Checklist for a Pharmacy 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 Pharmacy 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.PSI.ie and www.irishstatutebook.ie and PSI guidelines accessible via the PSI website and the links below.

1.0	**Registration Certificates**	**Yes**	**No**
1.1	Is the current certificate of registration for the pharmacy available at the pharmacy and is it displayed such that it is legible from the public pharmacy area?		
1.2	Is the current certificate of the supervising pharmacist available at the pharmacy and is it displayed such that it is legible from the public pharmacy area?		
2.0	**Storage of Medicinal Products**	**Yes**	**No**
2.1	Are all prescription-only medicines, including veterinary prescription-only medicines (if applicable) stored in the dispensary?		
2.2	Are all codeine containing non-prescription medicines and other schedule 5 controlled drugs stored in the dispensary?		
2.3	Are all pharmacy only medicines stored behind the medicines counter?		
2.4	Are all other non-prescription medicines stored in an area of the pharmacy under the control of the pharmacist?		
2.5	Does the pharmacy have a pharmaceutical grade fridge?		
2.6	Is the fridge clean and is food stored in a separate fridge?		
2.7	Are all medicines stored in the fridge in good condition?		
2.8	Is the fridge of an adequate capacity to permit the orderly storage of medicines?		
2.9	Is the fridge serviced annually?		
2.1O	Is the maximum/minimum fridge temperature monitored, recorded and reviewed on a daily basis as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business?		

2.11	Are all medicines stored in the pharmacy in date and is there an active documented expiry date management system in place? The expiry dates of medicines may be checked.		
2.12	Is the maximum/minimum temperature in the dispensary and any additional storage areas monitored, recorded and reviewed on a daily basis as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business?		
2.13	Are medicinal products only removed from their primary packaging in exceptional circumstances? If they have been removed are they labelled with all information required as per the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business? Have all stability implications been considered?		
	PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business		
3.0	**Policies and Standard Operating Procedures**	**Yes**	**No**
	Inspectors Advice on SOP Preparation		
3.1	Has the pharmacy a full suite of procedures for all processes carried out in 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 the dispensing of different types of medicines, including high-risk medicines (Methotrexate, High-tech medicines , Controlled drugs etc.)		
	b) Sourcing of medicines		
	c) Storage of Medicines		
	d) Expiry Date checking		
	e) Sale and supply of non-prescription medicinal products. These procedures should address the general supply of non-prescription medicines and the supply of specific products (EllaOne , Norlevo , Alli , Domperidone , Curanail etc.)		
	f) Sale and supply of non-prescription codeine containing medicines		
	g) Management of controlled drugs (including storage and record keeping)		
	h) Disposal of medicines and destruction of controlled drugs		
	i) Management of additional services provided, including (as applicable): Point of care testing services , seasonal influenza vaccination services, monitored dosage systems, veterinary services , methadone services etc.		

	j) Error and incident management. There should be error records in place and corrective actions should be recorded. Please see *Inspector's Advice on Medication Error Management*, which includes templates that can be downloaded and used in your pharmacy.		
	k) Locum Procedure		
	l) Housekeeping and cleanliness of the dispensary (including equipment), public pharmacy area and all other areas of the pharmacy. There should be a cleaning schedule or sign off sheet in place.		
	m) 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.		
	n) Pest control policy		
	o) Policy on use of child resistant containers		
	p) Management of emergency situations, e.g. loss of electricity/ power		
	q) 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? *Note: Non-pharmacist staff members should not have access to the dispensary and any other areas where medicines are stored in the absence on a pharmacist or pharmaceutical assistant.*		
3.2	Have all policies and procedures been approved by the Superintendent and Supervising Pharmacist?		
3.3	Is there an implementation date for all procedures?		
3.4	Is there a review date for all procedures and is documentation relating to previous reviews available?		
3.5	Are dated policy and procedure training records available for all staff for all relevant procedures?		
4.0	**Duty Register**	**Yes**	**No**
4.1	Does the pharmacy have a duty register for the current year?		
4.2	Is there a pharmacist supervising the pharmacy for all hours of opening and is this recorded in the duty register?		
4.3	Is the duty log being maintained correctly? Are all entries maintained contemporaneously, are they signed by the pharmacist and do they include the pharmacists' arrival and departure times?		
4.4	Does the supervising pharmacist work in the pharmacy for a significant proportion of the opening hours? Guidance for superintendent and for supervising pharmacists and forms for the appointment of a superintendent and/or supervising pharmacist are available on the PSI website.		

4.5	Is the duty register reviewed regularly to ensure all details are correct?		
4.6	Pharmaceutical Assistant (if applicable). If a pharmaceutical assistant is employed at the pharmacy and providing temporary cover in the absence of the pharmacist, are they operating in accordance with the Code of Practice Governing Temporary Absence? *Note: A pharmaceutical assistant may act on behalf of a registered pharmacist during the temporary absence of the registered pharmacist under section 30 of the Pharmacy Act 2007. The PSI's understanding of temporary absence under the Act is consistent with the terms of the Code of Practice Governing the Temporary Absence Clause of the Pharmacy Act 1890 (issued 1994). This provides that the assistant who will be performing professional duties of the pharmacist in his/her temporary absence shall be employed in the pharmacy concerned on a permanent basis for not less than 15 hours per week. The assistant shall be entitled to cover short absences, such as lunch hours, two half days or one day off per week, unscheduled short absences or holiday cover.*		
5.0	**Prescription Register/Daily Audit/ Daily Dispensing Report**	**Yes**	**No**
5.1	Is the prescription register/ daily dispensing report printed on a daily basis (within 24 hours)?		
5.2	Is the prescription register/ daily dispensing report dated and signed by the pharmacist?		
5.3	Is the prescription register/ daily dispensing report completed in the correct format in accordance with the requirements of regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)? Are emergency supplies recorded and if at the request of a patient is the reason for the emergency supply recorded?		
5.4	Is the prescription register/ daily dispensing reports for the previous two years available for review at the premises?		
5.5	Are all prescriptions for the previous two years available for review at the premises?		
6.0	**Controlled Drugs (CD) Register**	**Yes**	**No**
6.1	Does the pharmacy have a Controlled Drugs register?		
6.2	Is the CD register completed in accordance with legislation and instructions, i.e. is a dedicated page provided for each product, are all required details entered, are the details entered in chronological order within 24 hours of supply and are errors corrected by marginal/ footnotes etc.?		
6.3	Is there evidence of the pharmacist routinely reviewing and checking stock balances?		
6.4	Are all CD registers for the last two years available for review?		

6.5	Where controlled drugs have been removed from the active balance and destroyed is there documentation relating to the witnessed destruction of controlled drugs available for review?		
7.0	**Controlled Drug Inventory**	**Yes**	**No**
7.1	Do the quantities of CDs recorded in the register match the quantities located in the CD safe?		
8.0	**Controlled Drug Safe**	**Yes**	**No**
8.1	Is there a lockable safe for the storage of medicines (schedule 2 and 3 controlled drugs) in place in the dispensary?		
8.2	Is the CD safe secured (bolted to a solid wall/ floor) in accordance with regulations?		
8.3	Has the CD safe been certified by the Gardaí and is the certificate available for review at the pharmacy?		
8.4	Does the CD safe have sufficient capacity to permit the orderly storage of all schedule 2 and 3 controlled drugs?		
8.5	Are all schedule 2 and 3 controlled drugs stored in the CD safe? Is the CD safe reserved solely for the storage of medicines?		
8.6	Are expired/ patient returned controlled drugs stored in a designated part of the CD safe and appropriately labelled?		
10.0	**Extemporaneous Medicinal Products (if applicable) - on foot of prescriptions**	**Yes**	**No**
10.1	Are there procedures in place for preparing extemporaneous products?		
10.2	Are detailed records of products prepared maintained?		
10.3	Is all required equipment available in the pharmacy?		
10.4	Is all equipment clean and appropriately calibrated?		
	Note: Extemporaneous preparation is only permissible on foot of prescriptions in limited circumstances.		
11.0	**Prescriptions** A number of controlled drug and medicinal product prescriptions will be requested and reviewed during the course of the inspection.	**Yes**	**No**
11.1	**Controlled drugs (CD2 and CD3) Prescriptions:**		

	Are the original prescriptions available for review?		
	Are they valid and in date (dispensed within 14 days of the date on the prescription and not dispensed prior to the date on the prescription)?		
	Do they meet the handwriting requirements for controlled drugs?		
	Have they been entered correctly into the CD register (CD2 only) and prescription register?		
	Have they been endorsed with the date of dispensing and the word 'dispensed'/ quantity dispensed?		
11.2	**Medicinal Product Prescriptions:**		
	Are the original prescriptions available for review?		
	Are they valid and in date (dispensed within 6 months of the date on the prescription)?		
	Are they correctly written?		
	Have they been entered correctly into the prescription register?		
	Have they been endorsed with the date of dispensing and the word 'dispensed'/ quantity dispensed?		
12.0	**Premises**	**Yes**	**No**
	PSI Premises Guidelines		
12.1	Is the premises self-contained?		
12.2	Has the PSI/Garda Security Assessment been completed and are there adequate security arrangements in place, e.g. alarm, shutters, CCTV, panic buttons, as applicable? Have any/all recommendations made by the crime prevention officer been implemented?		
12.3	Is the external and the internal premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard?		
12.4	Are all storage areas in the premises in a good state of repair and decoration, and are all fixtures and fittings of an acceptable standard?		
12.5	Are all entrances to the premises well maintained, clear and accessible?		
12.6	Is the trading name of the pharmacy displayed at all entrances to the premises?		
12.7	**Dispensary** - Is the dispensary area easily identifiable by signage?		
12.8	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?		

12.9	Is a dispensing bench with a smooth impervious & washable surface and adequate space for expected volume of activity in place?		
12.1O	Is there a dedicated dispensary sink with access to hot and cold (potable) water?		
12.11	Are dedicated areas for preparing Extemporaneous Products/ Monitored Dosage Systems in place (if applicable)?		
12.12	Is adequate lighting/ ventilation provided in the dispensary?		
12.13	**Medicines Counter** - Does the location of the medicines counter restrict access to pharmacy only medicinal products?		
12.14	Is access to the dispensary/ non-prescription medicines area and all areas where medicines or confidential records are stored restricted to authorised personnel?		
12.15	Is a suitable waiting area provided for patients?		
12.16	**Patient Consultation Area** - Does the premises have a separate, designated, conveniently located private patient consultation area, which is directly accessible from the public area of the pharmacy?		
12.17	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? Note: The area can't be the only access route to another area of the pharmacy.		
12.18	If the seasonal influenza vaccination service is provided in the pharmacy does the patient consultation area meet the requirements of the PSI's Guidelines?		
12.19	Is there a clean and well maintained staff toilet with wash hand basin and a staff break area provided at the premises?		
12.2O	Are all areas of the premises where medicines or records are stored included in the floor plan of the registered premises submitted to the PSI?		
12.21	Is housekeeping in all areas of the pharmacy maintained at an acceptable standard?		
13.O	**Residential Care Settings (if applicable)**		
13.1	Are there procedures in place which address the management of the supply of medication to patients in residential care homes? The procedures should address the entire process, including the receipt of prescriptions, the delivery of medicines, the management of controlled drugs, medicine therapy reviews and patient counselling etc. Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes. Letters to Superintendents on Residential Care Homes: Letter 1, Letter 2.		

13.2	Are records of the following available for review for all patients in residential care settings:		
	Patient consent?		
	Medicines delivery?		
	Pharmacist visits?		
	Patient counselling?		
	Interdisciplinary medicine therapy review?		
14.0	**Veterinary Medicinal Products (if applicable)**	**Yes**	**No**
	Inspector's Advice on Animal Remedies (Veterinary Medicines)		
14.1	Are veterinary medicinal products stored in a designated area(s) of the pharmacy?		
14.2	Are prescription medicines, prescription only exempt medicines, pharmacy only medicines, licenced merchant medicines, companion animal remedies and veterinary medicines requiring refrigeration stored appropriately? Note: A separate pharmaceutical grade fridge is required for veterinary medicines.		
14.2	Does the pharmacy have a veterinary register?		
14.3	Are records of all incoming and outgoing veterinary medicines (VPOM, VPOM (E), PS and LM) recorded in the veterinary register in accordance with legislative requirements?		
14.4	**Veterinary Prescriptions:**		
	Are they available?		
	Are they in date (dispensed within one year of the date on the prescription)?		
	Are they correctly written?		
	Have they been entered correctly into the veterinary register?		
	Have they been endorsed with the date of dispensing, the word 'dispensed' and signed by the pharmacist?		
14.5	Are all records (register and prescriptions) for the last five years available for review at the premises?		
15.0	**Miscellaneous**	**Yes**	**No**
	PSI Pharmacy Equipment Guidelines		
15.1	Does the pharmacy have all required equipment?		
	General Equipment (telephone, fax, label printer etc.)?		

	Computer, with pharmacy email and internet access?		
	Electronic dispensing system and drug interaction software?		
	Dispensing Equipment (tablet counter, dispensing containers (tablet vials, bottles, ointment jars, plastic bags/ cardboard cartons), child resistant containers (CRCs), disposable plastic cups etc.?		
	Extemporaneous equipment (graduated cylinders, ointment slab, electronic NAWI compliant balance (accurately measures 100mg to 200g), certified metric weights, mortars and pestles weighing boats, spatulas & stirrers etc.)?		
15.2	Does the pharmacy have appropriate reference books?		
	Martindale or other complete drug reference (current or most recent edition)?		
	Current BNF & Current BNF for children (or other appropriate current children's reference)?		
	Current Stockley's (or other detailed drug interaction reference) and drug interaction software?		
	Access to relevant current PSI guidelines, pharmacy and medicines legislation and SmPCs of medicinal products authorised in Ireland (hard copy or internet access)?		
	Additional references if additional services are provided, e.g. veterinary reference, if providing veterinary services?		
15.3	Does the pharmacy have a medicinal product waste bin and a designated storage area for the bin?		
	Is all waste and patient returned medication stored in a designated area of the pharmacy segregated from active stock pending timely processing?		
	Is evidence of waste collections by an authorised waste management company available?		
15.4	Does the pharmacy have a methylated spirits register and license (if applicable) and is there a designated area for the storage of methylated sprits?		
15.5	Does the pharmacy have a poisons register (if applicable) and are poisons stored in an appropriate designated area of the pharmacy?		
15.6	Does the pharmacy have a shredder for confidential paper waste?		
15.7	Is the pharmacy registered with the Data Protection Commissioner and is a policy which covers all electronic and manual records in place?		
15.8	Does the pharmacy have a confidentiality policy in place for all staff?		