

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)

Pharmaceutical Society of Ireland

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Updates made following the enactment of the Misuse of Drugs Regulations 2017¹ (which replaced the Misuse of Drugs Regulations 1988 (as amended)² 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 ('the Act') 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 needed for 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

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, 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.

(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) and shall ensure that the said safe or cabinet has a sufficient capacity to permit the orderly storage and safe keeping of all the relevant controlled drugs, including such veterinary medicinal products as are relevant controlled drugs, as required by the aforementioned Regulation 5.

3. Guidance

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 enable the safe provision of 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 Equipment Requirements

- The pharmacy must operate with a direct, dedicated telephone line. Internet and email access must also be provided.
- A high quality printer and photocopier/ scanner are recommended. A fax machine must also be available in the pharmacy.
- An appropriate computerised patient medication record system must be available and password protected. An arrangement for regular maintenance by a reputable hardware/ software provider is recommended. Adequate backups must be made of records which are maintained electronically.

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) and equipment must be available to provide for the safe storage and appropriate supply of medicinal products, such as:

- Containers 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 plastic medicine bottles and CRC closures for methadone (if required)
- A range of spoons and/or syringes for measuring oral liquid doses
- Re-sealable plastic bags or cardboard cartons for broken bulk blister packed medicinal products
- A range of graduated Type A glass measures and appropriate measuring devices to measure volumes from 0.05ml to 500ml, e.g. pipettes and/or syringes
- A supply of disposable plastic cups should be available for patients who wish to consume medicinal products in the pharmacy

Child Resistant Closures

Every pharmacy must have Child Resistant Closures (CRCs) and non-CRCs available for dispensing. All medicinal products must be supplied in a container utilising a CRC or be supplied in child resistant packaging, 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.

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 that it is 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.
- A high quality printer should be used.

- 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).

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 (e.g. triangle, tablet counter). If a tablet counter is used, test counts should be carried out regularly. The supplier or manufacturer should be contacted if inaccuracies are found.

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 a product where there is a 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*.

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 in line with *PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business*.

Disposal facilities for confidential information must be in place. An on-site shredder or access to appropriately secure shredding facilities must be provided.

3.2.2 Equipment for Extemporaneous Dispensing

- Electronic weighing apparatus ('balance')³
- 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/or syringes
- Ceramic mortar and pestle and glass mortar and pestle
- Range of ointment jars including amber glass jars, and a suitable range of amber glass bottles
- 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

All extemporaneous equipment must be fit for purpose, properly cleaned and properly maintained.

3 See Appendix 1 Notes on Weighing Instruments used in Pharmacies.

Pharmacy Balances and Calibration Weights

Appropriate and accurate measuring apparatus must be available in a pharmacy.

Weighing apparatus must comply with Directive 2009/23/EC, the Non-Automatic Weighing Instruments (NAWI) Directive⁴.

To conform to the NAWI Directive, the weighing scales used must fulfil 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 majority of extemporaneous preparations prepared in pharmacies will require substances in the weight range 100mg to 200g to be weighed. Therefore the pharmacy should have a weighing instrument at least capable of accurately weighing in this weight range. The pharmacist must be aware of the limitations of the scales and must not weigh substances outside its range (i.e. scales may read a weight of 50mg but this does not necessarily mean it is capable of accurately measuring this weight). The range within which the apparatus can accurately weigh must be set out in the pharmacy's written policies and procedures.

Checks of the pharmacy balance must be performed frequently and prior to each use and appropriate records, including calibration certificates, must be maintained accordingly⁵. 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.

⁴ Directive 2009/23/EC has been transposed into Irish Law by S.I. No. 424 of 1992.

⁵ See Appendix 1 Notes on Weighing Instruments used in Pharmacies, 'Regular Self-checks'.

For further detail on weighing scales, balances and weights that are appropriate for use in a retail pharmacy business and for guidance on self-checks and calibration, see Appendix 1 - Notes on Weighing Instruments used in Pharmacies.

3.3 Equipment Safety/ Cleaning within the Pharmacy

Equipment Safety

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, amongst 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

Equipment Cleaning Schedule

Measures must be in place to prevent or reduce contamination of equipment:

- All equipment used in the dispensing and compounding of medicinal products must be cleaned by a trained member of staff regularly in order to minimise microbial and/or cross-contamination.
- Cleaning records should be maintained and be readily available for inspection.
- Gloves should be worn when cleaning the equipment within the pharmacy.
- No extemporaneous preparation should be undertaken while cleaning is in progress.

3.4 Required Reference Material

A specified range of reference materials relating to the sale and supply of medicinal products 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. They must 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, or next most recent edition, or access to up-to-date online edition (e.g. Martindale: The Complete Drug Reference).

- British National Formulary (BNF): Access to the most up-to-date edition must be available.

- Access to a reference for medicinal products authorised in Ireland: It is important that pharmacists must be able to access up to date information on medicines licensed in Ireland and to be aware of a product's status in Ireland for discussions with prescribers and patients. Information on the licensed status of a medicinal product is available from the Health Products Regulatory Authority's (HPRA) website www.hpra.ie, or an up to date version of the Irish Medicines Formulary (IMF), which is an Irish specific publication containing all the licensed information on products authorised in Ireland.

- 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, available at www.psi.ie and www.irishstatutebook.ie.

- Access to Summary of Product Characteristics (SmPCs) for medicinal products authorised in Ireland: For example, the HPRA's website (www.hpra.ie), Irish Pharmaceutical Healthcare Association (IPHA) (www.ipha.ie), Medicines Compendium (www.medicines.ie) for proprietary medicines or IMF as discussed above.

- Access to PSI guidelines, guidance documents, alerts and publications, such as the monthly PSI pharmacist eNewsletter.

- Access to the National Medicines Information Centre (NMIC) information and enquiry answering service which is freely available to all pharmacists practising in Ireland (www.nmic.ie).

Recommended Texts

A current pharmacology textbook, MIMS (current edition), a medical dictionary and an up-to-date reference for non-prescription medicines are also recommended⁶.

Additional References (as dictated by the scope of services provided in the pharmacy)

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. Examples include but are not limited to the following:

- Psychiatric care services

- Alternative/herbal medicinal products

- Palliative care

- Pregnancy

- Breast-feeding

- Contraception

- Immunisation services

- Veterinary medicines

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

6 A comprehensive range of reference materials are available online from sources such as Pharmaceutical Press (www.pharmapress.com) and www.medicinescomplete.com. The NMIC website (www.nmic.ie) provides a list of recommended sources of information.

7 Further guidance is provided in the PSI's Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business.

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

3.5 Controlled Drug Safe Requirements

Controlled Drugs (CDs) listed in either Schedule 2 or Schedule 3 of the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017), must be stored in a CD safe/cabinet compliant with all relevant legislation (See Appendix 2) and related guidance⁷.

Standards and Requirements that must be met by CD Storage Safes or Cabinets

Appendix 2 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 (S.I. No. 321 of 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 2⁸.

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

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 0.08m⁵ 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 on 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.

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 Irish Standard 267: 1985 and the Schedule⁹ (*Requirements in Relation to Safes and Cabinets Used for Keeping Drugs*) of the Misuse of Drugs (Safe Custody) Regulations (as amended).

In these cases where the safe does not have the markings or meet criteria as outlined in Irish Standard 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 (as amended) (and Schedule therein) and all other relevant legislation, are fully complied with.

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. These should also 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.

⁹ Provided in Appendix 2 of these guidelines.

Supplementary policies and procedures should be put in place in retail pharmacy businesses operating monitored dosage systems and utilising robotics in dispensing.

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.

4. References

- Pharmacy Act 2007.

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

- Directive 2009/23/EC of The European Parliament and of the Council of 23 April 2009 on Non-Automatic Weighing Instruments.

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

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

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

- Safety, Health and Welfare at Work, (General Application) Regulations 2007, Chapter 5 of Part 2.

- European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No.786 2007) (as amended).

- Pharmaceutical Society of Northern Ireland's Standards for Registered Pharmacy Premises (Community); January 2010.

- UKAS (United Kingdom Accreditation Service) LAB14 Calibration of Weighing Machines, Edition 4 November 2006.

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

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1	January 2015
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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 a dedicated telephone line, internet and email access, and a fax machine available in the pharmacy?				
Is a computerised patient medication record system available and password protected?				
Are all data protection requirements being adhered to in the managing of data?				
Is adequate backup made of records which are maintained electronically?				
Are a suitable range of containers and equipment available to provide the safe storage and appropriate supply of medicinal products?				
Are all medicinal products supplied in a container utilising a CRC or supplied in child resistant packaging, unless directed otherwise?				
Is adequate labelling equipment available in the pharmacy?				
Is a suitable means of counting tablets and capsules available?				
Is a purpose-built pharmaceutical refrigerator used for the storage of cold chain medicinal products?				
Are appropriate disposal facilities in place for the various types of pharmacy waste?				
Are disposal facilities for confidential information in place?				
Is suitable equipment for extemporaneous dispensing available, including an appropriate weighing instrument?				
Does the employer ensure the employees' safety, health and welfare at work as far as is reasonably practicable?				
Is all equipment used in the dispensing and compounding of medicinal products cleaned by a trained member of staff regularly?				
Are all required reference materials provided appropriate, up-to-date and sufficient to meet the practice-specific requirements of the pharmacy?				
Is a certified Controlled Drug Safe or Cabinet available?				
Are suitable written policies and procedures in place?				
Is the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures?				

Appendix 1

Notes on Weighing Instruments used in Pharmacies

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).

If any of the requirements 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.

The NSAI Legal Metrology Service (LMS)¹⁰ 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.

Suitable Weighing Instruments

Traditionally, the weighing instruments most commonly found in pharmacies were 'Class II' dispensing beam balance. A Class II modern electronic equivalent is now required.

As a result of the introduction of international standardisation of accuracy classes, the 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.

Additional Factors to consider when choosing a Weighing Apparatus for use in a Pharmacy

- Typical amounts of substance that will be weighed. The majority of extemporaneous preparations prepared in pharmacies will require substances in the weight range 100mg to 200g to be weighed.

- 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 scales 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.

¹⁰ NSAI Legal Metrology Service: www.n sai.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). Class M2 or higher are required 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, signalling 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.

Appendix 2

Extract from the Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended):

Schedule of Requirements in Relation to Safes and Cabinets used for Keeping Drugs

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.

