Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business

to Facilitate Compliance with Regulations 4(5) and 6(3) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

Pharmaceutical Society of Ireland

Version 3 October 2017

Updates made following the enactment of the Misuse of Drugs Regulations 2017¹ (which replaced the Misuse of Drugs Regulations 1988 (as amended)² are highlighted in grey).

Contents	
1. Introduction	2
2. Legislative Basis	2
3. Guidance	3
3.1 Disposal of Medicinal Products	3
3.1.1 General Guidance	3
3.1.2 Waste Management Companies and Waste Documentation	4
3.1.3 Storage of Waste Medicinal Products	5
3.1.4 Disposal of Waste Medicinal Products	5
3.1.5 Medicinal Product Waste Containers	5
3.1.6 Patient Counselling	6
3.1.7 Patient-returned Medicinal Products	6
3.2 Disposal and Destruction of Controlled Drugs	6
3.2.1 Storage of Waste Controlled Drugs	6
3.2.2 Witnessed Destruction of CD2 Medicinal Products	7
3.2.3 Destruction of CD3 and CD4 Medicinal Products	7
3.2.4 Patient-Returned Controlled Drugs	7
3.2.5 Destruction Criteria	8
3.2.6 Disposal of Destroyed Controlled Drugs	8
3.3 Policies and Procedures	8
3.4 Particular Care Settings	9
4. Legislative References	9
5. Self-assessment Checklist	10
Appendix 1	12

¹ Please note: where the Misuse of Drugs Regulations are cited in other legislation please refer to Schedule 9 'Provisions of revoked Misuse of Drugs Regulations 1988 and corresponding provisions in these Regulations' of the Misuse of Drugs Regulations 2017.

² Misuse of Drugs (Safe Custody) Regulations 1982, as amended, remain applicable.

1. Introduction

The purpose of these guidelines is to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the disposal of medicinal products, including veterinary medicinal products, within retail pharmacy businesses (i.e. pharmacies). Compliance with the regulations and these guidelines will ensure that the disposal of medicinal products, within a pharmacy, is carried out in a manner which will not result in any danger to public health or any risk to the environment.

Every pharmacy should operate a comprehensive, auditable system for the disposal of waste medicinal products which assures the safety of patients and the public.

Waste medicinal products are medicinal products, including veterinary medicinal products, which are not fit for sale or supply, i.e. patient-returned, expired or otherwise non-conforming medicinal products. Non-conforming medicinal products are medicinal products unfit for sale or supply, for example, a medicinal product which is damaged or has been stored outside the terms of its Marketing Authorisation.

2. Legislative Basis

The operation of a retail pharmacy business is governed by Section 26(1) of the Pharmacy Act 2007, which requires every retail pharmacy business to be registered, and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which have been made by the Minister for Health and Children under Section 18 of the Pharmacy Act 2007, for the purposes of the health, safety and convenience of the public. Retail pharmacy business owners, superintendent pharmacists and supervising pharmacists are all required to conduct the retail pharmacy business in compliance with these provisions.

These guidelines have been prepared with a view to publication in accordance with Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) which provides that the PSI Council may publish detailed guidelines for the purpose of facilitating compliance with these Regulations. In that context, these guidelines are intended to facilitate better compliance with regulations 4(5) and 6(3), insofar as those regulations relate to the disposal of medicinal products in pharmacies.

Disposal of waste medicinal products must also occur in a manner compliant with waste management legislation, primarily the Waste Management Act 1996 (as amended). Other relevant legislation includes, for example, the Waste Management (Collection Permit) Regulations 2007 (S.I. No. 820 of 2007) and the Waste Management (Shipments of Waste) Regulations 2007 (S.I. No. 419 of 2007). When disposing of hazardous waste, pharmacists should be cognisant of any additional legislative requirements, e.g. those set out in the European Communities (Shipments of Hazardous Waste exclusively within Ireland) Regulations 2011 (S.I. No. 324/2011).

Additional requirements may apply in particular circumstances; for example, the Carriage of Dangerous Goods by Road Regulations (S.I. No. 288/289 of 2007), which implement European ADR³ requirements, apply to certain hazardous waste, e.g. cytotoxic medicinal products. The competent authority in Ireland for the transport of dangerous goods by road is the Health and Safety Authority (HSA).

3. Guidance

3.1 Disposal of Medicinal Products

Regulation 4(5) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) concerns the requirements for the safe disposal of medicinal products.

Regulation 4(5):

4.(5) The pharmacy owner shall ensure that any disposal of medicinal products, including veterinary medicinal products, that may be required to be carried out in the course of conducting a retail pharmacy business, is carried out in a manner which will not result in any danger to public health or risk to the environment.

Regulation 6(3) concerns the requirements for the segregation and disposal of previously dispensed or supplied medicinal products.

Regulation 6(3):

6.(3) Notwithstanding paragraphs (1) and (2), a person carrying on a retail pharmacy business may accept the return of a medicinal product, including a veterinary medicinal product, that had previously been dispensed or supplied, and such product shall be kept in a secure manner that is segregated from other medicinal products, including other such veterinary medicinal products, and shall be disposed of in a manner otherwise than for the purpose of use as a medicinal product.

3.1.1 General Guidance

A person carrying on a retail pharmacy business must have appropriate arrangements in place for the storage and disposal of waste medicinal products.

Pharmacy owners and pharmacists, as the generators and holders of waste, must ensure that all waste medicinal products are appropriately stored, transported and disposed of.

The disposal of waste medicinal products must be carried out in a manner which:

- · protects public health and safety,
- protects the health and safety of staff and patients, and
- causes no risk to the environment.

Any scheduled poisons or other chemicals held at the pharmacy should also be disposed of in a manner that will not result in any danger to public health or risk to the environment.

Pharmacists should ensure they are aware of all their legal obligations, particularly those set out in the legislation section of these guidelines. Lists of waste management legislation are available via the Department of the Environment, Community and Local Government Website (www.environ.ie), via the Enviromental Protection Agency (EPA) website (www.epa.ie), or in the HSE Waste Management Awareness Handbook 2011 (these lists are neither exclusive nor exhaustive). Further information on pharmacists' and pharmacy owners' legislative obligations are also available from sources such as, the Dublin City Council National TFS Office, the EPA, the HSA or your waste management company, as appropriate.

3.1.2 Waste Management Companies and Waste Documentation

European Communities (Shipments of Hazardous Waste exclusively within Ireland) Regulations 2011 (S.I. No. 324/2011) apply to the collection, transport and transfer of hazardous waste exclusively within Ireland and set out the duties and responsibilities of producers, notifiers, carriers, collectors, holders and consignees in such matters. Dublin City Council is designated as the National Competent Authority in Ireland for the export, import and transit of waste shipments under this legislation. The National TFS Office (NFTSO) at Dublin City Council has been established to implement and enforce the Regulations. Pharmacy owners and superintendent pharmacists should ensure that their waste management company is authorised to accept waste medicinal products and the waste is being taken to an appropriately authorised facility for storage or processing. A copy of the facility's authorisation permit or licence should be obtained by, and retained in, the pharmacy. **Current Waste Facility Permits and Certificates** of Registration issued by Dublin City Council can be viewed at: www.dublincity.ie.

Waste management companies must hold valid Waste Collection Permits issued by the National Waste Collection Permit Office (www.nwcpo.ie). These permits detail the types of waste the company is permitted to collect and carry (European Waste Catalogue Codes should be stated on the permit). A copy of the permit should be obtained by, and retained in, the pharmacy.

Movement of hazardous waste, including hazardous waste medicinal products, within the State must be accompanied by a Waste Transfer Form (WTF). This is a tracking document which must be used whenever hazardous waste is shipped or transferred within the State to ensure that the consignment is delivered to an authorised facility. Details of each consignment of waste, including the relevant forms, should be retained in the pharmacy.

Substances classified as hazardous for transport must be classified, packaged, labelled and documented in accordance with ADR requirements. Waste management companies have a Dangerous Goods Safety Advisor who should be consulted on all such matters.

Waste management companies transferring waste outside the State must comply with the requirements of the Waste Management (Shipments of Waste) Regulations 2007 (S.I. No. 419 of 2007) and related legislation. Subsequent to a pharmacy's waste being exported for disposal, a copy of documentation, which indicates that the waste has been disposed of and destroyed, should be obtained by the pharmacy from their waste management company.

Detailed records for the disposal of waste medicinal products should be obtained by, and retained in, every pharmacy. These records should include a copy of the waste management company's waste collection permit, the waste facility's authorisation permit or licence and details of each consignment of waste.

Further information on these requirements is available from sources such as Dublin City Council, the EPA, the HSA or your pharmacy's contracted waste management company, as appropriate.

3.1.3 Storage of Waste Medicinal Products

Waste medicinal products should be processed immediately, into specialised waste bins, following their removal from pharmacy stock or return from patients. Waste bins should be stored securely, in an area of the pharmacy designated for their storage. This storage area should be under the control of the pharmacist, inaccessible to members of the public and of sufficient capacity to allow for the safe storage of all waste medicinal products. It is recommended that a dedicated storage area is included in the premises, ideally at the fit out stage.

If waste medicinal products cannot be processed immediately they should be segregated from pharmacy stock, clearly labelled 'Medicines for Destruction' and stored under the control of the pharmacist in a specifically designated area of the pharmacy, pending timely processing for disposal. Such waste should never be allowed to accumulate in the pharmacy. The designated storage area(s) for waste bins and waste medicinal products awaiting processing should not be in the dispensing/working area of the pharmacy, i.e. where stock is stored or dispensed. This minimises the risk of waste medicinal products inadvertently re-entering the supply chain.

3.1.4 Disposal of Waste Medicinal Products

Waste medicinal products should be assessed prior to their disposal, as particular disposal requirements apply to certain medicinal products, for example, controlled drugs, cytotoxic and cytostatic medicinal products, and liquid medicinal products. Clarification on how to safely dispose of such waste should be obtained from the pharmacy's waste management company.

Waste medicinal products must be disposed of in specialised waste bins. Particular precautions should be taken to separate hazardous waste, e.g. cytotoxic or cytostatic medicinal products, and dispose of such waste in an appropriate hazardous waste bin. Sharp

waste, e.g. needles or glass, should be disposed of in specialised sharps bins. Waste medicinal products should never be disposed of in regular waste and should never enter the mains water drainage system.

Normally when disposing of liquid medicinal products they should remain within an intact container prior to placing them in the waste disposal bin. Waste bins containing liquids should have sufficient absorbent material in the bin to absorb the bin's entire liquid content.

Appropriate safety precautions, which minimise the risk to the health and safety of pharmacy staff, should be taken when handling waste medicinal products. Extra precautions should be taken by staff in highrisk groups, e.g. pregnant women or women of childbearing age, as they may be at increased risk if they come into contact with particular substances.

3.1.5 Medicinal Product Waste Containers

Medicinal product waste bins are usually yellow with a sealable lid. Different colour lids are used to identify different types of waste. Purple lids are normally used for medicinal product waste bins; this indicates that the contents are healthcare risk waste intended for incineration⁴.

Medicinal product waste containers should be United Nations (UN) approved and this should be marked on the waste bin. If appropriate, the bin should carry a hazard label and a further label containing specific information about the contents. The information label should, when appropriate, contain a UN number which indicates the type of waste in the container. Most medicinal product waste is not subject to ADR requirements but certain medicines may be classified as hazardous for transport, e.g. cytotoxic and cytostatic medicinal products. These waste medicinal products and hazardous clinical waste, e.g. used needles, should be separated appropriately and disposed of in correctly labelled UN approved containers. The only waste which should be placed in these containers is the specific type of waste for which they are intended.

⁴ Department of Health and Children and Health Service Executive. Healthcare Risk Waste Management. Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste. 4th Edition Nov 2010.

Medicinal product waste bins should not be overfilled; they should be securely sealed when filled to the manufacturer's fill line or, if no fill line is present, when three-quarters full. When full and sealed, the bins should be removed from the pharmacy promptly by an appropriately authorised waste management company for incineration.

3.1.6 Patient Counselling

Pharmacists should ensure patients and/or their carers have sufficient and appropriate information on the safe disposal of medicinal products, e.g. in the event of a course of treatment not being completed. Patients should be facilitated and encouraged to return unwanted or expired medicinal products to the pharmacy for disposal. Pharmacists should inform patients that it is not appropriate to dispose of waste medicinal products in their household waste or through the mains water drainage system.

3.1.7 Patient-Returned Medicinal Products

Medicinal products previously dispensed or supplied must never re-enter the supply chain. A pharmacy is not permitted to re-use a medicinal product which they or another healthcare provider previously dispensed or supplied, e.g. medication returned from a patient's home or from a residential care home. Such products should be treated in the same manner as other waste medicinal products. This means they should be processed immediately or, if this is not possible, stored in a specifically designated area of the pharmacy under the control of the pharmacist, segregated from pharmacy stock and clearly labelled 'Medicines for Destruction', pending timely processing for disposal. They should never be allowed to accumulate in the pharmacy.

Appropriate safety precautions (as outlined in section 3.1.4), which minimise the risk to the health and safety of pharmacy staff, should also be taken when handling patient-returned medicinal products. The risk of sharps in returned medicinal products should also be considered when preparing safety procedures. Returned medicinal products which contain confidential patient information, e.g. patient-specific labels, should be treated in a manner which maintains patient confidentiality.

3.2 Disposal and Destruction of Controlled Drugs

There are specific requirements for the destruction and disposal of CD2, CD3 and CD4 controlled drugs, i.e. medicinal products specified in Schedule 2, 3 and 4 of the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017). Requirements, additional to those detailed in section 3.1, are outlined below.

3.2.1 Storage of Waste Controlled Drugs

Any waste medicinal products, which are expired or non-conforming controlled drugs⁵ (CDs) awaiting processing, should be segregated from CD stock and clearly labelled 'CDs for Destruction'. CD2 and CD3 medicinal products should be stored securely in a specifically designated part of the CD safe or cabinet, pending timely destruction and disposal. Waste CDs should never be allowed to accumulate.

⁵ Non-conforming controlled drugs: controlled drugs unfit for sale or supply, for example, a controlled drug which is damaged or has been stored outside the terms of its Marketing Authorisation.

3.2.2 Witnessed Destruction of CD2 Medicinal products

Waste CD2 medicinal products, which are expired or non-conforming, can only be destroyed in the presence of an authorised person, e.g. a member of An Garda Síochána or a PSI inspector. (A full list of authorised persons is set out in Appendix 1). The authorised person must witness and record that the CD has been destroyed. The destruction should be carried out in accordance with any directions given by the authorised person and should be recorded either in the designated section at the back of the Controlled Drugs Register provided by the PSI⁶, or in a designated record book kept specifically for this purpose, which is also retained on site. When recording the destruction of a CD2 medicinal product, a record of the name, strength and form of the medicinal product, the date of destruction, the quantity destroyed and the signature of the authorised person/witness is required. The record should also include a brief description of the destruction method used. If a member of An Garda Síochána is witnessing the destruction it is recommended that they also record their Garda number.

The destruction should be cross referenced to the page of the CD Register where it is recorded and the stock balance in the Controlled Drugs Register should be adjusted down to reflect the quantity destroyed.

3.2.3 Destruction of CD3 and CD4 Medicinal Products

Waste CD3 and CD4 medicinal products should be destroyed before disposal. Their destruction should be recorded in the Controlled Drugs Witnessed Destruction Record Book provided by the PSI⁶ or in a designated record book set aside for this purpose (separate to the record kept of expired/non-conforming CD2s which require witnessed destruction by an authorised person, as detailed above). This book should be retained in the pharmacy. This record should, at a minimum include the name, strength and

form of the medicinal product, the date of destruction, the quantity destroyed and the signature of the witness. The record should also include a brief description of the destruction method used. The destruction of CD3 and CD4 medicinal products should be witnessed by a second pharmacist or another responsible member of the pharmacy staff.

3.2.4 Patient-Returned Controlled Drugs

Any CD2, CD3 or CD4 medicinal products that have been returned to the pharmacy, e.g. patient returns, must not be reused and must be destroyed. They should be destroyed promptly. While the return of CD2 medicinal products should not be reflected in the active balance in the CD register, their return and destruction should be recorded in, the **Controlled Drugs Witnessed Destruction** Record Book, or in a designated record book set aside for this purpose (separate to the record kept of expired/non-conforming CD2s which require witnessed destruction by an authorised person, as detailed above). This book should be retained in the pharmacy. The return and destruction of CD3 and CD4 medicinal products should also be recorded in this manner.

This record should, at a minimum, include the name, strength and form of the medicinal product, the date of destruction, the quantity destroyed and the signature of the witness. The record should also include a brief description of the destruction method used. The destruction of patient-returned CD2, CD3 and CD4 medicinal products should be witnessed by a second pharmacist or another responsible member of the pharmacy staff.

If a pharmacist is unable to destroy such CDs on receipt, they should be clearly labelled as 'Patient-Returned CDs for Destruction'. To avoid the potential for re- use they should be stored securely in a specifically designated area of the CD safe or cabinet, segregated from CD stock, pending timely destruction and disposal. Patient—returned CDs should never be allowed to accumulate.

⁶ A Controlled Drugs Register and Controlled Drugs Witnessed Destruction Record Book can be obtained by emailing the request to info@psi.ie

3.2.5 Destruction Criteria

When destroying a CD medicinal product there are two main criteria which must be fulfilled to ensure that the final product is no longer considered to be a controlled drug:

- the dosage unit must be broken down, rendering the CD unusable as a medicinal product, and
- the active ingredient must be irretrievable from the final mixture.

There are many ways to satisfy the destruction criteria. To render a CD unusable as a medicinal product, pharmacists can:

- · grind up tablets with a mortar and pestle,
- dissolve or cut capsules and, if necessary, grind up the contents,
- cut patches or remove the backing from patches and fold the patch over on itself,
- · open and empty ampoules, or
- · mix liquids with solid matter.

Empty ampoules or glass bottles should be placed in a sharps bin.

Having broken down the dosage unit, the resulting material should be mixed with a product which will render the drug substance unrecoverable from the final mixture. A CD denaturing kit can be used for this purpose. The manufacturer's instructions should be followed when using CD denaturing kits.

If an alternative method of destruction is used, the pharmacist should be able to adequately demonstrate, to the authorised person, that the medicinal product has been destroyed.

Any method of destruction employed should safeguard the environment and the health and safety of pharmacy staff and members of the public. Appropriate safety precautions should be taken when destroying CD medicinal products, including the wearing of appropriate personal protective equipment.

3.2.6 Disposal of Destroyed Controlled Drugs

The appropriate destruction of CDs results in a 'destroyed material', which is not classified as a CD. This material should be disposed of into a medicinal product waste bin. Such waste should never be disposed of in regular waste and should never enter the mains water drainage system. The destruction of CDs negates the requirement for an export licence to allow removal of the material from the jurisdiction for incineration; therefore, medicinal product waste management companies should accept such material for disposal by incineration.

3.3 Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of the disposal of medicinal products outlined in these guidelines. There should be procedures outlining the processes involved in the segregation and disposal of patient-returned medicinal products, patient-returned controlled drug medicinal products, expired or nonconforming medicinal products and expired or non-conforming controlled drug medicinal products.

Each procedure should state the persons involved in the process and be signed by such persons. The staff involved in a particular procedure should be trained in the relevant procedure and records of such training maintained. It is recommended that a pharmacist carry out all matters in relation to the destruction and disposal of controlled drug medicinal products. If other members of staff are involved, the destruction and disposal of such products should only be carried out under the supervision of a pharmacist, the staff should be appropriately trained and records of such training should be maintained.

All policies and procedures should state their implementation date and the review date. The superintendent and supervising pharmacists should ensure they are reviewed regularly, e.g. when any element of the process changes, and at a minimum annually. When a review takes place, the review should be documented, i.e. dated and signed by the appropriate person, and the policy or procedure should be updated if necessary. The relevant staff members should be made aware of any amendments, appropriately trained, and the updated policies and procedures should be signed by such persons.

3.4 Particular Care Settings

All retail pharmacy businesses must comply with these guidelines. However, in particular care settings, e.g. where a retail pharmacy business is located within a hospital, it may be appropriate to put alternative policies and procedures in place in respect of specific aspects of the guidelines. Such policies and procedures should take account of all legal and professional responsibilities. It may be necessary, for certain aspects of practice, to work with other healthcare professionals to put interdisciplinary policies and procedures for disposal of medicinal products in place.

Where, in particular care settings, such alternative policies and procedures are in place, the PSI expects the pharmacy owner, superintendent pharmacist, supervising pharmacist and any relevant registered pharmacist to ensure the disposal of medicinal products never causes any risk to public health or any environmental damage. Any deviation from the guidelines and the justification for the deviation should be recorded.

4. Legislative References

- · Pharmacy Act 2007.
- Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
- Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017).
- Waste Management Act 1996 (as amended).
- Waste Management (Collection Permit) Regulations 2007 (S.I. No. 820 of 2007).
- Waste Management (Shipments of Waste)
 Regulations 2007 (S.I. No. 419 of 2007).
- Carriage of Dangerous Goods by Road Regulations (S.I. No. 288 of 2007).
- European Communities (Shipments of Hazardous Waste exclusively within Ireland) Regulations 2011 (S.I. No. 324 of 2011).

Relevant legislation can be accessed through the PSI website <u>www.psi.ie</u>, and is also available from www.irishstatutebook.ie.

Version Number	Date Issued
1	May 2011
2	January 2015
3	October 2017

5. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with these guidelines and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with these guidelines and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Are the pharmacy owner and pharmacists aware of, and do they have access to, relevant waste management legislation?				
Are the waste management company and facility used by the pharmacy appropriately authorised, and are appropriately approved and labelled waste containers used?				
Are copies of the relevant documents retained in the pharmacy, including the waste management company's facility authorisation permit/license, waste collection permit, and disposal or destruction certificates?				
Are all waste medicinal products processed in a timely manner into specialised waste bins which are stored securely in a designated area of the pharmacy, segregated from other stock and under the control of the pharmacist?				
Are all waste medicinal products assessed, prior to disposal, for the presence of cytotoxic medicinal products, CDs, sharp waste, liquids, etc.?				
Are appropriate safety precautions taken when handling waste medicinal products?				
Are waste bins only filled to their fill line, securely sealed and removed promptly by the waste management company?				
Are patients and/or their carers, given information and advice on the safe disposal of medicinal products and encouraged to return unwanted and expired medicines to the pharmacy for disposal?				
Are all previously dispensed or supplied, i.e. patient-returned, medicinal products processed appropriately in a timely manner and never allowed to re-enter the supply chain?				

Ask Yourself	Yes	No	N/A	Required Action
Is the destruction of expired or non- conforming CD2 medicinal products witnessed by an authorised person and are the appropriate records maintained?				
Are all waste CD3 and CD4 medicinal products, and patient returns of CD2, CD3 and CD4 medicinal products, destroyed prior to disposal, with this destruction being appropriately recorded and witnessed within the pharmacy?				
Are all patient-returned CD2 and CD3 controlled drugs awaiting processing segregated from CD stock, clearly labelled and stored securely in a designated part of the CD safe?				
When destroying CDs, is the dosage unit broken and is the active ingredient rendered irretrievable from the final mixture using the destruction methods outlined in the guidelines, or alternative suitable methods?				
Does the pharmacist carry out all matters related to the destruction and disposal of CDs and if not are such matters only carried out by trained staff, under the pharmacist's supervision?				
Are suitable written policies and procedures in place?				
Is the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures?				

Appendix 1

The Minister has authorised the following persons to witness the destruction of controlled drugs:

- 1. Officers of the Minister for Health and Children, who are registered medical practitioners, registered dentists or registered pharmacists.
- 2. The following officers of the Health Service Executive:
 - (a) Directors of Community Care, or
 - (b) Chief Pharmacists, not being persons who themselves, at any time, have been responsible for the possession, dispensing or supply of any of the controlled drugs which are to be destroyed, or
 - (c) Community Care Pharmacists, or
 - (d) Community Services Pharmacists.
- 3. Chief administrators of hospitals or nursing homes, who are not personally responsible for the dispensing or supply of medicines in such hospitals or nursing homes.
- Persons employed or engaged as inspectors in connection with a scheme for the licensing of manufacturers or wholesalers of medicinal products under the Irish Medicines Board Act, 1995 (No. 29 of 1995) (as amended).
- 5. Persons appointed as inspectors by the Pharmaceutical Society of Ireland.
- 6. Persons appointed as inspectors by the Health Products Regulatory Authority.
- 7. Members of An Garda Síochána.
- 8. Officers of Customs and Excise.