

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

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

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Updates made following the introduction of Regulation 5(1)(ea) of the Regulation of Retail Pharmacy Businesses Regulations (S.I. 80/2016) are highlighted in grey.

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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) (as amended) 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 with 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) (as amended), which have been made by the Minister for Health 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)(as amended) 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)(ea) 5(1)(f), 6(3) and 7, insofar as those regulations relate to the storage of medicinal products in pharmacies. It is the responsibility of the pharmacy owners and superintendent pharmacists to ensure compliance with these legislative provisions in their 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)(as amended)

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 subparagraph (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 Health Products Regulatory Authority (HPRA).

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.

² PSI Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business.

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-conforming³ medicinal products should be stored in a specifically designated area of the pharmacy, segregated from pharmacy stock and clearly labelled 'Medicinal Products 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 Package Leaflet (PL), 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.

Medicinal products should not be removed from the primary⁵ 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 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 (SmPC) and/or verifying the medicinal product's stability with the Marketing Authorisation Holder (MAH). 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 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 Disposal of Medicinal Products for a Retail Pharmacy Business.

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.

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 30°C.

Appropriate ambient 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.

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 ambient 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.

6 European Medicinal products 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 Health Products Regulatory Authority. Guidance note on the wholesaling of medicinal products for human use in Ireland, October 2004.

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 ranges of 2°C-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°C-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°C 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 the 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.

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 Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017) 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.

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.

⁹ Further information on controlled drugs safes and cabinets is provided in the PSI ‘Guidelines on the Equipment Requirements of a Retail Pharmacy Business’.

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 be 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°C-8°C storage should be kept in a separate animal medicinal products 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 medicinal products, 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

‘High Tech’ medicinal products should be stored separately from other stock in a patient-specific manner. Similarly, ‘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. 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), in Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended), 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

¹⁰ Further guidance on Codeine medicinal products can be found in the guidance document: Non-Prescription Medicinal Products Containing Codeine - Guidance for Pharmacists on Safe Supply to Patients.

3.8 Storage of Pharmacy-Only and General Sale Medicinal Products

Regulation 5(1)(ea) details the storage requirements for the supply of pharmacy-only medicinal products.

Regulation 5(1)(ea):

“5.(1)(ea) medicinal products other than medicinal products referred to in sub-paragraph (e), and not being medicinal products on a general sales list, are stored in a part of the premises to which the public does not have access,”

Pharmacy-only medicinal products are a category of medicinal products which are only available to the public under the personal supervision and guidance of a pharmacist. Pharmacists have a professional role and statutory duty to carry out, or personally supervise, the sale and supply of all non-prescription medicinal products from the pharmacy to ensure that the patient/purchaser is made aware of the safe and appropriate use of the product and that it is not intended for abuse and/or misuse.

As per Regulation 5(1)(ea), pharmacy-only medicinal products must be stored in a part of the pharmacy to which the public does not have access. There are a number of ways in which pharmacies can comply with the requirements of this legislation including:

- Storage of pharmacy-only medicinal products behind the medicinal products counter/Over The Counter (OTC);
- Any other arrangements within the premises which ensures that the public does not have direct or physical access to pharmacy-only medicinal products.

If a member of the public is able to self-select (i.e. physically access/pick up) a pharmacy-only medicinal product from a publicly accessible part of the pharmacy, then this product is not stored in a part of the premises to which the public does not have access. Pharmacy-only medicinal products do not need to be stored in the dispensary.

Medicinal products categorised as ‘general sale’ (i.e. GSL medicinal products) by the HPRA should be stored in a part of the pharmacy that is under the personal supervision of a pharmacist. However, GSL medicinal products are not subject to Regulation 5(1)(ea) and therefore do not need to be stored in a part of the pharmacy to which the public does not have access.

It is the responsibility of the pharmacy owners and superintendent pharmacists to ensure compliance with these legislative provisions.

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 act in the best interest of patients and 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.

4. 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.

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.

5. Legislative References

- Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended).

- Pharmacy Act 2007.

- Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003)(as amended).

- Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017).

- Misuse of Drugs (Safe Custody) Regulations, 1982 (S.I. No. 321 of 1982) (as amended).

- Poisons Regulations 2008 (S.I. No. 511 of 2008).

- 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.PSI.ie and is also available from www.irishstatutebook.ie.

Version Number	Date Issue
1	May 2011
2	April 2018

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 by a Retail Pharmacy Business.

6. Self-assessment Checklist

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

Ask Yourself	Yes	No	N/A	Required Action
Are 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 HPRA 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?				

Ask Yourself	Yes	No	N/A	Required Action
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?				
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?				

Ask Yourself	Yes	No	N/A	Required Action
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?				
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 pharmacy-only medicinal products stored in a part of the pharmacy to which the public does not have access?				