Hampshire NHS
Primary Care Trust

POLICY FOR THE MANAGEMENT OF CONTROLLED DRUGS IN PRIMARY CARE

Title:	Policy for the Management of Controlled Drugs in Primary Care	
Policy Reference Number:	**CLI/MED.02/V1.00**	
Summary:	The purpose of this policy is to promote the safe, secure and effective use of all CDs, which are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm..	
Associated Documents:		
Target Audience:	All staff and General Practitioners of Hampshire Primary Care Trust	
Document Version:	Version 1.00	
Date of this Version:		
Date Issued:	24 Oct 2008	
Author's Name:	M Thomas, Accountable Officer, Controlled Drugs	
Custodian's Name:	R Samuel, Director, Corporate Affairs, HPCT	
Approved by:	Care Services Integrated Governance Committee	Date of meeting:
Ratified by:	Care Services Board Hampshire Primary Care Trust Board	Date of meeting: 11 Aug 2008 25 Sep 2008
Signature of Chief Executive:		Date:

POLICY DEVELOPMENT DOCUMENT CONTROL PANEL

Policy Title: Policy for the Management of Controlled Drugs in Primary Care		
Policy Reference Number: CLI/MED.02/V1.00		
Version Number: 1.00	**Date of Issue: 24 Oct 2008**	**Review Date: Aug 2009**
Policy Custodian: R Samuel		
Designation: Director, Performance and Standards		
Email Address: Code A		
Is this a new policy?		**No**
If 'Yes', why is it required? *(i.e. new legislation necessitating Trust compliance)*		
How does the Policy link to:		
Standards for Better Health	*Core Standards:*	
NHSLA PCT Risk Management Standards	*Standards:*	
National Service Framework	*NSF*	
Other (please specify):		
If 'No', name of previous policy and reason for replacement:		
Who has been involved/consulted in order to develop this Policy?		
Has the Trust's Legal Services Manager checked this policy?		**Yes**
Summary of significant changes made:		
Approval Route:	CSIG	**Date: Aug 2008**
Ratification Route:	CSB HPCT Board	**Date: Aug 2008** **Sep 2008**

POLICY FOR THE MANAGEMENT OF CONTROLLED DRUGS IN PRIMARY CARE

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1 Policy Statement

In 2000, Dr Harold Frederick Shipman was convicted of 14 murders and one case of forgery. In 2001, Dame Janet Smith commenced an enquiry covering the period 1974 to 1998, which concluded that Shipman had killed 215 of his patients, with a further 45 suspected killings. Shipman used illegally obtained controlled drugs (CDs) to carry out these killings and went undetected due to the trust placed on GPs, poor audit procedures and inadequate information exchange. Notwithstanding, **it is recognised that the vast majority of practitioners who purchase, prescribe, dispense, administer and destroy CDs do so in keeping with legislative requirements and their professional code and practice to a high standard.**

The purpose of this policy is to promote the safe, secure and effective use of all CDs, which are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. The Government has introduced strengthened measures to make sure CDs are managed safely and these came into force on 1 January 2007 [http://www.opsi.gov.uk/si/si2006/20063148.htm]. These arrangements need to be implemented in a way that supports professionals and encourages good practice around the management and use of these important medicines when clinically required by patients.

The Government has set up new monitoring and inspection arrangements for CDs in the Health Act 2006. These will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. The 2006 Regulations require each healthcare organisation to appoint an AO, responsible for the safe and effective use of CDs in their organisation. The 2006 Regulations also initiate standard operating procedures (SOPs) for the use and management of CDs. These are one of the practical measures that will help to ensure good practice throughout the health and social care system.

2 Scope

This document aims to introduce the SOPs for the management and use of CDs in Primary Care, specifically within those services provided by Hampshire Primary Care Trust, with a template SOP for use within GP practices. The SOPs will be circulated independently and will form the basis of audits, visits and inspections carried out by or on behalf of the AO, Hampshire PCT.

This document does not quote directly from Statutory Instruments or Acts of Parliament. Source documents must be used where accuracy is required in particular cases.

3 Rationale

The regulations require an AO to ensure that his or her organisation, or a body or person acting on behalf of, or providing services under contract with, his or her organisation, has adequate and up-to-date SOPs in relation to the management and use of CDs.

4 Definition of Terms

Term	Meaning
The Prescription Only Medicines Order	The Prescription Only Medicines (Human Use) Order 1997
The 2001 Regulations	The Misuse of Drugs Regulations 2001
The 2006 Act	The Health Act 2006
The 2006 Regulations	The Controlled Drugs (Supervision of Management and Use) Regulations 2006
Accountable Officer	A person nominated or appointed under regulation 4 of the 2006 Regulations (AO)
Controlled drugs	As specified in Schedules 1 to 5 of The 2001 Regulations, as amended – see Appendix 1
Management and use of controlled drugs	a. The storage, carriage and safe custody of such drugs, b. The prescribing and supply of such drugs, c. The administration of such drugs, d. The recovery of such drugs when no longer needed, e. The disposal of such drugs.
Misuse of drugs legislation	Misuse of Drugs Act 1971 and any subordinate legislation made under that Act.
PGD	Patient Group Direction
POM	Prescription Only Medicines
Responsible Person	The person responsible for the controlled drugs at a given location.

5 Responsibilities

5.1 *The PCT*

The Primary Care Trust is a designated body for the purposes of section 17 of the 2006 Act and must, therefore, nominate or appoint an AO. Such appointment may be made jointly with one or more similar bodies.

5.2 *The Accountable Officer*

In discharging his responsibilities, an Accountable Officer (AO) must have regard to best practice in relation to the management and use of CDs.

The AO may require a periodic declaration and a self-assessment from a general medical practitioner.

The AO must not routinely supply, administer or dispose of CDs as part of his duties.

The AO must:

- secure the safe management and use of CDs;
- ensure adequate destruction and disposal arrangements for CDs;
- ensure monitoring and auditing of the management and use of CDs by the PCT and by any body or person acting on behalf of, or providing services for, the PCT;
- ensure relevant individuals receive appropriate training;
- assess and investigate concerns concerning the management and use of CDs;
- establish and operate appropriate arrangements for making periodic inspections of premises which are:
    - used in connection with management or use of CDs; and
    - not subject to inspection by one of the organisations below.

  The AO is not required to give notice of such inspection to the owner or occupier of the premises and powers of entry are conferred by the 2006 Act.

5.3 *Clinical Service Providers*

All organisations and individuals providing clinical services will need to:

- Complete a periodic declaration, at least every two years, on whether or not their organisation keeps stocks of CDs;
- Complete a self-assessment of their management of CDs, where stocks are held.

The PCT Accountable Officer will provide a declaration and self-assessment questionnaire to general medical practitioners on the performers' list. A model declaration and assessment form, provided by the Department of Health, has been modified for local use. The modified declaration and assessment are attached to this policy, although these are subject to amendment by the Accountable Officer.

Health care professionals who prescribe, dispense or administer CDs should demonstrate that they keep up-to-date on all aspects of CD management, including safe custody, safe storage, record keeping, supply and disposal of CDs. For those professions that have formal revalidation processes, an annual appraisal to identify gaps in knowledge and skills should form an integral part of that revalidation.

5.4 *The Commission for Social Care Inspection*

The Commission for Social Care Inspection (CSCI) may request an appropriate periodic declaration and an appropriate self-assessment from a care home.

5.5 *The Royal Pharmaceutical Society of Great Britain*

The Royal Pharmaceutical Society of Great Britain may request an appropriate periodic declaration and an appropriate self-assessment from a registered pharmacy.

5.6 *The Healthcare Commission*

The Healthcare Commission may request an appropriate periodic declaration and an appropriate self-assessment from an NHS Trust, an NHS foundation trust or a person registered with them that provides health care.

5.7 *Local Intelligence Network*

The AO of a PCT is required to establish and operate a Local Intelligence Network (LIN) to ensure the proper sharing of information regarding the management and use of CDs.

Membership of the LIN is mandated for designated bodies but any person or body can, and should, provide information to the network when necessary, via the AO.

Accountable Officers of other organisations within the LIN are required to render quarterly reports to the PCT Accountable Officer, regarding their management and use of CDs. The PCT AO is required to render a quarterly report to the Healthcare Commission.

6 An Overview of the Law Relating to CDs

The Misuse of Drugs Act, 1971 controls certain classes of dangerous drugs, which are listed and known as "controlled drugs". Its main purpose is to prevent the misuse of these drugs by imposing a total ban on the possession, supply, manufacture or importation of CDs, except as allowed by regulations. The prescribing and use of CDs in medicine is regulated by the Prescription Only Medicines Order (as amended) and the Misuse of Drugs Regulations, 2001 (as amended). Separate regulations deal with the safe custody of CDs (The Misuse of Drugs (Safe Custody) Regulations 1973, as amended) and their supply to addicts (The Misuse of Drugs (Supply to Addicts) Regulations 1997, as amended)

The 2001 Regulations set out a number of schedules, which classify CDs according to different levels of control (see Appendix 1):

Schedule 1 (CD Lic). These drugs have virtually no therapeutic use, e.g. hallucinatory drugs (LSD, "Ecstasy") and cannabis. A special Home Office licence is required for their possession, usually for academic or research purposes.

***Schedule 2* (CD).** This includes the opiates (e.g. morphine, diamorphine, methadone), synthetic opiates/related compounds (e.g. pethidine, fentanyl), and the major stimulants (e.g. amphetamines). This is the class of drugs to which this policy applies. It should also be noted that medicines that contain these drugs are not only CDs but also Prescription Only Medicines, which is also true of schedules 3 and 4.

Schedule 3 (CD No Register). These are drugs less likely to be misused or are considered less harmful than Schedule 2 CDs. Temazepam and buprenorphine are included in this class. Safe custody requirements apply to these two drugs, which mean they must be kept in the CD cupboard. However, there is no legal requirement for records of receipt or administration of Schedule 3 drugs to be kept in the CD Record Book. Apart from the storage requirement, they do not come under the jurisdiction of this policy. Security requirements (e.g. for temazepam) may be increased.

Schedule 4, Part 1 (CD Benz). This includes most benzodiazepines, (e.g. midazolam, diazepam, but not temazepam - see above). They are POMs and need to be safely and securely stored and their use carefully controlled by prescribing but they do not come under the jurisdiction of this policy.

Schedule 4, Part 2 (CD Anab). This includes many of the anabolic and androgenic steroids. Again, they are POMs and need to be safely and securely stored and their use carefully controlled by prescribing but they do not come under the jurisdiction of this policy.

Schedule 5 (CD Inv). This applies to certain medicines that contain CDs in strengths low enough for them not to require the same degree of control as for other schedules. The name comes from the fact that pharmacies are required to record and retain invoices relating to the procurement of these medicines for at least 2 years. They do not come under the jurisdiction of this policy.

7 Standard Operating Procedures (SOPs)

An SOP is a document describing the responsibilities and the procedures, including audit, necessary to safely and accountably manage any set of processes, in this case around the total management of CDs.

SOPs need to be accessible to staff at all times.

A large organisation will require an overarching policy for SOPs, and smaller organisations such as GP practices will need to have an appropriate process in place to agree and adopt SOPs for use. Different health and social care settings may have practice areas in addition to those outlined below.

The Regulations require that:

- All health care providers will have and comply with an approved SOP.
- SOPs for organisations will be agreed by the relevant AO.
- Each GP practice or pharmacy should have clear, written SOPs in place that are known, understood and followed by practitioners and their staff.
- Every PCT should have SOPs for handling CDs for all of its directly managed services and staff.

The Regulations state that SOPs must cover the following:

- Assigning responsibilities
- Ordering and receipt of CDs
- Who has access to CDs
- Where the CDs are stored
- Security in relation to storage and transportation of CDs
- Disposal and destruction of CDs
- Who is to be alerted if complications arise

- Record keeping, including CDs registers and records of Schedule 2 drugs that have been returned by patients.

Controlled drug SOPs for Hampshire PCT will be circulated separately to this policy, in order to ease periodic review and availability. Each SOP is a standalone document, which must be read by each person involved in the management and use of CDs. A signature sheet is included and must be completed as proof of reading. The most up to date versions of the SOPs are available on the Hampshire PCT intranet.

8 Training Plan

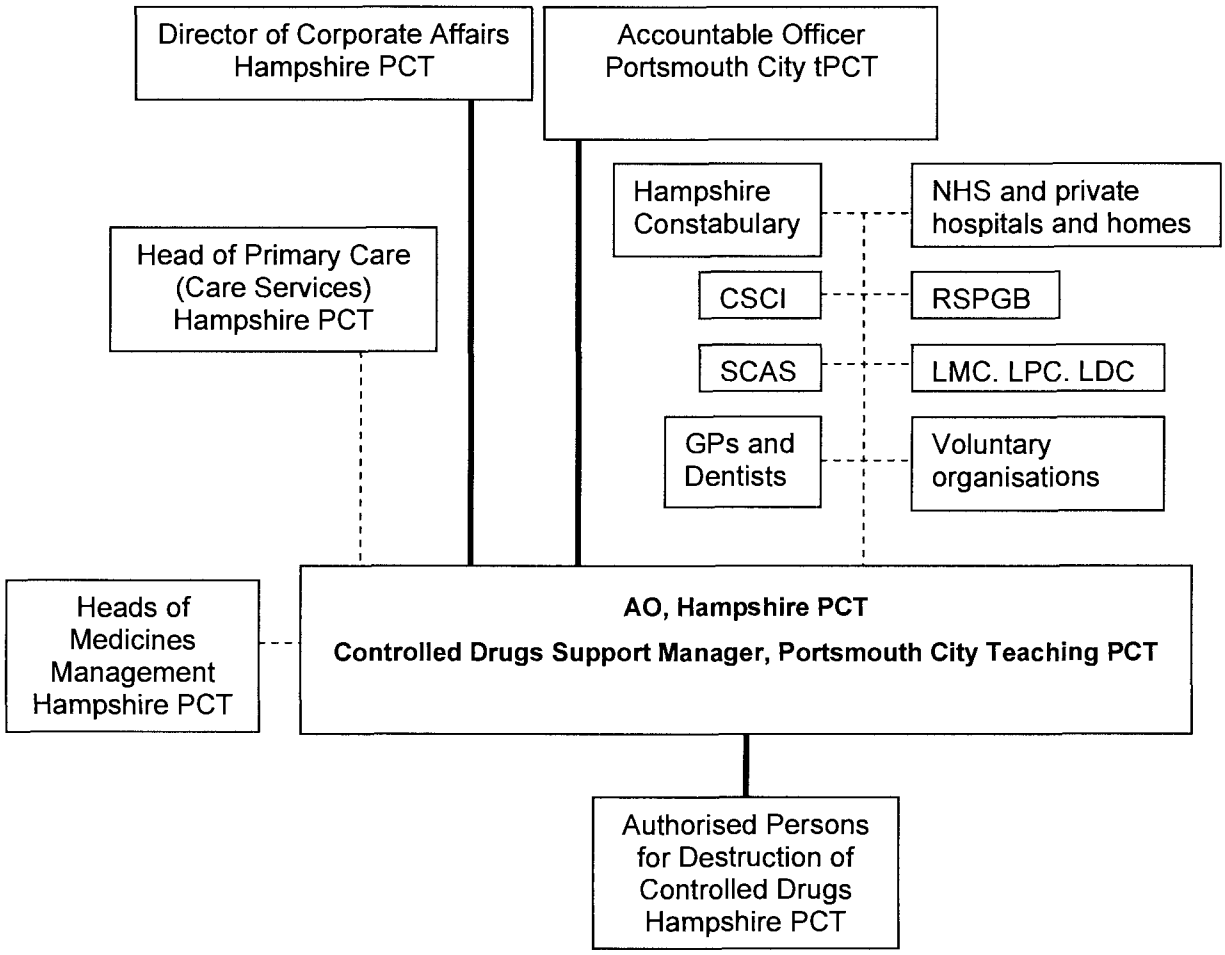
All staff will receive basic awareness training during site inductions. Subsequent training will take place during the routine visits conducted by the Accountable Officer and Medicines Management staff. Legislation requires that each location where controlled drugs are managed and/or used must be visited at least once every 3 years.

9 Cross References

A guide to good practice in the management of controlled drugs in primary care (England) 2007

Royal Pharmaceutical Society of Great Britain Guidance on changes in the management of controlled drugs [http://www.rpsgb.org/worldofpharmacy/useofmedicines/controlleddrugs.html]

10 Organisational Chart



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Appendix 1: 2001 Regulations - Schedules 2, 3 and 4 CDs

SCHEDULE 2 Regulation 3 CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15, 16, 18, 19, 20, 21, 23, 26 AND 27

1. The following substances and products, namely –

Acetorphine	Levophenacylmorphan
Alfentanil	Levorphanol
Allylprodine	Lofentanil
Alphacetylmethadol	Medicinal opium
Alphameprodine	Metazocine
Alphamethadol	Methadone
Alphaprodine	Methadyl acetate
Anileridine	Methyldesorphine
Benzethidine	Methyldihydromorphine (6-methyldihydromorphine)
Benzylmorphine (3-benzylmorphine)	Metopon
Betacetylmethadol	Morpheridine
Betameprodine	Morphine
Betamethadol	Morphine methobromide, morphine N-oxide and other pentavalent nitrogen morphine derivatives
Betaprodine	Myrophine
Bezitramide	Nicomorphine
Carfentanil	Noracymethadol
Clonitazene	Norlevorphanol
Cocaine	Normethadone
Desomorphine	Normorphine
Dextromoramide	Norpipanone
Diamorphine	Oxycodone
Diampromide	Oxymorphone
Diethylthiambutene	Pethidine
Difenoxin	Phenadoxone
Dihydrocodeinone O-carboxymethyloxime	Phenampromide
Dihydroetorphine [1]	Phenazocine
Dihydromorphine	Phencyclidine
Dimenoxadole	Phenomorphan
Dimepheptanol	Phenoperidine
Dimethylthiambutene	Piminodine
Dioxaphetyl butyrate	Piritramide
Diphenoxylate	Proheptazine
Dipipanone	Properidine
Dronabinol	Racemethorphan
Drotebanol	Racemoramide
Ecgonine, and any derivative of ecgonine which is convertible to ecgonine or to cocaine	Racemorphan
Ethylmethylthiambutene	Remifentanil[2]
Etonitazene	Sufentanil
Etorphine	Thebacon
Etoxeridine	Thebaine
Fentanyl	Tilidate
Furethidine	Trimeperidine
Hydrocodone	Zipeprol

[1] Inserted by SI 2003/1432
[2] Inserted by SI 2003/1432

Hydromorphinol	4-Cyano-2-dimethylamino-4,4-diphenylbutane
Hydromorphone	Hydroxypethidine4-Cyano-1-methyl-4-piperidine
Isomethadonephenyl	2-Methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid
Ketobemidone	$^{\alpha}$ -Methylphenethylhydroxylamine
Levomethorphan	1-Methyl-4-phenylpiperidine-4-carboxylic acid
Levomoramide	4-Phenylpiperidine-4-carboxylic acid ethyl ester

2. Any stereoisomeric form of a substance specified in paragraph 1 not being dextromethorphan or dextrorphan.
3. Any ester or ether of a substance specified in paragraph 1 or 2, not being a substance specified in paragraph 6.
4. Any salt of a substance specified in any of paragraphs 1 to 3.
5. Any preparation or other product containing a substance or product specified in any of paragraphs 1 to 4, not being a preparation specified in Schedule 5.
6. The following substances and products, namely –

Acetyldihydrocodeine	Methaqualone
Amphetamine	Methylamphetamine
Codeine	Methylphenidate
Dextropropoxyphene	Nicocodine
Dihydrocodeine	Nicodicodine (6-nicotinoyldihydrocodeine)
Ethylmorphine (3-ethylmorphine)	Norcodeine
Fenethylline	Phenmetrazine
Glutethimide	Pholcodine
Lefetamine	Propiram
Mecloqualone	Quinalbarbitone

7. Any stereoisomeric form of a substance specified in paragraph 6.
8. Any salt of a substance specified in paragraph 6 or 7.
9. Any preparation or other product containing a substance or product specified in any of paragraphs 6 to 8, not being a preparation specified in Schedule 5.

SCHEDULE 3 Regulation 3 CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 14, 15 (EXCEPT TEMAZEPAM), 16, 18, 22, 23, 24, 26 AND 27

1. The following substances, namely -

(a)

Benzphetamine	Mephentermine
Buprenorphine	Meprobamate
Cathine	Methylphenobarbitone
Chlorphentermine	Methyprylone
Diethylpropion	Midazolam [3]
Ethchlorvynol	Pentazocine
Ethinamate	Phendimetrazine
Flunitrazepam	Phentermine
Mazindol	Pipradrol
	Temazepam

(b) any 5, 5 disubstituted barbituric acid not being quinalbarbitone.

2. Any stereoisomeric form of a substance specified in paragraph 1 not being phenylpropanolamine.
3. Any salt of a substance specified in paragraph 1 or 2.
4. Any preparation or other product containing a substance specified in any of paragraphs 1 to 3, not being a preparation specified in Schedule 5.

[3] Inserted by SI 2007/2154

SCHEDULE 4 Regulation 3

PART I - CONTROLLED DRUGS SUBJECT TO THE REQUIREMENTS OF REGULATIONS 22, 23, 26 AND 27

1. The following substances and products, namely -

Alprazolam	Ketamine [4]
Aminorex	Ketazolam
Bromazepam	Loprazolam
Brotizolam	Lorazepam
Camazepam	Lormetazepam
Chlordiazepoxide	Medazepam
Clobazam	Mefenorex
Clonazepam	Mesocarb
Lorazepam acid	~~Midazolam~~[5]
Clotiazepam	Nimetazepam
Cloxazolam	Nitrazepam
Delorazepam	Nordazepam
Diazepam	Oxazepam
Estazolam	Oxazolam
Ethyl loflazepate	Pemoline
Fencamfamin	Pinazepam
Fenproporex	Prazepam
Fludiazepam	Pyrovalerone
Flurazepam	Tetrazepam
Halazepam	Triazolam
Haloxazolam	N-Ethylamphetamine
4-Hydroxy-n-butyric acid[6]	Zolpidem [7]

2. Any stereoisomeric form of a substance specified in paragraph 1.
3. Any salt of a substance specified in paragraph 1 or 2.
4. Any preparation or other product containing a substance or product specified in any of paragraphs 1 to 3, not being a preparation specified in Schedule 5.

PART II - CONTROLLED DRUGS EXCEPTED FROM THE PROHIBITION ON POSSESSION WHEN IN THE FORM OF A MEDICINAL PRODUCT; EXCLUDED FROM THE APPLICATION OF OFFENCES ARISING FROM THE PROHIBITION ON IMPORTATION AND EXPORTATION WHEN IMPORTED OR EXPORTED IN THE FORM OF A MEDICINAL PRODUCT BY ANY PERSON FOR ADMINISTRATION TO HIMSELF; AND SUBJECT TO THE REQUIREMENTS OF REGULATIONS 22, 23, 26 AND 27

1. The following substances, namely -

4-Androstene-3, 17-dione [8]	Methenolone
5-Androstene-3, 17-diol [9]	Methyltestosterone
Atamestane	Metribolone
Bolandiol	Mibolerone
Bolasterone	Nandrolone
Bolazine	19-Nor-4-Androstene-3, 17-dione [10]
Boldenone	19-Nor-5-Androstene-3, 17-diol [11]
Bolenol	Norboletone
Bolmantalate	Norclostebol
Calusterone	Norethandrolone
4-Chloromethandienone	Ovandrotone

[4] Inserted by SI 2005/3372
[5] Deleted by SI 2007/2154
[6] Inserted by SI 2003/1432
[7] Inserted by SI 2003/1432
[8] Inserted by SI 2003/1432
[9] Inserted by SI 2003/1432
[10] Inserted by SI 2003/1432
[11] Inserted by SI 2003/1432

Clostebol	Oxabolone
Drostanolone	Oxandrolone
Enestebol	Oxymesterone
Epitiostanol	Oxymetholone
Ethyloestrenol	Prasterone
Fluoxymesterone	Propetandrol
Formebolone	Quinbolone
Furazabol	Roxibolone
Mebolazine	Silandrone
Mepitiostane	Stanolone
Mesabolone	Stanozolol
Mestanolone	Stenbolone
Mesterolone	Testosterone
Methandienone	Thiomesterone
Methandriol	Trenbolone

2. Any compound (not being Trilostane or a compound for the time being specified in paragraph 1 of this Part of this Schedule) structurally derived from 17-hydroxyandrostan-3-one or from 17-hydroxyestran-3-one by modification in any of the following ways, that is to say -
   (a) by further substitution at position 17 by a methyl or ethyl group;
   (b) by substitution to any extent at one or more of positions 1, 2, 4, 6, 7, 9, 11 or 16, but at no other position;
   (c) by unsaturation in the carbocyclic ring system to any extent, provided that there are no more than two ethylenic bonds in any one carbocyclic ring;
   (d) by fusion of ring A with a heterocyclic system.
3. Any substance which is an ester or ether (or, where more than one hydroxyl function is available, both an ester and an ether) of a substance specified in paragraph 1 or described in paragraph 2 of this Part of this Schedule.
4. The following substances, namely -
   Chorionic Gonadotrophin (HCG)
   Clenbuterol
   Non-human chorionic gonadotrophin
   Somatotropin
   Somatrem
   Somatropin
5. Any stereoisomeric form of a substance specified or described in any of paragraphs 1 to 4 of this Part of this Schedule.
6. Any salt of a substance specified or described in any of paragraphs 1 to 5 of this Part of this Schedule.
7. Any preparation or other product containing a substance or product specified or described in any of paragraphs 1 to 6 of this Part of this Schedule, not being a preparation specified in Schedule 5.

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Appendix 2: Authorised Persons for the Destruction of CDs

The Misuse of Drugs Regulations 2001 Regulation 27 enables the Secretary of State for Health and AOs to specify groups of people and individuals who are authorised to witness the destruction of stock.

Within the PCT, such authorisations are enabled by written authority from the AO:

The Home Secretary authorises:

1. Inspectors of the Royal Pharmaceutical Society of Great Britain;
2. Inspectors of the Home Office Drugs Branch;
3. Police constables;

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Appendix 3: Controlled Drugs: Declaration

Please complete a form for each location owned / used by the organisation

General Details		
Name and contact details of person completing this form		
Designation of person completing this form		
Controlled Drug (CD) designated lead, if different from above		
Type of organisation	E.g. General practice, Dental Practice, prison, out of hours provider.	
Name and Address of organisation		
Names and Registration details of Healthcare Professionals within the organisation (e.g. Doctors, Dentists, other CD prescribers) :		
About your organisation (Please include as much detail as possible)		
NHS / Private / Both		
Are there any special circumstances about your organisation that might influence the use and storage of CDs?	E.g. Palliative care, Home Office licence to prescribe for treatment of drug addiction, supervised ingestion on site.	
Does the organisation have SOPs for the management and use of CDs?		
Is the organisation a dispensing practice?		
Do you store / hold any CDs at the organisation's premises? If so, which?		
Do you prescribe CDs? If so, which?		
Do members of the organisation undertake any roles requiring them to carry CDs?	E.g. Forensic medical advisor, sports doctor, BASICS, out of hours provider.	

Have any members of your organisation received any special training relevant to the use of CDs?	E.g. Substance misuse training, palliative care training, trauma training.	
Do any of the practitioners keep CDs in their personal possession?	E.g. Doctor's bags for out of hours use.	
Do any of the practitioners keep CDs in other settings?	E.g. Sports club.	
Do you believe that your organisation complies with the Misuse of Drugs Act 1971, Misuse of Drugs Regulations 2001 and Safe Custody Regulations 1974?		
If yes, how do ensure continued compliance?		
Has any member of your organisation been convicted of an offence under the MDA 1971?		
Signature		
Date of Signing		

Please note that you must notify any material changes to the answers above, within 14 days of the change.

Please return the completed form to:

The Accountable Officer (Controlled Drugs)
Hampshire Primary Care Trust
3rd Floor
Raebarn House
Hulbert Road
WATERLOOVILLE
Hampshire
PO7 7GP

This form is taken from the "Clinical Governance Toolkit for Controlled Drug Management in Primary Care in the NHS", produced by NCAS, CGST, NPSA and the RPSGB.

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Appendix 4: Controlled Drugs: Self Assessment

Table A: General Information

Please complete in all cases

	Y / N	Details (Where applicable)
Do you have written standard operating procedures or written policies covering the handling and management of CDs, appropriate to the activities carried out at the premises? If yes, please provide copies.		
Do you have in place a local procedure for dealing with a significant event** involving CDs? If yes, please provide copies.		
Do you have appropriate procedures for the initial and continuing training or development of all staff involved in the prescribing, handling, supply and administration of CDs? If yes, please provide copies.		
Are there any special factors which influence the prescribing or use of CDs by your organisation? If yes, please give details.		
Do you keep an up to date CD register?		
Do you keep running balances of stock CDs? If yes: a) Do you audit your running totals? (how often and when last done) b) Are the running totals audited by outside management staff (area / regional managers)? (how often and when last done)		
Have you identified any discrepancies between running totals and actual CDs held during the last 12 months? If yes, what was the explanation for the difference? What action was taken?		
Do you maintain records of all receipts and supplies of CDs? If yes, for how long do you keep records?		
Have there ever been any complaints involving the storage, transport or record keeping of CDs?		
Have there been any significant events** involving the storage, transport or record keeping of CDs?		
Completed by:		
Location:		

+The Accountable Officer, Hampshire PCT, Raebarn House, Hulbert Road, WATERLOOVILLE PO7 7GP
matthew.thomas@ports.nhs.uk

**Significant event includes any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong

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Section 1: Prescribing of CDs

Q1	Do you prescribe CDs?	

ONLY complete the remainder of this section if the answer to Q1 is yes

	Y / N / NA	Details (Where applicable)
Do you provide advice on the safekeeping and disposal of unwanted CDs?		
Are patient information leaflets supplied to all patients receiving CDs?		
Are there any specific restrictions on the CD prescribing abilities of any of the healthcare professionals involved?		
Have there been any complaints*** involving the prescribing of CDs?		
Have there been any concerns expressed by colleagues, police, drugs misuse services or others about unusual, excessive or inappropriate prescribing of CDs?		
Have there been any significant events** involving the prescribing of CDs?		

*** This includes complaints about failing to prescribe appropriate doses and / or appropriate medicines.

**Significant event includes any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong.

Section 2: Administration of CDs

Q2	Do you administer CDs (or supervise or assist patients' own administration)?	

ONLY complete the remainder of this section if the answer to Q2 is yes

	Y / N / NA	Details (Where applicable)
Are the CDs that are used for administration: a) Stock CDs? b) Patient's own CDs? c) Both a) and b)		
Do you maintain records of administration? If yes, where? (Register, MAR Chart, etc)		
Is the administration of CDs witnessed? If not, what risk management policies are in place to cover administration? Please provide copies.		
Have there been any complaints involving the administration of CDs?		
Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the administration of CDs?		
Have there been any significant events** involving the supply of CDs?		

**Significant event includes any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong.

Section 3: Security and Safe Custody of CDs on Premises

Q3	(i)	Do you hold stock CDs either on the premises or off site e.g. in doctors' bags?	
	(ii)	Do you hold patients'/clients' CDs?	

ONLY complete the remainder of this section if the answer to Q3 is yes

	Y / N / NA	Details (Where applicable)
Do you store CDs in: i) A central store? ii) Doctors' bags? iii) Other places? (please give details)		
Do you have any current Chief Constable exemption certificates in operation for your CD storage facilities? (NB Not all premises will need exemption certificates for CD storage facilities)		
Are all CDs kept under lock and key (including patient returned CDs or unwanted / obsolete CDs)?		
Is access to CDs controlled? If yes, how?		
Do you utilise the CD storage facilities for storage of anything other than CDs? If yes, please give details.		
How often does date checking of CD stock take place? Please give details of the procedures used.		
How often does date checking of CD stock in doctors' bags take place? (where applicable) Please give details of the procedures used.		
Are all stock CDs kept in the original containers?		
Are dispensed patients' medicines appropriately labelled?		
Are different strengths of the same medicine segregated in any way?		
Do you have out of date or obsolete **patient returned** CDs currently stored?		
Are out of date / obsolete / patient returned CDs segregated from other CDs?		
Are patient returned medicines ever re-used?		

Section 4: Destruction or Disposal of CDs

Q4	Do you destroy or dispose of CDs (patient returned / stock)?	

ONLY complete the remainder of this section if the answer to Q4 is yes

	Y / N / NA	Details (Where applicable)
Patients' CDs		
What records do you keep of CDs returned to you by patients for disposal (where applicable)?		
Are patient returned medicines ever re-used?		
Do you routinely destroy patients' old or obsolete CDs?		
What systems do you have in place for the disposal of patients'/clients' old or obsolete CDs?		
Is the destruction of patients'/clients' old or obsolete CDs witnessed? If yes, by whom?		

	Y / N / NA	Details (Where applicable)
Do you keep records of the destruction of patients'/clients' old or obsolete CDs? If yes, for how long are these records retained?		
Stock CDs		
How often do you aim to destroy out of date or obsolete stock CDs?		
Do you have any out of date or obsolete **stock** CDs currently awaiting destruction?		
Who usually witnesses your stock destruction?		
When was the last witnessed CD stock destruction?		
Are records of stock destruction kept in the CD register?		
Have there been any complaints involving the destruction or disposal of CDs?		
Have there been any concerns expressed by colleagues, police, drugs misuse services or others about the destruction or disposal of CDs?		
Have there been any significant events** involving the destruction or disposal of CDs?		

**Significant event includes any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong.

Section 5: Supply of CDs

Q5	Do you supply CDs? (e.g. to addicts or other doctors)	

Section 6: Transporting CDs

Q6	Do you transport or are you responsible for the transport of CDs (this includes sending CDs using third party carriers, such as delivery drivers and postal system)?	
Contact e-mail:		
Contact telephone number:		