



Royal
Pharmaceutical
Society
of Great Britain

Guidance for Pharmacists on the safe destruction of Controlled Drugs England, Scotland and Wales

The guidance below has been produced to ensure that the destruction of Controlled Drugs (CDs) within pharmacies is undertaken safely and in accordance with the requirements of the Misuse of Drugs Regulations 2001, as amended, relevant Waste Regulations and with due regard to minimising the risk of such an activity causing pollution or harm to health.

The following organisations have collaborated in the development of this guidance:

- Company Chemists Association
- Community Pharmacy Scotland
- Community Pharmacy Wales
- National Pharmacy Association
- Pharmaceutical Services Negotiating Committee

Some of the elements of this guidance are not statutory requirements but are good practice guidance which pharmacists would be expected to follow wherever practicable.

A. Patient returned Controlled Drugs

These are CDs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Currently, in the whole of Great Britain, CDs returned by patients from their own homes and from care homes providing residential care can be accepted by pharmacies for safe destruction and / or onward disposal.

Pharmacies in England and Wales are not able to accept waste medicines, including CDs, from care homes that provide nursing care.

However, in Scotland, the Scottish Parliament has approved legislation which allows pharmacies to accept a range of waste, including CDs, from individuals, households and “Care Services” as defined by section 2 of the Regulation of Care (Scotland) Act 2001. It should be noted that the definition of “care services” may exclude certain NHS premises.

Patient returned CDs must not be re-used and should be destroyed as soon as possible in order to avoid storage problems and an increased security risk. Pharmacists are reminded that, *for now*, patient-returned CDs can be destroyed without the need for an authorised witness to be present.

Pharmacists must render Schedules 1-4 (part I) CDs irretrievable and are strongly advised to do this as soon as possible after the CDs are returned to avoid large quantities building up. Until they can be destroyed, patient returned CDs requiring safe custody, according to arrangements appropriate to their Schedule, must be kept segregated from stock CDs in the CD cupboard. Patient returned CDs must also be clearly marked to minimise the risk of errors and inadvertent supply to patients.

Although recording of patient-returned CDs 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 require Standard Operating Procedures to be in place for maintaining a record of the CDs specified in Schedule 2 that have been returned by patients. These Regulations came into force on 1st January 2007 in England and 1st March 2007 in Scotland. Arrangements for Wales have yet to be finalised

Pharmacists are therefore advised to record patient returned Schedule 2 CDs and their destruction, and to ensure another member of staff, preferably a pharmacist or pharmacy technician if available, witnesses the destruction. The record of destruction should currently be made somewhere other than the CD 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 CDs
- the name, quantity, strength and form of the CDs
- the role of the person who returned the CDs (if known)
- the name and signature of the person who received the CDs
- the patient's name and address (if known)
- the name, position and signature of the person destroying the CDs and the witness ; and
- the date of destruction

The Society recommends that these records be retained for a period of at least 7 years. Forms to record these details are available from the Society's website at <http://www.rpsgb.org.uk/pdfs/restooldestrcd.pdf> and other organisations / bodies / suppliers, such as the NPA, can supply a record book for this purpose.

B. Obsolete, expired and unwanted stock Controlled Drugs

Until they can be destroyed, obsolete, expired and unwanted stock CDs requiring safe custody, according to arrangements appropriate to their Schedule, must be kept segregated from other CDs in the CD cupboard. Stock CDs awaiting destruction must be clearly marked in order to minimise the risk of errors and inadvertent supply to patients.

When stock Schedule 2 CDs are destroyed, the following details must be entered into the CD register:

- the drug name
- the drug form
- the drug strength
- the quantity of drug being destroyed
- the date of destruction

- the signature of the authorised person in whose presence the drug was destroyed.

Any person required by the Misuse of Drugs regulations to keep records of CDs, may only destroy them in the presence of a person authorised by the Secretary of State, either personally or as a member of a class. The latter includes inspectors of the Royal Pharmaceutical Society and CD Liaison Officers (certain police constables). An Accountable Officer is also able to authorise a person, or class of persons, to be an authorised witness.

It is good practice for the person carrying out the destruction to also sign against this record and the authority of the witness should be identified e.g. RPSGB inspector

The Home Secretary may also grant authority to individuals within their licensed companies.

There are a number of pharmacy multiples that have staff authorised to witness the destruction of CDs. Pharmacists working for multiples should contact their superintendent if they are unsure whether the company they work for has authorised witnesses.

Those authorities issued by the Home Office which apply to public limited companies operating retail pharmacies and persons in charge of private hospital providing palliative care or hospices wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions will cease at the end of 2007. They should now look to their local Accountable Officer to ensure they have enough authorised witnesses to maintain safe and effective destruction of CDs.

i. England

From 16th August 2007 an amendment to the Misuse of Drugs Regulations 2001 gave Accountable Officers the power to authorise people to witness the destruction of CDs. The new authorisation is in addition to the existing authorisations listed below. The Regulations prevent Accountable Officers from undertaking the role of witnessing themselves. Any person nominated to witness destruction should have appropriate training and be accountable for this activity directly to the Accountable Officer. Practitioners who are actively involved in the day-to-day management of CDs or, for example, anyone directly involved with GP practices e.g. practice pharmacists who have access to CDs in GP practices, or an individual who is authorised to supply CDs from the GP practice e.g. clinical governance lead working in their own GP practice, should not, be asked to witness the destruction of CDs in that GP practice.

For a list of Accountable Officers in England please refer to <http://www.healthcarecommission.org.uk/serviceproviderinformation/controlleddrugs/accountableofficers.cfm>

The following list of people are authorised to witness the destruction of controlled drugs in England:

- Chief Dental Officer of the Department of Health or a Senior Dental Officer to whom authority has been delegated;
- Supervisors of Midwives appointed by the Local Supervising Authority;
- Senior officers in an NHS Trust who report directly to the Trust Chief Executive and who have responsibility for health and safety, security or risk management matters in the Trust;

- Chief Executives of NHS Trusts;
- A Primary Care Trust Chief Pharmacist or Pharmaceutical/Prescribing Adviser who reports directly to the Chief Executive or to a Director of the Primary Care Trust;
- A Registered Medical Practitioner who has been appointed to the Primary Care Trust Professional Executive Committee or equivalent;
- The Primary Care Trust Board Executive member with responsibility for Clinical Governance or Risk Management;
- Medical Director of a Primary Care Trust.

In September 2006, the Department of Health in England confirmed that all those currently authorised to witness destruction of CDs retain that authorisation. In addition, this direction authorised any officer of the healthcare organisation who, for this purpose, is directly accountable to an executive officer of the organisation to witness the destruction of CDs. The new authorised groups could include Strategic Health Authority pharmacy leads, Medical Directors, and clinical governance leads. However, these individuals must be independent of the routine supply and administration of controlled drugs.

The guidance, which outlines the former list of authorised witnesses, plus the additional groups, can be found at

<http://www.dh.gov.uk/assetRoot/04/13/97/03/04139703.pdf>

ii. Scotland

In Scotland the classes of people currently authorised by the Secretary of State to witness the destruction of CDs requires updating. This is currently being considered.

In Scotland, Accountable Officers can authorise certain individuals to witness destruction of CDs. The Regulations prevent Accountable Officers from undertaking the role of witnessing themselves. Any person nominated to witness destruction should have appropriate training and be accountable for this activity directly to the Accountable Officer. Practitioners who are actively involved in the day-to-day management of CDs or, for example, anyone directly involved with GP practices e.g. practice pharmacists who have access to controlled drugs in GP practices, or an individual who is authorised to supply controlled drugs from the GP practice e.g. clinical governance lead working in their own GP practice, should not, be asked to witness the destruction of controlled drugs in that GP practice.

A list of Accountable Officers in Scotland can be found at

http://www.sehd.scot.nhs.uk/mels/CEL2007_03.pdf

iii. Wales

In Wales there is currently no definitive list of people eligible to witness the destruction of CDs. However, certain individuals have the authority to witness the destruction of CDs and all queries around this should be directed to the office of the Chief Pharmaceutical Officer for Wales.

C. Methods of Destruction

All medicines should be disposed of in a safe and appropriate manner. Medicines should be disposed of in relevant waste containers which are then sent for incineration and should not be disposed of in the sewerage system.

All CDs in Schedule 2, 3 and 4 (part I) can be placed into waste containers **only** after the controlled drug has been rendered irretrievable (i.e. by denaturing).

Wherever practicable, pharmacists are advised to use CD denaturing kits in order to denature CDs. Where this is not possible or practical other methods of denaturing may be used. In the past, various methods have been used to denature controlled drugs, including grinding together with other waste medicines, and / or dissolving in soapy water or adsorbing onto cat litter.

Having considered the risks posed by destruction of CDs in a pharmacy, the Environment Agency (EA), which covers England and Wales, has decided that it does not believe it is in the public interest to expect pharmacies to obtain a waste management license for denaturing CDs and this is seen by the EA as a 'low risk' activity. The EA emphasises, however, that it may amend or revoke its position at any time and will continue enforcement in all circumstances where activity has or is likely to cause pollution or harm to health. So, pharmacists must ensure that the activities they undertake to denature CDs protect the environment and workers and others within the pharmacy.

In Scotland, pharmacies should register an exemption under paragraph 39 of Schedule 3 to the Waste Management Licensing Regulations 1994 (as amended) with the Scottish Environment Protection Agency (SEPA). The exemption covers the secure storage of CDs at a pharmacy prior to subsequent collection and disposal. SEPA is willing, at the present time, to accept that the denaturing of CDs forms part of the exempt activity of secure storage. However, SEPA may reconsider this position and pursue enforcement action if the denaturing activity causes, or is likely to cause, pollution of the environment or harm to human health.

Solid dose formulations

Tablets and capsules can be removed from their outer packaging, removed from blister packaging and placed in a CD denaturing kit. If a person is removing tablets / capsules from blister packs they should wear gloves. CD denaturing kits can be obtained from some PCOs, waste contractors and the NPA. Best practice would be to grind* or crush* the solid dose formulation before adding to the CD denaturing kit to ensure that whole tablets or capsules are not readily recoverable.

An alternative method of denaturing is to crush or grind the solid dose formulation and place it into a *small* amount of hot, soapy water stirring sufficiently to ensure the drug has been dissolved or dispersed. The resulting mixture may then be added to an appropriate waste disposal bin supplied by the waste contractor.

**If grinding or crushing of tablets or capsules takes place, steps must be taken to ensure that particles of CD dust are not released into the air or that this is minimised. The use of a small amount of water whilst grinding or crushing may assist. It may also be necessary for the person involved in the grinding or crushing to wear a suitable face mask for protection, suitable gloves and ensure that the area is well ventilated.*

Liquid dose formulations

A CD liquid can be poured from its container and added to the normal CD denaturing kit where it will mix with the other waste materials, thus rendering it irretrievable.

An alternative method of disposing of a large quantity of a liquid controlled drug is by adding and adsorbing it into an appropriate amount of cat litter, or similar product. However, this activity would need to take account of health and safety regulations so that the person destroying the CDs and the environment are safeguarded from harm and pollution. The cat litter or similar product should be disposed of for incineration via the usual waste disposal methods for medicines.

Parenteral formulations

Liquid ampoules should be opened and as much of the content as possible emptied into the CD denaturing kit or disposed of in the same manner as disposing of liquids outlined above. The ampoule should be disposed off in the sharps bin. The sharps bin should be labelled "contains mixed pharmaceutical waste and sharps – for incineration".

Ampoules containing the CD in a powder form can be opened, water added to dissolve the powder and the resultant mixture poured into the CD denaturing kit or the bin that is used for disposal of liquid medicines. The ampoule can then be disposed of in the sharps bin. The sharps bin should be labelled "contains mixed pharmaceutical waste and sharps – for incineration". These are the ideal methods of denaturing ampoules. Suitable gloves should be worn by the person breaking open glass ampoules as a safety measure and to minimise the risk of injury from sharps.

An alternative but less preferable, disposal method is where the ampoules are crushed with a pestle inside an empty plastic container. Once broken, a small quantity of hot soapy water (for powder ampoules) or cat litter (for liquid ampoules) is added. If these methods are used, care should be taken to ensure that the glass does not harm the person destroying the CD. The resulting liquid mixture should then be disposed of in a CD denaturing kit or in the bin that is used for disposal of liquid medicines.

Fentanyl and buprenorphine patches

The active ingredient in the patches can be rendered irretrievable by removing the backing and folding the patch over on itself and then placing it in a waste disposal bin, or preferably a CD denaturing kit. Gloves must be worn by the person destroying the CD.

Aerosol formulations

Aerosol formulations should be expelled into water (to prevent droplets of drug entering the air). As a further precaution, it would be advisable for a facemask to be worn by staff undertaking the activity and to ensure that the area where the destruction takes place is well ventilated. The resulting solution can then be disposed of in accordance with the above guidance on destruction of liquid formulations.