Managing Controlled Drugs -
Summary Guidance for Primary Care Prescribers

This guidance is primarily aimed at sessional GPs who may not have access to CD Standard Operating Procedures (SOPs) for the practices in which they work. Sessional GPs who regularly work in the same practice should be familiar with the practice’s CD SOP. GP practices and OOHs centres who wish to develop an SOP for Managing CDs should refer to the full ‘HSCB Guidance for Developing a CD SOP for Primary Care Prescribers’ (see link at end of document).

Background

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation in October 2009. The regulations require all practices to have in place adequate and up to date CD SOPs covering the management and use of CDs. This applies to ALL controlled drugs, and not just Schedules 2 and 3. Under the regulations, the Accountable Officer (AO) Mr Joe Brogan, is responsible for ensuring the safe management and use of CDs within the HSCB.

The management and use of CDs by GPs should be considered in the context of the following statement from DHSSPSNI:

‘All healthcare professionals who hold personal CDs stock must keep their own CD register for any Schedule 2 CDs that they possess, administer or supply, and they are personally responsible for keeping this accurate and up-to-date. This will provide a clear and identifiable audit trail. GPs should not share controlled drugs stock or share a central controlled drugs register as there would be concerns about the legality of possession, onward supply and audit.’

CD Stock

a. Sessional and other GPs without their own cipher number should obtain CD stock via practices that they work in using a HS21S stock order form. Authorisation for this should be given by the GP whose name appears on the HS21S form. The form must be signed by the recipient, in this case the sessional GP.

b. Requisitions for Schedule 2 and 3 controlled drugs may be either computer generated or handwritten. Requisitions must include the name, address, profession and signature of the recipient, the purpose for which the drug is supplied and the total quantity of the drug to be supplied (this does not have to be written in words and figures). Orders should be for complete original packs.

c. The CDs stocked should be those required for immediate patient care. Oral forms of Schedule 2 & 3 CDs would not routinely be considered essential items for a doctor’s bag. Naloxone should also be kept for reversal of opioid overdose.

Receipt of CDs for Stock

a. GPs should order and collect their own CDs in person.

b. For Schedule 2 CDs the GP should bring their CD register to the pharmacy when they collect their stock. A check should be made of the quantity, form and strength of the CD and the CD register updated with the receipt. The community pharmacist should be asked to sign the register as a witness.

c. CDs must be stored appropriately immediately on receipt.
Collecting CDs on Behalf of Patients

Health care professionals should not routinely collect dispensed CDs to deliver to patients.

Record-Keeping

The CD register which may be in the form of a bound book (not loose-leaved) or an electronic register, MUST comply with current regulations. Headings must include:

<table>
<thead>
<tr>
<th>Entries for drugs obtained</th>
<th>Entries for drugs supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Date supply received</td>
<td>• Date supplied</td>
</tr>
<tr>
<td>• Name and address from whom received</td>
<td>• Name/address of person supplied</td>
</tr>
<tr>
<td>• Quantity received</td>
<td>• Details of authority to possess (the prescriber’s details)</td>
</tr>
<tr>
<td></td>
<td>• Quantity supplied</td>
</tr>
<tr>
<td></td>
<td>• Role of person collecting Schedule 2 CDs (patient/patient’s representative/healthcare professional) and if a healthcare professional, name and address. (If unknown to the supplier proof of identification must be requested and recorded as below)</td>
</tr>
<tr>
<td></td>
<td>• Was proof of identity requested of patient/patient’s representative?</td>
</tr>
<tr>
<td></td>
<td>• Was proof of identity of person collecting provided?</td>
</tr>
</tbody>
</table>

a. Schedule 2 CD receipts and supplies must be recorded in the CD register in chronological order on the day of the transaction, or if this is not practical, on the next day. Records must also be maintained of *Sativex®* transactions and these should be recorded in the CD register.

b. Records of CDs received and supplied may be made on the same page or separate pages of the register. Entries on the same page will facilitate the maintenance of ‘running balances’ which is recommended as good practice.

c. Where part ampoules are used, the register should contain details of the quantity administered and the quantity destroyed.

d. CD registers should be kept separate from CD stock so that records are not lost in the case of theft or loss but must also be accessible to ensure proper record keeping.

Storage of CDs

a. All Schedule 2 and certain Schedule 3 drugs e.g. buprenorphine and temazepam, must be stored in either a CD safe/cabinet or locked doctor’s bag.

b. A locked doctor’s bag is regarded as a suitable receptacle for storing CDs, but an unlocked bag in a locked car is not.

c. Doctors’ bags should be stored safely i.e. not left unattended in an unlocked consulting room or in a vehicle for prolonged periods/overnight. If a bag is left unattended at any time in a car, it should be locked and kept out of sight. The car should be locked and any security system activated.

*Sativex®* has been re-scheduled from Schedule 1 to Schedule 4. Records of all Sativex® transactions must be kept. This is not a requirement for other Schedule 4 CDs.
Prescribing CDs

a. Prescriptions must be written indelibly. They may be handwritten, typed or computer generated. The signature must be in the prescriber’s handwriting.
b. If a prescription for a CD is issued on a home visit, this should be recorded in the prescribing section of the patient’s computer record as soon as possible.
c. Prescriptions for Schedule 2, 3 and 4 CDs are valid for 28 days from whichever is later of either the date on which a prescription was signed by the person issuing it or the date indicated by the prescriber as the date before which it shall not be supplied.
d. Prescriptions for Schedule 2, 3 and 4 CDs should be limited to up to 30 days’ supply.
e. Schedule 2 and 3 CDs should not be prescribed under repeat dispensing**
f. Emergency supplies of Schedule 2 and 3 CDs are not permitted. The only exception is phenobarbital for the treatment of epilepsy.
g. Prescribers should not prescribe CDs or any other drugs for themselves, their family or friends except in an emergency.
h. Private prescriptions for Schedule 2 or 3 CDs should be written on a PCD1 form. If a PCD1 form is not available and treatment is considered to be immediately necessary, it is acceptable to prescribe the Schedule 2 or 3 CD on a HSC prescription (HS21). PCD1 forms can be obtained by registering with the BSO.

http://www.hscbusiness.hscni.net/services/2272.htm

i. Prescribing for Substance Misusers – refer to full HSCB guidance

Prescriptions requirements for Schedule 2 and 3 CDs (except temazepam)

- Patient’s full name, address and, where appropriate, age
- Name and form of the drug (even if only one form exists)
- Strength of the preparation (if more than one strength exists)
- The dose to be taken
- The following must be stated in both words and figures:
  - the total quantity of the preparation to be supplied or
  - the number of dosage units to be supplied.

If the prescriber intends that the prescription is not to be supplied before a certain date then, in addition to recording the date on which the prescription was signed, he must also indicate the date before which it must not be supplied. This date is referred to as the ‘appropriate date’

The prescriber’s address must be stated on the prescription and must be within the UK.

Administering CDs

a. Prior to administration a check should be made to ensure the correct drug is to be given to the correct patient, the drug is suitable for use and the dose is appropriate. Wherever possible, another appropriate and competent individual should witness the administration. Administration should be recorded in the patient’s notes and, for schedule 2 CDs, must also be recorded in the CD register.

** Repeat dispensing is the process by which patients can obtain supplies of their repeat medicines over a defined period from a pharmacy of their choice, without the need to contact their GP practice on each occasion a new supply is needed.
Checks of CD Stock

a. Running balances should be recorded and checked with the physical amount of stock after each transaction and at regular intervals. Checks should be done in the presence of another trained member of staff and should be initialled and dated.
b. Balance checks should include checking the expiry date of stock.

Dealing with CD Balance Discrepancies and Incidents Involving CDs

a. All CD discrepancies should be investigated as soon as possible. Once resolved, a dated footnote should be made in the CD register correcting the discrepancy. Records should be kept of the action taken.
b. All adverse incidents involving CDs should be recorded and investigated.
c. The AO for the Board must be notified of all incidents or concerns involving CDs as soon as possible. This includes unresolved CD register discrepancies.

CD Destruction

a. Where it is necessary to dispose of the partially-used contents of an ampoule or syringe, CDs (Schedule 2, 3 and 4 (part I)) should be denatured before disposal. This may be done by placing the drug liquid on absorbent material (e.g. paper towels on to which a little soap has been added) and then disposing in the incineration bin for pharmaceutical waste.
b. Where this is impractical e.g. in a patient’s home, and subject to local policy, CDs in Syringe Drivers and partially-used injectable CDs may be disposed of directly into the sewerage system. Volumes disposed by this route should not normally exceed 25mls.
c. Schedule 2 CDs that are out-of-date or no longer required (eg due to change in circumstances) should be returned to a community pharmacy for destruction in the presence of an authorised witness. The appropriate records must be made in the doctor’s CD register. It is good practice to return all CDs that are out-of-date/not required to a community pharmacy for destruction.
d. Patients (or their representative) should be encouraged to return unused medication to a community pharmacy for destruction.

Monitoring and Auditing of Prescribing Data

To facilitate monitoring the management and use of CDs by practitioners CD prescribing data is produced and reviewed quarterly by HSCB staff. Any concerns are followed up with the prescriber.

Further Information

For further details on the safe management and use of CDs in primary care, please refer to:

1. HSCB guidance for developing a CD SOP for primary care prescribers
   http://primarycare.hscni.net/PharmMM_Resources_Non%20Clinical%20Resources.htm

2. DHSSPS ‘Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)

3. BNF Guidance on Prescribing Section 8 Controlled drugs & drug dependence.