



Controlled drugs

Advice correct as of April 2014

In Northern Ireland, unlike England and Wales, out-of-hours (OOH) organisations may expect GPs to carry and use controlled drugs (CDs) from their own stock. This factsheet highlights what you should be aware of when carrying, storing and recording controlled drugs.

Legislation

The Misuse of Drugs Act 1971 and its Regulations controls the availability of drugs that are considered sufficiently “dangerous or otherwise harmful” with the potential for diversion or misuse. The Regulations divide controlled drugs into five Schedules, which are graded on the medicinal or therapeutic benefit of the drug balanced against its harm when misused.

Safe storage

A register must be kept for Schedule 2 CDs, such as opiates, the major stimulants, secobarbital and amphetamine, which must comply with the requirements of the Misuse of Drugs Regulations. Schedule 2 drugs must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe. One person within the premises should take overall responsibility for the keys/codes. The cabinet should only be opened by the designated person, or by a person authorised by them, eg, a locum.

Most Section 3 drugs, eg, synthetic opioids, do not need to be stored in a locked safe, but it is good practice to do so. There is no legal requirement to record transactions involving Schedule 3, 4 or 5 drugs in a CD register.

Safe storage in a doctor’s bag

CDs used for home visits should be stored in a locked bag, box or case. A digital combination lock on a case is often the most practical and convenient solution and avoids problems with keys. Bags containing CDs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods.

It is advisable to keep stock levels held in the doctor’s bag to a minimum, eg, only one strength of each CD, in order to minimise the risk of confusion, error and inappropriate administration.

Consideration should be given as to where to store the CD register. The register needs to be ready to hand but

not stored in the bag in case it is stolen, which would result in the loss of both the CDs and the audit trail.

Recording of controlled drugs

The DHSSPSNI has produced guidance for primary care in Northern Ireland on good practice for the management of CDs. Section 9 states that: “All healthcare professionals who hold personal stock must keep their own CD register, and they are personally responsible for keeping this accurate and up-to-date.” This can take the form of a bound book or an electronic form. The RCGP Northern Ireland has developed a CD register compliant with the most recent legislation and is a useful tool (see further information).

In the CD register, a separate page must be used for each strength and form of that drug. Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register. On the page relating to that drug you must record:

- the date the supply was obtained
- the name and address from whom it was obtained (eg, wholesaler, pharmacy)
- the quantity of ampoules obtained.

In addition, it is best practice to ensure accuracy and veracity of the entries, to record:

- running balances of each drug
- the prescriber’s identification number and/or the professional registration number of the prescriber (where known), and also the name and professional registration number of the healthcare professional supplying the CD.

If practitioners operate from more than one set of premises and maintain a stock of Schedule 2 drugs at each, they must keep a separate register at, and for, each premises.

All CD registers must be kept for a minimum of two years after the date of the last entry, once completed.

It is best practice to store the CD register separately from the CD receptacle. The advantage of an electronic register is that it can be kept separately and securely from CD stock. As the register contains confidential information, access should be restricted to those who make entries in it or are authorised to inspect it.

Electronic registers

If the CD register is electronic, it should be attributable and capable of being audited. It must be printable and display the name, form and strength of the drug at the top of each display or printout to comply with requirements.

Supplying controlled drugs

All supply of CDs must be documented in the relevant page of the register. This applies to both drugs supplied or administered to patients from the doctor's bag or from practice stock. The details will include:

- The name, strength and form of the drug
- The date of use and quantity administered or supplied
- The name of the patient or representative.

Patients who collect CDs, or those who collect CDs on a patient's behalf, may be required to provide evidence of identity. It is good practice to record this information.

If CDs that are kept in a doctor's bag expire, they must be returned to a pharmacy for future destruction in the presence of an authorised individual. The appropriate records must be made in the doctor's CD register

Accountable officers (AO)

All designated bodies must appoint an AO, eg, the Board, a HSE Trust, Northern Ireland Ambulance Service and an Independent Hospital. AOs ensure the safe and effective management and use of CDs within their own organisation and by any person acting on behalf of or providing services to their organisation. The AO cannot be a person who routinely supplies, administers or disposes of CDs as part of their duties and they must be a senior person in the organisation.

Top ten tips for handling controlled drugs

1. Ensure that CDs are kept in a metal lockable cupboard or safe and if for home visits in a lockable bag, box or case with a combination lock. Do not leave the bag in a car overnight.

2. Maintain a CD register – either a bound book or electronic register.
3. It is best practice to maintain a running balance of stock in the practice CD register.
4. Ensure that entries are recorded on the correct page of the practice CD register, ie, a separate page for each drug.
5. Wherever possible, two members of staff (at least one clinical) should check all stock received or removed; both individuals should initial the entry in the CD registers. You may wish to carry this out monthly as part of your standard operating routine.
6. Ensure that all doctors have individual registers for CDs carried in their bags.
7. Develop a practice system for checking expiry dates for drugs carried in the doctors' bags. Consider creating a log of all drugs carried in the bags, including expiry dates, onto a computer spreadsheet. This should be regularly checked and managed by a designated member of staff.
8. Ensure CDs that have expired are destroyed by an authorised person.
9. Develop standard operating procedures for the management of CDs in accordance with DHSSPSNI guidance.
10. Contact MPS if you have any queries relating to the management of CDs within your practice.

Further information:

- DHSSPSNI, *Safer Management of Controlled Drugs: A Guide to Good Practice in Primary Care (Northern Ireland) Version 3, May 2013* – www.dhsspsni.gov.uk/pas-guidance
- Northern Health and Social Services Board, *Use of Medicines in General Practice, August 2004* – www.nhssb.n-i.nhs.uk/prescribing
- Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 – www.opsi.gov.uk
- RCGP Northern Ireland, *Controlled drug register* – www.rcgp.org.uk/college_locations/rcgp_northern_ireland
- UK National Prescribing Centre, *A Guide to Good Practice in the use of Controlled Drugs in Primary Care, Third edition, December 2009* – www.npc.nhs.uk/controlled_drugs

For medicolegal advice please call us on:

0845 605 4000

or email us at: querydoc@mps.org.uk

www.mps.org.uk

This factsheet provides only a general overview of the topic and should not be relied upon as definitive guidance. If you are an MPS member, and you are facing an ethical or legal dilemma, call and ask to speak to a medicolegal adviser, who will give you specific advice.

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