Sections of this manual have been superseded.
For up-to-date information see the relevant section within this manual and the practice guidance section on www.thepsi.ie

The Pharmaceutical Society of Ireland

(Standards and Practice Unit)

PHARMACY PRACTICE GUIDANCE MANUAL

A self-audit tool for pharmacists and pharmacy owners

1st edition May 2008

PSI
THE PHARMACEUTICAL SOCIETY OF IRELAND
Cumann Cógaiseoirí na hÉireann

THE PHARMACY REGULATOR

Following the coming into force of the Regulation of Retail Pharmacy Business Regulations 2008, the PSI has issued a series of Guidance. Therefore, sections of this manual have been superseded or additional information is now available. Please see the section notes in this document, the practice guidance section of our website and PSI eNewsletters.

Contents

* Updated information is available on this topic. See section page for further details
** This section has been superseded. See section page for further details

Introduction

The Pharmaceutical Society of Ireland (PSI) was established under the Pharmacy Act 2007. It is the statutory regulator of the practice and profession of pharmacy in Ireland and has responsibility to ensure that best practice in the provision of pharmacy services is promoted and delivered in the best interest of the health, safety and welfare of the public.

In carrying out this role, the PSI will issue guidance to assist pharmacists and pharmacy owners in meeting legislative and regulatory requirements. Regulatory standards, professional standards, guidance and Codes of Conduct will provide the future benchmarking framework. It will be the responsibility of the PSI to ensure that this is complied with, as provided for under the provisions of part 7 of the Act, and to then maintain the appropriate registers as required under part 4.

Specified standards are an important component in the measurement of quality of service and care provided to the patient. The pharmacist in charge of a practice, and providing care to a patient, is accountable for the professional activity and service delivered at that time, and must fulfill all requirements of the duty of care owed to the patient. Those pharmacists who fulfill supervisory roles, which involve taking personal responsibility for a pharmacy practice, will be accountable for the overall activity and performance of the pharmacy practice, and must ensure that appropriate policies, safeguards and resources are in place.

Not all sections of the Act have yet been commenced (as of May 2008), and it is understood that the Department of Health and Children (DOHC) intends to introduce the provisions of the Act on a phased and consultative basis.

Under Section 18 of the Pharmacy Act 2007, the Minister for Health and Children may "for the purposes of the health, safety and convenience of the public", make regulations about specified matters in respect of retail pharmacy businesses (pharmacies).

Failure to comply with the provisions of a regulation may impinge on the registration status of a retail pharmacy business, and may, in certain instances, be a criminal offence.

This document is a practical tool, based on best practice ideals. It is intended to be used as a reference check to allow self-audit of a pharmacy practice, and indicate areas that may be in need of further attention. It is hoped that it will assist pharmacy owners and operators to ensure that the environment in which pharmacy services are provided is appropriate, and that services provided are regulated and delivered by a practitioner who is accountable for this professional activity. Some matters which are currently (as of May 2008) legal requirements under pharmacy or medicines law are indicated in **bold** in each section's checklist.

This document is an initial version and is being disseminated for an educational, rather than a regulatory, purpose and as part of a consultative partnership process with the profession. It is envisaged that this document will evolve and will be revised once all the provisions of the Pharmacy Act 2007 are in force. Feedback from the profession, as well as pharmacy owners and other stakeholders, is welcomed as part of that process.

This document is not a Code of Conduct, a set of Rules or any form of Regulatory Requirement. It is not the law and is not intended to interpret the law. It is not intended to be a legal document or an exposition of the law governing the regulation of pharmacy in Ireland.

SECTION 1:
GUIDANCE FOR PREMISES

NOTE: This section should be read in conjunction with the draft Guidance on the Premises and Equipment Guidelines of an RPB available on the PSI website

Section 1: Guidance for Premises

PHARMACY PREMISES

SCOPE

All aspects of a pharmacy premises should be well maintained to reflect the professional role of the pharmacist in the partnership delivery of pharmaceutical services. A pharmacy premises should enable and facilitate a safe and effective working environment. The patient is entitled to expect that any part of the premises from which professional services are provided is readily identifiable and maintained.

CRITERIA

- **The premises must be easily identifiable as a healthcare facility.**
- **Appropriate pharmacy and premises management must be in place to ensure the wellbeing of patients and staff.**
- **The pharmacy must be safe and accessible to the public and comply with appropriate and relevant legislation.**
- **Security must be maintained in the pharmacy and there must be a comprehensive policy regarding the maintenance of security.**
- **Patients must have access to appropriate and relevant medical, pharmaceutical and health promotion information.**

GUIDANCE

All aspects of the pharmacy should be well maintained and facilitate a safe working environment, with the professional services area identifiable to the patient.

Within all areas of the pharmacy, decor should be of sound construction and in good repair. For example, wall, ceiling and floor coverings should be compliant with any legislative requirements and in accordance with all health, safety and environmental requirements.
Staff toilet and hand-wash facilities with hot and cold water, soap and hand drying facilities should be provided and should not open directly into the dispensary. These facilities should be of an appropriate standard with clean floors, walls, ceiling and paintwork. A professionally produced 'Wash your hands' notice should be displayed.

The pharmacy should be maintained in a clean and orderly condition. Appropriate cleaning schedules should be detailed and recorded. Adequate heating, lighting, ventilation and air conditioning should be provided.
Temperature and humidity conditions should be controlled and monitored with due regard to the requirements to store medicinal products within certain specified temperature parameters.

Any signage used in the pharmacy should be clear and not misleading and should take into account patient profiles and communication difficulties if appropriate. Posters on windows and doors should be kept to a minimum, be professional in character and in accordance with relevant security guidance. Notices relating to opening hours, duty rotations, after hours' service, etc. should be factual. No signage, whether inside or outside the premises, should draw an invidious distinction between it and any other pharmacy. Window displays should reflect the professional nature of pharmacy, and be kept free from dust and insects.

Illuminated exterior signs should be in good repair and in working order. The pharmacy title should be displayed on the premises.

The registration certificate of the supervising pharmacist responsible for the professional activity of the pharmacy should be on public display.
A safe and accessible entrance to the pharmacy premises should be provided. Publicly accessible areas should be clear of stock and any other obstructions.
The pharmacy should operate with a direct, dedicated telephone line.

Medicine sales counters should not be cluttered. All pharmacy medicines should be located so that the pharmacist is able to intervene personally in the supply of a medicinal product. The pharmacy should site hazardous products out of the reach of children.

The pharmacy should provide a patient services area in which counselling can take place. This area should be outside, but adjacent to, the dispensary where advice can be given by the pharmacist. This area should have visual and sound barriers which provide for complete privacy for patients.
The pharmacy should have a seating area where patients can wait for prescriptions.

The pharmacy should have an appropriate alarm system, and should also provide a panic button for staff members.

The pharmacy should ensure that adequate staff facilities are available, e.g. a clothing hanging area, water heating facility, microwave and a refrigerator in a private area are suggested.

SECTION 1: PHARMACY PREMISES

Ask Yourself	Yes	No	N/A	Required Action
Are the premises readily identifiable as a healthcare facility?	☐	☐	☐	
Is signage appropriate and in good repair?	☐	☐	☐	
Are all window displays appropriate to a healthcare facility and do not compromise security?	☐	☐	☐	
Are the premises accessible to all patient groups?	☐	☐	☐	
Do the premises comply with relevant building and fire safety regulations?	☐	☐	☐	
Does the overall ambience reflect that of a healthcare facility?	☐	☐	☐	
Is the dispensary accessible only to those authorised to access it and readily identifiable?	☐	☐	☐	
Is the professional services area of the pharmacy readily identifiable?	☐	☐	☐	
Does the layout of the pharmacy allow for pharmacist supervision of all supplies of medicinal products?	☐	☐	☐	
Are adequate and suitable lighting, heating and ventilation in place?	☐	☐	☐	
Are the premises maintained in an orderly, clean and hygienic manner?	☐	☐	☐	
Is the building of sound construction and of a permanent nature?	☐	☐	☐	
Are the premises safeguarded by appropriate alarm systems in respect of fire and theft?	☐	☐	☐	
Has the premises been assessed or visited by the Garda Crime Prevention Officer or against the PSI/Garda security assessment template?	☐	☐	☐	
Is a suitable waiting area provided for patients, with adequate seating?	☐	☐	☐	
Is a dedicated health promotion area provided for patients?	☐	☐	☐	
Is the complete floor area clean and free from obstructions?	☐	☐	☐	
Is the cleaning schedule available?	☐	☐	☐	
Is a dedicated professional services area provided, within which all medicinal products are controlled?	☐	☐	☐	
Is an appropriate counter or facility available for counselling in respect of pharmacist-prescribed medication?	☐	☐	☐	
Is a dedicated area which allows for patient counselling available, with a visual barrier to prevent unauthorised sight of patient records, prescriptions or product?	☐	☐	☐	
Does the patient counselling area have suitable sound barriers to prevent any other individual from overhearing private discussions?	☐	☐	☐	
Is the patient counselling area solely used for this designated activity?	☐	☐	☐	
Is the certificate of registration of the supervising pharmacist visible to the public?	☐	☐	☐	

NOTE: This section should be read in conjunction with the draft Guidance on the Premises and Equipment Guidelines of an RPB available on the PSI website

Section 1: Guidance for Premises

DISPENSARY

SCOPE

The professional dispensing activity of the pharmacist is inherently dependent on the environment in which the core activities of the pharmacy occur. The dispensary should be of sufficient size for the safe and proper storage, handling, compounding and preparation of prescription medicines.

CRITERIA

- **The physical environment and layout of the dispensary must be robust, hygienic and provide for the safe delivery of patient care.**
- **The physical layout of the dispensary must provide for and facilitate the activities and processes carried out there.**
- **The dispensary must be of a sufficient size to allow effective workflow and take account of practice-specific variables such as staffing, work-flow and prescription volume.**
- **The dispensary must have adequate means of storage and waste disposal.**
- **The dispensary must have appropriate and adequate equipment to carry out the operations of the pharmacy.**

GUIDANCE

The dispensary in the pharmacy should be suitably sited to allow for ease of access of all patients to this service. Access to the dispensary service must not be hindered in any manner which would impinge on any particular grouping in the community.

The dispensary should be maintained in good order. Walls, ceiling and floor covering should be compliant with any legislative requirements and in accordance with all health, safety and environmental obligations. The dispensary should be free from all sources of contamination, have clean floor coverings and surfaces which are clean, uncluttered, smooth and impervious to dirt and moisture.

The dispensary itself should be designed to discourage uninvited or unauthorised access. Public access to the dispensary should be prohibited except for persons authorised for a specific purpose.
The dispensary should be well-lit and sufficiently ventilated. The dispensary fixtures and fittings should be adequate for the purpose for which they are intended and sinks should be clean and have hot and cold running water.

The dispensary should have a lockable drug cabinet/safe compliant with legislative requirements for the safe storage of Controlled Drugs (CDs). Any alternative method of storage should be certified by An Garda Síochana as provided for in the relevant regulations.

The dispensary refrigerator should be cleaned regularly and appropriately maintained to ensure the integrity of storage conditions.

The dispensary should have arrangements for the proper storage and disposal of waste materials. Appropriate, designated, covered bins should be used and these should be emptied and cleaned regularly. No waste material should be permitted to collect in the dispensing area.

Disposal of pharmaceutical waste should occur in a manner compliant with environmental and other legislation. Waste medicines, whether out of date stock held or patient returns, should be stored appropriately under the control of the pharmacist until removed for destruction. Paper waste containing confidential information should be shredded or treated in a manner which renders it indecipherable before disposal.

An approved, appropriate type of fire extinguisher should be present.

A dispensary should have a suitable range of equipment for extemporaneous dispensing. Measuring, weighing, recording and control equipment should be calibrated and checked/serviced at appropriate intervals, with adequate records maintained.
Dispensary equipment should be for the sole purpose of preparing and dispensing medicines.

Equipment and utensils should be suitable for their purpose and easy to clean and maintain, and be adequately stored in order to prevent contamination of products.

A dispensing area should have a sink/wet area which should be used for the sole purpose of dispensing.
A source of drinking (potable) water should also be present in the dispensary. If fresh, safe, potable water is not available, then purified water B.P. that is freshly boiled and cooled should be used. This water (i.e. boiled and cooled purified water B.P.) should be discarded after 24 hours.

SECTION 1: DISPENSARY

Ask Yourself	Yes	No	N/A	Required Action
Is the dispensary accessible only to authorised persons?	☐	☐	☐	
Is the dispensary clean, tidy and free of contamination?	☐	☐	☐	
Is a dispensary cleaning schedule available?	☐	☐	☐	
Is the dispensary floor covering clean and cleanable?	☐	☐	☐	
Are all working surfaces clean, cleanable, uncluttered and impervious to dirt and moisture?	☐	☐	☐	
Are counter surfaces clean, smooth and uncluttered?	☐	☐	☐	
Are shelves clean and hygienically maintained?	☐	☐	☐	
Does the dispensary layout facilitate uninterrupted and safe workflow?	☐	☐	☐	
Are ceilings, walls and paintwork in a good state of repair?	☐	☐	☐	
Is the dispensary appropriately ventilated and lit?	☐	☐	☐	
Is the temperature in the dispensary noted and a written record made daily?	☐	☐	☐	
Is sufficient space available to store all dispensary medicines?	☐	☐	☐	
Are medicines stored at accessible shelf height, i.e. you do not have to reach/stretch excessively to access them?	☐	☐	☐	
Is a structured classification layout used in the organisation of the medicines in the dispensary?	☐	☐	☐	
Is a dedicated wet area with hot and cold running water provided?	☐	☐	☐	
Do toilet and wash hand facilities provided open directly into the dispensary?	☐	☐	☐	
Does the dispensary hold the required equipment ?	☐	☐	☐	
Is the equipment stored hygienically and in an appropriate, accessible location?	☐	☐	☐	
Is a fire extinguisher/fire blanket available in the dispensary?	☐	☐	☐	
Are suitable bins provided for waste material?	☐	☐	☐	
Is a suitable disposal mechanism available for pharmaceutical waste in compliance with environmental provisions?	☐	☐	☐	
Is a shredder provided for disposal of paper waste containing confidential patient information?	☐	☐	☐	
Is the dispensing area suitable in size for the prescription volume, so that individuals dispensing can easily and identifiably segregate the prescriptions from one another?	☐	☐	☐	
Does the dispensary layout allow efficient workflow to accommodate the number of dispensary staff employed?	☐	☐	☐	
Is a pharmaceutical refrigerator available with a temperature monitoring facility?	☐	☐	☐	
Is a designated shelf provided in the refrigerator for items awaiting collection?	☐	☐	☐	
Is an appropriate, legislatively safe, storage facility provided for controlled drugs?	☐	☐	☐	

NOTE: This should be read in conjunction with the draft Guidance on the Premises and Equipment Guidelines of an RPB available on the PSI website

Section 1: Guidance for Premises

EQUIPMENT

SCOPE

Equipment should be located, adapted and maintained to suit the professional operations carried out in the pharmacy environment. The suitability, accessibility, maintenance and cleaning of equipment should be ensured to prevent any adverse impact on the quality of pharmaceutical products processed therein.

CRITERIA

- **Equipment must be fit for purpose and fit for use. Equipment must be appropriate for purpose, easy to clean and maintain, adequately stored to prevent contamination and used exclusively for the purpose for which it has been designed.**
- **An appropriate minimum range of equipment must be maintained in a clean and usable state of operation and be consistent with the provision of a full pharmaceutical service.**
- **Obsolete equipment must not be used. All apparatus must be routinely assessed and replaced if not of a suitable standard.**
- **An appropriate, minimum specified range of reference materials must also be readily accessible.**

GUIDANCE

An appropriate computerised mechanism of record retention and retrieval should be available, and the necessary equipment to facilitate this should be present. A suitable secure back-up should be made each day, and this back-up should be regularly verified.

An appropriate pharmaceutical refrigerator, with forced air circulation, capable of storing products between 2°C and 8°C should be present. This should be equipped with a maximum/minimum thermometer which is checked each day the pharmacy is open, and the maximum and minimum temperatures recorded by a designated member of staff. The results should be entered in a log. Appropriate action should be documented in order to rectify any identified deficiency. The refrigerator should be large enough to store all the medicines which will be kept in it so that there is adequate airflow and uniform temperature in the interior. The refrigerator should not be overfilled, as this will reduce its ability to regulate the temperature.

The refrigerator should be a designated pharmacy fridge. A domestic fridge which contains an ice box is not appropriate. The refrigerator should not be publicly accessible. Food and drink should never be stored in this refrigerator.

A locked safe, meeting the minimum standards set down in the Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended), should be maintained on site for the safe keeping of Controlled Drugs (CDs). The keys (or access code if it is an electronic key pad) to the safe should be kept solely in the custody of the pharmacist or a delegated member of the professional staff. Any alternative method of storage should be certified by An Garda Síochana as provided for in regulation and the certificate should be readily available for inspection.

The capacity of the safe (or other appropriately certified storage system) should be sufficient to safely store all CDs listed in Schedules 2 and 3 of the Misuse of Drugs Regulations 1988-2006 in the pharmacy.

A suitable range of containers should be available to provide for the safe and appropriate supply of product. All dispensed oral medications should be supplied in a container utilising a child resistant closure (CRC) unless

- the prescriber, the patient or their representative directs otherwise, and the pharmacist in their professional judgment considers this appropriate, and a record of this decision is maintained by the pharmacist;
- A CRC is not suitable due to the physical nature of the product.

Plain containers for liquids, and containers suitable for the packaging and dispensing of creams, ointments and pastes, should be stored on site for dispensing purposes. Re-using containers is not appropriate under any circumstances.

Adequate labelling facilities should be present on site. All labels for dispensed medicines should be mechanically or electronically printed in order to ensure the clarity and legibility of the written instructions.

A suitable means of counting tablets and capsules should be available. This equipment should be cleaned regularly and routinely to prevent cross-contamination of product.

A supply of disposable plastic cups and drinking water should be available for patients who wish to consume medicines in the pharmacy.

There should be a telephone and fax service available in the dispensing area of the pharmacy. A computer with broadband internet access is desirable.

A library should be provided for staff and should be adequately stocked with up-to-date reference books, journals and statutory regulations pertaining to the practice of pharmacy and to the sale and supply of medicines. Essential references include Martindale (current or most previous edition), an Irish Medicines Formulary, the current British National Formulary and the current British National Formulary for Children. The pharmacy should have either a drug interaction package as part of its computer dispensing programme or a copy of Stockley's Drug Interactions (most recent edition). A pharmacology textbook, a medical dictionary and an up-to-date 'over-the-counter' medicines reference are also recommended.

SECTION 1: EQUIPMENT

Ask Yourself	Yes	No	N/A	Required Action
Is an appropriate refrigerator available?	☐	☐	☐	
Is the refrigerator clean and free from frost and mould?	☐	☐	☐	
Is the refrigerator cleaned regularly?	☐	☐	☐	
Is an electronic dispensing system with printer, producing legible and durable labels, available?	☐	☐	☐	
Is a safe, or otherwise appropriately certified storage mechanism, available for controlled drugs?	☐	☐	☐	
Is an apparatus provided which allows for the accurate weighing of substance within the range of 10mg to 2kg?	☐	☐	☐	
Is a range of weighing boats and a set of certified metric weights available?	☐	☐	☐	
Is a range of graduated Type A glass measures and pipettes provided to allow for the accurate measurement of volumes from 0.05mls to 500ml?	☐	☐	☐	
Is a suitable set of mortars and pestles, including one glass set, provided in the dispensary?	☐	☐	☐	
Is a glass or marble ointment slab provided?	☐	☐	☐	
Are glass stirring rods and stainless steel spatulas provided?	☐	☐	☐	
Is an adequate range of containers and closures available?	☐	☐	☐	
Is an adequate and appropriate range of auxiliary dosage aids available?	☐	☐	☐	
Is the counting apparatus for tablets and capsules clean?	☐	☐	☐	
Is all the equipment in the pharmacy clean?	☐	☐	☐	
Is all the equipment in the pharmacy in good working order?	☐	☐	☐	
Are suitable bins provided for pharmacy waste?	☐	☐	☐	
Recommended reference texts				
• Martindale	☐	☐	☐	
• Irish Medicines Formulary	☐	☐	☐	
• Current BNF	☐	☐	☐	
• Current BNF for Children	☐	☐	☐	
• Drug Interaction Reference (Stockley's or appropriate software)	☐	☐	☐	
• Pharmacology Text (optional)	☐	☐	☐	
• Medical Dictionary (optional)	☐	☐	☐	
Can the staff access relevant current legislation?	☐	☐	☐	

NOTE: Storage and Stock has been superseded by the PSI Guidelines on Sourcing, Storage and Disposal

Section 1: Guidance for Premises

STORAGE AND STOCK

SCOPE

A pharmacy practice should operate a comprehensive, auditable system for the control and maintenance of an appropriate level of legitimate stock which is held within prescribed storage conditions and facilities.

CRITERIA

- Stock must be sourced from a licensed supplier to ensure that the requirements of safety, quality and efficacy are upheld and the risk of counterfeit stock entering the supply chain is eliminated.
- Appropriate controls must be exercised internally to ensure appropriate receipt of goods and an appropriate accountability chain within each pharmacy.
- Stock must be stored in appropriate and auditable environmental conditions. Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured. All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of product authorisations.
- There should be appropriate classification and retrievability of stock to ensure safe and efficient practice.

GUIDANCE

An appropriate control and operational procedure should be in place to ensure the control, accessibility, receipt, storage and maintenance of stock.

There should be adequate security provisions appropriate to the particular circumstances, and proper safety procedures should be in place. All medicines should be stored in locations appropriate to their potential for misuse and in accordance with legal and pharmaceutical requirements, and any professional standards issued by the PSI.

Pharmacists should only purchase stocks from wholesalers holding a current wholesaler's licence issued by the Irish Medicines Board.
All medicinal products obtained and supplied must conform to legal requirements. Pharmacists should not purchase or supply any medicines, food supplements or healthcare related products unless the quality, safety and efficacy can be objectively guaranteed. All products supplied from a pharmacy, other than directed by a prescriber, which make any form of therapeutic claim, purpose or benefit, must be appropriately licensed.

Pharmacy stock should be stored under suitable conditions appropriate to the nature and stability of the product concerned. Particular attention should be paid to protection from contamination, sunlight, UV rays, moisture, atmospheric moisture and extreme temperatures. During storage, medicines should be retained in the manufacturer's original packaging. Any product received in packaging that is damaged or discoloured should be quarantined and returned to the supplier.
All stock of medicines in the pharmacy should have batch numbers and expiry dates. Medicines must not be removed from blister or foil packs at the time of dispensing, except in particular cases where repacking is required to assist patients. Open/split packs should be clearly marked, and mixing of stock of the same product from different batches avoided.

Particular care should be exercised in the storage of different medicines presented in similar packaging, and of different strengths of medicines presented in similar packaging. To minimise the incidence of a dispensing error occurring, such similarly packaged medicines should not be stored adjacent to each other on the dispensary shelf. The problem of inadvertent dispensing of the wrong medicine due to similar packaging can be overcome by educating staff, and by making sure all dispensary staff are aware of products which are likely to be prone to such dispensing errors.
A documented procedure for regular and systematic checking of expiry dates should be in place. All stock which has reached expiry date should be removed for disposal or destruction. The pharmacy owner should ensure that any disposal of medicinal products is carried out in a manner consistent with legal requirements.

If the packaging of a medicine has suffered any damage which has not adversely affected the contents, then the medicine should be repackaged before dispensing. This applies to dispensary medicine only. If repackaging occurs, it must be ensured that the supply of patient information is not compromised. Over-the-counter (OTC) medicines should not be repackaged from their original container, and any OTC medicine whose packaging is damaged or otherwise rendered unusable should be returned to the supplier or disposed of in a suitable manner.

Pharmacists should exercise their knowledge of materials to segregate them for disposal or destruction. This includes any stock that is likely to have deteriorated, or has been in stock for unduly long periods.
Medicines returned to a pharmacy from a patient's home or from a nursing or residential home should never be supplied to any other patient. They should be stored in a dedicated area, under the control of the pharmacist, for disposal as soon as possible in an appropriate manner.

A medicine and product recall procedure should be developed, documented and regularly reviewed to ensure efficient responses to recall notifications.
There should be documented, internal management communication mechanisms for 'hard to source' or procured items, to ensure optimal patient supply.

Environmental conditions in the pharmacy should be monitored on a

daily basis. All pharmacies should have a documented temperature recording procedure. Maximum and minimum temperature should be recorded twice a day at a specified time by a designated member of staff and entered in a log. All recording equipment should be calibrated as recommended by the manufacturer. Particular attention should be paid to areas of extreme temperature variation such as areas near windows, heaters, lighting or cooling equipment.

Medicines should not be stored in close proximity to areas where food and drink is stored, prepared or eaten.
Medicines dispensed to the patient should be presented in a saleable condition.
All stock should be dusted and cleaned regularly to ensure this.

Controlled Drugs (CDs) listed in Schedule 2 or Schedule 3 to the Misuse of Drugs Regulations, 1988 (as amended) must be stored in accordance with the terms of Misuse of Drugs (Safe Custody) Regulations, 1982. The main requirement is that Schedule 2 and Schedule 3 drugs be kept in a locked safe, with the key (or the access code if the safe has an electronic key pad) in the custody of the pharmacist or a delegated member of the professional staff. The safe should be used solely for the storage of medicines.

When a delivery is received by the pharmacy, the invoice or delivery note should be examined for the presence of CDs, these should be removed immediately, entered into the CD register (if applicable) and placed in the safe. The controlled drugs delivery note should then be signed by the pharmacist and returned to the wholesaler no later than three working days from the date of receipt of the drugs.

When a delivery is received by the pharmacy, the delivery note or invoice should also be checked to determine whether there are any thermolabile medicines present and these should be placed immediately into the pharmacy refrigerator.

Careful consideration should be given to the storage in the pharmacy of OTC medicines where there is potential for misuse, such as preparations including codeine, especially multi-ingredient preparations, cough suppressants, slimming products, potent laxatives and paracetamol. These medicines should be stored behind the counter and consideration should be given to placing them out of sight, so they are only supplied to patients whose condition, in the opinion of the pharmacist, warrants their use.

Hazardous substances, including those listed in Schedule 2 to the Poisons Regulations 1982, should be kept separate from the main pharmacy stocks, i.e. in a press, drawer or on a shelf reserved solely for the storage of such substances. Any reconstitution or preparation involving hazardous substances should be performed according to the details of the manufacturer contained in the data sheet, or other product information.

Animal remedies should be kept in a separate section of the pharmacy which should be clearly identified as such. Special care should be taken with veterinary medicines, feed additives or other materials which might have a strong or lingering odour. Thermolabile veterinary medicines should be kept in a separate animal medicines refrigerator reserved solely for this purpose. Certain veterinary vaccines are live vaccines, and these should not be kept in close proximity to human medicines.

All pharmacy waste should be handled and disposed of in a safe and effective manner that complies with all legal provisions regulating such disposal. Particular precautions should be taken to segregate hazardous waste.

SECTION 1: STORAGE AND STOCK

Ask Yourself	Yes	No	N/A	Required Action
Are written procedures in place for the control, ordering and receipt of medicinal products?	☐	☐	☐	
Is a policy in respect of immediate need/procured products available, to ensure a patient receives medication as required?	☐	☐	☐	
Is an appropriate policy utilised to address the receipt and handling of controlled drugs?	☐	☐	☐	
Is a dedicated unpacking area for the receipt, handling, and checking of stock received into the pharmacy provided?	☐	☐	☐	
Is a policy in respect of the receipt, handling and storage of thermolabile products available and utilised?	☐	☐	☐	
Is an appropriate CD safe/certified storage area available for the storage of CD2 and CD3 medicinal products in accordance with legislative requirements provided and utilised? Is the safe of sufficient capacity to allow for orderly storage of all CDs, including a separate segregated area for any expired products awaiting destruction?	☐	☐	☐	
Is the refrigerator used for the storage of medicinal products adequate for the quantity of product stored, with appropriate monitoring, cleaning, temperature mapping and maximum and minimum temperature recording occurring and documented?	☐	☐	☐	
Is there provision for maintenance of the cold chain when the refrigerator is being cleaned?	☐	☐	☐	
Are medicines the only product stored in the refrigerator?	☐	☐	☐	
Is adequate shelving, drawers or fixtures provided to allow for a structured system of stock management?	☐	☐	☐	
Are expired or returned products awaiting disposal clearly and securely segregated from stock held?	☐	☐	☐	
Is each and every storage area of sufficient size to facilitate the orderly management of stock and appropriate stock rotation?	☐	☐	☐	
Are all storage areas for medicinal products under the control of the pharmacist?	☐	☐	☐	
Are dedicated storage areas maintained in a clean and tidy fashion?	☐	☐	☐	
Is a cleaning schedule for specific storage areas, with sign off sheets on completion, used?	☐	☐	☐	
Do the premises and storage areas show any signs of pest infestation?	☐	☐	☐	
Are appropriate shelving and structures in place to ensure no product is stored on the floor?	☐	☐	☐	
Are hazardous substances stored separately in a manner which minimises risk and is legislatively compliant?	☐	☐	☐	
Are flammable substances stored separately in a manner which minimises risk and is legislatively compliant?	☐	☐	☐	
Are any expired medicines located in the general stock? Is there an effective and appropriately documented system of expiry date monitoring?	☐	☐	☐	
Is the stock assessed on receipt for quality, quantity and expiry date?	☐	☐	☐	
Are veterinary and human medicinal products segregated?	☐	☐	☐	
Are any unauthorised products held, excepting those whose presence is justified by a written order from a practitioner for a specific named patient which can be produced on inspection?	☐	☐	☐	

SECTION 2:
GUIDANCE FOR STAFF AND SUPERVISION

NOTE: Section 2 should be read in conjunction with advice on the Roles and Responsibilities of the Supervising and Superintendent Pharmacist

Section 2: Guidance for Staff and Supervision

PHARMACISTS

SCOPE

The activity of a pharmacy is the professional responsibility of the pharmacist in charge. Differing levels of accountability will apply in respect of differing roles fulfilled, but all practitioners are required to possess, maintain, update and display competence and accountability in respect of the management of the health of a patient and the delivery of an acceptable standard of pharmaceutical care.

CRITERIA

- **Any pharmacist exercising their professional role must be registered, safe and competent to practise, and must not be aware of any personal impediment to practise which would impact negatively on the health of a patient.**
- **A pharmacist must be fully aware of the particular professional role they fulfill and the boundaries and accountability of that particular role.**
- **The regulation of individual pharmacists, the pharmacy team, the pharmacy environment and the external healthcare environment is a function of government, delivered through appropriate statutory and regulatory agencies. Pharmacists must recognise, and facilitate, this regulation in a partnership framework.**

GUIDANCE

Any professional activity of a pharmacy should occur under the direct supervision of a registered pharmacist who accepts responsibility for the dispensing and compounding of medicines, and the provision of all pharmacy services, for the time period within which that pharmacist is present. Additional responsibilities and accountabilities will be required of pharmacists fulfilling supervisory professional roles.

A registered pharmacist who is "in whole time charge of the carrying on of the business of a pharmacy", and is named as Supervising Pharmacist in the statement provided to the Registrar of the PSI, operates in accordance with the following guidance.
A supervising pharmacist:

- Is accountable for all professional activities carried out in the pharmacy.
- Is responsible for personally managing, controlling and supervising the pharmacy.
- Is responsible for prohibiting any individual from unduly influencing, directing, controlling or supervising the professional activity of the pharmacy.
- Is responsible for the generation and application of policies and procedures for all personnel operating in a pharmacy in accordance with current law and best practice.
- Attends for a reasonable period of the operating time of the pharmacy, at the professional services area of the practice.
- May not be named as the supervising pharmacist in respect of more than one pharmacy at any one time.
- Is responsible for ensuring notification of the names of all pharmacists operating at the pharmacy to the PSI Registrar, and notifying when any pharmacist ceases to operate there.
- Should ensure that any pharmacist operating, while the supervising pharmacist is absent from the pharmacy, is suitably qualified to do so.
- Is charged with the maintenance of an appropriate duty log, clearly indicating the identity of the pharmacist in attendance at any given time within the notified operating hours of the pharmacy.
- Should ensure that all personnel operating within a pharmacy are aware of the limits and scope applicable to the management of the professional services provided.
- Should ensure that all members of the pharmacy team possess and maintain adequate competence to successfully and safely carry out their assigned duties.
- Should ensure that all personnel employed are adequately and appropriately identified, referencing name and role in a manner which is clear to the patient.
- Should ensure that continuing professional development is undertaken by themselves, and by any other pharmacist operating in the pharmacy.
- Should ensure that standards and guidance issued by the regulator are adhered to.
- Should ensure that full co-operation be provided to the regulator, and all requests for information from the Registrar be answered within the appropriate timeframe.

Any registered pharmacist operating in a pharmacy (who is not the supervising pharmacist) must act in accordance with all legislative requirements, guidance of the regulator, Code of Conduct and appropriate internal policy procedures, and is personally accountable for all professional practices overseen and carried out by him or herself .

A pharmacist should only engage in activities which are within their normal scope of practice and for which they have the required skills and competencies. It is the duty of the individual pharmacist to maintain competence, and to undertake regular continuing professional development and education relevant to their professional duties. Any pharmacist who is unable to assist a patient by virtue of this provision should source an alternative accessible practitioner for the patient to attend.

A pharmacist should ensure that all activities they undertake are covered by professional indemnity insurance, held either personally or by the pharmacy in which they are practising. The supervising pharmacist should ensure that the pharmacy has the appropriate insurance cover.
A pharmacist should ensure that

the environment within which they practise enables compliance with their professional responsibilities. Any pharmacist operating in an environment which is not in accordance with safe practice should formally notify the pharmacy owner of the apparent deficiency. A pharmacist should ensure that the requisite facilities, equipment and materials are available to enable the provision of the service to professionally accepted standards.

A pharmacist in charge of a pharmacy, in any professional capacity, should ensure that all personnel present at that particular time are competent and fit to provide the service intended. Where this is not the case, the pharmacist should bring this to the attention of the employer to be addressed. In any event, no situation should be facilitated which would impact negatively on patient health.

The provision of standard operating procedures (SOPs) contributes to the safe and efficient running of any pharmacy. Pharmacists should therefore ensure that they and other staff work within SOPs where possible, and undertake ongoing review, assessment, critical analysis and amendment.

A pharmacist should report to the prescriber and relevant regulatory authorities, suspected adverse drug reactions (ADRs). This is important as it may have an effect on the future treatment of the patient, or the future use of the particular medicine.

A pharmacist should honour their obligation to provide professional services. Before accepting employment, a pharmacist should disclose to their employer any reason, belief, impediment or competence issue which may affect their capability to provide services.

If a pharmacist becomes aware that a person has received a pharmaceutical service of less than the required standard, they should ensure that all necessary steps are immediately taken to rectify it in the interest of the patient's safety and welfare. Where possible, an explanation should be provided to the patient concerned for what happened, even if that pharmacist is not directly responsible for it.

The safety of patients and the public should be the prime consideration of a pharmacist, over-riding any personal, professional or commercial loyalties. Where a pharmacist has good reason to believe that they, or a colleague from their own or another profession, may not be fit to practise for reasons of health, conduct or competence, they must address this, bearing in mind that the primary responsibility is to the patient. The appropriate authorities, including regulatory authorities, must be notified.

SECTION 2: PHARMACISTS

Ask Yourself	Yes	No	N/A	Required Action
Are all pharmacists employed in the pharmacy registered with the PSI?	☐	☐	☐	
Are all pharmacists employed fit and competent to practise and unimpeded by any health issue in respect of practice?	☐	☐	☐	
Are all pharmacists employed aware of their professional role and the associated boundaries and accountabilities?	☐	☐	☐	
Are all professional activities of a pharmacy carried out under the supervision of a pharmacist at all times?	☐	☐	☐	
Does the supervising pharmacist personally manage, control and supervise all professional aspects of the pharmacy?	☐	☐	☐	
Does the supervising pharmacist produce and review policies and procedures for the operation of the pharmacy?	☐	☐	☐	
Does the supervising pharmacist attend for a reasonable period of time at the pharmacy?	☐	☐	☐	
Is the supervising pharmacist responsible in this respect for one pharmacy only?	☐	☐	☐	
Is a duty log maintained and signed by the pharmacist(s) in charge?	☐	☐	☐	

NOTE: Section 2 should be read in conjunction with advice on the Roles and Responsibilities of the Supervising and Superintendent Pharmacist

Section 2: Guidance for Staff and Supervision

OWNER OF A RETAIL PHARMACY BUSINESS

SCOPE

The operation of a pharmacy must be subject to defined parameters of regulation and service delivery. This should be consistent with the delivery of safe, efficient and effective pharmaceutical care, from an appropriately regulated environment, by suitably qualified individuals.

CRITERIA

- **The premises must be of an appropriate standard suitable for the provision of a safe service.**
- **The personnel employed must be appropriately qualified to provide the service they are employed to provide.**
- **Appropriate resources must be provided to safeguard the public.**
- **Accountability mechanisms must be in place to ensure no inappropriate considerations influence the management of patients.**

GUIDANCE

A pharmacy owner should ensure that the premises is suitable for this purpose, and complies with all relevant legislation, including building and health and safety, and appropriate guidance issued.

A pharmacy owner should ensure that all processes and activities conducted in the pharmacy are carried out in a manner compliant with applicable legislation including, but not limited to;

- the Pharmacy Acts 1875 – 2007
- the Irish Medicines Board Act, and regulations made under section 32 thereof
- the Animal Remedies Act
- European Communities (Animal Remedies) (No. 2) Regulations.

A pharmacy owner should ensure that the pharmacy is fully equipped with a suitable operational range of equipment to safely provide for the range of pharmaceutical services provided.

A pharmacy owner (who is not a registered pharmacist) should not seek to unduly influence, direct, control or interfere with the professional activity of the pharmacy. A pharmacy owner should not impose conditions which would compromise the delivery of professional pharmaceutical care and service.

A pharmacy owner should ensure that the pharmacy operates with an adequate number of staff to ensure the safe and effective delivery of care, in accordance with legislative requirements and best practice. In assessing the need in this respect, the pharmacy owner must have due regard for previous and anticipated work load.

A pharmacy owner should ensure that all personnel employed at a pharmacy are trained and competent to fulfill the duties assigned to them, and that they are able to communicate effectively with the patients attending the practice. It is the pharmacy owner's responsibility to ensure prior reference checks are carried out in respect of all individuals employed.

A pharmacy owner should ensure that each staff member is readily identifiable to patients and a clear indication is provided of the role each staff member fulfills.

A pharmacy owner should ensure that all staff members are provided with a suitable period of orientation training, and undergo a suitable induction period in which performance will be assessed and any skills or knowledge deficit addressed.

A pharmacy owner should ensure that any pharmacist employed is in a position to satisfy continuing professional development requirements specified by the regulator.

A pharmacy owner should ensure that staff members do not engage in any professional activity outside their area of competence and expertise, and that appropriate delegation pathways and policies are adhered to.

A pharmacy owner should ensure, insofar as possible and permissible by law, that no staff member is involved in outside work activity or practice which would compromise the safe management of the pharmacy practice.

A pharmacy owner should ensure that clear direction is provided in respect of scope and limits of activity.

A pharmacy owner should take reasonable steps to ensure that the pharmacy is being operated in accordance with best practice, and that appropriate policies, management, record keeping and quality assurances are in place.

A pharmacy owner should ensure that the pharmacy provides a reasonable number of hours service to patients.

SECTION 2: OWNER OF A RETAIL PHARMACY BUSINESS

Ask Yourself	Yes	No	N/A	Required Action
Are the premises of solid construction and a suitable quality to deliver an appropriate professional service?	☐	☐	☐	
Do the premises comply with relevant legislative requirements?	☐	☐	☐	
Do the premises comply with relevant guidance issued by the regulator?	☐	☐	☐	
Are relevant procedures and policy documents produced?	☐	☐	☐	
Is the pharmacy equipped with a suitable range of equipment?	☐	☐	☐	
Are adequate staff numbers in place to safely carry out the professional pharmacy activities?	☐	☐	☐	
Are all staff members trained and competent to fulfill their assigned roles?	☐	☐	☐	
Is a staff training record maintained?	☐	☐	☐	
Do all staff members possess adequate communication skills to ensure the provision of a safe pharmacy service?	☐	☐	☐	
Are all staff members, and their respective roles, readily identifiable to patients?	☐	☐	☐	
Is the pharmacy open for a reasonable number of hours?	☐	☐	☐	
Is clear direction provided to staff in respect of scope and limitations of roles, and when referral to a pharmacist/supervisor is appropriate ?	☐	☐	☐	
Is a staff duty log maintained to ensure that at all times the pharmacy is operated under the supervision of a pharmacist and this pharmacist is identifiable?	☐	☐	☐	

NOTE: Section 2 should be read in conjunction with advice on the Roles and Responsibilities of the Supervising and Superintendent Pharmacist

Section 2: Guidance for Staff and Supervision

THE PHARMACY TEAM

SCOPE

The professional activities of a pharmacy at any time are the responsibility of the pharmacist in charge. These activities may be carried out in the temporary absence of the pharmacist by a registered pharmaceutical assistant, who is required to possess, maintain, update and display the requisite competence and accountability in respect of the management of the health of a patient and the delivery of an acceptable standard of pharmaceutical care. The provision of all pharmacy services is critically linked to having individuals who possess and develop appropriate skills to ensure a high level of competence.

CRITERIA

- **All staff must be appropriately informed and trained in respect of their area of operation.**
- **All staff must be aware of the necessity to appropriately refer patients to a pharmacist.**
- **All staff must be involved with quality assurance and risk assessment programmes.**
- **All staff must be aware that the patient is the primary focus of service provision, and must respect the confidentiality and integrity of their interaction with patients.**
- **Pharmaceutical assistants, registered with the PSI, must be competent to operate safely, be aware of their particular professional role and responsibilities within their defined role, and avail of continuing professional development.**

GUIDANCE

The pharmacy owner should ensure that all staff undergo a defined and rigorous selection process, having due regard to the importance of their probable access to patients, as well as scheduled medicines. It is the responsibility of the employer to ensure that appropriate reference checks are performed.

Staff should receive a written job description outlining areas of responsibility and should address any issues requiring clarity with the employer. The job description should include a written confirmation by the staff member of their understanding of the duties involved.

The pharmacy owner should ensure that all staff members are given an opportunity to undergo suitable orientation in all aspects of the pharmacy's operational policies and procedures for services provided.

The pharmacy owner should ensure that all staff are provided with, and fully engage in, a structured training programme which addresses the needs of the individual, and the needs of the pharmacy practice. This training programme should provide a comprehensive understanding and information base in respect of the position filled and associated responsibilities.

All staff members should be in possession of appropriate education, experience, communication skills, training, health status and registration required to carry out assigned tasks and functions.

All personnel should be familiar with, and not exceed, the limitations of their role and should understand the scope of their activities. Unauthorised individuals should not engage in restricted activities in a pharmacy, and job descriptions should address the necessity and requirement for referral.

Staff training and recruitment should address the level of qualification, competence, experience, training and supervision required to fulfill a particular role. Staff should be encouraged to interact in a positive manner with their professional bodies and other healthcare professions.

A pharmaceutical assistant should have current registration and be in regular employment under the supervision of a registered pharmacist.

A pharmaceutical assistant who will be performing the professional duties of a pharmacist in his/her temporary absence should be permanently employed in that pharmacy for at least 15 hours per week.

A pharmaceutical assistant should cover short absences such as lunch hours, one day (or two half-days) off per week and unscheduled short absences. In the event of the absence caused by the pharmacist's holiday entitlements, the maximum number of days that the pharmaceutical assistant can cover shall not exceed 14 days in any one absence.

The supervising pharmacist, at all times, retains full responsibility for the supervision and management of the pharmacy, and should be satisfied that the operation of the pharmacy during cover by a pharmaceutical assistant is in accordance with the specified policies and procedures in place governing the operation of that pharmacy.

SECTION 2: THE PHARMACY TEAM

Ask Yourself	Yes	No	N/A	Required Action
Prior to recruitment, is a dedicated assessment provided of the role to be filled and the necessary competencies required by an individual to do so?	☐	☐	☐	
Is an on-going training programme provided for all staff?	☐	☐	☐	
Does the staff training programme assess current and future requirements and developments in care?	☐	☐	☐	
Are all staff members included in staff meetings?	☐	☐	☐	
Are all staff members facilitated in informing themselves of the pharmacy's policies and procedures?	☐	☐	☐	
Are all staff members aware of the requirement to refer on appropriately?	☐	☐	☐	
Are personnel records maintained for each staff member?	☐	☐	☐	
Do newly-appointed staff members receive appropriate orientation and induction training and information (dispensary and pharmacy)?	☐	☐	☐	
Are job descriptions maintained and regularly reviewed?	☐	☐	☐	
Are continuing education and external training courses documented?	☐	☐	☐	
Is there a policy in respect of personal hygiene and dress code in place?	☐	☐	☐	
Are all staff attired in a manner that befits the nature of the service being provided?	☐	☐	☐	
Is a nominated member of staff responsible for health and safety issues?	☐	☐	☐	
Are all current legislative employment issues addressed in policy documents?	☐	☐	☐	
Are members of staff facilitated in their inter-professional activities with other healthcare professionals?	☐	☐	☐	
Does the pharmacy employ a registered pharmaceutical assistant?	☐	☐	☐	
Is the pharmaceutical assistant employed for a minimum of 15 hours per week?	☐	☐	☐	
Does the pharmaceutical assistant cover for annual and other holidays?	☐	☐	☐	

SECTION 3:
GUIDANCE FOR SERVICES AND SYSTEMS OF OPERATION

NOTE: This section should be read in conjunction with PSI Guidance on Good dispensing Practice for High Tech Medicines and the draft PSI Guidance on the delivery of prescription only medicines from a RPB (consultation)

Section 3: Guidance for Services and Systems of Operation

DISPENSING OF PRESCRIPTION-ONLY MEDICINES

SCOPE

Dispensing involves the complete process which occurs from receipt of the prescription or request at the pharmacy, to the prescribed item or medicine being collected by the patient or their representative. The patient is the primary focus of the dispensing process, and prescribed medicines must be assessed as appropriate for that individual, and delivered in a manner which reflects diligence and care in the receipt, review, assembling, checking, recording and dispatch.

CRITERIA

- The pharmacist must ensure that dispensing is carried out accurately, reflects the prescriber's intentions and is consistent with the needs and safety of the patient.
- Patient confidentiality must be respected and safeguarded in the dispensing process.
- Each prescription must be critically reviewed prior to dispensing to ensure that the medicinal product(s) supplied are safe and in the best interest of the patient.
- The pharmacist must be aware of good dispensing practices and implement them.
- The patient's medicinal history must be recorded accurately and reviewed when dispensing a medicine.
- The pharmacist must contact the prescriber regarding medicines and patient issues when the need arises, and must always exercise his/her professional role and expertise in the appropriate use of medicines.
- Patients must be given complete and comprehensive details regarding their medicines at the time of dispensing, so that they fully understand what the medicine is and what it is for.
- Adequate information must be given to the patient regarding the safe storage of their medicine.
- The medicine dispensed must be of suitable quality, fit for use over the course of treatment and provided in a suitably packaged and labelled manner.
- Pharmacists should ensure that the necessary facilities, equipment and materials are present to enable the provision of the service to professionally accepted standards.
- All dispensing of medicines must be carried out by, or under the personal supervision of the pharmacist, who should ensure that appropriate robust policy and procedures are utilised in the receipt, assembly, review, checking and delivery of the medicine to the patient.

GUIDANCE

All dispensing of medicines should be carried out by or under the supervision of the pharmacist who bears the associated legal liability and professional responsibility for the dispensing.

All prescriptions should be received by the pharmacist or an appropriately experienced staff member, who will review the document with the patient to ascertain their needs and ensure understanding.

The individual who accepts a prescription from a patient should ensure that the identifying personal details are legible, and that the person presenting the prescription is authorised to do so. The patient details should be clear, legible and complete. The pharmacist must be in a position to contact the patient based on the information detailed on the prescription and any other ancillary information recorded in the patient history.

In the case of a prescription for a child, the child's age should be ascertained and written on the prescription (if the prescriber has not already done so). In the case of infants or children the date of birth should be ascertained and entered in the patient medication record (PMR).
When setting up a new PMR, the pharmacist (or another member of staff acting on his/her behalf) should establish from the patient or his/her representative, where possible, if the patient has any known allergies or has experienced any ADRs in the past.

It should be ascertained that the prescription is written in a manner that complies with the legislative requirements in place, in respect of the particular medication requested on the prescription, the location and nature of the practice, and authorisation of the practitioner issuing the prescription.

Notwithstanding Emergency Supply situations as legislatively provided for, it must be ascertained that the validity period of the prescription has not elapsed. To supply a medication in this instance would be essentially supplying a medicine without a prescription. The maximum period of validity of any prescription is six months, with shorter periods for particular drug classes and substances. Emergency Supply should always be done with appropriate patient counseling.

The authenticity of any prescription presented for dispensing should be established prior to supplying any medicinal product. The pharmacist must be satisfied that the prescription is written by a practitioner authorised to do so and that this person did in fact do so.

When a prescription is completely dispensed, the pharmacist is legally required to retain it on the premises for at least two years from the date of its last dispensing. It is generally considered reasonable practice for prescriptions and other relevant records to be retained by the pharmacy for a further three years, i.e. five years in total, notwithstanding that the period of lawful retention is only two years.

The prescription should be legible and the pharmacist must be satisfied that they

are in a position to safely and correctly interpret the identity of the product prescribed. There must be no ambiguity in respect of product, method of use or dosage regime. If no specific directions for use are stated by the prescriber, the pharmacist should first ascertain whether these have been verbally transmitted to and understood by the patient. If this is not the case, then the prescriber should be contacted and the pharmacist should agree the directions in consultation with the prescriber. If the prescriber cannot be contacted, then the pharmacist should proceed by exercising their professional knowledge and judgment as to the appropriate dosage directions to safely dispense the medicine. "As directed" is not an appropriate direction.

The pharmacist should ensure the patient details are correct, and make a clinical assessment as to the appropriateness of the prescribed medicine therapy for the individual for whom the prescription is issued. This should include screening for any potential drug therapy problems, including therapeutic duplication, drug-drug interactions (including with OTC medicines), food-drug interactions, incorrect drug dosage or duration of treatment, known drug allergies and clinical misuse/abuse.

Where a prescriber specifies a particular branded product on the prescription, the pharmacist is required to dispense the product specified. The pharmacist cannot supply a different equivalent brand without consulting the prescriber concerned, except where such supply is covered by a brand substitution agreement entered into in advance by both the pharmacist and prescriber concerned.
In circumstances where the prescriber cannot be contacted, and the patient is in need of the medication, the pharmacist may exercise professional judgment and dispense an alternative equivalent brand of the medicine if satisfied that it is safe and clinically appropriate to do so. The pharmacist should notify the prescriber subsequently of this action and record details of this notification.
In cases where a patient is receiving a particular brand of medication and is then prescribed another brand, or the prescription is written using the drug's non-proprietary ('generic') title, the pharmacist should ensure that the brand being prescribed or intended to be supplied is appropriate for the patient, having due regard to any issues of bioequivalence for the drug concerned. Switching between brands is in general not clinically appropriate for certain drugs, such as those with a narrow therapeutic index.

In reviewing a prescription, each assessment should relate to that prescription at that particular point in time. If there is any change with a repeat prescription, this should be confirmed with the patient prior to dispensing the prescription. If there is no change in a repeat prescription, the continuation of the therapy at the same dose and regime should be confirmed with the patient.

When the clinical review of medicine therapy reveals an issue needing further clarification, the pharmacist should exercise professional judgment in order to evaluate and decide on a course of action. When deemed necessary, the pharmacist should act in consultation with the practitioner who issued the prescription. In a case where the prescriber cannot be contacted, or where such contact fails to solve the problem, the pharmacist must exercise professional judgment in the best interests of the patient as to whether or not to dispense the prescription.
Where the pharmacist cannot contact the prescriber but in exercising professional judgment dispenses the prescription other than in accordance with the prescriber's directions for use, the pharmacist should record the circumstances leading to this decision. He or she should also bring this to the attention of the prescriber at the earliest opportunity and record details of this notification. Such records should be maintained in conjunction with dispensing records.

All dispensed oral products that are not blister packed should be supplied in a container utilising a Child Resistant Closure (CRC). 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 possible. Any patient receiving a product that does not have a CRC should be advised of the imperative to keep this out of the reach of children.

In particular circumstances, the pharmacist may use non-CRCs where the prescriber, the patient or their representative directs otherwise and the pharmacist in his/her professional judgment considers it appropriate, or where 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 the intervention. It is not appropriate to use a CRC in situations where the patient will have excessive difficulty on an on-going basis in getting the medication out of the container, and where this is likely to compromise the safe, effective and compliant use of the medication. These interventions and decisions should be recorded by the pharmacist in the PMR.

All medicines should be checked for expiry dates. A product must not be supplied after its expiry date. No product that is short-dated can be supplied where it is likely that the course of treatment with that product will continue beyond the expiry date specified on the product.

Labelling of dispensed medicinal products should be clear, legible and computer-generated. The label must contain the relevant information required for the safe and effective use of the product, in a manner that is legislatively compliant. When affixing the label, important information present on the manufacturer's original pack should not be obscured if the product is being supplied in this packaging. If the product is being repackaged, the pharmacist should ensure that any such information

is relayed to the patient, via additional labelling, inclusion of Patient Information Leaflets and counselling.

Under no circumstances should returned medicines be reused. Any medicines returned by patients or their representatives, should be disposed of in an appropriate manner.

A thorough and robust dispensing checking mechanism should be used for the dispensing process, and where possible, a double check system should be employed. The final check should involve reviewing the prescription against the label and the product against the prescription. Particular attention should be paid to ensure that the correct labels are on the correct container and the prescription's instructions are interpreted correctly.

Once dispensed and checked, the medication should be placed in a pharmacy bag that is labelled with the patient's name and address. It is imperative that the product is checked into the bag against the prescription to ensure only medication intended for the named individual is placed ready for collection. There should be a process in place to alert the pharmacist as to particular issues to be raised with the patient or their representative when they collect the prescription. Sticky notes are not appropriate.

Where it is not possible to dispense a prescription in its entirety, the patient or their representative should be informed at the outset and be given the opportunity to take the prescription to another pharmacy. A legible note detailing the name and quantity of the medication outstanding should be provided and a record kept in the pharmacy. Wherever possible the patient or representative must be informed when the balance will be available for collection.

Before leaving the pharmacy the pharmacist should offer to counsel the patient or their representative on the following matters:

- the nature and use of the medicine,
- the directions for use, including how to take/administer it and duration of treatment,
- potential side effects that are likely to be experienced and how to deal with them,
- any special precautions to be taken while on the medication, e.g. foods, drinks or other medicines to be avoided,
- the appropriate storage of the medicine,
- what to do if they think the medicine is not working,
- what to do with any residual medicine as appropriate,
- if the patient is on the medication long term, whether they are experiencing any difficulties with it,
- if a patient's usual medication is changed, then the pharmacist should draw the patient's attention to it, and counsel them on any new medications being introduced.

Where the dispensing of a prescription is complete, it should be endorsed as per relevant legislation, with the date of supply and the word 'dispensed' (or its abbreviation 'disp'), and this prescription document should be retained at the pharmacy . Where there are still items available on the prescription, and it is a repeatable prescription, it should also be endorsed with the name and address of the supplying pharmacy, the quantity of each product supplied and the prescription reference number. A prescription which is not completely dispensed is the property of the patient. If the prescription is written generically, the name of the product dispensed should be specified on the back of the prescription.

Appropriate and required records of each dispensing must be maintained in the pharmacy in accordance with legislative requirements.

No dispensed medication should be handed out to a patient without the pharmacist present at the practice and in a position to exercise personal supervision and intervention at that point. Counselling should be available, accessible and offered to the patient in respect of the dispensed medicine.
The name and address of the person on the prescription should be verified with the individual presenting to collect it prior to handing out any medicinal product.

Home delivery services should be conducted personally by the pharmacist who has dispensed the prescription or by another pharmacist who has checked each dispensed product with the prescription and the pharmacy's PMR before it leaves the pharmacy. Home delivery services conducted by non-pharmacists are not appropriate, as the pharmacist cannot offer to counsel the patient or their representative on their medications in the usual manner in such circumstances.

SECTION 3: DISPENSING OF PRESCRIPTION-ONLY MEDICINES

Ask Yourself	Yes	No	N/A	Required Action
Are all dispensary staff members trained in all aspects and steps of the dispensing process?	☐	☐	☐	
Does a written dispensing procedure exist?	☐	☐	☐	
Are all prescriptions checked for legibility and reviewed with the patient on receipt to check name, address, needs and understanding of the patient?	☐	☐	☐	
Do all staff members routinely ascertain if the prescription is for a child and if so, ask the age of the child?	☐	☐	☐	
Is the prescription assessed routinely for validity?	☐	☐	☐	
Is the prescription routinely assessed for authenticity?	☐	☐	☐	
Does the label used clearly indicate				
• **patient name?**	☐	☐	☐	
• **name and address of supplying pharmacy?**	☐	☐	☐	
• **date of dispensing?**	☐	☐	☐	
• **name of the preparation, its form and its strength, where applicable?**	☐	☐	☐	
• **directions for use including dosage, frequency of use and method of administration?**	☐	☐	☐	
• **where the preparation is being supplied as an emergency supply, at the request of the patient in the absence of a prescription, the words 'emergency supply'?**	☐	☐	☐	
• **the words 'keep out of reach of children'?**	☐	☐	☐	
• **for external medicines, words such as 'Not to be Taken' or 'For External Use Only'?**	☐	☐	☐	
Is the font size used on the label easy for patients to read?	☐	☐	☐	
Are labels placed on medicine packaging in a way that does not obscure important information?	☐	☐	☐	
Are all dispensed prescriptions endorsed as required?	☐	☐	☐	
Are all completed prescriptions retained in the pharmacy for two years from the date of last dispensing?	☐	☐	☐	
Does the pharmacist obtain all relevant patient information before dispensing the prescription?	☐	☐	☐	
Does the pharmacist evaluate the prescription for possible problems prior to dispensing?	☐	☐	☐	
Are all medicines checked for expiry dates in routine management of the dispensary and during each and every dispensing process?	☐	☐	☐	
Is the following information recorded in the prescription book/daily audit?				
• **the date of supply.**	☐	☐	☐	
• **the name, quantity, form and strength of the product supplied.**	☐	☐	☐	

SECTION 3: DISPENSING OF PRESCRIPTION-ONLY MEDICINES (Continued)

Ask Yourself	Yes	No	N/A	Required Action
• **name of the prescriber and, where the prescriber is not known to the pharmacist, his/her address.**	☐	☐	☐	
• **the name and address of the patient.**	☐	☐	☐	
• **the date of prescription.**	☐	☐	☐	
For Repeat Prescriptions:				
• **date of supply.**	☐	☐	☐	
• **reference number of the original entry in the register or all the particulars required for the original prescription.**	☐	☐	☐	
Where the prescription was dispensed at another pharmacy:				
• **the name and address of that pharmacy.**	☐	☐	☐	
• **the reference number used by that pharmacy.**	☐	☐	☐	
For Emergency Supply:				
• **in the case of an emergency supply at the request of a prescriber, the date on which the prescription is subsequently received.**	☐	☐	☐	
• **in the case of an emergency supply at the request of a patient, the nature of emergency and the name and address of the pharmacy where the medicine was previously supplied and the prescription reference number from that pharmacy.**	☐	☐	☐	
Are all returned medicines disposed of in a manner which is safe, controlled and compliant with environmental requirements?	☐	☐	☐	
Are owed medicines indicated by label to inform the patient, and does the label on the prescription product indicate the actual quantity in the container?	☐	☐	☐	
Are all dispensed items labelled appropriately, i.e. the label is affixed to the actual container and one label is affixed to every container?	☐	☐	☐	
Are the data holding and record keeping requirements of the Misuse of Drugs Regulations complied with?	☐	☐	☐	
Are suitable containers used for packing of prescription medicines? Are CRC closures used?	☐	☐	☐	
When a prescriber is contacted to clarify a prescription, is a record maintained in an easily retrievable form?	☐	☐	☐	
Is a secure area available, under the control of the pharmacist, where prescriptions awaiting collection are stored in a safe manner?	☐	☐	☐	
Does the pharmacist hand out the medication to the patient whenever possible?	☐	☐	☐	
Is the patient offered counselling when the prescription is handed out?	☐	☐	☐	
Is such counselling carried out in an area which has suitable sound and sight barriers to preserve patient confidentiality?	☐	☐	☐	

Section 3: Guidance for Services and Systems of Operation

NON-PRESCRIPTION CONTROLLED MEDICATION

SCOPE

Any patient attending at a pharmacy for health information and guidance is entitled to expect that any medicines recommended and supplied during the course of a consultation with a health professional will be safe, effective and appropriate for the condition to be treated and for the intended recipient. This includes the supply of all non-prescription medicines obtained at a pharmacy, whether or not they are also available at non-pharmacy outlets.

CRITERIA

- **Any medicinal product to be supplied in the course of a consultation with a health professional must be known to be sourced from a licensed and attributable source.**
- **Any medicinal product provided in the course of a consultation must be appropriate for the condition it is intended to treat.**
- **Any medicinal product provided in the course of a consultation must be appropriate for the patient it is intended for.**
- **Any medicinal product provided as a result of a direct specific patient request must be assessed as appropriate to need before supply is made.**
- **Any medicinal product must be supplied in a manner which provides for and includes appropriate counselling and information to allow the safe and effective use of the medication.**
- **The patient's medical history must be reviewed when supplying any non-prescription medicine, and this must take account of health status and all medicines usage.**

GUIDANCE

Any patient attending a pharmacy to avail of advice and treatment with non-prescription medicines, should have their autonomy and rights respected when such supply occurs. No medication should be supplied which is not fit for use or fit for purpose.

All staff whose work regularly includes the supply of non-prescription medicines should receive training on this service and related procedures, including circumstances necessitating referral. The patient should be aware that a pharmacist is available to provide advice if they wish to avail of it.

The pharmacy should have adequate resources, including an adequate number of trained staff accessible to patients, to encourage the safe and effective use of medicines. Pharmacists should regularly review and document any internal training provided to staff, and ensure appropriate external resources are available and utilised.

Medicine sales protocols should be in place and should be developed, reviewed, assessed and amended regularly. Documented training and review of staff performance in this area should be available having due regard to the availability of new therapies and products. Protocols should be clear, concise and understandable and should clearly indicate those circumstances where referral to the pharmacist is appropriate.

Pharmacists or trained individuals should always obtain sufficient information from a patient to allow an objective assessment of the nature of product needed for the particular conditions or symptoms the patient wishes to treat. The patient should be central in the decision as to if and what medication is necessary, and should be facilitated in making choices which govern their own health and wellbeing.

In circumstances where, in the professional judgment of the pharmacist, a non-prescription medication is not appropriate, or where a particular non-prescription medication masks symptoms which warrant further investigation, the patient must be counselled and referred to another suitable health professional for treatment.

Patients should receive appropriate and sufficient advice to facilitate the safe, effective use of the medicine and ensure they are empowered in the management of their own health status.
The pharmacy should maintain an adequate range of resource and health promotion material which is available and easily accessible to the patient in a distinct area. It must be clear that if particular information is not available the pharmacy will attempt to source appropriate material if required. All staff should be aware of local and national health initiatives which would be beneficial to the community.

An adequate range of medicines obtained from an authorised source must be maintained. The choice of the most appropriate product for the specific individual and circumstances must be facilitated at all times, with particular care taken in the treatment of more vulnerable patient groups including older people, children and patients with chronic disease states.

Non-prescription medicines are not ordinary items of commerce, and must be stored and supplied in accordance with the applicable legal requirements. The patient must be facilitated to access information and advice in respect of these medicines, which should be sited in a professional services area of the pharmacy and not in the general body of stock. These medicines should not be available for self selection by a patient.

Pharmacists should ensure that they are in a position to intervene in the decision to supply any medicine, particularly those which are exempted from prescription control under the specified legislative conditions, and those that have a particular potential to be abused or misused.

The pharmacist should regularly review and audit usage of stock with particular reference to those products which may be abused. This review should inform the pharmacist in respect of siting of medicines and any patient-specific issues that would need to be addressed.
All staff should be aware that, in certain cases, persistent and consistent use of medicines may indicate the presence of an untreated medical condition. It is advised that the quantity of any product supplied be limited to that sufficient to treat a particular bout of illness. Bulk buying or provision of incentives to bulk buy should not be encouraged and is not appropriate.

The provision of non-prescription medicines to patients, or the provision of advice in respect of the management of a health issue, should always respect the privacy of the individual. The patient should always be aware that they have a right to refuse the advice given. All staff should be aware that they have a shared responsibility to patients in regard to their own health and wellbeing, and that this should not compromise the ability of patients to exercise free choice regarding a health issue.

SECTION 3: NON-PRESCRIPTION CONTROLLED MEDICATION

Ask Yourself	Yes	No	N/A	Required Action
Are adequate staff employed to ensure patients have timely access to advice?	☐	☐	☐	
Are all staff members adequately trained and competent to fulfill their duties?	☐	☐	☐	
Is a documented record of staff training maintained?	☐	☐	☐	
Are adequate information resources available to the pharmacist, support staff and patients to facilitate proper provision of service and informed choices?	☐	☐	☐	
Are medicines sales protocols used?	☐	☐	☐	
Is the use of medicines sales protocols regularly reviewed and assessed?	☐	☐	☐	
Is a procedure in place which informs all staff of the requirements in respect of when to refer a patient to the pharmacist?	☐	☐	☐	
Is a secure professional services area available in which all non-prescription medicinal products are located?	☐	☐	☐	
Can the pharmacist on duty supervise the supply of all medicines – i.e. are all sales occurring within the sight, hearing and supervision of the pharmacist?	☐	☐	☐	
Can patients self select medicines without any provision for intervention prior to them leaving the pharmacy?	☐	☐	☐	
Is there a distinct area where patients can access health information?	☐	☐	☐	
Is an area available where a patient may have a private discussion with the pharmacist?	☐	☐	☐	
Is a mechanism provided whereby the patient is aware that there is ready access to a pharmacist?	☐	☐	☐	
Are patients encouraged through any on-site mechanism to routinely seek health advice?	☐	☐	☐	
Is a regular audit carried out by the pharmacist to ensure that abuse of non prescription medicines is minimised?	☐	☐	☐	
Is a policy in place to assist individuals who may be abusing/misusing non prescription medicines?	☐	☐	☐	
Are items identified as having potential for misuse/abuse stored in a suitable publicly inaccessible area?	☐	☐	☐	
Are staff members who are trained to provide advice in respect of the use of non-prescription medicines visible and approachable?	☐	☐	☐	
Are all staff members aware of the legal requirement in respect of the necessity of the presence of the pharmacist to supply POM(E) medicines and/or poisons?	☐	☐	☐	

NOTE: This section should be read in conjunction with relevant articles from the September 2012 and March 2013 eNewsletter

Section 3: Guidance for Services and Systems of Operation

EXTEMPORANEOUS DISPENSING

SCOPE

Extemporaneous dispensing should only occur on receipt of a patient-specific request from a practitioner for a particular safe and effective formulation which is not available as a licensed manufactured product. Such a product must be required by that patient for a particular health condition, and be assessed, formulated, prepared and dispensed in an auditable manner, in an appropriate environment.

CRITERIA

- The product must be prepared in a manner which guarantees its quality, safety, efficacy and appropriateness for use.
- A complete auditable trail in respect of each extemporaneous preparation should be generated and maintained for at least two years, with such audit facilitating a checking mechanism at each stage of the procedure.
- Appropriate facilities and equipment must be provided and maintained in a hygienic manner to facilitate the preparation of such products.
- All professional staff involved in the extemporaneous dispensing of a product must be competent, and maintain an appropriate skill level to safely perform this function.
- The component substances for any extemporaneous dispensing must be obtained from a reputable source, and stored and managed in a manner consistent with their properties.
- The final product should be presented in a manner consistent with facilitating the safe and appropriate storage, retention and use by the patient.

GUIDANCE

A patient presenting a prescription for a product required to be extemporaneously compounded should expect that this product will be compounded by the pharmacist or under their direct supervision in a manner that delivers a safe, effective and high quality product.

The facilities provided for the extemporaneous compounding of any product should be maintained in a clean and hygienic manner.

The equipment used for extemporaneous compounding should be easily accessible, maintained in an hygienic and operable condition, be regularly calibrated (where appropriate) and must contain at least the following items – apparatus which allows for the accurate weighing of substance within the range of 10mg to 2kg , range of weighing boats, a range of graduated Type A glass measures and pipettes to allow for the accurate measurement of volumes from 0.05mls to 500ml or a range of syringes and syringe filters, a suitable set of mortars and pestles including one glass set, a glass or marble ointment slab, a glass stirrer and a stainless steel spatula. All equipment should be cleaned prior to and after use.

A pharmacy receiving a prescription or request to compound an extemporaneous product, which by virtue of its nature, properties, method of preparation, or final method of use, requires specialist expertise and/or equipment, over and above the minimum specified, should not attempt to compound such product if the integrity of the process and product would be compromised, or risk posed to the personnel involved, or the patient using the product. In this instance the original pharmacy receiving the prescription should refer the patient to a practice equipped to deal with the request and should facilitate and liaise with this practice in the best interest of the patient.

A pharmacy should have a policy in place which addresses the responsibilities of any individual involved in extemporaneous compounding including personal hygiene, health issues including allergies and appropriate protective clothing.
All chemicals and materials used in the extemporaneous compounding process should be of appropriate pharmaceutical grade and quality. Expiry dates and safety material and information should be available.

A pharmacy should have a written policy in place which provides for an auditable trail in respect of every product extemporaneously compounded. Records should be maintained which clearly indicate, at least, the formulation used, the material used with batch and expiry references where appropriate, the quantities used, source of materials, preparation processes and workings and identity of the compounder and checking system. A record sheet should be produced for each individual preparation and a duplicate label affixed thereon. Ideally, all calculations and measurements should be double checked by a second appropriately trained member of staff.

A request to provide an extemporaneously compounded product should be assessed in a manner such that the dispensing pharmacist is satisfied that it is safe, appropriate and in the best interest of the patient to provide the product.
The availability of an appropriate and equivalent commercially prepared product should be ruled out.

The formulation used must be obtained from a reputable, peer reviewed source and external expertise obtained where necessary.

The extemporaneously compounded product should be packaged in a container with due regard to the properties of the product including, but not limited to, form, thermostability and photostability.

The product should be clearly and appropriately labelled to comply with regulatory provisions in place. Clear and legible directions should indicate precautionary warnings and directions for use. "As directed" is not appropriate and should not be used. Labelling must include an expiry date for the product and any special storage instructions.
Regular assessment of the procedures used for extemporaneous dispensing should be carried out.

SECTION 3: EXTEMPORANEOUS DISPENSING

Ask Yourself	Yes	No	N/A	Required Action
Are the facilities present to allow for the safe compounding of an extemporaneous product?	☐	☐	☐	
Is a written cleaning schedule and sign off sheet utilised for cleaning of the extemporaneous area?	☐	☐	☐	
Is the dispensing bench smooth and impervious?	☐	☐	☐	
Is a sink with draining board and hot and cold water supply provided within the dispensary area?	☐	☐	☐	
Is the following equipment present:				
• apparatus which allows for the accurate weighing of substances within the range 10mg to 2kg,	☐	☐	☐	
• range of weighing boats,	☐	☐	☐	
• range of graduated Type A glass measures and pipettes to allow for the accurate measurement of volumes from 0.05mls to 500ml or a range of syringes and syringe filters,	☐	☐	☐	
• suitable sets of mortars and pestles including one glass set,	☐	☐	☐	
• glass or marble ointment slab,	☐	☐	☐	
• glass stirrer and stainless steel spatulas.	☐	☐	☐	
Are written policies in place in respect of appropriate personnel responsibilities when compounding?	☐	☐	☐	
Is a range of specialised protective clothing available including overalls, gloves and masks where appropriate?	☐	☐	☐	
Are all personnel trained and competent to provide the service?	☐	☐	☐	
Are all substances appropriately sourced?	☐	☐	☐	
Are all substances held for the use of compounding appropriately stored?	☐	☐	☐	
Are all substances held accompanied by all relevant safety data?	☐	☐	☐	
Is an individual work sheet generated for each and every product compounded?	☐	☐	☐	
Does the worksheet detail at least the following:				
• Patient details	☐	☐	☐	
• Constituents	☐	☐	☐	
• Formulation, calculations and procedure	☐	☐	☐	
• Storage and usage requirements	☐	☐	☐	
• Duplicate labels	☐	☐	☐	
• Prescription reference	☐	☐	☐	
• Expiry	☐	☐	☐	

SECTION THREE: EXTEMPORANEOUS DISPENSING (Continued)

Ask Yourself	Yes	No	N/A	Required Action
Are such records easily retrievable and stored in an appropriate manner for at least two years from date of compounding?	☐	☐	☐	
Is an appropriate range of containers available for packaging of extemporaneously compounded products?	☐	☐	☐	
Is an appropriate range of measuring devices available to provide to patients when necessary?	☐	☐	☐	
Are CRCs available for use?	☐	☐	☐	
Is a regular audit system in place to facilitate ongoing quality assurance?	☐	☐	☐	

NOTE: This section should be read in conjunction with the Guidance for Pharmacists on Data Protection, available on the PSI website

Section 3: Guidance for Services and Systems of Operation

DATA MANAGEMENT WITHIN THE PHARMACY

SCOPE

A pharmacy must recognise the importance of data management and provide for the associated responsibilities. Suitable procedures must be provided that make due provision for the safe management of personal patient information, and allow for records to be maintained that are compliant and satisfy all legal and ethical responsibilities.

CRITERIA

- **A data management policy must be in place to account for the appropriate management, utilisation and retrievability of any data and information obtained in the course of the operation of a pharmacy. Such information must be collected, recorded and used in a manner that protects confidentiality and privacy.**
- **The data management policy must provide for the adherence to all legislative requirements in respect of medicines and pharmacy law, and also provide for the provisions of the Data Protection Act.**
- **An appropriate system of management of data must provide structure and clarity in respect of the holding of all relevant material.**
- **Appropriate authorised levels of access to data must be specified and adhered to in the operation of the pharmacy.**
- **Information should be held in a clear, concise and consistent manner which will not create any ambiguity in interpretation.**
- **On ceasing the operation of a pharmacy, appropriate provision must be made to provide for retention and retrievability of data for patients who wish to access it.**

GUIDANCE

Recording keeping requirements for the dispensing of prescriptions and other supplies of medicines are set down in the Medicinal Products (Prescription and Control of Supply) Regulations 2003-2007, and the Misuse of Drugs Regulations 1988-2007. These records should be maintained either electronically or in a bound prescription book. If maintained electronically, it is necessary to print out the record on a daily basis and have it signed and dated by the pharmacist. These should be filed and retained for at least two years in the pharmacy. It should be noted that adequate secure backups must be made of records which are maintained electronically, and this back-up process regularly verified.

A Controlled Drugs (CD) register (in bound book form) must be used for recording all incoming and outgoing CDs. Each product/strength must be entered on a separate page, and running balances maintained. Entries must be made in the CD register as soon after the transaction occurs as is practical, but in any case within 24 hours.
Suitable registers for recording the sale and supply of poisons, methylated spirits and animal remedies should also be readily available.

The pharmacy should have suitable filing facilities available to file all records, registers and dispensed completed prescriptions, and allow for their timely and efficient retrieval by all interested parties authorised to have access to such records. Records are legally required to be retained on the premises for two years from the relevant date.

The pharmacist must be aware of the provisions of the Data Protection Act 1988-2003 and must ensure that they are familiar with the practical implications. The trust and confidentiality shared between the pharmacist and the patient must not be dishonoured.

SECTION 3: DATA MANAGEMENT WITHIN THE PHARMACY

Ask Yourself	Yes	No	N/A	Required Action
Has the pharmacy completed a Data ProtectionStatement under the terms of the Data Protection Act?	☐	☐	☐	
Is an appropriate filing system used in respect of all prescriptions dispensed at this practice?	☐	☐	☐	
Does the filing system allow for the prompt retrieval of each and every prescription dispensed and retained at the pharmacy?	☐	☐	☐	
If the filing system provides for the retention of "repeat" prescriptions, are these easily retrieved when subsequent dispensing occurs?	☐	☐	☐	
If a "repeat" file is maintained, is this file culled on a monthly basis, and when patient medication regimes change, to minimise the risk of inappropriate dispensing?	☐	☐	☐	
Are the following available?				
• **Prescription book/daily audit**	☐	☐	☐	
• **CD register**	☐	☐	☐	
• **Poisons register**	☐	☐	☐	
• **Methylated spirits register**	☐	☐	☐	
• **Veterinary sales register**	☐	☐	☐	
If a prescription book is used, are all entries in chronological order and complete?	☐	☐	☐	
If a daily audit is done, is this produced within 24 hours and checked, signed, dated and appropriately filed by the pharmacist on duty?	☐	☐	☐	
Is the following information recorded in the prescription book/daily audit?				
• **the date of supply**	☐	☐	☐	
• **the name, quantity, form and strength of the product supplied**	☐	☐	☐	
• **name of the prescriber and where the prescriber is not known to the pharmacist, his/her address**	☐	☐	☐	
• **the name and address of the patient**	☐	☐	☐	
• **the date of prescription**	☐	☐	☐	
For Repeat Prescriptions:				
• **date of supply and reference number of the original entry in the register or all the particulars required for the original prescription**	☐	☐	☐	
Where the prescription was dispensed at another pharmacy:				
• **the name and address of that pharmacy, and reference number used by that pharmacy**	☐	☐	☐	
For Emergency Supply:				
• **In the case of an emergency supply at the request of a prescriber, the date on which the prescription is subsequently received**	☐	☐	☐	
• **In the case of an emergency supply at the request of a patient, the nature of the emergency and the name and address of the pharmacy where the medicine was previously supplied and the prescription reference number from that pharmacy.**	☐	☐	☐	

SECTION 3: DATA MANAGEMENT WITHIN THE PHARMACY (Continued)

Ask Yourself	Yes	No	N/A	Required Action
Are dispensed prescriptions retained on the premises for at least two years from the date of dispensing?	☐	☐	☐	
Are prescription books/daily audits retained for a minimum period of two years from the date of dispensing?	☐	☐	☐	
Are prescriptions correctly annotated/endorsed at each dispensing?	☐	☐	☐	
Is the CD register maintained in the form of a bound book with one preparation per page, and in accordance with the requirements of the Misuse of Drugs Regulations 1988?	☐	☐	☐	
Is the CD register up to date and does it accurately reflect the content of the safe?	☐	☐	☐	
Are entries in the CD register made within a maximum period of 24 hours?	☐	☐	☐	
Is the CD register retained on the premises for two years from the date of last entry?	☐	☐	☐	
Is controlled access to patient records and confidential information observed?	☐	☐	☐	
Is a secure method for disposing of obsolete confidential patient information provided, e.g. a shredder?	☐	☐	☐	
Is sufficient information provided to the patient to allow for safe use of the medicinal product provided?	☐	☐	☐	
Are prescription labels clear and legible and contain the following information:				
• **date of dispensing**	☐	☐	☐	
• **the name of the patient**	☐	☐	☐	
• **the name and address of the pharmacy, doctor or dentist who supplied the preparation**	☐	☐	☐	
• **unless the prescriber directs otherwise, the proprietary name of the preparation or the generic name with the name of the producer**	☐	☐	☐	
• **the directions for use and any precautions specified on the prescription**	☐	☐	☐	
• **such of the cautionary or warning notices, as specified in the Fifth Schedule, as the pharmacist deems appropriate**	☐	☐	☐	
• **the words '*Keep out of the reach of children*'**	☐	☐	☐	
• **in the case of a preparation for external use, the words *'For external use only'*?**	☐	☐	☐	
Does the pharmacist document the following if appropriate:				
• interventions	☐	☐	☐	
• consultation with other health professionals	☐	☐	☐	
• non-compliance	☐	☐	☐	
• side effects/adverse reactions/interactions	☐	☐	☐	
• "No CRC" requests	☐	☐	☐	
• drug regime changes	☐	☐	☐	

NOTE: Blood Pressure Monitoring and Cholesterol Testing has been superseded by the PSI Guidance on the Provision of Testing Services in Pharmacies.

Section 3: Guidance for Services and Systems of Operation

BLOOD PRESSURE MONITORING

SCOPE

A pharmacy providing blood pressure screening and monitoring services must provide the service in an appropriate facility, with appropriately trained personnel responsible for such service, and in accordance with a protocol which accounts for a partnership with the primary physician and the patient.

CRITERIA

- Appropriate equipment that is safe, reliable, consistent and easy to use must be available.
- Appropriate procedures must be in place which detail, describe and provide for a safe and reproducible mechanism for measurement.
- Interpretation of results must take account of best practice standards, and all personnel delivering the service must be trained and audited in their performance of this role.
- Appropriate systems of documentation, record keeping, referrals and follow-up must be specified.

GUIDANCE

An adequate range of equipment should be readily available and accessible and should be situated in a dedicated testing area which is comfortable and private. This equipment should be accurate, reliable, simple to use, regularly calibrated and easily cleaned and maintained.

A suitable quality control system should be in place to assess ongoing accuracy of the testing process and applied regularly to ensure that accurate, reliable readings are obtained on a consistent basis.

Suitable health information resources should be available to patients to explain and answer queries in respect of the procedure, results and management of a hypertensive condition. Advice should be available relating to lifestyle, preventative actions and medicines used or taken.

Any patient availing of the service should be comfortable with the process, and appropriate consent should be provided to the tester. The patient should be advised and aware that for 30 minutes prior to carrying out the test no strenuous exercise, smoking or ingestion of caffeine should have occurred. The effect of any medicines being taken, health status, gender, risk factors and age should be considered.
The patient should be relaxed and seated for a number of minutes prior to carrying out the process. Ideally the cuff should be on the same horizontal level as the heart and the patient's arm comfortably relaxed on a table with palm facing up.

Criteria for referral to another health professional should be compiled using appropriate current expertise, and referral of patients should be done in a manner that does not raise undue concern.

SECTION 3: BLOOD PRESSURE MONITORING

Ask Yourself	Yes	No	N/A	Required Action
Is blood pressure testing carried out in a private, dedicated, comfortable area?	☐	☐	☐	
Is the equipment easy to use and reliable?	☐	☐	☐	
Are relevant personnel trained in the carrying out of the test process?	☐	☐	☐	
Are information leaflets available for patients?	☐	☐	☐	
Are results provided in a documented format?	☐	☐	☐	
Are copies of results maintained in the pharmacy?	☐	☐	☐	
Is the relevance of test results explained in a clear, understandable manner?	☐	☐	☐	
Are patients advised of the necessity of having no strenuous exercise, smoking or caffeine 30 mins prior to testing?	☐	☐	☐	
Are patients allowed and facilitated to relax for 5 minutes prior to conducting the test?	☐	☐	☐	
Are there appropriate criteria for referral?	☐	☐	☐	

NOTE: Blood Pressure Monitoring and Cholesterol Testing has been superseded by the PSI Guidance on the Provision of Testing Services in Pharmacies.

Section 3: Guidance for Services and Systems of Operation

CHOLESTEROL TESTING

SCOPE

Cholesterol testing should be carried out in a safe, hygienic and designated area of the pharmacy by an adequately trained member of pharmacy staff. Testing procedures should be robust and produce an accurate reading in which the pharmacist will advise an appropriate recommendation dependent on the result and the patient's medical history.

CRITERIA

- Patients must be counselled prior to conducting a test and appropriate consent sought prior to proceeding.
- Cholesterol testing must be carried out in a private area of the pharmacy by personnel who are appropriately trained and competent.
- Adequate information must be available to the patient for future cholesterol management.
- Standard operating procedures (SOPs) must be in place to ensure an appropriate service.
- External quality control must be exercised regularly to ensure robust test results.
- Equipment and facilities must be adequate for the service provided.

GUIDANCE

Any pharmacy practice providing a cholesterol testing service to the public should ensure that patients understand the scope of the test, and accept the indicative, but not definitive, nature of the result. Testing of cholesterol levels is an invasive procedure and appropriate signed patient consent should be obtained.

Suitable health information and advice should be provided before any testing procedures are carried out. Information leaflets, if available, should be provided at the testing site.
Cholesterol testing should be conducted by suitably trained and competent personnel, in an appropriately non-public and hygienic setting. The privacy and permission of the patient and the safety of the procedure should be ensured.

The testing procedure must be robust and a written SOP should be developed for all aspects of the process, which should include referral to another health professional when necessary.

All necessary equipment should be available at the testing site and should reflect the safety of the testing procedure, having due regard to the required precautions in the handling of blood and body fluids.

Appropriate staff training should be conducted which covers the understanding of the physiology and health implications of the management of cholesterol levels. The procedure and equipment utilised should be of a clinical standard and the process conducted by trained personnel. It may not be sufficient to rely solely on training provided by a manufacturer of testing products and/or reagents. A documented record of the training undertaken by staff should be kept.

Regular internal audits and review of procedures should be undertaken and assessment of facilities, equipment, staff and the delivery of service carried out. This should be performed by the supervising pharmacist who should avail of appropriate external clinical and laboratory expertise in this assessment. No service should be provided if there are any doubts in respect of its robustness, efficacy and integrity. An external evaluation should also be done to verify the procedure, test reagents and the reporting processes.

The results should be provided to the patient in a comprehensive report. The language used should be easily understood by the patient, and it should also be ensured that the patient availing of the service understands the implications of the procedure and the results.

Maintenance of testing equipment should be conducted regularly in accordance with manufacturer's guidance. Calibration of electronic apparatus, computers and printers should be conducted to ensure the integrity of the equipment. All maintenance, calibration and quality assessment records should be retained for inspection.

The personnel involved in testing procedures should be provided with appropriate protective clothing and gloves. A 'Sharps' disposal container must be available along with suitable hand washing and drying facilities. Staff training should address the immediate action to be taken in the event of a needle stick incident. Appropriate vaccinations should be provided for staff involved in testing and appropriate precautions taken at all times to avoid infection with blood borne disease and cross contamination.

Personnel involved in the testing procedures should not provide medical diagnosis, notwithstanding that the results are provided to the patient in an objective and comprehensive manner. If the test results are indicative of the possibility of a medically significant issue, the patient should be advised to consult a health professional trained in the management and diagnosis of adverse health states.

Advice and information on diet, high risk categories, lifestyle issues and management of related health issues should be given to the patient. Information leaflets or website details should be available and provided in the course of a consultation.

Copies of results and other related records should be retained in the pharmacy, as well as provided to the patient. Where appropriate and with patient consent, it may also be necessary to provide these to the patient's GP. In all instances, patient confidentiality and the requirements of the Data Protection Act must be adhered to.

SECTION 3: CHOLESTEROL TESTING

Ask Yourself	Yes	No	N/A	Required Action
Is the cholesterol testing service provided carried out in a suitable location within the pharmacy?	☐	☐	☐	
Are the staff members who are conducting tests adequately trained?	☐	☐	☐	
Is staff training documented?	☐	☐	☐	
Is the counselling made before tests are undertaken documented?	☐	☐	☐	
Are health promotion leaflets available for patients?	☐	☐	☐	
Is the test procedure quality assured?	☐	☐	☐	
Is the equipment utilised in testing of an appropriate quality?	☐	☐	☐	
Are protective clothing and hand washing resources provided?	☐	☐	☐	
Are internal and external audits of procedures made?	☐	☐	☐	
Is the result given to the patient verbally and/or in writing?	☐	☐	☐	
Is calibration of electronic equipment done and records kept?	☐	☐	☐	
Is a 'Sharps' container available?	☐	☐	☐	
Are appropriate procedures in place to address inadvertent needle stick injury?	☐	☐	☐	
Are paper towels and appropriate hand wash facilities provided?	☐	☐	☐	
Are appropriate records maintained?	☐	☐	☐	

NOTE: This section has been superseded by the PSI Guidance on the safe supply of Methadone

Section 3: Guidance for Services and Systems of Operation

MANAGEMENT OF SERVICE PROVISION TO OPIOID MISUSERS

SCOPE

A pharmacist who delivers specialised care to patients with health issues associated with the misuse of opioids, must provide that care in an integrated partnership system within a structured programme of management. This must provide the patient, in his/her local community, with adequate resources to mitigate against the negative effects of inappropriate drug consumption.

CRITERIA

- Pharmacists providing opioid treatment services must be aware of, and operate in a manner which complies with relevant legislation, systems advice and management, issued in conjunction with the drug treatment programme.
- Any patient availing of treatment for opioid misuse must not be stigmatised by any action of the pharmacist, or have their health need identifiable to other patients attending at the pharmacy.
- Any pharmacy providing this service must have appropriate and adequate resources to ensure a safe and effective operation.
- Any pharmacy providing this service must have structured protocols in place to facilitate safe and effective operation.
- A pharmacy providing this care must ensure that all staff have the requisite level of specialist knowledge that may be required to effectively manage the programme.

GUIDANCE

Dispensing of methadone for the treatment of opioid misuse ideally should be for patients from the local community and the prescriber should be a local, appropriately trained and registered GP, or from a drug clinic.

Sufficient resources should be provided to ensure the delivery of an appropriate and safe level of service.

All legislative provisions and requirements of the Methadone Treatment Protocol should be adhered to in the provision of the service.

A written protocol should be drawn up between the patient and the pharmacist and it should outline what is expected of both parties and lay down the rules of the programme. It should also include mutual standards of behaviour, aspects of confidentiality, liaison with the prescriber, time of treatment and how the treatment is to be taken.

A suitable, legislatively compliant, locked facility should be used for the storage of methadone, and the pharmacist should take responsibility for the security of the facility keys.

Legislatively compliant records should be maintained in respect of the drug and the patient. All legislative requirements in respect of the record keeping pertaining to Schedule 2 CDs must be adhered to, and patient-specific records should be administered detailing the patient's treatment regime, missed doses, warnings given and decisions.

Staff involved in all aspects of the programme (including part time and locum staff) should undergo specific training. The training should include how the programme operates, management of the programme, preparation of the doses, procedures to facilitate reconciliation of the CD register, storage criteria and re-ordering of stock.

Special training may be needed to deal with patients who do not follow the established protocols, or who are non-compliant with agreed behaviour.

Patients presenting on the first occasion should be allocated a specific appointment with the pharmacist to discuss mutual expectations in their health management. Communication and liaison with the prescriber are essential to ensure best outcome for the patient and it is essential that the patient understands that all relevant health issues will be discussed with their practitioner. In certain specific circumstances, supervision of specific patients may have to be put into place. Security and protection for staff involved with the programme should be provided, including appropriate health protection such as vaccination.

SECTION 3: MANAGEMENT OF SERVICE PROVISION TO OPIOID MISUSERS

Ask Yourself	Yes	No	N/A	Required Action
Are all staff members involved in the methadone programme appropriately trained?	☐	☐	☐	
Are appropriate specialised resource materials provided for staff?	☐	☐	☐	
Are the pharmacists fully briefed in respect of all relevant health information pertaining to each particular patient using this specialised service?	☐	☐	☐	
Is the pharmacy in possession of a full range of contact numbers to ensure the maximum level of accessibility to the prescriber?	☐	☐	☐	
Are security and protective measures discussed with staff?	☐	☐	☐	
Are the local Garda advised that the service is being provided?	☐	☐	☐	
Is a written contract between the patient and the pharmacy in place outlining rules and conditions of supply provided?	☐	☐	☐	
Is the Drug Treatment Card present at the pharmacy prior to initiation of therapy?	☐	☐	☐	
Is the identity of the patient routinely established by checking this card?	☐	☐	☐	
Are patients using the service known to staff members?	☐	☐	☐	
Are appropriate records maintained?	☐	☐	☐	
Is a quiet confidential area available for the patient to consume daily doses?	☐	☐	☐	
Are take away doses dispensed with CRCs and appropriate measures?	☐	☐	☐	
Are empty bulk methadone containers rinsed with water after use and disposed of appropriately?	☐	☐	☐	
Is all methadone stored in a secure facility before and after dispensing, and is the key in the possession of the pharmacist?	☐	☐	☐	
Is a written protocol in place for re-ordering methadone stock?	☐	☐	☐	
Are all staff members involved competent and confident to interact with, and manage, an intoxicated patient according to protocols?	☐	☐	☐	
Are all staff involved competent and confident to interact with and manage a patient who has missed doses, according to protocol?	☐	☐	☐	
Is a written procedure available and are staff trained in the management of possible contaminated spillages?	☐	☐	☐	
Is a written procedure available and are staff trained if a breach of skin or other danger to health occurs?	☐	☐	☐	

NOTE: Residential Home Supply has been superseded by the PSI Guidance on the care of patients in Nursing homes/Residential care settings

Section 3: Guidance for Services and Systems of Operation

RESIDENTIAL HOME SUPPLY

SCOPE

The provision of pharmacy services to a residential unit (not having a pharmacist employed therein) must ensure that an equivalent level of care is provided to each and every patient as would be received at a visit to the pharmacy practice.

CRITERIA

- The pharmacy must have a policy consistent with best practice which addresses, at a minimum, the ordering, storage, dispensing, compounding, delivery and supply of medicines, as well as the provision of information and advice, accessibility to the patient and quality assurance.
- The safe supply of the appropriate medication to the appropriate patient must at all times be guaranteed, and the pharmacist must be aware of the particular challenges that a collective domiciliary environment creates.
- A partnership model should be established with the management and staff of the residential unit to ensure that procedures are robust, appropriate and understood.
- A resident's right not to avail of a pharmacy contracted to a particular residential unit should be upheld, and the supplying pharmacy must ensure that this has been addressed with all residents, including implications for patient care if their pharmacy is not accessible out-of-hours.
- All legislative controls in respect of the management of medicines must be adhered to and prescription should only be issued by a practitioner authorised to do so.

GUIDANCE

The residential unit should be provided with a comprehensive pharmacy service which facilitates the accurate and timely supply of medicines, information and care to ensure best patient outcomes.

A structured policy and system of communication should be in place which makes clear provision for the ordering of a required service or product. A prescription controlled medicinal product should only be provided on the basis of receipt of a prescription issued by a person authorised to do so.
Telephone or fax ordering of prescription controlled medicinal products should not occur – emergency supply provisions should be complied with if, in appropriate and exceptional circumstances, a prescription is not readily available.

The Patient Medication Record (PMR) should not be utilised to facilitate the generation of the prescription by the prescriber. Routine requesting of repeat prescriptions should not be carried out by the pharmacy but should be carried out by the patient or the management of the residential unit on the patient's behalf.

Patient choice and consent must be provided for, and a pharmacy should make provision for appropriate recognition of this right. This choice is both in respect of the use of a particular pharmacy, where it is suggested that consent forms are availed of, and in respect of the use of a particular medicine.
Dispensed medicinal products for a patient of a residential unit should be processed in the same manner as other prescriptions, and should satisfy all legislative requirements in respect of labelling and record keeping.

The pharmacy should make appropriate provision to address its operational requirements associated with service provision to a residential unit, and provide adequate facilities, equipment, staff and resources to allow for the safe and effective delivery of care.

A patient domiciled in a residential unit is entitled to receive access to the pharmacist providing the pharmacy service. Delivery of medicines should ideally be carried out by the pharmacist responsible for the dispensing. Provision should be made to address the acute requirement for a medicinal product by a patient.

The pharmacy should provide support services to staff, patients and management of the residential unit and provide advice and information in respect of medicines storage requirements, medication review, interactions, adverse effects, drug information, destruction of product, health promotion and clinical pharmacy. Additional care must be taken in respect of items with specific storage requirements, such as refrigeration, to ensure that advice is given.
There should be a named pharmacist responsible for the supply, who is readily contactable in emergency situations.
The pharmacy should document the service arrangement in place and should implement quality assurance systems and procedures in respect of all aspects of the service delivery.

SECTION 3: RESIDENTIAL HOME SUPPLY

Ask Yourself	Yes	No	N/A	Required Action
Are all medicines prescribed by an appropriate practitioner?	☐	☐	☐	
Is the initiation of prescription controlled medicines use always directed by a prescribing practitioner?	☐	☐	☐	
Are all prescriptions received prior to the supply of a medicinal product?	☐	☐	☐	
Does telephone or fax ordering of prescription medicines occur?	☐	☐	☐	
Are all prescriptions written in a legislatively compliant manner?	☐	☐	☐	
Are appropriate dispensing procedures utilised in the provision of service?	☐	☐	☐	
Are all medicines appropriately labelled with the label affixed to the immediate container holding the product?	☐	☐	☐	
Are sufficient pharmacists employed to facilitate the appropriate level of diligence required in the checking, supervision, and service provision?	☐	☐	☐	
Are sufficient support staff employed to facilitate safe and effective working?	☐	☐	☐	
Is sufficient space provided in the pharmacy to facilitate the work required?	☐	☐	☐	
Are sufficient stocks held to facilitate appropriate service levels?	☐	☐	☐	
Is there an adequate suitable and operational range of equipment provided?	☐	☐	☐	
Are suitable additional specialist reference information material and resources available to address any specialist needs of the residential unit?	☐	☐	☐	
Does the pharmacist undertake the delivery?	☐	☐	☐	
Are appropriate verification documentation kept in respect of the delivery service?	☐	☐	☐	
Are CDs handled in an appropriately secure manner?	☐	☐	☐	
Is a designated person nominated to whom CDs are delivered?	☐	☐	☐	
Are any products supplied in a monitored dose system (MDS) format, and if so is the preparation and presentation of such in adherence with guidelines?	☐	☐	☐	
Does the pharmacist conduct a scheduled visit to the home not less than once per week?	☐	☐	☐	
Does the pharmacist provide counselling to patients and staff?	☐	☐	☐	
Does the pharmacist conduct reviews of patients' medication and charts?	☐	☐	☐	
Does the pharmacist monitor supply and stock?	☐	☐	☐	
Does the pharmacist ensure appropriate arrangements are available for the destruction of expired products?	☐	☐	☐	
Do the pharmacists encourage reporting of adverse drug reactions and are these reported to the IMB?	☐	☐	☐	
Does the pharmacist advise patients on health management and self-medication?	☐	☐	☐	
Are patient consent forms routinely obtained?	☐	☐	☐	
Is there a documented quality assurance system in place?	☐	☐	☐	
Is a complaints mechanism available to patients?	☐	☐	☐	

Section 3: Guidance for Services and Systems of Operation

MONITORED DOSAGE SYSTEMS

SCOPE

The provision by a pharmacist of dispensed medicinal products in a monitored dosage system (MDS), to facilitate patient compliance, must be carried out in a robust and auditable manner.

CRITERIA

- **The pharmacy must have appropriate and adequate facilities, personnel, premises and equipment to allow for the safe preparation of products in MDS format, according to the volume of activity required.**
- **The appropriate responsibilities and accountabilities must be addressed to facilitate adequate and appropriate checking of the compiled system.**
- **The suitability of the product for dispensing in this manner must be determined.**
- **The operation of service must comply with all legislative and ethical obligations inherent on the pharmacist.**

GUIDANCE

The delivery of a medicinal product in MDS format should be carried out in a manner which is documented by a standard operating procedure (SOP). The SOP should, at a minimum, address the internal issues related to the ordering, assembly, preparation processes, supervision, checking, labelling and delivery of the system. The steps involved in the process of preparation should be analysed in a methodical manner and all aspects of risk removed in so far as possible. All personnel involved in the process should be consistently and appropriately trained to follow the specified procedures.

Dedicated facilities and all necessary equipment should be available, to allow competent personnel to work effectively and safely, so that all MDS are prepared in a timely and accurate manner.

Staff should be trained in all aspects of the complete process. Ongoing reviews, assessment and amendment of all aspects of the process should be made regularly. New personnel, who at any stage may be required to assist in this procedure, should be aware of and familiar with all aspects of the SOP.

Any patient requesting the supply of medicinal products in a MDS format must have their request assessed in partnership with the pharmacist before deciding to avail of the service. It must be apparent that MDS is appropriate, that the patient will be able to use it properly, that it will improve compliance, and will be cost effective and risk neutral to the patient. The counselling process is important and should take due regard of patient confidentiality and promote the use of the prescribed medicine in a safe and rational manner.

The dispensing of a prescription utilising an MDS format should be carried out in a sequential manner similar to the dispensing of any other prescription. The patient details and the medicines are entered in the computer and labels generated. Warning labels should be used where appropriate. Details of any prescribed changes in medicines, strengths, doses, quantities or MDS method are noted in the computer comments box and must be entered by, or under, the supervision of the pharmacist. Patient Information Leaflets (PILs) should be provided for changed medicines.

The medication must be suitable to be packed in an MDS. Medicines which have a variable dose, (e.g. warfarin and PRN medicines), and hygroscopic and photosensitive products are not suitable and must be supplied in alternative containers.

Protective gloves should be worn when MDS containers are being loaded. Individual tablets or capsules should be loaded with as little handling as possible, using tweezers and tablet counting trays. The equipment must be cleaned regularly and the preparation area kept clutter-free.

The SOP must have systems for recording and checking that the MDS has been loaded correctly, checked against the medicine's original container and signed off by the person who has completed it. A further check should be done by the pharmacist. 'Dispensed by' and 'Checked by' boxes which are initialled by the dispenser/checker are recommended. If spare trays are prepared in advance, they must contain all the information required as if the tray was going directly to the patient (i.e. patient name, medication name, dose, identifiers, expiry date, etc.).

Non-disposable trays must be thoroughly cleaned and dried before re-use. An appropriate system for disposal of returned waste medicines in, or from, MDS should be in place. Returned medicines may not be re-used. A risk assessment of the process must be carried out regularly if there are changes in procedures in the pharmacy, or if a significant event relating to MDS occurs.

The presentation of an MDS to the patient must be clean and professional and must be analogous to the presentation of any dispensed medicinal product, with due regard to information provision and appropriate and suitable counselling.

SECTION 3: MONITORED DOSAGE SYSTEMS

Ask Yourself	Yes	No	N/A	Required Action
Is a written SOP utilised, including reporting of adverse events, pertaining to the supply of medicines in an MDS?	☐	☐	☐	
Have all personnel involved in the preparation and delivery of medicines in an MDS system read the SOP and signed off on it?	☐	☐	☐	
Are patients counselled regarding the utilisation of a MDS prior to the dispensing process?	☐	☐	☐	
Is a private area provided for counselling?	☐	☐	☐	
Are samples of the various MDS products available?	☐	☐	☐	
Is a dedicated adequate area provided for storage and loading of the MDS?	☐	☐	☐	
Is the essential equipment maintained in a hygienic condition?	☐	☐	☐	
Are effective written and verbal communication facilities established for the pharmacist to be able to supervise staff for safe and efficient work flow?	☐	☐	☐	
Is adequate equipment and protective equipment provided?	☐	☐	☐	
Is the equipment checked regularly to see it is operational?	☐	☐	☐	
Do the written prescriptions arrive in the pharmacy before the MDS are packed?	☐	☐	☐	
Are patient details and medicines, including changes, entered into the computer and labels printed, before written prescriptions are received?	☐	☐	☐	
Are the labels checked against the written prescription? Is a 'Dispensed by/Checked by' box initialled by the dispenser?	☐	☐	☐	
Is the medication suitable to be packed into a MDS?	☐	☐	☐	

NOTE: This section should be read in conjunction with PSI Inspector's advice on Animal Remedies

Section 3: Guidance for Services and Systems of Operation

VETERINARY PHARMACY

SCOPE

The provision of veterinary pharmacy services is governed by current legislative provisions, which impose requirements in respect of the purchase, possession and sale of animal medicines. A pharmacy providing such service must be competent and equipped to do so, and maintain sufficient expertise to provide a safe, effective and comprehensive service.

CRITERIA

- **Animal remedies supplied from a pharmacy must be appropriately licensed for supply and must be sourced only from a licensed wholesaler of animal remedies.**
- **The legislative provisions applicable to the management of animal remedies must be adhered to in the supply of any animal remedy.**
- **Satisfactory provision must be made to ensure adequate facilities, resources and competent personnel are available to safely and effectively provide veterinary pharmacy services.**

GUIDANCE

The management and supply of veterinary medicines and care should be performed by personnel who have sufficient expertise in veterinary pharmacy and are competent to manage all issues arising.

The provisions of the Animal Remedies Regulations 2007 must be adhered to in respect of the routes of supply.
Any prescription accepted for dispensing by a pharmacist should be written in ink or printed. Prescriptions should be legible, signed and bear in block letters the name and address of the registered veterinary practitioner. The prescription must contain the required legislative details, and consist of an original and duplicate copy.

The validity period of the prescription must not have elapsed when any animal remedy is supplied. The maximum period of validity of any prescription is twelve months from the date of signature by the prescribing veterinary practitioner. All appropriate professional considerations in respect of the dispensing of any prescription must be taken in respect of clear, unambiguous understanding of the therapy required. The pharmacist should exercise their professional knowledge and judgement as to the appropriateness and safety of the prescription.

The authenticity of any prescription presented for dispensing should be established prior to supplying any medicinal product. The pharmacist must be satisfied that the prescription is written by a practitioner who is authorised to do so and that this person did in fact do so.
All animal remedies should be checked for expiry dates and should not be supplied after their expiry date. No product that is short-dated may be supplied, where it is likely that the course of treatment with that product will continue beyond the expiry date specified on the product.
Labelling of dispensed animal remedies should be clear, legible and computer-generated. The label should contain the information required by legislation to allow the safe, effective use of the product.
Pharmacies should have arrangements in place to take back unused or out of date animal remedies from their customers, for return to their suppliers.

Pharmacies should display a price list for all animal remedies.
Any pharmacy practice providing internet/mail order/solicit order service in respect of animal remedies must be licensed for such activity and should be aware that only animal remedies that are designated LM (licensed merchant) and CAM (companion animal medicine) may be supplied under such licence.

Appropriate and required records in respect of the management of animal remedies must be maintained in the pharmacy in accordance with the legislative provisions in place.

A pharmacy should not sell an animal remedy into another EU member state unless the animal remedy concerned is authorised in that state, and also unless the manner of sale is in accordance with the law of that state.
The pharmacist should be aware of the provisions of the cascade system which facilitates the "off label" use of animal remedies, in certain cases human remedies and in certain cases extemporaneously prepared products. Extemporaneous dispensing should only be in response to a veterinary prescription and such products should not be prepared in advance.

SECTION 3: VETERINARY PHARMACY

Ask Yourself	Yes	No	N/A	Required Action
Are all staff members involved in the provision of veterinary pharmacy services appropriately trained and competent?	☐	☐	☐	
Are appropriate facilities, resources, staff and equipment available?	☐	☐	☐	
Are all animal remedies sourced from an authorised supplier?	☐	☐	☐	
Are all animal remedies stocked authorised for use in this jurisdiction?	☐	☐	☐	
Are all prescriptions dispensed within their validity period with an original and duplicate document presented for dispensing?	☐	☐	☐	
For partial dispensing of a prescription, is the following procedure adhered to:				
• **the original and duplicate are endorsed with identity and quantity of animal remedy received, date dispensed and signature.**	☐	☐	☐	
• **photocopy of the prescription is retained and the original and duplicate returned to the patient?**	☐	☐	☐	
When a prescription is fully dispensed is it endorsed as fully dispensed, is the original retained and the duplicate returned to the patient?	☐	☐	☐	
Does the label of a dispensed animal remedy contain the following:	☐	☐	☐	
• **name and address of the dispensing pharmacy**	☐	☐	☐	
• **serial number of the prescription**	☐	☐	☐	
• **name of prescribing practitioner**	☐	☐	☐	
• **date of supply**	☐	☐	☐	
• **dose and duration of treatment (unless indicated on packaging)?**	☐	☐	☐	
Are emergency supply provisions adhered to in an appropriate manner?	☐	☐	☐	
Are records maintained in respect of all incoming and outgoing transactions in respect of all purchases and sales of animal remedies for a period of 5 years?	☐	☐	☐	
Are all animal remedies classified as POM (E) sold personally by the pharmacist?	☐	☐	☐	
Are all animal remedies designated P sold under the personal supervision of the pharmacist?	☐	☐	☐	
When a human product is prescribed for an animal is the pharmacist satisfied, prior to dispensing, that this is justified, i.e. that there is no animal remedy authorised in the State for the treatment of the condition in the animal, no animal remedy for another animal species, nor for another condition in the same species?	☐	☐	☐	
Are all medicines stored in appropriate conditions?	☐	☐	☐	
Is a separate veterinary medicines refrigerator with temperature monitoring available and utilised?	☐	☐	☐	
Are all CDs stored in an appropriate controlled drug safe?	☐	☐	☐	
Are prescription-only medicines stored out of reach of the public?	☐	☐	☐	

SECTION 4:
GUIDANCE FOR GOVERNANCE AND QUALITY ASSURANCE

NOTE: This section should be read in conjunction with the Responsibilities of the Superintendent Pharmacist, available on the PSI website.

Section 4: Guidance for Governance and Quality Assurance

ERROR MANAGEMENT

SCOPE

A pharmacy must have a policy, which requires evaluation and ongoing amendment, of systems to prevent and/or minimise the risk of error in the management and supply of medicines and information. Any adverse incident occurring in a pharmacy should be dealt with promptly, efficiently and professionally and should always ensure that the welfare and safety of the patient is the primary focus.

CRITERIA

- **Systems must be in place which ensure that the patient is encouraged to bring any apparent error occurring to the attention of the pharmacist, whether or not any adverse event or damage to health ensued.**
- **A policy must be in place to address any 'near miss' events that occur and which provides a learning outcome for all staff.**
- **A policy must be in place to address all discovered and reported errors and which provides for a learning outcome.**
- **All errors must be addressed promptly, efficiently and professionally in a robust manner which provides for an appropriate level of follow-up care.**
- **A designated staff member must be responsible for ensuring that all errors are managed in accordance with the current policy, and ensuring that learning and appropriate remedial action occurs.**

GUIDANCE

A pharmacy should operate a structured error handling system which ensures that when an adverse event occurs, the safety of the patient is the primary focus and learning from the incident occurs to prevent or reduce the risk of re-occurrence.

The pharmacy policy should accept that errors will occur, and should foster conditions which allow assessment and management of the interaction of processes, facilities, staff and error-inducing conditions. This policy should aim to reduce the probability of an error occurring, and minimise potential consequences. Ongoing definition of quality and ongoing quality review in the operation of the pharmacy should assist in the generation of the policy. An incident reporting system should be used to address 'near miss' incidents and allow learning from these incidents. This should provide a mechanism to identify and anticipate probable future issues and allow for the institution of appropriate preventative action.

If an error occurs, it should be clearly delineated as to what the immediate action and notification pathways are, to facilitate the prompt handling of the issue. The pharmacist on duty should always be the person notified, whether the error is noted by staff or by a patient. The discovery of an error should always be notified irrespective of the nature or degree of severity or resulting impact.

Error avoidance should be built into all of the process and policy documents utilised in the pharmacy and these should be regularly reviewed and updated. Detection of errors should be proactive and the daily activity of the practice should be continuously critically assessed and monitored in an ongoing manner. SOPs should be utilised to introduce uniform safe practice procedures and reduce variability. All personnel should be encouraged to be aware of conditions which may impact on their ability to safely deliver care and should be encouraged to adapt their actions to allow for prioritisation of work to avoid this.

If an error has reached the patient level, the patient should be immediately contacted and informed of the nature of the error with the pharmacist making every effort not to cause undue alarm or distress and expressing regret that the error occurred. The response to an error must be prompt and the cause established in the handling of the error. Appropriate remedial action should be taken to ensure that the minimum impact occurs as a result. The pharmacist should exercise professional judgement in deciding on the course of corrective action that is required. This may include, for example:

- Amending any labelling errors.
- Replacing incorrect medicines.
- Referring to a GP or hospital.
- Counselling the patient on any possible adverse consequences.
- Making follow-up contact where appropriate.
- Establishing the reason or cause of the error.

Where an error has occurred specific to a process or procedure, the complete process for that particular activity should be reviewed, e.g. for a dispensing error the procedure and the actions in handling the particular prescription should be assessed and checked.

Corrective procedures should be implemented to prevent a re-occurrence, and the patient should be made aware of these. Corrective action should be taken to avoid a repeat of the error, examples of this include:

- In the case where an incorrect strength was dispensed, separate or distinguish more effectively these products on dispensary and over-the-counter shelves.
- The dispensing procedures and medicines sales protocols, or staff training, should be reviewed in the light of the error

Full details of all errors should be recorded accurately and comprehensively, including all actions taken. It should be recorded in the PMR or other appropriate place. It is recommended that an error incidence log be maintained in the pharmacy. The pharmacy professional indemnity insurers should be informed of any dispensing errors.

A pharmacy should have a structured and specified complaints handling process to address any issue arising for a patient, member of the public or staff. Patients, members of the public and staff are entitled to know the complaints procedure when making a complaint. The complaints handling process must be documented and available to all.

SECTION 4: ERROR MANAGEMENT

Ask Yourself	Yes	No	N/A	Required Action
Is a clear written policy in place to deal with errors, addressing at a minimum the detection, reporting, response and remedial action?	☐	☐	☐	
Are all staff aware of the policy and have they been trained in all aspects of error handling?	☐	☐	☐	
Are staff members advised on the outcomes after an error has been dealt with?	☐	☐	☐	
Are errors documented and an error file maintained?	☐	☐	☐	
Within the process, is any further training required by staff after an error has been identified?	☐	☐	☐	
Is the error file used as a training tool for staff?	☐	☐	☐	
Does all dispensing occur from the original prescription as legislatively provided for?	☐	☐	☐	
Are similarly packaged products stored and sited in a manner which minimises the possibility for mix-up?	☐	☐	☐	
Are those products with a narrow therapeutic index highlighted as requiring extra caution in use?	☐	☐	☐	
Is a rigorous checking system used for the dispensing process?	☐	☐	☐	
Are inter-professional relationships managed to facilitate open and effective communication at all times?	☐	☐	☐	
Are all staff competent and trained in the delivery of the role they fulfill and aware of the necessity of referral at appropriate times?	☐	☐	☐	
Are all staff trained in the safe and effective recommendation and supply of OTC medicines?	☐	☐	☐	
Are all staff aware of the medicines sales protocols that are utilised in the practice?	☐	☐	☐	
Do regular quality and safety audits and reviews occur?	☐	☐	☐	

Section 4: Guidance for Governance and Quality Assurance

QUALITY ASSURANCE

SCOPE

A pharmacy practice must strive to ensure delivery of excellence in care, to safeguard the health and wellbeing of the patient, by continuously evaluating and reviewing operating systems in an objective manner. A pharmacy practice must verify that the care provided meets patient needs and expectations. This involves an overview of the activity of the practice, including the planning of service delivery , a consistent implementation process, monitoring and evaluation of the implemented process, with any necessary actions for improvement taken. Any change must be evidence based and in line with accepted best practice. The process of quality assurance is continual and outcome dependent.

CRITERIA

- **A quality assurance programme must be implemented and maintained in a pharmacy.**
- **A verifiable method of operation must be planned and detailed in respect of all aspects of the pharmacy practice, and must be consistent with the delivery of best patient outcomes. Such planned processes must govern the daily operation of the practice and reflect current best practice standards, and must be documented.**
- **Continual review and evaluation of all processes must occur in a robust and measurable manner involving assessment of adherence to planned processes. Specific areas for improvement must be identified and appropriate human, financial and physical resources required for the pharmacy provided.**
- **External advice and references should be taken into account when reviews are made.**

GUIDANCE

The pharmacy owner should ensure the implementation, with the co-operation and assistance of all staff, of a documented, ongoing quality management programme that provides a systematic verification that the pharmacy service is delivering the highest achievable quality. This should monitor, at a minimum, staff performance, equipment, facilities and adherence to standards of practice.
The quality assurance programme should include a plan for each of the service areas in the pharmacy, to provide confidence that requirements will be met.

The management structure within the pharmacy should be documented, with clearly defined allocation of duties and responsibilities outlined for all staff members. Each staff member should be trained in the aspects of service quality and quality management which are relevant to their work responsibilities.
The programme should provide for an organisation of the practice such that its service conforms to the highest level of pharmaceutical care. It should also plan the development and implementation of targets and measure effectiveness in achieving the desired output.

As the processes are patient focussed, the characteristics of the pharmacy's patients and their health needs, as well as a process of patient feedback, should be developed. The patients and the public should be able to ascertain the services, and availability of the services, being offered by the pharmacy. The programme should include provisions to protect the confidentiality of information given to and relating to specific patients or persons.

The programme should include a process for the reporting and documentation of known, alleged and suspected errors, 'near-miss' and adverse events, and their follow-up, and a process for the efficient and prompt action of product recalls and caution-in-use events.

The pharmacy should have a consistent mechanism and policy in place in respect of suspected incidences of misuse and/or abuse of non-prescription medicines, whereby the issue is addressed to account for the health and wellbeing of the patient.
The pharmacist/owner should provide services which recognise the cultural identity, literacy and language issues, and health needs of its patients.
Procedures for training staff and improving quality of service should be put into place.
A documented risk management system should be integrated into the quality improvement process and risk management training should be availed of.
SOPs should be developed, documented and used in the pharmaceutical and retail activities, and reviewed regularly.
Documentation of all pharmacy quality standards, procedures, policies and guidelines should be comprehensive, current and readily available to all staff.

SECTION 4: QUALITY ASSURANCE

Ask Yourself	Yes	No	N/A	Required Action
Does the pharmacy have a current, structured, written quality assurance programme?	☐	☐	☐	
Is the planning of service delivery carried out?	☐	☐	☐	
Does ongoing evaluation and monitoring of performance occur?	☐	☐	☐	
Is there a process for documenting prescription errors and adverse incidents?	☐	☐	☐	
Is there a process for actioning product recalls and caution-in-use notifications promptly?	☐	☐	☐	
Are existing schemes reviewed continuously and changed as a response to error assessment?	☐	☐	☐	
Is a documented programme for staff training followed?	☐	☐	☐	
Is the quality assurance programme reviewed regularly?	☐	☐	☐	
Is the quality assurance programme formulated with staff assistance?	☐	☐	☐	
Is the documented programme readily available for all staff, including locums?	☐	☐	☐	
Are staff employment contracts written and included with the quality assurance documents?	☐	☐	☐	
Do any 'outside' agencies assist with the quality assurance documentation?	☐	☐	☐	
Does the pharmacy monitor patient satisfaction with the services offered?	☐	☐	☐	
Does the pharmacy have a written infection control policy?	☐	☐	☐	
Are all staff members aware of the pharmacy policy for dealing with misuse/abuse of non-prescription medicines?	☐	☐	☐	
Are there up-to-date written procedures, and documented evidence of staff training, for fire, Civil Defense, armed hold-up, hazardous substance spills, etc?	☐	☐	☐	
Are all toxic and harmful substances exposed for retail sales stored out of the reach of children?	☐	☐	☐	
Are the cultural characteristics, literacy or language issues of patients addressed?	☐	☐	☐	
Are patients made aware of a complaints procedure or any other relevant information regarding the pharmacy services?	☐	☐	☐	
Are the business hours of the pharmacy prominently displayed, together with advice for the provision of after-hours services?	☐	☐	☐	

NOTE: This section should be read in conjunction with PSI Inspector's advice on Writing and Maintaining SOPs

Section 4: Guidance for Governance and Quality Assurance

STANDARD OPERATING PROCEDURES

SCOPE

A written standard operating procedure (SOP), or set of procedures, that describes how to perform a given operation, should be generated where possible for each individual operation or procedure carried out in the pharmacy practice. This document should indicate what the procedure is, who has responsibility for carrying it out, and what actions should be taken if the procedures are not performed according to the written protocol. Each document should prescribe chronological steps to follow, and decisions to make, in carrying out a task or function. The implementation of SOPs allows new staff to become familiar with existing processes, and existing staff to continually review and improve their work habits and processes.

CRITERIA

- **The co-ordination and writing of SOPs must be the responsibility of the supervising pharmacist, who must involve staff to provide for good communication and robust procedures.**
- **SOPs must be clear and easy to understand, in short statements or flow charts.**
- **SOPs must be viewed as evolving documents and as part of the Quality Assurance framework, they must be reviewed when new legislation, code of ethics or standards are produced, or when an error or 'near miss' incident occurs.**

GUIDANCE

In so far as possible, all activities occurring in a pharmacy practice should be identified and categorised, and SOPs should be in place for all procedures. SOPs should be reviewed on an ongoing basis, when appropriate external triggers occur and at least on an annual basis.

SOPs should be clear and should address the subject matter in a sequential or chronological manner. The steps in carrying out a task from start to finish must be described in sufficient detail to facilitate an individual with a basic understanding to successfully reproduce the procedure or activity without supervision. An SOP should be written in a concise, step-by-step, easy-to-read format and should not be ambiguous or overly complicated. The best approach to creating an SOP is to write it, then test it.

An SOP must outline a specific mechanism which applies at all times, and define the objective, scope and stages of the procedure, responsibility, other relevant information and a review date. Each document produced is specific for the practice it is produced for, notwithstanding that processes may be very similar at other locations. Variables at each location, such as differing resources, may impact on the operation in the delivery of a particular task or function. All staff should be involved in the development of an SOP, be familiar with its content, and committed to using it.

SECTION FOUR: STANDARD OPERATING PROCEDURES

Ask Yourself	Yes	No	N/A	Required Action
Is there an SOP for hygiene procedures?	☐	☐	☐	
Is there an SOP for pest control?	☐	☐	☐	
Is there an SOP for receipt of stock?	☐	☐	☐	
Is there an SOP for effective stock management?	☐	☐	☐	
Is there an SOP for management of the disposal of expired stock?	☐	☐	☐	
Is there an SOP for products requiring specialised storage?	☐	☐	☐	
Is there an SOP for products requiring specialised handling?	☐	☐	☐	
Is there an SOP for medicines recall?	☐	☐	☐	
Is there an SOP for reporting of adverse drug reactions to the IMB?	☐	☐	☐	
Is there an SOP for key holding?	☐	☐	☐	
Is there an SOP for cash management?	☐	☐	☐	
Is there an SOP for contingency in the event no pharmacist is present?	☐	☐	☐	
Is there an SOP for daily tasks?	☐	☐	☐	
Is there an SOP for complaints handling?	☐	☐	☐	
Is there an SOP for stock taking?	☐	☐	☐	
Is there an SOP for fire safety?	☐	☐	☐	
Is there an SOP for incident management?	☐	☐	☐	

For all relevant up-to-date legislative texts see www.irishstatutebook.ie or the PSI website.

Legislation

The following list identifies those pieces of current (as of May 2008) legislation pertinent to the practice and operation of a pharmacy in this jurisdiction. It relates to pharmacy and medicines legislation and does not include reference to other pertinent legislation, e.g. Health and Safety, Employment. The full texts may be accessed on a number of websites including www.irishstatutebook.ie and www.dohc.ie

A registered pharmacist practising in the Republic of Ireland should have a sufficient knowledge of the law relating to the practice of pharmacy as it applies and as set out, *inter alia,* in the Acts, Regulations, Orders and European Council Regulations and Directives listed below, to be competent to discharge in full the professional responsibilities and duties of a registered practising pharmacist.

Irish Legislation

Misuse of Drugs Acts, 1977 and 1984
Misuse of Drugs Regulations, 1988 and (Amendment) Regulations 1993, 1999, 2006 and 2007
Misuse of Drugs (Safe Custody) Regulations, 1982 as amended
Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998
Misuse of Drugs (Scheduled Substances) Regulations, 1993 and (Amendment) Regulations 2004
Medicinal Products (Prescription and Control of Supply) Regulations, 2003 to 2007
Medicinal Products (Control of Manufacture) Regulations, 2007
Medicinal Products (Control of Wholesale Distribution) Regulations, 2007
Medicinal Products (Control of Placing on the Market) Regulations, 2007
Medicinal Products (Control of Advertising) Regulations, 2007
Medical Preparations (Labelling & Package Leaflets) Regulations, 1993 to 1999
Medicinal Products (Amendment) Regulations, 1999
Poisons Act, 1961
Poisons Regulations, 1982 and (Amendment) Regulations, 1983, 1984, 1986, 1991 and 2003
Animal Remedies Act, 1993
European Communities (Animal Remedies) Regulations, 2007
European Communities (Control of Animal Remedies and their Residues) Regulations, 2007
Pharmacy Act 2007
Pharmacy Act 2007 (Commencement Order) 2007
Pharmacy Act (Ireland), 1875
Pharmacy Act Ireland, 1875, (Amendment) Act, 1890
Pharmacy Act, 1962
Regulations of the Pharmaceutical Society of Ireland, 1971-2002.
Regulations controlling the purchase and sale of Methylated Spirits
Irish Medicines Board Acts, 1995 and 2006
Irish Medicines Board (Miscellaneous Provisions) Act, 2006
European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations, 2007

European Legislation

Directive 2001/83/EC, as amended, concerning the Community code relating to medicinal products for human use **–** *Overall framework for human medicines*
Directive 2003/94/EC – *Good manufacturing practice (GMP) for human medicines*
Regulation (EC) No. 141/2000 – *Orphan medicinal products*
Regulation (EC) No. 1901/2006 – *Medicinal products for paediatric use*
Directive 2001/82/EC, as amended, concerning the Community code relating to medicinal products for veterinary use – *Overall framework for veterinary medicines*
Directive 91/412/EEC – *Good manufacturing practice (GMP) for veterinary medicines*
Directive 90/167/EC – *Medicated feeding stuffs*
Regulation (EC) No. 726/2004 – laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency (EMEA)

Glossary

Act: the Pharmacy Act 2007.

Adverse drug reaction: an undesirable or unexpected medication or related event that requires discontinuing a medication or modifying the dose, requires or prolongs hospitalisation, results in disability, requires supportive treatment, is life threatening or results in death, or occurs following vaccination.

Animal remedy: a product used to amend the health status of an animal and authorised for such use under the terms of the current applicable legislation in force, i.e. European Communities (Animal Remedies) (No. 2) Regulations, 2007.

Auditable trail: a chronological set of steps by which the activity can be charted from start to finish.

Auxiliary Dosage Aids: any aid which facilitates a patient using their medicinal product. Some examples include recording devices, medicine reminder charts, information leaflets, compliance boxes, monitored dosage systems, liquids, inhalers, pill splitters, tube squeezers, eye drops, CRCs and blister packs.

Calibrate: a testing procedure carried out to check the accuracy of a measuring instrument or process.

Child resistant closure (CRC): a type of closure used on a bottle or vial which is designed to "squeeze and turn" so as to restrict ease of opening of the container and restrict access to the content thereof.

Completely dispensed: no additional products are authorised for supply under the authority of a particular prescription.

Compounding: the act of combining two or more substances in the course of professional pharmacy practice to fulfill the individual needs of a patient, either on the direction or decision of the practitioner, patient and/or pharmacist.

Controlled Drugs (CDs): drug substances which are listed in the schedules to the Misuse of Drugs Regulations, 1988 as amended and are subject to specific controls laid down in these regulations, i.e. storage, record keeping, etc.

Confidential information: information provided to a pharmacist in respect of an individual in the course of a professional interaction which would not be accessible or known in the usual course of personal interaction by individuals.

Consultation: two way discussion between the pharmacist and patient regarding health and medicine matters.

Counselling: the communication of information by the pharmacist to the patient or care-giver in order to improve health outcomes, and ensure effective and proper use of therapy, medicines, procedures and/or devices.

Dispensary: an allocated area of the pharmacy which is dedicated to and used at a minimum for the preparation, dispensing and compounding of medicines.

Dispense: the transfer of possession of one or more doses of suitably packaged and appropriately labelled medicinal products or medical devices by a pharmacist, or under the direct personal supervision of a pharmacist, to the end user (patient) or his representative.

Dispensing: the process starting from receipt of a prescription request, assessment of the request, review of medicines therapy and health information, the preparation of the product, recording the prescription, and delivery of the final product with appropriate counselling.

Endorsed: legislatively appropriate annotations are written or stamped on the back of the prescription.

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

Garda Crime Prevention Officer: a member of An Garda Síochána whose assigned responsibility in an area focuses on preventing crime against person and property.

Hazardous product: a product which by nature of its properties and characteristics may cause topical or systemic physical effects to the person handling it or coming into contact with it.

Healthcare facility: the physical premises where services are provided to individuals or communities to promote, maintain, monitor or restore health.

Health professional: an appropriately qualified practitioner who has expertise and holds a recognised and regulated qualification in a particular and specific health discipline.

Health promotion information: information provided in a readily accessible format which informs patients in respect of health-related issues and the support, maintenance and development of good health status.

Human medicines: a product used to amend the health status of an individual and authorised for such use under the terms of the current applicable legislation in force, i.e. Medicinal Products (Control of Placing on the Market) Regulations, 2007.

Intervention: an activity or set of activities aimed at modifying a process, course of action or sequence of events, in order to change the expected outcome.

Job description: the formal documented explanation of those tasks, responsibilities, expectations and activities with which a particular employee is charged.

Legislative requirements: those conditions specified in statute applicable to the carrying out of a function, task or process.

Glossary

Maximum/minimum thermometer: a thermometer which indicates the current temperature and the maximum and minimum temperatures reached since it was last reset.

Medicine therapy: a particular regime of use of medicines which is intended to modify, improve or alter an individual's or animal's health or quality of life.

Non-pharmacy outlets: a commercial outlet which sells commodities which may/may not include certain specified medicinal products.

Non-prescription medication: medical products and devices that may be purchased without the requirement that a prescription authorising such supply be presented to a pharmacist.

Patient services area: the area provided adjacent to the dispensary where professional activity is carried out including the provision of information, and the supply of medicinal products.

Patient's representative: a person who has the authority to act on behalf of an individual wishing to avail of the pharmacy services.

Pharmaceutical Assistant: a person who is named in the current register of Assistants to Pharmaceutical Chemists.

Pharmaceutical Service: the direct provision of drug therapy and other associated pharmacy patient care services through which pharmacists, in co-operation with the patient and other healthcare providers, design, implement, monitor and manage therapeutic plans for the purpose of improving a patient's quality of life.

Pharmaceutical waste: all waste generated by the pharmacy which could be deemed sensitive or hazardous.

Pharmacist: an individual whose name is entered in the register maintained for that purpose by the Registrar of the PSI.

Pharmacy medicines: the medicinal products restricted for sale solely by pharmacies.

Pharmacy premises: the physical building at a specified location in which prescription drugs and devices are maintained, compounded and dispensed for patients by a pharmacist. This definition includes a location where pharmacy-related services are provided by a pharmacist.

Pharmacy team: Registered pharmaceutical assistants, pharmacy technicians, trainee technicians, pre-registration students, students, other dispensary staff, counter assistants and supplementary pharmacy staff.

PILS : patient information leaflets

PMR: patient medication record.

Potable water: water supplied as suitable for drinking.

Prescribed medicines: medicines specifically ordered for the health condition of a patient by a practitioner authorised to do so.

Prescription: the written form of the requirements of a practitioner for the health condition of a patient.

Professional standards: the ethical, moral and legal principles expected of the profession.

PSI: Pharmaceutical Society of Ireland**.**

Quarantined: the process whereby out-of-date, unwanted or obsolete products are placed in a dedicated, separate area of the pharmacy for disposal.

Residential home: any collective environment other than the usual home environment, where people are domiciled on either a temporary or permanent basis and includes homes for the older person, those with a mental and/or physical disability, hospitals, prisons, remand centres and hostels.

Retail pharmacy premises: the building where a retail pharmacy business carries out its activities.

Risk management: the culture, processes and structures that are directed toward effective management of risk.

SOPs: standard operating procedures are written documents outlining all the procedures and protocols that are specific to all activities in the pharmacy business.

Supervising pharmacist: the pharmacist who takes personal responsibility for the professional practice and operation of the pharmacy.

Thermolabile medicines: medicines whose efficacy and stability are affected by changes in temperature.

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Notes

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18 Shrewsbury Road,
Ballsbridge, Dublin 4, Ireland.
T: +353 1 2184000
F: +353 1 2837678
e: info@pharmaceuticalsociety.ie
w: www.pharmaceuticalsociety.ie