GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Witnessing the destruction of Controlled Drugs by Authorised Persons

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The latest approved version of this document is online.
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SOP authorisation

Name	Job title and organisation	Signature	Date
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	5/28/2021

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Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
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Circulated to the following for Consultation

Date	Role / Designation
1/4/2020	MMT including but not limited to AW's
1/7/2020	New Chief Pharmacist Jacqueline Seaton
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1. Introduction

In accordance with The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008, Controlled Drugs Accountable Officers (CDAO) must ensure that adequate destruction and disposal arrangements for controlled drugs are in place.

An accountable officer must:

a) establish and operate, or ensure that his or her designated body establishes and operates appropriate arrangements for securing the safe destruction and disposal of controlled drugs by his or her designated body, and
b) ensure that any body or person acting on behalf of, or providing services under arrangements made with, his or her designated body establishes and operates appropriate arrangements for securing the safe destruction and disposal of controlled drugs by that body or person.

The same regulations require the CDAO to ensure that their designated body has adequate and up-to-date standard operating procedures in place covering all aspects of the management and use of controlled drugs.

Health professionals and service providers who are required by The Misuse of Drugs Regulations 2001 to maintain a controlled drugs register must have an authorised person present to witness the destruction of stock controlled drugs in Schedule 2 in line with Regulation 27 of the 2001 Regulations.

This standard operating procedure covers the witnessing the destruction of Controlled Drugs by Authorised Persons

In recognition of the need for HBs 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) the power to appoint appropriate individuals as authorised witnesses from within the Organisation for which they have responsibility.

Any person nominated to witness destruction should have appropriate training (to include a legislation, documentation and practice), governance arrangements , be subject to a professional code of ethics and/or have been subject to an enhanced Disclosure and Barring Service (DBS) check and be signed off by their organisation's CDAO.

Patient's own or returned CDs may be destroyed by registered HCPs without an authorised person present, although it is recommended as good practice that these destructions are witnessed by another HCP.

2. Objective

The safe and appropriate destruction of CDs in compliance with current legislative requirements and good practice guidance. This SOP applies to staff employed by PTHB who have been authorised to witness the destruction of controlled drugs by the CDAO. It provides advice and guidance on the correct procedures for witnessing the destruction of CDs in a secondary, primary or community setting.

3. Scope

This Standard Operating Procedure (SOP):

- Applies to all witnesses authorised by the CDAO on behalf of the Health Board, who must have read this SOP, agreed to abide by it and signed the declaration in Appendix A. The AW will carry a letter confirming that they are authorized by the CDAO to witness the destruction of CDs (Appendix C)
- Relates to the destruction of out of date or unwanted CD stock and patient's own CDs.
  Note - Patient returns. It is not a legal requirement for patient returns to be destroyed in the presence of an Authorised Witness.
- Explains how CDs should be destroyed in the presence of authorised witnesses.
- Outlines how to address any discrepancies/problems found during the destruction process.
- THIS SOP DOES NOT INCLUDE THE DESTRUCTION OF ILLICIT DRUGS OR UNKNOWN SUBSTANCES.

4. Definitions

- PTHB – Powys Teaching Health Board
- SOP- Standard Operating Procedure
- AW- Authorised Witness
- HCP- Heath Care Professional
- CDAO – Controlled Drugs Accountable Officer
- CD – controlled drug
- Datix - PTHB Accident and Incident Reporting System

- MMT – Medicines Management Team (pharmacists, pharmacy technicians, nurses and administrative staff working in Medicines Management department)

5. Role / Responsibilities

Authorised Witness

In order for a person to be nominated by the CDAO for the Health Board, they should:

- Have attended appropriate training within the last 3 years.
- Have appropriate governance arrangements in place
- Be subject to a professional code of ethics or have been subject to an annual enhanced DBS check.

Powys MMT Administrative staff

The administrative team within Medicines Management are responsible for processing requests for CD destructions, including but not limited to:-

- Sending out the CD destruction request form for completion.
- Contacting the requestor within 5 working days of the request being received to arrange a date for the destruction to be witnessed (every effort will be made to align destructions geographically to ensure the best use of AW time, but ideally destructions should be witnessed within 28 days of the request being received).
- Making contractor sites aware of what preparation is required before the visit (see below). See notes section of CD destruction request form (appendix B)
- Ensure that the AW has a copy of the appropriate completed CD destruction request form that was provided by the requestor prior to attending the destruction.

Party requesting destruction

When requesting the destruction of CDs: -

- the sector appropriate CD request form should be fully completed and submitted to Powys MMT.
- in preparation for the visit a balance check must have been completed less than 24 hours before the visit for any medication with stock requiring destruction.
- the CD register should be complete, available and in order for the visit.
- A suitable person should be available to assist with the CD destruction for the duration of the visit.

6. Notes for witnesses

- AWs cannot delegate the task of witnessing the destruction.
- AWs should be independent of the day-to-day use or management of CDs.
- AWs cannot witness the destruction of CDs that have been supplied to them or by them.
- AWs should not witness destruction of CDs in ward/department/ GP practice/community pharmacy where they are directly involved/ based or where they have worked within the last 3 months.
- Where there may be practical difficulties in finding a suitably independent AW to witness the destruction of CDs at a particular premises, the risks posed by the CDs awaiting destruction should be considered. Where possible, advice should be taken from the Accountable Officer, or senior health board pharmacist.
- The CDs to be destroyed should have been appropriately recorded, marked and segregated as necessary prior to the visit. Additionally, a denaturing kit(s) should have been obtained by the CD holder and must be available when the visit takes place.
- Details of CDs to be destroyed should be entered onto the CD Destruction Request and Record by the requesting site (Appendix B). A copy should be provided to the AW prior to the visit to facilitate planning.
- The CD Destruction Request and Record (Appendix B) should be fully completed whenever witnessing of CD destruction takes place. The original should be forwarded to the HB Medicines Management Team. A copy should be kept by the contractor for their records.
- CDs should ideally not await destruction for more than 3 months.
- AW's should familiarize themselves with guidance on appropriate infection prevention measures, including the use of PPE, prior to visiting. The AW should ensure that they have access to appropriate PPE prior to attending the destruction.

7. Arranging Visits for the Destruction of CDs

When a Community Pharmacy, GP Practice, Hospital Ward or other appropriate body has CDs requiring destruction, contact should be made with the Health Board Medicines Management Team. A sector appropriate CD Destruction Request and Record (Appendix B) will be sent out for completion. Once this completed form is returned to the MM Department, the requesting party will be contacted within 5 working days of its receipt to arrange a mutually suitable date & time for destruction to take place (ideally within 28 days of the request being received). If electronic controlled drugs registers are

used, arrangements should be made by the requesting site to allow access to these by the authorised witness.

The management of CD destruction visits is the responsibility of Medicines Management Project Manager (HR and Community Pharmacy Contracts).

8. Record Keeping

A CD Destruction Request and Record form (Appendix B) must be completed on each occasion that CD destruction is witnessed by the HB.

Note - This record sheet is not a legal requirement, but it is an audit/feedback tool providing potentially useful information to the Accountable Officer and the Local CD Intelligence Network.

9. Discrepancies

Discrepancies encountered during the visit that are not able to be traced and corrected (e.g. a mathematical error) should be recorded in the CD Register and on the CD Destruction Request and Record form. No CD destruction can take place for a drug with an unresolved discrepancy.

If a discrepancy cannot be resolved, destruction of that item **should not usually take place** until after an investigation has been completed. Destruction of other controlled drugs may continue. The Authorised Witness should consider the risks (if any) of not destroying the CDs during the visit, and consider taking advice from the Accountable Officer, or Senior Medicines Management Pharmacist. A clear record should be made of what has, or has not been destroyed, and the reasons why.

It is not the function of the authorised witness to investigate untraced discrepancies at the time of destruction. The authorised witness should make a detailed note of the discrepancy and feed it back to the Accountable Officer, and the Chief pharmacist and complete a DATIX report. Site staff must complete an incident report and follow up the discrepancy via their company/health board processes.

10. General Information/Notes

Environmental legislation
Arrangements for destroying and disposing of controlled drugs must be in line with the 2001 Regulations and the Controlled Waste (England and Wales) Regulations 2012, a T28 exemption (https://nrwregulatory.naturalresources.wales/Exemptions/PublicRegister/Search) from Natural Resources Wales is needed in order to sort and denature controlled drugs.

CD Registers 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
- The name of the drug, its strength and form must be 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 – it must be clear who any amendments made are attributable to (e.g. name, initials/signature, GPhC number if applicable)
- 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, at branch surgeries)
- Be kept for a minimum of two years after the date of the last entry, in line with Regulation 23 of the 2001 regulations
- Not be used for any other purpose
- It is good practice that all CD registers contain a running balance
- Examples can be seen in Appendix 1

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.

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
- Details 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
- Person collecting Schedule 2 CDs (patient / representative / healthcare professional), and if a healthcare professional, their name and address.
- Was proof of identity requested of patient / representative (Yes / No).
- Was proof of identity of person collecting provided (Yes / No)

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.

11. 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. It therefore also follows that there is no legal requirement for patient returns to be destroyed in the presence of an authorised witness, but again, this often happens in practice.

A dedicated Patient Returns Record Book should be used and it is recommended these records are retained for at least seven years. 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 & address (if known) & role of person returning CDs (if known)
- Address of the dispensing Pharmacy/Practice (if known)

- Drug details (name, strength, form) and quantity returned
- Name & signature of person accepting the return
- Name & signature of person destroying the CDs
- Name & signature of person witnessing the destruction
- Date of destruction

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. One witness should be a registered Healthcare Professional.
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 (this may also help make best use of the denaturing kit).

If the Authorised Witness does oversee the destruction of patient returned CDs, they are asked to make a note of this on the CD Destruction Record sheet (The patient must not be identifiable from the 'Destruction Record', but their initials [if known] should be included in case it ever became necessary to identify them in a subsequent investigation).

12. Procedure for Destruction of CDs

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

All parts of the process must take place in the presence of the AW.

The area where destruction takes place should have been identified as appropriate by risk assessment. This should be free from clutter with sufficient space to work effectively. Consideration should be given to the proximity to the controlled drugs cupboard.

The preferred method of destruction is using a denaturing kit designed for that purpose. In exceptional circumstances, such as when unusually large volumes of liquid make this impractical, then other methods as detailed in "Medicines, Ethics and Practice (MEP)" may be used. Note - CD/Drug Denaturing Kits include instructions for use, these must be followed to ensure effectiveness. *These kits should be supplied by the contractor requesting the destruction but spares taken along to the destruction visit by the AW just in case none are available.*

Process

Remove CDs quarantined for destruction from the CD cupboard and reconcile with the CD Register and/or Patient Returns Record Book and the CD destruction record (Appendix B).
For CD stock, the balance remaining should be reconciled with the CD Register and signed by the persons witnessing destruction

NOTE
In extenuating circumstances (e.g. during a pandemic), the destruction process may be completed without a balance check during the visit by the AW. This should only be the case if a risk assessment by the AW concludes that the destruction without balance check is the safest option.
For any such cases the following MUST be completed.

1. The CD register completion must include the phrase 'Following risk assessment, destroyed without balance check' for all CDs destroyed outside normal procedure.
2. A balance check must have been completed by the requesting contractor for all affected CDs less than 24hrs prior to the visit by the AW

Once satisfied that there are no discrepancies,

Add CDs to the denaturing kit according to the instructions on the kit. If no instructions are given CDs should be added in the following order:
1st – solid oral dose forms (e.g. tablets/capsules), and transdermal patches
2nd – small volume liquids (e.g. injection ampoules/vials)
3rd – large volume liquids (e.g. oral liquids, larger volume injection vials)

Processing products before adding to kit:

- Disposable gloves should be worn for the destruction process. These should be supplied by the contractor.
- The instructions on the individual destruction kit should be followed.
- The MEP advises the following: -

    - tablets and capsules: remove from all packaging and crush if stated on the kit. The use of a small amount of water whilst grinding or crushing may assist in minimising particles of dust being released into the air.

- Ampoules and vials: open, add liquid to the CD denaturing kit. For ampoules containing powder add water to dissolve the powder and pour the resultant mixture into the CD denaturing kit.
- transdermal patches: remove the backing, fold patch over onto itself (sticky to sticky side) and place in denaturing kit. Do not touch the sticky side of the patch.
- Aerosols: Expel into water and dispose of the resulting liquid in the denaturing kit. If this is not possible, expel into an absorbent material and dispose of this as pharmaceutical waste. A face mask should be worn and the area should be well ventilated.
- Liquids (other than the small volumes in ampoules/vials): add last and 'all at the same time' including any water used to rinse residue from liquid bottles.
- Actiq® lozenges are best destroyed by dissolving in a small amount of hot water. The resulting liquid should then be disposed of as for liquid dose formulations. The 'lolly-pop' sticks should then be placed in the pharmaceutical waste container.

NOTE

- A sharps bin is needed to dispose of any needles and syringes used during the destruction process. Emptied ampoules and vials are added to the denaturing kits

All patient identifiable packaging should be disposed of in confidential waste or the details obliterated before putting into general waste.

Once ALL products being destroyed have been added to the kit, water should be added, as necessary*, in accordance with the kit manufacturer's directions.

*Note. If larger volume CD liquids are being destroyed their volume should be considered and the volume of water required adjusted accordingly.

Mark the kit with the date and time used, and 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.
After 24 hours the kit, or time specified on the kit, should be added by staff to a standard medicines waste bin for disposal.

Once denatured write CDs out of the CD Register and/or Patient Returns Record Book. The entry must specify; the name, strength and form of the product, date, quantity destroyed, printed name & professional registration number of authorised person witnessing the destruction followed by their signature, printed name and signature of the person destroying the controlled drugs and the balance remaining. Initial the appropriate line on the CD destruction record (Appendix B).

The completed CD Destruction Record Sheet (Appendix B) should be copied, and the copy left at the premises. The original sheet should be returned to the Health Board's Locality medicines management team and kept for their records.

13. Monitoring Compliance / Audit *(Mandatory section header)*

- Annual internal audit of processes relating to management of requests by MM Team as set out in this SOP. Reporting to CDAO
- Annual documented self- assessment by all AWs against agreed checklist. Submitted to CDAO

14. Review and Change Control

June 2021 or sooner if the following apply:

- Following a serious untoward incident, if learning points identify the need for a change to the SOP
- Following a significant change in legislation or best practice guidance

15. References / Bibliography

Controlled drugs: safe use and management NICE guideline [NG46] Published date: 12 April 2016 https://www.nice.org.uk/guidance/ng46

Controlled Drugs (Supervision of management and use) Regulations https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf

Medicines and Ethics in Practice (MEP) online https://www.rpharms.com/publications/the-mep

Appendix A

DECLARATION

All authorised witnesses must read the Destruction of Controlled Drugs by Authorised Witnesses Standard Operating Procedure and sign the declaration below.

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

Name: …….

Designation: ……...

Registration No……

Date of enhanced DBS check (if not covered by Professional Code of Ethics)

……

Details of attendance at authorised witness training

Location (Health Board) ……..……

Date…….

Signature……. Date……

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Controlled Drug Destruction

Authorised Witness Appointment Request Form (Community Pharmacy) & Destruction Record

If you require an Authorised Witness to attend your pharmacy please complete this form and return it to:
Email: Powys.cdao@wales.nhs.uk
Post: Chief Pharmacist/Controlled Drugs Accountable Officer, Powys Teaching Health Board, Hafren Ward, Bronllys Hospital, Brecon, Powys, LD3 0LU
Fax: 01874 712651

You will be contacted within 5 working days of receipt of the request to arrange an appointment

Pharmacy Name		**Contact Number**	
Address		**Contact Name**	

☐ *I confirm that the Controlled Drugs listed overleaf (and on additional sheets if necessary) require destruction in the presence of an Authorised Witness and that sufficient CD denaturing kits are available to carry out the process.*

☐ *I confirm that the premises requiring a witness to CD destruction has a valid T28 exemption in place*

Signature of Authorised Person ……. Role……..Date ……

FOR OFFICE USE ONLY	**Completed by:**		
Completed Form Received on	**Visit Date Agreed on**	**CD destruction date**	**Comments**

Pharmacy Use	***THB Use Only***

Name of CD	Form	Strength	Quantity	Batch No.	Expiry Date	*CD Register Balance check*	*Qty Destroyed*	*Recorded in CD Register*

For Powys THB use only

Authorised Witness (name, designation and signature)	**Second Witness (name, designation and signature)**
Date of Destruction:	
Comments *(please continue on a separate sheet in necessary)*	

Controlled Drug Destruction

Authorised Witness Appointment Request Form (General Practice) & Destruction Record

If you require an Authorised Witness to attend your practice please complete this form and return it to:
Email: Powys.cdao@wales.nhs.uk
Post: Chief Pharmacist/Controlled Drugs Accountable Officer, Powys Teaching Health Board, Hafren Ward, Bronllys Hospital, Brecon, Powys, LD3 0LU
Fax: 01874 712651

You will be contacted within 5 working days of receipt of the request to arrange an appointment

Practice Name		**Contact Number**	
Address		**Contact Name**	

☐ *I confirm that the Controlled Drugs listed overleaf (and on additional sheets if necessary) require destruction in the presence of an Authorised Witness and that sufficient CD denaturing kits are available to carry out the process.*

☐ *I confirm that the premises requiring a witness to CD destruction has a valid T28 exemption in place*

Signature of Authorised Person ……Role……Date……

FOR OFFICE USE ONLY	**Completed by:**		
Completed Form Received on	**Visit Date Agreed on**	**CD destruction date**	**Comments**

Practice Use						THB Use Only		
Name of CD	**Form**	**Strength**	**Quantity**	**Batch No.**	**Expiry Date**	***CD Register Balance check***	***Qty Destroyed***	***Recorded in CD Register***

For Powys THB use only

Authorised Witness (name, designation and signature)	**Second Witness (name, designation and signature)**
Date of Destruction:	
Comments *(please continue on a separate sheet in necessary)*	

Controlled Drug Destruction

Authorised Witness Appointment Request Form (Community Hospital) & Destruction Record

If you require an Authorised Witness to attend your ward please complete this form and return it to:
Email: Powys.cdao@wales.nhs.uk
Post: Chief Pharmacist/Controlled Drugs Accountable Officer, Powys Teaching Health Board, Hafren Ward, Bronllys Hospital, Brecon, Powys, LD3 0LU
Fax: 01874 712651

You will be contacted within 5 working days of receipt of the request to arrange an appointment

Ward		**Contact Number**	
Hospital Address		**Contact Name**	

☐ *I confirm that the Controlled Drugs listed overleaf (and on additional sheets if necessary) require destruction in the presence of an Authorised Witness.*

☐ *I confirm that the premises requiring a witness to CD destruction has a valid T28 exemption in place*

Signature of Authorised Person ……..……..……..…… Role……..……..……..…..Date ……..……..……

FOR OFFICE USE ONLY	**Completed by:**		
Completed Form Received on	**Visit Date Agreed on**	**CD destruction date**	**Comments**

Hospital Use						LHB Use Only		
Name of CD	**Form**	**Strength**	**Quantity**	**Batch No.**	**Expiry Date**	***CD Register Balance check***	***Qty Destroyed***	***Recorded in CD Register***

For Powys LHB use only

Authorised Witness (name, designation and signature)	**Second Witness (name, designation and signature)**
Date of Destruction:	
Comments *(please continue on a separate sheet in necessary)*	

Appendix C

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Powys Teaching Health Board

Tîm Rheoli Meddiginiaethau
Bwrdd Iechyd Addysgu Powys
Ward Harfren, Ysbyty Bronllys
Bronllys, Aberhonddu, Powys
LD3 0LU
Ffôn: 01874 712 641
Ffacs: 01874 712 651

Medicines Management Team
Powys Teaching Health Board
Harfen Ward, Bronllys Hospital
Bronllys, Brecon, Powys
LD3 0LU
Phone: 01874 712 641
Fax: 01874 712 651

Individuals Authorised to Witness the Destruction of Controlled Drugs

Where controlled drugs (CDs) are destroyed, it is important that the act is witnessed as required under regulation 27 of the Misuse of Drugs Regulations 2001.

It is the responsibility of Controlled Drugs Accountable Officers (CDAOs) to ensure that there are sufficient fully trained witnesses in place to avoid the build-up of expired or unwanted stocks of controlled drugs.

The following members of Powys Teaching Health Board's Medicines Management Team are authorised by the CDAO to witness the destruction of CDs at appropriate premises across Powys. This includes but is not limited to controlled drugs held on PTHB sites, by general practices and by community pharmacies :-

- List members of team who are authorise to witness destruction here

All nominated individuals are either subject to a professional code of ethics **and/or** have been subject to an enhanced annual DBS check. All have undertaken appropriate training and are accountable for this activity directly to PTHB's CDAO.

Locations where destruction of CDs will take place.

a) Community hospitals and community clinics.
b) GP practices in the area covered by Powys Teaching Health Board
c) Community pharmacies in the area covered by Powys Teaching Health Board

The Accountable Officer will monitor the destruction of controlled drugs closely. If necessary, additional individuals will be authorised to witnesses the destruction of controlled drugs to ensure that expired or unwanted controlled drugs are destroyed promptly and are not allowed to build up.

Signed **Date**