

Guide for Pharmacists and Pharmacy Owners on the Complaints Process



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About this guide

The purpose of this guide is to assist pharmacists and pharmacy owners in understanding the process that is followed when a complaint is made to the Pharmaceutical Society of Ireland (PSI), the pharmacy regulator. The complaint process is divided into two stages. Stage one is referred to as the **screening stage**, and stage two refers to the **inquiry stage**.

This guide deals with the first stage of the complaints process, the screening stage, which considers whether further action needs to be taken in relation to a complaint made to the PSI about a pharmacist or a pharmacy.

There is a separate guide available on our [website](#) which deals with the second stage of the complaint process, the inquiry stage. It outlines what can be expected at stage two, if a complaint is referred for inquiry after the screening stage. The PSI has also published guidelines on what can be expected if a matter is referred to mediation.

At the back of this guide you will find an explanation of some the words and terms used throughout the complaints and disciplinary process.

The PSI

The PSI is the statutory regulator of pharmacists and pharmacies in the Republic of Ireland. We regulate the profession and practice of pharmacy in the interest of patient safety and public protection.

One of the ways in which the PSI carries out its function is by handling complaints raised about pharmacists and pharmacies. Part 6 of the Pharmacy Act 2007 (as amended)¹ sets out the process to be followed when a complaint is made. Once the PSI receives a complaint that falls within its remit, it is required by law to follow the procedure set out in

¹ The Pharmacy Act 2007 has been amended by a number of Acts including the Regulated Professions (Health and Social Care)(Amendment) Act 2020.

Part 6 of the Pharmacy Act 2007 (as amended) to its conclusion.

Please note that references to the Pharmacy Act 2007 throughout this document shall mean the Pharmacy Act 2007 (as amended). This guide is not a legal interpretation of the Pharmacy Act 2007. The details of the complaints and disciplinary process is available on the PSI [website](#).

Who can make a complaint?

Anyone can make a complaint about a pharmacist or pharmacy, including a patient, an employer or another health professional. The Registrar of the PSI may also make a complaint about a pharmacist or pharmacy. For example, the Registrar may decide to make a complaint after considering a report prepared by an Authorised Officer of the PSI following an inspection or investigation of a pharmacy or where it comes to the Registrar's attention that a pharmacist has been convicted of an offence triable on indictment.

What type of complaints will the PSI consider?

The complaints screening committee, called the **Preliminary Proceedings Committee (PPC)**, considers complaints against registered pharmacists that deal with one or more of the following:

- professional misconduct;
- poor professional performance;
- impairment of the registered pharmacist's ability to practise because of a physical or mental ailment, an emotional disturbance or an addiction to alcohol or drugs;
- failure to obey the conditions attached to the pharmacist's registration;
- failure to comply with an undertaking or to take agreed action following a request from a Committee of Inquiry under Section 46 of the Pharmacy Act 2007;
- failure to comply with certain provisions of the Health (Pricing and Supply of Medical Goods) Act 2013;

- failure to comply with any duties imposed by section 18(1)(A) of the Pharmacy Act 2007 which relate to the Health (Pricing and Supply of Medical Goods) Act 2013;
- failure to comply, as a pharmacist, with provision(s) of the following Acts or any statutory instruments made under any of these Acts: the Poisons Acts 1961 and 1977, the Misuse of Drugs Acts 1977 to 2017, the Animal Remedies Acts 1993 and 2006, the Irish Medicines Boards Acts 1995 and 1996, the Health (Pricing and Supply of Medical Goods) Act 2013² ;
- failure to comply, as a pharmacist, with provision(s) of the European Communities (Animal Remedies)(No 2) Regulations 2007 (S.I. 786 of 2007)³;
- breaching a provision of the Pharmacy Act 2007 or any statutory instrument made under the Pharmacy Act 2007;
- a prohibition imposed against the pharmacist providing one or more kinds of health or social care⁴ in the State or outside the State⁵;
- a restriction imposed on the pharmacist's ability to provide one or more kinds of health or social care in the State or outside the State⁶;
- conviction in the State or outside the State for indictable offences.

The PSI will consider complaints against **registered pharmacies** if:

- the pharmacy owner, partner, employee or representative of the pharmacy owner has been convicted of certain offences listed in Section 36(1)(a) of the Pharmacy Act 2007;
- the pharmacy owner, partner, employee or representative has been convicted of any other offence in the State or outside the State or has committed misconduct in the State or outside the State that would cause the Council of the PSI to refuse an

² This ground of complaint was inserted into the Act by a provision of the Regulated Professions (Health & Social Care)(Amendment) Act 2020. This provision commenced on 13 February 2021.

³ This ground of complaint was inserted into the Act by a provision of the Regulated Professions (Health & Social Care)(Amendment) Act 2020. This provision commenced on 13 February 2021.

⁴ Health or social care means the health or social care that the person provides or has provided in his or her capacity or former capacity as either a dentist, a designated profession within the meaning of section 3 of the Health and Social Care Professionals Act 2005, a medical practitioner, midwife, nurse or a pharmacist.

⁵ This ground of complaint was inserted into the Act by a provision of the Regulated Professions (Health & Social Care)(Amendment) Act 2020. This provision commenced on 13 February 2021.

⁶ This ground of complaint was inserted into the Act by a provision of the Regulated Professions (Health & Social Care)(Amendment) Act 2020. This provision commenced on 13 February 2021.

application for registration;

- the pharmacy owner has failed to comply, in his/her capacity as a pharmacy owner, with provision(s) of the following Acts and any statutory instruments made under any of these Acts: Poisons Acts 1961 and 1977, the Misuse of Drugs Acts 1977 to 2017, the Animal Remedies Acts 1993 and 2006, the Irish Medicines Boards Acts 1995 and 1996, the Health (Pricing and Supply of Medical Goods) Act 2013 or the European Communities (Animal Remedies)(No 2) Regulations 2007 (S.I. 786 of 2007)⁷;
- the pharmacy owner has failed to comply with any of the duties referred to in section 18(1)(A) of the Pharmacy Act 2007 imposed on the pharmacy owner by regulations made under section 18 which relate to the Health (Pricing and Supply of Medical Goods) Act 2013;
- the pharmacy owner has breached a provision of the Pharmacy Act 2007, including any statutory instruments made under the Act⁸.

Are there any complaints the PSI cannot consider?

The PSI cannot consider complaints about:

- professionals who are not pharmacists
- businesses that are not pharmacies
- commercial matters, such as pricing or non-payment of rent on commercial premises
- employment issues, such as hours of work or contracts of employment

What should you do if a complaint is made about you?

If you are notified by the PSI that a complaint has been made about you, it is advisable that you consult your insurers/indemnifiers, representative body or solicitor. The PSI cannot

⁷ This ground of complaint was inserted into the Act by a provision of the Regulated Professions (Health & Social Care)(Amendment) Act 2020. This provision commenced on 13 February 2021.

⁸ This ground of complaint was inserted into the Act by a provision of the Regulated Professions (Health & Social Care)(Amendment) Act 2020. This provision commenced on 13 February 2021.

provide legal advice.

We appreciate that having a complaint made against you can be difficult and stressful. It may be useful to consider having support and appropriate advice available to you during this time.

The Practitioner Health Matters Programme is a confidential service that provides support and appropriate medical care for health practitioners, including pharmacists, in Ireland who may be going through a difficult time with stress, mental health difficulties, or who may have an alcohol or drug misuse problem. It is fully independent and separate from the PSI. The Practitioner Health Matters Programme can be contacted by telephone on 01 297 0356 or visit www.practitionerhealth.ie.

Explaining the PSI complaint process

What happens when a complaint is received by the PSI?

The complaint is first dealt with by a Case Officer, who works within the PSI's Legal Affairs team. The Case Officer is a neutral point of contact for all parties to a complaint and you can contact the Case Officer if you have a query during your involvement in this process.

In general, we will write to all parties relevant to the complaint, which can include the superintendent pharmacist, the supervising pharmacist and the owner of the pharmacy. A copy of the complaint will be provided in this first correspondence.

If a complaint does not identify the pharmacist connected with the incident, this information will be requested from the superintendent pharmacist, supervising pharmacist and/or owner of the pharmacy, as appropriate.

You will be given the opportunity to submit observations and comments in relation to the complaint. However, you are under no obligation to do so. If you decide to submit observations these must be provided in writing, and within the timeframe given. This is usually 14 days from the date of the letter.

We will then send a copy of your observations to the complainant. The complainant may

wish to respond to your observations. If the complainant has further comments, you will be provided with a copy of the response and you will be given the opportunity to respond to it. When all observations and comments have been received the matter will then be referred to the Preliminary Proceedings Committee (PPC).

If you do not respond to correspondence from the PSI or submit any observations, the file will be referred to the PPC and the PPC will proceed to meet to consider the complaint.

We will write to you after the complaint has been considered by the PPC and advise you of the outcome of the meeting.

On occasion, if the complaint suggests that there is a serious and immediate risk to the health and safety of the public, the Council of the PSI can refer the matter to the High Court to suspend the registration of a pharmacist or pharmacy until the complaint process is over. Please see page 10 for more information.

Additional information

Sometimes we receive complaints that relate to the work or the responsibility of another organisation. When this happens, we have a duty to let them know about it. For example, if a complaint raises a concern about the protection of children or a vulnerable person, we are obliged to tell the relevant authority such as TUSLA and/or the Gardaí.

Throughout the process all correspondence will be sent to the address that you provided to the PSI as part of your registration record. It is your responsibility to ensure the contact details that the PSI holds for you are correct and up to date at all times. If you would prefer to be contacted on a different email or postal address, please notify the PSI Case Officer.

What is the role of the PPC?

The PPC is an independent Committee that meets regularly to consider complaints. It consists of up to 16 members, and the majority of the PPC members are not pharmacists. Their role is to decide if further action is necessary in relation to a complaint, not whether the complaint is proven or not. The PPC will consider the complaint and all observations received from you and the complainant.

Before arriving at its decision, the PPC may request further information and/or documentation from you or the complainant. If this happens, a decision in relation to the complaint will not be made until this information is received, or until the time within which it is required to be submitted has expired. The PPC will also consider whether a complaint is trivial, vexatious or made in bad faith.

When the PPC has reviewed all information received in relation to a complaint, it will advise the Council of the PSI whether further action should be taken. The PPC may decide:

1. there is a case for further action. If this happens the PPC will refer the complaint to either mediation or a Committee of Inquiry.
2. there is insufficient cause to take further action. If this is the case, the complaint is put before the Council of the PSI and they are asked whether they agree with the advice of the PPC not to take any action in relation to the complaint. Council may agree with the advice of the PPC, in which case no further action will be taken.

However, it is also open to Council to disagree with the advice of the PPC and decide that further action should be taken. If Council decide that further action should be taken, the complaint is referred to mediation or to a Committee of Inquiry by the PPC.

Figure 1 gives an overview of this stage of the complaints procedure.

What happens if the complaint is referred to mediation?

Mediation is a confidential process where a neutral third party (a mediator) sits down with both sides to the complaint to help resolve the matter and to agree an outcome suitable to everyone.

Mediation can only take place where the PPC has decided that the complaint requires further action. Not all complaints are suitable for mediation. If the complaint is referred to mediation, we will write to you and explain how the process works. Please see our [Mediation Guidelines](#) for more information on this process which is available on our website.

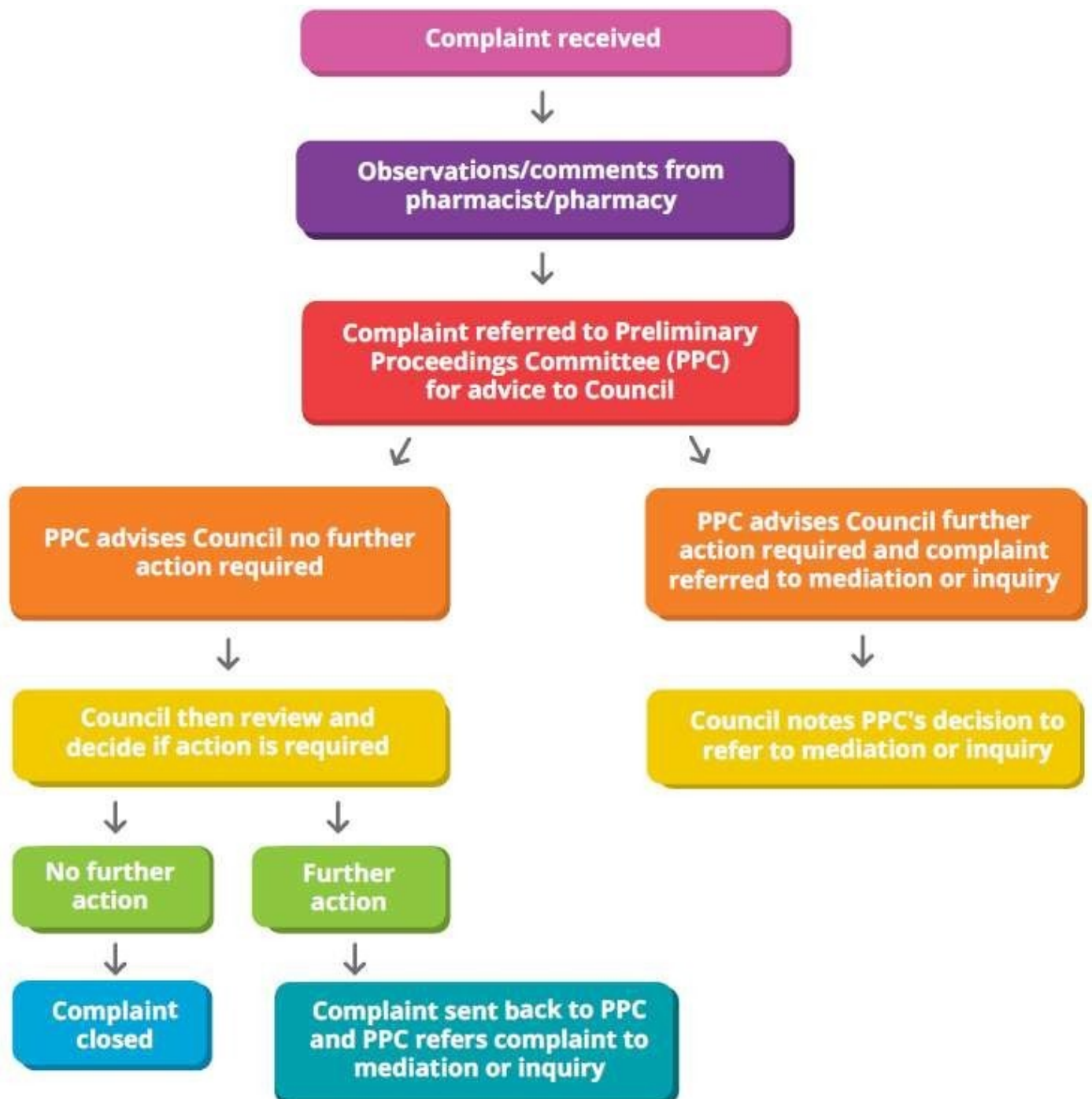
What happens if the complaint is referred to a Committee of Inquiry?

There are two Committees of Inquiry:

1. The **Professional Conduct Committee** deals with complaints about professional misconduct or poor professional performance, or any other ground of complaint under section 35 of the Pharmacy Act 2007, except impairment. These hearings are normally heard in public. The Professional Conduct Committee will have a legal assessor to advise it about law and procedure, but the legal assessor does not take part in decisions.
2. The **Health Committee** deals with complaints about the impairment of a pharmacist's ability to practise due to a physical or mental ailment, emotional disturbance or an addiction to alcohol or drugs. However, it can also deal with complaints about professional misconduct, poor professional performance and other grounds of complaint. These hearings are normally heard in private. As well as having a legal assessor available to the Committee, the Health Committee will also have a registered medical practitioner to advise it on medical issues. The medical practitioner will not take part in decisions.

For more information on the inquiry process, please see our 'Guide for Pharmacists and Pharmacy Owners regarding the Inquiry Process'.

Figure 1. Summary of the initial complaints procedure.



Other information you should know

1. How long will it take to deal with a complaint?

We recognise that having a complaint made against you can be stressful. We always try to ensure complaints are considered promptly. However, some complaints are complex and it may take some time to gather all the information needed to reach a fair decision. As much as possible, we will keep you informed at each stage of the complaints process and we will endeavour to conclude the complaint process within two years from the date of receipt of the formal complaint.

2. How is my registration affected when a complaint is made about me?

Your registration status does not change when a complaint is received about you; you can still work and carry out your duties as required. The only exception to this is where the High Court orders an interim suspension of your registration pending the conclusion of the complaint process (see below).

If you are subject to a complaint, you must declare it on your annual PSI continued registration form. If you are registered with another regulator you may also have to notify them as part of the registration process.

Voluntary removal: The PSI cannot accept an application from you to voluntarily remove your name from the register if you are the subject of an ongoing complaint.

Certificate of current professional status: The PSI may provide a certificate of current professional status for you while you are involved in an ongoing complaint. The certificate will state that you are the subject of an unproven complaint but will not provide any details of the complaint.

3. Can the PSI suspend my registration, or that of the pharmacy, following receipt of a complaint?

If a complaint indicates that there is a serious and immediate risk to the health and safety of

the public, the Council of the PSI will consider whether it is appropriate for the pharmacist to continue to practise or for the pharmacy to continue to operate while the complaint is progressed. This is generally considered when the complaint is first received, however, it can take place at any stage of the complaint process.

An emergency meeting of the PSI Council must be held to consider whether it is appropriate to apply to the High Court under section 45 of the Pharmacy Act 2007, for an order to suspend the registration of the pharmacist or the pharmacy. At the Council meeting the pharmacist and/or pharmacy owner in question will be invited, with a legal representative if they wish, to address the Council in its consideration of whether an application to the High Court is necessary.

If the Council decides an application to the High Court is necessary, the Council will proceed to apply to the High Court for an interim suspension of registration. It is ultimately a decision for the High Court as to whether an interim suspension should be granted.

Some words explained

Conditions

The PSI Council can impose a sanction where conditions are attached to a pharmacist's registration, including restrictions on how they can practise as a pharmacist.

Indictable offence

An indictable offence is a criminal offence that may be tried by a jury in court.

Inquiry

A hearing similar to a hearing before a court or tribunal.

Legal Assessor

A barrister or solicitor who advises the Committees of Inquiry on legal issues.

Pharmacy Owner

A pharmacy owner refers to the person who is carrying on a retail pharmacy business (pharmacy). The owner is entitled to the profits of the pharmacy and they are liable for any losses sustained by the pharmacy. Under the Pharmacy Act 2007, a pharmacy owner has particular responsibilities. The ownership of a pharmacy can be held by a:

- a) Sole trader who is a registered pharmacist;
- b) Partnership which is made up of two registered pharmacists;
- c) Corporate Body; or
- d) Representative of (a), (b), or (c) in certain exceptional circumstances which are described in the Pharmacy Act 2007.

Poor professional performance

Any failure to meet the standards of competence that would be reasonably expected of a

registered pharmacist. Any such failure must be serious.

Preliminary Proceedings Committee

The committee that considers or screens all complaints received by the PSI and advises the Council on the action to take.

Professional Conduct Committee

The Committee of Inquiry which deals with complaints about professional misconduct or poor professional performance.

Professional misconduct

Behaviour that goes against the code of conduct for registered pharmacists or that involves fraud, dishonesty or other unacceptable behaviour. Professional misconduct is defined in full in the Pharmacy Act 2007.

Registrar

The Registrar is also the Chief Officer of the Pharmaceutical Society of Ireland (PSI).

Other useful documents

The following documents can be found on the PSI website www.psi.ie:

- The Pharmacy Act 2007.
- Code of Conduct - professional principles, standards and ethics for pharmacists.
- Guide to assist you in making a complaint about a pharmacist or pharmacy.
- Guide for pharmacists and pharmacy owners on the inquiry process.
- PSI Frequently Asked Questions on Remote Hearings.
- PSI Mediation Guidelines.