



SOURCING, STORAGE AND DISPOSAL OF MEDICINAL PRODUCTS WITHIN A RETAIL PHARMACY BUSINESS:

Draft Guidelines for Public Consultation

PUBLIC CONSULTATION DOCUMENT

Comments are welcome in writing to consultation@pharmaceuticalsociety.ie or to
Public Consultation, Pharmaceutical Society of Ireland,
18 Shrewsbury Road, Ballsbridge, Dublin 4

This period of public consultation will end at 5.00pm on Friday, 27 August 2010

**SOURCING, STORAGE AND
DISPOSAL OF MEDICINAL
PRODUCTS WITHIN A
RETAIL PHARMACY BUSINESS:**

**Draft Guidelines
for
Public Consultation**

**Draft Guidelines on the Sourcing of Medicinal
Products for sale or supply in conducting a
Retail Pharmacy Business**

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

1 INTRODUCTION

This document provides guidance 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 for sale or supply in conducting a retail pharmacy business (pharmacy). Compliance with these regulations ensures that the integrity of the final link in the supply chain for a medicinal product,¹ from the manufacturer to the patient, is maintained. This assures the safety, quality and efficacy of medicinal products sold and supplied through pharmacies and thus enhances patient safety. A pharmacy should operate a comprehensive, auditable system for the control and maintenance of an appropriate level of legitimate stock.

2 LEGISLATIVE BASIS

The operation of a retail pharmacy business is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).

These regulations 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 required to conduct the retail pharmacy business in compliance with these regulations.

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 allows the PSI Council publish detailed guidelines for the purpose of facilitating better compliance with these Regulations. These guidelines seek to facilitate compliance with regulations 5(1)(g), 6 and 8, in particular, in respect of the sourcing of medicinal products.

¹ Medicinal Product: as defined in Part 1 of the Pharmacy Act 2007

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

(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.*

²*(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.

² The segregation and disposal of patient-returned medicinal products is dealt with in greater detail in the PSI Draft Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business and the PSI Draft Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business.

3.1.1 Sourcing from Authorised Manufacturers or Wholesalers

A person carrying on a retail pharmacy business must only source 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 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.

A list of all Irish authorised manufacturers and wholesalers is available from the Irish Medicines Board (IMB) website, www.imb.ie. In reviewing the authority of the 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.

Documentation should be available in the pharmacy which permits the supplier of each consignment of medicinal product received by the pharmacy to be clearly identified, e.g. supplier invoices, delivery dockets.

3.1.2 Medicinal Products which should not be Sold or Supplied

If a pharmacist or pharmacy owner suspects 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, i.e. stored in a designated area of the pharmacy and clearly labelled. The medicinal product 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 general 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 and should never be dispensed or supplied.

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 exchange(s) should be maintained. This documentation should be signed off by a pharmacist in both the lending and receiving pharmacies and a copy of this document should be retained in both pharmacies.

This documentation should include details of the medicinal product(s) involved, quantity supplied, batch number, expiry date, supplier (wholesaler or manufacturer), date of supply, details of 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 obtained. Only the amount of stock required to meet the immediate patient need(s) should be transferred.

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, requisitions, etc. Any CD2 medicinal products⁴ entering or leaving the pharmacy in the manner outlined must be recorded in the controlled drugs register.

3.1.4 Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place which outline the steps to be followed for the ordering, receipt, checking and entering into stock of medicinal products. 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.

³ PSI. Draft Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business

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

In addition to these checks, procedures for the receipt of medicines should also 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 sourcing, ordering, receipt or checking procedures should state the persons involved in the process and be signed by such persons. The staff involved in a particular procedure, e.g. ordering medicinal products, should be trained in the relevant procedure and records of such training maintained. Procedures should be reviewed and updated regularly, e.g. when any element of the process changes and, at a minimum, annually.

3.2 Medicinal Products which may be Sold or Supplied from a Pharmacy

Regulation 8 sets out the requirements regarding the 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.

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.

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 Irish Medicines Board (IMB). A medicinal product which has a **Marketing Authorisation** granted by the Irish Medicines Board 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 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/xxxx. 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.** The IMB also operates a **Dual Pack Import Registration** scheme. 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, and which is packaged in dual-market, identical packaging carrying 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 an '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 number '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 retail pharmacy business must take extra care when ordering dual pack registered medicinal products and confirm that the products are appropriately authorised for sale in Ireland. If any doubt exists as to the status of a medicinal product, this should be confirmed 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 distributor. 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: (<http://www.ema.europa.eu/htms/human/parallel/introduction.htm>). 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' or 'PVPA' and/or may have additional details included, depending on the route of authorisation.

3.2.2 Policies and Procedures

In addition to the information outlined in section 3.1.4, there must be written procedures in place which outline the processes involved in ensuring all medicinal products sourced are appropriately authorised. This can be achieved by using authorised suppliers and checking each medicinal product 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.

There should also be procedures in place which outline the steps to be followed when sourcing medicinal products.

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 from the requirement for a medicinal product to be authorised for sale or supply. This exemption allows a practitioner, i.e. a registered doctor or a registered dentist, to prescribe unauthorised medicinal products for individual patients who are under their direct responsibility, in order to fulfil the special needs of those patients. 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 their direct care.⁶

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, e.g. the medicinal product was recently withdrawn from the Irish market or the medicinal product has never been authorised in Ireland. A record outlining that this information has been imparted should be inserted in the patient's file. Pharmacists should be aware, and should ensure prescribers are informed, that the IMB does not permit 'exempt' medicinal products to be sourced and supplied if an authorised alternative is available in Ireland.

⁶ IMB. Guidance Note on the Notification System for Exempt Medicinal Products 2008

Patients should be appropriately informed of the unauthorised or 'exempt' status of the medicinal product. They should be made aware of what this means and reassured that their practitioner has decided that the 'exempt' medicinal product prescribed is the most appropriate treatment for their individual condition. 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.

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

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

Documentation should be available in the pharmacy which permits the supplier of each consignment of medicinal product received by the pharmacy to be clearly identified, e.g. supplier invoices, delivery docketts. Specific written procedures should be in place for ordering 'exempt' medicinal products.

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.

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 cooperates 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 quickly respond to a request from 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 the recall or withdrawal.

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

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)

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

**SOURCING, STORAGE AND
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**Draft 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

This document provides guidance 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 products¹ in a retail pharmacy business (pharmacy). A 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. Medicinal products must be stored in accordance with their marketing authorisations to assure the quality, safety and efficacy of the medicinal products supplied and thus enhance patient safety.

2 LEGISLATIVE BASIS

The operation of a retail pharmacy business is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).

These regulations 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 and supervising pharmacists are required to conduct the retail pharmacy business in compliance with these regulations.

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 allows the PSI Council publish detailed guidelines for the purpose of facilitating compliance with these Regulations. These guidelines are intended to facilitate better compliance with regulations 4(4), 5(1)(e), 5(1)(f), 6(3) and 7, in particular, in respect of the storage of medicinal products.

These guidelines also seek to facilitate compliance with the general requirements outlined in regulations 4(1)(a) and 4(1)(b) as they relate to the storage of medical products in a retail pharmacy business.

¹ Medicinal Product: as defined in Part 1 of the Pharmacy Act 2007

Regulation 4:

Staff, premises, equipment and procedures

(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.

(1)(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 GUIDANCE

3.1 Storage of Medicinal Products

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

Regulation 7:

Appropriate storage of medicinal products

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.

Regulation 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

Only premises² 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 no medicinal products may 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.

² Premises as defined in the Regulations of Retail Pharmacy Businesses Regulations 2008: premises, in relation to a retail pharmacy business, means a fixed premises, and includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored;

To ensure the quality, safety and efficacy of medicinal products supplied to patients, all medicinal products stocked by a pharmacy must be stored in accordance with the manufacturer's instructions, all other relevant standards and within the requirements of the medicinal product's Marketing Authorisation.

Medicinal products should be stored separately from non-medicinal products. They must be stored in a secure fashion under the control and supervision of the pharmacist.

Good pharmacy practice would be to ensure the appropriate quantity of each medicinal product is stocked, consistent with stock turnover, local prescribing habits, local patient need and any national public health initiatives that may be in place.

3.1.2 Storage Areas

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 clean, free from litter, dust and pests and free from spillage or breakage. Storage areas should be well maintained. Surfaces should be impervious and non-shedding and walls and floors should be intact. All storage areas should be incorporated in the cleaning and housekeeping schedules.

Medicinal products should not be stored in close proximity to sources of heat, e.g. unit heaters or artificial lights, and should not be stored in direct sunlight. They should not be stored directly on the floor or at a height which creates a hazard for staff.

Storage of food and drink should be prohibited in areas used for the storage of medicinal products. There should be procedures in place which deal with the storage of personal medication. Such medication should be stored with personal belongings or in a designated area of the pharmacy, segregated from normal medicinal product stock.

3.1.3 Stock Management

All medicinal products stored in the pharmacy must be legitimately authorised for sale or supply and must have a batch number and expiry date.³

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

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.

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. There should be a procedure in place outlining the repackaging/labelling process. 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.

Medicinal products must not be removed from the primary⁴ protective packaging at the time of dispensing, except in cases where repackaging 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 these 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 themselves 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.

⁴ 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.

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. There should be a procedure in place which outlines the measures in place to control non-conforming medicinal product. 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.

A documented procedure for the regular and systematic checking of expiry dates should be in place. Short-dated stock should be identified and appropriately marked. All medicinal products which are close to their expiry date should be removed from stock and transferred to a specifically designated area. 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 medicinal products should be stored in a specifically designated area of the pharmacy, segregated from general stock and clearly labelled 'Medicines for Destruction', pending timely removal for disposal and destruction.⁵ There should be a procedure in place outlining the process involved in the storage and disposal of waste medicinal products.

3.1.4 Patient Counselling

The pharmacist must ensure that, on receipt of a medicinal product, each patient is given sufficient information and advice on its proper storage. Patients 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/or encouraged to read the storage section of the patient information leaflet, as appropriate.

3.1.5 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.

⁵ PSI. Draft Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business

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 30°C.

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 ongoing monitoring as described below.

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.

3.1.6 Temperature Monitoring

Environmental temperature must be monitored, in all parts of the premises in which medicinal products are stored, in order to ensure that appropriate storage conditions are maintained.

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 and appropriate records maintained.

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

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.

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 outlining the frequency of and staff member responsible for temperature monitoring. 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

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 fridge 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.

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

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. All refrigerators used for storing medicinal products must remain free from frost at all times.

In a pharmacy, standard domestic refrigerators are not suitable for storing medicinal products requiring 2-8°C storage, as these do not provide the required level of temperature control. Lack of temperature control occurs as a result of minimal air circulation and because they typically operate within a range of 0 to 10°C. Opening and closing the fridge door can cause significant temperature fluctuations, making controlling the internal temperature difficult. 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 fridge.

A fridge containing medicinal products must never be used to store food and drink, in order to limit changes in temperature and minimise the risk of contamination. Personal medication requiring refrigeration should not be stored in the same fridge as general 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 daily maximum and minimum temperatures of the pharmacy refrigerator, i.e. the maximum and minimum internal temperatures reached since the previous measurement, should be monitored and recorded in a log. Readings should be taken in accordance with the manufacturer's instructions. The temperature-recording equipment should also be calibrated, as recommended by the manufacturer and appropriate records maintained. Temperature-monitoring records should be reviewed and approved regularly by the supervising pharmacist to ensure compliance with the required conditions.

There should be a written procedure in place outlining the frequency of 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 instruction and records of the calibration maintained.

3.2.3 Stock Management

When medicinal products requiring refrigeration are received from suppliers, they should be checked 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 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):

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 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 key, 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.

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). A member of an Garda Síochána, not below the rank of Superintendent, may inspect a safe or cabinet in which controlled drugs are kept and provided it meets the requirements, certify the safe or cabinet. The certificate issued certifies that the safe or cabinet provides an appropriate degree of security. The certificate is valid for two years and should be retained in the pharmacy.

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.

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. The controlled drugs delivery docket should then be signed by the pharmacist and returned to the wholesaler. There should be a written procedure in place which deals specifically with the receipt of CD2 and CD3 medicinal products.

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.

3.4 Storage of Poisons

The requirements for the storage of poisons are set out in the Poisons Regulations 2008 (S.I. No. 511 of 2008) and are detailed in Regulation 9 (reproduced below).

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.*

3.5 Storage of Veterinary Medicinal Products

All the storage requirements for medicinal products outlined in sections 3.1, 3.2 and 3.3 above 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 2-8°C storage should be kept in a separate animal medicines refrigerator reserved solely for this purpose.

Special care should be taken with veterinary medicines, feed additives or other materials which might have a strong or lingering odour. These medicinal products should be stored in a part of the premises isolated from other medicinal products and food. Certain veterinary vaccines are live vaccines, and these should not be kept in close proximity to other veterinary medicinal products, human medicinal products or food.

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

'High Tech' medicinal products should be stored separately from other medicinal products in a patient-specific manner. All relevant documentation should be kept with the 'high tech' medicinal product, e.g. supplier's invoice, copy of prescription. Subsequent to dispensing, this documentation should be retained on site.

'Exempt' medicinal products previously referred to as 'unauthorised' or 'unlicensed' medicinal products should be stored separately from authorised medicinal products. These medicinal products should be stored in a patient-specific manner and all relevant documentation should be kept with the 'exempt' medicinal product, e.g. supplier's invoice, copy of prescription. Subsequent to dispensing this documentation should be retained on site.

'High-Tech' and 'exempt' medicinal products requiring refrigeration should be stored in a designated area of the fridge, in a patient-specific manner. The appropriate documentation should accompany the medicinal product or should be kept in a designated file adjacent to the refrigerator.

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):

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):

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 supervision of the pharmacist.

Prescription medicinal products should be stored in the dispensary area of the pharmacy.

Non-prescription codeine medicinal products (CD5 controlled drugs) should be stored in line with any requirements outlined in the guidance document: '*Non-Prescription Medicinal Products Containing Codeine. Guidance for Pharmacists on Safe Supply to Patients*'.⁹ Such products 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 pharmacists direct supervision.

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. Procedures should also be generated for any pharmacy-specific methods of storing medicinal products. All storage procedures should state the persons involved in the process and be signed by such persons. The staff involved in a particular procedure, e.g. checking of medicinal product expiry dates, should be trained in the relevant procedure and records of such training maintained. Procedures should be reviewed and updated regularly, e.g. when any element of the process changes, and at a minimum annually.

⁹ PSI. Non-Prescription Medicinal Products containing Codeine. Guidance for Pharmacists on Safe Supply to Patients.

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) The Poisons Regulations 2008 (S.I. No. 511 of 2008).
- (g) The European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007).

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

**SOURCING, STORAGE AND
DISPOSAL OF MEDICINAL
PRODUCTS WITHIN A
RETAIL PHARMACY BUSINESS:**

**Draft Guidelines
for
Public Consultation**

**Draft 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

This document provides guidance 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 products¹ within a retail pharmacy business (pharmacy). Compliance with these regulations ensures medicinal product disposal, 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. A pharmacy should operate a comprehensive, auditable system for the disposal of waste medicinal products² which assures the safety of patients and the public.

2 LEGISLATIVE BASIS

The operation of a retail pharmacy business is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S. I. No. 488 of 2008).

These regulations 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 required to conduct the retail pharmacy business in compliance with these regulations.

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 allows the PSI Council publish detailed guidelines for the purpose of facilitating better compliance with these Regulations. These guidelines are intended to facilitate compliance with regulations 4(5) and 6(3), in particular, in respect of the disposal of medicinal products.

¹ Medicinal Product: as defined in Part 1 of the Pharmacy Act 2007.

² Waste medicinal products: Any medicinal product not fit for sale or supply, i.e. patient-returned, expired or non-conforming medicinal products.

3 GUIDANCE

3.1 Disposal of Medicinal Products

Regulation 4(5) states the requirements for the safe disposal of medicinal products.

Regulation 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) states the requirements for the segregation and disposal of previously dispensed or supplied medicinal products.

Regulation 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.

Disposal of waste medicinal products must occur in a manner compliant with waste management legislation, e.g. Waste Management Act 1996 (S.I. No. 10 of 1996)(as amended)), related regulations, and any other relevant legislation. The pharmacy owner, superintendant and supervising pharmacists must ensure that the disposal of any medicinal product never causes any risk to public health or any environmental damage.

Particular precautions should be taken to segregate hazardous waste, e.g. cytotoxic or cytostatic medicinal products. When disposing of hazardous waste, pharmacists should be cognisant of any additional legislative requirements, e.g. Waste Management (Hazardous Waste) Regulations 1998 (S.I. No.163 of 1998).

3.1.2 Storage of Waste Medicinal Products

Waste medicinal products should be stored appropriately, under the control of a pharmacist. Such products should not be stored in the dispensing/working area of the pharmacy but may, if they cannot be processed immediately, be stored in an alternative, specifically designated area of the pharmacy. They should be segregated from normal stock and clearly labelled 'Medicines for Destruction', pending timely processing for disposal.

3.1.3 Disposal of Waste Medicinal Products

Waste medicinal products must be disposed of in specialised waste bins; these disposal units are usually yellow with a sealable lid. Sharp waste medicinal products, e.g. needles or glass, should be disposed of in specialised sharps bins. Hazardous waste medicinal products should be disposed of in specialised hazardous medicinal product waste bins. All waste bins should be stored securely, i.e. under the control of the pharmacist, in a designated area of the pharmacy which is inaccessible to members of the public.

Medicinal products should never be disposed of in regular waste and should never enter the mains water drainage system. Medicinal product waste bins should not be overfilled. When full, the bins should be removed from the pharmacy promptly by an appropriately licensed disposal agency for incineration. Details of the waste management company should be retained in the pharmacy.

3.1.4 Patient Counselling

Pharmacists should ensure patients 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.

3.1.5 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, segregated from normal stock and clearly labelled 'Medicines for Destruction', pending timely processing for disposal.

Appropriate safety precautions, which minimise the risk to the health of pharmacy staff, should be taken when sorting through patient-returned 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 medication. The risk of sharps in returned medicinal products should also be considered when drawing up safety procedures.

Returned medicinal products should be examined for the presence of confidential waste, e.g. patient specific labels, and such waste should be shredded or treated in a manner which renders it indecipherable prior to disposal.

3.1.6 Policies and Procedures

Each pharmacy should have written policies and procedures outlining the processes involved in the segregation and disposal of patient-returned medicinal products and the segregation and disposal of expired or non-conforming medicinal products. These procedures should state the persons involved in the process and be signed by such persons. There should also be training procedures in place for the staff involved and records of such training should be maintained. All procedures should be reviewed and updated regularly, e.g. when any element of the process changes, and at a minimum annually.

3.2 Disposal and Destruction of Controlled Drugs

There are specific requirements for the destruction and disposal of Schedule 2 (CD2) controlled drugs, i.e. medicinal products specified in Schedule 2 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 (CDs), should be segregated from normal CD stock and clearly labelled 'CDs for Destruction'. They should be stored securely in a specifically designated part of the CD safe/cabinet, pending timely destruction and disposal.

3.2.2 Witnessed Destruction

Pharmacists who maintain a stock of CD2 medicinal products can only destroy such products in the presence of an authorised witness, e.g. a member of an Garda Síochána or a PSI Inspector. The authorised witness must record that the controlled drug has been destroyed. This destruction should be recorded either in the CD register or in a specific controlled drug destruction record book which is also retained on site. If the destruction is not directly recorded on the relevant page in the CD register, there should be a reference to the page/ book where it is recorded inserted on the relevant page.

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 witness is required. 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. The destruction of the medicinal product should be carried out in accordance with any directions given by the authorised witness. (A full list of authorised persons/witnesses is outlined in **Appendix 1**).

3.2.3 Patient-returned Controlled Drugs

Any CD2 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 and without recording them in the CD register. The return and destruction of such CDs should, however, be recorded in a specific controlled drug 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.

If a pharmacist is unable to destroy such CDs on receipt, they should be clearly labelled as 'Patient-Returned CDs for Destruction'. They should be stored securely in a specifically designated area of the CD safe/cabinet and segregated from normal CD stock, to avoid the potential for re-use. It is recommended that the destruction of patient-returned CD2 medicinal products be witnessed by a second pharmacist or another responsible member of the pharmacy staff.

3.2.4 Destruction Criteria

When destroying a CD2 medicinal product, there are two main criteria to be fulfilled to ensure that the final product is no longer considered to be a controlled drug

- it must be no longer usable
- and the active ingredient must be irretrievable from the final mixture.

There are many ways to satisfy the destruction criteria. To render the medicinal products unusable, pharmacists can

- grind up tablets with a pestle and mortar;
- 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;
- mix liquids with solid matter.

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

Having rendered the medicinal product unusable, it should be mixed with a product which will render the drug substance unrecoverable from the final mixture. A controlled drug denaturing kit may be used for this purpose or an alternative suitable product.

Any method of destruction employed should safeguard the environment and the health of pharmacy staff and members of the public. Appropriate safety precautions should be taken when destroying CD2 medicinal products, including the wearing of appropriate personal protective equipment.

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

3.2.5 Disposal of Controlled Drugs

Once the destruction criteria have been met, the resultant mixture must 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 waste should be removed by an appropriately authorised disposal agency for incineration. Details of the waste management company should be retained in the pharmacy.

3.2.6 Policies and Procedures

There should be written policies and procedures in place outlining the processes involved in the segregation and disposal of patient-returned CD2 medicinal products and the segregation and disposal of expired or non-conforming CD2 medicinal products. These procedures should state the persons involved in the process and be signed by such persons. It is recommended that a pharmacist carry out all matters in relation to the disposal and destruction of CD2 medicinal products. If other staff are involved in the disposal of such products, they should be trained and records of such training maintained. All procedures should be reviewed and updated regularly, e.g. when any element of the process changes, and at a minimum annually.

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 (S.I. No. 10 of 1996)(as amended)
- (e) Waste Management (Hazardous Wastes) Regulations 1998 (S.I. No.163 of 1998)

Relevant legislation can be accessed through the PSI website www.pharmaceuticalsociety.ie. and is also available from www.irishstatutebook.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 pharmaceutical chemists.
2. The following officers of a 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).
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.