PSI GUIDELINES ON THE SOURCING, STORAGE AND DISPOSAL OF MEDICINAL PRODUCTS WITHIN A RETAIL PHARMACY BUSINESS

May 2011

Guidelines on the Sourcing of Medicinal Products for Sale or Supply within a Retail Pharmacy Business

to facilitate compliance with Regulations 5(1)(g), 6, 8 and 11 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

1 INTRODUCTION

The purpose of these guidelines is to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the sourcing of medicinal products, including veterinary medicinal products, for sale or supply in conducting retail pharmacy businesses (pharmacies).

As pharmacies are the final link in the chain of supply of medicinal products from manufacturers to patients, all medicinal products sold and supplied through pharmacies must be sourced from appropriate manufacturers or wholesalers to assure the safety, quality and efficacy of such products. Compliance with the regulations and these guidelines is therefore essential if this objective is to be achieved and patient safety is to be maintained.

Every pharmacy should operate a comprehensive, auditable system for the sourcing and receipt of medicinal products.

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 by 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, the guidelines are intended to facilitate better compliance with regulations 5(1)(g), 6, 8 and 11 insofar as those regulations relate to the sourcing of medicinal products for sale or supply through pharmacies.

3 GUIDANCE

3.1 Sourcing of Medicinal Products

Regulation 6 sets out the requirements regarding the suppliers from whom pharmacies must obtain their medicinal products.

Regulation 6:

Sourcing of medicinal products

"6.(1) A person carrying on a retail pharmacy business shall obtain his or her supplies of medicinal products (including medicinal products on a general sales list) from persons—
(a) who are themselves the holders of a manufacturer's authorisation or a wholesaler's authorisation in respect of such products, or
(b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.

(2) A person carrying on a retail pharmacy business shall obtain his or her supplies of veterinary medicinal products from persons—
(a) who are themselves the holders of a manufacturer's licence granted under Regulation 20 of the animal remedies regulations, or an animal remedies wholesaler's licence granted under Regulation 30 of those Regulations, in respect of such products, or
(b) who are the holders of a licence granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.

[1](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 or as a veterinary medicinal product.

(4) The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient."

3.1.1 Sourcing from Authorised Manufacturers or Wholesalers

A person carrying on a retail pharmacy business must only source medicinal products, including veterinary medicinal products and non-prescription medicinal products, from an authorised manufacturer or an authorised wholesaler. This is necessary in order to ensure the security and integrity of the supply chain, to assure the quality, safety and efficacy of the medicinal product sourced and to maintain its traceability. Ensuring that medicinal products are only sourced from an authorised manufacturer or authorised wholesaler reduces the risk of counterfeit stock entering the medicinal product supply chain, thereby minimising any risk to patient health or safety.

A list of authorised manufacturers and authorised wholesalers from whom medicinal products are sourced should be maintained by each pharmacy. There should be a written procedure in place which outlines the steps to be taken to verify the authenticity of suppliers. It is important that these verification procedures are applied retrospectively for existing suppliers and are performed prior to sourcing medicinal products from new suppliers.

Lists of and information on all Irish authorised manufacturers and wholesalers are available on the Irish Medicines Board (IMB) website (www.imb.ie). In reviewing the authority of a supplier to supply medicinal products, it is important to take into consideration the particular category of medicinal product involved. In relation to wholesale suppliers, the information available on the IMB's website includes the particular categories of medicinal products that the wholesaler can supply.

[1] The segregation and disposal of patient-returned medicinal products is dealt with in greater detail in the PSI Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business and the PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business.

The authorisation status of wholesalers and manufacturers based in other EU/EEA countries can be checked with the competent authority in the relevant country, e.g. the Medicines and Healthcare products Regulatory Agency (MHRA) in UK, etc. Where there is difficulty in checking this information with the competent authority in the relevant EEA country, clarification should be sought from the IMB. It is the responsibility of the pharmacy owner, superintendent pharmacist and supervising pharmacist to ensure all medicinal products available for sale or supply in their pharmacy are authorised to be on the Irish market.

Documentation should be available in the pharmacy which permits clear identification of the supplier of each consignment of medicinal products received by the pharmacy and of the medicinal products therein, e.g. supplier invoices,[2] delivery dockets. Such documentation should be retained so as to ensure full traceability.

3.1.2 Medicinal Products which should not be Sold or Supplied

If a pharmacist or pharmacy owner suspect they are being offered a counterfeit, defective or inappropriately authorised medicinal product, the product should not be ordered and the supplier should be reported to the IMB.

If a pharmacist or pharmacy owner suspect they have been supplied with a counterfeit, defective or inappropriately authorised medicinal product, the product should be segregated from legitimate pharmacy stock; it should be stored in a designated quarantine area of the pharmacy and clearly labelled, and must not be used for sale or supply pending review and clarification with the IMB.

Medicinal products previously dispensed or supplied must never re-enter the supply chain. A pharmacy is not permitted to sell or supply a previously dispensed or supplied medicinal product, e.g. medication returned from a patient's home or from a residential care home. Such products should be stored in a designated area of the pharmacy, segregated from stock and labelled 'Medicines for Destruction', pending timely removal for disposal and destruction.[3]

Medicinal products which are medical samples should not be stocked in a pharmacy or dispensed or supplied through a pharmacy.

3.1.3 Inter-Pharmacy Exchange of Medicinal Products

Inter-pharmacy exchange of medicinal products is only permitted, by the regulations, when it is necessary to meet the immediate prescription needs of an individual patient. A detailed documented trail of any such exchanges should be maintained. This documentation should be signed off by a pharmacist in both the lending and receiving pharmacies and a copy should be retained in both pharmacies.

The documentation should include details of the medicinal product(s) involved, quantity supplied, batch number, expiry date, supplier (wholesaler or manufacturer), date of supply, the lending and recipient pharmacy and the reason for the exchange. When stock is obtained from another pharmacy, every effort should be made to assure the quality of the medicinal product(s) obtained. Only the amount of stock required to meet the immediate prescription needs of an individual patient, or the nearest size original pack, should be transferred.

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[2] Copies of invoices are appropriate where there is no other legislative requirement to keep the original invoice.
[3] PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business.

It is important to take extra care when dealing with controlled drugs, due to the nature of the medicinal products involved and the legal requirements for record keeping, etc. The receiving pharmacy should requisition the lending pharmacy and the lending pharmacy should provide a signed copy of the documentation outlined above to the receiving pharmacy. The requisition should be of the format set out in article 12 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended). Any CD2 medicinal products[4] entering or leaving the pharmacy in the manner outlined must be recorded in the controlled drugs register.

3.2 Medicinal Products Which May be Sold or Supplied from a Pharmacy

Regulations 8 and 11 set out the requirements regarding the medicinal products, including veterinary medicinal products, which may be sold or supplied from a pharmacy.

Regulation 8:

Medicinal products which may be sold or supplied

"8.(1) Subject to paragraph (2), a person carrying on a retail pharmacy business shall not sell or supply a medicinal product (including a medicinal product on a general sales list) unless—
(a) there has been granted in respect of such product a marketing authorisation which is for the time being in force, or
(b) the said product is not required to be the subject of such a marketing authorisation by virtue of Regulation 6(4) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

(2). Paragraph (1)(a) shall not apply until the 30 April 2011 in the case of—
(a) traditional herbal medicinal products, or
(b) homeopathic medicinal products to which Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) applies, which were on the market in the State on 20 July 2007."

Regulation 11

Veterinary medicinal products which may be sold or supplied

"11. A person carrying on a retail pharmacy business shall not sell or supply a veterinary medicinal product unless—

(a) the sale or supply of the said product is in accordance with the requirements of Regulation 28(1) of the animal remedies regulations,

(b) the sale or supply of the said product is in accordance with Regulation 28(4) (a) of the animal remedies regulations, except where Regulation 44 of the said regulations applies and has been complied with, and

(c) (i) there has been granted in respect of such product an animal remedies authorisation which is for the time being in force, or
(ii) the said product is not required to be the subject of an animal remedies authorisation by virtue of Regulation 3(2) of the animal remedies regulations, or

[4] Controlled Drugs (CDs) listed in Schedule 2 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended).

(iii) it has been determined by the Board that the said product is not required to be the subject of an animal remedies authorisation by virtue of Regulation 3(3) of the animal remedies regulations, or
(iv) there has been granted in respect of the product by the Minister for Agriculture, Fisheries and Food, a licence, pursuant to Regulation 18(11)(c) of the animal remedies regulations, which is for the time being in force, or
(v) it is a product within the meaning of Regulation 18(2)(c)(ii) or Regulation 18(9)(c)(ii) of the animal remedies regulations."

3.2.1 Marketing Authorisations

All medicinal products sold or supplied from a pharmacy must be appropriately authorised, unless exempted from such a requirement, to ensure the quality, safety and efficacy of the medicinal product. Pharmacies must obtain their medicinal products from authorised suppliers and each medicinal product should be checked on receipt for an authorisation number and appropriate packaging. The authorisation status of any medicinal product or of any wholesaler or manufacturer can be clarified with the IMB.

Under European and Irish legislation, all medicinal products must be authorised before being placed on the market. The types of marketing authorisations a medicinal product may hold are:[5]

(a) **An Irish Marketing Authorisation (previously called a Product Authorisation), denoted by a 'PA' number.** Medicinal products on the market in Ireland must be authorised by the IMB. A medicinal product which has a **Marketing Authorisation** granted by the IMB is authorised for sale in Ireland and is identified by the letters **'PA'** in front of the authorisation number, e.g. PAxxxx/xxx/xxx. A marketing authorisation for a veterinary medicinal product is identified by the letters **'VPA'** in front of the authorisation number.

(b) **A Community Marketing Authorisation denoted by an 'EU' number.** A medicinal product may have a **Community Marketing Authorisation** granted by the European Commission. A community marketing authorisation is identified by the letters **'EU'** in front of the authorisation number, e.g. EU/x/xx/xxx/xxx. A medicinal product with an 'EU' number is authorised for sale in all EU/EEA Member States and must be labelled with the approved product labelling and leaflets for the specific market. The approved language for Ireland is English. (Section (e) deals with the parallel distribution of these medicinal products).

(c) **A Parallel Product Authorisation denoted by a 'PPA' number.** A medicinal product may have a **Parallel Product Authorisation**. Parallel-importation is the importation of a medicinal product, authorised both in Ireland and another EU/EEA Member State, from that EU/ EEA Member State by an importer who is someone other than the importer appointed by the marketing authorisation holder for the medicinal product in the Irish market. The imported medicinal product may then be parallel-distributed in Ireland provided that the importer obtains an authorisation to market the product from the IMB. An authorisation for a parallel-distributed medicinal product is identified by the letters **'PPA'** in front of the authorisation number, e.g. PPAxxxx/xxx/xxx. An authorisation for a parallel-distributed veterinary medicinal product is identified by the letters **'PVPA'** in front of the authorisation number. Further information on the licensing of parallel-imported products is available on the IMB website.

[5] IMB Guide To Parallel Imports, Human Medicines 2010.

(d) **A Dual Pack Import Registration.** Medicinal products on the market in Ireland may have a **Dual Pack Import Registration**, granted by the IMB. This applies to the parallel-import of a medicinal product which is identical in all respects (including identical packaging, labels and leaflets) to the product on the Irish market, which is packaged in dual-market, identical packaging and which carries the marketing authorisation numbers of both countries, i.e. the source country and Ireland. Therefore, such products must have a 'PA' number on the packaging and may also have a 'PL' number if the medicinal product is authorised in the UK or a 'MA' number if the medicinal product is authorised in Malta, i.e. the Member States whose packaging and leaflets are also written in English. A wholesaler must be licensed by the IMB to distribute such products and the wholesaler should have a dual-pack registration **'DPR'** number on record for each medicinal product. All DPR medicinal products supplied by wholesalers are over-printed/over-labelled to denote the DPR number and the parallel importer for the product. A person conducting a pharmacy must take extra care when ordering dual pack registered medicinal products and must be satisfied that the products are appropriately authorised for sale in Ireland. If any doubt exists regarding the authorisation status of a medicinal product, its status should be checked with the IMB.

(e) **Parallel-distribution within the EU of medicinal products authorised by the European Commission.** Medicinal products authorised by the European Commission are granted a Community Marketing Authorisation denoted by an 'EU' number. These medicinal products may be parallel-distributed within the EU by a parallel distributer. The label of such products indicates the parallel distributor, the repackager (if repackaging has been carried out) and the manufacturer or the marketing authorisation holder. Importers wishing to parallel distribute these medicinal products in Ireland must notify the European Medicines Agency (EMA) and the IMB. A list of these notifications is posted on the website of the EMA (www.ema.europa.eu). Each notification includes information on the specific medicinal product which is being parallel distributed.

In summary, a pharmacist must not sell or supply a medicinal product unless it has been correctly authorised, or is an 'exempt' medicinal product. Correctly authorised medicinal products carry a 'PA', a 'VPA', an 'EU', a 'PPA' or a 'PVPA' number. Some medicinal products may also have additional numbers, e.g. DPR medicinal products. Medicinal products that have been parallel imported/distributed should have a 'PPA', 'PVPA' or 'EU' number and may have additional details included, depending on the route of authorisation.

3.2.2 Veterinary Medicinal Products

Requirements related to the veterinary medicinal products which may be sold or supplied from a pharmacy are set out in the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) (as amended) and further information on these requirements is available from the IMB.

3.2.3 Medicinal Products Exempted from the Requirement to be Authorised - 'Exempt' Medicinal Products

Notwithstanding the marketing authorisations outlined above, Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) includes an exemption for the supply of an unauthorised medicinal product in response to a bona fide unsolicited order from a practitioner. This exemption allows for the supply of an unauthorised product in response to a prescription from a practitioner, i.e. a registered doctor or a registered dentist, for an individual patient under his or her direct responsibility, in order to fulfil the special needs of the patient. Such products are defined as 'exempt' medicinal products. These products were previously known as 'unauthorised' or 'unlicensed' medicinal products. A medicinal product can only be defined as 'exempt' when it is supplied to the order of a registered practitioner for use by a patient under his or her direct care.[6]

Any 'exempt' medicinal product ordered must only be sourced from manufacturers and wholesalers authorised to supply such products. These suppliers must be authorised within the EEA. A list of manufacturers and wholesalers used should be maintained in the pharmacy.

Pharmacists should ensure they keep themselves informed of any requirements regarding the sourcing of 'exempt' medicinal products, e.g. IMB requirements.

To ensure full traceability, documentation should be available in the pharmacy which permits clear identification of the supplier of each 'exempt' medicinal product, e.g. supplier invoices,[7] delivery dockets. There are additional record-keeping requirements for the sale and supply of 'exempt' medicinal products set out in paragraph 7 of Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) (as amended).[8]

Pharmacists should only keep an appropriate level of stock of any 'exempt' medicinal product to meet normative patient needs, e.g. one month's supply plus broken bulk per patient prescribed the medicinal product.

When a pharmacist receives a prescription for an 'exempt' medicinal product, the pharmacist should ensure that the prescribing practitioner is aware of the unauthorised status of the product. The pharmacist should, where possible, inform the practitioner why the medicinal product is unauthorised, for example, if the medicinal product was recently withdrawn from the Irish market. A record, outlining that this information has been imparted, should be inserted in the patient's file.

Pharmacists should be aware, and should inform prescribers, that 'exempt' medicinal products should not be sourced and supplied if a suitable authorised alternative is available in Ireland.

In circumstances where, due to a medicinal product being in short supply, a pharmacist has dispensed an 'exempt' medicinal product in response to a prescription for an authorised product, the pharmacist should check, prior to each supply, if the authorised medicinal product has become available again. It is important to always inform and obtain the consent of the prescriber prior to supplying an unauthorised medicinal product on foot of his or her prescription.

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[6] IMB Guidance Note for the Notification System for Exempt Medicinal Products 2008.
[7] Copies of invoices are appropriate where there is no other legislative requirement to keep the original invoice.
[8] These requirements will be dealt with in more detail in future guidelines, for example, those on the record keeping.

Patients, or their carers, should be appropriately informed of the unauthorised or 'exempt' status of the medicinal product. They should be made aware of what this means and given the necessary reassurances, as appropriate. A record, outlining that this information has been imparted, should be inserted in the patient's file.

Pharmacists should also be cognisant of the availability of information on the medicinal product in English and, where possible, supply the patient with a patient information leaflet or other written information. Pharmacists should ensure patients are informed that any information provided is from another jurisdiction. If no patient information is available in English, the pharmacist should ensure that they can counsel the patient on the correct use of the product.

3.3 Withdrawal or Recall of Medicinal Products from the Market

Regulation 5(1)(g) sets out the requirements regarding the withdrawal or recall of medicinal products from the market.

Regulation 5(1)(g):

"5.(1) The pharmacy owner and the superintendent pharmacist shall, inter alia, ensure that—
(g) he or she co-operates with the directions of the Board, or other such authority, in respect of the withdrawal or recall from sale or supply of any medicinal product, or veterinary medicinal product, as may be given, or as may be implemented, by the Board"

A medicinal product withdrawal/recall procedure should be developed, documented and regularly reviewed to ensure that a pharmacy can respond quickly to a request from the marketing authorisation holder, in agreement with the competent authority (the IMB), to withdraw or recall any medicinal product from sale. The recall procedure should be regularly challenged to verify effectiveness and should consider all aspects of a potential recall or withdrawal situation including those that extend to patient level.

The procedure should be actioned as soon as possible following notification of a recall or withdrawal. Records detailing the recall should be maintained.

All stock of the medicinal product subject to a recall should be segregated from general stock, i.e. stored in a designated quarantine area of the pharmacy and clearly labelled. Such products should be processed in accordance with the directions of the marketing authorisation holder and/or the IMB.

On receipt of a recall letter, documentation related to the inter-pharmacy exchange of medicinal products should be reviewed and if any of the medicinal products transferred are the subject of the recall, the pharmacy supplied should be alerted and a copy of the recall letter provided.

3.4 Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of the sourcing of medicinal products outlined in these guidelines. These procedures should outline the processes involved in the verification of the authenticity of suppliers and medicinal products and the ordering, receipt, checking and entering into stock of medicinal products. Specific written procedures should be in place for the sourcing of 'exempt' medicinal products, the segregation and disposal of patient-returned medicinal products, the inter-pharmacy exchange of medicinal products and the withdrawal or recall of medicinal products from the market.

The procedure for the receipt of medicinal products should state the processes involved in the receipt and examination of new stock prior to its addition to existing pharmacy stock. These checks should include, but are not limited to, verification that each medicinal product is appropriately authorised, appropriately intact and within its shelf life. In addition to these checks, procedures for the receipt of medicines should ensure that medicinal products requiring particular storage conditions, e.g. products requiring refrigeration or controlled drugs, are given immediate priority by the staff that are authorised to accept their delivery.

All procedures 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.

All policies and procedures should state their implementation date and the review date. The superintendent and supervising pharmacists should ensure they are reviewed regularly, i.e. 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 must be made aware of any amendments, appropriately trained, and the updated policies and procedures should be signed by such persons.

3.5 Particular Care Settings

All retail pharmacy businesses must comply with these guidelines. 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 in place.

Where such alternative policies and procedures are in place, in particular care settings, the PSI expects the superintendent pharmacist, supervising pharmacist, any relevant registered pharmacist and the pharmacy owner to act in the best interest of patients and to ensure the integrity of the final link in the supply chain for a medicinal product, from the manufacturer to the patient, is maintained. Any deviation from the guidelines and the justification for such deviation should be recorded.

LEGISLATIVE REFERENCES

(a) Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
(b) Pharmacy Act 2007.
(c) Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).
(d) Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended).
(e) Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended).
(f) European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) (as amended).

Relevant legislation can be accessed through the PSI website www.thePSI.ie. and is also available from www.irishstatutebook.ie.

Self-Assessment Checklist to Enable Pharmacists and Pharmacy Owners Comply with the Guidelines on the Sourcing of Medicinal Products for Sale and Supply in Conducting a Retail Pharmacy Business

This Self-Assessment Checklist is a practical tool intended to aid compliance with these Guidelines and should be used as a reference check to allow self-audit of a pharmacy practice, and indicate areas that may be in need of further attention. The checklist captures the most critical issues from the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with the guidelines.

Policies and Procedures

There should be documented policies and procedures in place in every pharmacy which detail the operating systems of the pharmacy. It is important that these are documented so as to ensure that the processes to which they pertain are carried out in a consistent manner, to facilitate appropriate staff training, and to allow appropriate risk management and review.

The most critical elements of these guidelines, for which policies, procedures, records or other documentation should be in place, are detailed in the checklist below. The guidelines should be referred to for more comprehensive information on the requirements in each area. When drawing up policies and procedures, pharmacists should ask themselves the following questions:

Ask Yourself	Yes	No	N/A	Required Action
Are all relevant staff aware of, and trained in, the pharmacy's policies and are training records maintained?				
Do all pharmacy procedures state the staff involved in the process, are they signed by such staff, are such staff trained and are training records maintained?				
Does each policy and procedure state its implementation and review date and are these documents reviewed regularly, i.e. when any element of the process changes and, at a minimum, annually?				
Is the review of a policy or procedure documented, i.e. signed and dated, and the policy or procedure updated, if necessary, and are all relevant staff members made aware of any amendments, appropriately trained and records of the training maintained?				

Guidelines on the Sourcing of Medicinal Products for Sale or Supply in Conducting a Retail Pharmacy Business

Ask Yourself	Yes	No	N/A	Required Action
Are all medicinal products, including veterinary medicinal products and all non-prescription medicinal products, sourced from authorised manufacturers or wholesalers?				
Is there a list of all manufacturers and wholesalers, from whom medicinal products are sourced and whose authorisation has been verified, maintained in the pharmacy?				
Is documentation retained in the pharmacy which permits clear identification of each consignment of medicinal products received and of the medicinal products therein, e.g. suppliers' invoices?				
Are all staff involved in the sourcing and ordering of medicinal products aware of the types of marketing authorisations a medicinal product may have and are all medicinal products checked on receipt from suppliers?				
Does inter-pharmacy exchange of medicinal products only occur when necessary to meet the immediate prescription needs of an individual patient, and is a documented trail of all inter-pharmacy exchanges, with the appropriate details, maintained?				
Does the inter-pharmacy exchange of CD2 controlled drugs only occur on foot of an appropriately written requisition and are such exchanges always recorded in the CD register?				
Are there policies and procedures in place for the ordering, receipt, checking (examination of authorisation, packaging, expiry date, batch number etc.) and entering into stock of medicinal products?				
Do the pharmacy's receipt procedures deal specifically with the receipt, examination and immediate processing of refrigerated medicinal products and CDs (the relevant CDs must be placed in the CD safe and recorded in the CD register)?				
Are all pharmacy staff aware of the necessity to contact the Irish Medicines Board (IMB) if they suspect counterfeit, inappropriately authorised or defective medicinal products, and to quarantine such stock appropriately?				

Ask Yourself	Yes	No	N/A	Required Action
Is there a specific written procedure in place for sourcing 'exempt' medicinal products, is a list of appropriately authorised suppliers maintained and is documentation retained in the pharmacy which permits identification of these suppliers?				
Does the pharmacist always ensure the prescriber is aware that a medicinal product is unauthorised, inform the prescriber of the availability of any suitably authorised alternative and note this in the patient's file?				
Are patients always informed of the unauthorised or 'exempt' status of a medicinal product, made aware of what this means, provided with counselling, information and necessary reassurances, as appropriate and is this noted in the patient's file?				
Is there a withdrawal/recall procedure in place which ensures the pharmacy can respond quickly to the recall of any medicinal product, including to patient level, is it regularly challenged and are records of all recalls maintained in the pharmacy?				
Are all medicines subject to a recall appropriately quarantined and processed in accordance with the directions of the marketing authorisation holder and/or the IMB?				

Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business

to facilitate compliance with Regulations 4(1), 4(4), 5(1)(e), 5(1)(f), 6(3) and 7 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

1 INTRODUCTION

The purpose of these guidelines is to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the storage of medicinal products, including veterinary medicinal products, in retail pharmacy businesses (i.e. pharmacies).

As pharmacies are the final link in the chain of supply of medicinal products, from manufacturers to patients, it is essential that all medicinal products held in pharmacies remain of the same quality, safety and efficacy as when they were released by their manufacturers. To achieve this, all medicinal products must be stored in accordance within the terms of their Marketing Authorisation. Compliance with the regulations and these guidelines is therefore essential if this objective is to be achieved and patient safety is to be maintained.

Every pharmacy should operate a comprehensive, auditable system for the control and maintenance of an appropriate level of legitimate stock, held within appropriate storage conditions and facilities.

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 by 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, the guidelines are intended to facilitate better compliance with regulations 4(1)(a), 4(1)(b), 4(4), 5(1)(e), 5(1)(f), 6(3) and 7, insofar as those regulations relate to the storage of medicinal products in pharmacies.

It should be noted that wherever premises are referred to in the regulations and in these guidelines, they refer to fixed premises, which includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored.[1]

[1] Refer to the definition of premises in Regulation 3(1) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

3 GUIDANCE

3.1 Storage of Medicinal Products

Regulation 7 provides that the storage of medicinal products, within a pharmacy, must be in accordance with the requirements of their marketing authorisation or any other relevant standard that is applicable.

Regulation 7:

Appropriate storage of medicinal products

"7. A person carrying on a retail pharmacy business shall ensure that the quality of the medicinal products, including veterinary medicinal products, that are being handled by him or her, or that are otherwise under his or her control, is maintained in accordance with the requirements of any marketing authorisation, animal remedies authorisation, or other standard that is applicable to those products."

Regulation 6(3) states the storage requirements for medicinal products previously dispensed or supplied, which have been returned to the pharmacy.

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 or as a veterinary medicinal product."

Regulations 4(1)(a) and 4(1)(b) provides that the pharmacy maintains the staff, premises, equipment and procedures required for storing medicinal products.

Regulation 4(1):

Staff, premises, equipment and procedures

"4.(1)(a) The pharmacy owner shall provide and maintain such staff, premises, equipment and procedures for the storage, preparation, dispensing, compounding, sale and supply of medicinal products, including veterinary medicinal products, that he or she stores, prepares, dispenses, compounds, sells and supplies in his or her retail pharmacy business, as are necessary to avoid deterioration of the products and he or she shall not use for any such purposes premises other than those that constitute his or her retail pharmacy business and which have been specified in his or her application for registration under section 17 of the Act.

(b) The pharmacy owner shall ensure that, in the conduct of his or her retail pharmacy business and in particular in making provision for the staff, premises and other matters referred to in sub-paragraph (a) of this paragraph, he or she has regard for the health, safety and convenience of the public."

3.1.1 General Guidance

Only premises that are the subject of registration as part of the retail pharmacy business may be used for the storage of medicinal products. It follows that medicinal products may not be stored in connection with a retail pharmacy business unless the premises concerned are clearly covered by the registration required under Section 26(1) of the Pharmacy Act 2007.

To assure the quality, safety and efficacy of medicinal products stocked in a pharmacy, they must be stored in accordance with the requirements of their relevant marketing authorisations, or other relevant standards such as manufacturers' instructions.

The construction and layout of the pharmacy premises, the fixtures and fittings, for example, shelving, and equipment, for example, pharmaceutical grade refrigerators, must be appropriate and fit for the purpose of storing medicinal products as outlined in the regulations and these guidelines. The staff of the pharmacy must be appropriately trained and alert to the need for medicinal products to be stored appropriately. Adequate pharmacy staff should be available, so as to ensure that all the necessary storage requirements are being met on an on-going basis for all medicinal products stored in the pharmacy.

All medicinal products must be stored in a secure fashion under the control and supervision of the pharmacist.

Good pharmacy practice would be to store medicinal products separately from non-medicinal products. However, the storage of medical devices or health-related items with medicinal products may, in certain circumstances, be appropriate.

An appropriate quantity of each medicinal product should be stocked, consistent with local patient need, stock turnover, local prescribing habits and any national public health initiatives that may be in place.

3.1.2 Storage Areas

Adequate storage facilities must be available and all storage areas should be suitable for their purpose, structurally sound and free of damp and mould. Any storage facilities used for medicinal products should be well maintained and clean, i.e. free from litter, dust and pests and free from spillage or breakage. Surfaces should be impervious and non-shedding and walls and floors should be intact. All storage areas should be incorporated in cleaning and housekeeping schedules and cleaning records should be maintained.

Medicinal products should only be stored in areas designated for their storage. They should not be stored in close proximity to sources of heat or cold, e.g. unit heaters, artificial lights, in direct sunlight or close to windows. They should not be stored on floors, on stairs, in passageways, in toilets or at a height which creates a hazard for staff.

Storage of food and drink, other than medicinal foods for sale or supply, should be prohibited in areas used for the storage of medicinal products. Staff members' personal medication should be stored with personal belongings or in a designated area of the pharmacy, segregated from pharmacy stock.

3.1.3 Stock Management

All medicinal products stored in a pharmacy must be legitimately authorised for sale or supply and must have a batch number and expiry date.[2] Each medicinal product should, therefore, be checked on receipt to ensure it has an authorisation number, appropriate packaging, a batch number and an appropriate expiry date.

Any medicinal product received in packaging that is damaged or discoloured, should be segregated on receipt and returned promptly to the supplier. Consideration should also be given to returning any short-dated medicinal product received. It is important that the return is appropriately documented, through completion of the supplier's 'returns form' or other appropriate means.

Medicinal product stocks should be reviewed regularly and if a medicinal product is damaged, defective, or if contamination is suspected, it should be withdrawn from stock. If a product is thought to be defective this should be reported to the Irish Medicines Board (IMB).

Appropriate stock rotation and monitoring should be performed, based on a system of first expiry, first out, and it should not be assumed that the most recent deliveries will have a longer expiry date. The expiry dates of medicinal product stock should be regularly and systematically checked in accordance with the pharmacy's documented expiry date-checking procedure. Short-dated stock should be identified and appropriately marked. Pharmacists should pay particular attention to medicinal products which are close to their expiry date and must ensure that, prior to their expiry, such products are removed from stock and transferred to a specifically designated area for disposal. A medicinal product must not be dispensed if the duration of treatment extends beyond the expiry date of the medicinal product.

Patient returned, expired and non-conforming[3] medicinal products should be stored in a specifically designated area of the pharmacy, segregated from pharmacy stock and clearly labelled 'Medicines for Destruction', pending timely removal for disposal and destruction.[4]

3.1.4 Medicinal Product Packaging

During storage, medicinal products should be retained in the manufacturer's original packaging. In exceptional circumstances, if a medicinal product is removed from its original packaging it should be labelled with its name, strength, marketing authorisation number, batch number, expiry date, the name of the supplier (wholesaler or manufacturer), and packaged with a copy of the patient information leaflet, prior to returning it to storage. When medicinal products are removed from their original packaging the stability implications for the medicinal product must be considered.

If original packs of medicinal products are opened or split, they should be clearly marked in the manner outlined in the pharmacy procedure. Stock of the same medicinal product from different batches must not be stored together in the same container.

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[2] PSI Guidelines on the Sourcing of Medicinal Products for Sale or Supply in conducting a Retail Pharmacy Business.
[3] 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.
[4] PSI. Guidelines on the Sourcing of Medicinal Products for Sale or Supply in conducting a Retail Pharmacy Business.

Medicinal products should not be removed from the primary[5] protective packaging, at the time of dispensing, except in cases where repacking is required to assist patient compliance. Certain medicinal products must never be removed from the primary packaging, as their stability will be impacted. There should be a policy in place which identifies such medicinal products. There should also be a procedure in place for checking the stability of all medicinal products subject to repackaging. This procedure should include checking the medicinal product's Summary of Product Characteristics and/or verifying the medicinal product's stability with the marketing authorisation holder. Relevant stability data may also be available from various other sources. A pharmacist should satisfy him/herself of the validity of any stability data used. Documentation outlining the relevant stability information for each medicinal product should be retained in the pharmacy.

The stability of certain medicinal products, including some liquids or creams, may be altered once they have been opened. The pharmacy should have a procedure in place for checking the stability of such products. Such products need to be clearly labelled with the date of opening and a 'discard by' date.

3.1.5 Patient Counselling

The pharmacist must ensure that, on receipt of a medicinal product, the patient, or their carer, is given sufficient information and advice on its proper storage. The patient should be advised not to remove the medicinal product from the original/ dispensing container, informed of any specific storage requirements particular to the medicinal product and encouraged to read the storage section of the patient information leaflet, as appropriate.

3.1.6 Marketing Authorisation and Manufacturers' Directions

All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of their Marketing Authorisation. The storage conditions for a medicinal product are normally specified on the outer packaging of the product.

The following are examples of specific storage statements that may be specified on the packaging of a medicinal product.[6,7]

- Do not store above 25°C/Do not store above 30°C
- Store below 25°C/Store below 30°C
- Store in a refrigerator (2°C-8°C)
- Store in the outer carton
- No special storage requirements

Where there are no specified storage conditions, the medicinal product may be stored at ambient room temperature not exceeding 30ºC.

Appropriate environmental conditions must be maintained, at all times, in all areas of the pharmacy in which medicinal products are stored. These storage areas should also be subjected to on-going monitoring as described below.

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[5] The primary packaging is the material which first envelops the product and holds it, e.g. the foil packaging, blister packaging or container. The secondary packaging is the packaging which encloses the primary packaging, e.g. the cardboard packaging which contains the blister (primary) packaging.
[6] European Medicines Agency (Committee for Medicinal Products for Human Use). Guideline on declaration of storage conditions: A: In the product information of medicinal products, B: For active substances, November 2007.
[7] Irish Medicines Board. Guidance note on the wholesaling of medicinal products for human use in Ireland, October 2004.

The labelled storage requirements of medicinal products may, infrequently, prescribe particular humidity storage requirements. Where particular humidity storage requirements are prescribed, humidity monitoring should be incorporated as part of the monitoring of the storage area.

3.1.7 Temperature Monitoring

Environmental temperature must be monitored at appropriate locations throughout the premises. This ensures that appropriate temperatures are maintained in all parts of the premises in which medicinal products are stored. Particular attention, including the use of increased monitoring, should be paid to areas of marked temperature variation, such as areas near windows, heaters or lighting.

At a minimum, a max/min thermometer should be installed to facilitate temperature monitoring of the storage area(s). Such thermometers record the current temperature and the maximum and minimum temperatures reached since the previous measurement. The temperature recording equipment should be calibrated as recommended by the manufacturer or, at a minimum, annually and appropriate records maintained.

The environmental temperature (maximum and minimum) should be recorded, at a minimum, on a daily basis, at a specified time, by a designated member of staff and the results should be entered in a log which should be retained in the pharmacy. Temperature control should be adequate to ensure that all parts of the pharmacy, where medicinal products are stored, remain within the specified temperature range.

Temperature monitoring records should be reviewed and approved regularly by the supervising pharmacist to ensure compliance with the required conditions. Evidence of these reviews should be maintained and these records should be retained on the premises.

Pharmacies should have a documented temperature recording procedure which outlines the frequency of temperature monitoring and details the staff member responsible. The procedure should also outline the investigation to be performed and the action to be taken if the temperature falls outside of the required range; this action should include a documented assessment of the medicinal products affected.

3.2 Storage of Medicinal Products Requiring Refrigeration

Extra care and precaution should be taken with medicinal products that require refrigeration, i.e. storage between the range of 2-8°C. It is necessary to ensure that the narrow temperature range required for the storage of such products has been maintained and that appropriate records are in place to demonstrate this.

3.2.1 Pharmaceutical Refrigerators

In a pharmacy, standard domestic refrigerators are not suitable for storing medicinal products requiring 2-8°C storage, as they do not provide the required level of temperature control. Lack of temperature control occurs as a result of minimal air circulation. Domestic refrigerators typically operate within a range of between 0 and 10°C and opening and closing the refrigerator door can cause additional temperature fluctuations. There is also a risk that products could freeze, particularly if they come into contact with the chiller plate or coil at the back of the refrigerator.

Therefore, a purpose-built pharmaceutical refrigerator must be used for the storage of cold chain medicinal products. The air within this type of refrigerator is circulated by a fan, which provides a uniform temperature profile and a rapid temperature pull down after the door has been opened. These units are typically equipped with temperature monitoring capability which permits the operating temperature to be read without opening the refrigerator door. These refrigerators can also be locked and some have the option of either an audio or visual alarm system to alert staff in the event of temperature deviations outside the pre-established range.[8]

A pharmacy refrigerator should be verified as fit-for-purpose prior to use and critical aspects should be re-validated at regular intervals thereafter. Initial verification should include, but not be limited to, establishing operating ranges and alarm conditions, challenging alarms, verification of displayed temperature and mapping of internal temperature. Validation should establish procedures for routine maintenance and monitoring of the refrigerator including the action to be taken in the event of failure. Regarding routine maintenance, the refrigerator should be serviced at least annually. Records of verification and validation should be retained. If fitted with an audible or visual alarm or with an electronic alert system this should be routinely challenged to confirm correct operation. Test results should be documented and retained.

The refrigerator should be of adequate capacity to allow for organised, well-spaced storage of all medicinal products on the shelves of the unit. No medicinal products should be stored on the floor of the unit. Sufficient space should be maintained between the products and the internal surfaces. These measures will assist in maintaining adequate air circulation and consistent temperatures throughout.

The refrigerator should be cleaned regularly as part of a general cleaning rota and cleaning records should be maintained. Refrigerator cleaning procedures should be in line with the manufacturer's instructions. While the refrigerator is being cleaned due care should be taken to preserve cold storage conditions, to ensure the quality of the medicinal products is not adversely affected. All refrigerators used for storing medicinal products must remain free from frost at all times.

A refrigerator containing medicinal products must never be used to store food and drink, other than medicinal food or drink, in order to minimise the risk of contamination. Personal medication requiring refrigeration should not be stored in same refrigerator as medicinal product stock.

3.2.2. Temperature Monitoring

Refrigerators should not be sited in an environment where extremes of temperature may affect their performance. The maximum and minimum temperatures of the pharmacy refrigerator, i.e. the maximum and minimum internal temperatures reached since the previous measurement, should be recorded, at a minimum, on a daily basis, at a specified time, by a designated member of staff and the results should be entered in a log which should be retained in the pharmacy. Readings should be taken in accordance with the manufacturer's instructions. The temperature recording equipment should be calibrated as recommended by the manufacturer or, at a minimum, annually and appropriate records maintained. Temperature monitoring records should be reviewed and approved regularly by the supervising pharmacist to ensure compliance with the required conditions.

[8] Taylor, J. Refrigerated products: What pharmacists need to know. The Pharmaceutical Journal. 281; 2008.

There should be a written procedure in place outlining the frequency and staff member responsible for temperature monitoring. The procedure should outline the action to be taken if the temperature falls outside of the required range; this action should include a documented assessment of the medicinal products being stored in the refrigerator.

It is important to consider additionally equipping the unit with an independent temperature monitoring probe, particularly where the unit is being used to store high risk products, e.g. vaccines. Temperature monitoring probes should be placed between medicinal products in a location which has been assessed to be the 'worst case' and the temperature should be measured continuously. The location of the temperature monitoring probes should be recorded. Such monitoring equipment should be calibrated in accordance with the manufacturer's instructions or, at a minimum annually, and records of the calibration maintained.

3.2.3 Stock Management

When medicinal products requiring refrigeration are received from suppliers they should be checked immediately on receipt and placed in a refrigerator. The person responsible for receiving the delivery must also satisfy himself/herself that the medicinal products have been transported under appropriate conditions, i.e. there has been no direct contact between the medicinal products and gel or ice blocks and that the product is not warm. There should be a written procedure in place which deals specifically with the receipt of medicinal products requiring refrigeration and the action to be taken if there is any doubt regarding their stability.

The stock within the refrigerator should be subject to effective stock rotation based on a system of first expiry, first out, and it should not be assumed that the most recent deliveries will have a longer expiry period. Refrigerated products should be included in all date checking procedures.

Additional requirements for the storage of refrigerated 'High Tech' and 'Exempt' medicinal products are outlined in section 3.6.

3.3. Storage of Medicinal Products which are Controlled Drugs

Regulation 4(4) states the storage requirements under which Schedule 2 (CD2) and Schedule 3 (CD3) controlled drugs must be stored in a retail pharmacy business.

Regulation 4(4):

Staff, premises, equipment and procedures

"4.(4) The pharmacy owner shall provide and maintain a safe or cabinet that meets the requirements of Regulation 5 of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) (as amended by Regulation 26(2) of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988)) and shall ensure that the said safe or cabinet has a sufficient capacity to permit the orderly storage and safe keeping of all the relevant controlled drugs, including such veterinary medicinal products as are relevant controlled drugs, as required by the aforementioned Regulation 5."

3.3.1 Storage of Controlled Drugs in a Safe or Cabinet

Controlled Drugs (CDs) listed in either Schedule 2 or Schedule 3 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) must be stored in accordance with the terms of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) (as amended).

CD2 and CD3 controlled drugs must be kept in a locked safe or cabinet. The appropriate storage of controlled drugs facilitates pharmacists in fulfilling their obligation to protect the health and safety of the public.

The key to the safe, or the access code if the safe has an electronic key pad, should be kept in the custody of the pharmacist. Access to the safe should be controlled by the pharmacist and only the pharmacist or a designated member of their staff, operating under the pharmacist's supervision, should be permitted to access the safe. Keys to the CD safe must be stored securely overnight.

The requirements, in relation to safes and cabinets used for storing controlled drugs, are set out in the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) (as amended).

- These regulations state that a controlled drugs safe or cabinet must comply with the specifications set out in the Standard Specification (Burglar-Resistant Cabinets for the Storage of Controlled Drugs) 1985 (I.S. 267:1985). Enquiries have indicated that CD safes, with the inscription required under I.S. 267:1985, may not be currently manufactured. If this information is not marked on your CD safe or cabinet the unit may nevertheless be acceptable if, when examined, it does not depart from specifications which are necessary to render the unit fit for purpose and, thereafter, certification is issued by a member of an Garda Síochána, not below the rank of Superintendent.

- Article 6(2)(b) of these regulations state that a member of an Garda Síochána, not below the rank of Superintendent, may on receipt of an application, in writing, inspect or cause to be inspected, any safe or cabinet in which controlled drugs are kept. Thereafter, he or she may certify that the safe or cabinet meets the constructional and other specifications which are necessary to render the unit fit for purpose as outlined in the Schedule of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) and that the unit, therefore, provides an appropriate degree of security. The certificate issued is valid for two years and should be retained in the pharmacy.[9]

The controlled drugs safe or cabinet should be used solely for the storage of medicinal products. This restricts access to the safe and reduces the frequency with which the safe is opened and closed, therefore increasing the security of the storage of CD2 and CD3 medicinal products.

[9] Further information on controlled drugs safes and cabinets will be provided in the forthcoming 'Draft Guidelines on the Equipment Requirements of a Retail Pharmacy Business'.

3.3.2 Controlled Drug Stock Management

When a delivery is received by the pharmacy, the invoice or delivery note should be examined for the presence of CD2 and CD3 medicinal products; these should be removed immediately, entered into the CD register, if applicable, and placed in the safe or cabinet. Any discrepancies should be noted on the controlled drugs delivery docket which should be signed by the pharmacist and returned to the supplier. There should be a written procedure in place which deals with the receipt of CD2 and CD3 medicinal products.

The pharmacist should regularly review the running balances of the CD register for each CD2 medicinal product stocked, i.e. check that the balance in the CD register matches the quantity of each controlled drug stocked. Where an inconsistency exists the cause of the inconsistency should be investigated and, when identified, rectified. Where appropriate, a procedure to minimise future errors should be put in place.

The stock within the safe should be subject to effective stock rotation based on a system of first expiry, first out. CD2 and CD3 medicinal products should be included in all date checking procedures. The safe should be cleaned regularly as part of a general cleaning rota and cleaning records should be maintained.

3.4 Storage of Poisons

The requirements for the storage of schedule 1 poisons, for example, certain phosphorus compounds which can found in pesticides, are set out in regulation 9 of the Poisons Regulations 2008 (S.I. No. 511 of 2008) (reproduced below). These requirements do not apply to any human or veterinary medicinal products.

"9. A poison shall not be stored in any retail shop or premises used in connection therewith unless it is stored
(a) in a cupboard or drawer reserved solely for the storage of poisons, or
(b) on a shelf reserved solely for the storage of poisons and no food is kept directly underneath that shelf, or
(c) in a part of the shop, or premises used in connection therewith, which is partitioned off or otherwise separated from the remainder of the shop or premises
(i) to which customers are not permitted to have access, and
(ii) in which no food is kept."

Poisons must be stored separately from medicinal products and food in a specific section of the pharmacy premises. Poisons sold or supplied through a pharmacy must be sold or supplied by or under the personal supervision of a pharmacist and should, therefore, be stored in an area of the pharmacy under the control of the pharmacist. Any other chemicals stored in the pharmacy should be stored in a similar manner to scheduled poisons.

3.5 Storage of Veterinary Medicinal Products

The storage requirements for medicinal products outlined in sections 3.1, 3.2 and 3.3 also apply to veterinary medicinal products. In addition, the following storage requirements should be adhered to.

Veterinary medicinal products should be stored separately from human medicinal products in a specific section of the pharmacy premises. The parts of the premises used for the storage of veterinary medicinal products should be clearly identified as such.

Veterinary medicinal products requiring 2-8ºC storage should be kept in a separate animal medicines pharmaceutical grade refrigerator reserved solely for this purpose. Certain veterinary vaccines are live attenuated vaccines, and these should not be kept in close proximity to other veterinary medicinal products, human medicinal products or food.

Special care should be taken with veterinary medicines, feed additives or other materials which might have a strong or lingering odour. These products should be stored in a part of the premises isolated from other medicinal products and food.

3.6 Storage of 'High Tech' and 'Exempt' Medicinal Products

'Exempt' medicinal products, previously referred to as 'unauthorised' or 'unlicensed' medicinal products, should be stored separately from authorised medicinal products, in a patient-specific manner. Similarly, 'High Tech' medicinal products should be stored separately from other stock in a patient-specific manner. All relevant documentation, suppliers' invoices (or copies thereof), copies of prescriptions etc., should also be stored in a patient-specific manner, e.g. with the medicinal product or in a dedicated file. Where documentation is stored in a dedicated file the medicinal product should be marked in a way which allows it to be tracked back to the appropriate record. Subsequent to dispensing, the documentation should be retained in the pharmacy.

'High Tech' and 'exempt' medicinal products requiring refrigeration should be stored in a designated area of the refrigerator, in a patient-specific manner. The appropriate documentation should also be stored in a patient-specific manner, i.e. with the medicinal product or in a designated file. Where documentation is stored in a dedicated file the medicinal product should be marked in a way which allows it to be tracked back to the appropriate record.

3.7 Storage of Prescription Medicinal Products and CD5 Controlled Drugs

Regulations 5(1)(e) and 5(1)(f) state the storage requirements for human and veterinary medicinal products subject to prescription control and human and veterinary medicinal products which are Schedule 5 (CD5) controlled drugs.

Regulation 5(1)(e):

"5.(1)(e) Medicinal products that are subject to prescription control under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) and medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) are not accessible to the public for self-selection"

Regulation 5(1)(f):

"5.(1)(f) Veterinary medicinal products that are designated prescription only under the animal remedies regulations and veterinary medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) are not accessible to the public for self-selection"

Prescription medicinal products, including prescription veterinary medicinal products, and CD5 controlled drugs must not be available to members of the public for self-selection. They must be stored in a secure fashion under the direct management and supervision of the pharmacist.

Prescription medicinal products should be stored in the dispensary area of the pharmacy. A structured classification system should be used to organise medicinal products within the dispensary. This will help ensure safe, efficient practice and aid accurate stock retrievability, control and rotation. It is recommended that medicinal products with abuse potential are stored out of the line of patients' sight.

Non-prescription CD5 controlled drugs, e.g. Codeine, Pholcodine, should be stored in the dispensary area of the pharmacy unless, for justifiable reasons, e.g. a shortage of storage space, an alternative out-of-sight location within the pharmacy is used. This area must be close to the dispensary and therefore under the pharmacist's direct supervision.[10]

Other pharmacy-only, non-prescription medicinal products should be stored behind the pharmacy counter, under the control of the pharmacist. While medicinal products that have been classified as 'general sale' by the IMB may be stored outside this area, all medicinal products sold or supplied through a pharmacy, must be sold or supplied under the personal supervision of a pharmacist and should, therefore, be stored in an area of the pharmacy under the control of the pharmacist.

3.8 Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of the storage of medicinal products outlined in these guidelines and for any pharmacy-specific methods of storing medicinal products. Cleaning procedures should be developed for all medicinal product storage areas, including pharmacy refrigerators.

There should be procedures in place which outline the processes involved in stock management, including the checking of medicinal product expiry dates (including medicinal products stored in the refrigerator or safe), the control of damaged, defective or contaminated stock and the receipt, checking and entering into stock of medicinal products.[11] There should be specific procedures for the receipt of CD2 and CD3 medicinal products and medicinal products requiring refrigeration.

If original packs of medicinal products are opened or split, they should be marked in the manner outlined in the relevant pharmacy procedure and where medicinal products are repackaged or relabelled there should be procedures in place outlining these processes. There should be a policy in place which identifies medicinal products which should not be repackaged and a procedure for checking the stability of all medicinal products subject to repackaging and of opened medicinal products such as liquids or creams.

[10] Further guidance on Codeine medicines can be found in the guidance document: Non-Prescription Medicinal Products Containing Codeine - Guidance for Pharmacists on Safe Supply to Patients.
[11] For further guidance on the receipt, checking and entering into stock of medicinal products please refer to PSI Guidelines on the Sourcing of Medicinal Products for Sale or Supply in Conducting a Retail Pharmacy Business.

Every pharmacy should have a documented temperature recording procedure which details the monitoring of all areas in which medicinal products are stored, including pharmacy refrigerators. There should be procedures in place which detail how the pharmacy refrigerator is validated and its routine maintenance. Other pharmacy activities which should be documented include the review of the running balances of the CD register, the CD safe key-holding procedure and how staff members' food, drink and personal medication should be stored.

If the pharmacy stocks veterinary medicinal products, 'High-Tech' medicinal products, 'exempt' medicinal products or poisons, their specific storage arrangements should be set out in pharmacy procedures.

All storage procedures 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.

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 must be made aware of any amendments, appropriately trained, and the updated policies and procedures should be signed by such persons.

3.9 Particular Care Settings

All retail pharmacy businesses must comply with these guidelines. 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 in place.

Where such alternative policies and procedures are in place, in particular care settings, the PSI expects that the superintendent pharmacist, supervising pharmacist, any relevant registered pharmacist and the pharmacy owner to act in the best interest of patients and to ensure that the quality, safety and efficacy of all the medicinal products stored, is maintained. Any deviation from the guidelines and the justification for the deviation should be recorded.

LEGISLATIVE REFERENCES

(a) Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
(b) Pharmacy Act 2007.
(c) Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended).
(d) Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended).
(e) Misuse of Drugs (Safe Custody) Regulations, 1982 (S.I. No. 321 of 1982) (as amended).
(f) Poisons Regulations 2008 (S.I. No. 511 of 2008).
(g) European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) (as amended).

Relevant legislation can be accessed through the PSI website www.thePSI.ie and is also available from www.irishstatutebook.ie.

Self-Assessment Checklist to Enable Pharmacists and Pharmacy Owners Comply with the Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business

This Self-Assessment Checklist is a practical tool intended to aid compliance with these Guidelines and should be used as a reference check to allow self-audit of a pharmacy practice, and indicate areas that may be in need of further attention. The checklist captures the most critical issues from the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with the guidelines.

Policies and Procedures

There should be documented policies and procedures in place in every pharmacy which detail the operating systems of the pharmacy. It is important that these are documented so as to ensure that the processes to which they pertain are carried out in a consistent manner, to facilitate appropriate staff training, and to allow appropriate risk management and review.

The most critical elements of these guidelines, for which policies, procedures, records or other documentation should be in place, are detailed in the checklist below. The guidelines should be referred to for more comprehensive information on the requirements in each area. When drawing up policies and procedures pharmacists should ask themselves the following questions:

Ask Yourself	Yes	No	N/A	Required Action
Are all relevant staff aware of, and trained in, the pharmacy's policies and are training records maintained?				
Do all pharmacy procedures state the staff involved in the process, are they signed by such staff, are such staff trained and are training records maintained?				
Does each policy and procedure state its implementation and review date and are these documents reviewed regularly, i.e. when any element of the process changes and, at a minimum, annually?				
Is the review of a policy or procedure documented, i.e. signed and dated, and the policy or procedure updated, if necessary, and are all relevant staff members made aware of any amendments, appropriately trained and records of the training maintained?				

Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business

Ask Yourself	Yes	No	N/A	Required Action
Are all medicinal products stored in a secure fashion, under the control of the pharmacist, and within the registered areas of the premises?				
Are all medicinal products stored in accordance with the requirements of their marketing authorisations and any other relevant standards, such as manufacturers' instructions?				
Are the premises, fixtures, fittings and equipment, e.g. pharmaceutical grade refrigerator(s), appropriate and fit for the purpose of storing medicinal products, i.e. structurally sound, well maintained, free from damp and mould and clean, etc.?				
Is an appropriate level of each medicinal product stocked, consistent with local patient need, stock turnover, local prescribing habits and any public health initiatives which may be in place?				
Are all medicinal products only stored in areas designated for their storage, and not on floors, on stairs, in toilets, in close proximity to sources of heat or cold, or at an inappropriate height?				
Are all storage areas incorporated in cleaning schedules, including the refrigerator(s) and safes, and are cleaning records maintained?				
Is the storage of food and drink, other than medicinal food for sale or supply, and staff members' personal medication prohibited in medicinal product storage areas, including refrigerators?				
Are medicinal product stocks regularly reviewed, removed from stock if suspected to be damaged, defective or contaminated, and the IMB informed if a medicinal product is thought to be defective?				
Is there an appropriate stock rotation system in place, based on a system of first expiry, first out for all medicinal products, including those stored in the refrigerator or safe?				
Is there a documented expiry date checking procedure in place for the regular checking of the expiry dates of all medicinal products, including those stored in the refrigerator or safe, and is all short dated stock appropriately identified and marked?				

Ask Yourself	Yes	No	N/A	Required Action
Are the stability implications for the medicinal product always considered prior to repackaging and are products which must never be removed from their primary packaging identified in a policy?				
Are repackaged medicinal products always labelled appropriately and packaged with a copy of the patient information leaflet?				
Are patients and/or their carers given the necessary information and advice about the proper storage of their medicinal products?				
Are environmental conditions, primarily temperature, monitored on an ongoing basis at appropriate locations throughout the parts of the premises in which medicinal products are stored?				
Is the environmental temperature (maximum and minimum) monitored on a daily basis, at a specified time, by a designated member of staff using a calibrated max/min thermometer and are the results recorded and the records retained in the pharmacy?				
Does the temperature monitoring procedure outline the actions to be taken if the temperature falls outside the required range?				
Is a pharmaceutical refrigerator used for the storage of cold chain medicinal products?				
Is any new pharmaceutical refrigerator verified as fit for purpose prior to use and appropriately validated at regular intervals thereafter, e.g. is it routinely maintained and monitored?				
Is the refrigerator of adequate capacity to allow for organised, well-spaced storage of medicinal products?				
Is the refrigerator cleaned in accordance with the manufacturer's instructions and is due care taken to preserve the cold storage requirements of medicinal products during cleaning?				
Is the refrigerator temperature (maximum and minimum) monitored on a daily basis, at a specified time by a designated member of staff using a calibrated max/ min thermometer and are the results recorded and the records retained in the pharmacy?				

Ask Yourself	Yes	No	N/A	Required Action
Does the refrigerator temperature monitoring procedure outline the actions to be taken if the temperature falls outside the required range?				
Is an independent calibrated temperature monitoring probe used to monitor refrigerator temperatures?				
Are all CD2 and CD3 medicinal products stored in a CD safe or cabinet which meets the requirements of I.S. 267:1985 or is certified by An Garda Síochána?				
Is access to the CD safe, including custody of the safe key/access code, controlled by the pharmacist?				
Does the pharmacy regularly check the running balances of the CD register, and if an inconsistency exists is the cause investigated, rectified and a procedure to minimise future errors put in place?				
Are all poisons stored separately from medicinal products and food?				
Are all veterinary medicinal products stored separately from human medicinal products, with the appropriate specific precautions taken regarding refrigerated products and live attenuated vaccines?				
Are all 'exempt' and 'High-Tech' medicinal products and related documentation stored in an appropriate patient-specific manner?				
Are all prescription medicinal products and CD5 controlled drugs, e.g. codeine, stored in the dispensary and is a structured classification system used to organise such products?				
Are all non-prescription medicinal products stored under the control of the pharmacist?				

Guidelines on the Disposal of Medicinal Products within 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)

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 LEGISLATION

2.1 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.

2.2 Waste Legislation

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 Waste Management (Hazardous Waste) Regulations 1998 (S.I. No.163 of 1998) and the Waste Management (Movement of Hazardous Waste) Regulations 1998 (S.I. No. 147 of 1998).

The competent authorities in Ireland for most waste management regulation are the local authorities and the National Transfrontier Shipment Office (NTFSO). The Environmental Protection Agency (EPA) supervises the statutory environmental responsibilities of local authorities and regulates EPA licenced facilities.

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 ADR[1] 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 or as a veterinary 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.

[1] ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road.

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. Relevant Irish legislation can be accessed via www.irishstatutebook.ie. Lists of waste management legislation are available via the Department of the Environment, Community and Local Government Website (www.environ.ie), via the 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 relevant local authority, the NTFSO, the EPA, the HSA or your waste management company, as appropriate.

3.1.2 Waste Management Companies and Waste Documentation

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. Details of facilities with a 'waste licence' can be checked on the EPA website and details of facilities with a 'waste facility permit' can be checked with the relevant local authority. Hazardous waste is primarily managed at facilities with a hazardous waste licence obtained from the EPA.

Waste management companies must hold valid waste collection permits issued by the appropriate local authority. 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 consignment note (C1 form) in accordance with Waste Management (Movement of Hazardous Waste) Regulations 1998 (S.I. No. 147 of 1998). New regulations will shortly (mid-2011) replace the C1 form with the Waste Transfer Form (WTF) and will make the NTFSO the competent authority for supervising and controlling the internal shipments of hazardous waste. 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 Adviser 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 (who will have obtained such documentation from the disposal company in the relevant country).

Detailed records for the disposal of waste medicinal products should be obtained by, and retained in, every pharmacy. These records should include 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. The pharmacy will be given a copy of the C1/WTF form when the waste is collected from the pharmacy. Evidence of waste medicinal products having been destroyed should also be obtained from the waste management company, e.g. a disposal/ destruction certificate, or a copy thereof, which details the waste consignment and the date of destruction.

Further information on these requirements is available from sources such as the relevant local authority, the NTFSO, 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 high risk groups, e.g. pregnant women or women of child-bearing 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 incineration.[2]

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.

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.

[2] 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

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 1988 (S.I. No. 328 of 1988) (as amended). 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 drugs[3] (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.

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 CD register or in a specific CD destruction record book which is also retained on site. If the destruction of a CD2 medicinal product is not directly recorded on the page in the CD register relating to that particular CD, the destruction should be cross referenced to the page and, if necessary, the book where it is recorded.

At a minimum 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 balance in the CD register and/or destruction record book should be adjusted down to reflect the quantity destroyed, as appropriate.

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, for example, a CD destruction record book and 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] 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.

3.2.4 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, for example, a CD destruction record book, and 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.

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 non-conforming 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.

LEGISLATIVE REFERENCES

(a) Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
(b) Pharmacy Act 2007.
(c) Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended).
(d) Waste Management Act 1996 (as amended).
(e) Waste Management (Collection Permit) Regulations 2007 (S.I. No. 820 of 2007).
(f) Waste Management (Shipments of Waste) Regulations 2007 (S.I. No. 419 of 2007).
(g) Waste Management (Hazardous Waste) Regulations 1998 (S.I. No.163 of 1998).
(h) Waste Management (Movement of Hazardous Waste) Regulations 1998 (S.I. No. 147 of 1998).
(i) Carriage of Dangerous Goods by Road Regulations (S.I. No. 288 of 2007).

Relevant legislation can be accessed via www.irishstatutebook.ie. Relevant pharmacy legislation can also be accessed via www.thePSI.ie.

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.

4. 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 Irish Medicines Board.

7. Members of An Garda Síochána.

8. Officers of Customs and Excise.

[4] In December 1998, the Minister for Health and Children authorised the above persons to be authorised persons for the purposes of article 22 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988)

Self-Assessment Checklist to Enable Pharmacists and Pharmacy Owners Comply with the Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business

This Self-Assessment Checklist is a practical tool intended to aid compliance with these Guidelines and should be used as a reference check to allow self-audit of a pharmacy practice, and indicate areas that may be in need of further attention. The checklist captures the most critical issues from the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with the guidelines.

Policies and Procedures

There should be documented policies and procedures in place in every pharmacy which detail the operating systems of the pharmacy. It is important that these are documented so as to ensure that the processes to which they pertain are carried out in a consistent manner, to facilitate appropriate staff training, and to allow appropriate risk management and review.

The most critical elements of these guidelines, for which policies, procedures, records or other documentation should be in place, are detailed in the checklist below. The guidelines should be referred to for more comprehensive information on the requirements in each area. When drawing up policies and procedures pharmacists should ask themselves the following questions:

Ask Yourself	Yes	No	N/A	Required Action
Are all relevant staff aware of, and trained in, the pharmacy's policies and are training records maintained?				
Do all pharmacy procedures state the staff involved in the process, are they signed by such staff, are such staff trained and are training records maintained?				
Does each policy and procedure state its implementation and review date and are these documents reviewed regularly, i.e. when any element of the process changes and, at a minimum, annually?				
Is the review of a policy or procedure documented, i.e. signed and dated, and the policy or procedure updated, if necessary, and are all relevant staff members made aware of any amendments, appropriately trained and records of the training maintained?				

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

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, C1/WTF forms 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?				
Is the destruction of expired or non-conforming CD2 medicinal products witnessed by an authorised person and are the appropriate records maintained?				

Ask Yourself	Yes	No	N/A	Required Action
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?				