



The Pharmaceutical Society of Ireland

Short Guide on What to Expect During the Inspection Process

- PSI Authorised Officers (the formal title of the inspectors) will identify themselves at the start of an inspection. All Authorised Officers carry a PSI identity card and their warrant as Authorised Officer, which is their authority to enter pharmacies and other premises. You can ask to see the warrant to assure yourself the person is an Authorised Officer of the PSI.
- On arrival at a pharmacy for inspection, the inspector will first ask to see the pharmacist or pharmacists who are present.
- Most pharmacists will choose to keep the pharmacy open during an inspection, which means that patients and members of the public will need to be attended to during the inspection. The PSI and its Authorised Officers make it clear that patient needs are everyone's priority. During the inspection, the pharmacist will be asked to source particular records or documents for the inspector, but this will be done while ensuring that patients are being dealt with as the priority, and where necessary, the inspector will wait while the pharmacist attends to patients.

So what will the inspectors look for during an inspection?

The PSI has produced a checklist to assist pharmacy owners and pharmacists in preparing for a future inspection and to inform them what to expect during an inspection.

The following areas should be covered in any self-assessment:

- **Premises:** security arrangements, 'keyholding' policy (including policy around the pharmacy not opening when no pharmacist is present), layout to allow for supervision of professional activities and to restrict access to dispensary and medicinal products, patient consultation area; also storage areas, staff areas, bathroom; housekeeping/cleaning records; clean, uncluttered dispensary and professional areas, including proper paper record-filing arrangements.
- Registration certificates (retail pharmacy business and supervising pharmacist) on conspicuous display.

- Documented policies and procedures/SOPs recommended by PSI, including those listed in the checklist, as well as any recommended in PSI guidelines or practice notices.
- Compliance with codeine guidance, including location of non-prescription codeine medicines in the dispensary.
- Properly maintained duty register; evidence that supervising pharmacist practises at the pharmacy for a significant proportion of the opening hours; superintendent and supervising pharmacists properly notified to the PSI.
- Prescription records/daily dispensing report (signed and dated) – you may be asked to produce original prescriptions and records of emergency supply dispensing.
- Controlled Drugs (CD) register – balances will be checked and you may be asked to produce original CD prescriptions.
- CD safe – ‘keyholding’ policy, Garda certification, segregation of out-of-date/returned CD stock for destruction.
- Pharmacy fridge – cleanliness, temperature monitoring, condition of stock, expiry dates of stock.
- Dispensary stock – expiry dates of stock, documented policies and procedures for sourcing, storage and disposal of medicines.
- Extemporaneous dispensing – SOPs, records, equipment.
- Veterinary medicines – storage/location, expiry dates, records.
- Supply to nursing homes/residential care settings – documented policies and procedures, in line with PSI Practice Notice, record-keeping, e.g. patient visits.
- Clinical waste bins/disposal policy.
- Shredder for confidential paper waste.
- Reference material – current reference books, e.g. BNF, or easy access to online versions, copies of or access to PSI guidance documents and legislation.
- Error/Incident log and management policy.
- Locum induction/communication policy.

Regular pharmacy inspections may typically take up to about two to three hours.

After an inspection has been carried out, an inspection report will be generated and sent to the pharmacy, with a response sought to any issues highlighted in the report.