

Checklist for a New Pharmacy Opening Inspection by The Pharmaceutical Society of Ireland

The following is a non-exhaustive list of what may be reviewed by an Authorised Officer of the PSI during a New Pharmacy Opening Inspection. This checklist is intended as a self-assessment tool to assist you in preparing for an inspection. In addition, you should be familiar with pharmacy and medicines legislation, accessible via the PSI website www.thePSI.ie. and www.irishstatutebook.ie and PSI guidelines accessible via the PSI website and the links below.

| 1.0 | Registration/Staffing Details | | |
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| <p>The registration details, opening hours and staffing details will be checked against those in the application form and the working hours of supervising pharmacist will be confirmed to ensure they are working for sufficient hours to be in whole time charge of the pharmacy.</p> | | | |
| 2.0 | Premises | Yes | No |
| 2.1 | Are all areas of the premises included in the floor plan submitted with the application for registration? Are all areas where medicines & records are to be stored included in the proposed premises to be registered? | | |
| 2.2 | Is the external premises, including fascia, windows, sills, doors, roof, guttering, signage and paintwork in a good state of repair and decoration? | | |
| 2.3 | Are all entrances to the premises well maintained, clear and accessible? Are the premises accessible to wheelchair users? | | |
| 2.4 | Is the trading name of the pharmacy displayed at all entrances to the premises? | | |
| 2.5 | Is the internal building work and installation of the fixtures and fittings complete (including lighting fixtures, electrical sockets, pharmacy shelving units/counters, pharmacy flooring, walls, ceiling, plaster and paintwork, wiring, patient consultation area and all plumbing works)? | | |
| 2.6 | Have all excess building materials been removed from the premises and is the premises clean? | | |
| 2.7 | Is the premises self-contained and are all relevant security measures at the premises in place, eg monitored alarm, shutters, CCTV, panic buttons, as applicable? | | |

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| 2.8 | Has the PSI Security Assessment Template been completed? If any issues have been identified, have they been addressed? Have any/all recommendations made by the crime prevention officer been implemented? | | |
| 2.9 | Is the dispensary and non-prescription medicines area easily identifiable by signage? | | |
| 2.10 | Does the layout enable the pharmacist to both maintain patient confidentiality and exercise supervision of the sale and supply of medicinal products in the dispensary, at the medicines counter and while in the patient consultation area? | | |
| 2.11 | Is adequate lighting/ ventilation provided in the dispensary? | | |
| 2.12 | Is access to the dispensary/ non-prescription medicines area and all areas where medicines or confidential records are stored restricted to authorised personnel? | | |
| 2.13 | Is a suitable waiting area provided for patients? | | |
| 2.14 | Is there a staff toilet & wash hand basin? | | |
| 2.15 | Is there a staff break area? | | |
| 2.15 | Does the premises have a separate, designated, conveniently located private patient consultation area, which is directly accessible from the public area of the pharmacy? | | |
| 2.16 | Does the patient consultation area comply with the PSI's Guidelines on Patient Consultation Areas in terms of size, wheelchair accessibility, signage, provision of a table/ worktop & three chairs etc.? Note: The area can't be the only access route to another area of the pharmacy. | | |
| 2.17 | If the seasonal influenza vaccination service will be provided in the pharmacy, does the patient consultation area meet the requirements of the guidelines? | | |
| <i>Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses and Draft Guidelines on the Premises and Equipment Requirements of a Retail Pharmacy Business</i> | | | |
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| 3.0 | Dispensary Equipment | Yes | No |
| Is the following equipment available: | | | |
| 3.1 | Dispensing bench with a smooth impervious & washable surface and adequate space for expected volume of activity. | | |
| 3.2 | Dedicated areas for preparing Extemporaneous Products/ Monitored Dosage Systems (if applicable) | | |
| 3.3 | Telephone, Fax, Printer. | | |

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| 3.4 | A Computer with Internet Access and Pharmacy Email | | |
| 3.5 | Electronic dispensing system: You will be asked to print sample labels, a sample daily prescription report, a sample prescription receipt, a sample patient medication record and a sample daily audit and to demonstrate that drug-interaction software is in place. The sample daily audit should demonstrate that all information required by regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) can be recorded. | | |
| 3.6 | Calibrated NAWI compliant electronic balance which allows for accurate weighting of substances. The balance should at least cover the range 100mg -200g and have a verification scale interval (error value) of 10mg (not just readability to the nearest 10mg). | | |
| 3.7 | Range of weighting boats | | |
| 3.8 | Set of certified metric weights (recently calibrated) | | |
| 3.9 | Counting apparatus for tablets & capsules | | |
| 3.10 | Range of approved graduated Type A glass measures & pipettes (with pipette pump)/ or syringes (range 0.05mls-200ml) | | |
| 3.1 | Pestles & mortars (of an appropriate size, including one glass set) | | |
| 3.12 | A glass or marble ointment slab | | |
| 3.13 | Glass stirring rods and stainless steel spatulas | | |
| 3.14 | Range of auxiliary dosage aids e.g. 5ml spoons/ syringes etc. | | |
| 3.15 | Disposable Plastic Cups | | |
| 3.16 | Range of containers for dispensing tablets/capsules | | |
| 3.17 | Range of containers for dispensing of liquids (including amber glass & clear bottles) | | |
| 3.18 | Containers for dispensing creams, ointments and/or pastes | | |
| 3.19 | Range of child resistant containers (CRCs) & non CRCs for all oral containers | | |
| 3.20 | Plastic bottles, CRCs, measures and other equipment for Methadone (if applicable) | | |
| 3.21 | Plastic bags/ cardboard cartons | | |
| 3.22 | A dispensary sink, with hot & cold water. Access to potable water. | | |
| 3.23 | Medicinal product waste bins. A designated storage area for bin the and waste medicines awaiting processing is required. | | |

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| 3.24 | Shredder for confidential paper waste | | |
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| 4.0 | Controlled Drug (CD) Safe | Yes | No |
| 4.1 | Is there a lockable safe/ cabinet for the storage of medicines (schedule 2 & 3 controlled drugs) in place in the dispensary? | | |
| 4.2 | Will the CD safe be reserved solely for the storage of medicines? | | |
| 4.3 | Is the CD safe secured (bolted to a solid wall/ floor) in accordance with regulations? | | |
| 4.4 | Has the CD safe been certified by the Gardaí and is the certificate available for review at the pharmacy? | | |
| 4.5 | Does the CD safe have sufficient capacity to permit the orderly storage & safekeeping of all schedule 2 & 3 controlled drugs? | | |
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| 5.0 | Storage of Medicinal Products | Yes | No |
| 5.1 | Will all prescription-only medicines, veterinary prescription-only medicines & CD5 controlled drugs, including codeine containing medicines, be stored in the dispensary? | | |
| 5.2 | Are there dedicated appropriate areas for the storage of veterinary medicines, poisons & methylated spirits (if applicable)? | | |
| 5.3 | Will all pharmacy only medicines be stored behind the medicines counter? | | |
| 5.4 | Will all other non-prescription medicines be stored in an area of the pharmacy under the control of the pharmacist? | | |
| 5.5 | Is there adequate and appropriate shelving & fittings provided in the dispensary for the orderly storage of medicines? | | |
| 5.6 | Is a pharmaceutical grade refrigerator, with temperature monitoring facility provided? | | |
| 5.7 | Is a separate pharmaceutical grade refrigerator provided for the storage of veterinary medicines (if applicable)? | | |
| 5.8 | Have the refrigerator(s) been validated as operational and are records of the validation retained? | | |

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| 5.9 | Is there method for monitoring, recording and pharmacist review of the maximum/minimum fridge temperature as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business? | | |
| 5.10 | Is there method of monitoring, recording and pharmacist review of the maximum/minimum temperature in the dispensary and any additional storage areas as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business? | | |
| <i>PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business</i> | | | |
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| 6.0 | Reference Materials | Yes | No |
| 6.1 | Martindale or other complete drug reference (current edition) | | |
| 6.2 | Current Stockleys or other detailed drug interaction reference(current edition) | | |
| 6.3 | Current BNF | | |
| 6.4 | Current BNF for children (or other appropriate current children's reference) | | |
| 6.5 | Access to SmPCs of medicinal products authorised in Ireland (hard copy or internet access www.medicines.ie . etc.) | | |
| 6.6 | Access to PSI guidelines, guidance documents, publications etc. (hard copy or internet access www.thePSI.ie) | | |
| 6.7 | Access to relevant current pharmacy legislation (hard copy or internet access www.irishstautebook.ie/ www.thePSI.ie .) | | |
| 6.8 | Additional references are required if additional services are provided, e.g. a veterinary reference if providing veterinary services | | |
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| 7.0 | Policies and Standard Operating Procedures | Yes | No |
| 7.1 | Does the pharmacy have a full suite of written procedures for all processes which are carried out at the pharmacy? | | |
| | At a minimum, the following procedures should be in place: | | |
| | a) Dispensing: This includes the entire process from the receipt of the prescription, through therapeutic review to the transfer of the medicine to the patient and patient counselling. Dispensing procedures should address different types of medicines, including high-risk medicines (Methotrexate etc.), High-tech medicines , Methadone , Controlled drugs etc. | | |
| | b) Sourcing of medicines . | | |

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| c) Storage of medicines | | |
| d) Expiry date checking | | |
| e) Sale and supply of non prescription medicinal products. These procedures should address the supply of specific products (Norlevo , Alli , Domperidone , Curanail etc.) | | |
| f) Sale and supply of non-prescription codeine containing | | |
| g) Management of controlled drugs, including storage and record keeping | | |
| h) Disposal of medicines and destruction of controlled drugs | | |
| i) Management of Supply to patients in Residential Care Homes (if applicable). Residential Care Home procedures should address the entire process, including the receipt of prescriptions, the delivery of medicines, the management of controlled drugs, medicine therapy reviews and counselling etc. Template records of patient consent, medicines delivery, pharmacist visits, patient counselling and medicine therapy reviews should be available for review. Practice Notice: Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes. Letters to Superintendents on Residential Care Homes: Letter 1 , Letter 2 | | |
| j) Management of additional services provided, including (as applicable): Point of care testing services , seasonal influenza vaccination services , monitored dosage systems, veterinary services, etc. | | |
| k) Error and incident management. There should be error templates and/or an error log in place, which includes an area for recording corrective actions. | | |
| l) Locum Procedure | | |
| m) Housekeeping and cleanliness of the dispensary (including equipment), public pharmacy area and all other areas of the pharmacy. The procedure should include a cleaning schedule/ sign off sheet. | | |
| n) Use of the patient consultation area. This should address directing patients to the area and supervision of the pharmacy while a pharmacist is engaged in a consultation. | | |
| o) Pest control policy (as required) | | |
| p) Policy on the use of child resistant containers | | |
| q) Management of emergency situations, e.g. loss of electricity or power | | |

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| | r) Keyholding Policy for the premises and CD Safe and security procedures. Is access to the pharmacy and medicines only permitted in the presence of the pharmacist? | | |
| 7.2 | Have all policies and procedures been approved by the Superintendent and Supervising Pharmacist? | | |
| 7.3 | Is there an implementation date for all procedures? | | |
| 7.4 | Is there a review date for all procedures? | | |
| 7.5 | Are dated policy and procedure training records available for all staff on all relevant procedures? | | |
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| 8.0 | Registers | Yes | No |
| | Are the following registers available in the pharmacy? | | |
| 8.1 | Duty register | | |
| 8.2 | Controlled drugs register | | |
| 8.3 | Methylated spirits register and license (if applicable) | | |
| 8.4 | Poisons register (if applicable) | | |
| 8.5 | Veterinary register (if applicable) | | |
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| 9.0 | Miscellaneous | Yes | No |
| 9.1 | Is the certificate of the supervising pharmacist displayed and is it legible to the public from the public pharmacy area? | | |
| 9.2 | Is the pharmacy registered with the Data Protection Commissioner? | | |
| 9.3 | Is there a policy on data protection in place, which covers all electronic and manual records? | | |
| 9.4 | Does the pharmacy have a confidentiality policy in place for all staff? Has it been signed by all relevant staff? | | |