

Miscellaneous queries on CD regulations

1. Have the CD requirements for take home medications (TTAs), which are dispensed internally in the hospital, been altered in any way?

The requirements to use a standardised prescription form and to include the prescriber's identification number on private prescriptions for Schedule 2 and 3 CDs do not apply to TTAs. However, the new CD prescription requirements outlined in guidance will apply to hospital outpatient private prescriptions that are to be dispensed in a community pharmacy.

2. What should the Standard Operating Procedure (SOP) for CDs look like?

Currently, in England and Scotland (the implementation of this requirement in Wales has yet to be finalised), all healthcare providers who hold a stock of Controlled Drugs on their premises, including community pharmacies, must have up to date SOPs in place that cover the following matters:

- (a) who has access to the Controlled Drugs;
- (b) where the Controlled Drugs are stored;
- (c) security in relation to the storage and transportation of Controlled Drugs as required by misuse of drugs legislation;
- (d) disposal and destruction of Controlled Drugs;
- (e) who is to be alerted if complications arise (which may include details of when and how the relevant accountable officer (within a primary care organisation, trust or independent hospital) should be made aware of incidents); and
- (f) 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 2001, as amended, that have been returned by patients.

The Department of Health (in England) and the Scottish Government have issued guidance giving more detailed advice on the areas that may need to be covered by the SOP. It is anticipated that the Department for Health and Social Services in Wales will issue guidance on what should be covered by SOPs in Wales in due course.

3. Do patient returns have to be recorded as part of the SOP?

Although the recording of patient returned Controlled Drugs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001, as amended, the Controlled Drugs (Supervision of Management and Use) Regulations 2006, as described in (f)(ii), above, require SOPs to be in place for maintaining a record of Schedule 2 Controlled Drugs that have been returned by patients.

Pharmacists are therefore advised to keep a record of patient returned Schedule 2 Controlled Drugs, and their destruction, and to ensure that another member of staff, preferably a pharmacist or pharmacy technician if available, witnesses the destruction. The record of destruction should be made somewhere other than the Controlled Drug register, for example at the back of the private prescription register or in a separate book designated for that purpose.

It is recommended that the following details are recorded:

- the date of return of the Controlled Drugs;
- details of the Controlled Drugs:
 - (i) name of the Controlled Drug
 - (ii) quantity of the Controlled Drug;
 - (iii) strength of the Controlled Drug; and
 - (iv) form of the Controlled Drug;
- the role of the person who returned the Controlled Drugs (if known);
- the name and signature of the person who received the Controlled Drugs;
- the patient's name and address (if known);
- the names, positions and signatures of:
 - (i) the person destroying the Controlled Drugs; and
 - (ii) the person witnessing the destruction; and
- the date of destruction.

The recommendation is that these records be retained for a period of at least seven years as good practice.

4. Which drugs are included in Schedules 2 and 3?

The Home Office website has a link to a list of CDs and their Schedules:
<http://www.drugs.gov.uk/publication-search/drug-licences/controlled-list?view=Binary>

5. If a prescription is written for Methadone mixture, can I supply Methadone oral solution?

If a mixture was prescribed, as an oral solution is a type of mixture, this could be supplied.

6. If a prescription is written for Methadone oral solution, can I supply Methadone mixture?

If an oral solution is prescribed, a mixture could **only** be supplied if the product's licence stated that its form was an oral solution.

If an oral solution is prescribed, a mixture must **not** be supplied where it is not an oral solution, e.g. where it is an oral suspension etc.