PSI
The Pharmacy Regulator
An Rialtóir Cógaisíochta

PSI Inspection and Enforcement Policy

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1. Introduction

1.1 About the PSI – The Pharmacy Regulator

The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, is a public body established under the Pharmacy Act 2007 ('the Act') to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. At the end of 2021, there were 6,846 pharmacists and 254 pharmaceutical assistants registered with the PSI. In addition, there were 1,981 Retail Pharmacy Businesses (RPB) on our register, which included 75 operating under the governance of hospital pharmacy departments.[1]. Current registration data is available at Statistics and Data - PSI (thepsi.ie).

The PSI operates in accordance with a defined mission, vision and set of values, approved by the Council of the PSI and which collectively shape its commitment to the safety of patients and the public as its highest priority.

Our Mission is to protect and promote the health, safety and wellbeing of patients and the public by taking timely and effective action to ensure that pharmacists in Ireland are competent and that pharmacies are operating to high standards of safety and reliability.

Our Vision is that the public has access to trusted pharmacy services and that the PSI makes a clear and demonstrable contribution to the availability and quality of those services.

Our Values are set out under our current Corporate Strategy (2021-2023) and underpin how we deliver on our mission. They guide our behaviour, the expectations we set ourselves, and the experience of others who engage with us.

[1] While PSI has a remit to regulate the "retail" supply of medicines through hospital pharmacy departments, we do not regulate the many other activities of pharmacy departments. Regulating these other activities is a matter to be considered as part of work ongoing in the Department of Health to develop an appropriate licensing system for hospitals in Ireland.

1.2 About this paper

This revised Inspection and Enforcement policy reflects recent developments during the pandemic as we transition to a regulatory standards approach.

Under the Pharmacy Act 2007, the PSI is responsible, inter alia, for:

- Regulating the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public
- Supervising compliance with the Act and the instruments made under it.

The functions of the PSI were expanded through an amendment to the Act, which also afforded the function of supervising compliance with legislation that both governs the practice of pharmacy in Ireland and how practising registered pharmacists in Ireland competently discharge their professional responsibilities and duties. This is available at Practice Of Pharmacy Ireland - Legislation & Regulation -PSI (thepsi.ie)

The PSI has a dedicated Community Pharmacy Quality and Safety Team to deal with inspection and a separate team for investigations.

This document aims to inform the public, the pharmacy profession and pharmacy owners about the PSI's approach to inspection and investigation activity. The document is informed by the PSI's core remit to protecting the health, safety and well-being of the public.

During the COVID-19 pandemic (2020-2022), the inspection and investigation functions continued on a more limited capacity under government guidance. Pharmacies were visited where required, but the PSI also adapted to the prevailing circumstances and adopted its method of work to conduct 'virtual' pharmacy visits. The methods used and the lessons learnt from operating in those circumstances will be utilised and included in this policy.

2. Community Pharmacy Assurance

2.1 Quality and Safety – Inspection function

The PSI inspects RPBs to assess compliance with the Pharmacy Act 2007, guidelines and good pharmacy practise.

The inspection function aims to promote good and safe pharmacy practice within RPBs and promote and ensure high standards of compliance with legislative requirements,

guidelines, best practice requirements and the Statutory Code of Conduct for Pharmacists. Pharmacy inspections may be carried out on a notified or an unnotified basis. To maximise PSI's limited inspection resources, we currently direct most of our focus to risk-based inspections.

The PSI has published a checklist to assist pharmacy owners and pharmacists in preparing for these inspections and informing them of what to expect during an inspection. The checklist is available on the PSI website.

The Quality Assessor[2] conducts inspections under Section 67 of the Act. Once an inspection is completed, the PSI will issue the pharmacy owner and/or the superintendent pharmacist with a Quality Assessor's report. The report will identify non-compliance observed during the inspection and required actions, which must be undertaken to comply with legislative requirements and/or relevant guidelines. The PSI seeks written confirmation from the pharmacy owner and/or the superintendent pharmacist within a specified timeline that the required actions identified in the report have been remedied.

The PSI may conduct follow up inspections to check that the remedial actions confirmed in writing have been carried out.

The findings from inspections will assist the PSI to:

- Identify non-compliance trends and/or areas for improvement and keep pharmacy owners and pharmacists informed of any practice or safety concerns observed
- Inform the PSI's risk assessment methodology to ensure more targeted intervention for pharmacies that pose the highest risk to patient safety and public protection.

2.2 Types of Inspection

The different types of inspections utilised by PSI are outlined below:

2.2.1. Risk-based inspections

Risk-based inspections are undertaken following a review of information available to the PSI, including inspection/compliance history, staff turnover/frequency of changes to

[2] Quality Assessors are authorised officers under Pharmacy Act 2007, to include Part 7 of the Pharmacy Act 2007pursuant to sections 7(2)(b)(ix), 7(2)(b)(x) and 67 of the Pharmacy Act 2007. All purposes of the Irish Medicines Board Acts 1995 and 2006 pursuant to section 7(2)(b)(x) of the Pharmacy Act 2007 and section 32B of the Irish Medicines Board Acts
1995 and 2006; All purposes of section 24 of the Misuse of Drugs Act 1977 to 2007 pursuant to section 7(2)(b)(ix) of the Pharmacy Act 2007 and section 24(2) and section 24(4) of the Misuse of Drugs Act 1977 to 2007.

superintendent/supervising pharmacist staff, or where a concern has been raised by a member of the public or an external body.

2.2.2 Information from the public

The PSI receives a significant amount of unsolicited information in relation to pharmacies on a regular basis from members of the public. All unsolicited information received by the PSI is risk-assessed by a multi-disciplinary team within the PSI to inform our decision-making and regulatory actions, where necessary. Where a risk to the public becomes apparent, the PSI will take timely and effective action to address these risks, including conducting risk-based inspections.

These inspections may be focused on a particular area or the general operation of the pharmacy.

2.2.3 Systems Inspections

Whilst the PSI currently directs most of the focus to risk-based inspections, Systems inspections, or 'routine' inspections, are conducted on a regular basis to:

- review the quality systems and governance arrangements of the pharmacy.
- examine the way prescription-only medicines and controlled drugs are supplied.
- assure there is a legitimate and safe basis for the supply of medicines.
- assess the pharmacy premises and pharmacy workflow.

2.2.4 Themed inspections

Themed inspections are conducted to assess other services that pharmacists provide, including flu vaccination inspections and internet supply pharmacy inspections. Themed inspection programmes are undertaken periodically, for example, before the commencement of a flu vaccination season.

2.2.5 Re-inspections

Re-inspections are conducted to verify the implementation of any confirmations and assurances of compliance after the previous inspection of the pharmacy. Re-inspections can be directed to be undertaken by the Registrar following consideration of a Quality Assessor's report under Section 71 of the Act. They can be undertaken following risk assessment under the direction of management to verify that specific remedial actions in a pharmacy have been carried out.

2.2.6 Registration-related inspections

Registration-related inspections include new openings, changes of ownership and relocations of pharmacy premises. Before a pharmacy can open to the public, it must be registered with the PSI in accordance with statutory rules. The PSI registers RPBs in accordance with the Pharmacy Act and the regulations and rules made thereunder. The

PSI recognises that the standard of premises associated with new openings has increased significantly over the years. This, allied to the virtual inspections which occurred during the pandemic, meant that this type of inspection was developed to be undertaken virtually. The physical inspection has been replaced with undertakings provided by the pharmacy owner and superintendent pharmacist; these undertakings match the requirements contained within the checklist.

Inspections of new pharmacy openings are carried out as and when required. Physical inspections are still undertaken by Quality Assessors where circumstances warrant such inspections. These inspections are carried out under the authority of Section 19 of the Act to assess compliance with the Retail Pharmacy Business Regulations (S.I. No. 488 of 2008) (as amended) and PSI guidelines. These inspections must be notified in advance. Where the PSI conducts an inspection on foot of an application to register a new RPB, the PSI will give notice of the inspection in writing to the applicant. Once the inspection is completed, the Quality Assessor generates a report which is provided to the applicant. The report will identify required actions that must be undertaken by the applicant in order to comply with legislative requirements and/or relevant guidelines. The PSI seeks written confirmation from the applicant that the required actions identified in the report have been remedied before the registration application is progressed to its conclusion.

The PSI has published a checklist to assist pharmacy owners, and pharmacists prepare for new opening inspections and inform them what to expect during an inspection. The checklist is available at www.psi.ie

2.2.7 'Virtual /Remote' registration-related inspections

Due to COVID-19 restrictions, routine inspection activity was suspended in 2020 in line with government restrictions. The majority of registration-related inspections were carried out remotely using self-declarations and a combination of the following: photographs, video walkthroughs, submission of documents confirming calibration of equipment, and additional confirmations and declarations. The use of virtual/remote elements for registration-related inspections is a new engagement tool for the PSI, which has demonstrated value-for-money and efficiencies since its implementation.

2.2.8 Statutory bodies' joint inspections

Joint inspections are carried out with other statutory bodies when a multi-agency approach is required. The PSI engages with organisations such as the Health Products Regulatory Authority (HPRA), An Garda Siochána, The Health Service Executive (HSE) and the Department of Agriculture, Food and Marine.

2.2.9 Specialist surveyor exercises

The PSI engages specialist surveyors to assess certain quality and safety aspects of specific pharmacy services. They also provide information on specific pharmacies that are the subject of concerns from members of the public. The observations from these activities help us identify, measure, and respond to any relevant risks. The use of specialist surveyors to assess aspects of specific pharmacy services have been found to be more resourceful and cost-effective for the PSI rather than deploying our Quality Assessors nationwide. Specialist surveyors can conduct single one-off or extensive assessments of pharmacy services if requested.

3. Investigations function

3.1 Investigations

The PSI carries out investigations under Part 7 of the Pharmacy Act 2007. Investigations may involve a visit or a series of visits to the pharmacy concerned and speaking to the pharmacy owner, pharmacist(s) or other staff at the pharmacy or a member of the public connected with the investigation. Records and products are often reviewed and/or detained in evidence as part of the investigation process. Investigations may also involve taking witness statements as well as conducting interviews under caution.

3.2 Investigational matters

Investigations are carried out to ascertain, inter alia, whether:

- Offences have been committed under the Pharmacy Act 2007, the regulations made under the Pharmacy Act and/or other legislation for which the PSI has supervisory authority.
- Any breach of the PSI Code of Conduct for Pharmacists has been committed.
- Professional misconduct has been committed by either the RPB or pharmacists.

Investigations seek to establish the facts and obtain information or evidence about the above matters. PSI Investigation activity is risk-based and intelligence-led. Investigations are carried out as a result of non-compliances identified in the inspection process or using intelligence (from the PSI internally, other agencies or members of the public), which have been risk assessed. This ensures the most effective use of resources allowing the PSI to focus on those areas, which pose the greatest risk.

3.3 Collaboration with State Agencies

Investigations are undertaken where there is reason to believe that serious safety issues and/or non-compliance issues exist with a pharmacist or a pharmacy. We investigate pharmacies to look in-depth at serious, deliberate and/or illegal activities by pharmacies. This includes, for example, the diversion of medicines and controlled drugs, fraud, and other matters involving serious safety and/or health concerns. In conducting such investigations, the PSI collaborates with An Garda Siochána and other regulatory and state bodies, including the HPRA, the HSE and the Department of Agriculture, Food and Marine.

Once an investigation is concluded, a Quality Assessor's report is completed. The report may be furnished to the parties involved in the investigation, and they are invited to submit their comments on the contents of the report. The report and submissions (if provided) are then submitted for consideration to the Registrar of the PSI under Section 71 of the Pharmacy Act 2007.

4. Nature and Type of Enforcement Actions

4.1 Section 71 of the Pharmacy Act

Following consideration of a Quality Assessor's report, under Section 71 of the Act, the Registrar may:

- Take no action
- Commence disciplinary proceedings against pharmacists and/or pharmacies
- Refer matters to other agencies if it appears that the person to whom the report relates is guilty of an offence
- In cases where an offence appears to have been committed outside the scope of pharmacy or medicines legislation, the matter may be referred to another agency
- Take such other action as it considers appropriate in the circumstances

This may include:

- Issuing warning letters in the context of non-compliances
- Seeking undertakings from pharmacists and/or pharmacies
- Initiating District Court proceedings under the Pharmacy Act 2007 or the Irish Medicines Board Act 1995 (as amended) in the name of the Council of the PSI.

5. Future regulatory approach: Standards

5.1 COVID-19 Operational Standards

We will continue to inspect pharmacies to supervise compliance with statutory requirements and assess compliance with the Pharmacy Act and PSI Guidance. In our Corporate Strategy (2021-2023), we have also committed to developing more outcome-focused standards for pharmacies, in conjunction with all of the inspection activities described above. A standards-based approach differs from compliance-based inspections. Standards provide concise, outcome-focused statements against which a service provider establishes and delivers their service and which the PSI, as the regulator, can use to assess performance. Standards empower the service provider, in this case, the healthcare setting of an RPB, to meet the requirements of the standards in a range of different ways, i.e., it is not a prescriptive, one-size-fits-all approach. By introducing standards, we align pharmacy regulation with how healthcare settings are more generally regulated. Regulatory standards are an effective, flexible, and nonprescriptive means for regulating healthcare services. They inform patients and the wider public as to what they can expect from their pharmacies.

In response to the unprecedented public health emergency resulting from the COVID-19 pandemic, community pharmacies had to radically change their work practices and alter how they provided medicines, other healthcare services and counselling to patients. To support pharmacy teams and improve the way we regulate, we introduced COVID-19 Operational Standards in 2020. Our experience with our COVID-19 Standards to date is that regulatory standards are of value, and they should play an important part in how PSI regulates community pharmacies in the future. An overview report on the development and lessons learned from the COVID-19 operational standards was published in 2021 and outlined PSI's extensive work to date in this area. The report is available at www.psi.ie

5.2 PSI Service Plan 2022

Objective 2: Evolving a more effective regulatory model for community pharmacy of the PSI Service Plan 2022 tasks the executive to 'Define and move towards a more effective regulatory model for community pharmacy'. It lists the outcomes expected for the period 2022/23 as:

- In 2022, the PSI will focus on determining the most appropriate future regulatory model for pharmacies based on our experience with our COVID-19 Operational Standards. We will also develop an appropriate methodology to assess performance against standards.

- This work will be progressed through a safety-focused collaboration with relevant stakeholders. The PSI will re-commence the previous project on governance and accountability standards, which was paused in 2020 due to the onset of the COVID-19 pandemic and resource issues.

This project is due to commence in August 2022, and standards will be rolled out in accordance with the Council-approved Service Plan and related project plan.

5.3 Operationalising this policy

The PSI annual service plan outlines key performance indicators for regulatory activities, including our inspection, quality assessment and investigation functions. These activity levels are considered by the Executive and presented to Council annually as part of service planning. Each service plan determines the proportion of pharmacies that will be assessed for the coming year.

5.4 Interim nature of this policy

This interim policy has been developed as the PSI evolves its regulatory approach over the course of the Corporate Strategy 2021-2023. We are committed to developing a standards-based regulatory model for community pharmacies. During 2022-23, the PSI plans to develop the standards model in conjunction with stakeholders. The plan will also see the standards model trialled in pharmacies. This interim policy will be revised when incorporating the standards approach as an additional tool in the regulatory and inspection model.