

Destruction of Controlled Drugs by Authorised Witnesses - Standard Operating Procedure

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Version Control Sheet

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Destruction of Controlled Drugs by Authorised Witnesses **Standard Operating Procedure (V1.3)**

Introduction

It is a legal requirement for stocks of Controlled Drugs (CDs) to be destroyed in the presence of an Authorised Witness. The witnessed destruction of stocks has, historically, been restricted to certain groups of individuals granted authority by the Home Office. The Shipman Enquiry has led to a wide ranging review of CD management. In recognition of the need for PCTs to manage witnessed destruction of CDs in a well regulated, safe and timely manner, the Home Office has extended the range of persons eligible to witness destruction and given the Accountable Officer (AO) of a PCT the power to appoint appropriate individuals as authorised witnesses from within the PCT/s for which they have responsibility.

Purpose

The safe and appropriate destruction of CD stock in compliance with current legislative requirements and good practice guidance.

Scope

This standard operating procedure (SOP) applies to witnesses authorised by the AO for the PCT and relates to the destruction of out of date or unwanted CD stock.

Note - Some premises may also, from time to time, have Patient returns. It is not a legal requirement for patient returns to be destroyed in the presence of an Authorised Witness. If, however, whilst attending to witness the destruction of stock CDs, the Authorised Witness may (at their discretion) also witness the destruction of patient returns.*

* Patient Returns = any CDs dispensed to and collected by an individual patient on prescription which are returned out of date or otherwise no longer required.

It will explain how CDs should be destroyed in the presence of authorised witnesses.

It will explain how any discrepancies/problems found during the destruction process should be addressed.

All PCT appointed authorised witnesses must read this SOP and by signing the declaration in appendix 4, agree to abide by it.

Note – Please refer to appendix 3 for background information regarding CD register and Patient Return Record Book completion.

Standard Operating Procedure

Receiving Requests & Arranging Visits for the Destruction of CDs

When a PCT clinical provider, Community Pharmacy*, GP Practice or other appropriate body has stock CDs requiring destruction they should contact the PCT Medicines Management Team Secretary (to allow effective monitoring of activity and re-direct requests as may be necessary).

* NB! Some of the larger Community Pharmacy chains have their own internal Authorised Witnesses. These Companies should not approach the PCT to witness the destruction of CDs on their premises. If they do, the Pharmacy concerned should be directed to their Superintendent Pharmacist's Office, or other point of contact, for

further help (A list of Companies that have their own Authorised Witnesses is available).

The MMT Secretary will notify one of the authorised witnesses who will contact the person/body making the request to arrange a mutually suitable date & time for destruction to take place.

Note – 1/ Authorised witnesses should not witness destruction of CDs for a GP Practice to whom they are providing Medicines Management Support or where they work at the time of destruction.

2/ Authorised witnesses should not act in that capacity within any Community Pharmacy premises in which they are currently also providing services as a Pharmacist.

3/ The CDs to be destroyed should have been appropriately recorded, marked and segregated as necessary prior to the visit. Additionally a denaturing kit/s must have been obtained by the stock holder and be available when the visit takes place. Staff working for the stock holder will carry out all physical elements of the destruction process. We therefore recommend that those staff have appropriate Health & Safety training and any protective equipment/clothing necessary to safely handle the various drug formulations that are to be destroyed, is made available to them by their employer.*

**It may be prudent to check this at the time the appointment is arranged.*

Record Keeping

Details of all CDs destroyed will be entered in the CD register in compliance with legislation (see appendix 1 for example entries. Please Note, some newer CD registers may contain additional columns to enable a record of the person collecting a CD prescription to be recorded. The presence of these additional columns does not however effect the requirements for recording destruction).

If the authorised witness has any concerns, questions or comments regarding the destruction visit (eg. quantity to be destroyed does not balance, CD register entries are poorly recorded etc they should detail their concerns/findings on the Controlled Drug Destruction Notes form (see appendix 2).

Note – Comments should be discussed with the AO or their deputy as soon as possible.

Procedure for Destruction of CDs

On arrival at the premises the authorised witness will identify themselves, using their PCT ID badge (if they are not already known to staff).

- 1/ All parts of the process must take place in the presence of the Authorised Witness. It is neither the role nor responsibility of the Authorised Witness to assist with the actual destruction process (i.e. removal of products from packaging and adding to the DOOP kit/s). This must be done by staff employed by the stock holder. It is the responsibility of the staff and their employers, to ensure that they are adequately trained and protected as necessary (e.g. wearing gloves).
- 2/ CDs must be destroyed using a denaturing kit designed for that purpose. The only deviation is where large volumes of liquids are involved (see below).

Note - CD/Drug Denaturing Kits include instructions for use, these must be followed to ensure effectiveness.

- 3/ The CDs quarantined for destruction should be removed from the CD cupboard and reconciled with the CD Register (CDR) and/or Patient Returns Record Book (PRRB).
- 4/ CDs should be added to the denaturing kit according to the process, described below.
Order of adding products to kit;
1st – solid oral dose forms (e.g. tablets/capsules), powder containing injection vials/ampoules and transdermal patches,
2nd – small volume liquids (e.g. injection ampoules/vials),
3rd – large volume liquids* (e.g. oral liquids, larger volume injection vials).
Note – after emptying the liquid into the denaturing kit, the container should be rinsed once with water and this to, added to the kit. The empty container can then be discarded with normal waste.

Processing products before adding to the kit

Tablets and capsules should be removed from all packaging, injection ampoules/vials should be opened and the contents + all glass added to the granules, transdermal patches should be cut in two, or folded over onto themselves.

** Liquids (other than the small volumes in ampoules/vials) should be added last and 'all at the same time'.*

Note - Denaturing kits are available up to 2L capacity. If a large volume of liquid requires denaturing the stock holder may either use the larger kits or cat litter. If using cat litter a sufficient quantity must be used to fully adsorb the liquid added. Suitable containers to hold the cat litter must be provided by the stock holder. The cat litter in its container must be discarded in the clinical waste sharps bin.

- 5/ The CDs should be 'written out' of the CDR and/or PRRB as they are added to the kit. The entry must specify; the name, strength and form of the product, date, quantity destroyed, printed name & professional registration number of authorised witness followed by their signature, printed name and signature of the second witness and the balance remaining (see examples in appendix 1).
- 6/ For CD stock, the balance remaining should be reconciled with the CDR and signed by the persons witnessing destruction.
- 7/ Once ALL products being destroyed have been added to the kit, water should be added, as necessary*, in accordance with the kit manufacturers directions.
**Note, if larger volume CD liquids are being destroyed their volume should be taken into account and the volume of water required adjusted accordingly.*
- 8/ The used kit should then be put in the CD cupboard whilst the inactivation process is taking place. The CDs are now considered 'irretrievable' and the responsibility of the authorised witness is complete.

Note - the kit contents will form a gel within a few minutes and may become hot initially (this is normal). It may take up to 24 hours for the inactivation process to complete.
- 9/ After 24 hours the kit should be added to a standard clinical waste sharps bin for disposal by incineration.
- 10/ If necessary, ie if the authorised witness came across any issues or concerns during the destruction visit (eg. quantity to be destroyed does not balance, CD register entries are poorly recorded) they should detail their concerns/findings on the Controlled Drug Destruction Notes form (see appendix 2) and return this to the PCT AO.

Discrepancies

Discrepancies that are not traced and corrected (e.g. a mathematical error within the CDR) at the time should be recorded in the CDR and by the Authorised Witness on the CD Destruction Record Notes form*.

It is not the function of the Authorised Witness to investigate untraced discrepancies at the time of destruction. However, the Authorised Witness should make a detailed note of the discrepancy and feed it back to the Accountable Officer, or their deputy, within 2 working days.

Staff of the organisation holding the CDs should refer to their internal procedures for follow up and resolution.

* Note - The presence of discrepancies does not necessarily prevent the destruction of CDs from taking place. The Authorised Witness should consider the risks (if any) of not destroying the CDs during the visit, recording what has, or has not, been destroyed and include any relevant information on the CD Destruction Record Notes form (see appendix 2).

Training and information

The PCT will provide appropriate training for all Authorised Witnesses. The PCT will provide updates and where necessary additional training for all Authorised Witnesses as and when the need arises.

Appendix 1

Destruction –

Example page from an Intermediate Care CDR (these will be 'patient's own drugs')

<i>Mr Apu Nahasa, Quik-E-Mart, Springfield</i>										
NAME, FORM OF PREPARATION AND STRENGTH ... <i>Morphine Sulphate 10mg MR Tablets</i>								001		
AMOUNT(S) OBTAINED			AMOUNTS ADMINISTERED							
Amount	Date Received	Serial No. of Requisition	Date	Time	Patient's Name	Amount Given	Given by (Signature)	Witnessed by (Signature)	STOCK BALANCE	
45	17/5/07		<i>Received from Mr A Nahasa, by Sig. 1, Sig. 2,</i>							45
			17/5/07	22:00	<i>Apu Nahasa</i>	1	<i>Sig. 1</i>	<i>Sig. 2</i>	44	
			18/5/07	10:00	<i>Apu Nahasa</i>	1	<i>Sig. 1</i>	<i>Sig. 2</i>	43	
			18/5/07	22:00	<i>Apu Nahasa</i>	1	<i>Sig. 1</i>	<i>Sig. 2</i>	42	
			22/5/07	14:20	<i>42 Morphine Sulphate 10mg MR tablets destroyed - Authorised Witness Name, Registration No. & Signature - Name & Signature of 2nd Witness.</i>				Nil	

Example page from a Community Pharmacy/Dispensing Surgery CDR

Drug Class ... <i>Morphine Sulphate</i> Brand <i>MST</i> Strength <i>10mg</i> Form <i>MR Tablets</i>								
Date	Obtained		Supplied					Balance
	Name, address of person or firm from whom obtained	Amount obtained	Name, address of person or firm supplied	Authority to possess – Prescriber or license holder details	Name and registration number of pharmacist supplying	Name of person collecting (and ID shown)	Amount supplied	
7/5/06	<i>C/F from page 1</i>	45						45
8/5/06			<i>Mr Homer J Simpson, 742 Evergreen Terrace Springfield</i>	<i>Dr Julius Hibbert the Surgery, Springfield</i>	<i>P Pharmacist, 123456</i>	<i>Mrs Marge Simpson</i>	10	35
9/5/07			<i>35 tablets quarantined, out of date, awaiting destruction.</i>					35
9/5/07	<i>The Pharmacy Wholesalers.</i>	60						95
1/6/07			<i>35 out of date morphine sulphate 10mg MR tablets destroyed - Authorised Witness Name, Registration No. & Signature - Name & Signature of 2nd Witness.</i>					60

Example page from a Patient Return Record Book

Date	Name	Address	Description of CDs	Witnessed By	Witnessed By	BALANCE
	Of person to whom the CDs were dispensed		Name, Form, Strength, Quantity	(Signature)	(Signature)	
17/5/07	<i>Mr C Montgomery Burns</i>	<i>Burns Manor, Springfield</i>	<i>Morphine Sulphate 10mg MR (MST) tablets x 44, for destruction.</i>	<i>Sig. 1</i>	<i>Sig. 2</i>	44
22/5/07	<i>44 Morphine Sulphate 10mg MR tablets destroyed - Name & Signature of 1st Witness - Name & Signature of 2nd Witness.</i>					Nil

Appendix 2

Authorised Witness Controlled Drug Destruction Notes

NB! Patient identifiable information must not be included in these notes [the use of patient initials is acceptable if appropriate].

Date :	Location :
Visit Notes - for completion if required :	
Authorised Witness Signature:	
Please return to : PCT Accountable Officer, PCT,	

Appendix 3

General Information/Notes

CD Registers;

The format and requirements for CD registers are specified in Regulations 19, 20 and Schedule 6 of the Misuse of Drugs Regulations 2001 as amended.

Currently the register must:

- Be bound (not loose-leaved) or a computerised system which is in accordance with best practice guidance
- Contain class sections for each individual drug
- Have the name of the drug specified at the top of each page
- Have the entries in chronological order and made on the day of the transaction or the next day
- Have the entries made on consecutive lines (no blank lines).
- Have the entries made in ink or otherwise so as to be indelible or in a computerised form in which every such entry is attributable and capable of being audited and is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the NHS Act 1977
- Not have cancellations, obliterations or alterations; corrections must be made by a signed and dated entry in the margin or at the bottom of the page
- Be kept at the premises to which it relates and be available for inspection at any time.
- A separate register must be kept for each set of premises (for example, not just the main surgery)
- Be kept for a minimum of two years after the date of the last entry, once completed (*Note - we recommend 11 years now as it is proposed that legislation is amended to require this*)
- Not be used for any other purpose.

The definition of a CD register in the 2001 Regulations was amended in November 2005 to allow (not require) the register to be held on a computerised system which complies with specified best practice guidance. The Regulations require that entries in computerised registers must be attributable and capable of being audited.

At the time of writing there is no use of electronic CDRs locally that we are aware of.

Community Pharmacies and PCT services will use specially designed, pre-printed CDRs obtained from approved suppliers. Some GP surgeries will do likewise, particularly Dispensing Practices. It is not however a legal requirement to use such registers and you may find that some Surgeries will have drawn up their own registers using a bound book and this is fine provided that they comply with legislation.

For CDs received into stock the following details must be recorded in the CD register:

- The date on which the CD was received
- The name and address of the supplier, e.g. wholesaler, pharmacy
- The quantity received
- The name, form and strength of the CD.

For CDs supplied to patients (via prescriptions), or to practitioners (via requisitions), the following details must be recorded in the CD register:

- The date on which the supply was made
- The name and address of the patient or practitioner receiving the CD
- Particulars of the authority of person who prescribed or ordered the CD
- The quantity supplied
- The name, form and strength in which the CD was supplied.

Note - The 2001 Regulations were amended in July 2006 to make clear that the record keeping requirements of the CD Regulations are a minimum and do not prevent any person required to keep a CD register from including additional related information.

Patient Return Record Book

Whilst there is currently no legal requirement to keep any records of patient returns, it is good practice and strongly recommended that records are kept and in practice this usually happens. It therefore also follows that there is no legal requirement for patient returns to be destroyed in the presence of an authorised witness, but this sometimes happens in practice.

A dedicated Patient Returns Record Book should be used. There is no legally required format for this record, however it is recommended that such a book should be bound (not loose leafed), entries should be indelible, errors should not be erased but marked and a correcting entry and explanation made. They should contain the following details:

- Date of return
- Patient's name (if known)
- Address of the dispensing Pharmacy/Practice (if known)
- Drug details and quantity returned
- Signature of staff accepting the return and making the entry

It is good practice for 2 people to witness the destruction of patient returned CDs, using a denaturing kit and recording the destruction in the Patient Returns Record Book.

It is not necessary for one of the witnesses to be an 'Authorised Witness', but destruction may be arranged to take place at the same time as the destruction of stock CDs, in which case the authorised witness may be asked to oversee the destruction of patient returns. The Authorised Witness may do so if they have sufficient time available, but it is their decision and they are not obligated to do so (*In practice, Community Pharmacists seldom ask us to witness the destruction of patient returns as they understand witnessed destruction is not required*).

If the Authorised Witness does oversee the destruction of patient returned CDs AND there is a need to make a note of a discrepancy/issue on the Controlled Drug Destruction Notes sheet, the AW must ensure that the patient is not identified, their initials however, should be included [if known] in case it subsequently became necessary to identify them.

Appendix 4

All authorised witnesses must read this SOP and sign the declaration below.

I confirm that I have read, understood and will abide by the Destruction of Controlled Drugs by Authorised Witnesses Standard Operating Procedure.

Date	Name & Designation (please print)	Signature