and five other members appointed by the RPSGB Council, who are a combination of pharmacists and lay members, none of whom are Council members. The Statutory Committee may take the following action: issue a reprimand; or remove a pharmacist or pharmacy from the register to prevent the pharmacist from practising or the pharmacy from operating.

Under proposals for change further powers are currently being sought from Parliament including suspending a pharmacist from practice, imposing conditions on pharmacists practice and preventing pharmacists who are unfit because of ill health from practising.

Appendix 1 summarises the legal responsibilities of pharmacists.

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<sup>1</sup> Medicines Ethics and Practice- a Guide for Pharmacists, RPSGB

<sup>2</sup> The Pharmaceutical Society (Statutory Committee) Order of Council 1978, No.20

## **Inspection of Premises Holding Controlled Drugs**

### **RPSGB Inspectors**

RPSGB inspectors visit all registered pharmacy premises approximately every 18 to 24 months to ensure that the legal requirements and professional standards of practice are observed. The RPSGB has enforcement duties under the Poisons Act 1972, the Pharmacy Act 1954 and has been given powers and duties to enforce many provisions of the Medicines Act 1968.

Currently the RPSGB has no duties or enforcement authority under the Misuse of Drugs Act 1971 or its Regulations, but its inspectors are authorised to witness the destruction of controlled drug stock and are empowered to require the production of a controlled drug register.

The RPSGB methods of inspection have evolved over the years with the Inspectorate providing developmental and supportive guidance to the profession, in addition to carrying out enforcement responsibilities as necessary. The supportive role of the RPSGB Inspectorate has improved standards and clinical governance within community pharmacy and has become an integral part of the RPSGB inspection process.

### **Chemist Inspection Officers**

Chemist Inspection Officers (CIOs) are appointed by police forces at the direction of the Home Office. They inspect the stocks and records of controlled drugs in retail pharmacies to ensure that the law relating to controlled drugs is upheld.

The guidance for CIOs indicates twice yearly visits to retail pharmacies, but in practice few forces are able to meet this target. Not all police forces employ a CIO and according to the Shipman Inquiry Fourth Report, more than half the current CIOs also perform other duties.<sup>3</sup>

CIOs have no authority to inspect or monitor doctor's surgeries (including dispensing doctors), hospitals (other than the hospital pharmacies which are registered pharmacy premises), or other health professionals who use controlled drugs such as dentists and veterinary surgeons.

### **Home Office Inspectors**

The Home Office has a team of inspectors, who having assessed risk, undertake targeted inspections of pharmaceutical manufacturing companies. Any alleged criminal offences which come to light through such inspections are reported to the police and professional matters of concern are reported to the appropriate regulatory body.

### **Inspection of General Practitioners Surgeries by NHS Bodies**

In England, General Practitioner's controlled drug registers and storage facilities were previously inspected by Regional Medical Officers. The demise of these routine inspections not only reduced the level of support and guidance available to doctors, but was also identified as one of the systems failures in the Shipman case.<sup>4</sup>

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<sup>3</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community paragraph 9.3

<sup>4</sup> Baker R (2004) Patient centred care after Shipman J.R.Soc Med 2004, 97:161-165

A recent survey highlighted GP's concerns about the lack of routine inspection, with 71% of GPs surveyed stating that they would welcome regular inspection.<sup>5</sup>

### **Developing Inspection Arrangements**

The RPSGB welcomes the recommendation that dispensing doctors and doctors' surgeries should be inspected in the same way as pharmacies. The RPSGB suggests that inspection is based in Primary Care Trusts with regional and Healthcare Commission oversight and support

To ensure protection of patients, consideration will need to be given to the inspection and monitoring of the other health professionals who can currently prescribe, supply or administer controlled drugs e.g. dentists, veterinary surgeons, nurses and midwives and to the practices adopted within care homes and similar establishments. The Fourth Report is not specific about the future requirements for inspection of hospitals. This is a major issue that may require special consideration. This should cover specialist areas such as accident and emergency, theatres, and outpatient departments as well as hospital wards and pharmacies.

The RPSGB would wish to see uniform inspection principles but particular arrangements will be needed in different environments. As a leading authority in the management of medicines in the community the RPSGB believes it could contribute significantly to this work.

Peer review, audit and professional revalidation will be important tools supporting the inspection and monitoring regime. 'Desktop monitoring' based on intelligence from a number of sources will help identify potential areas of concern and allow targeted inspection and investigation, in addition, specific IT systems will be required.

In the RPSGB's experience, the routine inspection of pharmacy premises has been an important tool in identifying poor practice. There is a danger that relying on selective inspection may fail to detect problem areas. Furthermore as highlighted in the review of the Commission for Health Improvement (CHI) inspection processes, the prospect of inspection can, in itself, act as a catalyst for review and improvement of systems.<sup>6</sup> Thus, it would appear that regular inspection should be an essential element of controlled drug regulation.

Consistency of inspection requires the setting of clear standards that are both transparent and proportionate. The current Healthcare Commission method of inspecting against specific standards, using criteria to help determine whether standards have been reached, is a helpful model.

The multidisciplinary nature of the suggested inspectorate would be a key strength with the combined expertise of pharmacists, doctors, inspectors and investigators providing the necessary knowledge of legal requirements, clinical practice and data analysis. The RPSGB will also collaborate with the new State Veterinary Service to develop the controlled drug inspection arrangements for the veterinary service.

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<sup>5</sup> Baker R, Moss P, Pankhania J (2004) Investigation of systems to prevent diversion of opiate drugs in general practice in the UK. *J.Qual.Saf Health Care* 2004 13:21-25

<sup>6</sup> Day P, Klein R (2004) *The NHS Improvers, a study of the Commission of Health Improvement.*

## **The Current Role of the RPSGB Inspectorate and Potential for Development**

RPSGB inspectors not only have experience in investigative procedures and legal requirements, but the clinical background necessary to identify irresponsible or inappropriate prescribing of controlled drugs.

Throughout the Inquiry it was queried why RPSGB inspectors, with clinical background and knowledge, examined controlled drug registers for administrative compliance, but CIOs, with no clinical background, examined registers to make clinical assessments of prescribing.

*'I accept that the 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 much better equipped than CIOs to detect such signs.'*<sup>7</sup>

The current skills and knowledge of the RPSGB Inspectorate mean it is ideally placed to take a central role in the formation of controlled drug inspection. The RPSGB inspectorate has the professional expertise to carry out the controlled drug inspection function, but clearly additional funding would be necessary, especially if it were to extend to GP surgeries, hospital pharmacies and other premises holding controlled drugs.

Any development of the RPSGB Inspectorate's role may require additional powers under both Misuse of Drugs and Medicines Act legislation. Consideration might also need to be given to extending current powers of entry, search and seizure, and provision of powers of suspension, arrest and access to financial information.

### **Scope of Existing Powers**

Under the existing powers and authorities RPSGB inspectors could carry out the following:

#### Controlled Drug Registers

- Inspection of the controlled drug registers to ensure compliance with the Misuse of Drugs Regulations 2001.
- Clinical assessment to determine irresponsible and /or inappropriate prescribing.

#### Safe Custody

- Routine inspection of safe custody provisions and advice on best practice. (*NB enforcement would require additional powers and delegated authority to issue Certificates of Exemption from the Misuse of Drugs (Safe Custody) Regulations 1973*).

#### Destruction of controlled drugs

- Witness destruction of date expired controlled drugs.

### **Scoping Exercise to Develop a New Controlled Drug Inspection Regime**

The RBSGB suggests a comprehensive scoping exercise to achieve continuous improvement in practice within a framework of light touch regulation preventing undue burden on healthcare professionals or tax-payers.

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<sup>7</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.193

Matters which such an exercise could cover are:

- the purposes of the inspection regime;
- the most effective inspection methods;
  - premises to be inspected
  - frequency of visits
  - the inspection data to be used and for what purposes the data should be reviewed
  - the extent to which data and information will be shared and with whom
- how existing resources and arrangements for inspection will be used in the development of the new regime;
- the professionals to be included in the new inspection arrangements;
- the bodies with which the new regime should collaborate and how this will be achieved;
- how the advantages of self-regulation are to be preserved, alongside guaranteed independence, to protect the rigour of scrutiny and enforcement;
- to whom the inspectorate will be accountable;
- location of the inspection body;
- training, monitoring and evaluation of inspection to ensure capacity to identify inappropriate prescribing, unprofessional practices, diversion of controlled drugs and risk.

The Report said, “*the Inspectorate should be based on ‘neutral ground’ so that it cannot be dominated by either the medical or the law enforcement ethos. As it happens neither the Department of Health nor the Home Office would be willing to provide a base for such an inspectorate.*”<sup>8</sup>

The critical drivers for the inspectorate will be to what extent it can command public and professional confidence and deliver safeguards not currently in place.

The RPSGB recognises the need to enhance the monitoring and auditing of controlled drugs across Great Britain. Consistent, robust inspection and data analysis will be necessary throughout the controlled drug supply chain.

The RPSGB is concerned that any new arrangements have appropriate oversight and accountability. It was suggested in an earlier part of the Report that the Inspectorate could be based at Regional Government Offices.<sup>9</sup> However, the current move to reduce the number of bodies working at arms length from the Department of Health<sup>10</sup> could have an impact on the way in which the inspection and monitoring of controlled drugs will be developed. Ministers may decide to utilise and adjust the existing inspection arrangements with inter-agency working and information sharing forming a key part of controlled drug inspection.

Consideration needs to be given to whether the same inspection arrangements will apply across England, Scotland and Wales. If they do not, arrangements should deliver consistent and coherent programmes of inspection across the three countries.

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<sup>8</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.201

<sup>9</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.193

<sup>10</sup> Department of Health (July 2004) Reconfiguring Department of Health’s Arm’s Length Bodies

## **The Report's Recommendations**

While the Fourth report is concerned with the regulation of controlled drugs in the community, any changes to Misuse of Drugs legislation should apply across the healthcare sectors, with variations according to the particular sector.

The Report states that certain recommendations should not apply to Schedule 5 controlled drugs. The RPSGB supports this but also questions whether any of the recommendations should apply to Schedule 5 controlled drugs. The RPSGB endorses a review and restructuring of the current schedules in the Misuse of Drugs Regulations to ensure that those drugs with the greatest abuse potential are subject to tight controls, while controlled drugs posing less danger face less stringent requirements.

In responding to the recommendations, the extent to which they apply across the current schedules of controlled drugs has not been considered in detail as it has been assumed that the schedules will be revised.

## **Inspection Arrangements**

### **RECOMMENDATION 1**

'A controlled drugs inspectorate should be created, comprising small multidisciplinary inspection teams, operating regionally but co-ordinated nationally. Each team would include pharmacists, doctors, inspectors and investigators, at least some of whom would have a law enforcement background. The inspectorate would be responsible for inspecting the arrangements in pharmacies, dispensaries and surgeries, as to both the safe keeping of stocks of controlled drugs and the maintenance of controlled drugs registers (CDRs) and other records. It could be responsible for the supervised destruction of controlled drugs. The inspectorate would also be responsible for the monitoring of the prescribing of controlled drugs by means of examination of prescribing analysis and cost (PACT) data, which would include information derived from NHS and private prescriptions and requisitions. It might be responsible for the issue of special controlled drug prescription pads. If thought appropriate it might also assume many of the inspecting and other functions currently performed by Home Office drugs inspectors. Inspectors and investigators would require access to background information about a doctor or pharmacist under scrutiny. There must be the facility to investigate expertly any irregularities or unusual features discovered as the result of such inspection and monitoring'.

### **Response 1 from RPSGB**

**The RPSGB welcomes the creation of a multidisciplinary controlled drug inspectorate which builds on existing clinical governance arrangements. To ensure public safety the RPSGB recommends that the inspection and monitoring of controlled drugs should extend to all health professionals and establishments where controlled drugs are supplied or administered.**

**The RPSGB inspectorate has the professional expertise required to inspect and monitor controlled drugs and should be centrally involved in the development of multidisciplinary controlled drug inspection.**

**The RPSGB Inspectorate could extend its enforcement activity both within registered retail pharmacies and to other establishments, tailoring inspection to the establishment as appropriate. Resources and appropriate powers will be necessary to achieve this.**

## **Prescribing Rights of Medical Practitioners**

### **RECOMMENDATION 2**

'A medical practitioner should be entitled to prescribe or administer controlled drugs only if s/he needs to do so for the purposes of the 'actual clinical practice' in which s/he is engaged. For the vast majority of doctors, the existence or otherwise of such a need will be obvious. A practitioner who wishes to prescribe controlled drugs may, where the need is not obvious, have to justify such need when applying for the issue of a special controlled drug prescription pad'.

### **Response 2 from RPSGB**

**The RPSGB welcomes the Report's recommendation that medical practitioners should only prescribe or administer controlled drugs for the purposes of 'actual clinical practice' and recommends implementation of a system, updated daily, to permit a pharmacist to confirm that a practitioner is 'licensed to practise'.**

To ensure patient safety only those practitioners who have displayed up to date clinical knowledge and skills should be able to prescribe controlled drugs.

Restricting medical practitioners to prescribing or administering controlled drugs for the purpose of the 'actual clinical practice' in which they are engaged is an important patient safeguard.

The RPSGB welcomes the Report's definition of 'actual clinical practice' as *'the existence of a direct professional relationship between the prescriber and patient'*.<sup>11</sup> This definition will help address concerns about practitioners prescribing for patients without adequate knowledge of the patient's health or medical needs e.g. UK doctors prescribing for patients resident abroad. However, the RPSGB expects that this definition may cause some confusion for prescribers and additional guidance will be necessary.

The implementation of this recommendation will require adequate systems to be in place to allow pharmacists to confirm a practitioner's registration status and competency to prescribe controlled drugs. To ensure patient care is not compromised checking systems will need to be easily accessible 24 hours a day, seven days a week.

Any new system must ensure minimum bureaucracy coupled with maximum safeguards to prevent detriment to patient care. The procedure for obtaining controlled drug prescription pads must be clear and well publicised.

### **RECOMMENDATION 3**

'It should be a criminal offence for a doctor to prescribe a controlled drug for him/herself, or to self-administer a controlled drug from his/her own or practice stock save in circumstances of emergency, which circumstances should be covered by an appropriately worded statutory defence. The doctor should be required to declare the position on the prescription'.

### **RECOMMENDATION 4**

'When a general practitioner (GP) has members of his/her immediate family on his/her list (which should happen only vary rarely), s/he should inform his/her local primary care trust (PCT) of the position. It should be unacceptable for a doctor to prescribe a controlled drug for an immediate family member who is not on his/her list, save in circumstances of emergency.

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<sup>11</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.14

In all cases where a doctor prescribes a controlled drug for a member of his/her immediate family, the doctor should be required to declare on the prescription his/her relationship to the patient and, if it is the case, that s/he is prescribing in an emergency'.

### **Response 3 & 4 from RPSGB**

**The RPSGB recommends, except in emergencies or specified circumstances (e.g. in certain rural areas), that self-prescribing/ prescribing for immediate family of controlled drugs should be prohibited. Guidance should be drafted for medical practitioners and pharmacists on what circumstances constitute 'an emergency'. This recommendation should not apply to Schedule 5 controlled drugs.**

The RPSGB has previously expressed the view that routine self-prescribing or prescribing for families or friends should be prohibited, but recognises that in an emergency it would be wrong to deprive a patient (including a doctor or a member of his family) of medical attention. In such circumstances the RPSGB recommends that only the minimum quantity of controlled drug necessary for that emergency be prescribed. The Report's definition of the term 'immediate family'<sup>12</sup> is important to the consistent implementation of Recommendation 4.

The RPSGB believes that these recommendations should be a legal as well as a professional requirement. The General Medical Council's Guidance on Good Practice currently states '*doctors should avoid treating themselves or close family members wherever possible*'.<sup>13</sup> Despite this pharmacists are routinely presented with prescriptions for either the medical practitioner themselves, or a member of their family. A legislative prohibition (with appropriate statutory defences) would ensure that self-prescribing or prescribing for immediate family only takes place when absolutely necessary. The RPSGB suggests that an explanatory prescription endorsement should be required in such circumstances.

The application of these restrictions to Schedule 5 controlled drugs would be illogical as some of these drugs can be purchased over the counter from a registered pharmacy.

### **RECOMMENDATION 5**

The General Medical Council (GMC) should make plain that it will be regarded as professional misconduct for a doctor to prescribe controlled drugs for anyone with whom he/she does not have a genuine professional relationship.

### **RECOMMENDATION 6**

A medical practitioner convicted or cautioned in connection with a controlled drugs offence should be under a professional duty to report the conviction or caution to the GMC, which should immediately consider what, if any, interim action should be taken and should report the facts and its own action to the practitioner's employer or PCT.

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<sup>12</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.28

<sup>13</sup> [www.gmc-uk.org/standards/default.htm](http://www.gmc-uk.org/standards/default.htm)

## RECOMMENDATION 7

The Government should commission an independent review and audit of the way in which the GMC and PCTs are using their powers to restrict the rights of medical practitioners involved in controlled drugs offences to prescribe and administer controlled drugs. Only if satisfied that these powers are being properly exercised for the protection of the public should the Government allow the provisions of section 12 of the Misuse of Drugs Act 1971 to remain in abeyance or to be repealed.

## RECOMMENDATION 8

Whenever a restriction is placed on a doctor's prescribing powers, this information must promptly be made available (preferably by electronic means) to those who need to know it, especially pharmacists who require access to such information at all times.

### **Response 5, 6, 7 & 8 from RPSGB**

**The RPSGB supports limitations on prescribing rights for those prescribing controlled drugs. Best practice in this area can be achieved by sound professional guidance being issued by the GMC and others e.g. The National Prescribing Centre. In addition the NHS IT strategies should support greater access by pharmacists to information about the registration status of those individuals who prescribe controlled drugs.**

The RPSGB welcomes the recommendation that prescribing controlled drugs by a doctor for anyone with whom he/she does not have a professional relationship, should be regarded as misconduct. The RPSGB would be pleased to collaborate with the GMC to disseminate guidance on this issue.

The recommendation that medical practitioners should inform the GMC of any conviction or caution in connection with a controlled drug offence is also welcomed and the RPSGB will provide similar guidance for pharmacists and pharmacy technicians in its revised Codes of Ethics. Other regulators should be encouraged to adopt the same requirement. The arrangements for limiting prescribing powers in these circumstances should be made clear and should be implemented without delay.

The RPSGB supports the proposal for an independent review of the way in which the GMC and primary care organisations are using their powers to restrict the prescribing rights of medical practitioners involved in controlled drug offences. The current Regulations require redrafting and updating to make them fit for purpose. The RPSGB foresees no problem with the repeal of Section 12 of the Misuse of Drugs Act 1971.

## **Prescriptions**

### RECOMMENDATION 9

'A special printed form should be introduced for use when prescribing a controlled drug, whether within the NHS or on a private basis. Pads of such forms should be supplied only to doctors who need to prescribe such drugs in the course of their clinical practice. For the time being, these forms should be completed by hand, to the extent required by the Misuse of Drugs Regulations 2001 (MDR 2001). However, prescribers should be encouraged, where practicable, to print the prescribing information on the prescription form using a computer and to copy the information by hand. The existing handwriting requirements should not be repealed until Government is satisfied, by the conduct of pilot schemes, that the arrangements for computer generation and/or transmission of controlled drug prescriptions are sufficiently secure.'

### **Response 9 from RPSGB**

**A standardised private prescription form should be developed for use within the community setting. The current NHS prescription forms for controlled drugs should be streamlined. A central body should clinically monitor private and NHS prescribing.**

**Computer generated controlled drugs prescriptions should be implemented as soon as possible and electronic transmission of controlled drug prescriptions should be adopted once robust, secure systems are in place.**

A number of different types of NHS prescription forms are currently used to prescribe controlled drugs in the community. The arrangements for prescribing controlled drugs by instalment for the treatment of drug misuse are complex, with Scotland, England and Wales each having different prescription forms and prescribing restrictions. Prescribers and pharmacists can at times be confused as to which controlled drugs may be prescribed by instalment on a particular NHS prescription form and patient care may be compromised when the prescription forms are used inappropriately.

There is no standardised prescription form within the private sector and, unlike NHS prescriptions, no analysis or monitoring of private prescribing is carried out.

The Report states that the precise practical details would require consideration but suggests the special printed form should be

*'similar to the FP10 but should be printed on paper of a different colour. It should have a tick box to show whether the drugs are being prescribed on the NHS or privately.'*<sup>14</sup>

The introduction of a single controlled drug prescription form for use in the community setting would standardise prescribing within the NHS and private sector and streamline current NHS arrangements. However, the recommendation that a tick box be used on controlled drug prescriptions to denote whether the prescription is private or NHS may be a potential source of confusion to patients and could present a problem to pharmacists should the prescriber fail to tick a box. Additionally, special controlled drug prescription pads could increase the number of prescription pads a GPs requires, which may pose a security risk.

An alternative solution would be for a standardised private prescription form to be introduced, based on the format of NHS prescriptions but distinct enough to prevent confusion. For controlled drug prescribing within the NHS, consolidation of the current community NHS prescription forms would enable misuse to be more readily identified and help prevent patient care being compromised as a result of forms being used incorrectly.

Consolidation of prescribing requirements in Misuse of Drugs legislation, rather than NHS legislation, would ensure consistency across the UK. However, any changes to legislation about prescription forms should not impede the current arrangements for prescribing controlled drugs in hospitals and similar institutions.

Standardisation of prescription forms will not by itself increase the level of scrutiny and control sufficiently. This can only be achieved if private and NHS prescription forms are monitored collectively.

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<sup>14</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.75

The RPSGB is concerned that computer generating controlled drug prescriptions and then adding the information by hand will be an onerous task that will not provide significant benefits to patient care, or reduce the risk of forgery, and would expect that there is insufficient space on current forms to permit this information being written in a legible manner. The RPSGB do not support this proposal.

The 'own handwriting' requirement for Schedule 2 and 3 controlled prescriptions was intended to ensure the prescriber personally wrote the prescription, making the prescription more difficult to tamper with or forge. A person would have to forge most of the information on the prescription, not just the signature.

Currently some prescribers with a large number of patients regularly requiring controlled drug prescriptions, e.g. treatment of drug misuse, have exemption from the handwriting requirements. The prescriber must sign the prescription but other details can either be computer generated (except the date), or rubberstamped onto the prescription.

It can be argued that computer printed prescriptions for controlled drugs will reduce the chance of controlled drug prescriptions being altered or forged, reduce the number of technical errors in prescriptions and improve patient safety by reducing the likelihood of the prescription being misread. A Home Office consultation document released in May 2003 proposed that computer printed Schedule 2 and 3 controlled drug prescriptions be permitted, stating that '*there is probably little risk that the proposed change would result in more fraudulent prescriptions for controlled drugs*'.<sup>15</sup>

A review of the instances of forgery in controlled drug prescriptions where the prescriber has handwriting exemption compared with hand-written prescriptions may be of value in assessing the current risks.

Systems must be sufficiently secure before controlled drug prescriptions can be transmitted electronically, thus robust paper based prescribing systems will be needed until such time as the electronic transmission of prescriptions is in widespread use. The RPSGB supports the implementation of computer printed controlled drug prescriptions at the earliest opportunity.

#### RECOMMENDATION 10

'The special form should be in such format as will enable the Prescription Pricing Authority (PPA) to scan the prescribing information into its database so as to permit subsequent analysis and monitoring'.

#### **Response 10 from RPSGB**

**The RPSGB agrees with the recommendation that all controlled drug prescriptions are analysed and monitored and recommends speedy action if anomalies are identified.**

The RPSGB agrees that the submission of all controlled drug prescriptions to the PPA, or similar body, will allow comprehensive monitoring of private and NHS prescribing and thereby enhance public safety. However, as pharmacists are currently required to keep all private prescriptions for 2 years from the date of last supply, legislative change will be required to implement this recommendation.

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<sup>15</sup> Home Office Public Consultation- Computer Generated Prescriptions, Registers and Requisitions for Controlled Drugs, 21 May 2003.

#### RECOMMENDATION 11

'The special form should show the GMC registration number of the medical practitioner to whom the pad of forms has been issued. No other practitioner should be permitted to use it. The form should require the prescriber to indicate whether the prescription has been issued under the NHS or privately. Each prescription would have its own unique identification number'.

#### **Response 11 from RPSGB**

**The RPSGB supports the Report's suggestion that prescribers should use their own pad for all prescription only medicines as a matter of good practice.<sup>16</sup> A prescriber should be required to record their name and professional registration number (or similar unique identifier) on each prescription they issue. Failure to do so should not invalidate the prescription so long as the pharmacist judges this to be a purely technical breach. The RPSGB welcomes the opportunity to issue guidance on what constitutes a technical breach and would wish to see legislative changes to cover these requirements.**

The inclusion of a prescriber's professional registration number on a prescription to enable accurate attribution to the authorising prescriber is a welcome recommendation. This will permit accurate auditing and monitoring of prescribing habits and help identify abnormal prescribing. It will also aid pharmacists in their record keeping requirements for controlled drugs.

A prescriber's failure to enter this number should not automatically invalidate the prescription if the pharmacist judges this to be a technical breach. The pharmacist would need to confirm the prescriber's number retrospectively to comply with subsequent recommendations for controlled drug register records. The RPSGB suggests that this omission could be dealt with in a similar manner to other technical defects, with a pharmacist being permitted to add the missing details without returning the prescription to the prescriber.

A prescriber's omission of their number from a controlled drug prescription should be monitored by the PPA, or similar body, and action taken if there is persistent failure to comply.

A balance should be struck between audit trail and the need for timely access to treatment. There may be times where preventing a prescriber from using another prescriber's prescription pad may compromise patient care e.g. where there is a need to prescribe but a prescriber does not have access to his/her own prescription pad. If a prescriber uses a prescription pad other than their own, there should be a requirement for an explanatory endorsement and for the prescriber to print their name and registration number on the prescription.

#### RECOMMENDATION 12

'The special form should provide the prescriber with a space in which to record a brief description of the condition for which the controlled drug has been prescribed. Prescribers should be expected, as a matter of good practice, to ask patients to consent to the provision of this information'.

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<sup>16</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.92

*'I hope that pharmacists will be given access to the common spine so that they will be able to find out the nature of the condition for which any medication has been prescribed'.<sup>17</sup>*

### **Response 12 from RPSGB**

**The RPSGB is pleased that the Inquiry has recommended that pharmacists have access to patient care records. The RPSGB agrees that this is the way to provide pharmacists with the information they need to be satisfied that the prescribing is appropriate. This will provide a better patient safeguard than including the patient's medical condition on the prescription. Any change in practice should be accompanied by a campaign to ensure that patients are aware that a wider group of healthcare professionals will have access to this information. The awareness campaign should emphasize the safeguard this will provide for patients.**

Presently details of a patient's medical condition are only recorded in the GP's records there is no requirement for such details to appear on the prescription. The report highlights that had the patient's medical condition appeared on the prescription, it would have been much more difficult for Shipman to obtain single 30mg ampoules of diamorphine.

The RPSGB's Code of Ethics requires that *'Every prescription must be professionally assessed by a pharmacist to determine its suitability for the patient'*.<sup>18</sup> At present pharmacists do not usually have access to patient care records and this may inhibit their ability to confirm that the prescription is appropriate for the condition being treated.

The RPSGB has been concerned that a requirement to include the medical condition on a controlled drug prescription might compromise patient confidentiality and that the pharmacist might be compelled to require such information before a prescription could be dispensed. The RPSGB is pleased that the Report does not recommend details of a patient's condition be a compulsory requirement, or that a pharmacist should be prevented from dispensing the prescription if such information is not present.

The NHS National Programme for IT will facilitate pharmacist access to patient care records.

### **RECOMMENDATION 13**

*'Consideration should be given to requiring that the patient's NHS number or some other patient-specific identifier should be included on the special form'.*

### **Response 13 from RPSGB**

**A patient specific identifier number should be entered on every prescription form. Failure to do so should not invalidate the prescription so long as the pharmacist judges this to be a purely technical breach.**

Requiring a patient specific number on controlled drug prescriptions may help detect patients who are obtaining prescriptions from multiple sources. Consideration will need to be given to whether this would be a statutory requirement and what implications there would be if the prescriber failed to enter this number on the form.

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<sup>17</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.117

<sup>18</sup> Medicines, Ethics and Practice, Edition 28 Page 89

The RPSGB would not wish to see patients deprived of essential treatment due to technical omissions of this nature.

A patient specific identifier currently appears on every computer-generated prescription issued in Scotland. This is a 10-digit identifier, the first 6 digits are the patient's date of birth and the remaining four are unique to the patient.

#### RECOMMENDATION 14

'The amount of a controlled drug that can be dispensed on a single prescription should be limited to a supply sufficient to last 28 days. This restriction would not apply to drugs in Schedule 5 to the MDR 2001'.

#### **Response 14 from RPSGB**

**The RPSGB supports a restriction on the duration of controlled drug treatment that can be prescribed at one time, provided patient care is not compromised. The RPSGB recommends that pharmacists have discretion to dispense a maximum of 28 days supply of medication against a controlled drug prescription calling for more than 28 days supply. This should be treated as a technical defect and pharmacists should not be required to return the prescription to the prescriber for amendment. The Misuse of Drugs Regulations should be amended accordingly.**

Prescribing up to a maximum 28 days supply of controlled drugs at one time should reduce the volume of controlled drugs in the community and may help tackle the significant wastage of unused medication.

Pharmacists should have discretion to dispense 28 days supply if a prescriber inadvertently prescribes more than 28 days supply, provided the pharmacist judges this to be a technical defect.

The introduction of this restriction will require prescription directions such as 'one as directed' to be deemed insufficient for the purposes of prescribing controlled drugs. Additional prescribing guidance may be required and the British National Formulary should be amended accordingly.

In England and Wales, instalment prescribing using NHS forms is permitted for the treatment of drug misuse. Instalment prescribing in wider circumstances would help further reduce the volume of controlled drugs in the community. The RPSGB suggests that consideration be given to the current prescribing arrangements in Scotland where prescribers can use the standard prescription form (GP10) to prescribe any medicines by instalment as appropriate for individual patients. A consolidated approach based on the Scottish model may have long term benefits.

#### RECOMMENDATION 15

'The duration of validity of a prescription for controlled drugs should be limited to 28 days. This restriction would not apply to drugs in Schedule 5 to the MDR 2001'.

#### **Response 15 from RPSGB**

**The RPSGB supports the limitation on the validity of controlled drug prescriptions. To ensure patient care is not compromised, prescribers should inform patients of the expiry date of controlled drug prescriptions.**

Currently prescriptions for Schedule 2 and 3 controlled drugs are valid for 13 weeks from the date of issue, while prescriptions for Schedule 4 and 5 controlled drugs can be dispensed up to 6 months after the date on the prescription.

The RPSGB supports the principle behind limiting the validity of a controlled drug prescription. To ensure patient care is not compromised, the RPSGB recommends that patients are advised of the expiry date of their prescription and where appropriate, how a new prescription can be obtained. The inclusion of the phrase *'This prescription is valid until.....'* would help ensure patients are aware of the time frame in which the prescription must be dispensed.

To ensure continuity of care for patients in chronic pain, the RPSGB recommends the ability to issue a controlled drug prescription in advance of its start date, provided the start date and expiry date (i.e. date before and after which it could not be dispensed) are clearly stated. Good practice guidance to support this should be developed for both prescribers and dispensers.

Provision of a transitional period for the implementation of this recommendation would enable all prescribers, dispensers and patients to be properly informed of the changes and help ensure patient care is not compromised. A public awareness campaign is critical to these new arrangements.

#### RECOMMENDATION 16

'When computer generated prescriptions are in general use for controlled drugs and when the electronic transmission of prescriptions is introduced, the software should be so designed as to ensure that both the time of issue of a prescription and the time at which it is dispensed are recorded'.

#### **Response 16 from RPSGB**

**The RPSGB supports the recommendation that the time a prescription is issued and the time it is assembled should be recorded once the necessary IT systems are in place. The time at which a prescription is assembled will not always be the same as the time at which the drug is supplied to the patient or their representative. The RPSGB would issue guidance on this area to ensure standard practice in time recording.**

#### **Safe Custody and Record Keeping Requirements for General Practitioners**

##### RECOMMENDATION 17

'The purchase of all stocks of controlled drugs for practice use should follow a procedure that is capable of being monitored. The same form which I have recommended for use when prescribing controlled drugs should also be used when ordering controlled drugs on requisition. The forms should be sent to the PPA for entry into its database so that all purchases of controlled drugs by any doctor can be monitored'.

#### **Response 17 from RPSGB**

**The RPSGB recommends the use of standardised forms to obtain controlled drug stock for surgery use and believes subsequent submission of the requisition form to the PPA, or other appropriate body, will provide an important safeguard in ensuring consolidated monitoring of comprehensive national data.**

**The controlled drug requisition form should be distinct from controlled drug prescription forms. The current arrangements in Scotland and Northern Ireland may provide a model for a new system.**

**The requirement to use a standard requisition form should extend to others authorised to obtain stocks of controlled drugs. Requisition via electronic means should also be standardised and encouraged, to allow fast requisition where necessary.**

The use of a standardised requisition form to obtain controlled drug stock for surgery use and the subsequent submission of this to the PPA, or other appropriate body, is necessary for comprehensive auditing and monitoring of controlled drugs. This requirement should also apply to surgeries which obtain supplies of controlled drugs directly from wholesalers. Wholesalers should send requisition forms to the PPA, or other appropriate body.

It is not only medical practitioners who are authorised to obtain stocks of controlled drugs from pharmacies or wholesalers. Any requirements should also apply to others; for example, persons in charge of a laboratory concerned with scientific education or research, owners/masters of a ship and managers of offshore installations. Special consideration would need to be given to the documentation required by the master of a foreign ship requiring stocks of controlled drugs when docked in a port in Great Britain and to midwives who are currently required to obtain stocks of some controlled drugs using a midwife supply order form.

The Report suggests that that the special controlled drug prescription form could also be used when ordering controlled drugs. The RPSGB would not wish systems to be unnecessarily complicated, but the use of the same form could lead to abuse and would not allow the ready identification and monitoring of controlled drugs which are supplied against a requisition rather than against a patient specific prescription. Instead the RPSGB would recommend that consideration be given to the systems currently working in Scotland and Northern Ireland.

In Scotland a stock order form (GP10A) exists. This form is distinct from the GP10 prescription form. It is a duplicate form with one copy retained by the pharmacist while the other copy is sent to the pricing authority. In Northern Ireland a triplicate form is in operation, with one copy being kept by the GP, one kept by the supplying pharmacy and the third sent to the pricing authority. For ease of monitoring it may be advisable to separate the forms used to order stocks of controlled drugs from stock order forms requisitioning stocks of other medication.

The current Misuse of Drugs Regulations do not require pharmacists to issue a written requisition in order to obtain stocks of controlled drugs. Controlled drug stock is generally ordered electronically by pharmacists in community or hospital practice from wholesalers, in the same way as other stocks of medicines. Because of the volume of controlled drug stock ordered and the need to have same day/ next day delivery, any requirement for pharmacists to use a written form when ordering controlled drug stock would be impractical and would not be in the patient's best interests in many instances. The monitoring of wholesaler and pharmacy requisition records by the PPA, or other appropriate body, would ensure monitoring of pharmacy controlled drug stock without an additional burden for pharmacists.

The RPSGB recommends robust arrangements to ensure that controlled drug stock from wholesalers is delivered to an authorised person. Formal records should help complete the audit trail and reduce the risk of diversion of stock.

### RECOMMENDATION 18

'GPs who keep a stock of Schedule 2 controlled drugs should be required (as now) to keep a CDR and to observe existing safe custody requirements. They should be permitted to keep the CDR in electronic form. The CDR should provide for the keeping of a running stock balance for each drug stocked. Each GP who is either a principal in or employed by a practice that keeps controlled drugs for practice use should be under a legal obligation to comply with the terms of a standard operating procedure (SOP) devised or approved either by the PCT with which the practice contracts or, if and when a controlled drugs inspectorate is set up, by that body. The SOP should specify, among other things, the frequency with which the stock must be checked. Adherence to such SOPs should be mandatory and should be subject to regular inspection. Any doctor working as a locum should be under an obligation either to comply with the practice SOP or to make his/her personal arrangements to provide Schedule 2 drugs and to accept responsibility for keeping the necessary CDR. I suggest that the Healthcare Commission (or, if it comes into being, the controlled drugs inspectorate) should be responsible for approving SOPs for GPs in private practice and for ensuring compliance. Advice as to compliance and best practice should be issued nationally and should also be available from PCT officers in the course of the annual clinical governance visit or review'.

### **Response 18 from RPSGB**

**The RPSGB welcomes this recommendation. All those authorised to possess and supply controlled drugs should be subject to the same safe custody and record keeping requirements. The minimum details to be recorded in a controlled drug register should be defined and adherence to the requirements should be monitored by audit and inspection. Appropriate arrangements should be developed in line with this recommendation for hospitals.**

A standardised controlled drug register would help to ensure the consistency of information recorded and prevent confusion arising when, for example, a locum doctor is presented with unfamiliar documentation.

At present there is no legal requirement for GPs to store surgery stock in a cabinet, safe or room that meets the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973. The legislation requires that GPs keep controlled drugs that are subject to safe custody in a 'locked receptacle', but no further definition or requirements for the locked receptacle are specified. For controlled drugs which are kept in a doctor's bag, the only requirement is the bag be lockable, although the Home Office has advised that the 'boot of a car' is not considered to be a locked receptacle.

The RPSGB would suggest that controlled drugs stored in a GP's surgery should be kept in a cabinet, safe or room which adheres to the standards of the Misuse of Drugs (Safe Custody) Regulations 1973. Clear practice guidance, such as that issued by the National Prescribing Centre, should be provided when controlled drugs are kept in a doctor's bag.

This recommendation should apply to all persons authorised to possess, supply or administer controlled drugs. Notable anomalies in the current Misuse of Drugs Regulations are the absence of a legal requirement for controlled drug registers to be maintained on hospital wards or any reference to the register and safe keeping requirements in care homes (although practice guidance exists).

### RECOMMENDATION 19

'When the new arrangements for the provision of out of hours services come into effect, PCTs should establish protocols governing responsibility for the provision of Schedule 2 drugs and for the keeping of any CDR. I recommend the use of an appropriate SOP'.

### **Response 19 from RPSGB**

**The RPSGB supports the need for robust protocols and guidance for out of hours service providers which safeguard patients and promote high quality patient care.**

Primary care organisations will require guidance about the supply of controlled drugs via out of hours service providers to ensure consistency of arrangements and adequate safeguards. Particular consideration should be given to circumstances where private companies employ NHS GP's to provide out of hours services and to situations where other health professionals i.e. nurses and midwives are the main providers of care for out of hours services. The arrangements for ordering stocks of controlled drugs should also apply to out of hours service providers.

### **Controlled Drugs in the Pharmacy**

#### **RECOMMENDATION 20**

'There should be some relaxation of the strict requirement that a pharmacist is not permitted to dispense a controlled drug prescription unless there is full compliance with every technical requirement of the MDR 2001. Where the defect is only technical and the pharmacist is confident that the intention of the prescriber is clear, and is willing to accept professional responsibility for dispensing the prescription in the form in which it is presented, s/he should have the discretion to amend the prescription, to correct the technical defect and to dispense the drugs'.

### **Response 20 from RPSGB**

**The RPSGB welcomes the recommendation that pharmacists have the discretion to amend and dispense controlled drug prescriptions with technical defects without returning the prescription to the prescriber and will produce practice guidance on this.**

The current prescription requirements for Schedule 2 and 3 controlled drugs, together with the need for any alterations to be effected by the prescriber in his/her handwriting pose a frequent, practical problem for pharmacists.

One of the key responsibilities of a pharmacist is to '*act in the interest of patients and other members of the public*'.<sup>19</sup> Therefore, pharmacists are often faced with an ethical dilemma when presented with a controlled drug prescription that does not comply with all the requirements of the Misuse of Drugs Regulations, but where the prescriber's intentions are clear.

Supply against such a prescription would not currently be lawful, but refusing to supply, especially in the case of palliative care may not be in the best interests of the patient. In circumstances such as this pharmacists are expected to use their professional judgement and be able to justify the decision they make.

Consideration will need to be given to whether the implementation of this recommendation will also require amendment to legislation. The RPSGB will provide guidance to assist pharmacists in determining whether the prescription has a technical defect and the circumstances in which it needs to be returned to the prescriber.

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<sup>19</sup> Medicines Ethics and Practice- a Guide for Pharmacists, RPSGB Edition 28 Page 85

#### RECOMMENDATION 21

'In the case of a controlled drug supply that must be recorded in the pharmacy CDR, a pharmacist should be required to ask the name and address of the person collecting the drugs, unless that information is already known to him/her. If the pharmacist does not know the person, s/he should also ask the person collecting the drugs to produce some form of personal identification. The name and address and a note of the form of identification provided should be recorded in the CDR, unless the collector is personally known to the pharmacist, in which case s/he should record that fact. If no identification is provided, the pharmacist should have discretion to supply or withhold the drugs and, if the drug is supplied, should record the fact that no identification was provided'.

#### RECOMMENDATION 22

'Any healthcare professional, acting in his/her professional capacity, presenting a prescription or requisition for a controlled drug, the supply of which must be recorded in the pharmacy CDR, should, if not known to the pharmacist, be required to provide identification, preferably his/her professional registration card. The relevant information should be recorded in the CDR'.

#### RECOMMENDATION 23

'Any person collecting controlled drugs in Schedules 3 and 4 from the pharmacy should be required to write and sign his/her name on the back of the prescription form'.

#### **Response 21, 22 & 23 from RPSGB**

**The RPSGB supports the recommendation to record details of persons collecting controlled drugs from community pharmacies and believes that Recommendations 22 and 23 can be readily implemented. Recommendation 21 could raise concerns about patient confidentiality. Other issues such as the scope of new legislation may need further consideration. The RPSGB would produce practice guidance to help pharmacists meet any additional requirements without compromising patient care. There should be patient and public education about this change.**

Presently there is no legal requirement to identify and record the person collecting controlled drugs from a community pharmacy. Dame Janet Smith found this '*wholly unsatisfactory*'<sup>20</sup> and felt that recording the name and address of persons collecting controlled drugs would be important information if it appeared that controlled drugs were being diverted.

The RPSGB informed the Inquiry that many patients ask friends, relatives, neighbours and home help/carers to collect medicines on their behalf and special arrangements for the collection of controlled drugs may pose patient confidentiality issues.

The RPSGB is also concerned about deterring individuals who have previously collected medication to assist the patient.

It is the RPSGB's view that a record of a health professional collecting controlled drugs and confirmation of the type of identification provided could be implemented with relative ease, as the majority of health professionals carry identification as a matter of routine. However, for patients or their representatives the type of acceptable identification would need to be determined and the public would need to be informed of the requirement to provide identification when collecting controlled drugs.

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<sup>20</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.146

Pharmacists may face practical difficulties if they refuse to supply controlled drugs to a person who does not or cannot produce evidence of identity. The Report identified one such problem - the threat of violence.<sup>21</sup>

The RPSGB would be concerned if it could be deemed that a criminal offence was committed where a pharmacist, acting in good faith and the patient's best interests, supplies a controlled drug to an individual without identification. Professional practice guidance should provide safeguards where pharmacists have to exercise discretion.

Recommendation 21 is likely to pose a particular challenge for pharmacists who provide pharmaceutical services for large numbers of drug misusers on a daily basis. In such circumstances consideration should be given to some of the more innovative practices currently in use, for example keeping a photographic record of patients on the pharmacy computer to allow staff to be satisfied of the identity of the person collecting the controlled drug supply.

An increasing number of pharmacists are providing on-line/mail order pharmacy services. The information to be recorded in such situations should be specified.

Any legislative changes made following these recommendations should be specific to the community setting to prevent the different systems and requirements of hospitals and other institutions being compromised.

#### RECOMMENDATION 24

'Pharmacies should be permitted to keep their CDRs in electronic form'.

#### **Response 24 from RPSGB**

**The RPSGB supports the recommendation to allow an electronic controlled drug register and believes that this should be implemented at the earliest opportunity, provided the electronic record system has a frequent and regular back-up facility and adequate security.**

The maintenance of controlled drug registers is intended to permit monitoring of Schedule 2 controlled drugs stock held and supplied. Currently controlled drug registers are required to take the format of a bound book and electronic records are not permitted. The entering of data into controlled drugs registers can be time consuming and the scope for comprehensive monitoring of records is limited.

The Home Office Drugs Inspectorate is able to exempt licence holders (but not doctors, dentists, veterinary surgeons and pharmacists) from this requirement, provided secure software is in place to prevent entries being subsequently altered.

The Home Office Inspectorate has allowed computerised registers for at least 25 years and does not recall any cases where licence holders have improperly altered records.<sup>22</sup>

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<sup>21</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.147

<sup>22</sup> Home Office Public Consultation- Computer Generated Prescriptions, Registers and Requisitions for Controlled Drugs. May 2003

The RPSGB's view is that electronic controlled drug registers will be necessary to implement many of the recommended changes in record keeping and would facilitate closer monitoring and underpin inspection. Integrated solutions could be developed with the NHS National Programme for IT and the NHS IT programmes in Scotland and Wales.

Electronic registers would allow an automatic running balance to be maintained. Provided that there was no requirement to record details of the person collecting Schedule 3 to 5 controlled drugs in the register, electronic records would facilitate records of the lower Schedule controlled drugs to be kept without placing an additional administrative burden on pharmacists. Electronic registers would also permit records to be kept for a much longer time period than at present.

The RPSGB supports the proposal to link electronic pharmacy controlled drug registers to wholesalers' records if adequate safeguards are in place to ensure that patient details are not shared with wholesalers or commercially sensitive data revealed, for example, details of controlled drugs purchased from other sources.

As with any electronic records, safeguards will be required to ensure data is not lost as a result of a systems failure. Valuable data may be lost if systems are only backed up on a daily basis, especially in pharmacies which supply large quantities of controlled drugs.

Instead of using a bound book, pharmacists may currently elect to keep electronic records of the private prescriptions they have dispensed (supplies of Schedule 2 controlled drugs must still be recorded in the controlled drug register). However, they must ensure that an adequate backup is made and that arrangements are in place so that inspectors can examine the records with minimal disruption to the dispensing process. Such requirements would be equally applicable to the maintenance of electronic controlled drug registers.

#### RECOMMENDATION 25

'The keeping of a running balance in pharmacy CDRs should henceforth be regarded as good practice. The Home Office should make its view on this clear to pharmacists, and the Royal Pharmaceutical Society of Great Britain (RPSGB) should publicise the new position. When electronic CDRs have come into general use, the keeping of a balance should be made obligatory'.

#### **Response 25 from RPSGB**

**The RPSGB welcomes the recommendation that pharmacists should maintain running balances of controlled drugs. The RPSGB will provide appropriate practice guidance to support the implementation of this recommendation and will publicise the new position to pharmacists. The RPSGB recommends that when running balances become a legal requirement there should not be a strict liability offence in the event of a difficulty with reconciliation, when there is a justifiable reason.**

**To prevent the provision of services being diminished, specific requirements on reconciliation should be devised for liquid preparation controlled drugs which are used in the treatment of drug misuse.**

Running balances of controlled drug stock have been in common practice in hospitals for a number of years.

In recent years running balances have also been operated by some community pharmacies. Running balances provide pharmacists with the capacity to identify irregularities and take action with speed.

Before either a legal or professional requirement is placed on pharmacists to maintain running balances, consideration of, and guidance on, a number of practical issues is required including:

- Liquid preparations

Allowance will need to be made for loss occurring due to the viscosity of certain liquids and the small (but not insignificant) overage/underage that will arise due to manual measurement. This will be a particular problem when pharmacies supply large volumes of methadone mixture. Measuring pumps may be of assistance for such pharmacists but a certain volume of liquid will still be lost.

The following indicates the scale of discrepancies that might arise in extreme cases. A pharmacist who currently provides pharmaceutical services for approximately 170 drug misusers and dispenses approximately 7.5 litres of methadone per day calculated that using a conical measure with 1ml discrepancy per dispensing, he would 'lose' 62 litres of methadone per year. Even using a measuring pump with a discrepancy of 7ml per day, 4.4 litres of methadone would still be 'lost' each year.

The majority of manufacturer's packs have some degree of overage. Overage can vary from manufacturer to manufacturer and between different batches from the same manufacturer.

Audit systems that reflect a general monitoring of incomings and outgoings would take account of these unavoidable discrepancies and should provide sufficient safeguards.

- Frequency of reconciliation

Practice guidance will be required as to how often stock should be reconciled with the running balance figures e.g. daily/weekly/monthly/each time a different pharmacist assumes responsibility for the stock. While the aim is to ensure irregularities are identified as quickly as possible, consideration will need to be given to pharmacists' workloads. Stock reconciliation will be a time consuming exercise which must not undermine the standard of patient care.

The need for reconciliation each time a new pharmacist assumes professional responsibility for stock will have implications for the increasing number of pharmacies which have more than one pharmacist in charge over the course of the day e.g. those with extended opening hours. A pragmatic approach is likely to be required, with consideration of the current practices adopted by hospitals.

- Action to be taken when discrepancies arise.

Discrepancies between the theoretical and actual balance of stock will arise. Clear guidance on what action should be taken is necessary and pharmacists will be encouraged to report such discrepancies without fear of automatic disciplinary action. The RPSGB will issue guidance about these monitoring arrangements. Such guidance will be especially important in pharmacies which are operating without a regular pharmacist and which instead rely on the services of a number of different locum pharmacists.

If, or when, the maintenance of a running balance becomes a legal requirement, consideration should be given as to whether any discrepancies would be regarded as an offence. During previous correspondence with the Inquiry the RPSGB said that it supported the inclusion of a running balance, but because of the unavoidable discrepancies e.g. due to viscosity of liquids, did not believe that there should be a strict liability offence if the actual balance and theoretical balance did not reconcile. Judgement by those monitoring in such situations would be necessary.

To ensure that improvements in pharmaceutical services for drug misusers are not undermined, consideration should be given to the impact that additional recording requirements will have on pharmacists who are serving large numbers of methadone patients. It may be necessary to devise special record keeping requirements for liquid preparation controlled drugs such as methadone.

The proposed changes to record keeping requirements for controlled drugs will undoubtedly impact on a busy community pharmacist's workload. To ensure patient care is maintained, the current schedules of controlled drugs should be revised. Streamlining the arrangements would help ensure that detailed records are kept for those drugs that are most harmful when misused without the requirements extending to drugs that pose a lower risk.

Similarly the reconciliation of stock with the theoretical balances will be a time consuming exercise, especially for liquid preparations. While it is recognised that original pack dispensing may not always be appropriate or feasible, more general implementation would go a long way to overcoming the reconciliation problem.

#### RECOMMENDATION 26

'The name and professional registration number of the prescriber should be entered in the CDR, as should the name of the pharmacist responsible for supplying controlled drugs to a patient or his/her representative'.

#### **Response 26 from RPSGB**

**The RPSGB supports the recommendation that the details of the prescriber who issues the prescription and the pharmacist who physically supplies a Schedule 2 controlled drug to a patient should be recorded in the controlled drug register.**

**To ensure accurate identification of the pharmacist making the supply, the RPSGB would recommend that the pharmacist's name and registration number be legibly recorded. The RPSGB will provide further practice guidance on recording details of the pharmacist responsible for the provision of professional services on a particular day. This will ensure an audit trail is maintained of all pharmacists involved in the preparation and supply of a controlled drug to a patient.**

The pharmacist who supervises the assembly of the patient's medication may not be the same pharmacist who supervises the supply of the controlled drug to the patient, especially in hospital pharmacies. It is the RPSGB's view that it is the pharmacist who supervises the supply of the controlled drug to the patient or their representative, rather than the pharmacist who dispenses the drug, whose details should be entered in the register.

The RPSGB's Code of Ethics requires that a retrievable record of the pharmacist taking responsibility for the provision of each pharmacy service be maintained.

Thus, a system for recording the pharmacist who supervises assembly and the pharmacist who supervises supply should be in operation. Different audit trails will need to be developed for the various settings in which controlled drugs are used.

#### RECOMMENDATION 27

'The current requirement that a pharmacy CDR be kept for two years should be amended and the period should be extended to seven or, possibly, ten years. When electronic records are used, it should be possible (and it may be desirable) for CDRs to be kept even longer'.

#### **Response 27 from RPSGB**

**The RPSGB recommends that controlled drug records should be retained for at least 7 years, or longer if other statutory record keeping requirements allow.**

The RPSGB agrees that the current requirement to retain controlled drug registers for 2 years is insufficient. When deciding how long controlled drug registers should be retained consideration must be given to other statutory records keeping requirements pharmacists may need to comply with, for example The Data Protection Act 1998, The Children's Act 1989 and the Mental Health Act 1983.

#### RECOMMENDATION 28

'The RPSGB should provide guidance to its members as to the information and advice to be given to patients and their representatives when receiving a supply of a controlled drug. This should usually comprise an accurate description of the controlled drug prescribed and advice about the need to keep the drug safe because of the risk of diversion. Patients and their representatives should be advised to return unused drugs to the pharmacy. This information and advice should be given both orally and in writing.'

#### **Response 28 from RPSGB**

**The RPSGB supports this recommendation on the provision of information to patients. The extent of information provided to third parties should be left to the professional judgement of the pharmacist. The RPSGB will produce practice guidance to support pharmacists in exercising professional judgement in such circumstances. Enforcement of breaches of such guidance should remain with the RPSGB.**

The RPSGB Code of Ethics states that 'Pharmacists *must ensure that a patient receives sufficient information and advice to enable safe and effective use of the medicine*'.<sup>23</sup>

The RPSGB said at the Inquiry that a recommendation which singled out controlled drugs from other prescription only medicines was inadequate. By definition, all prescription only medicines are potent and capable of abuse.

Many patients, especially in palliative care, rely on members of the local community to collect prescriptions for them. Information conveyed about the drug might have a detrimental effect on such arrangements.

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<sup>23</sup> Medicines Ethics and Practice- a Guide for Pharmacists, RPSGB Edition 28 page 89

Pharmacists providing a controlled drug to a patient's representative with whom they were unfamiliar would also face difficulty in determining whether they should limit the information they provide.

The RPSGB supports the provision of information to patients but is concerned about the nature of the information that might be conveyed to a third party collecting controlled drugs. This may place pharmacists in a difficult position with regard to their duties of patient confidentiality. Disclosing information about controlled drugs to third parties may also increase the risk of diversion of such drugs.

The RPSGB would like to see public awareness campaigns to encourage the safe keeping of all medicines, the return of unused medicines to pharmacies and to explain any changes in the control of injectable schedule 2 controlled drugs. Initiatives such as 'Ask about Medicines Week' could also help improve general public awareness of the keeping medicines safe and encourage the return of all unused drugs to the pharmacy.

Collaborative work between all healthcare professionals would aid the successful implementation of this recommendation.

### **Controlled Drugs in the Community**

#### **RECOMMENDATION 29**

'Pharmacists should be required to prepare a statutory patient drug record card (PDRC) to accompany every supply of injectable Schedule 2 drugs leaving the pharmacy. This should record the form and amount of the drug prescribed, the form and amount of the drug dispensed and the dosage instructions as they appear on the prescription'.

#### **RECOMMENDATION 30**

'The healthcare professionals who administer such Schedule 2 injectable drugs should be obliged to enter every administration and new supply of such a drug on a master PDRC and should keep a running balance of the remaining stock. The destruction of any unused Schedule 2 injectable drugs should be recorded on the PDRC, wherever it takes place. After the death of the patient or when the time has come when injectable drugs are no longer required by him/her, the completed PDRC should be sent to the PCT to which the patient's GP is contracted. The PDRCs should be examined for anomalies and then married up with the patient's GP records. The controlled drugs inspectorate (if and when there is one) might carry out an occasional audit of PDRCs.'

### **Response 29 & 30 from RPSGB**

**The RPSGB supports the introduction of a Patient Drug Record Card but would wish to be consulted on proposals about any new system to ensure efficiency.**

Once a controlled drug leaves the pharmacy there is no legal requirement for a record be kept of its subsequent administration or destruction. The report states, '*Above any other single factor, it was the absence of control after dispensing that enabled Shipman to obtain diamorphine illicitly and to avoid notice*'.<sup>24</sup>

Some drug misusers are currently prescribed injectable diamorphine or methadone. A process would need to be devised to operate a Patient Drug Record Card (PDRC) system in such cases.

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<sup>24</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.221

To ensure appropriate patient care, arrangements will need to be in place to allow emergency treatment to be provided and PDRCs to follow patients moving between primary and secondary care.

The public will need to be fully informed about the purpose of the PDRC.

To make PDRC's effective, there will need to be a speedy information flow to inform all healthcare professionals involved when a patient dies.

#### RECOMMENDATION 31

'Consideration should be given to changing the law so that all controlled drugs would become the property of the Crown on the death of the patient for whom they were prescribed'.

#### **Response 31 from RPSGB**

**The RPSGB recommends that on a patient's death, or when medication is no longer required, all prescription only medicines should become the property of the Crown. This will not only help avoid confusion, but prevent the diversion of medicines which, although not controlled drugs, still pose a risk if diverted. This change should be supported by a public awareness campaign.**

When controlled drugs are dispensed from a pharmacy, they become the property of the patient for whom they are prescribed. At the Inquiry's Stage 3 Seminars there was agreement that ownership of dispensed controlled drugs should not pass to the patient's estate on death.

Under the Misuse of Drugs Regulations 2001, a patient's representative has no authority to be in possession of the prescribed controlled drug other than when conveying the drug to the patient or returning it to a pharmacist, doctor or dentist for the purpose of destruction.

It would appear that current legislation prevents a patient's representative being in possession of controlled drugs on the patient's death. The RPSGB recommends greater clarity on this matter and suggests that any legislative change in this area should apply to all prescription only medicines.

Consideration would need to be given to whether a criminal offence would be committed if a patient's representative, unaware of the requirements, failed to return unused drugs to the pharmacy for destruction or destroyed the drugs themselves.

#### RECOMMENDATION 32

'There should be increased formality attaching to the destruction of injectable Schedule 2 controlled drugs dispensed for administration in the community. Their destruction and their removal from the home of the patient should be properly recorded and witnessed. The classes of person lawfully entitled to undertake or witness destruction should include doctors, pharmacists, nurses, suitably trained law enforcement officers or PCT officers, and inspectors of any new controlled drugs inspectorate'.

#### **Response 32 from RPSGB**

**The RPSGB welcomes the recommendation for tighter controls on the destruction of controlled drugs and would wish its Inspectors and other authorised pharmacists to retain authority for witnessing the destruction of controlled drugs.**

**The RPSGB is concerned that patients and the public may not know the distinction between different drugs and could be deterred from returning any unused medicines to the pharmacy. There is also the possibility that the patient's family could inadvertently commit a criminal offence.**

**The RPSGB would recommend further consideration of this matter and suggests a major public awareness campaign to encourage people to return all unused drugs to pharmacists, provided that the volume of returns can be handled in small premises.**

**Any arrangements for the removal or destruction of controlled drugs following a patient's death should be operated so as not to cause further distress to the bereaved.**

The RPSGB's current advice is that the destruction of patient medicine returns by pharmacists should be witnessed by another member of staff and recorded.

The Report proposes that the witnessed destruction of injectable Schedule 2 drugs should be a formal statutory requirement and that members of the public, including the patient's family, should not be allowed to remove or destroy the drugs.<sup>25</sup> For non-injectable Schedule 2 drugs the Report states that these requirements should be a professional, not a statutory requirement. If the patient's treatment had not involved the creation of a PDRC, another form of record could be used. The same degree of formality would not apply to removal of the drugs by the patient's family, who would be encouraged to return unused non-injectable controlled drugs to the pharmacy.<sup>26</sup>

The RPSGB would be concerned if it were proposed that a patient's representative or carer could be guilty of a criminal offence when they were unaware that they were prohibited from removing or destroying injectable Schedule 2 drugs. Furthermore, fear of committing an offence might deter the public from returning any unused medication to the pharmacy which would pose a greater risk.

Patients and carers should be encouraged to return unused medicines to any pharmacy. This request could be made on a dispensing label and/or appear in the manufacturer's patient information leaflet. A public awareness campaign would reinforce this message.

The RPSGB suggests that pharmacists should maintain a separate register to record details of the destruction of controlled drugs. 'Patient Returns Registers' are currently available which record the patient for whom the drug was prescribed, the name of the person returning the drug, the date of return, drug details and details of the persons destroying and witnessing destruction. In the interim such records could be made a professional requirement.

Because reconciliation may be difficult, the record requirements for the destruction of injectable Schedule 2 drugs administered via a syringe driver will need special consideration.

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<sup>25</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.251

<sup>26</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.252

The report said that

*'All patient returns originally dispensed on a NHS prescription must be destroyed. Drugs dispensed on a private prescription can be put back into stock if they are still in date, although pharmacists are advised against this'.<sup>27</sup>*

The RPSGB's Code of Ethics says that any '*medicines that have been returned to a pharmacy from a patient's home, nursing home or residential home must not be supplied to any other patient*'.

Once a medicine leaves a registered pharmacy premises, the pharmacist has no control over how it is stored and cannot guarantee the product's continued safety and efficacy. To protect the public, the RPSGB recommends that medicines returned to any health professional, whether supplied under the NHS or privately, should not be returned to stock.

### RECOMMENDATION 33

It should be the responsibility of PCTs to ensure that suitable arrangements are in place for the disposal of controlled drugs.

### **Response 33 from RPSGB**

**The RPSGB supports the recommendation that primary care organisations should ensure that suitable arrangements are in place for the disposal of controlled drugs and would wish to see co-ordinated systems and a unified approach.**

The challenge will be to create a system which will guard against potential diversion and accommodate the range of circumstances in which controlled drugs are used. For example, in a palliative care situation a model could be devised of a lead healthcare professional assuming responsibility for the return of all medication after the patient's death.

Primary care organisation staff will need additional training and guidance in the destruction of controlled drugs. There should be a standard record to allow audit.

There may be practical implications such as the need for adequate storage space for controlled drugs awaiting destruction, especially in smaller pharmacies.

The RPSGB would be concerned if widely differing systems for disposing of controlled drugs were developed across the country. The RPSGB is aware of the overlapping and contradictory provisions in domestic and European legislation about the disposal of drugs, but the recent consultation document issued by DEFRA<sup>28</sup> deal with these variations.

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<sup>27</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 7.77

<sup>28</sup> "Review of the Special Waste Regulations 1996 for England Proposals for replacement of Hazardous Waste Regulations and List of Wastes Regulations A consultation paper"  
Department for Environment Food and Rural Affairs 2004.

## **Additional Issues for Consideration**

### **Prescribing of Controlled Drugs by Healthcare Professionals other than Doctors**

#### **Response 34 from RPSGB**

**The recommended restrictions on prescribing and administration of controlled drugs should apply to any health professional with prescribing rights. Any restriction of a health professional's prescribing rights must promptly be made available to those who need to know, especially pharmacists.**

Prescribing controlled drugs is no longer only undertaken by doctors, dentists and veterinary surgeons. Many nurses have independent prescribing rights and an increasing number of nurses and pharmacists are now supplementary prescribers. Currently Extended Formulary Nurse prescribers are permitted to prescribe or administer a limited number of Schedule 4 and 5 controlled drugs. Supplementary prescribers are unable to prescribe any controlled drugs.

The Medicines and Healthcare products Regulatory Agency (MHRA) released a consultation document (MLX 303) on 14 April 2004 proposing an extension of the range of prescription only medicines that may be prescribed by Extended Formulary Nurse prescribers. This list of medicines included morphine, diazepam, lorazepam and midazolam.

A MHRA consultation document (MLX 305) is currently seeking views on supplementary prescribing by chiropodists, physiotherapists, radiographers and optometrists.

To date there has been no formal proposal to permit supplementary prescribers to prescribe controlled drugs. However, it is probable that supplementary prescribing will be extended to some controlled drugs in the future, given the fact that a pharmacist can sell certain Schedule 5 controlled drugs (e.g. co-codamol) over the counter but supplementary pharmacist prescribers would be unable to prescribe the same drug.

Safeguards will need to be developed to satisfy concerns about circumstances where a pharmacist or other health professional is both the prescriber and the supplier of a controlled drug. This is an area where the professional organisations and regulators should issue guidance in collaboration.

The RPSGB supports the valuable role that supplementary and independent non-medical prescribing play in patient care and supports such prescribers being allowed to prescribe controlled drugs, especially in palliative care.

The prescribing of controlled drugs should be restricted to those prescribers in 'actual clinical practice' and other healthcare professionals should also be prohibited from self-prescribing/prescribing for immediate family.

Similarly, all health professionals who prescribe, supply or administer controlled drugs must have a duty to inform their professional body and employer/primary care organisation of any caution or conviction in relation to controlled drug offences.

This requirement should be incorporated into Codes of Ethics and Professional Conduct guidance for all prescribers.

## **Patient Group Directions**

### **Response 35 from RPSGB**

**The RPSGB highlights the importance of safeguarding the current and future arrangements for the supply and administration of medicines under a Patient Group Direction.**

The Report makes many recommendations and observations about prescribing, supplying and administration of controlled drugs, but makes no reference to the supply of controlled drugs in accordance with a Patient Group Direction (PGD).

PGDs play an important role improving the quality of patient care by providing ready access to suitable treatment within the NHS and private sector. The RPSGB is concerned to safeguard current and future arrangements for the supply and administration of medicines in accordance with a PGD and amendments to legislation should protect these.

A PGD is a written direction relating to supply and/or administration of medicines to persons generally (subject to specific exclusions) and is signed by a doctor or dentist and by a pharmacist. Certain classes of persons are permitted to supply or administer medicines under a PGD including pharmacists, registered nurses, midwives, ophthalmic opticians, state registered chiropodists, paramedics and physiotherapists.

Since October 2003 it has been possible for these authorised persons, when acting in that capacity, to supply any Schedule 4 Part 1 controlled drugs (except injectable Schedule 4 Part 1 controlled drugs that are being used for the treatment of addiction) or any drug specified in Schedule 5 in accordance with the terms of a PGD. It is also possible for a registered nurse to supply diamorphine in accordance with a PGD, provided the supply is for the treatment of cardiac pain to a person admitted to a coronary care unit or an A&E department of a hospital.

## **Format of Controlled Drug Registers**

### **Response 36 from RPSGB**

**The format of the controlled drug register should be revised. The revised register format should detail the minimum, not the absolute, fields of information to be recorded.**

Implementation of the various recommendations concerning information to be recorded in the controlled drug register will require a revised register format and clarity about the legal status of controlled drug stationery.

Most hospitals maintain separate registers for controlled drugs received and controlled drugs issued. An example of these registers can be found at *Appendix 2*.

The controlled drug stationery used in hospitals (i.e. registers and requisition forms) is provided by The Stationery Office (TSO). The registers contain numbered pages but the registers themselves are not numbered and therefore could be obtained and used fraudulently.

In recent years running balances have been maintained by some community pharmacies. The Report referred to the ASDA Pharmacy controlled drugs register which combines information about receipt and supply on the same register page. It permits a running balance to be maintained and details recorded as to whether the controlled drug was collected by the patient or their representative (*Appendix 3*).

There is concern that any increase in the administrative burden for recording supplies of methadone may result in pharmacists withdrawing or reducing the services and support offered to drug misusers. There is therefore a strong argument for separate register requirements being devised for the supply of methadone until electronic registers are in widespread use. An example of a controlled drug register currently being used to record supplies of methadone can be found in *Appendix 4*. This register lasts one calendar month and is designed so that each patient supplied has a separate page in the register. The name and address of the person supplied only needs to be entered once a month, instead of daily. Currently there is no provision for the maintenance of running balances, but this problem can be overcome.

The RPSGB proposes that the following format be considered for paper based registers.

- A separate section for each class of controlled drug. Within each section, separate pages should be maintained for different forms and strengths of the same drug. (*NB with paper based registers, this format will not allow ready identification of dose alteration or patients who are prescribed a combination of strengths of the same drug*).
- Running balances to be maintained with a record of the date, identity of the person carrying out the reconciliation and the frequency of reconciliation.
- For controlled drugs received the minimum particulars to be recorded:
  - Date received
  - Name and address of person and firm from whom received
  - Amount received
  - Identity of person authorised to take receipt.
- For controlled drugs supplied the minimum particulars to be recorded:
  - Date supplied
  - Name and address of person or firm supplied
  - Amount supplied
  - Licence or authority for supply to be made (i.e. prescriber identifier number)
  - Particulars of person authorised to make supply (i.e. pharmacist registration number)
  - Particulars of person collecting supply
  - Running balance.
- Space for additional notes, primarily instances where clinical/professional discretion was used.
- Medicine returns should be recorded in a separate register.

## **Bar Coding/Radio Frequency Tagging**

### **Response 37 from RPSGB**

**The RPSGB supports the development of a standardised bar code to be read by pharmacy computer systems. A radio frequency tagging system would also be supported. Future IT developments should explore these prospects.**

The report does not make recommendations regarding bar coding/radio frequency tagging but discusses the possibility of creating an audit trail using such tools.

Bar coding and radio frequency tagging could provide a complete audit trail from the point of manufacture to the point of destruction. No firm conclusions were reached at the Stage 3 Seminars of the Shipman Inquiry about such developments but the Report recognises the potential value:

*'It is not clear to me whether modern technology will allow there to be an audit trail of controlled drugs beyond the pharmacist and into the hands of an individual patient. If so the opportunity for the police or a controlled drug inspectorate to detect improper diversion of controlled drugs would be much improved.'*<sup>29</sup>

### **An Example of the Value of Barcoding**

A pharmacist currently uses barcodes to record the provision of pharmaceutical services to approximately 170 drug misusers a day. Each bottle of dispensed methadone is labelled with a bar code. The bar code is scanned at the time of supply to the patient, providing an automatic record of the patient supplied, the date and time of supply and the number of days supply given. The bottles of uncollected methadone are also scanned at the end of each day to provide a comprehensive record of missed doses.

This pharmacist is planning to use this system to record the controlled drugs returned by a patient or their representative and the removal and destruction by the waste disposal carrier.

## **Training and Education**

### **Response 38 from RPSGB**

**The RPSGB recommends an urgent review of the training of healthcare professionals who work with controlled drugs and looks forward to the Shipman Inquiry's Fifth Report.**

The RPSGB understands that the Fifth Report of the Shipman Inquiry is likely to make a number of recommendations regarding the professional development and revalidation of health professionals.

Better regulation of controlled drugs and improved patient care will depend on health professionals receiving upgraded multidisciplinary training in the legal and professional requirements of prescribing, supplying and administering controlled drugs.

<sup>29</sup> The Shipman Inquiry Fourth Report- The Regulation of Controlled Drugs in the Community, paragraph 14.220

The review of the training and education of all professionals working with controlled drugs should include:

- The Misuse of Drugs Act 1971, The Misuse of Drug Regulations 2001 (as amended) and The Misuse of Drugs (Safe Custody) Regulations 1973 (as amended)
- clinical practices for prescribing and administration of controlled drugs
- handling ethical dilemmas and making ethical decisions
- raising concerns about practices of other health professionals
- drug misuse
- record keeping, monitoring and risk assessment
- self-reporting of convictions and any restrictions relating to controlled drugs.

### **Review of Legislation**

#### **Response 39 from RPSGB**

**Implementation of many of the Report's recommendations will require a review of the Misuse of Drugs legislation. The RPSGB would wish to contribute to this.**

The RPSGB welcomes the opportunity to work with others to take the recommendations forward to improve patient care and public safety.



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