

# Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business

to facilitate compliance with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations (S.I. No. 488 of 2008)

Pharmaceutical Society of Ireland

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

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

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

# 1. Introduction

The purpose of these guidelines is to facilitate compliance by pharmacists with the requirements of Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) as they apply to the sale and supply of prescribed medicinal products.

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 carer<sup>3</sup>. Under Regulation 9, persons responsible<sup>4</sup> for the conduct of retail pharmacy businesses (i.e. pharmacies) must ensure that, prior to dispensing and prior to the supply of a prescribed medicinal product, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient. On completion of this review, the registered pharmacist is required under the regulations to offer to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his/her professional judgement, deems significant. It is also the duty of the registered pharmacist to ensure that each patient has sufficient information and advice for the correct use and storage of the prescribed medicinal product(s).

Regulation 9, therefore, provides a legislative basis for the therapeutic and pharmaceutical review that must be undertaken by a registered pharmacist upon receipt of a prescription. As a recognised expert in medicinal products, the pharmacist has a unique opportunity and duty to discharge that responsibility in the course of his/her interaction with patients.

If used correctly, medicinal products can greatly enhance the health and wellbeing of patients. However, if used incorrectly or inappropriately, medicinal products have the potential to do great harm. Pharmacists must ensure that their practice, at all times, is guided by the principles set out in the statutory Code of Conduct and must always put the patient first and make the patient's health, wellbeing and safety their primary focus. Patient counselling by pharmacists has a prime place in the ever evolving role of the pharmacist. As such, superintendent pharmacists and supervising pharmacists, must ensure that all staff members are aware of the professional role and responsibilities of pharmacists, particularly in regard to the obligatory review of medicine therapy to be conducted upon receipt of a prescription and the necessary counselling of patients in the dispensing of any prescribed medicinal products.

It should be noted that the Pharmacy Act 2007 requires the sale and supply of all medicinal products, including prescription only medicinal products to be conducted under the personal supervision of a registered pharmacist<sup>5</sup>. The requirement for the sale and supply of all medicinal products to be conducted under the personal supervision of a registered pharmacist is also contained in regulation 5 of the Regulation of Retail Pharmacy Businesses Regulations 2008. These guidelines must be read in conjunction with the overarching requirements of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations as they relate to the personal supervision of the sale and supply of all medicinal products.

3 Where the term 'carer' means patient representative and/or caregiver.

4 Pharmacy owners, superintendent pharmacists and supervising pharmacists.

5 Sections 26, 27, 28 and 29 of the Pharmacy Act 2007.

## 2. Legislative Basis

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

These guidelines are intended to facilitate compliance with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008, the full text of which is set out below.

### Regulation 9

*Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription*

9. (1) *A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned; a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient.*
- (2) *The review provided for in paragraph (1) shall include screening for any potential therapy problems which may arise out of the use of any medicinal product that may have been prescribed and which the registered pharmacist is, or, in the course of his professional practice, ought reasonably to be, aware of. The potential problems to be screened for shall include those which may be due to therapeutic duplication, interactions with other medicinal products (including serious interactions with non-prescription medicinal products, herbal products or foods), incorrect dosage or duration of treatment, allergic reactions, and clinical abuse and/or misuse.*
- (3) *Following completion of the review provided for in paragraph (1) the registered pharmacist shall ensure that each patient has sufficient information and advice*

*for the proper use and storage of the prescribed medicinal product and shall offer to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his/her professional judgement, deems significant, and which may include one or more of the following as may be appropriate—*

- (a) *the identity of the medicinal product, its dosage form, the method and route of administration and the duration of therapy;*
- (b) *the therapeutic benefit which may be expected from the use of the medicinal product;*
- (c) *any special directions and precautions for the correct preparation, administration and use of the medicinal product;*
- (d) *the importance of the need for compliance with the directions for use including techniques for self-monitoring during therapy;*
- (e) *any common severe side-effects and adverse reactions or interactions and therapeutic contraindications which may be encountered, including their avoidance and the action to be taken should they occur;*
- (f) *the action to be taken in the event of a missed dose;*
- (g) *the methods for the safe disposal of the medicinal product in the event of the course of treatment not being completed, and*
- (h) *any other matters which may be included or referred to in the summary of product characteristics for the medicinal product concerned.*

These guidelines must be read in conjunction with the overarching requirements of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations as they relate to the personal supervision of the sale and supply of medicinal products.

## 3. Guidance

### 3.1 Pharmacist's Role and Responsibilities

Under Regulation 9, persons responsible for the conduct of retail pharmacy businesses (i.e. pharmacies) must ensure that, prior to dispensing and prior to the supply of a prescribed medicinal product, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient. Pharmacists are experts in medicines and have a unique opportunity and duty to discharge that responsibility in the course of their interaction with patients. The pharmacist's role involves the responsible supply of medication for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include managing an illness, slowing of a disease process, preventing a disease from occurring or the relief of a patient's symptoms.

Pharmacists, in their role as custodians of medicinal products, should ensure that the review of medicinal therapy and patient counselling is consistent with the needs and safety of the patient. As such the pharmacist must implement robust systems in their pharmacy, reflecting good dispensing practices. The pharmacist must also support the patient in their knowledge and use of their prescribed medicinal products and in this way; empower the patient to make informed decisions regarding their own healthcare needs.

The pharmacist is professionally and legally responsible for the sale and supply of all medicinal products in the pharmacy. This includes any preparation, dispensing and compounding of prescribed medicinal products for the patient. Notwithstanding these legal obligations, certain tasks may be delegated to a suitably trained member of staff, working under the supervision of the pharmacist. If this occurs, the pharmacist must ensure that:

- He/ she can intervene at any point in a delegated process to ensure patient safety
- Staff are trained in the activities they are carrying out
- Appropriate procedures are in place and utilised for the safe supply of medicinal products at the pharmacy.

### 3.2 Initial Review of the Prescription

When a prescription is presented, a pharmacist must fully review the prescription to ensure that the prescription is legally valid and therapeutically appropriate for the patient. This involves assessing the contents of the individual prescription as it relates to the patient for which the prescription was issued. In order to be considered a valid prescription, it is necessary to confirm that the prescription is written in a manner that complies with the legislative requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended and Part 5 of the Misuse of Drugs Regulations 2017. A pharmacist may supply a medicinal product from a prescription if one of the prescription requirements is omitted, where the pharmacist exercises due diligence and care, and is satisfied that it is safe to do so<sup>6</sup>. There must be a standard operating procedure for reviewing the prescription, to ensure that all prescription reviews are conducted consistently, accurately and completely.

<sup>6</sup> Regulation 7(7) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 permits a pharmacist to supply medicinal products from a prescription which is only partially compliant with regulation 7(1) of these regulations where only one of the requirements listed in regulation 7(1) is not met

### 3.3 Pharmaceutical and Therapeutic Assessment of the Prescription by the Pharmacist

The original prescription must be clinically reviewed by the pharmacist before each dispensing to ensure the medicinal product is safe and appropriate for the patient to take. Pharmacists must ensure they have the original prescription when dispensing and not rely on the patient's medication record (PMR), as such a practise can serve to perpetuate any error made in the first dispensing. The pharmacist should use their professional knowledge and judgement to consider if the supply of the medicinal product is safe and appropriate for the patient at that point in time. The pharmacist should also be mindful that if the patient is not requesting all the medicinal products on their prescription that this could be a sign of non-adherence, which could jeopardize the patient's therapeutic outcome. Reasons for requesting a medicinal product too early or not at all should be discussed with the patient and the patient should be counselled appropriately.

When performing the pharmaceutical and therapeutic assessment of the prescription the pharmacist must consider the following points:

- Appropriate strength, dose and quantity of the medicinal product for the patient (particular care must be taken with calculation of doses)

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- Particular care should be taken with high risk patient groups e.g. paediatric patients, and high risk medicines e.g. high tech medicines

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- Suitability of formulation and route of administration for the patient

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- Appropriate directions for use

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- Appropriate duration of treatment

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- Potential duplication of therapy

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- Interactions with other medicinal products

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- Appropriate interchangeability of medicinal products

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- Contraindications, as defined by the relevant literature

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- Precautions for use

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- Known drug allergies

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- Food-drug interactions

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- Incorrect omission of any other medicinal product(s)

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- Known and potential misuse of a medicinal product

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The pharmacist should monitor the patient's medication therapy on an ongoing basis and discuss with the patient's prescribing practitioner any concerns they may have. In addition to the pharmacist's interaction check, the pharmacy must utilize a computer programme that can identify significant drug interactions<sup>7</sup>. The pharmacist must ensure that the patient or carer is appropriately counselled on these interactions with verbal and, where appropriate, written information.

If the pharmacist has concerns with regard to the content of the prescription they should discuss these with the prescriber. If having discussed these concerns with the prescriber the pharmacist still has concerns they may decide not to dispense the medicinal product, however before doing this they should consider the impact that this may have on the patient and their treatment and must be able to justify their actions. Their reasons should be clearly explained to the prescriber and the patient and should be documented in the patient's notes. Where necessary the patient should be referred to an appropriate healthcare professional.

The points addressed above are not exhaustive, and the pharmacist, in the exercise of his/her professional judgement, may deem it necessary to screen for additional issues when supplying the prescribed medicinal products.

### 3.4 Assembly, Labelling, and Supply of Prescribed Medicinal Products

The pharmacist is responsible for overseeing all steps in the dispensing process including the assembly, labelling, packaging and ultimate supply to the patient.

#### Assembly of Medicinal Products

Assembly of the medicinal products includes selecting the prescribed medicinal products (correct product and correct strength) from the appropriate storage area within the dispensary. Each pharmacy should have an organised system for storing prescription only medicines e.g. stored alphabetically or according to therapeutic class. Consideration should be given to which part of the dispensary medicines are stored in, for example it may be prudent to separate paediatric formulations from regular stock. Particular care should be exercised in the storage of different medicines presented in similar packaging and of different strengths of medicinal products presented in similar packaging i.e. sound alike look alike drugs (SALADS), in order to mitigate the likelihood of errors occurring. Assembly areas should be kept clean and free of clutter. The expiry dates of all medicinal products should be checked prior to dispensing.

#### Interchangeable Medicinal Products / Generic Substitution

In some cases a substitute medicinal product may be dispensed. However this must be done in line with the prescriber's instruction/consent or in accordance with the interchangeable list issued under the Health (Pricing and Supply of Medical Goods) Act 2013. When a medicinal product is substituted, the pharmacist must take the necessary steps to ensure the patient is aware of the substitution and is fully counselled on the change, as is the case with the initiation of any new medication. Further information on interchangeable medicinal products / generic substitution under the

Health (Pricing and Supply of Medical Goods) Act 2013 is available on both the PSI and Health Product Regulatory Authority (HPRA) websites.

#### Labelling of Dispensed Medicinal Products

The label of a dispensed medicinal product should be clear and legible and it should be computer generated. All instructions should be clear, specific and easily understood by the patient. Where possible "as directed" as a standalone instruction should not be used. The font size used on the label should be easy for the patient to read, being mindful of any sight issues the patient may have. Labels should not be written exclusively in upper case (capital letters).

If affixing the label to the container or outer packaging of the manufacturer's original pack, important information should not be obscured, for example the expiry date of the product and any braille markings that may be present. Particular attention should be paid to ensure that the correct labels are on the correct container.

The label must clearly show<sup>8</sup>:

- the patient name

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- the name and address of supplying pharmacy

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- the date of dispensing

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- the name of the preparation, its form and its strength, where applicable

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- the directions for use of the product

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- the precautions for use of the product (as specified by the prescriber)

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- the words 'Keep out of reach of children'

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- where the product is for external use only, the words 'For external use only'

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- any cautionary and warning notices that the pharmacist, in the exercise of his/her professional judgement, deems appropriate

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<sup>8</sup> Regulation 9 of Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended

## Packaging of Medicinal Products

The pharmacist should endeavour to dispense all prescribed medicinal products in the manufacturer's original pack (where practical), and include the Package Leaflet (PL) for the prescribed medicinal product concerned. If an original pack has to be split, the pharmacist should ensure that any relevant information is relayed to the patient via additional labelling, counselling and the inclusion of a PL. Additional PL's can be printed from the HPRA website. Child Resistant Closures (CRCs) should be used where possible. Where a preparation is supplied in a manufacturer's original pack, which is not a CRC, the pharmacist should replace it with a CRC unless this is not appropriate for the particular patient. 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. Where a medicinal product is repackaged from its original manufacturer's packaging, into another container, due regard should be paid to the suitability of that container for the medicinal product concerned (e.g. adequate protection from light and heat) as required by the product's Summary of Product Characteristics (SmPC).

## Endorsement of Prescriptions

Where the dispensing of a prescription is complete, it must be endorsed with the date of supply<sup>9</sup> and the word 'dispensed'. Where there are still items to be dispensed on the prescription, and/or it is a repeatable prescription, it must also be endorsed with the name and address of the supplying pharmacy, the quantity of each product supplied and the prescription reference number (if used). If the prescription is written generically, the name of the product dispensed should be specified on the back of the prescription.

## Checking of Prescriptions

The final check is fundamental to ensuring the safe supply of medicinal products to patients. A thorough and robust checking mechanism must be employed by any pharmacist, involved in the supply of prescribed medicinal products to ensure that the medicinal product is correct and safe for the patient. A double check system must be employed. When checking a prescription (particularly in situations where the pharmacist did not personally enter the prescription into the PMR), pharmacists should refer back to the patient history at the point of checking in order to complete the therapeutic review. The final check should involve reviewing the original prescription, against the label and against the product.

If the pharmacist is working on their own, they should ensure that they have a mental break between the assembly and labelling of the medicinal products and doing the final check, to reduce the risk of errors. Particular attention should be paid where a calculation has been required to obtain or check the dose. If possible the calculation should be checked by another appropriately trained member of staff.

Once dispensed and checked the medicinal product should be placed in a pharmacy bag that is labelled with the patient's name and address. It is imperative that the product being put into the bag is checked against the prescription to ensure only medicinal product(s) intended for the named individual are placed ready for collection. When a prescription is being collected two identifiers should be used to correctly identify the patient e.g. name and address.

There should be a process in place to alert the pharmacist or staff member handing the medicinal products to the patient as to particular issues that are required to be discussed or when intervention is needed by the pharmacist. It should be noted that in some instances the pharmacist handing out the prescription and offering to counsel the patient may be different from the pharmacist who performed the clinical check. There should be in-house processes established to deal with such situations.

<sup>9</sup> Regulation 7 of Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2011 and Regulation 16(2) and 16(3) Misuse of Drugs Regulations 2017

## Errors and Near Misses

Errors and near misses should always be reported and recorded and the staff members involved informed of the error. All errors and near misses should be regularly reviewed and used to amend practice, policies and procedures to minimise the risk of a similar incident happening again. Further information on the identification, recording and management of errors and near misses in the dispensing process is available on the PSI website (e.g. Observations and Learnings from PPC Annual Reports).

## 3.5 Counselling on Prescribed Medicinal Products by Pharmacists

Patient counselling involves the pharmacist communicating the correct information and advice to patients regarding their medicine therapy. This is an important role of the pharmacist and is essential in identifying the medical needs of the patient. The counselling process if properly implemented and consistently maintained should result in the safe supply of prescribed medicinal products and ensure that they are used rationally and appropriately. In order to comply with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations, the pharmacist must offer to discuss with the patient or their representative all such matters as the pharmacist, in the exercise of his/her professional judgement, deems significant.

The pharmacist must be satisfied that the patient has sufficient information to take their medicinal product safely and as prescribed, and that they know how to store the medicinal product. Patient counselling is a key component of pharmacy-based care. It is vital that pharmacists are in a position to give appropriate, reliable and trustworthy information to patients regarding their usage of prescribed medicinal products.

The amount and type of counselling required to be provided to patients by pharmacists varies depending on the patient's individual needs, and the individual situation in question. Pharmacists are reminded that they have a duty of care to their patients, and must at all times act in the best interests of their patients, exercising due diligence and his/her own professional judgement. Pharmacists should do their utmost to ensure that the person they are providing counselling to is in fact the patient themselves, or an approved representative of the patient to avoid any unintentional breaches of patient confidentiality. Any method of communication (including communication by digital electronic means) engaged with in the provision of counselling to patients must be in compliance with the appropriate Data Protection legislation.

Counselling is particularly important when supplying a substitute (i.e. generic) medicinal product. Therefore, when a medicinal product is substituted, the pharmacist must take the necessary steps to ensure the patient is aware of the substitution and is fully counselled on the change, as is the case with the initiation of any new medication. The pharmacist should ascertain that the patient has sufficient understanding of the active ingredient in the medicinal product and is aware of how to use their medicinal product safely. Care should be taken to explain which medicinal product has been replaced, to ensure that the risk of duplication of therapy is avoided.

Pharmacists should be readily identifiable when working in the retail pharmacy business and should be highly visible to members of the public so that they can answer concerns and queries patients may have about their medications. Patients should be made aware of the pharmacy's Patient Consultation Area and this area should be used where possible and when appropriate.



### 3.5.1 Counselling Considerations

The main aim of effective patient counselling is to enable and encourage the safe and proper use of medications by patients in order to achieve the required therapeutic outcomes.

To achieve such positive results, a pharmacist may undertake to counsel the patient or his/her representative on the following matters, as deemed appropriate:

- the nature and use of the medicinal product

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- the directions for use
  - how to take/administer it

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  - duration of treatment

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- the therapeutic benefit which may be expected from the use of the medicinal product

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- potential side effects that are likely to be experienced and how to deal with them

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- any special precautions to be taken while using the medication
  - special regard for food or drink
    - which foods to avoid

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    - which drinks to avoid

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    - take with(out) food

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    - take with(out) drink

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  - which other medicinal products to avoid

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- the importance of the need for compliance with the directions for use

- where a medicinal product has been interchanged in line with prescriber's instruction/consent, or in accordance with the HPRA interchangeable list, to avoid confusion for patients and to ensure that the risk of duplication of therapy is avoided

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- storage of the medicinal product

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- what to do if they think the medicinal product is not working

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- what to do in the event of a missed dose

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- what to do in the event of an overdose

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- the correct use of therapeutic devices (including demonstration, if applicable)

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- if the patient is using the medication long term, whether they are experiencing any difficulties with it

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- counselling on change to medication or any new medications being introduced

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- any other matters which may be included or referred to in the Summary of Product Characteristics (SmPC) for the medicinal product concerned

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- what to do with any previously dispensed medicinal product(s), no longer required (i.e. disposal of medicinal product)

The pharmacist should aim to confirm patient understanding at regular intervals in the counselling process, assessing whether or not the information was understood as intended. The pharmacist should ensure that the patient understands how to use the information furnished to them in order to improve the probability of positive therapeutic outcomes.

### 3.5.2 Overcoming Potential Barriers to Communication

Pharmacists should be aware of the potential barriers to effective pharmacist-patient communication, for example the patient's perceived embarrassment, emotional issues, low literacy and numeracy skills and language hesitancy. Pharmacists should be mindful that the patient may be only newly diagnosed and may require further and additional attention and counselling. In order to deliver effective counselling to patients, the pharmacist may decide to use appropriate information resources, such as pictograms and models.

Contact information for some useful resources and organisations to help pharmacists meet the needs of their patients can be found under the [Links Section](#) on the PSI website. Any such additional material should complement the counselling already delivered by the pharmacist, with a view to helping the patient recall at a later stage what was said during the counselling session and to aid patient concordance.

The pharmacist may also decide to utilise demonstration models (e.g. placebo inhalers/insulin pens). In this way the pharmacist can demonstrate the correct use of the product, and personally observe the patient correctly using it.

Medicinal products may only be supplied to a patient or their representative by or under the personal supervision of a pharmacist. Counselling by the pharmacist must be available, accessible and offered to the patient in respect of the dispensed medicinal product. The pharmacist should hand out all prescriptions, where possible.

When supplying prescribed medicinal products to patients at a distance, the pharmacist should exercise his/her professional judgement to ensure that the safety of the patient is protected, and that the obligatory review of medicinal products therapy and counselling of patients is effectively carried out, as appropriate. Further information on the supply of prescribed medicinal products at a distance can be found in the PSI's Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business.

## 4. Steps in the Dispensing Process on the Presentation of a Prescription



- It is acknowledged that in some instances the pharmacist handing out the prescription and offering to counsel the patient may be different from the pharmacist who performed the clinical check. There should be in-house processes established to deal with such situations.

## 5. Documentation

Where at all possible, and in line with best practice, the pharmacist should systematically record any counselling events considered clinically important. The PMR provides an ideal place to record such conversations. In situations where the patient refuses to be counselled, or the pharmacist decides not to provide counselling, if considered important, this should also be documented. If a patient requests that a medication is not dispensed or the pharmacist, in the exercise of his/her professional judgement, decides not to dispense any of the prescribed medicinal products, this too should be documented. Additionally, any follow up conversations with the patient or other healthcare professionals regarding the patient's care should be noted and be readily available for other colleagues to view.

There are other records that must be made when supplying medicinal products against a prescription; these will be dealt with in further PSI guidance.

## 6. Policies and Procedures

Standard Operating Procedures (SOPs) must be in place, detailing all aspects of the dispensing process, from receipt of a prescription, preparation and assembly of medicinal products, labelling, clinical and pharmaceutical review and checking a dispensed item to counselling the patient concerned. 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 relevant and up-to-date policies and procedures pertaining to the safe dispensing of medicinal products. It is essential that the Pharmacy Owner and/or the Superintendent Pharmacist ensures that there are adequate numbers of pharmacists on duty in a pharmacy to ensure the safe supply of prescription only medicinal products.

As personal patient information can be sensitive, due diligence must be applied when handling prescriptions and all staff must be cognisant of their duties under the Data Protection legislation, as amended when dealing with confidential data.

## 7. References

- Pharmacy Act 2007

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

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

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

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- PSI Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses

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- PSI Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicinal Products to Patients in Residential Care Settings/Nursing Homes.

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- PSI Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business.

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- PSI Guidelines on the Equipment Requirements of a Retail Pharmacy Business

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

## 8. Other Useful Resources

Contact information for some useful resources and organisations to help pharmacists meet the needs of their patients can be found under the [Links Section](#) on the PSI website.

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1	October 2015
2	May 2017
3	April 2019
4	October 2019

## 9. Self-assessment Checklist

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

Ask Yourself	Yes	No	Required Action
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 counselling carried out in a manner which preserves patient confidentiality, using the patient consultation area as necessary?			
Are all dispensed prescriptions endorsed as required?			
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 legal validity and authenticity?			
Does the label of the dispensed medicinal product contain any information required for the safe and effective use of the product, including any cautionary or warning labels needed?			
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 labels placed on medicinal product packaging in a way that does not obscure important information?			
Does the pharmacist obtain all relevant patient information before dispensing the prescription?			

Ask Yourself	Yes	No	Required Action
Does the pharmacist obtain all relevant patient information before dispensing the prescription?			
Does the pharmacist review the prescription for possible problems prior to dispensing?			
Are all medicinal products checked for expiry dates in routine management of the dispensary and during each and every dispensing process?			
Are all staff aware of their duties under the Data Protection legislation when managing patient data?			
Are suitable containers used for packing of prescription medicinal products? Are CRC closures used where appropriate?			
When a prescriber is contacted to clarify a prescription, is a record maintained in an easily retrievable form?			

# Appendix 1 - Requirements for the Legal Supply of Prescribed Medicinal Products

## 1. Validity of a Prescription

In order for a prescription to be considered valid, it is necessary to confirm that the prescription is written in a manner that complies with the legislative requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended<sup>10</sup> and Part 5 of the Misuse of Drugs Regulations 2017. Faxed/photocopied prescriptions and medication charts (or copies thereof) are only to be used in the support of an emergency request, and not as valid prescriptions.

The requirements under the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended are:

### 1.1 Patient Details

- The name and address of the patient must be stated on the prescription.
- It is a legal requirement for the prescription to specify the age of the patient if they are under 12 years old. Best practice indicates that the date of birth for such children is ascertained and entered in the PMR.

**Please note:** The pharmacist may wish to request other information from the patient to facilitate contacting the patient, which can be recorded in the PMR. Any recording of patient data must be done in line with the provisions of the relevant Data Protection legislation.

### 1.2 Validity Period of Prescriptions

It also must be ascertained that the validity period of the prescription has not elapsed, that it has not been already fully dispensed and that it is due to be dispensed.

- The maximum period of validity of a prescription for a human medicinal product is 6 months and for a veterinary prescription it is 12 months. It is not legally valid to supply a medicinal product outside of these parameters.
- The prescription must be dated.
- For further information on the requirements in place for High Tech medicines, please see the PSI's guidance document 'Good Dispensing Practice – High Tech Scheme'.

<sup>10</sup> Regulation 7(7) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 permits a pharmacist to supply a medicinal product from a prescription if one of the prescription requirements is omitted, where the pharmacist exercises due diligence and care, and is satisfied that it is safe to do so.



### 1.3 Details of Prescribing Practitioner

- The pharmacist must be satisfied that the prescription is issued and signed<sup>11</sup> by a practitioner who is authorised to do so and that the prescription can be legally dispensed in Ireland.

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- The prescription must clearly state whether the person issuing it is a registered medical practitioner, registered dentist or registered nurse prescriber.

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- If the prescription is issued by a registered nurse, the registration number assigned to the nurse in the register of nurses must be included.

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- Where the prescription is not a “health prescription”<sup>12</sup>, the prescriber’s address must be included on the prescription.

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- A prescribing practitioner includes any medical practitioner, dentist, nurse prescriber or any such prescribing practitioner as may be registered and authorised to prescribe in the EEA Member State where the practitioner is practising.

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### 1.4 Endorsement

- Prescriptions which are dispensed in full must be marked with the word ‘dispensed’ and the date on which it was dispensed.

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- Prescriptions which are dispensed in part must be marked with the quantity supplied and date of supply, of each medicinal product and the name and address of the pharmacy.

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11 Prescriptions from practitioners practising in another EEA Member State may be dispensed in cases where the practitioners have signed the prescription with his or her usual signature, either in handwriting or by electronic signature.

12 An example of a “health prescription” would be a GMS prescription.

## 2. Controlled Drug Legislation Requirements

- Controlled drugs (Schedule 2, 3, 4) can only be supplied on foot of an original valid prescription which must be physically present and reviewed by the pharmacist prior to dispensing to the patient. Faxed prescriptions are not an original prescription.
- The prescription must be signed and dated by the prescriber.
- All prescriptions, including GMS duplicate prescriptions, must be endorsed with quantity dispensed and the date on which it was dispensed. Prescriptions which are dispensed in full must be marked with the word 'dispensed'.
- When dispensing controlled drugs, pharmacists should remember to check for signs of unusual, excessive or inappropriate prescribing and bring concerns to the attention of the prescriber or the relevant statutory authority.
- For supply of methadone, complete guidance is available in the PSI's *Guidance for Pharmacists on the Safe Supply of Methadone*.

Under Part 5 of the Misuse of Drugs Regulations 2017 the following additional requirements apply to all prescriptions for **Schedule 2, Schedule 3 and Schedule 4 Part 1 controlled drugs**:

- The prescription shall be in ink or otherwise so as to be indelible
- The prescription shall specify the name (including the first name), and address of the patient, in the case of a prescription issued by a registered veterinary practitioner, the name (including the first name) and address of the person to whom the controlled drug prescribed is to be delivered;
- The pharmacist must be satisfied as to the identity of the patient, or in the case of a prescription issued by a registered veterinary practitioner, the identity of the person to whom the controlled drug is to be delivered
- The prescription must clearly indicate the full name (including the first name) of the practitioner issuing it
- The prescription must be signed by the practitioner issuing it with his or her usual signature and be dated by him or her;
- The prescription must state whether the prescriber is a registered medical practitioner, registered dentist, registered veterinary practitioner, registered nurse or registered midwife
- The prescription must state the prescribers registration number
- Where the prescription is not a "health prescription"<sup>12</sup>, the prescriber's address must be included on the prescription, and the address must be within the state.<sup>11</sup>
- The prescription must specify the telephone number on which the prescriber can be contacted

The following requirements must also appear on prescriptions for schedule 2, 3 and 4 Part 1 controlled drugs. These details **must be handwritten** by the prescriber on the prescription when prescribing a **Schedule 2 or Schedule 3 controlled drug**. These requirements can be computer generated when prescribing methadone or a Schedule 4 Part 1 controlled drug:

- The name of the controlled drug prescribed

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- Form and strength (where appropriate) of the preparation

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- Number of dosage units/total quantity (as appropriate) prescribed in both words and figures

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- Dose to be taken

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Additional requirements for prescriptions for **Schedule 2 and 3 controlled drugs**:

- Repeat prescriptions are not permitted.

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- A prescription is valid for 14 days from the date of issue indicated on the prescription.

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- For a prescription intended to be dispensed in instalments, the number of instalments and the intervals at which the instalments may be dispensed must be stated.

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- Where a prescription is to be dispensed by instalments, the first instalment must be dispensed within 14 days of the date stated on the prescription and no instalment shall be supplied later than 2 months after the date specified on the prescription.

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## 3. Repeat Supply

Schedule 2 and 3 controlled drugs may not be repeated. The general procedures which must be adhered to when issuing a repeat supply of an S1A or S1B medicinal product to a patient on foot of a prescription from a medical practitioner are listed below<sup>13</sup>.

Please note that the HPRA now classify S1A medicines as ‘non-renewable’ and S1B as ‘renewable’ medicines.

### *S1A Medicinal Products*

- A prescription for these medicinal products cannot be repeated unless this is specified by the prescriber (e.g. the prescription is marked ‘repeat x 3’, ‘repeat monthly’ or ‘repeat’).

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- If the prescription does not state the number of occasions nor the intervals (e.g. monthly, weekly) that the medicinal product may be repeated, S1A medicinal products can only be dispensed on one occasion.

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- If the prescription states the number of intervals that a medicinal product can be supplied, but omits the number of occasions (e.g. ‘repeat weekly’), S1A medicinal products cannot be dispensed on more than three occasions.

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- If the prescription states the number of occasions that a medicinal product can be supplied, but omits the intervals (e.g. repeat x 6), S1A medicinal products can be dispensed on the number of occasions indicated on the prescription, at such intervals that the pharmacist, in the exercise of their professional judgement, deems appropriate, having regard to the specified dose rate and the maximum 6 month validity period of the prescription.

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### *S1B Medicinal Products*

- A prescription for these medicinal products can be repeated by the pharmacist up to a period of 6 months from the date of issue, unless otherwise specified by the prescriber.

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- If the prescription does not state the number of occasions nor the intervals that the product may be repeated, S1B medicinal products may be supplied by the pharmacist for up to 6 months, at intervals that the pharmacist deems appropriate (taking account of the rate of dosage specified on the prescription).

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- If the prescription states the number of intervals that a product can be supplied (e.g. monthly, weekly), but omits the number of occasions, S1B medicinal products can be dispensed for up to 6 months, at the intervals stated on the prescription.

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- If the prescription states the number of occasions that a product can be supplied (e.g. repeat x 5), but omits the intervals, S1B medicinal products can be dispensed at such intervals that the pharmacist, in the exercise of their professional judgement, deems appropriate, having regard to the specified dose rate and the maximum 6 month validity period of the prescription.

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<sup>13</sup> Regulation 7 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2011.

## 4. Emergency Supply of Prescription Only Medicinal Products

The 'emergency supply' provisions of Regulation 8 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended, permit pharmacists, in emergency circumstances, to supply certain prescription only medicines without a prescription. Emergency supply can be carried out at the request of a patient or at the request of a prescriber. When supplying a medicine under these provisions, the pharmacist must be satisfied that there is an immediate need for the medicine to be supplied and that it is impracticable to obtain a prescription without undue delay. It is important that pharmacists are aware of the potential risks, both to the safety and welfare of patients and in the context of their own liability, where medicines are supplied in the absence of an original prescription. Pharmacists should also be aware of their own professional responsibilities as well as those of prescribers.

### 4.1 Emergency Supply at the Request of a Patient

Where the emergency supply is made at the request of a patient, the pharmacist must interview the patient and satisfy themselves that:

- There is an immediate need for the medicine

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- It is not practicable to obtain the prescription without undue delay

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- The treatment has been prescribed for the patient on a previous occasion

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- They can safely specify the dose of the medicine for the patient

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When assessing the appropriateness of supplying a medicine at the request of a patient, please consider:

1. The patient has not been reviewed or assessed by a prescriber

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2. The pharmacist is reliant on information provided by the patient in the course of their decision making process

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3. The potential consequences for the patient if an inappropriate medicine is supplied

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4. The potential consequences for the patient if the medicine is not supplied

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5. Should the pharmacist decide to supply the medicine, this supply is made without the prior knowledge or approval of the prescriber

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6. Doctor on call services are available nationwide and patients may be referred to these services, if appropriate

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Additionally pharmacists should note the following regarding the emergency supply of medicines at the request of a patient:

- No more than a 5 day supply of the medicine may be made, with the exception of:
 

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  - aerosols, creams or ointments, where the smallest available size may be supplied
  - the oral contraceptive pill, where a full cycle may be supplied or
  - an antibiotic where the smallest quantity that will provide a complete course may be supplied.
- To include the words 'Emergency Supply' on the label of the dispensed medicine
- To document the reason for the emergency supply in the prescription register (daily audit report) and the PMR
- To document the name and address of the previous pharmacy which dispensed the medicine (where different to the pharmacy making the supply) in the prescription register (daily audit report) and PMR

## 4.2 Emergency Supply at the Request of a Prescriber

Where the emergency supply is made at the request of a prescriber (medical practitioner or dentist) the pharmacist must be satisfied that:

- The prescriber is, by reason of an emergency, not in a position to provide the prescription immediately
- The prescriber undertakes to provide the prescription within 72 hours

Additionally pharmacists should note the following regarding the emergency supply of medicines at the request of a prescriber:

- The medicine must be supplied in accordance with the directions of the practitioner
- To keep a record that the supply was made at the emergency request of a prescriber
- To document the date the original prescription was received from the prescriber into the prescription register (daily audit report).

## 4.3 Controlled Drugs

Controlled drugs may never be supplied under the emergency provisions, whether at the request of a patient or a prescriber. This includes Schedule 2 (e.g. morphine), Schedule 3 (e.g. temazepam) and Schedule 4 (e.g. diazepam) controlled drugs. The supply of controlled drugs is tightly controlled by the Misuse of Drugs Regulations 2017, due to the dangerous nature of these medicines, their potential for abuse and the associated risks to patients and the public if they are supplied inappropriately.

## 4.4 Patients' Best Interests

It is in patients' best interests that the emergency supply provisions are reserved for genuine emergency circumstances only. Pharmacists must ensure that complacency surrounding these provisions does not occur and that it is not employed on a regular and routine basis. The importance of regular attendance and consultation with the prescriber should be communicated to patients.



