



## 2 Medicines for Human Use: Controlled Drugs & Accountable Officer Regulations



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## 2.1 CONTROLLED DRUGS

A number of important amendments to the Misuse of Drugs Regulations 2002 have come into force in the period 2006 -2010. Pharmacists should ensure that they are aware of all the changes as they affect current practice.

A list of relevant legislation is given at the end of this section and further information may be accessed online at [www.opsi.gov.uk](http://www.opsi.gov.uk)

In addition a number of informative Guidance Documents have been issued by both the DHSSPSNI. These are included at the end of the section.

The information provided below should be read in conjunction with the following reference documents

- Safer Management of Controlled Drugs –A guide to good practice in secondary care (Northern Ireland) August 2009 (see [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk) )
- Safer Management of Controlled Drugs – A guide to good practice in primary care (Northern Ireland) – due 2010

The Misuse of Drugs Act 1971 controls “dangerous or otherwise harmful drugs” which are designated as “Controlled Drugs”. The primary purpose of the Misuse of Drugs Act is to prevent the misuse of Controlled Drugs. It does that by imposing a total prohibition on the possession, supply, manufacture, import or export of Controlled Drugs except as allowed by regulations or by licence or authority from the DHSSPS. The use of Controlled Drugs in medicine is permitted by the Misuse of Drugs (Northern Ireland) Regulations 2002 and subsequent amendment regulations. Other regulations deal with the safe custody of Controlled Drugs and with the notification of and supply of drugs to addicts. The schedules to the Act are of no practical importance to pharmacists and practitioners. In the Misuse of Drugs Regulations, the drugs are classified in five schedules according to different levels of control. It is those classifications that are described in the following paragraphs. They are marked “CD Lic”, “CD No Register”, etc.

### Schedule 1 Drugs (CD Lic)

Schedule 1 includes the hallucinogenic drugs (for example LSD) the ecstasy-type substances and cannabis, which have virtually no therapeutic use. Production, possession and supply of drugs in this schedule are limited, in the public interest, to purposes of research or other special purposes. A licence from the DHSSPS is needed for any of these purposes, and, apart from licence holders, the class of persons who may lawfully possess them is very limited. It does not include practitioners and pharmacists except under licence.

Some pharmacists, particularly those working within hospital, may be asked to deal with substances removed from patients on admission, which may be Schedule 1 products (for example cannabis). As a licence is required to possess Schedule 1

products, the pharmacist cannot take possession of the product other than in the two cases where exemptions are granted. The first exemption is where a person takes possession of a Controlled Drug for the purpose of destruction, and the second is for the purpose of handing over to a police officer.

The patient's confidentiality should normally be maintained, and the police should be called in on the understanding that there will be no identification of the source. If, however, the quantity is so large that the drug could not be purely for personal use, the pharmacist may decide that the greater interests of the public require identification of the source. Such a decision should not be taken without first discussing with the other health professionals involved in the patient's care, and the hospital's legal adviser, and if possible, the DHSSPS.

In theory, the patient should give authority for the removal and destruction of the drug. If the patient refuses, then the hospital may feel that it has no alternative other than to call in the police. Under no circumstances can a Schedule 1 drug be handed back to a patient at discharge, as the person doing so could be guilty of an offence of unlawful supply of a Controlled Drug. The penalties for this type of offence are high and often involve a custodial sentence.

In December 2009 the Misuse of Drugs Act 1971 was amended to include the so called "legal Highs" as Class C Controlled Drugs. The Dangerous Drugs, The Misuse of Drugs (Amendment) Regulations (Northern Ireland) inserted 1-benzylpiperazine (BZP), all but two of a group of substituted piperazines and the synthetic cannabinoid agonists into Schedule 1 of the Misuse of Drugs Regulations (Northern Ireland) 2002. Nabilone and Oripavine are inserted into Schedule 2 of the 2002 Regulations plus some other changes.

See Guidance Note 11 and SR No 389/390/397

In April 2010, Mephedrone (4-Methylmethcathinone) was included in Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002.

## **Schedule 2 Drugs (CD)**

Schedule 2 includes the opiates (such as diamorphine, morphine and methadone), the major stimulants (such as the amphetamines) and secobarbital (quinalbarbitone). In December 2009 Nabilone and Oripavine were added to this schedule.

A licence is needed to import or export drugs in this Schedule, but they may be manufactured or compounded by a licence holder, a practitioner, a pharmacist, or a person lawfully conducting a retail pharmacy business acting in his capacity as such. A pharmacist may supply them to a patient only on the authority of a

prescription in the required form (see below) issued by an appropriate practitioner. The drugs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of a doctor or dentist, a nurse independent prescriber (who may currently administer certain controlled drugs), a supplementary prescriber in accordance with a clinical management plan, or any person acting in accordance with the directions of a doctor, dentist, nurse independent prescriber or a supplementary prescriber in accordance with a clinical management plan.

NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.

Requirements as to safe custody in pharmacies apply to all Schedule 2 Controlled Drugs **except secobarbital (quinalbarbitone)**. Control over destruction applies to these drugs, and the provisions relating to the marking of containers and the keeping of records must also be observed (see below).

Pharmacists should bear in mind that the requirement for safe custody of Schedule 2 drugs also applies to patient returned Schedule 2 drugs, until they are denatured for disposal.

### Schedule 3 Drugs (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs such as benzphetamine, and other drugs such as buprenorphine, midazolam, phenobarbitone and temazepam that are not thought so likely to be misused as the drugs in Schedule 2, nor to be so harmful if misused. Midazolam is now a Schedule 3 controlled drug but the safe custody requirements do not apply.

The controls that apply to Schedule 2 also apply to drugs in this schedule, except

- (a) there is a difference in the classes of persons who may possess and supply them;
  - (b) the requirements as to destruction by an authorised witness do not apply unless the pharmacist is deemed to be "a producer" i.e. he compounds or manufactures the items;
  - (c) records in the register of Controlled Drugs need not be kept in respect of these drugs unless the pharmacist is "a producer" and
  - (d) safe custody requirements currently only apply to preparations of diethylpropion, buprenorphine, flunitrazepam and temazepam.
- Phenobarbital (phenobarbitone) and midazolam do not require safe custody. The requirement for safe custody of these Schedule 3 controlled drugs also applies to patient returned Schedule 3 drugs, until they are denatured for disposal.

Invoices need to be retained by retail dealers.

## Schedule 4 Drugs

Schedule 4 is split into two parts:

- Part I (CD Benz) contains benzodiazepines;  
Ketamine was added to this section in 2006 (SR No 44) and in December 2009 (SR 390/397) two substituted piperazines namely 1-(3-Chlorophenyl)-4-(3-chloropropyl) piperazine and 1-(3-Chlophenyl) piperazine were included.
- Part II (CD Anab) contains the anabolic steroids and androgenic steroids together with clenbuterol and growth hormones.  
Under SR 390/397 2009, 15 anabolic steroids and 2 non-steroidal agents were added to this section including:  
Bolidone, Danazol, Desoxymethyltestosterone, Gestrinone, Prostanazol, Tetrahydrogestrinone, Zeranol and Zilpaterol

### Part I (CD Benz)

- (a) A Home Office import or export licence is required for the importation or exportation of substances in Part 1.
- (b) No Restriction with respect to possession when contained in a medicinal product.
- (c) The prescription and labelling requirements are those laid down by the Medicines Act 1968. The validity of the prescription is limited to 28 days.
- (d) No records are required in the CD Register.
- (e) Destruction requirements apply only to importers, exporters and manufacturers but not to retail pharmacists.
- (f) Safe custody requirements do not apply.

### Part II (CD Anab)

- (a) Provided the substances are formulated as medicinal products for administration to individuals, they will be exempted from the prohibition on possession of controlled drugs.  
The CD safe custody requirements do not apply.  
Records of receipts and supplies are not required in the CD Register.

## Schedule 5 Drugs (CD Inv)

Schedule 5 contains preparations of certain Controlled Drugs, for example, codeine, pholcodine, cocaine and morphine that are exempt from full control when present in medicinal products of low strength.

- There is no restriction on the import, export, possession or administration of these preparations.
- Safe custody requirements do not apply.
- A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any of them.
- No record in the register of Controlled Drugs need be made in respect of drugs obtained or supplied by a person lawfully conducting a retail pharmacy

business, unless that person is a “producer” i.e. a manufacturer or compounder of such items.

- The invoice or a copy of it must be kept for two years.
- No authority is required to destroy these drugs.
- There are no special labelling requirements (but Medicines Act labelling requirements apply).

### Possession and supply of Controlled Drugs

It is unlawful for any person to be in possession of Controlled Drugs other than those in Schedule 5 unless:

- (a) he holds an appropriate licence or authority from the DHSSPS;
- (b) he is a member of a class specified in the regulations; or
- (c) the regulations provide that possession of that drug or group of drugs is not unlawful. In any case, possession or supply is not lawful unless the person concerned is acting in his capacity as a member of his class, or in accordance with the terms of his licence or group authority.
- (d) they have been lawfully prescribed for that person or for that person’s animal.

Practitioners and pharmacists are amongst those who have a general authority to possess, supply and procure all Controlled Drugs except those in Schedule 1.

Certain other persons, including wholesalers, importers and exporters, must obtain licences or authorities from the DHSSPS. “Wholesale dealer” in this context means a person who carries on the business of selling drugs to persons who buy to sell again.

Any person who is lawfully in possession of a Controlled Drug may supply that drug to the person from whom he lawfully obtained it.

### Requisitions for Schedules 1, 2 and 3 Controlled Drugs

See Guidance Note 7 and Guidance Note 13

A requisition in writing must be obtained by a supplier before he delivers any Controlled Drug (except those in Schedules 4 and 5). The requisition does not have to be in the recipient’s handwriting but must

- i be signed by the recipient
- ii state the recipient’s name and address
- iii state the recipient’s profession or occupation
- iv specify the total quantity to be supplied
- v state the purpose for which required

The supplier must be reasonably satisfied that the signature is that of the person purporting to sign the requisition and that he is engaged in the occupation stated.

A messenger sent by a purchaser ("recipient") to collect a Controlled Drug on his behalf, may only be supplied with the Controlled Drug if he produces to the supplier a statement in writing given by the recipient to the effect that the messenger is empowered to receive the drug on his behalf. The supplier must be reasonably satisfied that the document is genuine and must retain it for two years.

The requirement for the written statement does not apply to a person carrying on a business as a carrier engaged by the supplier.

On receipt of a requisition (not a veterinary requisition) for a controlled drug (except Schedule 4 and 5) the pharmacist

- should mark on the requisition in ink or otherwise to be indelible, his name and address. The pharmacy stamp may be used.
- Requisitions for controlled drugs should be submitted by community pharmacies to the Business Services Organisation (BSO) using the modified H30 form (NB: Requisitions written by veterinary practitioners must not be submitted to BSO, they should be retained at the pharmacy and drawn to the attention of the pharmacy inspector). See Guidance Note 13.

Requisitions presented on HS21S forms (Triplicate Stock Order Forms) should be submitted to the Business Services Organisation (BSO) as is current practice.

The above requirements do not apply where the supplier is either a wholesale dealer or is a person responsible for the dispensing and supply of medicines at a hospital or nursing home.

The requisition must be obtained prior to supply to any of the following:

- (a) a practitioner (a practitioner urgently requiring a drug and unable to supply a written requisition before delivery may be supplied on his giving an undertaking to furnish a requisition within the next 24 hours; failure to furnish the requisition within 24 hours is an offence on the part of the practitioner);
- (b) the person or acting person in charge of a hospital or nursing home (a requisition from the person in charge of a hospital or nursing home must be signed by a doctor or dentist employed there);
- (c) a senior registered nurse or acting senior registered nurse, for the time being in charge of any ward, theatre or other department of a hospital or nursing home, who obtains a supply of a Controlled Drug from the person responsible for dispensing and supplying medicines at that hospital or nursing home, must furnish a requisition in writing signed by her that specifies the total quantity of the drug required. She must retain a copy or note of the requisition. The person responsible for the dispensing and supply of the Controlled Drug must mark the requisition in such a manner as to show that it has been complied with and must retain the requisition in the dispensary;

- (d) a person who is in charge of a laboratory, the recognised activities of which consist in, or include, the conduct of scientific education or research and which is attached to a university, university college, hospital or institution approved for that purpose;
- (e) the owner of a ship or the master of a ship that does not carry a doctor among the seamen employed by it;
  - the installation manager of an offshore installation;
 the master of a foreign ship in a port in Northern Ireland (a requisition from the master of a foreign ship must contain a statement signed by an authorised medical officer of the Health and Social Care Board (HSCB) for the Area, within whose jurisdiction the ship is, that the quantity of the drug to be supplied is the quantity of drug necessary for the equipment of the ship).
- (f) A supplementary prescriber.
- (g) An operating department practitioner (ODP) can order S2, S3, S4 and S5 controlled drugs from a hospital pharmacy although currently a written requisition is not required. Good practice guidance in line with hospital policy and SOPs would stipulate that the supply of a controlled drug is dependant on the receipt of a requisition. (See Safer Management of Controlled Drugs - A guide to good practice in secondary care 2009).
- (h) An ODP is not permitted to obtain controlled drugs from a community pharmacy.

**NB. Pharmacists who make supplies to the owners or masters of ships should make sure that they are aware of the guidelines laid down in relation to the quantities of specific Controlled Drugs that may be supplied. The legal requirements relating to the requisitions required for such supplies must be fulfilled.**

### Controlled Drugs in hospitals

In hospitals additional requirements relating to administration and supply, prescriptions, requisitions and registers for Controlled Drugs include:

- (1) A senior registered nurse or acting senior registered nurse, for the time being in charge of a ward, theatre, or other department, may not supply any drug otherwise than for administration to a patient in the ward, theatre or department in accordance with the directions of a doctor or dentist, supplementary prescriber under and in accordance with the terms of a clinical management plan, or of a nurse independent prescriber subject to the limited list of Controlled drugs which they may prescribe which includes a specific purpose for which the drug may be prescribed. NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.
- (2) The senior registered nurse or acting senior registered nurse, for the time being in charge of a ward, theatre or other department, is not required by

the Misuse of Drugs (Northern Ireland) Regulations 2002 to keep any register. However, DHSSPS guidance should be followed – See Section 4.7 of Safer Management of Controlled Drugs: a guide to good practice in secondary care, 2009.

- (3) The person in charge or acting person in charge of a hospital or nursing home having a pharmacist responsible for the dispensing and supply of medicines may not supply or offer to supply any drug.
- (4) A prescription issued for the treatment of a patient in a hospital or nursing home may be written on the patient's bed-card or case-sheet.
- (5) An operating department practitioner in that hospital may not supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan, or of a nurse independent prescriber. The directions given by a nurse prescriber relate only to the limited list of Controlled Drugs which they may prescribe and are subject to restrictions on the purpose for which the drug may be prescribed. NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.
- (6)
  - (a) Private prescriptions for Schedule 2 and Schedule 3 Controlled Drugs issued within a hospital (within its legal entity) and supplied by a pharmacist in that hospital do not need to be on a standardised prescription form and do not need to specify the prescriber identification number.
  - (b) in the case where a private prescription for a Schedule 2 or Schedule 3 controlled drug is issued outside that hospital (i.e. outside its legal entity), the prescription would have to be issued on a standardised prescription form and would need to specify the prescriber identification number in order for the supply to be legal. This also applies where the prescription has been issued from a hospital in another legal entity. NB: In order to supply against a prescription presented from outside the legal entity of that hospital, the hospital would require to be registered with the Pharmaceutical Society)
- (7) Requisitions for Schedule 2 or 3 Controlled Drugs that are to be supplied by a pharmacist in a hospital do not need to be sent to the BSO and do not need to be marked with the name and address of the pharmacy.

### Prescriptions for Controlled Drugs

No prescription is required under the Misuse of Drugs Regulations for the supply by a pharmacist of a Schedule 5 drug but, for preparations above certain strengths, a prescription is required under the Medicines Act 1968. Prescriptions are necessary for all other categories of Controlled Drugs, which are always Prescription Only Medicines. The requirements of both the Misuse of Drugs Act and the Medicines Act must be satisfied.

It is not lawful for a practitioner to issue a prescription containing a Controlled Drug other than a drug specified in Schedule 4 or 5 or temazepam, or for a pharmacist to dispense it, unless it complies with the following requirements.

The prescription must:

- (a) be written so as to be indelible, be dated and be signed by the person giving it with his usual signature;
- (b) except in the case of a health prescription, specify the address of the person issuing it. N.B. The Medicines Act requires that all prescriptions for Prescription Only Medicines contain the prescriber's address;
- (c) have written on it, if issued by a dentist, the words "for dental treatment only";
- (d) specify the name and address of the person for whose treatment it is issued;
- (e) specify the dose to be taken and
  - i in the case of preparations, the form and, where appropriate, the strength of the preparation and either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied;
  - ii in any other case, the total quantity (in both words and figures) of the Controlled Drug to be supplied. DHSSPS/Home Office has expressed a view that a dose of "as directed" or "when required" is not acceptable but "one to be taken as directed/when required" is acceptable;
- (f) in the case of a prescription for a total quantity intended to be dispensed by instalments, contain a direction specifying the amount of the instalments that may be dispensed and the intervals to be observed when dispensing;
- (g) in the case of a private prescription for human use (including temazepam and midazolam) be on a standardised form PCD1 (in Northern Ireland) when dispensed in community pharmacy;
- (h) in the case of private prescriptions for human use (including temazepam and midazolam) contain the private prescriber's identification number on the prescription.

For the purposes of prescription writing temazepam can be written up as for any other Prescription Only Medicine. (See section on Prescriptions for Prescription Only Medicines).

A practitioner shall not issue a private prescription for temazepam for human use, unless it is written on a prescription form provided by the BSO or equivalent body for the purposes of private prescribing and it specifies the prescriber identification number and the address of the person issuing it. (This requirement does not apply to veterinary prescriptions.)

However under current legislation, private prescriptions for controlled drugs must be retained for 2 years.

A Controlled Drug (except Schedule 4 and Schedule 5) must not be supplied by any person on a prescription:

- (a) unless the prescription complies with the provisions set out above (except temazepam);
- (b) unless the prescriber's address on the prescription is within the United Kingdom;
- (c) unless the supplier is either acquainted with the prescriber's signature and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine;
- (d) before the appropriate date specified on the prescription;
- (e) later than 28 days after the appropriate date on the prescription. This requirement applies to temazepam, midazolam and Schedule 4 drugs. (The appropriate date is defined as "the later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied". Where a prescriber wishes the 28 day period to start on a date other than the date of signing, he may specify a start date from which the period will begin);
- (f) in the case of an instalment prescription, unless the first instalment is dispensed within 28 days of the appropriate date with the remaining instalments dispensed in accordance with the instructions.

Owings of dispensed prescriptions for Schedule 2, 3 and 4 controlled Drugs cannot be supplied more than 28 days after the appropriate date.

The date must be marked on the prescription at the time of supply.

### **Instalment prescriptions for Controlled Drugs, Schedule 2, 3 and 4**

- (a) the first instalment must be dispensed within 28 days of the appropriate date, and the remainder of instalments dispensed in accordance with the instructions given.
- (b) The 28 day period of validity starts from the appropriate date on the prescription, which may be the date of signing the prescription or the start date as indicated by the prescriber
- (c) Where a start date is given, it must be complied with and the instalment directions shall run from that date
- (d) In every other case, the instalment direction will run from the date of first dispensing of the prescription
- (e) The prescription must be marked with the date of each dispensing
- (f) Prescriptions that contain a direction that specified instalments of the total amount may be dispensed at stated intervals must not normally be dispensed otherwise than in accordance with the directions.

The Home Office has provided guidance on approved wording that may be used on prescriptions to cover situations where an instalment to be collected has been missed.

(For Home Office Wording – access  
[www.nta.nhs.uk/publications/documents/clinical\\_guidelines\\_2007.pdf](http://www.nta.nhs.uk/publications/documents/clinical_guidelines_2007.pdf)

### Private prescriptions for Controlled Drugs

All Private prescriptions for Schedule 2 and 3 controlled drugs including temazepam) must be

- written on dedicated private controlled drug prescription forms PCD1 issued by the BSO in Northern Ireland.
- the private prescription must contain the prescriber's identification number.

The above requirements do not apply to veterinary prescriptions for controlled drugs.

In line with current prescribing patterns, it is envisaged that the usage in practice of these forms will be low.

Equivalent forms have been issued by the relevant bodies in England, Scotland and Wales. (FP10PCD in England, PPCD (1) in Scotland and WP10PCD in Wales).

These prescriptions will be valid for dispensing in Northern Ireland and pharmacists must continue to verify the authenticity of the prescription before a supply is made.

For private prescriptions in a hospital situation see page 49

Private prescription forms PCD1 should be treated in the same way as for other private prescription

- enter in the prescription book
- endorse appropriately
- submit to the BSO

From April 1st 2010 PCD1 forms should be submitted by community pharmacies to the BSO using the modified HS 30 form.

See Guidance Note 4 and Guidance Note 13.

Sativex is an oromucosal spray containing derivatives of cannabis and has been available as an unlicensed medicine on a named patient basis for the treatment of spasticity associated with multiple sclerosis. In June 2010 it was granted a licence as a prescription only medicine. It is anticipated that the product will be classified as a Schedule 4 controlled drug in the future.

## Technical errors on prescriptions for Controlled Drugs.

Pharmacists may supply Schedule 2 or 3 controlled drugs (excluding temazepam) if the prescription contains minor typographical errors or spelling mistakes or if it does not comply with the provisions of regulation 15(1) f (Words and Figures requirements) provided that

- (i) having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that the prescription is genuine;
- (ii) having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that he is supplying the drug in accordance with the intention of the person issuing the prescription;
- (iii) the pharmacist amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes so that the prescription complies with the requirements of regulation 15 as the case may be; and,
- (iv) the pharmacist marks the prescription so that the amendment he has made (under (c) above) is attributable to him/her.

No other amendments can be made or added to the prescription including the date, the dose or the form as currently these are not regarded as minor typographical errors.

## Prescribing for up to 30 days treatment

Although not a legal requirement, it is recommended practice that quantities prescribed should not exceed 30 days supply except in exceptional circumstances. For further information see Guidance Note 8 and Pharmacy Inspectors' Newsletter Issue 3 November 2007 DHSSPS.

## Collection of Schedule 2 Controlled Drugs

HS21 prescription forms have been amended to have a space on the reverse of the form to permit the recording of the signature of the person collecting a Schedule 2 or 3 controlled drug. At present obtaining the signature is not a legal requirement (this may change in the future) but it is considered good practice to do so. See Guidance Note M150 18/09/06 DHSSPS.

Pharmacists are required to ascertain the role of any person collecting a Schedule 2 Controlled Drug to determine whether that person is (a) the patient, (b) the patient's representative or (c) a healthcare professional acting within their professional capacity on behalf of the patient.

If the person collecting the Schedule 2 drug is the patient or the patient's representative, the pharmacist may request evidence of that person's identity and may refuse to supply the CD if they are not satisfied as to the identity of the person.

In order not to deny patient access to the drugs that they require, it will not be a criminal offence to supply the CD without proof of identity, even if that person is not known to the pharmacist.

Circumstances where ID may not be required are when the person collecting the CD is known to the pharmacist (e.g. the patient, close relative or a local healthcare professional) or when the pharmacist considers that asking for ID may compromise patient confidentiality.

If the person collecting the Schedule 2 CD is a healthcare professional, the pharmacist must obtain the name and address of the healthcare professional and unless they are already acquainted with that person, they must request evidence of that person's identity. However, even if the pharmacist is not satisfied as to the identity of the person, they may still supply the CD.

Types of ID that may be considered suitable include:

Driving licence (with photo card section), passport, credit card, cheque book etc

For other examples of appropriate documentation that may be used as ID –See Appendix B of Guidance Note 3, issued 26/06/06

The requirement for record keeping with regard to proof of identity came into force on February 1st 2008.

In circumstances where a controlled drug is conveyed by messenger such as a porter or delivery driver the appropriate guidance should be consulted

- Safer Management of Controlled Drugs – A guide to good practice in secondary care (Northern Ireland) August 2009
- Safer Management of Controlled Drugs – A guide to good practice in primary care (Northern Ireland) due 2010.

### **Controlled Drug registers**

See Guidance Note 7.

Records must be kept, by the above persons authorised to possess Controlled Drugs, of all Schedule 1 and 2 drugs obtained or supplied. Entries in the controlled drugs register must be recorded under the following headings:-

- (a) In respect of entries made for drugs obtained
  - i Date supply received
  - ii Name and address from whom received
  - iii Quantity received
  
- (b) In respect of entries for drugs supplied
  - i Date supplied

- ii Name and address of person or firm supplied
- iii Details of authority to possess – prescriber or licence holder’s details
- iv Quantity supplied
- v Person collecting Schedule 2 controlled drugs (patient/patient’s representative, healthcare professional). If a healthcare professional collecting the Schedule 2 controlled drug, their name and address. If the healthcare professional is unknown to the pharmacist, proof of identification must be seen and recorded.
- vi Was proof of identity requested of the patient/patient’s representative? (Yes/No)
- vii Was proof of identity of the person collecting the drug provided? (Yes/No)

The above requirements represent the minimum fields of information to be recorded. The regulations allow for additional information to be recorded as appropriate.

The following points are important in relation to the keeping of Controlled Drug registers:

- (a) Entries must be in chronological sequence.
- (b) A separate register or a separate part of the register must be used for each class of drugs. Separate sections are required for amphetamines (which includes dexamphetamine) and methylamphetamine.
- (c) A separate page shall be used in respect of each strength and form of that drug.
- (d) The head of each such page shall specify the class of drug, its form and its strength.
- (e) Entries must be made on the day of the transaction or on the next day following.
- (f) No cancellation, obliteration or alteration may be made; correction must be by dated marginal note or footnote.
- (g) Every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible or shall be in a computerised form in which every such entry is attributable and capable of being audited and which is in accordance with best practice guidance endorsed by the Secretary of State under Section 2 of the National Health Services Act 1977.
- (h) The register must not be used for other purposes.
- (i) The register must be kept at the premises to which it is related and a separate register must be kept for each premises of the business,
- (j) where the register is in computerised form, it must be accessible from these premises.
- (k) With DHSSPS approval, separate registers may be kept for each department of a business.
- (l) Particulars of stock receipts and supplies must be furnished to any authorised person on request (this includes the inspectors for the DHSSPS and any

person authorised in writing by DHSSPS). Other documents and stocks of drugs must also be produced if required. The Department or other person authorised in writing by the Department in that behalf may request that a register which is kept in computerised form be produced by sending a copy of it in computerised or other form, to the appropriate person.

- (m) Registers must be kept for two years from the last date of entry.
- (n) The information to be contained in these records to be preserved in the original paper form, or as a copy on computer

### **Good practice points**

- It is good practice that the controlled drug register maintains a running balance
- Where an entry has been made in the controlled drugs register, no entry is required in the prescription only register, but it is good practice to make such entries

Pharmacists are advised that CD registers may only be held in computerised form if safeguards are incorporated into the software to ensure that all of the following requirements are met:

- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes
- Access control systems should be in place to minimise risk of unauthorised or unnecessary access to the data
- Adequate backups must be made.
- Pharmacists are advised that provisions must be in place to enable inspectors to examine computerised records during a visit with minimum disruption to the dispensing process.

Computerised registers for controlled drugs should not be maintained unless the pharmacist can be satisfied that the above requirements and any future guidance issued can be met.

### **Supply of Controlled Drugs under Patient Group Directions**

There are currently only three circumstances in which certain Controlled Drugs may be administered or supplied under a PGD. These are outlined below:

- (i) A registered nurse may, when acting in her capacity as such, supply or administer diamorphine under a PGD for the treatment of cardiac pain to a person admitted as a patient to a coronary care unit or accident and emergency department of a hospital.
- (ii) A registered nurse, pharmacist or any of the other named healthcare professionals listed in Schedule 8 of the Misuse of Drugs Regulations, as amended, may, when acting in their capacity as such, supply or administer any schedule 5 CD in accordance with a valid PGD.

- (iii) A registered nurse, pharmacist or any of the other named healthcare professionals listed in Schedule 8 of the Misuse of Drugs Regulations, as amended, may, when acting in their capacity as such, supply or administer any Part 1 Schedule 4 CD or midazolam in accordance with a valid PGD provided that it is not a drug in parenteral form for the treatment of addiction.

Midazolam is a Schedule 3 controlled drug and can be included in a PGD under certain circumstances.

Under no other circumstances can a controlled drug be considered for inclusion in a PGD. (The list of Controlled Drugs that may be included in a PGD and the circumstances in which they can be supplied or administered is being reviewed. Changes to legislation may occur in the future.)

Examples of named healthcare professionals include paramedics, health visitors, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists and radiographers.

### **Controlled Drugs and Supplementary Prescribing**

A supplementary prescriber is permitted, when acting under and in accordance with the terms of a clinical management plan (CMP) to administer and/or supply CDs in Schedules 2, 3, 4 and 5.

### **Supply of Controlled Drugs by Nurse Independent Prescribers**

NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.

Nurse independent prescribers are currently permitted to prescribe, supply, administer or direct any other person to administer, the following Controlled Drugs, solely for the medical conditions indicated:

- (i) diamorphine hydrochloride (orally or parenterally), morphine hydrochloride (rectally), morphine sulphate (orally, parenterally or rectally) or oxycodone hydrochloride (orally, or parenterally) for use in palliative care;
- (ii) buprenorphine (transdermal) and fentanyl (transdermal) in palliative care
- (iii) diamorphine hydrochloride (orally or parenterally), or morphine hydrochloride (rectally), morphine sulphate (orally, parenterally or rectally) for pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post operative pain relief
- (iv) chlordiazepoxide hydrochloride (orally) and diazepam (orally, parenterally or rectally) for treatment of initial or acute alcohol withdrawal symptoms;

- (v) codeine phosphate (orally), dihydrocodeine tartrate (orally) and co-phenotrope (orally) (no restrictions on medical conditions)
- (vi) diazepam (orally, parenterally or rectally), lorazepam (orally, or parenterally) or midazolam (parenterally or via the buccal route) for use in palliative care or treatment of tonic-clonic seizures.

### **Controlled drugs and pharmacist independent prescribers**

Pharmacist independent prescribers are not currently permitted to prescribe, administer in their own right or direct the administration of Controlled Drugs.

This situation is under review and legislation may change in the future and guidance would then be issued in this regard. Initial changes to legislation came into force on 1st April 2008, (SI No. 464) but further amendments to the Misuse of Drugs Regulations (NI) 2002 and the Pharmaceutical Services Regulations are required to implement the changes.

### **Midwives and Controlled Drugs**

A registered midwife may possess pethidine, diamorphine and morphine (S2) and pentazocine (S3), so far as is necessary for the practice of her profession. Supplies of pethidine, diamorphine, morphine and pentazocine may only be made to her on the authority of a Midwife's Supply Order signed by the "appropriate medical officer" who is authorised in writing by the local supervising authority, or the person appointed by the local supervising authority to exercise supervision over midwives. The midwife's supply order means an order in writing specifying the name and occupation of the midwife obtaining the drug, the purpose for which the controlled drug is required, and the total quantity to be obtained.

A midwife is required to keep a record of supplies of pethidine, diamorphine and morphine received and administered in a book used solely for that purpose. She must not destroy surplus stock but may surrender it to the "appropriate medical officer". (For destruction provision, see below.)

The pharmacist must retain the Midwife's Supply Order for two years. As pethidine, diamorphine and morphine are Schedule 2 Controlled Drugs, an appropriate entry is required in the CD register.

Pentazocine is a Schedule 3 Controlled Drug and therefore no entry is required in the CD register although an entry should be made in the prescription only register.

Under a Patient Group Direction, midwives are also permitted to supply all Part 1 Schedule 4 Controlled Drugs and all Schedule 5 CDs provided that it is not a drug in parenteral form for the treatment of addiction.

## Controlled drugs and operating department practitioners

An operating department practitioner may, when acting in their capacity as such possess and supply or offer to supply any Controlled Drug specified in Schedule 2, 3 or 5 or any drug specified in Schedule 4 which is contained in a medicinal product, for the purposes of administration to a patient in a ward, theatre or department, in accordance with the directions of a doctor, dentist, supplementary prescriber acting under a clinical management plan.

The directions given by a nurse prescriber relate only to the limited list of Controlled Drugs that they may prescribe and the restrictions on the purpose for which the drug may be prescribed.

See also additional information on the ordering of CDs by an ODP under Requisitions.

## 2.2 THE ACCOUNTABLE OFFICER REGULATIONS

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (SR No 225) (made under the Health Act 2006) came into operation on 1 October 2009. The legislation requires Designated Bodies to nominate an Accountable Officer who is responsible for the management and use of CDs to minimise risk to patients. This will include the identification of poor systems and / or poor clinical practice that may exist.

The Regulations contain three key elements

- Accountable Officers and their duties
- Powers of entry and periodic inspections
- Co-operation between health bodies and other appropriate organisations

The legislation addresses the following matters

- Identification of Designated Bodies
- Appointment and removal of an Accountable Officer
- Establishment of arrangements to secure the safe management and use of CDs including destruction and disposal.
- Monitoring Systems
- Investigations and concerns
- Duty of collaboration

The Designated Bodies include

- The Health and Social Care Board (the Board)
- The Health and Social Care Trusts (5)
- Northern Ireland Ambulance Service Trust
- Independent Hospitals (including Hospices)

An Accountable Officer (AO) must be nominated by each Designated Body, and an up-to-date list including contact details for each AO can be found on the DHSSPS website [www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm](http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm).

The AO is responsible for ensuring the safe and effective management and use of controlled drugs within their own organisation and by any body or person acting on behalf of or providing services to their organisation. This will include establishing and operating safe systems for the management and use of CDs, monitoring and auditing of the management and use of CDs and, where necessary, investigating concerns and incidents related to controlled drugs.

The Accountable Officer appointed by the Designated Body must be

- A senior person within their organisation.
- The AO must not routinely supply, administer or dispose of controlled drugs as part of his duties.
- The AO must submit a quarterly Occurrence Report to the Chair of the Local Intelligence Network (LIN).

The legislation gives power to require periodic declarations and self-assessments and these will be issued to all community and HSC Trust pharmacies annually and monitored by the Departmental Inspectors in conjunction with their established inspection arrangements. The Departmental Inspectors will, through their reporting arrangements, provide assurances to the Board Accountable Officer relating to the management and use of controlled drugs in contracted community pharmacies.

The completed form must be retained in the front of the Controlled Drug register and will become part of the routine record-keeping which will be examined by the Pharmacy Inspectors during their visits.

Forms should be retained, in accordance with the Pharmacy Inspectors advice, as part of the audit process. (Additional copies of the Declaration and Self Assessment Forms may be accessed from [www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-forms.htm](http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-forms.htm)).

A range of guidance documents and training resources on the "Accountable Officer" legislation may be downloaded from the website [www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm](http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm)

These include

- Safer Management of Controlled Drugs – A Guide to Strengthened Governance Arrangements in Northern Ireland October 2009
- Safer Management of Controlled Drugs – Guidance on Standard Operating Procedures for Northern Ireland October 2009
- Safer Management of Controlled Drugs Guidance-A Guide to Good Practice in Secondary Care 2009
- Safer Management of Controlled Drugs Guidance-A Guide to Good Practice in Primary Care 2010

- Contact List of Accountable Officers
- Contact List of Responsible Bodies

## 2.3 STANDARD OPERATING PROCEDURES FOR CONTROLLED DRUGS

For full details consult the following document:

“Safer Management of Controlled Drugs – Guidance on Standard Operating Procedures for Northern Ireland” October 2009

Pharmacists are required to have adequate and up-to-date standard operating procedures in place to cover the following matters as stated in Regulation 9 (SR 2009/225):

- who has access to the controlled drugs
- where the controlled drugs are stored
- security in relation to the storage and transportation of controlled drugs as required by the Misuse of Drugs legislation
- disposal and destruction of controlled drugs
- who is to be alerted if complications arise; and
- record keeping including:
  - (i) maintaining relevant controlled drugs registers under misuse of drugs legislation, and
  - (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002(17) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs are needed for every stage of the controlled drug’s journey from procurement (ordering, receipt, and transport), safe storage, supply, administration, destruction and guidance for dealing with an incident.

The SOPs need to be accessible to staff at all times.

### National Health prescriptions for the treatment of addicts (misusers)

#### Substitute Prescribing in Northern Ireland

**For details of the process, check guidance from the BSO.**

The system allows the prescribing of Methadone and Buprenorphine in certain circumstances. The prescription forms used in Northern Ireland are SP1 and SP2 available from the BSO. Prescribing of the drugs may be made in instalments for up to 14 days.

The system allows the prescribing of Methadone and Subutex in certain circumstances.

Details of the prescription format and the details to be completed by pharmacists are available from the BSO. For additional information, consult – Safer Management of Controlled Drugs - A guide to good practice in primary care (Northern Ireland) due 2010.

For systems in force in England, Scotland and Wales check the Department of Health website.

In England prescription form FP10 (MDA) is used for instalment prescribing by both drug treatment centres and GPs. A maximum of 14 days' supply of any Schedule 2 Controlled Drug, buprenorphine and diazepam can be prescribed for the treatment of addiction using this form. Computer based prescription forms FP10SS are also in use in England.

In Scotland form HBP (A) issued from drug addiction clinics can be used for instalment prescribing for drug addicts (misusers). General practitioners may prescribe by instalment for the treatment of addiction on a GP10 form.

In Wales two types of prescription form are used for the treatment of addicts (misusers) by instalment: WP10 (MDA), issued by general practitioners and WP10 (HP) Ad used by drug treatment centres. The prescription may be for up to 14 days supply.

**NB. Cocaine, diamorphine and dipipanone can only be prescribed for the treatment of addiction by doctors who hold the required Home Office licence.**

### **DHSSPS prohibitions**

Prohibitions under Sec 13 of the Misuse of Drugs Act are enforced under the Misuse of Drugs (Northern Ireland) Rules 1974 and power is exercised by the DHSSPS. This enables them to make a direction against a practitioner prohibiting him from having in his possession, prescribing, administering, manufacturing, compounding and supplying, and from authorising the administration and supply of those Controlled Drugs specified in the direction.

In order to confirm whether or not a practitioner has had a direction made against him under the Misuse of Drugs Act 1971, prohibiting him from dealing with Controlled Drugs as indicated above, pharmacists are advised to contact the DHSSPS 02890 523348. (The Home Office Tel No is 020 7035 4848).

### **Marking of containers for Controlled Drugs**

A container in which a Controlled Drug other than a preparation is supplied must be plainly marked with the amount of drug contained in it. If the drug is a preparation made up into tablets, capsules or other dosage units, the container

must be marked with the amount of Controlled Drug(s) in each dosage unit and the number of dosage units in it.

For any other kind of preparation, the container must be marked with the total amount of the preparation in it and the percentage of Controlled Drug(s) in the preparation.

These requirements do not apply to Schedule 4 or 5 drugs, or to drugs supplied on prescription, or to poppy straw. Also exempt are Schedule 3 drugs comprising a preparation that is required for use as a buffering agent in chemical analysis and is premixed in a kit. Also exempt is the supply of a CD for administration in a clinical trial or a medicinal test on animals.

### **Safe Custody of Controlled Drugs**

The regulations relating to safe custody apply to all Controlled Drugs included in Schedules 1 and 2 (except secobarbital (quinalbarbitone), plus buprenorphine, diethylpropion, flunitrazepam and temazepam which are Schedule 3 drugs.

Although secobarbital (quinalbarbitone) is not subject to the safe custody requirements, pharmacists may wish to keep the drug in the Controlled Drug cupboard to serve as a reminder that an entry is required in the Controlled Drug register.

Retail dealers, nursing homes and private hospitals must ensure that all Controlled Drugs to which safe custody applies are, so far as circumstances permit, kept in a locked safe, cabinet or room that is so constructed and maintained as to prevent unauthorised access to the drugs. This requirement does not apply in respect of any Controlled Drug that is for the time being constantly under the direct personal supervision of a pharmacist, for example, when dispensing a prescription.

The specifications with which safes, cabinets and rooms must comply are given in great detail in the regulations. The owner of a pharmacy may, however, elect to apply, as an alternative, to the DHSSPS for a certificate that his safes, cabinets or rooms provide an adequate degree of security. Applications must be made in writing. The certificate may specify conditions to be observed.

All community pharmacies in Northern Ireland have installed a Time Delay Safe for the storage of Controlled Drugs. Any exemptions to this requirement must have the approval of the Misuse of Drugs Inspector.

### **Supply of Controlled Drugs to addicts (misusers)**

A person is regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent on a drug that he has an

overpowering desire for the administration of it to be continued. Under the Regulations, any doctor who attends a person whom he considers is addicted to any drug in the prescribed list must within seven days furnish certain particulars to the Chief Medical Officer of the DHSSPS.

No doctor may administer or authorise the supply of cocaine, diamorphine or dipipanone, or their salts, to an addicted person, except for the purpose of treating organic disease or injury, unless he is licensed to do so by the DHSSPS.

There is provision for addicts (misusers) to receive daily supplies of cocaine, diamorphine, methadone, and other Schedule 2 drugs on special prescriptions. (See earlier Page 43).

Legislation permits practitioners, pharmacists, persons employed or engaged in the lawful provision of drug treatment services and supplementary prescribers acting in accordance with a clinical management plan to supply specified drug paraphernalia to drug users.

The exempted articles are: swabs, utensils for the preparation of controlled drugs, ascorbic acid, citric acid, filters and ampoules of water for injection.

Ampoules of sterile water for injection containing not more than 2ml of sterile water can be supplied by persons employed or engaged in the lawful provision of drug treatment services only in the course of those services.

A pharmacist who is not engaged or employed in such services can only supply water for injection against a prescription or under a PGD.

**(NB - Crushing of buprenorphine tablets prior to administration.** Pharmacists should follow the guidance laid down in the NPA protocol and ensure that they have the appropriate Indemnity Insurance cover.)

### **Destruction of Controlled Drugs**

Any person required by the regulations to keep records of Controlled Drugs, that is Schedule 1 and 2 drugs, may only destroy them in the presence of a person authorised by the DHSSPS either personally or as a member of a class; this includes pharmaceutical inspectors of the DHSSPS. Particulars of the date of destruction and the quantity destroyed must be entered in the register of Controlled Drugs and signed by the authorised person in whose presence the drug is destroyed. The authorised person may take a sample of the drug that is to be destroyed.

Date expired or unusable stocks of Schedule 2 Controlled Drugs should be segregated in the safe until destruction is witnessed by an authorised person. Appropriate records of the destruction must be made.

The master of a ship or the installation manager of an offshore installation may not destroy any surplus drugs but may dispose of them (for destruction) to a constable or a person who may lawfully supply them (that is, to any pharmacist or licensed dealer who could have supplied them to him).

A pharmacist or a practitioner may destroy prescribed Controlled Drugs returned to him by a patient or a patient's representative without the presence of an authorised person. Such Controlled Drugs should not be returned to stock. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 require a range of SOPs to be in place including a SOP for maintaining a record of Schedule 2 CDs that have been returned by patients. The record of the destruction for patient returned drugs must not be made in the CD Register but recorded either at the back of the Private Prescription Register or in a separate book designated as the "Destruction Book" (a number of such books are available commercially for this purpose.) It is advisable to have the destruction witnessed by an appropriate member of staff (e.g. another pharmacist or a pharmacy technician).

Details to be recorded in the destruction book should include:

- date of return of the Controlled Drug
- details of the Controlled Drug(s) - name, strength and form, plus the quantity
- role of the person who returned the Controlled Drugs (if this is known)
- name and signature of the person who received the Controlled Drugs
- the patient's name and address (if known)
- the name, position and signature of the person destroying the Controlled Drugs and the same details for the witness
- date of destruction

If such drugs are stored prior to destruction they should be segregated carefully in the CD safe to minimise the risk of inadvertent supply.

As the quantity of controlled drugs being returned by patients can often pose a storage problem, as well as an increased security risk, pharmacists are encouraged to destroy patient returned Controlled Drugs as soon as possible.

Out of date controlled drugs, which must be destroyed only in the presence of an authorised witness, should be destroyed by arrangement with the DHSSPS inspector.

### **Guidance on Destruction of CDs**

Pharmacists are recommended to use commercially available CD denaturing kits wherever possible to denature Controlled Drugs. Pharmacists should ensure that where such alternative methods are used to denature CD's that they should protect the environment and workers who might be affected by this activity.

Currently, the destruction (denaturing) of controlled drugs can be undertaken in a pharmacy without obtaining a waste management licence as the Environment Agency regards this as low risk activity.

The situation will be kept under review and enforcement may be considered in any circumstance where an activity is likely to cause pollution or harm to health.

Information on disposal of controlled drugs can be accessed at [www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf](http://www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf) or [www.rpsgb.org.uk](http://www.rpsgb.org.uk)

**Liquid Dose Formulations** should be added to, and absorbed by, an appropriate amount of cat litter, or similar product.

**Capsule and tablet formulations.** The outer packaging material should be removed and then the preparations removed from the blister packaging (if necessary) and placed in a CD denaturing kit. It is recommended that commercially available CD denaturing kits are used to ensure that whole tablets or capsules may not be recovered. Alternatively the solid dose formulation should be crushed and placed in a small amount of hot, soapy water ensuring that the drug has been dissolved or dispersed. The resultant mixture should be placed in an appropriate waste disposal bin.

**Parenteral Formulations (such as ampoules).** These should be opened and the liquid poured into the Controlled Drug denaturing kit. The ampoule itself may be added to the sharps bin. An ampoule that contains powder can have water added to it to dissolve the powder and the resulting mixture can be poured into the Controlled Drug denaturing kit.

**Aerosols.** The contents of the aerosol should be expelled into water to prevent droplets of drug entering the air. The resultant liquid should then be disposed of as a liquid preparation.

**Fentanyl and buprenorphine Patches.** The active ingredient in the patches can be rendered irretrievable by removing the backing and folding the patch over upon itself. The patch may then be placed in the waste disposal bin or preferably a Controlled Drug denaturation kit.

Personnel involved in the destruction of Controlled Drugs should wear suitable gloves and in addition suitable face masks for protection (in some circumstances) and work in an area that is well ventilated.

The table below summarises the legal requirements of the Regulations for Schedules 2 to 5 for the possession and supply of Controlled Drugs by pharmacists.

## Summary of legal requirements for Controlled Drugs as they apply to pharmacists

|   | Schedule 2                                 | Schedule 3  | Schedule 4, Part I | Schedule 4, Part II  | Schedule 5 |
|---|--|---|--------------------|--|------------|
| <b>Designation of legal category for a controlled drug</b>                                    | CD   | CD No Reg   | CD Benz            | CD Anab  | CD Inv     |
| <b>Safe custody</b>   | Yes, except *Secobarbital/ quinalbarbitone | No, except temazepam, diethylpropion, flunitrazepam and buprenorphine | No                 | No   | No         |
| <b>Prescription requirements (see Note 1)</b>   | Yes  | Yes, except temazepam   | No                 | No   | No         |
| <b>Requisitions necessary (see Note 2)</b>  | Yes  | Yes   | No                 | No   | No         |
| <b>Records to be kept in CD Register</b>  | Yes  | No  | No                 | No   | No         |
| <b>Emergency supplies allowed</b>   | No   | No, except phenobarbital for epilepsy                                 | Yes                | Yes  | Yes        |
| <b>Repeats allowed on prescription</b>  | No   | No  | Yes                | Yes  | Yes        |
| <b>Invoices to be retained for two years</b>  | No   | Yes   | No                 | No   | Yes        |
| <b>Address of prescriber must be in the UK</b>  | Yes  | Yes   | No                 | No   | No         |
| <b>Licences required for import and export</b>  | Yes  | Yes   | Yes                | Yes, unless the substance is in the form of a medicine and for administration by a person to himself | No         |
| <b>Validity of prescription (see Note 3)</b>  | 28 days                                    | 28 days   | 28 days            | 28 days (if POM)   | 6 months   |
| <b>Private CD prescriptions to be written only on standardised form[see Note 4]</b>           | Yes  | Yes   | No                 | No   | No         |
| <b>Private prescriber identification number required on private prescription [see Note 5]</b> | Yes  | Yes   | No                 | No   | No         |
| <b>Pharmacist must ascertain the identity of the person collecting the CD [see Note 6]</b>    | Yes  | No  | No                 | No   | No         |
| <b>Private CD prescription forms to be sent to the appropriate NHS agency [See note 7]</b>    | Check guidance by BSO                      | Check guidance by BSO   | No                 | No   | No         |

\*Note: A number of barbiturates have been discontinued in the BNF. Amobarbital sodium, butobarbital and secobarbital sodium are available only on a named patient basis

## Notes

**1. Prescription requirements:** This refers to the particulars that must be present for a prescription to be valid as a prescription for a Controlled Drug, i.e., it must include dose, form strength (where appropriate) and a total quantity of the preparation in both words and figures. These requirements do not apply to temazepam prescriptions, which need only comply with the requirements for POM medicines.

Private prescriptions for temazepam must be on the standardised form and must also contain the private prescriber's identification number.

**2. Requisitions:** i.e., whether a requisition is necessary before supply may be made to practitioners, persons in charge of hospitals, masters of ships. etc. From January 1st 2008, for requisitions (other than veterinary requisitions) for Schedule 2 and Schedule 3 controlled drugs, the pharmacist must mark on the requisition his name and address in ink or otherwise so as to be indelible. Requisitions should be submitted by community pharmacies to the BSO using the modified HS30 form.

**3. Validity of repeatable prescriptions:** Where a drug in Schedule 4 is prescribed on a repeatable prescription, the first supply must be made within 28 days of the date of issue or the date specified by the doctor as the valid period for that drug. Where a drug in Schedule 5 is prescribed on a repeatable prescription, the first supply must be made within six months of the date of issue of the prescription.

**4. Private prescription standardised forms:** Private prescriptions issued for human use must be on PCD1 in N. Ireland, (FP10PCD in England, PPCD (1) in Scotland and WP 10PCD in Wales).

**5. Private prescriber identification number:** This number is required on private prescriptions for human use issued in N. Ireland, England, Scotland and Wales.

**6. Identity of person collecting CD:** The pharmacist must ascertain the role of the person collecting a Schedule 2 CD supplied against a prescription. It must be ascertained whether the person is the patient, the patient's representative or a healthcare professional acting within their professional capacity. If a healthcare professional is collecting the CD, their name and address must be obtained and if they are not known to the pharmacist, ID must be requested. Details are recorded in CD register.

**7. Submission of private CD prescriptions to the appropriate agency:** Private prescription forms PCD1 should be submitted by community pharmacies to the BSO using the modified HS 30 form.

Guidance on all the above Notes can be accessed from the references in Section 1.4 Controlled Drugs.

## Useful References

Recent legislation:

- The Misuse of Drugs and the Misuse of Drugs (Notification and supply to Addicts) Regulations SR No. 564 2005 (16/01/06).
- The Misuse of Drugs (Amendment)(No.2) Regulations (Northern Ireland) 2006 SR No. 214 (1/06/06)
- The Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2006 SR No. 264 (14/06/06) – See below guidance from DHSSPS on Partial Revocation
- Misuse of Drugs (Amendment) (No 4) Regulations (Northern Ireland) 2006 SR No334, 1/09/06
- Misuse of Drugs Act 1971 (Amendment Order) 2006 SI No 3331 – Reclassification of Methylamphetamine, 18/01/07
- The Misuse of Drugs and Misuse of Drugs (Safe Custody)(Amendment) Regulations (Northern Ireland) 2007 SR No 348 – Midazolam becomes a Schedule 3 Controlled Drug,
- The Misuse of Drugs Act 1971 (Amendment) Order 2008, SI No 3130, 25/01/09 – reclassification of cannabis and cannabinol derivatives from Class C to Class B drugs
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR No 225, 1/10/09
- The Misuse of Drugs (Designation)(Amendment) Order (Northern Ireland) 2009 SR No 389, 23/12/09
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2009 SR No 390, 23/12/09
- The Misuse of Drugs (Amendment)(No 2) Regulations(Northern Ireland) 2009 SR No 397, 23/12/09
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2010 SR No 148, 16/04/10

Full details may be accessed on the [www.opsi.gov.uk](http://www.opsi.gov.uk) website.

## Guidance Notes

The DHSSPS has also circulated a series of Guidance Notes for pharmacists and these should be used as an additional reference source e.g.

1. Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 3/01/06
2. Prescriptions for Schedule 2, 3 and 4 Controlled Drugs 16/05/06.
3. Amendments to the Misuse of Drugs Regulations (Northern Ireland)2002 26/06/06
4. Prescription Form PCDI (Private Prescription) 29/06/06 See Amendment Guidance Note 13 below.

5. Partial revocation of Statutory Instrument 2006/264 11/08/06 –delay with regard to implementation of the recording details in the controlled drugs register until January 1st 2008.
6. Prescribing of Schedule 2 and 3 Controlled Drugs in the Repeat Dispensing Scheme, 6/07/07
7. Amendments to the Misuse of Drugs Regulations(Northern Ireland) 2002 17/08/07 Delete(M77), ODPs Nursing Homes, Requisitions, Midazolam, CD Registers See amendment on requisitions Guidance Note 13 below.
8. Prescribing of Schedule 2, 3 and 4 Controlled Drugs, 22/02/08
9. Prescribing of Controlled Drugs by Nurse Independent Prescribers, 22/05/08
10. Controlled Drugs: Licensing of Paramedics, 07/09. (See list of substances with exemption for paramedics Section 1.5 Page X (formerly Page 60)
11. Changes to the legal control over substances formerly known as “legal highs” – BZP and others, 25/01/10
12. Controlled Drugs: Private Prescriptions (PCD1 Forms) and Private Prescriptions, 01/03/10
13. The Controlled Drugs (Supervision of Management and Use)
  - Regulations (Northern Ireland) 2009 – Guidance on SOPS for CDs, Declaration and Self Assessment Form 2010, issued 28th January 2010
14. Pharmacy Inspectors’ Newsletters – information relevant to Controlled Drugs
  - Issue 1 June 2006,
  - Issue 2 April 2007,
  - Issue 3 November 2007,
  - Issue 4 November 2008,
  - Issue 5 December 2009.

Further details and information can be accessed at [www.dhsspsni.gov.uk/index/pas](http://www.dhsspsni.gov.uk/index/pas)

### Reference Documents:

- Safer Management of Controlled Drugs - A guide to good practice in secondary care (Northern Ireland) August 2009.
- Safer Management of Controlled Drugs - A guide to good practice in primary care (Northern Ireland) due in 2010.