

Controlled Drugs

An Information Booklet For Admin/Clerical Staff In General Practice On The Management And Use Of Controlled Drugs (CDs) And Prescription Stationery In NHS Scotland



Co-ordinators: Accountable Officers for Controlled Drugs Network Scotland - Working Group	Consultation Group: See page 10	Approver: AO Network Scotland
---	---	---

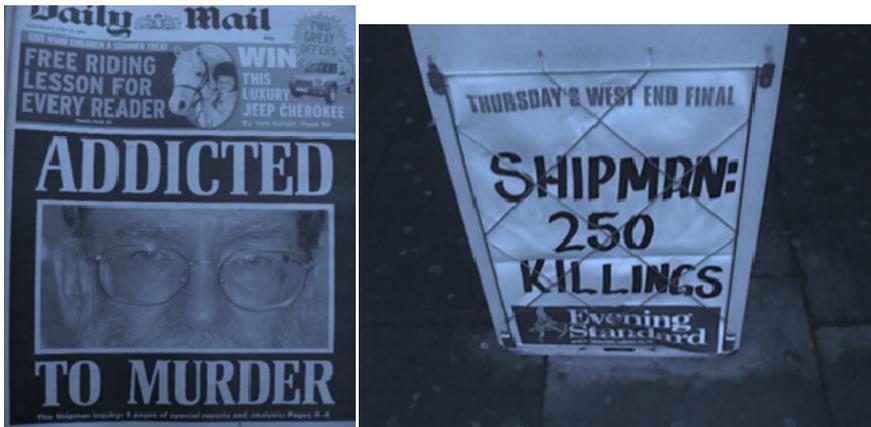
Signature: 		Signature: 
--	--	--

Identifier: NHSG/Guid/CD_book/MGPG496	Review Date: October 2013	Date Approved: October 2011
---	---	---

Contents

	Page
Introduction	2
What Was The Shipman Report And What Does It Have To Do With Controlled Drugs (CDs)?	2
Definitions	3
What Are Controlled Drugs	4
The Law And Controlled Drugs	4
Misuse Of Drugs Act 1971	4
Misuse Of Drugs Regulations 2001	4
Health Act 2006	5
What Do The Changes In Law Mean For General Practice?	5
Prescription Stationery In General Practice	6
GP10/GP10(SS)	6
GP10A	7
Other Types Of CD Prescriptions	7
Management Of CD Prescription Stationery In General Practice	7
Dealing With CD Prescriptions	7
Printing CD Prescriptions	8
Uncollected CD Prescriptions	8
Patient Returned CDs	8
Delivery To And Storage Of CDs At A GP Practice	8
Standard Operating Procedures	9
Consultative Group	10
Appendix 1 The CD Schedules	11-12
Appendix 2 Guidance On Recording Of Receipt And Issue Of Computer GP10SS And GP10 Prescription Pads	13
Sample Excel Spreadsheet	14
Label On Box Of Blank Prescription Forms	15

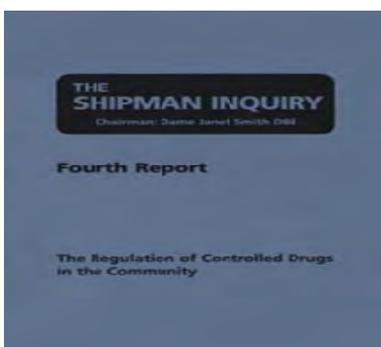
Introduction



What Was The Shipman Report And What Does It Have To Do With Controlled Drugs?

Dr Harold Fredrick Shipman had a career spanning 25 years as a GP. Shipman was convicted at Preston Crown Court on 31 January 2000 for the murder of 15 of his patients and one count of forgery of a will. He was sentenced to life imprisonment. While working in Hyde, Greater Manchester between 1977 and 1998, it has been established that he killed at least 215 patients, by injecting them with lethal doses of diamorphine. Despite the regulatory controls in place, Shipman's diversion of diamorphine went undetected for more than 20 years. As a result of his actions, the Shipman Inquiry was set up under Dame Janet Smith in 2001 to recommend what steps should be taken to protect patients in the future. Between 2002 and 2005 the Inquiry published six reports.

The Inquiry's concerns as to why Shipman's illicit acquisition of CDs had not been detected for so long required an examination of the systems and rules relating to the prescribing, dispensing and storage of controlled drugs. The Inquiry noted that many of the problems identified in connection with his abuse of diamorphine prescribing could occur for all CDs. As a result of this examination, 33 recommendations were made for improving clinical management of CDs, mostly with respect to audit trail, record keeping and management of CDs. This has resulted in changes to the laws relating to CDs with associated changes to the way CDs and prescriptions must and should be managed in General Practice.



Definitions

Controlled Drug (CD): A drug sometimes used as a medicine which is controlled by law and this restricts who can prescribe and possess it.

Prescription stationery: Includes all forms used in General Practice to either order or prescribe all medicines and includes GP10 prescription forms and GP10A stock order forms.

GP10 prescriptions: Are used by General Practitioners (GPs) to prescribe medicines for patients in their care. There are two types:

GP10 prescription - Supplied as a prescription pad and once issued to a GP, are under the control of the GP. The name, work address and prescriber number appear, pre-printed, on the prescription. They are normally used by GPs during home visits. They are peach coloured. They are only valid when patient and medicine details have been added by the prescriber and the prescription has been signed.

GP10SS prescriptions - These are the computer generated prescriptions normally used by a GP during a consultation at the practice when he/she wishes to prescribe or when repeat medicines are being generated. They are only valid once signed by the prescriber; all prescribing and prescriber details are computer generated at the time of issue. They are also peach coloured but are supplied as computer stationery in large boxes.

GP10(N) prescriptions: Issued and signed by suitably qualified nurse(s). They are lilac coloured.

GP10A prescriptions: Known as “stock order forms” and are used by GPs to obtain supplies of a drug or dressings for the immediate treatment of patients in the practice. They are pink and white and A4 in size.

Patient returned CDs: A patient returned CD is a CD which is no longer required by the patient (either for reasons of dose change, intolerance or change in clinical condition or because they are now out of date).

Standard Operating Procedures (SOPs): Describe the current responsibilities and procedures within a practice for dealing with, in this case, CDs and controlled stationery.

What Are Controlled Drugs (CDs)?

Controlled Drugs are medicines that are controlled under the Misuse of Drugs Legislation. They are classified (by law) based on their benefit when used in medical treatment and their harm if misused. They are controlled more strictly than other medicines which a GP may prescribe in terms of how the prescription is written and the quantity to be supplied.

The Law And Controlled Drugs

All medicines are controlled by the Medicines Act 1968 which sets out the requirements for the legal sale, supply and administration of medicines.

Stricter legal controls apply to CDs to prevent them:

- Being misused
- Being obtained illegally
- Causing harm.

CDs are further governed by the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

These legal controls govern:

- Storage
- Manufacture
- Supply
- Prescribing
- Possession.

The Misuse Of Drugs Act 1971

The main purpose of this Act is to prevent the misuse of CDs. It does this by imposing a complete ban on the possession, supply, manufacture, import and export of CDs except as allowed by regulations, e.g. as a prescription from a GP or by licence from the Secretary of State. Drugs are divided into 3 classes, the class reflecting the relative harm to an individual or to society if that drug is misused. The classes are in order of descending severity A, B and C. These classes determine the penalty (e.g. jail term/fine) which could be imposed when the Act is breached and includes both legal and illegal drugs. Many of these drugs have legitimate medical use so the Act has regulations which enable their legal use.

The Misuse Of Drugs Regulations 2001

These regulations divide CDs into 5 schedules according to the level of control they need and their therapeutic or medicinal benefit. They inform health professionals on matters such as the storage and prescription writing requirements of CDs.

Schedule 1 – These CDs have little or no recognised medicinal use, are addictive and have a high potential for abuse. They are the most strictly regulated CDs and

can be lawfully dealt with only with a Home Office licence and include ecstasy and LSD.

Schedule 2 – These CDs include stronger opiate drugs such as diamorphine, morphine, methadone and pethidine, as well as stimulants such as amphetamines. These drugs have real therapeutic value but are highly addictive. Their use is strictly controlled and there are special prescription requirements and regulations relating to record keeping, safe storage, possession and destruction that apply.

Schedule 3 – These CDs include barbiturates (e.g. phenobarbital) and some benzodiazepines, such as temazepam or midazolam. They are less rigorously controlled than drugs in Schedule 2.

Schedule 4 - These CDs are only lightly regulated.

Part 1 - contains most of the benzodiazepines, such as diazepam and nitrazepam.

Part 2 - contains the anabolic and androgenic steroids which have a potential for abuse by athletes e.g. clenbuterol.

Schedule 5 - These preparations containing CDs such as dihydrocodeine, codeine (e.g. cocodamol 8/500) or morphine (e.g. Oramorph[®] 10mg/5mL), used in such low strength that they present reduced risk of abuse and some can even be sold over the counter, e.g. in a community pharmacy. The pack size which can be sold is small in comparison to the quantity which a GP may choose to prescribe.

(Other examples of CDs are listed in Appendix 1).

The Health Act 2006

The Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations 2006 introduced the changes which were required resulting from the recommendations of the Shipman Inquiry.

- Appointment of an Accountable Officer (AO) to routinely monitor arrangements for the safe and secure handling of CDs in healthcare organisations.
- Appoint personnel to oversee CD destruction if required in GP practices, community pharmacies and other sites including hospitals.
- Share information relating to safer management of CDs between organisations, e.g. police, Social Care and Social Work Improvement Scotland (SCSWIS) (previously Care Commission) etc.
- Record any incidents and concerns relating to CDs and investigate if required and report to the AO or CD Team.

What Do The Changes In Law Mean In General Practice?

- Each Health Board has appointed an AO who has responsibility for the safe management and use of CDs in his/her board area.
- In Scotland most AOs are Directors of Pharmacy.

- In most health boards the AO is supported by a CD team who carry out CD inspections and destructions but also offer support and advice on any matters related to CDs.
- All GPs and practices are required to be inspected to ensure their management of CDs and prescriptions associated with CDs are dealt with in a safe and secure way.
- All GP practices require to have SOPs in place for the use and management of CDs.
- Any incidents or concerns connected with CDs or CD prescriptions should be reported to local manager and to the AO. Contact details for AO must **be included in the practice SOP**.

Prescription Stationery In General Practice

All clerical staff working in a GP practice will be involved in handling, issuing and storage of prescription stationery. CD prescriptions and stationery require a high level of control and security.

GP10/GP10 (SS)

- Prescriptions for CDs in Schedules 2, 3 and 4 are valid for only **28 days from the date signed by the prescriber or from the start date specified by the prescriber**.
- Prescriptions for Schedule 2 and 3 CDs (except temazepam) must include the following details:
 - The patient's full name, address and, where appropriate, age (No fixed abode is acceptable as an address but a PO box number or email address is not allowed).
 - The name and form of the drug, even if only one form exists.
 - The strength of the preparation, where appropriate.
 - The dose to be taken.
 - The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures. Practice computer systems are set up to add these details automatically.
 - Signature and date.
- CD prescriptions can be typewritten, handwritten or computer printed. Only the signature of the prescriber has to be handwritten.
- GP computer systems are configured to request this information.
- The maximum quantity should be limited to 30 day supply for prescriptions of Schedule 2, 3 and 4 CDs but prescribers may still consider it clinically appropriate to supply more than a 30 day quantity. Such decisions should be recorded in the patient's clinical notes.
- In community pharmacies proof of identity may be asked for on collection of CD prescriptions by the patient or the patient's representative.
- If a healthcare professional acting in their professional capacity on behalf of the patient is collecting a CD prescription then the community pharmacist must obtain the persons name and work address and ask for proof of identity.

GP10A forms

- Used by GPs to order stock for use in the treatment room or for stock in their emergency bag.
- Must be signed by the doctor to whom the drug is being supplied.
- Blank forms should not be stored in a local community pharmacy but retained securely by the GP or practice nurse (s) according to practice policy.
- It is best practice for the practice to keep a copy of any GP10A form to enable a check that items delivered are the items ordered.

Other Types Of CD Prescriptions

- Form HBP (A) is used for prescribing CDs to substance misuse patients (most commonly methadone). This form allows supply of instalment prescriptions for CDs prescribed by secondary care facilities such as the Substance Misuse Service (SMS). These prescriptions are blue in colour.
- Private prescription forms in Scotland are called PPCD forms. These are only available after a doctor applies to his Health Board and are doctor specific.

Management Of CD Prescription Stationery In General Practice:

The security of prescription forms (NHS or private) and stock order forms (GP10A) is the responsibility of the employing organisation or practice and individual GPs employed by that organisation or practice. Blank prescription forms should never be pre-signed and prescription pads/forms should never be left unattended as advised in HDL 27(2006).

Blank computer stationery (GP10SS) and GP10 pads could be very valuable to the opportunistic thief or drug misuser. GP surgeries should have a SOP in place to ensure storage and use of prescription stationery is controlled. SOPs should include information on how the practice:

- Restricts access to unused stationery by placing in a locked cupboard.
- Limits access to keys for the stationery cupboard, i.e. they should not be available to everyone.
- Controls the issue of computer prescription forms or prescription pads, e.g. by obtaining and recording signatures as stationery is handed out. For further information on such record keeping refer to Appendix 2: Guidance on recording of receipt and issue of GP10SS and GP10 prescription pads.
- Locks consulting rooms when not in use.
- Ensures patients are not left unattended in consulting rooms.

Dealing With CD Prescriptions:

All GP practices will have their own protocols for dealing with prescriptions but the following points should be noted;

- When dealing with requests from patients for CDs particular attention should be paid to unexplained early requests. This applies to all CD schedules including repeat requests for Schedule 4 or 5 CDs, e.g. diazepam and dihydrocodeine.

- Be aware that signed CD prescriptions are valuable to those who have a drug abuse problem.
- Completed prescriptions awaiting collection should be stored securely.
- Uncollected prescriptions should be locked away at night.
- Identity checks should be carried out for those collecting prescriptions (e.g. asking for the address).
- Secure arrangements should be made for sending CD prescriptions to community pharmacies (e.g. could include a signature for uplift or request community pharmacy staff collecting to carry some form of ID. These arrangements should be agreed with the collecting community pharmacy).
- Be alert for any unusual prescription requests, e.g. an unknown “family member” attending to collect a CD prescription on behalf of the patient.
- It is good practice for all Schedule 2 CDs to be issued as an acute prescription, not a repeat prescription however; practice policy may dictate exceptions to this.
- A system should be in place for alerting the prescriber if CD is prescribed as a repeat to ensure appropriate clinical review.

Printing CD Prescriptions:

- It is good practice to keep Schedule 2 CD prescriptions separate from other prescriptions while awaiting the signature of a GP.

Uncollected CD Prescriptions:

- Clerical staff must be aware of and follow the practice procedures regarding the collection of CD prescriptions.
- Clerical staff must follow the practice procedure for dealing with long standing (e.g. more than 1 month old) uncollected CD prescriptions.
- Ideally these should be shredded after appropriate consultation with prescriber, the issue cancelled and a record made in the patient clinical notes.

Patient Returned CDs

All drugs prescribed for a patient become the property of the patient and in the case of CDs the act of prescribing allows a patient to be in possession of a CD. When a CD is no longer required by a patient and they attempt to give it/them back to a member of practice staff or community pharmacy staff it is called a “patient returned CD”.

All staff should be aware that it is best practice to advise patients to return any unwanted drugs to a local pharmacy. This advice is the same for CDs. However, in exceptional circumstances, CDs may be accepted - all clerical staff should be aware of the practice procedure for dealing with patient returned drugs should this situation arise.

Delivery And Storage Of CDs At A GP Practice

Community pharmacies may sometimes deliver CDs to a practice for the attention of the ordering GP or practice nurse. The practice SOP should make clear which members of staff are authorised to take receipt of CDs and to pass them directly to

someone who has responsibility for recording and storage of these CDs without delay.

Community pharmacies that provide such a delivery of CDs should be asked to provide a delivery note. This delivery note should be signed by the dispensing community pharmacy and by the authorised member of practice staff receiving the CDs. The signed delivery note can be copied and may then be used by both the community pharmacy and practice as proof of delivery. Practice staff can also use the delivery note to verify that CDs delivered match the original GP10A.

CDs may be stored in the practice in a locked cupboard/cabinet reserved solely for CDs and managed normally by the practice nurse. Arrangements must be made for secure key control within the practice. Alternatively the practice may operate a central “emergency CD bag” which is used by GPs of the practice during an emergency home visit.

Some GPs keep their own CD stock to use in an emergency. These should be kept locked in their own GP bag.

Standard Operating Procedures (SOPs)

Most GP practices keep small amounts of CDs in a central stock cupboard and/or in doctor’s emergency bags. Regulations made under the Health Act 2006 require a GP practice to produce SOPs for the use and management of CDs. GP practices will need to have an appropriate process in place to agree and adopt SOPs for their use.

- A SOP is a document that describes the responsibilities and the procedures, including audit, necessary to manage CDs safely and accountably. The SOP must include information on:

- Ordering and receipt of CDs
- Where the CDs are stored
- Who has access to the CDs
- Security in the storage and transportation of CDs as required by Misuse of Drugs legislation
- Disposal and destruction of CDs
- Who is to be alerted if complications arise
- Record keeping, including:
 - Maintaining relevant CD registers under misuse of drugs legislation
 - Maintaining a record of the CDs specified in Schedule 2 to the Misuse of Drugs Regulations 2001 that have been returned by patients.

- The practice SOP should also include:

- Responsibilities within the practice team
- When the SOP will be reviewed, e.g. one, two or three years
- Lead author and named people contributing to the SOP.

- A template SOP is available from the CD team.

Consultative Group (NHS Grampian)

Frances Adamson	Controlled Drug Inspector
Anne Coombes	Practice Manager
Gerry Cronin	Practice Manager
Alison Davie	CHP Lead Pharmacist
Sandra Jamieson	Controlled Drug Inspector
Liz Kemp	Development Pharmacist
Joan Macleod	CHP Pharmacy Manager
Kate Robinson	Admin Assistant
Shonagh Swan	Practice Manager
Lesley Thomson	Lead Pharmacist Controlled Drug Team
Judith Webster	PGD Pharmacist

Consultative Group (NHS Scotland)

Accountable Officers for Controlled Drugs Network Scotland- Working Group

The CD Schedules

Schedule 1 Controlled Drugs (CD Lic)

The drugs listed in Schedule 1 have no recognised medicinal use. Examples of drugs listed in Schedule 1 include coca leaf, lysergamide, lysergide (LSD) and mescaline. Only certain persons have been licensed by the Home Office to possess them for research and other special purposes in the public interest and they are not available in general practice.

Schedule 2 Controlled Drugs (CD PoM)

Examples of Schedule 2 controlled drugs include:

Alfentanyl [®]	Durogesic [®]	MST Continus [®]	Rapifen [®]
Cocaine	Equasym XL [®]	MXL [®]	Remifentanil
Codeine Phos Inj	Fentanyl	Oromorph conc soln [®]	Ritalin [®]
Concerta [®] XL	Hydromorphone	Oxycodone	Seconal sodium
Cyclimorph [®]	Medikinet XL [®]	Oxycontin [®]	Sevredol [®] tablets
Dexamfetamine	Methadone	Oxynorm [®]	Sublimaze [®]
Dexedrine [®]	Methadose [®] Oral Conc	Palladone [®] SR	Tuinal [®]
Diamorphine	Methylphenidate	Pethidine	Ultiva [®]
Diconal [®]	Morphgesic SR [®]	Physeptone [®]	
Dihydrocodeine Injection	Morphine	Quinalbarbitone (secobarbital)	

Schedule 2 Controlled Drugs are subject, under the Misuse of Drugs [Safe Custody] Regulations 1973, to safe custody requirements, except secobarbital.

Schedule 3 Controlled Drugs (CD No Register)

Examples of Schedule 3 Controlled Drugs include:

Barbiturates (except quinalbarbitone/secobarbital)	Hypnovel [®]	Meprobamate	Suboxone [®]
Buprenorphine	Midazolam	Pentazocine	Subutex [®]
Temgesic [®]	Temazepam		

Schedule 3 Controlled Drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf (temazepam and buprenorphine are exceptions to this rule and must be stored in a complying cupboard or, for GPs a locked receptacle).

Schedule 4 Controlled Drugs (CD Benz PoM or CD Anab PoM)

This schedule is split into two parts, Part 1 (CD benzodiazepines) and Part 2 (CD anabolic steroids). Schedule 4 Controlled Drugs are subject to lesser control. Controlled drugs prescription requirements do not apply and there is no requirement for storage in a locked receptacle.

Examples of Schedule 4 (part 1) include alprazolam, chlordiazepoxide, clobazam, clonazepam, diazepam, loperazolam, lorazepam, lormetazepam, nitrazepam, oxazepam and zolpidem.

Schedule 5 Controlled Drugs (CD Inv.P or CD Inv.PoM)

Schedule 5 Controlled Drugs are subject to minimal control and includes certain CDs (e.g. codeine, pholcodine, morphine) which are exempt from full control when present in medicinal products of low strengths.

Examples of Schedule 5 include: aspirin and papaveretum tablets, co-codamol, co-codaprin, codeine linctus BP, codeine phosphate tablets 15mg and 30mg, co-dydramol, DHC Continus[®], Lomotil[®], Oramorph[®] oral solution 10mg in 5mL, Paracodol[®], Pavacol-D[®] and Tylex[®].

These lists are not exhaustive, for further information please refer to:

- The Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.
- British National Formulary current edition.
- Medicines, Ethics and Practice Guide – current edition.

Guidance On The Recording And Issue Of Computer GP10SS And GP10 Prescription Pads.

GP10SS

On receipt of prescription forms from the supplier, please check that the number of prescription form boxes received against the order placed, as the supplier does not provide a delivery note. If there is a discrepancy advise the senior administrator or Practice Manager. They should then contact the supplier immediately.

Record on, for example, an excel spreadsheet (see below) the date boxes received, individual box number, and serial numbers of prescription forms. Equally a notebook preferably bound, will suffice if kept only for this purpose. This information is found on the box label (See sample box label on page 15). The person receiving the order must sign the spreadsheet/notebook. The prescription forms must be stored in a secure, lockable area that can not be accessed by the public or non-authorized staff.

The actual serial numbers of the prescriptions can be found by removing the last number, e.g. in the example shown the numbers of the forms are from 3906908001 to 3906910000.

Recording this basic amount of information will allow the practice to know what serial numbers of GP10SS forms they have received into the practice and may aid in an investigation into any stolen prescriptions.

This is the minimum information we would expect a Practice to maintain for recording receipt and use of computer prescription forms. However this can be expanded to include the date the box is opened and closed and this will further assist in identifying timescales if prescriptions are missing.

Other data which may be recorded by adding columns to spreadsheet/notebook includes:

- Date transferred to consulting room
- Supplied to Dr's name or consulting room number
- Signature of person supplying.

GP10

Information for GP prescription pads can be recorded in a similar way and should include the date received the serial number of the first and last prescription in the pad, the doctor's name and the name of the person issuing the prescription pad. A record should be made of the date issued and the signatures of the issuer and the receiving doctor.

The completed spreadsheet/notebook should be kept for a minimum of 2 years.

Sample Excel Spreadsheet

Record of Receipt and Supply of Computer Prescription Forms.							
Date of Receipt	Box No.	Signature	Prescription Numbers	Date Box Opened	Signature	Date Box finished	Signature
e.g.							
1st January 2011	3055	J.Smith	39069080012- 3906910005	03/01/2011	A.N. Other	02/02/2011	J. Bloggs
1st January 2011	3056	J.Smith	3906910016 - 3906912009	02/02/2011	J.Bloggs		
1st January 2011	3057	J.Smith	3906912014 - 3906914007				

Label On Box Of Blank Computer Prescription Forms



Type Of Prescription Form In Box

Box Number

Prescription Serial Numbers