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PSI
THE PHARMACEUTICAL SOCIETY OF IRELAND
Cumann Cógaiseoirí na hÉireann
THE PHARMACY REGULATOR

DRAFT GUIDELINES FOR PUBLIC CONSULTATION

GUIDELINES ON THE PREMISES AND EQUIPMENT REQUIREMENTS OF A RETAIL PHARMACY BUSINESS

To facilitate compliance with Regulations 4(1), 4(2) and 4(4) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

Comments are welcome in writing, preferably by email to consultation@thePSI.ie or by post to **Public Consultation, The Pharmaceutical Society of Ireland (PSI), PSI House, Fenian Street, Dublin 2.**

The closing date for receipt of submissions is **Friday 20th July**, 2012.

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)

Contents

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 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 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 sub-paragraph (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".

By signing the "*Statement by Pharmacist and on Behalf of a Corporate Body"*, as required by Section 28(a) of the Act, the superintendent undertakes to comply in full with the Act and all Regulations and professional guidelines as are in force. It must also be borne in mind that pharmacy owners, in completing their annual continued registration application forms, provide an undertaking, in the form of a declaration, that they too will ensure full compliance with the Act and all Regulations and professional guidelines as are in force. Failure to comply with these guidelines may be regarded as misconduct on the part of a pharmacy owner for the purposes of sections 36 of the Act and/or pharmacists, as appropriate, for the purposes of sections 35 of the Act. The reference to a pharmacy owner also includes references to a director of the corporate body which owns the pharmacy.

By virtue of section 19 and Part 7 of the Act, the premises of any pharmacy may be inspected to ascertain if they comply with the provisions of the Act and the Regulation of Retail Pharmacy Businesses Regulations 2008 made by the Minister under section 18 of the Act.

3. GUIDANCE ON PREMISES REQUIREMENTS

3.1 'Registered Premises'
3.2 External premises requirements
3.3 Internal premises requirements
3.4 Health and Safety in a retail pharmacy business
3.5 Fire Safety in a retail pharmacy business

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[1].

A pharmacy owner or pharmacist must not carry on a retail pharmacy business from unregistered premises. The name and certificate of registration[2] of the registered 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.

Fixed premises

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 should meet all relevant local bylaws and planning regulations.

Sketch plan / Floor plan

In application for registration or continued registration of a retail pharmacy business, a sketch 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[3].

Pharmacists 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.

1 Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008. (S.I. 495 of 2008)
2 "*Certificate of registration*" refers to a certificate issued under section 20 of the Pharmacy Act and which is for the time being in force.
3 For registration forms and further information contact the PSI, www.thePSI.ie

Notifications of changes in premises

If changes to the sketch plan or any other material changes are required or proposed to be made to those specified in the application for registration, the pharmacy owner or superintendent pharmacist must notify the PSI of the proposed changes[4].

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.
- Public entrances to the pharmacy must be clear and accessible at all times. Pathways to the front of the premises must be safe, well maintained and level.
- All areas of the external pharmacy premises and façade, including all windows, sills, doors, and roofs must be must be of sound construction, intact, in a good state of repair and decoration.
- 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.
- Effective pest control measures should be adapted to prevent entry of rodents and other pests.
- 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 hour's services, etc. should be present, prominently displayed, factual and up-to-date.
- 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.
- Illuminated exterior signs should be in good repair and in working order. The pharmacy title/trading name must be clearly displayed near public entrances.

[4] As required by Rule 6, Pharmaceutical Society of Ireland (Retail Pharmacy Businesses)(Registration) Rules 2008. Further information is available via www.thePSI.ie.

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 from the PSI and on its website www.thePSI.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.

- 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 and 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.

- The pharmacy should be fitted with appropriate internal and external security, such as intruder and panic attack alarms, preferably linked to a central monitoring station. External security signage and evidence of the intruder alarm are recommended.

- The superintendent pharmacist must ensure that the storage of all medicinal products, including all associated records and recording equipment, takes place appropriately and securely within the retail pharmacy premises itself. 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[5]. They must ensure the necessary training is implemented and take all reasonable precautions to prevent burglary and ensure the safety of premises and staff.

- The PSI may request evidence of security documentation during the course of routine inspections, prior to the opening of 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.

[5] For detailed guidelines on the storage of medicinal products, please refer to *Guidelines on the Storage of Medicinal Products within a Retail Pharmacy,* accessible via PSI website www.thePSI.ie.

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.

- Under the Equal Status Acts 2000 to 2004[6], 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.

- Reasonable accommodation must be made in order for patients with disability, as well as for employees with disability, to access the premises unaided and with ease[7]. Examples of measures taken should include signage to indicate that guide dogs and other service dogs are welcome on the premises and ensuring that there are no steps, lips or saddles at the door and that it is wide enough to admit wheelchair users (at least 800mm clear opening width)[8].

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. Pharmacists and pharmacy staff must present themselves in a manner that clearly identifies their role and function.

- The layout and fittings in respect of the storage of medicinal products must facilitate their appropriate storage and supervision of their sale or supply by the pharmacist. A mechanism should be in place whereby the patient is made aware that there is ready access to a pharmacist.

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

- A suitable waiting area with seating option should be provided for patients, giving consideration to the privacy of others.

- 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[9].

- 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 health care facility.

- All floors within the registered premises should be undamaged, intact and with an even surface. Flooring should be of a cleanable material and should be clean. Carpets are not recommended. Spillages should be dealt with directly and appropriate safety notices must be used to identify wet or slippery floors[10]. In so far as is practical, aisles must be clear of obstacles.

- 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.

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.

- 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.

[9] Refer to *Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses*, accessible via www.thePSI.ie.

[10] Further information on prevention of *Slips, Trips and Falls*, accessible from the Health and Safety Authority: www.hsa.ie).

- Public entry into the dispensary itself must be restricted, with appropriate surveillance and barriers in place and such entry should be prohibited except for persons authorised for a specific purpose.

- 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 activity is facilitated, while also maintaining adequate security and confidentiality of the dispensary activity.

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.

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

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

- The dispensary should be organised to keep distractions to a minimum and provide for the safe delivery of patient care.

- Sufficient space must be available for the safe and effective storage of all dispensary medicines and medicines should be stored at an accessible shelf height i.e. pharmacy staff should not have to reach excessively to access them.

Fixtures and Fittings

- All fixtures and fittings within the dispensary must be fully finished to a high 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.

- The dispensing bench and all working surfaces must be clean, cleanable, uncluttered 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.

- Specific work areas should be identified and appropriately maintained for the purpose of extemporaneous preparation and for monitored dosage services.

- The dispensary should be well-lit and sufficiently ventilated and must be maintained hygienically and be free from all sources of contamination. The dispensary must have arrangements for the proper storage and disposal of all types of waste materials.

- A clean sink of impervious nature and surround and 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.

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

- 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.

3.3.3 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 health care 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.

- 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.

3.3.4 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 health care facility and maintained at a good standard. Entry to all staff areas and facilities, including stock rooms, toilet facilities, communal areas and administration offices must be controlled and restricted.

- 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. A "Now wash your hands" or similar reminder notice (professionally produced) should be displayed in the toilet area.

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. Pharmacy owners must ensure that working conditions comply with all relevant Health and Safety Legislation, as well as tobacco and smoking related legislation[11].

- Premises occupiers must also act in accordance with the Occupiers Liability Act, 1995 and the laws relating to negligence and take all steps required to prevent personal injury occurring in their premises.

- Pharmacy owners should be familiar with the principles of ergonomics[12] and proactively implement relevant recommendations in order to reduce health risks to staff members and prevent associated errors in the dispensary.

- Premises must comply with all relevant Building and Fire regulations[13], including the Fire Services Act of 1981 and 2003. The "duty of care" in respect to Fire Safety in Buildings rests with the Owner/Occupier under the Fire Service Act, 1981. The local Fire Officer should be contacted for further information and advice in relation to relevant requirements.

- In the event that renovating, decorating or refitting is likely to impact on the health and safety of the public and/or staff then it is advisable to schedule such works after hours (bearing in mind the requirement to restrict access to the pharmacy to authorised personnel/supervised by authorised personnel at all times) or to close the pharmacy for the duration of the works or relocate temporarily[14].

[11] 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.

[12] For more information on the application of the principles of ergonomics and information on negligence and occupiers liability visit www@hsa.ie.

[13] For more information on fire regulations, individual premises requirements and compliance guidance visit the Department of the Environment's website at www.environ.ie

[14] Contact the PSI for further advice, www.thePSI.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. Cleaning and maintenance procedures should be developed and maintained for all areas of the premises.

There should be procedures in place which outline the processes involved in maintaining effective security, including security assessments, on-going security audits and appropriate training of personnel.

There should be a specific policy ensuring reasonable accommodation is made for patients and employees with disability, ensuring the equal access requirements under the Equal Status Acts are fulfilled.

The arrangements and layout of the premises must 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 and a policy must be in place which ensures this.

Every pharmacy should have documented procedures and policies in place to facilitate compliance with all relevant Building and Fire Regulations as well as Health and Safety legislation.

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 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. In all care settings appropriate premises standards must be achieved and maintained by the pharmacy owner as well as the superintendent and supervising pharmacists.

References

1. The Pharmacy Act 2007
2. Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)
3. Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008
4. *Community Pharmacies serving people with disabilities* (joint initiative of Equality Authority and IPU)
5. The Safety, Health and Welfare at Work, (General Application) Regulations 2007
6. Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) (S.I. No. 540 of 2003) (as amended)
7. Pharmacy Practice Guidance Manual, www.thePSI.ie
8. NHS National Patient Safety Agency - *Design for patient safety*
9. The Pharmaceutical Society of Northern Ireland's *Standards for Registered Pharmacy Premises (Community).* January 2010.
10. Misuse of Drugs Regulations 1988 (S.I. No. 328)(as amended)
11. Article 26(2) Misuse of Drugs Regulations 1988; Standard Specification (Burglar-Resistant Cabinets for the Storage of Controlled Drugs) Declaration, 1985 (I.S. 267:1985)
12. Misuse of Drugs (Safe Custody) Regulations, 1982 (S.I No.321 of 1982) (as amended)
13. European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No.786 2007)(as amended).
14. *Accessibility for Customers with Disabilities in Community Pharmacies – Some Practical Advice*; accessed via www.equality.ie.

All Relevant legislation is accessed via www.irishstatutebook.ie and/or www.thePSI.ie

Guidelines on the Equipment Requirements of a Retail Pharmacy Business

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

Contents

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 equipment that is 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 the delivery of pharmacy services using equipment that is fit for purpose and well maintained, and to ensure that the required governance arrangements are in place at all times so as to adequately protect and promote the health and safety of the public.

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. 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 equipment requirements 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.

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 equipment and facilities are fit for purpose for the provision of pharmacy services and are well maintained, facilitating a safe and effective working environment.

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 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(4) of the Regulation of Retail Pharmacy Businesses Regulations 2008, in respect of equipment and procedures requirements and appropriate staffing arrangements, which are set out as follows:

"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 sub-paragraph (a) of this paragraph, he or she has regard for the health, safety and convenience of the public".

(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".

By signing the "*Statement by Pharmacist and on Behalf of a Corporate Body*", as required by Section 28(a) of the Act, the superintendent undertakes to comply in full with the Act and all Regulations and professional guidelines as are in force. It must also be borne in mind that pharmacy owners, in completing their annual continued registration application forms, provide an undertaking, in the form of a declaration, that they too will ensure full compliance with the Act and all Regulations and professional guidelines as are in force. Failure to comply with these guidelines may be regarded as misconduct on the part of a pharmacy owner for the purposes of sections 36 of the Act and/or pharmacists, as appropriate, for the purposes of sections 35 of the Act. The reference to a pharmacy owner also includes references to a director of the corporate body which owns the pharmacy.

By virtue of section 19 and Part 7 of the Act, the premises of any pharmacy may be inspected to ascertain if they comply with the provisions of the Act and the Regulation of Retail Pharmacy Businesses Regulations 2008 made by the Minister under section 18 of the Act.

3. GUIDANCE ON EQUIPMENT REQUIREMENTS

The pharmacy owner and superintendent pharmacist must ensure that the pharmacy is fully equipped with a suitable operational range of equipment, including equipment appropriate for extemporaneous dispensing, to safely provide for the range of pharmaceutical services provided.

A high standard of equipment maintenance and cleanliness must be consistently applied. Equipment should be maintained, serviced and calibrated in accordance with the manufacturer's instructions and records of such service and calibration should be kept.

3.1 Pharmacy Communication Equipment Requirements
3.2 Dispensing Equipment Requirements
3.3 Equipment safety within the pharmacy
3.4 Required Reference Material
3.5 Controlled drug safe requirements
3.6 Policies and Procedures
3.7 Particular Care Settings

3.1 Pharmacy Communication Equipment Requirements

- The pharmacy should operate with a direct, dedicated telephone line. A laser printer and photocopier/scanner are recommended. Internet access should also be provided. A fax machine should also be available and an operating procedure should be in place to ensure compliance with all relevant legislation and guidance.

- An appropriate computerised patient medication record system must be available and password protected. Written policies and procedures must be in place to ensure the acceptable usage of the patient medication records within the pharmacy and to facilitate compliance with applicable Data Protection legislation[15]. An arrangement for regular maintenance by a reputable hardware/software provider is recommended. Adequate backups must be made of records which are maintained electronically.

- Data protection requirements and information security procedures must be applied to the use of all exchange of information, electronic or otherwise, and includes governance of remote backups and transportable media. It is important that requirements for data protection must also be complied with in relation to the closure of a pharmacy[16].

[15] The Data Protection Act 1988 and 2003 impose certain obligations on those keeping personal information on computer and confers rights on whom such information is kept; accessible via www.dataprotection.ie.

[16] Refer to PSI *Guidelines on Managing the Closure and cancellation of the Registration of A Retail Pharmacy Business* which facilitate compliance with Section 59 of the Pharmacy Act 2007 and Rule 7 of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008)

- Computer Screens /Visual Display Units (VDUs): There is a range of measures that employers are required by law to take in order to minimise the risks to staff from working on VDUs[17]. The requirements apply to all staff that regularly use VDUs as a significant part of their daily work. Employers must ensure workstations are well designed by and any identified risks are remedied.

3.2 Dispensing Equipment Requirements

3.2.1 Equipment and containers for dispensed medication

A suitable range of containers (glass and/or plastic as appropriate) must be available to provide for the safe and appropriate supply of medicinal product, such as:

- Containers suitable for the packaging and dispensing of tablets/capsules, liquids, creams, ointments and pastes in a range of sizes
- A range of Child Resistant Closures (CRCs) to fit tablet and liquid containers of varying capacity
- A range of non-CRC closures (for appropriate patients)
- A range of opaque and clear glass medicine bottles as appropriate for product dispensed.
- A range of spoons and/ or syringes for measuring oral liquid doses.
- A range of plastic medicine bottles for methadone (if required). All take away methadone doses must be dispensed with CRCs and appropriate dosing measures[18]
- Re-sealable plastic bags or cardboard cartons for broken bulk blister packed medicinal products
- A supply of disposable plastic cups should be available for patients who wish to consume medicinal products in the pharmacy.

All such containers must be stored within the registered premises so as to be under appropriate storage conditions. Containers should have the lids applied as soon as the box or shrink wrap is opened in order to prevent contamination of containers. The re-using of containers is not appropriate under any circumstances.

[17] The Health and Safety Authority has published guidance on the Safety, Health and Welfare at Work (General Application) Regulations 2007 and a list of frequently asked questions about VDUs and the workplace, accessible via www.hsa.ie

[18] Methadone must be dispensed in accordance with the PSI's *Guidance for Pharmacists on the Safe Supply of Methadone*, accessible via www.thePSI.ie

3.2.2 Equipment for extemporaneous dispensing

- A fit for purpose electronic balance[19] – it may be necessary to have two instruments depending on the weights of products to be determined (appropriately maintained and calibrated).
- Set of certified metric weights (appropriately maintained and calibrated).
- Weighing boats.
- Range of graduated Type A glass measures and appropriate measuring devices to measure volumes from 0.05ml to 500ml, e.g. pipettes and syringes.
- Suitable set of mortars and pestles including one glass set.
- A suitable range of ointment jars including amber glass jars and suitable range of amber glass bottles. The pharmacist must be satisfied that the container ensures stability of the product.
- Suitable ointment slab (glass or marble depending on product).
- Glass stirrer and stainless steel spatula.
- Specialised clothing such as protective gloves, masks and hair nets should be available and worn where appropriate.
- Compounding Worksheets must be available in order to record details of the compounding process, working formula and any specific formulation or reference sources used where applicable.

A pharmacist must be prepared to dispense an extemporaneous preparation on foot of a prescription except where the prescribed formulation of a product or suitable alternative with an appropriate marketing authorisation is available commercially, or where, in their professional opinion, to do so is not in the best interest of the patient, in which circumstances the pharmacist should facilitate alternative arrangements for the patient[20].

Child Resistant Closures (CRCs)

Every pharmacy must have CRCs and non-CRCs available for dispensing. All dispensed liquid medicinal products should be supplied in a container utilising a CRC unless the prescriber, the patient or their representative directs otherwise (for example where a patient will have a physical difficulty opening the container) and/or the pharmacist in their professional judgment considers this appropriate; or unless a CRC is not suitable due to the physical nature of the product. Any such decision not to use a CRC should be supported by appropriate recording of this intervention in the patient's medication record.

[19] See Appendix 2, Note on Weighing Instruments used in Pharmacies
[20] See also explanatory note on extemporaneous dispensing provided in Appendix 1: Note on Extemporaneous Dispensing

Where a preparation is supplied in a manufacturer's original pack which is not a CRC, the pharmacist should replace the closure with a child-resistant one where suitable. Any patient receiving a product that does not have a CRC should be advised of the imperative to keep this out of the reach and sight of children.

Labelling Equipment

Adequate labelling facilities must be present on site. All labels for dispensed medicinal products must be indelible and be mechanically or electronically printed, using a suitable font type and size, in order to ensure the clarity and legibility of the written instructions.

Thermal or laser printers should be used where possible. If a dot matrix printer must be used, the ribbon should be changed regularly to avoid faint type.

Hand written labels must not be used except in a short-term, emergency situation. In situations where hand written labels are unavoidable, all labelling requirements must be included as per *Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended),* and any instructions or details on the hand written label should be reinforced verbally when counselling the patient or their representative/carer. When hand writing labels, a manual record should be maintained for future input into the patient's electronic medication record.

Tablet/capsule counter

A suitable means of counting tablets and capsules should be available. The pharmacist must select the most appropriate apparatus for the particular medication. Test counts should be carried out regularly. The supplier or manufacturer should be contacted if inaccuracies are found.

Medicinal products should not be touched by hand. Counting equipment must be carefully cleaned routinely after use to prevent cross-contamination of product, particularly after working with uncoated tablets. Special care must be taken when dispensing product where there is particular risk associated with potential cross-contamination (such as penicillins).

Pharmaceutical Refrigerators

A purpose-built pharmaceutical refrigerator must be used for the storage of cold chain medicinal products and used and maintained in accordance with PSI *Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business*. A domestic fridge is not appropriate for the storage of medicinal products. Food and drink should never be stored in this refrigerator.

Waste Disposal Facilities

Appropriate disposal facilities are required for the various types of pharmacy waste including waste/expired medicinal products, sharps, hazardous waste and general waste. Disposal facilities for confidential information must be in place and, as appropriate, for additionally proposed services. An on-site shredder or access to appropriately secure shredding facilities must be provided.

Any excess labels, used printer ribbon or paper containing patient's details should be rendered indecipherable or destroyed in a manner appropriate for confidential material, prior to disposal. To protect the patient's right to privacy, the pharmacist must satisfy themselves that appropriate measures have be taken to prevent disclosure of sensitive information, inadvertently or otherwise.

Pharmacy Balances and calibration weights

Appropriate and accurate measuring apparatus must be available in a pharmacy and superintendent and supervising pharmacists must ensure that there are robust written policies, procedures and training in place for its use and maintenance. Balances and calibration weights used in pharmacies must be fit for purpose and verified as such prior to use.

Checks of the pharmacy balance must be performed frequently and prior to each use and appropriate records, including calibration certificates, must be maintained accordingly[21]. Certified metric weights should never be handled as this will affect their accuracy and introduces a risk of contamination.

All apparatus must be routinely assessed and replaced if not of a suitable standard. Obsolete or damaged equipment must not be used and must not be retained on the premises.

For further detail on weighing scales, balances and weights that are appropriate for use with a retail pharmacy business and for guidance on self-checks and calibration, see Appendix 2: Notes on Weighing Instruments used in Pharmacies.

Equipment cleaning schedule

Preventative measures to reduce incidence of contamination must be in place. All equipment used in the dispensing and compounding of medicinal products must be cleaned by a trained member of staff regularly and before and after use in order to minimise microbial and/or cross-contamination. Cleaning records should be maintained and available for inspection. Severe allergic reactions can be initiated in previously sensitised persons by very small amounts of certain drugs or excipients. Gloves should be worn when cleaning the equipment within the pharmacy.

No extemporaneous preparation should be undertaken while cleaning is in progress.

[21] See Appendix 2 'self-checks': Notes on Weighing Instruments used in Pharmacies

3.3 Equipment safety within the pharmacy

The pharmacy employer has a legal duty to ensure the employees' safety, health and welfare at work as far as is reasonably practicable. In order to prevent workplace injuries and ill health the employer is required, among other things, to:

- Provide and maintain a safe workplace which uses safe equipment
- Prevent risks from use of any article or substance and from exposure to physical agents
- Provide instruction and training to employees on health and safety
- Provide protective clothing and equipment to employees
- Appoint a competent person as the organisation's Safety Officer

PPE (Personal Protective Equipment)

The employer and the superintendent pharmacist must inform all pharmacy staff about any risks and tasks that require the wearing of protective equipment for example, the compounding of specific extemporaneous preparations or the handling of cytotoxic medication. Protective equipment must be provided depending on the service being provided (such as protective clothing, eyewear, and gloves).

Only employees who have received appropriate training and have reached the required level of proficiency should operate pharmacy equipment and carry out the tasks within a particular procedure. Employees also have a duty to take reasonable care for their own safety and to use any protective equipment supplied.

3.4 Required reference material

A minimum specified range of reference materials relating to the sale and supply of medicinal products, as well as to the statutory regulations pertaining to the practice of pharmacy, must be readily accessible on an on-going basis to all pharmacists and pharmacy staff.

Reference sources provided must be appropriate, up to date and sufficient to meet the practice-specific requirements of the individual pharmacy and promote the informed and rational use of both prescription and non-prescription medicines.

Access to electronic databases and online reference sources is acceptable and in many cases preferred, as only current reference material should be made available. Old versions of reference sources should be discarded where there is a risk of out of date information being used.

Essential references

There are a number of essential references that must be present on site within all pharmacy premises, including:

- A complete **drug reference source**, current edition or access to up-to-date online edition (such as Martindale: The Complete Drug Reference).

- **Current British National Formulary (BNF)**, access to the most up-to-date edition must be available.
- **Paediatrics reference**, current edition or access to up-to-date online edition (such as the BNF for Children (BNFC), Paediatric Formulary (Guy's, St. Thomas' and Lewisham Hospitals), Neonatal Formulary (The Northern Neonatal Network).
- **Drug interaction reference**: The pharmacy must have a drug Interaction Alert functionality as part of its computer dispensing system as well as an up to date hard copy and/or access to an online edition of an appropriate Interactions publication such as Stockley's Drug Interactions (Ed. Stockley) (Pharmaceutical Press); Medscape Drug Interaction Checker (Online www.medscape.com). The interactions alert functionality should not be disabled during dispensing and the superintendent and supervising pharmacist must ensure the appropriate alert setting is activated.
- Access to **up-to-date pharmacy legislation**, including www.thePSI.ie and www.irishstatutebook.ie.
- Access to **Summary of Product Characteristics (SmPCs)** for medicinal products authorised in Ireland, accessible via, for example, the Irish Medicines Board (www.imb.ie); The Irish Medicines Formulary (IMF) and/or IPHA Medicines Compendium (www.medicines.ie).
- Access to **PSI guidelines**, **guidance documents, alerts and publications**, such as monthly PSI pharmacist eNewsletter.

Recommended texts

A current pharmacology textbook; MIMS (current edition); A medical dictionary and an up-to-date reference for non-prescription medicines are also recommended[22].

Service-related references

Comprehensive and up-to-date reference material and support documentation must be made available relating to the implementation, practice and standards requirements for the provision of pharmacy services and pharmaceutical care offered by the specific pharmacy. The superintendent pharmacist must review the services provided and ensure appropriate reference sources are made available where relevant, such as for Psychiatric care services, Alternative/Herbal Medicinal Products, Palliative Care, Pregnancy and/or Lactation, A veterinary medicines reference, Contraception and Immunisation services.

A range of good quality, up-to-date health care leaflets, promotional material and information should be available to promote health awareness to individual patients and the broader community.

[22] A comprehensive range of reference sources is available online from sources such as Pharmaceutical Press (www.pharmapress.com) and www.medicinescomplete.com.

3.5 Controlled Drug Safe Requirements

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 a CD safe/cabinet compliant with all relevant legislation. CDs awaiting destruction should be segregated from stock, clearly labelled and stored in a specifically designated part of the CD safe/ cabinet. The key (or access code, if the cabinet has an electronic keypad) should be in the safe keeping of the pharmacist personally supervising the pharmacy at any given time and all access controlled by that pharmacist. Keys to the CD cabinet must be stored securely overnight.

Standards and requirements that must be met by CD storage safes or cabinets

Appendix 3 of this document outlines the Schedule of Requirements In Relation To Safes And Cabinets Used For Keeping Drugs taken from the *Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended)*. Although this Schedule does not specify 'Controlled' drugs in the title, Article 5 within the Regulation itself specifies that such requirements must be met (or exceeded) when storing any schedule 2 and 3 CDs. Therefore CD cabinets must, at a minimum, meet the requirements listed in Appendix 3.

The (Misuse of Drugs) Regulations, 1988 (S.I. No. 328/1988) also impose an obligation on persons lawfully having possession of CDs to keep such drugs in a locked, fixed container so as to prevent unauthorised access to them. To further facilitate article 26(2) of the Regulations, the Minister for Health requested the Institute for Industrial Research and Standards to develop an Irish Standard for such a safe or cabinet. This resulted in the development of *Standard Specification 267: 1985 (Burglar Resistant Cabinets For the Storage of Controlled Drugs)*[23].

Regulation 4(4) of the Retail Pharmacy Businesses Regulations 2008 also states that the pharmacy owner shall ensure that the safe or cabinet has a sufficient capacity to permit the orderly storage and safe keeping of all relevant CDs. An arbitrary capacity limit of 0.08m^3 is imposed by the Irish Standard 267:1985. Stock should be well spaced and easily seen. If more storage space is required, more than one cabinet must be used.

Certification of CD Cabinets

There are many cabinets on the market which purport to be designed specifically to meet or exceed the requirements for the safe storage of CDs and other substances. The onus lies with both the superintendent pharmacist and the pharmacy owner to provide and maintain evidence that all CD safes or cabinets used for the storage of schedule 2 and 3 CDs meet or exceed the legal requirements.

[23] For access to Irish Standard 267: 1985 (Burglar Resistant Cabinets For the Storage of Controlled Drugs), visit: www.standards.ie.

Manufacturers and suppliers of safes or cabinets are advised to seek certification, as third party endorsement, under the Scheme for the Irish Standard 267: 1985, the standard currently referred to in the Misuse of Drugs (Safe Custody) Regulations 1982 (as amended). When purchasing a safe or cabinet for the storage of CDs, the superintendent pharmacist and pharmacy owner must request valid and appropriate certification from the manufacturer or supplier, verifying that the unit is fit for purpose.

Irish Standard 267: 1985 (section 5 'Marking') states that CD cabinets should be permanently and legibly marked with the following information:

(a) The manufacturer's name and address
(b) The capacity of the cabinet in cubic metres
(c) The type approval test reference number
(d) The inscription "I.S.267: 1985"

If this exact information is not permanently and legibly marked on the CD safe or cabinet, the unit may nevertheless be acceptable if, when examined, it does not depart from the constructional and other specifications which are necessary to render the unit fit for purpose as outlined in IS 267: 1985 and the Schedule[24] ('Requirements in Relation to Safes and Cabinets Used For Keeping Drugs') of Misuse of Drugs (Safe Custody) Regulations.

In these cases where the safe does not have the markings or meet criteria as outlined in IS 267:1985, in order for the unit to be deemed acceptable, a certificate can also be issued by the Gardaí (provided by sub-article 5(3) of the 1982 Misuse of Drugs (Safe Custody) Regulations). It must be noted however, that unless previously revoked, these certificates are only valid for two years. This certificate issued should be kept readily available in the pharmacy. If the CD safe or cabinet in the pharmacy does not hold a certificate of compliance to the relevant legal standards, it is necessary to apply to An Garda Síochána for this certification. Regulation 6(2)(b) of the Misuse of Drugs (Safe Custody Regulations) indicates 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 CDs are kept and certify that that safe or cabinet meets the requirements and provides an appropriate degree of security.

Although a third party may certify a CD safe or cabinet, the superintendent pharmacist, as the individual responsible for the overall control of medicines management in the retail pharmacy business, must ensure appropriate standards of storage of CDs and has a legal obligation to ensure the Misuse of Drugs (Safe Custody) Regulations 1982 (and Schedule therein) and all other relevant legislation, are fully complied with.

[24] Provided in appendix 3 of these guidelines

3.6 Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of equipment requirements outlined in these guidelines and for any pharmacy-specific methods of equipment maintenance. Cleaning and maintenance procedures should be developed and maintained to include all equipment used within the premises.

Policies and procedures must be in place to govern the safe and appropriate use and maintenance of equipment and to ensure the orderly storage and safe keeping of all medicinal products within the premises, maintaining and improving the health, wellbeing, care and safety of patients and the public.

3.7 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. 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.

The pharmacy owner and superintendent pharmacist must ensure that appropriate equipment is provided for the storage, preparation, dispensing, compounding, sale and supply of medicinal products and the effective maintenance of such equipment must be demonstrable by the superintendent pharmacist in all care settings.

Appendix 1

Notes on Extemporaneous Dispensing

Extemporaneous dispensing/compounding is defined as the preparation and supply of a single unit of issue of a product which is intended for immediate use by a specific patient.

Proprietary products commercially available are preferable to compounded products because they are subject to formal quality control procedures[25]. However, some preparations continue to be routinely prescribed and compounded in practice for a variety of reasons e.g. sensitivity to commercial products/ingredients or availability issues. The pharmacist, in co-operation with relevant health-care professionals involved in patient care should jointly assume responsibility for determining whether a pharmacy-preparation could be of added value, prioritising the medical and safety needs of the patient.

To enable the provision of a full pharmaceutical service, all retail pharmacy businesses must have an appropriate minimum range of equipment available on the premises. It must be remembered that the same standards of safety are expected from a pharmacy-prepared extemporaneous preparation as is expected from a licensed industrial manufacturer. The pharmacist is responsible for ensuring that the product is compounded in a manner that guarantees its quality, safety and efficacy.

All chemicals and materials used in the extemporaneous compounding process must be of appropriate pharmaceutical grade and quality and sourced though appropriately authorised channels.

Labels for extemporaneous products should be prepared before the product is compounded. This is to allow the product to be labelled as soon as it is prepared to avoid potential mislabeling or dispensing errors.

[25] EDQM: Resolution CM/ResAP(2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients, Section 3.1.*Pharmaceutical equivalents on the national market.* Adopted by the Council of Europe Committee of Ministers, 19 January 2011.

Appendix 2: Notes on Weighing Instruments used in Pharmacies

What weighing apparatus are appropriate for use in a pharmacy?

Weighing apparatus must comply with Directive 2009/23/EC, *The Non-Automatic Weighing Instruments Directive*[26] (NAWI). NAWI is the European legislation that sets down the essential requirements for weighing instruments used 'for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories'.

The weighing instrument must be verified (i.e. – the manufacturer or his authorised representative has ensured and declared that the instrument conforms to the requirements of the NAWI Directive and has the certificate referred to in point 4.2 of that Directive which relates to EC unit verification.

To conform to the NAWI directive, the weighing scales used must fulfill criteria outlined in *Annex IV* of that directive, such as:

- The **'CE'** conformity marking shall be affixed to the instrument in a clearly visible, easily legible and indelible form and
- A green sticker at least 12,5 mm × 12,5 mm square bearing a capital letter **'M'** printed in black;

- The identification number(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification.
- As outlined in Annex IV, point 1 of the NAWI Directive, the instrument should also be marked with, for example the manufacturer's mark or name; the accuracy class; maximum and minimum capacity; verification scale interval, (in the form e = …) and the last two digits of the year in which the 'CE' conformity marking was affixed.

If any of these markings are missing, the supplier or manufacturer should be contacted to confirm conformity with the NAWI Directive.

Although many balances originate from non-EU countries, the suppliers have a legal obligation to ensure the instrument is fit for purpose, authorised and certified for the European market. In turn the pharmacist has an obligation to purchase from an authorised supplier that ensures compliance with the NAWI Directive and is therefore capable of ensuring traceability and an effective after-sales service.

[26] Accessible via PSI website, www.thePSI.ie. Directive 2009/23/EC has been transposed into Irish law by S.I. No. 424 of 1992.

The NSAI Legal Metrology Service (LMS)[27] is the statutory body responsible for regulating and supervising weights and measures in the Republic of Ireland. The LMS have powers of inspection in relation to weighing instruments in use in trading premises and the compliance of these instruments with the NAWI Directive.

Which weighing instruments are commonly found in pharmacies?

The weighing instruments most commonly found in pharmacies are either traditional 'Class II' dispensing beam balance or a modern electronic equivalent (recommended). Class II are similar to the 'Class B' beam balances commonly used prior to the introduction of international standardization of accuracy classes.

This classification of a modern electronic balance requires that the manufacturer declares the Maximum and Minimum Capacity of the instrument.

The Minimum Capacity (product of the value of the scale interval (increment) multiplied by either 20 or 50, this being decided by the manufacturer) denotes the point in the range below which the allowed error of the scale is relatively large. It may be necessary to use two scales to cover the range of substances to be weighed.

Older Class B or Class II beam balances do not have the same declaration on Minimum Capacity; however the same attention must be made to ensure that the Minimum capability of the balance is suitable for the amount weighed. Typically, a 50 g balance with increment of 10 mg has a minimum limit of 100 mg. Class B or Class II beam balances must only be used with the weights provided.

Factors to consider when choosing a weighing apparatus for use in a pharmacy

- Typical amounts of substance that will be weighed
- Majority of extemporaneous preparations prepared in pharmacies will require substances in the weight range 100mg to 200g to be weighed, the range of 10mg-2Kg will weigh to 2 decimal places, and (i.e. they can read 10mg changes and not less than 10mg).
- Awareness of the limitations of the scales and not weighing substances outside its range must be set out in the pharmacy's written policies and procedures.
- Where extemporaneous preparations are prepared on a large scale of >200g, a balance weighing in the range of mg-Kg should be used.
- For the weighing of potent active ingredients where weights <100mg are required it is recommended to use a scale capable of reading 1mg
- Minimum capacity, readability and verification scale interval of the scales, and the degree of accuracy which is required must be considered
- The onus is on the individual pharmacist user to ensure that a particular weighing system provides the appropriate accuracy for the actual substance and quantities involved.

[27] NSAI Legal Metrology Service: www.nsai.ie

Which weights should be used with the weighing instrument?

Weights may be classified in accordance with the recommendations of the International Organisation of Legal Metrology (OIML), from Class E1 (highest accuracy class) to Class M3 (M3 - not suitable for pharmacy use).

Most major weight manufacturers make their weights to conform to OIML classifications, though weights designed to meet other/older national specifications are also sometimes available. The onus is on the pharmacist to ensure that the weights used are appropriate to the stability and accuracy required for the environment and application in which it is to be used.

Weights manufacturers should provide information and guidance as to which weights are appropriate for the individual weighing apparatus.

Calibration of dispensary balance and weights

Official annual calibration

It is recommended that the dispensary balance and weights are officially calibrated at a minimum annually. More frequent calibration may be required and pharmacists are expected to document the rationale for the calibration interval. The scales should be calibrated in accordance with the manufacturer's instructions.

In some cases, only the manufacturers can provide an official ‘certificate of calibration’ but the suppliers may provide a certificate of service i.e. proof that an appropriately authorised engineer has serviced the instrument. Calibration of the balance itself should always be carried out on site (i.e. in the pharmacy). If it was sent elsewhere for external certification, calibration would be required again when returned.

Regular ‘Self – Checks’

It should be noted that although many electronic balances have a ‘self-calibration’ function, the only processes that can officially be regarded as ‘true’ calibrations are those certified by a relevant authority. The regular checks for accuracy performed by pharmacists themselves are therefore referred to in this document as ‘self-checks’.

Ongoing self-checks must be performed frequently and prior to each use and appropriate records, including calibration certificates, must be maintained accordingly. When self-checks are carried out regularly, this increases the likelihood that deviations in the accuracy of the equipment are detected, signaling the need for a certified calibration or service. A balance should be self-checked if it has been moved or disturbed for any reason.

All staff carrying out self-checks, must be appropriately trained. The self-checking procedure will be specific to the type of scales or balance. Variations in manufacturers’ recommendations exist therefore the relevant user manual must be referred to, or the manufacturer contacted for information relating to self-checks and calibration.

Environmental considerations

Weighing instruments will be affected to a greater or lesser extent by draughts, vibration, inadequate support surfaces and temperature changes. Electronic weighing instruments can also be affected by other influences, including electrical and electromagnetic interference, and magnetic effects.

Influences may cause instability in the weighing indications, but some can cause consistent indication errors, therefore it should not be assumed that a machine is making correct measurements. Weighing apparatus should not be located close to sources of heat as these are likely to cause measurement problems due to direct heating and the presence of convection currents in the air.

The weighing apparatus should be levelled. The adequacy of the workbench can be checked by tapping and loading the surface next to the machine whilst it is indicating a small load value; If the indication changes, consideration should be given to using a firmer support.

Cleaning of weighing equipment

Weights should always be kept clean, ideally with light dusting with a soft brush. Other more rigorous forms of cleaning (such as with the use of abrasives or polishes) may alter the mass of the weight, in which case recalibration is required.

Except for cast iron weights, they should not be handled with bare hands, but be used either with tweezers, lifters or using nonabrasive gloves. Where tweezers and lifters are used, they should be designed with a suitable surface to avoid metal-to-metal contact.

All equipment used for extemporaneous compounding should be easily accessible and maintained in a hygienic and operable condition following the specific manufacturer instructions. All equipment should be cleaned prior to and after use and a written cleaning schedule and sign off sheet should be maintained.

Appendix 3

SCHEDULE OF REQUIREMENTS IN RELATION TO SAFES AND CABINETS USED FOR KEEPING DRUGS taken from the *Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended)*.

1. In this Schedule, the expression—

"two-leaf door" means a door having two leaves which either close on to each other or on to a central pillar, and the two leaves of any such door shall be treated for the purposes of this Schedule as a single door; "sheet steel" means mild steel sheet being not lighter than 16 gauge.

2. (1) A safe or cabinet shall be constructed of—
(a) pressed and welded sheet steel; or
(b) pressed and welded steel mesh; or
(c) sheet steel or steel mesh welded upon an angle-iron frame of at least 25 millimetres by 25 millimetres section and of at least 5 millimetres thickness.

(2) The clearance between the door and jamb or, in the case of a two-leaf door, between the two leaves of each leaf and a central pillar shall not be greater than 3 millimetres.

(3) Each door shall be fitted with an effective lock—
(a) having at least 5 levers differing from each other or, in the case of a pin and tumbler mechanism, at least 6 pins;
(b) designed to permit at least 1,000 effective key-differs independent of wards or any other fixed obstruction to the movement of the key; and
(c) provided with a dead-bolt which is either of mild steel of at least 19 millimetres by 8 millimetres section or incorporates a suitable anti-cutting device and which has a total throw of at least 12 millimetres.

(4) Where the length of the vertical closing edge of a door exceeds 914 millimetres and the length of the horizontal edge exceeds 457 millimetres the door shall be fitted with two such locks as are specified in sub-paragraph (3) above, one situated at not more than one third of the length of the vertical closing edge from the top and the other at not more than one third from the bottom, but otherwise the lock required by sub-paragraph (3) above shall be situated in the centre of the vertical closing edge.

(5) Where a safe or cabinet is fitted with a two-leaf door, either—
(a) the lock or locks required by sub-paragraphs (3) and (4) above shall be fitted with an integrated espagnolette bolt which is of at least 19 millimetres by 8 millimetres section and which has a total throw, at both the top and bottom, of at least 12 millimetres; or
(b) the second opening leaf shall be secured at the top and bottom by means of internal bolts of mild steel of at least 6 millimetres by 6 millimetres section or 6 millimetres diameter, each of which has a total throw of at least 12 millimetres, the bolt handles being returnable into a holding recess.

(6) A safe or cabinet shall be rigidly and securely fixed to a wall or floor which is soundly constructed by means of at least two rag-bolts each passing through an internal anchor plate of mild steel which is of at least 3 millimetres thickness and which has a surface area of at least 19,355 square millimetres.

(7) Nothing shall be displayed outside a safe or cabinet to indicate that drugs are kept in it.

(8) For the purposes of sub-paragraph (6) "soundly constructed", in respect of a wall or floor, means constructed of solid brick, concrete block or mass concrete, of sufficient thickness, depth and strength to provide a firm and secure anchor.

3. (1) Subject to sub-paragraph (2) below where sheet steel is used in the construction of a safe or cabinet, its edges shall be lapped inwards around the margins of apertures and around the edges of doors in such manner as to be inaccessible from the outside; and where sheet steel is fixed on a framework, it shall be so fixed as to prevent removal from outside the safe or cabinet of which the framework forms part.

(2) Where sheet steel is used in the construction of the door or the leaf of a door of a safe or cabinet, its edges shall not be required to be lapped inwards as required by sub-paragraph (1) above where the sheet steel used is not lighter than 10 gauge and the door or leaf of the door fits flush, or is recessed, so that no edge protrudes when the door is closed.

(3) Steel mesh used in the construction of a safe or cabinet shall be—
(a) welded steel mesh not lighter than 10 standard wire gauge having rectangular apertures not exceeding 75 millimetres by 12 millimetres; or
(b) expanded steel not lighter than 12 gauge having diamond apertures not exceeding 44 millimetres by 19 millimetres.

(4) Except where otherwise specified in this Schedule, the edges of each panel of sheet steel or steel mesh used in the construction of a safe or cabinet shall be arc-welded to a steel frame along their entire length, or, in the absence of a steel frame, continuously arc-welded along the entire length of all joints.

(5) Each hinged door in a safe or cabinet shall be fitted with at least two hinges.

(6) If any part of the hinges of such a door is on the outside of the door, it shall be fitted with at least two dog-bolts of mild steel of similar gauge and dimensions to the frame of the safe or cabinet or an internal flange or rebate running the entire length of the door and so fitted as to prevent access without unlocking in the event of damage to the hinges.

(7) Each lock, bolt assembly and other means of securing doors in a safe or cabinet shall be fitted internally.

(8) The bolt of each lock and each other bolt or catch securing the cover of any aperture in a safe or cabinet shall be protected against cutting or manipulation from the outside.

(9) Each screw, bolt or other fixing device used in the construction of a safe or cabinet shall be such as to be incapable of being removed from the outside and shall be of a strength at least equal to that of the component part which it fixes.

References

1. The Pharmacy Act 2007
2. Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)
3. The Safety, Health and Welfare at Work, (General Application) Regulations 2007, Chapter 5 of Part 2
4. DIRECTIVE 2009/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on non-automatic weighing instruments
5. The Data Protection Act 1988 and 2003
6. Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2008
7. Pharmacy Practice Guidance Manual, www.thePSI.ie
8. NHS National Patient Safety Agency's *Design for patient safety*
9. The Pharmaceutical Society of Northern Ireland's *Standards for Registered Pharmacy Premises (Community).* January 2010.
10. UKAS (United Kingdom Accreditation Service) LAB14 Calibration of Weighing Machines, EDITION 4 November 2006
11. Misuse of Drugs Regulations 1988 (S.I. No. 328)(as amended)
12. Article 26(2) Misuse of Drugs Regulations 1988; Standard Specification (Burglar-Resistant Cabinets for the Storage of Controlled Drugs) Declaration, 1985 (I.S. 267:1985)
13. Misuse of Drugs (Safe Custody) Regulations, 1982 (S.I No.321 of 1982) (as amended)
14. European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No.786 2007) (as amended).

All Relevant legislation is accessed via www.irishstatutebook.ie and/or www.thePSI.ie