

Guidelines on the Keeping of Records in Respect of Medicinal Products when Conducting a Retail Pharmacy Business

to facilitate compliance with Regulation 12 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) (S.I. 488 of 2008)
Pharmaceutical Society of Ireland

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Updates made following the enactment of the Misuse of Drugs Regulations 2017¹ (which replaced the Misuse of Drugs Regulations 1988 (as amended)² are highlighted in grey).

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

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

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1. Introduction

The main purpose of these guidelines is to facilitate compliance with Regulation 12 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended), which details the records to be kept in respect of medicinal products when conducting a retail pharmacy business (i.e. a pharmacy). The requirements for some other important records that ensure safe pharmacy practice are also detailed.

Pharmacists are the healthcare professionals authorised in legislation for the safe keeping and supply of medicinal products to patients. The keeping of accurate records which clearly show when prescription-only medicines are supplied, and to whom, is a key requirement of this role. The keeping of appropriate records also supports the provision of safe services, continuity of care, evidence-based healthcare, good professional practice and management of the medicines supply chain.

These guidelines do not cover record keeping requirements pertaining to the sale or supply of medicinal products intended for use in animals, for information on this topic please refer to the PSI [website](#).

A Summary table of record keeping requirements is provided in Appendix 1.

2. Legislative Basis

The operation of a registered pharmacy is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) (S.I. No. 488 of 2008).

These guidelines focus on the requirements of Regulation 12 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended), the full text of which is set out below. The need to keep records in respect to medicinal products, when conducting a pharmacy, is set out under a number of different legislative requirements, including Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. 540 of 2003) (as amended) and Regulation 19 of the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017) which are included in Appendix 2 and 3 for reference.

It should be noted that in addition to pharmacy and medicines legislation, records must comply with the provisions of the Data Protection Acts 1988 and 2003. Further information on the general principles of data protection can be found in the PSI's 'Guidance on Data Protection for Pharmacists', and on the Data Protection Commissioner's website www.dataprotection.ie.

All legislation can be accessed in full through the PSI website or www.irishstatutebook.ie.

Regulation 12 **Keeping of records in respect of medicinal products**

12.(1) A person carrying on a retail pharmacy business shall keep—

(a) such records as are prescribed under Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended);

(b) such register as is prescribed under Regulation 16 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended); and

- (c) *such other records in electronic form as will enable the patient in respect of whom a medicinal product has been supplied on foot of a medical prescription to be identified together with the said patient's medication record in respect of his or her previous supplies of such products made by the pharmacy.*
- (2) *Where the records referred in paragraph (1)(a) are retained in electronic format, the computer software in use for the retention of such records shall have been independently validated and certified as being suitable for the retention of such records, having regard to the purpose of such controls under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003). Such certification shall appropriately show the version of the software to which the certificate relates and the date on which it was last updated³.*
- (3) *The person responsible for the conduct of such validation and for the issue of the required certification shall be a person approved by the Minister for Health and Children.*
- (4) *A person carrying on a retail pharmacy business shall—*
- (a) *in the case of records referred to in paragraph (1)(a), keep such records readily available for inspection as required under Regulation 10(3) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), and*
- (b) *in the case of the certificate referred to in paragraph (2), keep a certified copy of the said certificate readily available for inspection.*

3. Guidance

The following guidance outlines the record keeping requirements when a prescription-only medicine, including a controlled drug, is supplied to a patient. Record keeping requirements for supply of medicines in other circumstances are also detailed.

3.1 Records Related to Supply of a Prescription-Only Medicine

Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, (as amended) specifies the details that must be recorded in a register when a prescription-only medicine is supplied on foot of a prescription and when supplied without a prescription as an emergency supply.

3.1.1 Supply of a Prescription-Only Medicine on foot of a Prescription⁴

When a prescription-only medicine is supplied on foot of a legally valid prescription, the following must be recorded in a register:

- date on which the product is supplied,

- name, quantity, and except where it is apparent from the name, the pharmaceutical form and strength of the product,

- name of the prescriber and, where they are not known to the pharmacist, their address,

- name and address of the patient,

- date written on the prescription.

3 Regulation 12(2) allows the prescription register to be kept solely in electronic format if the computer software has been independently validated by a body approved by the Minister for Health and certified as suitable for the retention of such records. However to date, the Minister for Health has not approved a body to carry out this function. Therefore, a hard copy print out of these records must be made to meet the requirements of the legislation.

4 Regulation 10(1)(a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

3.1.2 Supply of a Prescription-Only Medicine on foot of a Repeat Prescription⁵

Where the prescription is repeatable the following must be recorded in the register on the second or subsequent supply of a prescription-only medicine:

Either:

- date on which the product is supplied,

- name, quantity, and except where it is apparent from the name, the pharmaceutical form and strength of the product,

- name of the prescriber and where they are not known to the pharmacist, their address,

- name and address of the patient,

- date written on the prescription, and

- where the supply on the last previous occasion was at another pharmacy, the name and address of that pharmacy, and any reference to the entry in the register for that pharmacy in respect of the supply.

Or, where the prescription has been previously supplied by the dispensing pharmacy:

- date on which the product is supplied and a reference to the entry in the register made on the first occasion the product was supplied against that prescription.

3.1.3 Retention of Prescriptions

Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, (as amended) also specifies that prescriptions, (in the case of a health prescription⁶ the duplicate copy of that prescription) must be retained for a period of two years on the pharmacy premises and be readily available for inspection. The retention period begins from the date on which the medicinal product was supplied, or for repeatable prescriptions from the date on which the prescription was dispensed for the last time.

When a prescription which is not completely dispensed is returned to the patient for future supplies, it is recommended to keep a copy of the prescription for reference, in the event that there is a query with the supply or the patient's care.

3.1.4 Emergency Supply of a Prescription-Only Medicine

(i) Where an emergency supply of a prescription-only medicine is made without a prescription at the request of a patient, the following must be recorded in the register⁷:

- date on which the product is supplied,

- name, quantity, and except where it is apparent from the name, the pharmaceutical form and strength of the product,

- name and address of the patient,

- nature of the emergency which made it necessary to supply the product without a prescription,

- name of the prescriber who prescribed the product on the previous occasion and where they are not known to the pharmacist, their address,

⁵ Regulation 10(1)(b) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

⁶ An example of a 'health prescription' would be a GMS prescription or methadone prescription.

⁷ Regulation 10(1)(c) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

- where the supply on the previous occasion was at another pharmacy, the name and address of that pharmacy and any reference to the entry in the register for that pharmacy in respect of the supply.

(ii) Where an emergency supply of a prescription-only medicine is made without a prescription, at the request of a doctor, dentist or nurse prescriber the following must be recorded in the register⁸:

- date on which the product is supplied,
- name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the product,
- name of the prescriber and where they are not known to the pharmacist, their address,
- name and address of the patient.

When the prescription is received the following must be recorded:

- date written on the prescription,
- date on which the prescription is received.

Further information on the legal requirements for the emergency supply of prescription-only medicines is available in the PSI 'Guidelines on Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business' and the PSI Inspectors' Advice on 'Emergency Supply'.

3.2 Records for Supply to a Person for Administration in their Professional Practice and other Circumstances

Legislation provides exemptions to the prescription requirement for the supply of prescription-only medicines, by a pharmacist, to specified persons. For example a pharmacist can supply a prescription-only medicine to a registered medical practitioner, registered dentist or registered veterinary surgeon, for administration to patients in the course of their professional practice or service⁹. A pharmacist can also supply a medicinal product in other circumstances, for example to a University or other institution concerned with higher education or scientific research for the purposes of such education or research¹⁰.

The practitioner/person making the request for such a supply should provide a written order/requisition to the pharmacist¹¹. Every order or invoice, or copy of these, relating to the supply of a medicinal product under these Regulations must be kept for a period of two years on the pharmacy premises, and be readily available for inspection.

Where an order or invoice, or copy of these, is not retained by the supplying pharmacy, the following must be recorded in a register kept for that purpose:

- date product is supplied,
- name, quantity, and except where it is apparent from the name, the pharmaceutical form and strength of the product,
- name, address and trade, business or profession of the person to whom the product is supplied,
- purpose for which the product is supplied.

8. Regulation 10(1)(a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

9. Full details of this exemption are provided in Regulation 6 of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (as amended).

10. Full details of this exemption are provided in Regulation 20 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

11. While the format for such an order is not specified in legislation, it is recommended in the circumstances outlined here to follow the format specified for requisitions in Regulation 14 of the Misuse of Drugs Regulations 2017.

A pharmacist who supplies medicinal products under these regulations should be satisfied, in so far as is possible, that the medication will be used appropriately. If a pharmacist receives a request for a supply of a medicinal product, and is unsure if it is legally permitted, or what records need to be made, they can contact the PSI for further guidance.

3.3 Requirements for the Register/Daily Dispensing Report

The requirements outlined above in Sections 3.1 and 3.2, must either be made in a physical, hard copy register kept for that purpose, or can be kept as computerised records provided that this record is also retained in the form of a print-out for each day that the pharmacy is open. This register is often referred to as the 'prescription register', 'daily dispensing report', 'daily audit' or 'daily print-out'.

Where these records are made electronically and printed each day, the print-out must be dated and signed by the pharmacist on duty on the day to which the print-out relates, or within 24 hours. The print out provides an accurate record of prescription-only medicines supplied from the pharmacy on a given day.

The register, (i.e. the daily dispensing report, signed and dated) must be kept for a period of two years from the date of the last entry made in the register, or the date the print out was signed by the pharmacist on duty. This record must be kept on the pharmacy premises and be readily available for inspection.

The legislation¹² provides an exception to the requirements to keep the records detailed in Sections 3.1 and 3.2, where the medicinal product is supplied in accordance with a health prescription, as the duplicate part of the prescription is retained, and also where a separate record of the supply has been made in the controlled drugs register. However, in

order to maintain a complete and accurate record of all medicines dispensed on a given day it is recommended that these supplies are also included in the prescription register/daily dispensing report.

3.4 Records Relating to Supply and Administration of Medicinal Products in Emergencies, Supply and Administration of Vaccines and Supply of Emergency Medicines to Listed Organisations

Regulation 10A of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), details the particulars that must be recorded when a pharmacist administers an emergency medicine or vaccine in the course of his or her professional practice¹³. These requirements are detailed in the PSI's 'Guidance for Pharmacists on the Safe Supply and Administration of prescription-only medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency' and 'Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses'.

Regulation 10B of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) details the particulars that must be recorded when a pharmacist supplies a prescription-only medicine to a listed organisation for administration in an emergency situation (guidance on supply under this provision will be published shortly).

¹² Exceptions to the requirements to keep certain records are detailed in Regulation 10(2) of the Medicinal Products (Prescription and Control of Supply) Regulations (as amended).

¹³ The Eighth Schedule of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), details the prescription-only medicines which may be supplied and administered by a pharmacist.

3.5 Patient Medication Record

Regulation 12(1)(c) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) requires an electronic record to be kept to enable identification of a patient's medication history. A record of supply must be made each time a medicinal product is supplied to a patient on foot of a prescription. This record is commonly known as the Patient Medication Record (PMR). This record allows the pharmacist to check the patient's previous medication history when dispensing medicines and helps to inform their decisions, for example with regard to potential interactions or contraindications. The PMR should contain all information that the pharmacist deems necessary for the accurate identification of a patient and the safe supply of their medicinal products, for example the patient's date of birth, any known allergies or adverse drug reactions and full contact details for the patient, and the practitioner who prescribed the medicinal product.

Recording professional advice or services provided to the patient in the PMR, can also contribute to good patient care and demonstrate the reasons behind the pharmacist's actions. Information that would be useful to document may include interactions with other healthcare professionals, patient counselling, an intervention, or supplies of non-prescription medicines as deemed appropriate. Information should be recorded in a clear, concise and consistent manner which can be easily understood by colleagues in the pharmacy and does not create ambiguity.

3.6 Controlled Drugs

3.6.1 Records for Receipt and Supply of Schedule 2 Controlled Drugs

Regulation 16 of the Misuse of Drugs Regulations 1988 (as amended) details the requirements for the keeping of registers for receipt and supply of Schedule 2 controlled drugs. Pharmacists have a responsibility to supervise the supply of controlled drugs and ensure that these medicinal products are supplied safely and within the requirements of the legislation. In order to fulfil this role the legislation requires that an accurate and contemporaneous record of the receipt and supply of Schedule 2 controlled drugs from the pharmacy, is made in a controlled drugs register.

The controlled drugs register is defined in legislation as 'a bound book and does not include any form of loose leaf register or card index'¹⁴; Schedule 6 and 7 of the Misuse of Drugs Regulations 2017, provides details of the form that the register must take i.e. headings for details to be recorded. The legislation does not permit the controlled drugs register to be kept electronically.

A separate register must be kept in respect of each pharmacy premises, the PSI provide a Register of Controlled Drugs to all pharmacies to assist in meeting the requirements of the legislation¹⁵. The register was reviewed and reformatted in 2011 to take account of the requirements set out in the legislation.

¹⁴ Regulation 2, Misuse of Drugs Regulations 2017.

¹⁵ A pharmacy can develop their own customised register to suit their particular needs, provided they meet all relevant legislative requirements set out in the Misuse of Drugs Regulations 2017.

The following points set out both the legal requirements and PSI guidance for completing the Register of Controlled Drugs:

- 1) A separate page should be used for each controlled drug product, i.e. for each dosage form (tablet, capsule, ampoule, suppository, syrup etc.) and each strength.

- 2) For every controlled drug product obtained or supplied, the product's name, strength and form and the page on which it is recorded should be noted in the Index.

- 3) It is good practice to take into account the expected usage of the various controlled drugs when setting up the register, an appropriate number of pages should be reserved for the records of each controlled drug depending on the frequency of dispensing.

- 4) The class of drug (drug name) must be entered on the first line on the top of the relevant page. The product name, strength and form should be entered on the second line at the top of each page.

- 5) The register should be completed at the time of the receipt of, or the dispensing of, the controlled drug and must legally be completed on the day of dispensing or the following day.

- 6) The entries must be recorded in chronological order and in a manner which shows the running stock balance.

- 7) Every entry must include the date on which the supply is received or transaction effected, the name and address of person from whom obtained (e.g. wholesaler) or to whom supplied, (e.g. patient), the authority of person supplied to be in possession (e.g. prescription reference), the amount obtained or supplied and the stock balance.

- 8) It is good practice to record the supplier's invoice number for each supply received.

- 9) It is good practice for the pharmacist to sign and/or enter their registration number after each entry. The signature and/or registration number should be legible, thereby ensuring the pharmacist responsible for the accuracy of each entry is clearly identifiable.

- 10) Where a portion of a prescription is dispensed, only the actual amount supplied is to be entered in the controlled drugs register. Any outstanding balance on the prescription should only be entered in the register on the date it is supplied.

- 11) In the event of an error in an entry, no cancellation, obliteration or alteration of the entry should be made. A correction must only be made by way of a dated note, preferably in the footnote section at the bottom of the page. This note should be signed by the relevant pharmacist.

- 12) Every entry and correction of an entry must be in ink or otherwise so as to be indelible.

- 13) When a page has been completed, entries for the controlled drug product should be continued on the next available page, and the new page number should be noted, both in the index and in the box at the bottom right of the completed page. The controlled drug product's stock balance should then be transferred to the new page and the page it has been transferred from should be noted in the box at the bottom left of the new page.

- 14) The Controlled Drugs Destruction Record section of the register should be used for recording the witnessed destruction of all controlled drugs for which a record is maintained in this register. The destruction record should be cross-referenced to the relevant page in the register and the stock balance should be adjusted down to reflect the quantity destroyed.

15) The supervising pharmacist should regularly review the register and satisfy themselves that the register has been completed correctly, by reconciling the register's running stock balances with the contents of the controlled drugs safe, and should sign the page in the register included to facilitate compliance with this¹⁶.

16) The controlled drugs register must not be used for any other purpose.

17) Not more than one register can be kept at any one time in respect of each class of drug (each drug).

18) The register must be kept at the retail pharmacy business premises and must be available for inspection for at least two years from the date on which the final entry is made.

The record keeping requirements for the destruction and disposal of controlled drugs are detailed in the PSI's 'Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business'¹⁷.

3.6.2 Retention of Other Controlled Drugs Records

The Misuse of Drugs Regulations 2017 require that every order, prescription or requisition against which a controlled drug is supplied must be kept for a period of two years on the pharmacy premises, and be readily available for inspection. In the case of a health prescription, or health service requisition, the duplicate copy must be retained for two years. The retention period begins from the date on which the last supply of a controlled drug was made against the order, prescription or requisition.¹⁸

For prescriptions for Schedule 4 Part 1 controlled drugs which can be dispensed on more than one occasion i.e. are repeatable, where the dispensing is not complete a scanned or physical copy of the prescription and the endorsement must be retained on the pharmacy premises. The copy must show the quantity of each Schedule 4 Part 1 controlled drug supplied, the date of supply and the name and address of the pharmacy from which the supply was made¹⁹.

Under this legislation there is also a requirement to keep every invoice, or other like record issued in respect of a Schedule 3 or Schedule 4 Part 1 controlled drug obtained or supplied from the pharmacy, and in respect of every Schedule 5 controlled drug obtained, for a period of two years²⁰.

3.7 Supply of Exempt Medicinal Products

Legislation permits a pharmacist to supply an 'exempt' (i.e. unauthorised/unlicensed) medicinal product to a patient on foot of a legally valid prescription. When an exempt medicinal product is sold or supplied, a record showing the following details must be kept:

- source from which the product is obtained,
- name of the patient,
- date on which the product is supplied,
- quantity of each product supplied,
- batch number of the product,
- details of any suspected adverse reactions to the product supplied, of which the pharmacist is aware.

16 A section to record that the supervising pharmacist has completed an accuracy check of the register has been included at the front of the PSI Register of Controlled Drugs. Additional information on how to carry out an accuracy check is included in the PSI's 'Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business'.

17 To enable compliance with the legislation there is a designated section for recording the witnessed destruction of Schedule 2 controlled drugs in the Register of Controlled Drugs provided by the PSI. The PSI also provide a Controlled Drugs Destruction Record Book to facilitate the recording of the destruction of waste Schedule 3 and 4 controlled drugs and Schedule 2, 3 and 4 controlled drugs which have been returned to the pharmacy e.g. patient-returns.

18 Regulation 22 of the Misuse of Drugs Regulations 2017.

19 Regulation 22(7) of the Misuse of Drugs Regulations 2017.

20 Regulation 23 of the Misuse of Drugs Regulations 2017.

This record can be kept in electronic or paper format, or by a combination of both formats. For example, to meet the requirements of the legislation, the invoice for the product could be kept, which specifies the source from which the product is obtained and the batch number of the product, and the additional requirements could be recorded in the PMR at the time of dispensing.

Regardless of how this record is made, the details specified in the above bullet points must be captured in order to facilitate any recall of an exempt medicinal product. These records must be retained for at least 5 years²¹ and be readily available for inspection.

A procedure should be in place that outlines the steps to follow in the event an exempt medicinal product is recalled in order to identify and contact the patients which may be affected.

As well as keeping a record of any suspected adverse reactions to an exempt medicine in the pharmacy, as with any suspected adverse reaction to a medicine, these must also be reported to the Health Products Regulatory Authority (HPRA), preferably online via their website, www.hpra.ie.

Further information on sourcing exempt medicinal products can be found in the PSI's 'Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business'.

3.8 Other Important Records to be Kept to Ensure Safe Practice

When operating a pharmacy, in addition to recording the supply of medicinal products, there are other important records that must be kept in order to demonstrate that the pharmacy is operating safely. For example, a record of the registered pharmacist responsible for the personal supervision of the sale and supply of medicinal products at the premises (i.e. the Duty Register)²², records for the preparation of extemporaneously prepared medicinal products, for the delivery of medicinal products to patients, medicinal product recalls in response to a recall notification, the recording of fridge temperatures and records for professional services provided in the pharmacy. Many of these records are detailed in other PSI guidance. It is the responsibility of the pharmacy owner, in partnership with the superintendent and supervising pharmacist, to identify all necessary records which relate to the safe operation of their business and ensure these are being made and kept.

It is recommended that records to show the safe operation of the pharmacy are kept for a minimum period of two years.

21 Paragraph 7 of Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) (as amended).

22 This requirement is set out in Regulation 5(1)(c) of the Regulation of Retail Pharmacy Businesses Regulations 2008. The PSI provide a Duty Register to facilitate compliance with this legislation.

3.9 Ensuring Accuracy of Pharmacy Records

It is important that records are complete, accurate and up to date. Full details for the patient and the prescriber should be recorded so that they can be clearly identified and contacted if needed. Pharmacists should be alert to any errors or discrepancies in pharmacy records. This may be anything from the incorrect doctor or an old address recorded on the PMR, to a dose recorded in the patient's history which differs from that which is on their current prescription. Discrepancies or errors in records should not be ignored, as this can have serious consequences for the patient, and also in certain circumstances for colleagues and the safe operation of the pharmacy. It should be clear when an amendment has been made to a record for example by providing details of the amendment in the notes section of the PMR. All errors and discrepancies in records should be followed up and investigated further as needed.

The pharmacy's policies and procedures, as well as practice within the pharmacy should be reviewed following the identification of a discrepancy or error in the pharmacy records, and staff retrained to minimise the chance of a similar incident happening again.

3.10 Access to Records

A system should be in place to enable the timely and efficient retrieval of records, registers and dispensed completed prescriptions when they are needed, whether records are maintained in paper or electronic form. Where records are held electronically, regular back-ups should be made, and the back-up process regularly verified. Any area where paper records are stored should ensure that security and confidentiality is maintained at all times to protect patient privacy.

As records held in the pharmacy often contain personal data about patients' medication history and medical conditions, there should be systems in place to ensure that records are only accessed by authorised persons in the course of their professional practice or duty within the pharmacy. Appropriate access and confidentiality must also be maintained when records are stored off the pharmacy premises.

On ceasing the operation of a pharmacy, appropriate provision must be made for the transfer of pertinent records to another pharmacy and for the retrieval of personal data as required by patients. For further guidance please see the PSI's 'Guidelines on Managing the Closure and Cancellation of the Registration of a Retail Pharmacy Business'.

4. Staff Training

Staff members dealing with records should be competent and trained on the creation, maintenance and use of records. They should understand the importance of records being accurate, complete and made in a timely fashion. This training should include an understanding of:

- what is being recorded

- how it is recorded

- why it needs to be recorded

- what the records are used for

- when to access records

- how to report any errors or discrepancies found in pharmacy records to the pharmacist

All Staff members should also be trained on the importance of confidentiality with regards to patient records and other information which they see and use in the course of the business of the pharmacy.

5. Policies and Procedures

The pharmacy owner, superintendent pharmacist and supervising pharmacist have overall responsibility for ensuring that appropriate records are being made and kept securely in line with medicines and pharmacy legislation, Data Protection legislation and PSI guidance.

Policies and procedures should be in place detailing all records that need to be made in the course of the business of the pharmacy, and to ensure that the correct records are consistently made. Procedures must ensure that records are kept in a secure and confidential manner, and access to the records is restricted to trained staff members in the course of their duties in the pharmacy.

When developing and maintaining policies on the retention of records, as well as complying with the requirements set out in legislation, it is important to consider whether it is necessary to retain the record for a longer period to ensure the provision of safe services to patients, or for other legal or insurance purposes. Notwithstanding this, data protection requirements require that there be a defined retention period for all records, which is clearly documented. Where it is decided to keep a record for longer than the period set out in legislation, the records can be stored for the period exceeding the legal requirement in a location outside the pharmacy premises, if necessary. However, this location must be secure and at all times maintain the confidentiality of the records. All policies and procedures in place in the pharmacy should reflect the principles of appropriate and adequate retention and Data Protection.

The superintendent pharmacist and supervising pharmacist must be satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and are following, the policies and procedures relevant to their role. Compliance with policies and procedures should be regularly evaluated and training records should be maintained.

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1	December 2016
2	May 2017

6. Self-assessment Checklist

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

Ask Yourself	Yes	No	N/A	Required Action
Each time a prescription-only medicine is supplied to a patient, is an electronic record made on the Patient Medication Record?				
For each day the pharmacy operates, is a prescription register, or a daily dispensing report (printed, dated and signed by the pharmacist) maintained, that details all prescription-only medicines supplied from the pharmacy?				
Are all Schedule 2 controlled drugs received by, or supplied from, the pharmacy recorded in the controlled drugs register?				
When an exempt medicinal product is supplied against a legally valid prescription to a patient, are records made and kept for a period of 5 years?				
Are written policies and procedures in place detailing all records that need to be made in the course of the business of the pharmacy?				
Are the retention periods for all records clearly documented?				
Are all records kept in compliance with the provisions of the Data Protection Acts 1988 and 2003?				
Are the pharmacy owner, superintendent pharmacist and supervising pharmacist satisfied that all pharmacists in the pharmacy, and relevant staff members, are trained on, and following the policies and procedures?				

Appendix 1 - Summary Table of Record Keeping Requirements in Respect of Medicinal Products when Conducting a Retail Pharmacy Business

The table below summarises the record keeping requirements detailed in this document; these are the requirements as set out in legislation unless otherwise specified. It should be noted that when considering how long to retain a particular record, as well as the requirements set out in legislation, it is important to consider whether it is necessary to retain the record for a longer period to ensure the provision of safe services to patients, or for other legal or insurance purposes. Notwithstanding this, data protection requirements require that there be a defined retention period for all records, which is clearly documented. Where it is decided to keep a record for longer than the period set out in legislation, the records can be stored for the period exceeding the legal requirement in a location outside the pharmacy premises, if necessary. However, this location must be secure and at all times maintain the confidentiality of the records.

Record	Retention Period	Where
Prescriptions	2 years	On the pharmacy premises
Orders and invoices, or a copy of these, relating to the supply of medicinal products to a registered medical practitioner, registered dentist, or registered veterinary surgeon for administration to a patient in the course of their professional practice	2 years	On the pharmacy premises
Prescription Register i.e. the daily dispensing report signed and dated by the pharmacist on duty	2 years from date of the last entry made in the register, or date the print out was signed by the pharmacist on duty	On the pharmacy premises
Register of Controlled Drugs	2 years from date of the last entry made in the register	On the pharmacy premises
Orders, prescriptions or requisitions against which a controlled drug is supplied	2 years	On the pharmacy premises
Scanned or physical copies of Schedule 4 Part 1 controlled drug repeatable prescriptions which are dispensed in part and any endorsements made	2 years	On the pharmacy premises

Appendix 1

Record	Retention Period	Where
Invoices, or other like record, issued in respect of all Schedule 3 and Schedule 4 Part 1 controlled drugs obtained or supplied from the pharmacy	2 years	Recommended to be kept on the pharmacy premises, but not specified in legislation
Invoices, or other like record, issued in respect of all Schedule 5 controlled drugs obtained by the pharmacy	2 years	Recommended to be kept on the pharmacy premises, but not specified in legislation
Records in relation to sale or supply of exempt medicinal products	5 years	On the pharmacy premises
A record of the registered pharmacist responsible for the personal supervision of the sale and supply of medicinal products at the premises i.e. the Duty Register	Recommended minimum 2 years, but not specified in legislation	Recommended to be kept on the pharmacy premises, but not specified in legislation
Records to show the safe operation of the pharmacy e.g. fridge and storage room temperature records, invoices for medicinal products not listed above	Recommended minimum 2 years, but not specified in legislation	Recommended to be kept on the pharmacy premises, but not specified in legislation

Appendix 2 - Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)

Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) details the pharmacy records that must be kept when a prescription-only medicine is supplied from a pharmacy:

Pharmacy Records

10.(1) Subject to paragraphs (2), (3) and (5), a person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts, 1875 to 1977 shall, in respect of every supply of a medicinal product which by virtue of these Regulations may not be supplied except in accordance with a prescription, enter or cause to be entered in a register kept for that purpose, the following particulars, that is to say -

(a) where the product is supplied in accordance with a prescription or in compliance with regulation 8(1) -

- (i) the date on which the product is supplied;*
- (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the product;*
- (iii) the name of the prescriber and where he is not known to the authorised person, his address;*
- (iv) the name and address of the person for whom the product is prescribed;*
- (v) the date of the prescription; and*
- (vi) in relation to the supply of a product in compliance with regulation 8(1), the date on which the prescription is received.*

(b) where the product is supplied in the dispensing of a repeatable prescription on a second or subsequent occasion -

- (i) the date on which the product is supplied, and a reference to an entry in the aforementioned register which was made on the first occasion on which the product was supplied in the dispensing of that prescription; or*
- (ii) the particulars specified in paragraph (1)(a); and*
- (iii) where the supply on the last previous occasion was at another shop, the name and address of such shop and the reference to the entry in the aforementioned register for such shop in respect of such supply.*

(c) where the product is supplied in accordance with regulation 8(2) -

- (i) the date on which the product is supplied;*
- (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the product;*
- (iii) the name and address of the person requiring the product;*
- (iv) the nature of the emergency which rendered it necessary to supply the product otherwise than in accordance with a prescription;*

- (v) *the name of the prescriber who on the previous occasion prescribed the product and where he is not known to the authorised person, his address; and*
 - (vi) *where the supply on the previous occasion was at another shop, the name and address of such shop and the reference to the entry in the aforementioned register for such shop in respect of such supply.*
- (d) *where the supply is supply by wholesale or is a supply referred to in Regulation 20(1)(a) and no order or invoice, or copy thereof, relating to such supply has been retained by the supplier -*
- (i) *the date on which the product is supplied;*
 - (ii) *the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the product;*
 - (iii) *the name and address and trade, business or profession of the person to whom the product is supplied; and the purpose for which the product is supplied.*
- (2) *The provisions of paragraph (1) shall not apply where -*
- (a) *the product is supplied in accordance with a health prescription, or*
 - (b) *a separate record of the supply is made in accordance with regulation 16 of the Misuse of Drugs Regulations 1988, or*
 - (c) *the supply is supply by wholesale and the order or invoice relating to the supply or a copy thereof is retained by the supplier, or*
 - (d) *the supply is to a sampling officer.*
- (3) *A person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts 1875 to 1977 shall preserve and keep readily available for inspection at such shop for a period of two years from the relevant date –*
- (a) *the register kept under paragraph (1);*
 - (b) *in the case of a health prescription, the duplicate copy thereof and in the case of any other prescription, the prescription; and*
 - (c) *every order or invoice referred to in paragraph (2)(c).*
- (4) *In paragraph (3) “the relevant date” means -*
- (a) *in relation to sub-paragraph (a) the date on which the last entry is made in the register; and*
 - (b) *in relation to sub-paragraphs (b) and (c) -*
 - (i) *where the product is supplied in accordance with a repeatable prescription, the date on which the prescription is dispensed for the last time, and*
 - (ii) *in every other case, the date on which the product is supplied.*
- (5) *The requirements of paragraph (1) shall be satisfied in the case of computerised records provided that the information required to be kept by virtue of the said paragraph is also retained in the form of a print-out for each day on which the shop is open. Such print-out shall be dated and certified, on the day to which the print-out relates or within the period of twenty four hours thereafter, by the authorised person by whom the shop is managed.*
- (6) *References in this regulation to a register shall include the computerised records and daily print-out referred to in paragraph (5).*

Appendix 3 - Regulation 19 of the Misuse of Drugs Regulations 2017

Regulation 19 of the Misuse of Drugs Regulations 2017 details the requirements for keeping a register when a Schedule 2 controlled drug is obtained or supplied from a pharmacy:

Keeping of registers for drugs in Schedules 1 and 2.

- 19.(1) *Subject to paragraph (4) and Regulation 20, every person authorised by or under Regulation 6, 8 or 9 to supply any drug specified in Schedule 1 or 2 shall comply with the following requirements:*
- (a) *he or she shall, in accordance with the provisions of this Regulation, keep a register and shall enter therein in chronological sequence and in a manner which will show a running stock balance, particulars of every quantity of such a drug obtained by him or her and of every quantity of such a drug supplied whether by way of administration or otherwise by him or her whether to persons within or outside the State;*
 - (b) *he or she shall use a separate register or separate part of a register for entries made in respect of each class of drug; and*
 - (c) *the entries in the register referred to in subparagraph (a) shall be—*
 - (i) *in the form specified in Schedule 6, or*
 - (ii) *as the case may require, in the form specified in Part 1 or Part 2 of Schedule 7.*
- (2) *For the purposes of paragraph (1)(b), each of the drugs specified in paragraphs 1 and 3 of Schedule 1 and paragraphs 1, 3 and 6 of Schedule 2 (together with its salts) and any preparation or other product containing it or any of its salts shall be treated as a separate class and any stereoisomeric form of a controlled drug or its salts shall be treated as being in the same class as that drug.*
- (3) *Nothing in paragraph (1) shall be taken as preventing the use of a separate section within a register or a separate part of a register in respect of different controlled drugs or strengths of controlled drugs comprised within the class of controlled drugs to which that register or separate part relates.*
- (4) *The foregoing provisions of this Regulation shall not have effect in relation to—*
- (a) *a person licensed under section 14 of the Principal Act to supply any controlled drug, where the licence so directs, or*
 - (b) *the clinical nurse manager or clinical midwife manager or sister for the time being in charge of a ward, theatre or other department in a hospital or nursing home.*

- (5) Any person required to keep a register under this Regulation shall comply with the following requirements:
- (a) the class of controlled drugs to which the entries on any page of any such register relate shall be specified at the head of that page;
 - (b) every entry required to be made under this Regulation in a register shall, where it is reasonably practicable to do so, be made on the day on which the controlled drug is obtained or on which the transaction in respect of the supply of the controlled drug by the person required to make the entry takes place or, in any case, on the day next following that day;
 - (c) no cancellation, obliteration or alteration of any such entry shall be made, and a correction of such an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made;
 - (d) every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible;
 - (e) a register shall not be used for any purpose other than the purposes of these Regulations;
 - (f) subject to subparagraph (g), not more than one register shall be kept at one time in respect of each class of controlled drug in respect of which he or she is required to keep a separate register;
 - (g) a separate register shall be kept in respect of each premises at which the person required to keep the register carries on his or her business or occupation and where the business is carried on in separate departments within a premises a separate register may, with the approval of the Minister, be kept in respect of each such department; and
 - (h) every such register in which entries are currently being made shall be kept at the premises to which it relates and shall be readily available for inspection under section 24 of the Principal Act.