

# Guidelines on the Premises Requirements of a Retail Pharmacy Business

to Facilitate Compliance with Regulations 4 (1) and 4 (2) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

Pharmaceutical Society of Ireland

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Updates made following the enactment of the Misuse of Drugs Regulations 2017<sup>1</sup> (which replaced the Misuse of Drugs Regulations 1988 (as amended)<sup>2</sup> are highlighted in grey).

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

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

# 1. Introduction

The purpose of these guidelines is to facilitate compliance with the requirements of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the premises that are to be used for the conduct of retail pharmacy businesses (i.e. pharmacies) under the Act.

These guidelines are intended to assist pharmacy owners (those applying to open a pharmacy and owners of existing pharmacies), as well as superintendent and supervising pharmacists, in ensuring that their premises meet required standards and with planning for changes in their premises such as refurbishments.

The Regulation of Retail Pharmacy Businesses Regulations 2008, in particular, sets out the various responsibilities of pharmacy owners in respect of pharmacy staff, premises, equipment and procedures. In that respect, pharmacy owners must ensure that the premises are fit for purpose and appropriately equipped and staffed and that the required governance arrangements are in place at all times so as to adequately protect the health, safety and convenience of patients, the public and staff.

Pharmacy owners must recognise and facilitate compliance with their own legal obligations and with those of the superintendent pharmacist. All decisions and processes pertaining to the sale and supply of medicinal products are under the personal control of the superintendent pharmacist. In the discharge of their responsibilities for the appropriate management and administration of the respective pharmacies for which they are responsible, the superintendent pharmacist must be satisfied that the staff, premises, equipment and procedures are adequate for their purpose.

These guidelines outline the minimum requirements relating to the premises of all existing pharmacies as well as for planned new pharmacy openings. Pharmacy owners and their superintendent and supervising pharmacists are required to conduct the retail pharmacy business in compliance with these guidelines and must ensure that these minimum standards are met.

Pharmacy premises should provide an environment which facilitates the adherence by pharmacists to the core principles set out in the Code of Conduct for pharmacists. All registered pharmacists have an obligation to ensure the pharmacy is operated in accordance with all legislation and guidance, promoting the highest professional standards in the delivery of pharmacy care, treatment and service. They must ensure that the premises and facilities are fit for purpose for the provision of pharmacy services and are well maintained, facilitating a safe and effective working environment and reflecting the professional nature of a healthcare facility.

## 2. Legislative Basis

The operation of a retail pharmacy business is governed by section 26(1) of the Pharmacy Act 2007 (the Act) and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I 488 of 2008). Those regulations have been made by the Minister for Health and Children under Section 18 of the Act, for the purposes of the health, safety and convenience of the public.

These guidelines have been prepared with a view to publication in compliance with regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008, which provides that the PSI Council may publish detailed guidelines for the purpose of facilitating compliance with these Regulations.

These guidelines seek to facilitate compliance with regulation 4(1) and 4(2) of the Regulation of Retail Pharmacy Businesses Regulations 2008 in respect of pharmacy premises, which are set out below.

### *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, 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.*
- (2) The pharmacy owner shall ensure that the arrangements and layout of the premises are such as to enable personal supervision to be exercised by a registered pharmacist of any preparation, dispensing or compounding and of the sale or supply of medicinal products, including veterinary medicinal products, at one and the same time.*

## 3. Guidance

### 3.1 ‘Registered Premises’

“Premises” in relation to a retail pharmacy business means a fixed premises that has been registered in the retail pharmacy businesses’ register kept by the Council under section 13(1) of the Pharmacy Act 2007 and includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored<sup>3</sup>.

#### 3.1.1 Fixed Premises

It is understood that a fixed premises does not include a vehicle, trailer, caravan, or other thing which may be transported on, in or attached to a vehicle. It does not include unroofed and/or temporary structures. The premises must meet all relevant local bylaws and planning regulations.

It should also be noted that, Section 64 of the Pharmacy Act 2007 provides that a registered retail pharmacy business and medical practice shall not be carried on in the same premises or in premises which although separate share access if there is an arrangement between the pharmacy owner or registered pharmacist and the medical practitioner which provides for or acknowledges or regulates financial benefit to any of them arising from the co-location of the pharmacy and medical practice.

A pharmacy owner or pharmacist must not carry on a retail pharmacy business from unregistered premises. The certificate of registration<sup>4</sup> of the supervising pharmacist as well as the certificate of registration of the retail pharmacy business must be conspicuously displayed at the premises in which the business is carried on.

In designing a pharmacy layout the pharmacy owner and superintendent should be aware that, pharmacists in the pharmacy must be able to maintain personal supervision of all preparation, dispensing, compounding or sale and supply of prescription and non-prescription controlled medicines, including veterinary medicines, at one and the same time. The layout of the pharmacy should facilitate this.

#### 3.1.2 Sketch Plan/Floor Plan

In an application for registration or continued registration of a retail pharmacy business, a sketch plan/ floor plan must be submitted to the PSI, setting out all those areas where medicinal products are, or intended to be, sold or supplied, prepared, dispensed, compounded or stored at the registered premises. It is not permissible to use any other area for these purposes, other than the specific areas that constitute the registered premises. The actual layout of the pharmacy must be in line with the floor plan given to PSI as part of the registration of the premises.

It should be noted that, if changes to the sketch plan/floor plan or any other material changes are made or are proposed to be made to those specified in the application for registration, the pharmacy owner or superintendent pharmacist must notify the PSI of the changes/ proposed changes<sup>5</sup>. Before proposed changes are made to premises, it may be useful to consult with the PSI if advice is required.

3 Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008. (S.I. 495 of 2008).

4 “Certificate of registration” refers to a certificate issued under section 20 of the Pharmacy Act and which is for the time being in force.

5 As required by Rule 6, Pharmaceutical Society of Ireland (Retail Pharmacy Businesses)(Registration) Rules 2008.

## 3.2 External Premises Requirements

### 3.2.1 Structure and External Appearance

- The pharmacy premises must be easily identifiable as a healthcare facility and must reflect the professional nature of pharmacy.
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- Public entrances to the pharmacy must be clear and accessible at all times.
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- Pathways to the front of the premises must be safe, well maintained and level. Ensuring that pathways are maintained adequately is not always under the direct control of the pharmacy owner. In situations where concerns arise, these should be brought to the attention of the relevant authority.
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- All areas of the external pharmacy premises and façade, including all windows, sills, doors, and roofs must be of sound construction, intact, in a good state of repair and decoration.
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- Fascia, guttering and paintwork must be kept clean and in good order and surfaces must be non-shedding. Both the external and internal premises must be free from leaks and exposed wiring.
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- Any signage used on the exterior of the pharmacy must be clear, legible and not misleading. Notices informing the public of arrangements for accessing pharmacy services such as opening hours, duty rotations, after-hours services, etc. should be present, prominently displayed, factual and up-to-date.
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- Window displays must be professional in nature, free from dust, clutter and insects and be appropriate to that of a healthcare facility. Posters on windows and doors should be kept to a minimum, be professional in character and facilitate sufficient visibility to ensure security is not compromised.
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- Illuminated exterior signs should be in good repair and in working order. The pharmacy title/trading name must be clearly displayed near public entrances.
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- Effective pest control measures should be adapted to prevent entry of rodents and other pests.
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### 3.2.2 Security

- The superintendent pharmacist, in co-operation with the pharmacy owner, is recommended to carry out a security audit to assess the security standard of their retail pharmacy business, independently or with the assistance of a Garda Crime Prevention Officer. A Security Assessment Template, developed jointly by the PSI and An Garda Síochána, is available on the PSI website ([www.psi.ie](http://www.psi.ie)) to assist with this audit. Security arrangements should be regularly reviewed, at a minimum annually, and for example in response to an incident or to advice from a relevant authority such as An Garda Síochána.
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- The registered premises must be “self-contained” in terms of access, or appropriately secured/ sealed off within the building. It is possible that the entire building may be registered as the retail pharmacy business and if so, all areas of the building must be of the appropriate standard. All windows, doors and skylights, must be secured from any unregistered and adjacent areas within or surrounding the premises. Sufficient measures must be in place to prevent unauthorised access to or breach of security, of the registered premises both during and outside ‘opening’ hours. All external and internal doors must be well fitting and of an appropriate quality. The type of roofing should be assessed as part of the pharmacy’s security audit as well as the need to introduce shutters or reinforced exits and/or CCTV.
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- The pharmacy should be fitted with appropriate internal and external security, as determined by the security audit.
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- The superintendent pharmacist must ensure that the storage of all medicinal products, including all associated hard and electronic records, takes place appropriately and securely within the retail pharmacy premises itself<sup>6</sup>. They must ensure accessibility of medicines is strictly controlled and must facilitate the pharmacy owner in complying with obligations in respect of the premises security. They must ensure the necessary training is implemented and take all reasonable precautions to prevent burglary and ensure the safety of premises and staff.
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- The PSI may request evidence of security documentation during the course of routine inspections, prior to the opening of a new retail pharmacy business, on the temporary or permanent relocation of a retail pharmacy business to new premises or after significant refitting/refurbishment, or material or layout changes, of an existing retail pharmacy business. The required documentation would include the Security Assessment Template/security audit record and evidence that a security review is being carried out at least annually by the superintendent pharmacist.
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### 3.2.3 Accessibility

- A safe and accessible entrance to the pharmacy premises must be provided. Publicly accessible areas must be clear of stock and all other obstructions. All services to the pharmacy premises, such as refuse areas, should be secured and kept clear and inaccessible to the public.
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- As a healthcare facility accessible to the public and patients, reasonable accommodation must be made in order for members of the public and patients with disability, as well as for employees with disability, to access the premises unaided and with ease.
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- In addition, under the Equal Status Acts 2000 to 2004<sup>7</sup>, as providers of goods and services, retail pharmacy businesses have a legal obligation to make their services accessible and prohibit discrimination against people with a wide range of disabilities, including people with mobility, sensory, mental health and intellectual impairments.
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## 3.3 Internal Premises Requirements

### 3.3.1 General Guidance

This general guidance applies to all relevant areas within the pharmacy, including the dispensary, the patient consultation area and the public areas of the pharmacy including all areas where professional pharmacy services are accessed.

- Patients entering the pharmacy should be readily able to identify where they can access the pharmacist and where prescriptions are dispensed. Appropriate signage (e.g. Advice and Consultation Area / Prescriptions) must be displayed and the prescription reception area kept free of clutter.
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- The layout of the pharmacy must facilitate the pharmacist to supervise the sale and supply of medicines.
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- The fittings used to store medicinal products must be adequate to facilitate the proper storage of these medicinal products. A mechanism/sign should be in place whereby the patient is made aware that there is ready access to a pharmacist.
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6 Refer to PSI's Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business.

7 Equal Status Acts accessible via: [www.irishstatutebook.ie](http://www.irishstatutebook.ie). Further information about public access requirements and reasonable accommodation, available via the Equality Authority's website: [www.equality.ie](http://www.equality.ie). Further information on how to implement improvements and make premises accessible, available via [www.nda.ie](http://www.nda.ie).

- Adequate heating, lighting and ventilation/air conditioning should be provided to ensure the correct storage and safe dispensing of medicinal products within the pharmacy. The PSI has issued *Guidelines on the Storage Requirements for Medicinal Products in a Retail Pharmacy Business*, which should be consulted for further information.
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- A suitable waiting area with a seating option should be provided for patients, giving consideration to the privacy of others.
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- Pharmacies are required to provide a separate, designated, conveniently located patient consultation area within the pharmacy which, at a minimum, allows for a private discussion between the pharmacist and patient and/or their carer about matters related to their medicine therapy or general health. The PSI has previously issued guidelines to facilitate compliance with this requirement<sup>8</sup>.
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- All pharmacy fixtures, fittings and décor (including all storage areas) must be fit for purpose, of sound construction and compliant with all health, safety and environmental requirements. The finish of all fixtures, fittings and décor must be professional, complete, well maintained and free of any damp and mould. All walls, ceiling, plaster and paintwork must be safe, non-shedding, cleanable, and clean and in keeping with that expected from a healthcare facility.
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- All floors within the registered premises should be undamaged, intact and with an even surface. Flooring should be of a non-slip, cleanable material and should be clean. Carpets are not recommended, particularly in the dispensary, in the interest of maintaining a hygienic environment. In so far as is practical, aisles must be clear of obstacles.
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- All areas of the pharmacy should be kept clean and a written and regular cleaning schedule and sign off sheet should be in place for all areas of the pharmacy, including the dispensary and all staff/public/storage areas and such records maintained for inspection upon request<sup>6</sup>.
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- ### 3.3.2 Dispensary
- The dispensary should be suitably sited within the premises so as to allow all patients ease of access to dispensing services.
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- Medicinal products that are subject to prescription, including prescription veterinary products, as well as CD5 controlled drugs must not be accessible to the public for self-selection, and should therefore be stored in the dispensary. A designated and adequate space must be provided in the dispensary for the storage of prescription veterinary medicines<sup>6</sup>.
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- Public entry into the dispensary itself must be restricted and such entry should be prohibited except for persons authorised for a specific purpose.
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- The boundary between the dispensary and the non-prescription medicines/other professional services area should be appropriate in design, ensuring that the supervision of the sale and supply of all medicinal products and other professional activities is facilitated, while also maintaining adequate security and confidentiality of the dispensary activity.
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8 Refer to PSI's Guidelines on Patient Consultation areas in Retail Pharmacy Businesses.

### 3.3.3 Space and Layout

- The environment within which a pharmacist carries out their professional role in particular within the dispensary, should support high quality patient care.

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- The dispensary size and layout, including the surface area of the dispensary bench, must reflect and be sufficient for the volume of prescriptions dispensed. It must take practice-specific variables, such as service provision and staffing levels, into account.

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- The dispensary size and layout must facilitate a safe and efficient workflow. It must permit direct supervision by the pharmacist of, and communication between, all staff involved in the preparing, compounding or dispensing of medicinal products.

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- The dispensary should be organised to keep distractions to a minimum. Adequate, clear uncluttered bench space must be available to accommodate all dispensing activities.

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- Sufficient space must be available for the safe and effective storage of all dispensary medicines.

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### 3.3.4 Fixtures and Fittings

- All fixtures and fittings within the dispensary must be fully finished to a professional standard and in good condition, suitable and adequate for the purpose for which they were intended. Appropriate shelving and fixtures must be in place so that no medicinal products are stored on the floor, on stairs, in passageways or in toilets<sup>6</sup>.

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- The dispensing bench and all working surfaces must be clean and uncluttered, cleanable, and impervious to dirt and moisture. All working surfaces should be smooth and have a minimal number of joints, which must be sealed to prevent entry of moisture or liquids.

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- Specific work areas should be identified and appropriately maintained for the purpose of extemporaneous preparation and for monitored dosage services, including the use of additional equipment such as robotics.

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- The dispensary should be well-lit and sufficiently ventilated and must be maintained hygienically and be free from all sources of contamination.

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- The dispensary must have arrangements for the proper storage and disposal of all types of waste materials<sup>9</sup>.

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- A clean sink of impervious nature and surround, with a plumbed waste pipe must be present in the dispensing area. The sink should be used for professional activity only and both hot and cold water must be available.

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- A source of drinking (potable) water should also be present in the dispensary.

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- The use of televisions or radios and/or other broadcast telecommunications devices or media should be appropriate to a healthcare facility and should not be a source of distraction within the dispensing area.

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9 Refer to PSI's Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business.

### 3.3.5 Storage Areas within the Registered Premises

- All storage areas and facilities within the registered premises, including fixtures and fittings, walls, ceiling and paintwork must be in keeping with that expected from a healthcare facility and maintained to a high standard. Storage areas should be self-contained. Sufficient storage space should be allocated to allow the orderly management of stock and effective stock rotation<sup>6</sup>.
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- The pharmacist must be able to effectively control all medicinal products and confidential records within the pharmacy, including all areas accessible to employees, and no unauthorised access must be permitted. Control and supervision must be demonstrable with appropriate security and stock control policies and procedures in place.
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- Staff areas, kitchen, bathrooms or unregistered parts of the premises must not be used as storage areas.

### 3.3.6 Staff Areas

- Adequate staff facilities should be available, including a separate area for staff to prepare and eat food. Eating must not be permitted in the dispensing area. Adequate heating and lighting should be provided in all employee areas. All staff areas, including fixtures and fittings, walls, ceiling and paintwork should be in keeping with that expected from a healthcare facility and maintained at a good standard.

- Provision should be made for toilet and hand-washing facilities for staff, with both hot and cold water. The toilet area should not open directly into the dispensary and must not be used for storage. Sanitary facilities must be appropriate to the particular purpose of such area in line with health and safety requirements in the workplace.

## 3.4 Health and Safety, and Related Legislation, in a Retail Pharmacy Business

- Regard and due consideration must be given to the health and safety of the public and pharmacy staff at all times.
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- Pharmacy owners and superintendent pharmacists should be aware of other legislation relevant to premises including relevant Health and Safety Legislation<sup>10</sup>, The Occupiers Liability Act 1995<sup>11</sup>, Equal Status Acts, Building and Fire regulations, including the Fire Services Act of 1981 and 2003<sup>12</sup>. The “duty of care” in respect to Fire Safety in Buildings rests with the Owner/Occupier under the Fire Services Act 1981.
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- The local Health and Safety Officer and Fire Officer should be contacted for further information and advice in relation to relevant requirements.

10 The main legislation providing for the health and safety of people in the workplace is the Safety, Health and Welfare at Work Act 2005 and the Safety, Health and Welfare at Work (General Application) Regulations 2007; accessible, with all related legislation, via: [www.irishstatutebook.ie](http://www.irishstatutebook.ie).

11 For more information on the application of the principles of ergonomics and information on negligence and occupiers liability visit [www.hsa.ie](http://www.hsa.ie).

12 For more information on fire regulations, individual premises requirements and compliance guidance visit the Department of the Environment’s website at [www.environment.ie](http://www.environment.ie).

### 3.5 Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of premises requirements outlined in these guidelines and for any pharmacy-specific methods of premises maintenance to govern the following:

- Cleaning and maintenance for all areas of the premises.
- Security, including security assessments, on-going security audits and appropriate training of personnel.
- Disability access.
- Management of emergency situations, such as loss of electrical power or flooding.

These policies and 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.

### 3.6 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 written policies and procedures in place in respect of specific aspects of the guidelines, taking into account 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. In all care settings appropriate premises standards must be achieved and maintained by the pharmacy owner as well as the superintendent and supervising pharmacists.

Notwithstanding that an appropriate standard of premises must be maintained, it is recognised that some specific requirements of these guidelines may not be directly applicable to certain care settings.

## 4. References

- The Pharmacy Act 2007.
- Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
- Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008.
- Community Pharmacies serving people with disabilities; Equality Authority and Irish Pharmacy Union.
- The Safety, Health and Welfare at Work, (General Application) Regulations 2007.
- Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended).
- Design for patient safety: a guide to the design of the dispensing environment; NHS National Patient Safety Agency; 2007.
- The Pharmaceutical Society of Northern Ireland's Standards for Registered Pharmacy Premises (Community); January 2010.
- Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017).
- European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No.786 2007) (as amended).
- Accessibility for Customers with Disabilities in Community Pharmacies – Some Practical Advice; Equality Authority.

Relevant legislation can be accessed through the PSI website [www.psi.ie](http://www.psi.ie), and is also available from [www.irishstatutebook.ie](http://www.irishstatutebook.ie).

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## 5. Self-assessment Checklist

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

Ask Yourself	Yes	No	N/A	Required Action
Is the premises a fixed premises (that does not include a vehicle, trailer, caravan, or other structure which may be transported on, in or attached to a vehicle)?				
Is the certificate of registration of the supervising pharmacist and of the retail pharmacy business conspicuously displayed at the premises?				
Is the pharmacy premises easily identifiable as a healthcare facility?				
Is the building of the registered premises of the appropriate standard?				
Are the public entrances to the pharmacy clear and accessible at all times and are pathways to the front of the premises safe, well maintained and level?				
Are all areas of the external pharmacy premises and façade, including signage, in a good state of repair and decoration?				
Is the pharmacy title/trading name clearly displayed near public entrances?				
Are all window displays appropriate to a healthcare facility and do not compromise security?				
Has a security audit been carried out?				
Is the storage of all medicinal products, including all associated hard and electronic records, taking place appropriately and securely within the retail pharmacy premises itself?				
Are the premises safe and accessible to all patient groups?				
Does the layout of the pharmacy facilitate the pharmacist to supervise the sale and supply of medicines?				
Are adequate and suitable lighting, heating and ventilation in place in the pharmacy?				

Ask Yourself	Yes	No	N/A	Required Action
Is there a suitable waiting area provided for patients, with adequate seating?				
Is a dedicated area which allows for patient counselling available, with a visual barrier to prevent unauthorised sight of patient records, prescriptions or dispensed medicines?				
Are the premises maintained in an orderly, clean and hygienic manner?				
Is the cleaning schedule available?				
Do patients have ease of access to dispensing services?				
Is the dispensary accessible only to those authorised to access it and is it readily identifiable?				
Are medicinal products that are subject to prescription and CD5 controlled drugs stored in the dispensary?				
Is the dispensary organised, clean and uncluttered?				
Is sufficient space available for the storage of all dispensary medicines?				
Are all storage areas and facilities maintained to a high standard?				
Are adequate staff facilities available?				
Are suitable written policies and procedures in place?				
Are the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures?				