

SOP 27

Sale and Supply of Non-Prescription Medicines

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1. Introduction

1.1 Context

All non-prescription medicines supplied from a pharmacy (i.e. 'Pharmacy Only' and 'General Sale Medicines'*) must be supplied by or under the personal supervision of a pharmacist. This supervision requirement is in place to ensure that, prior to recommending and supplying a medicinal product, checks are carried out to confirm that the product best meets the patient's needs, and improves their health, whilst assuring the wellbeing, and safety of patients and the public. This supply can be delegated to certain suitably trained members of staff who are working under the supervision of the pharmacist. However, the pharmacist on duty must be satisfied that the staff members have the required level of competence to carry out the roles and duties assigned to them and know when it is appropriate to refer to the pharmacist.

***Note: General Sale Medicines or GSLs can be sold from non-pharmacy premises. In pharmacies, they may be available for self-selection to the public, but they must still be supplied by or under personal supervision of a pharmacist.**

1.2 Purpose

This SOP provides an overview of the regulatory and administrative requirements that a pharmacy needs to comply with when supplying non-prescription medication in **all** circumstances. It also ensures all pharmacy staff understand the correct procedure for supply of non-prescription items.

This SOP covers:

- Pharmacist responsibilities in the supply of non-prescription medication
- Staff training requirements
- Patient consultation including referral criteria
- Patient counselling and special considerations
- Storage of non-prescription medication in the pharmacy

This SOP must be used in conjunction all relevant SOPs and guidance, including:

- Allcare Pharmacy Online Olive OTC Training Course
- SOP 13 Managing Pharmacy Errors and Near Misses
- SOP 23 Use of Patient Consultation Areas
- SOP 28 OTC Supply of Codeine Containing Medicines
- SOP 41 Sale and Supply of OTC Domperidone
- SOP 46 Supply of Dovonex Psoriasis Ointment
- SOP 54 Sale and Supply of Sumatran Relief 50mg Tablets OTC
- PSI Guidelines on The Sale or Supply of Non-Prescription Medicinal Products from A Retail Pharmacy Business (Version 1 November 2018)

1.3 Scope

- This SOP applies to all staff in the pharmacy who are involved in the supply of non-prescription medication.
- It is the ultimate responsibility of the supervising pharmacist to ensure that all staff are appropriately trained, and the SOP is implemented.
- It is also the responsibility of the supervising pharmacist to ensure this SOP reflects the day-to-day practice in their pharmacy.
- All pharmacists are expected to exercise their professional judgement when needed.
- Allcare Pharmacies do not currently supply non-prescription medicinal products online.

2. Procedure

2.1 Pharmacist Responsibility in the Sale or Supply of Non-Prescription Medicinal Products.

- The sale and supply of medicines must be carried out by or under the supervision of a registered pharmacist, and in compliance with the statutory Code of Conduct for Pharmacists:
- Pharmacists must use their professional judgement, skills, competence, and specialised knowledge about medicines for the benefit of patients and to encourage the rational and proper use of non-prescription medicinal products.
- Non-prescription medicinal products should only be supplied in line with their relevant marketing authorisation (e.g. authorised indications, dosages, age limits etc.)
- Pharmacists must ensure all products supplied and information provided is accurate, clinically validated, and in line with current evidence and best practice.
- The PSI expects that with each supply of a non-prescription medicine, a package leaflet (PL) is supplied with the product. The patient should be directed to read it and direct any questions they might have to the pharmacist. Additional PLs and SPC's are available on www.medicines.ie, www.hpra.ie and/or www.EMA.ie.
- Pharmacists must satisfy themselves that the product is only being used for therapeutic uses and not for abuse/dependency/misuse. Suspected abuse/misuse should be recorded in the relevant section on the Pharmapod platform. <https://www.pharmapodhq.com/>.
- If a medicinal product is deemed inappropriate or unsafe for a patient, supply should not be made. The reason for refusal to supply should be communicated clearly and in a respectful caring manner. Appropriate referral to another healthcare service of professional should be made where appropriate.
- When buying medicines from a pharmacy, members of the public have the right to expect to speak to a pharmacist about their healthcare needs, and the pharmacist should be available to them for consultation, using the consultation room where appropriate.
- Supervising pharmacists must ensure all staff employed in the pharmacy, including other pharmacists have the required knowledge and skills to carry out the duties they are responsible for.
- Pharmacy staffing levels should be maintained to meet the level of services provided in the pharmacy. Pharmacists should discuss any concerns without undue delay with their Territory Manager and supervising and/or superintendent pharmacist.

2.2 Staff training

- All staff in the pharmacy who may be involved in the supply of non-prescription medication (including pharmacists, pharmaceutical assistants, technicians, trainee technicians, interns, APPEL students and front of counter staff) should be trained on this SOP.
- Allcare Pharmacy provide a training programme for all staff. Training is provided on induction and on an ongoing basis. Details of the current training provided is outlined in Appendix One "Allcare Pharmacy Staff Training."
- Staff should be clear on their roles and responsibilities and have appropriate skills to carry these out.
- All staff should familiarise themselves with the relevant product literature including product packaging and patient leaflets. If any aspect of a product is not understood, the staff member should discuss with the pharmacist.
- All staff should be mindful of their obligations around patient confidentiality when supplying non-prescription medicines.
- All staff members should be appropriately supervised by the pharmacist and any learning needs around non-prescription medication or minor ailments promptly recognised and addressed.
- Pharmacists should be readily identifiable to the public in the pharmacy and must always be able to intervene, as may be necessary.
- Name badges identifying all pharmacy personnel should be worn.

2.3 Patient Consultation

- Before recommending or supplying a product to a patient, it is essential that pharmacists and staff obtain adequate information to ensure that the product will deliver the best outcome to the patient.
- This ensures:
 - That potential medication risk factors are investigated. (interactions, allergies etc.)
 - The benefit of supplying the medication outweighs any risk.
 - That symptoms may not be masking a more serious or underlying condition.
 - That supply will benefit a patient's health and is not intended for abuse or misuse.
 - That patients needing a pharmacist referral are identified.
- An effective consultation between a patient and pharmacist/trained staff member should be achieved using clear user-friendly language, open-ended questions and active listening, being mindful that the pharmacist must be confident the required information has been obtained around condition, medication and lifestyle.
- It is important to be aware of privacy of the patient and direct them to the consultation room where appropriate.

- **Staff should always ask the 2WHAM questions:**

• <u>Who</u>	• is the medicine for?
• <u>What</u>	• are the symptoms?
• <u>How</u>	• long have you had the symptoms?
• <u>Action</u>	• already taken?
• <u>Medicines</u>	• being taken?

- This protocol should be applied to the sale of **all non-prescription** medicines, requests for **advice** on medicines and **advice** on treatment of symptoms.
- The patient should be central in the decision, as to if and what medication is necessary, and should be helped in making choices which govern their own health and wellbeing.
- An adequate selection of medicines obtained from an authorised source must be maintained in the pharmacy.
- The choice of the most appropriate product for the specific patient, treatment duration, and circumstances must be facilitated at all times, with particular care taken in the treatment of more vulnerable patient groups including older people, children and patients with chronic disease states.
- **IF IN DOUBT, REFER TO THE PHARMACIST.**

- **Pharmacy only medicine must only ever be sold under the supervision of the pharmacist.**
- **A product should never be sold from the dispensary without checking with the pharmacist first.**
- **A prescription – only medicine must never be supplied as an OTC product at any time.**
- **Medication which is not fit for use or fit for purpose must never be supplied to a patient**

2.3.1 Requests for repeat supply of a product

If a customer has confirmed they have used a product before:

- Check they are using the product correctly.
- Check that they are aware of the cautions and side effects of the product.
- Check if they are taking any other medicines or have any other illness – if they are, refer to the pharmacist.
- Ask if they require any further information about the product.

- All staff should be vigilant that, in certain cases, persistent and consistent use of medicines may indicate the presence of an untreated medical condition.
- It is advised that the quantity of any product supplied be limited to that sufficient to treat a bout of illness.
- Bulk buying or provision of incentives to bulk buy should not be encouraged and is not appropriate. Any requests for same should be referred to the pharmacist.

2.4 Pharmacist referral

Always refer patients to the pharmacists in the following situations:

- Patient is taking other medicines or has an illness
- Patient is in severe pain
- Patient has an eye problem
- Patient is bleeding from nose, mouth, ear or anus
- Patient has breathing problems
- Patient has unexplained weight loss
- Patient has difficulty swallowing
- Patient has a severe burn
- Patient has loss of power or pins and needles down their leg(s) / arm(s)
- Patient has had symptoms for longer than 48 hours
- Patient has tried a treatment already
- Medicine is for baby or child under 2 years
- Customer is pregnant or breastfeeding
- Customer is elderly
- Suspected abuse/misuse of medicine
- Frequent purchases of a medicine
- If you are unsure of the customer's symptoms

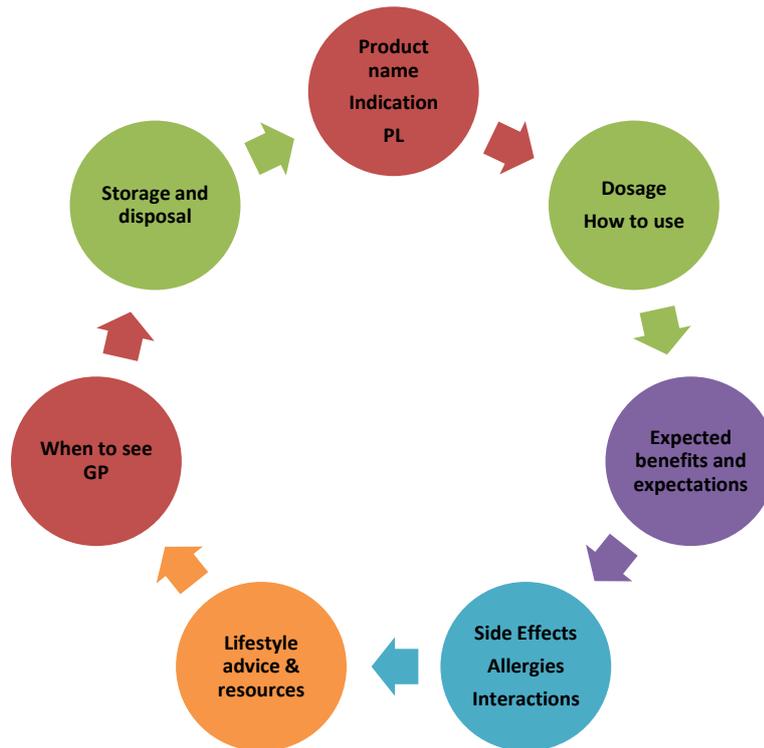
In circumstances where, in the professional judgment of the pharmacist, a non-prescription medication is not appropriate, or where a non-prescription medication masks symptom, which warrant further investigation, the patient must be counselled, and referred to another suitable health professional for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

- **It is vital that all pharmacy staff are aware of when the pharmacist on duty requires the patient to be referred to them.**

2.5 Patient Counselling

- Patients should receive appropriate and sufficient advice to facilitate the safe, effective use of the medicine.
- The pharmacist or trained staff member, should consider the needs and capacity of patient to understand the information, being mindful of such things as their literacy, numeracy and language skills. Each consultation should be given due care and attention, as a medicine that is regularly supplied in the pharmacy may be a first request for the patient who may not be aware of the common side effects or contraindications for taking the medicine.

- **Effective counselling should cover the following:**



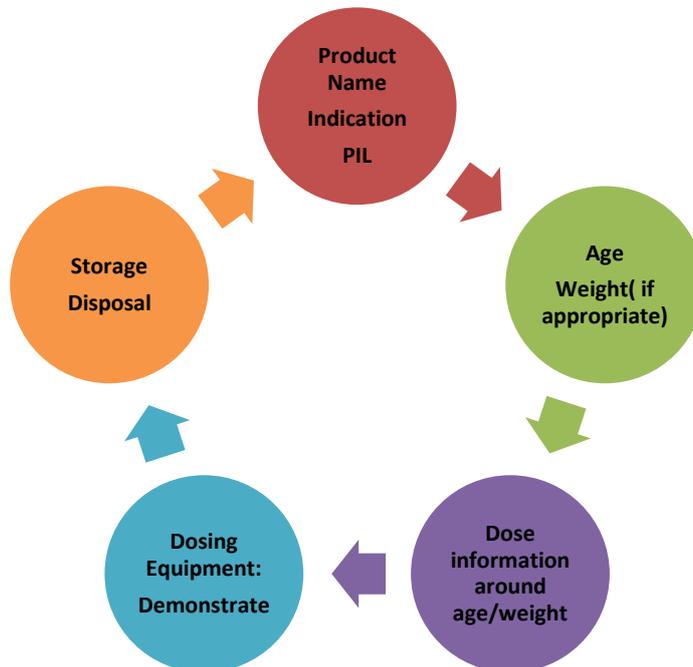
- The patient should always be aware that they have a **right to refuse** the advice given. All staff should be aware that they have a shared responsibility to patients regarding their own health and wellbeing, and that this should not compromise the ability of patients to exercise free choice regarding a health issue.

2.5.1 Supplying to a patient representative including patients in residential care

- The pharmacist must be satisfied that the representative has the requisite information and capacity to pass it on effectively to the patient when supplying a non-prescription medication so that the patient can make an informed decision to take the medication safely and appropriately
- The offer of pharmacist counselling via phone or other appropriate means should be offered.
- The potential for dependency and abuse/misuse should be considered when supplying for a third party.

2.5.2 Medicinal Products for Infants and Children

- When supplying medicinal products for infants or children, pharmacists should be alert to the danger of treating signs and symptoms that may point to an underlying condition, which may require immediate referral.
- Pharmacists should also ensure that appropriate advice is provided to parents/carers on the steps to be taken, should symptoms not improve or worsen, and circumstances where further healthcare professional advice should be sought.
- Pharmacists and trained staff members should be particularly vigilant in the supplying non-prescription medicinal products for use in infants and young children as they are particularly vulnerable to overdose, side effects and are generally at greater risk of harm from medication errors than adults. Pharmacist referral may be warranted in these circumstances and staff should verify with the pharmacist that the supply of a non-prescription medicinal product is appropriate
- **The following additional counselling points should be discussed with parents/carers of children:**



2.6 Decision not to supply a product

Pharmacists are required to practice in an autonomous way to ensure best outcome for patient. This sometimes involves making decisions around supply of non-prescription medication that is contrary to patient expectations.

- Pharmacists may need to highlight to patients that if used correctly, medication can offer great benefit to patient health but if used incorrectly, they have the potential to do harm.
- Staff should be trained on products which are likely to be abused and ask the pharmacist on duty if they are unsure or notice unusual patterns or medication use.
- Pharmacists should ensure that they are able to intervene in the decision to supply any medicine, particularly those which are exempted from prescription control under the specified legislative conditions, and those that have a potential to be abused or misused.
- The pharmacist should regularly review and audit usage of stock with particular reference to those products which may be abused.
- Decisions for non-supply should be communicated clearly and respectfully to the patient, and relevant advice/referral should be provided.

Commonly misused products are listed in Appendix Two: “Non-prescription products with potential for misuse”.

2.7 Storage of non-prescription medicines.

- Non-prescription medicines should always be stored as per the individual product SPC and only in fully temperature monitored storage areas on the pharmacy premises.
- Regulation of Retail Pharmacy Businesses (Amendment) Regulations 2016 contains regulation 5(1) (ea.) which states that pharmacy-only medicines ‘**are stored in a part of the premises to which the public does not have access.**’
- This does however, not require that all pharmacy-only medicines need to be stored in the dispensary.
- Under Irish law, medicines fall under three categories;
 - 1) Prescription only meds (POM)
 - 2) Pharmacy-only medicines (P meds)

- 3) General sale medicines (which may also be sold from non-pharmacy outlets). (GSL)

Supervising pharmacists must ensure the following:

- Pharmacy-only medicines are stored behind the medicines counter/OTC counter.
- Product placement and merchandising of the pharmacy must ensure that the public does not have direct or physical access to pharmacy-only medicines.
- Please consult your territory manager and/or superintendent pharmacist if you have any concerns around this storage requirement as failure to comply with this regulation constitutes an offence under section 18(3) of the Pharmacy Act 2007.
- The full list of pharmacy only medicines is available under the “Find a Medicine” section from the HPRA website where there are printable PDF lists: see HPRA link below. You can also look up a particular medication alphabetically.
- <https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine>
- Note: some products might have conditions of licence attached and may be subject to additional PSI restrictions such as supply by pharmacist only. These products or any other products a pharmacist assesses to be high risk for their particular pharmacy, should be stored in the dispensary.

2.8 Reporting Adverse reactions.

- Pharmacists should report any **suspected adverse reactions** via the HPRA online reporting form (<https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>) or via email (medsafety@hpra.ie). (Please use your pharmacy’s Healthmail account if reporting any patient-sensitive information. The HPRA is a ‘connected agency’ and can therefore receive emails via Healthmail).
- Any incidents should also be logged on Pharmapod.

3. Further References

For further information consult the resources below:

HPRA: “Legal Supply Status and Reclassification of Medicines”: <https://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/legal-supply-status-and-reclassification> (accessed 14/11/18)

IPU: Professional Guidelines. “Medicines Sales Protocols” https://ipu.ie/home/professional/sop-and-guidelines/medicines_sales_protocol/ (accessed 14/11/18)

PSI “Guidelines on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy Business” Version 1 2018
https://www.thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/01_11_Guidelines_on_Non-Prescription_Medicines.sflb.ashx (accessed 14/11/18)

PSI “Storage of Pharmacy-only Medicines in a Retail Pharmacy Business” Regulatory notice 01/2017
https://www.thepsi.ie/gns/inspection-enforcement/Regulatory_Notices/Storage_of_Pharmacy_only_Medicines.aspx (accessed 14/11/18)

Regulation Of Retail Pharmacy Businesses Regulations 2008 S.I. No. 488/2008
<http://www.irishstatutebook.ie/eli/2008/si/488/made/en/print> (accessed 14/11/18)

4. SOP Revision History

Version 3 June 2015, required review, updated to include;

- Allcare Pharmacy OTC Training Manual and Consultation Required Stickers.

Version 4 March 2017, required review, updated to include;

- Implementation Date
- Pharmacist supervision

Version 4 July 2019: Reformatted and updated to reflect;

- Updated PSI guideline on storage Oct 2017 Reg Notice 01/2017
- Updated PSI guideline on Guidelines on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy Business” Version 1 2018

5. Appendices

5.1 Appendix One: Allcare Pharmacy Staff Training

- Allcare Pharmacies provide comprehensive training for all their personnel. This is mandatory for all employees and it is the responsibility of the supervising pharmacist to ensure that staff are trained in full to the competency expected of the roles delegated to them.
- Failure to engage in staff training may result in the matter being referred to HR.
- Staff should be provided with:
 - 1) Access to the online Allcare Olive Online OTC training platform.
 - 2) Access to regular training seminars offsite organised by the dedicated team of the **Allcare Health Services and Pharmacy Training Co-Ordinator and the Allcare Pharmacy Trainer.**
 - 3) The Pharmacy Support team are happy to liaise with supervising pharmacists and pharmacy staff to help compile a programme that addresses the training needs of the individual pharmacy.
 - 4) On-the-job training via pharmacists, rep visits and more senior pharmacy team members.
 - 5) All team members must be signed up by their supervising pharmacist to Pharmapod to facilitate their training on Allcare SOP's
- Online assessments are available and will be available to all team members at the end of each e-learning topic. The pass mark is 70%. Failure to meet this criterion should be discussed with the supervising pharmacist
- On completion of the e-learning topics, a certificate will be made available that can be printed following successful completion of a module. This must be kept in the Allcare Training Folder.
- An Allcare Training Folder must be kept in the pharmacy and updated at regular intervals.
- The PSI may request to view this folder during an inspection and it is compulsory that a supervising pharmacist can demonstrate that a contemporaneous log is being kept of all staff training.
- If staff have any concerns around staff training and competencies, they should be discussed without undue delay with the supervising pharmacist and/or superintendent pharmacist.

5.2 Appendix Two: Products open to abuse

There are several classes of commonly abused medications that are supplied in pharmacies without prescription:

Class of Medication	Common Examples	Notes
Codeine based medication	Solpadeine® Nurofen plus® Codinex® Feminax® Migraleve®	Must not be on display to public
Decongestants	Sudafed® Sinutab® Benylin Day and Night®	Caution with pseudoephedrine products in particular
Sedating Antihistamines	Phenergan® Night Nurse® Dozol® Teedex®	
Cough Suppressants	Benylin night® Benylin original®	
Laxatives	Senokot® Dulcolax®	Refer to pharmacist if patient requesting large pack sizes or repeat purchase
Alcohol based products	Methylated Spirits	Entry must be made into methylated spirits register
Solvents		

If you are unsure of products which are likely to be abused, please consult the pharmacist on duty.

5.3 Appendix Three: Sale and Supply of Paracetamol

In March 2013 the PSI Newsletter highlighted recent accidental paediatric overdose of Paracetamol.

As parents or carers can also purchase paracetamol containing products in non-pharmacy outlets, and frequently purchase paracetamol in anticipation of use, pharmacists should take all reasonable steps to highlight the safe use of these medicines at every appropriate opportunity, regardless of the source of paracetamol supply.

Potential sources of error in the administration of paracetamol to children include:

- Use of multiple products, often with different brand names.
- Use of multiple dosage forms e.g. suppositories and oral liquid.
- Errors in dosage or dose frequency.
- Accidental use of an adult formulation/dose.
- Use of an inappropriate formulation for the child's age e.g. paracetamol 250mg/5ml rather than 120mg/5ml.
- A parent/carer believing that "more is better."
- More than one parent/carer administering medicine to a child simultaneously.
- Children drinking from unattended medicine bottles/inappropriate medicine storage.

Pharmacists should take steps to minimise the potential for these errors by ensuring that an appropriate product is sold and that the parent/carer has been adequately counselled on the safe and appropriate use and storage of the product.

Parent/carer counselling should include advice:

- On the amount to be administered and the frequency of administration, following confirmation of the child's age and an explanation that the dose is age-related.
- That many children's medicines contain paracetamol and that the simultaneous use of more than one product may be dangerous – therefore parents should always check if a medicine contains paracetamol and seek their pharmacist's advice if they are unsure about any aspect of a medicine's appropriate use.
- Never to give more than one medicine to a child except on the advice of a doctor or pharmacist.
- To follow the directions printed on medicine labels.
- To use the measuring device provided with their child's medicine. Household spoons are not suitable measuring devices.
- To store all medicines out of children's reach and sight, and to never leave medicines unattended where young children are around.
- **That paracetamol overdose may not be immediately apparent and must be treated immediately**
- **The National Poisons Information Centre number 01 809 2166 should be contacted for further information It is available from 8am to 10pm for members of the public and 24 hours for healthcare professionals.**

All pharmacy staff should be aware of the dangers of paracetamol overdose and the potential risks to children if paracetamol containing products are not used appropriately. All staff should be appropriately trained in the necessary counselling techniques required to ensure the safe use of these medicines.