

Annual Report of the Preliminary Proceedings Committee 2024

Foreword

The Preliminary Proceedings Committee (the "PPC") established under the Pharmacy Act 2007 (the "Act") is pleased to present its 15th annual report covering the calendar year of 2024.

The PPC performs a vital function on behalf of the Pharmaceutical Society of Ireland (the "PSI"), the pharmacy profession and most importantly, the public. The PPC considers whether further action is warranted when complaints are received concerning registered pharmacists and registered retail pharmacy businesses ("pharmacies") and, where appropriate, refers complaints for mediation or for inquiry before either the Professional Conduct Committee or Health Committee.

There were 9 meetings of the PPC during 2024 compared to 11 in 2023. The meetings are held in PSI House, although remote attendance was facilitated on certain occasions to ensure a quorum was achieved.

During 2024, 50 new complaints were considered by the PPC, compared to 77 complaints in 2023. Some of the complaints considered during 2024 had been received by the PSI in 2023. A total of 78 new complaints were received by the PSI in 2024.

An important function of the PPC is to keep its knowledge and information up to date regarding professional regulation. The PPC received one training session in 2024 in this regard.

This Annual Report outlines the work of the PPC and highlights to the Council of the PSI any comments and observations that the PPC may have following on from its consideration of the complaints received throughout 2024. It also aims to inform the public and the profession on the role and the learnings of the PPC arising from the performance of its statutory functions.

As Chairperson, I would like to commend the PPC for its response to adapting to meetings being held in a hybrid manner as required, and I would also like to thank the Executive for its support in this respect.

Signed:

Chairperson of the Preliminary Proceedings Committee

Introduction

This report is prepared and approved by the PPC and covers the period 1 January 2024 to 31 December 2024. The purpose of this report is to provide to the Council of the PSI, together with members of the profession and the public, information on the role of the PPC and other matters relating to the discharge of its functions. It is also used to report any trends observed by the PPC over the course of the performance of its statutory functions and to make recommendations for important learnings that may improve pharmacy practice in Ireland.

Legislative Background

Provision for investigation of complaints and the holding of inquiries is set out in Part 6 of the Act. Specifically, section 34 of the Act empowered the Council of the PSI to establish the PPC. Sections 38, 40 and 44 of the Act set out the salient functions and powers of the PPC in relation to the consideration of complaints. Please see Appendix A, which sets out the applicable sections of the Act.

Membership and Composition of the PPC during 2024

Non-Pharmacists

Mr. Hugo Bonar - appointed as Chairperson in October 2024

Ms. Molly Buckley

Mr. Richard Hammond SC (Deputy Chairperson) (Council Representative)

Ms. Jill Long (Chairperson) – resigned from the PPC in March 2024

Ms. Cindy J Mackie

Mr. John Murray

Ms. Karen Ruddy BL – resigned from the PPC in December 2024

Dr. John Lombard

Pharmacists

Mr. Derek Fehily MPSI

Mr. John Hillery MPSI - resigned from the PPC in December 2024

Ms. Fiona Rowland MPSI

Ms. Áine Shine MPSI

Mr. Mark McPhilips

Mr. Achal Gupta – resigned from the PPC in December 2024

Executive of the PSI

The PPC is supported in its work by the Executive comprising trained PSI employees.

Legal Advisor to the PPC

In 2024, independent legal advice was provided to the PPC by Fieldfisher Ireland.

Role of the PPC

The PSI is the statutory regulator for pharmacists and pharmacies in Ireland, and the principal function of the PSI is set out in Section 7 of the Act as follows:

"to regulate the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public".

The PSI carries out this role through the Council of the PSI and through various committees established by the Council. The PPC is one of these committees and forms part of the disciplinary structure of the PSI. Under the Act, the PPC is the initial committee to receive complaints regarding registered pharmacists and pharmacies. The PPC considers each complaint and advises the Council on whether there is sufficient cause to warrant further action being taken. It is not the function of the PPC to establish that a complaint has been proven or otherwise.

The PPC is aware that it must act in a considered and expeditious manner while ensuring its actions are lawful, fair, and in conformity with the principles of natural justice.

Consideration of the Complaint¹

Before arriving at its advice to the Council on whether there is sufficient cause to warrant further action in relation to a particular complaint, the PPC will consider whether the complaint is trivial, vexatious, or made in bad faith.

When considering a complaint, the PPC will also ensure, amongst other matters, that it has sufficient information to process the complaint. To do this, it may be necessary for the PPC to request a party to a complaint to provide further information. Once the PPC is satisfied that it has sufficient information to consider a complaint, it will decide whether:

- (a) There is sufficient cause to warrant further action or
- (b) There is not sufficient cause to warrant further action.

In deciding whether there is sufficient cause for further action and the complaint relates to a once-off error or failing, the PPC will consider whether it meets the threshold of "seriousness" as set down in the case of *Corbally v Medical Council & Ors [2015] IESC 9*.

Sufficient Cause to Warrant Further Action

Where the PPC has decided that there is sufficient cause to warrant further action being taken in relation to a complaint, it will either:

¹ In considering complaints the PPC must do so in accordance with the provisions of the Act which sets out the actions it is authorised to take. For the purposes of this Annual Report, only complaints in which a final decision was given by the PPC in 2023 are reported on.

- 1. Refer the complaint for mediation, if appropriate, and subject to the consent of the complainant and the pharmacist(s) and/or pharmacy against whom the complaint has been made; or
- 2. Refer the complaint to the Professional Conduct Committee for inquiry or
- 3. Refer the complaint to the Health Committee for inquiry.

Not Sufficient Cause to Warrant Further Action

Where the PPC forms the view that there is not sufficient cause to warrant further action following a complaint against a respondent, the following steps will be taken:

- 1. The PPC refers the complaint and the advice of the PPC in relation to the complaint to the Council.
- 2. The Council will consider the advice of the PPC.
- 3. If the Council disagree with the PPC's advice and decides to take further action in relation to a complaint, the matter is referred again to the PPC, who must then refer the complaint to mediation or for inquiry or
- 4. If the Council agrees with the advice of the PPC, no further action is taken, and the complaint concludes.

Activities from 1 January 2024 to 31 December 2024

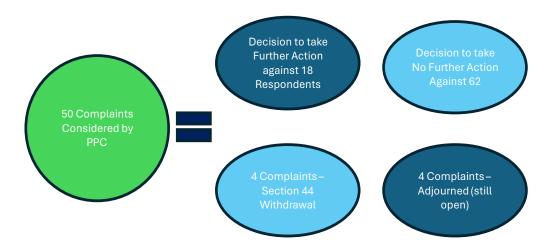
In 2024, the PPC held 9 meetings to consider complaints made by members of the public, pharmacists, other organisations and the Registrar of the PSI against registered pharmacists and pharmacies.

The PPC considered a total of 50 complaints in 2024. Whilst this number is lower than the 77 that were considered during 2023, there were a couple of contributory factors:

- there were two fewer meetings in 2024 compared to 2023
- there continued to be an increase in the complexity of complaints and the number of respondents (pharmacists and/or pharmacies) involved per complaint. For example, there were 88 respondents associated with these 50 complaints.
- there was an increase in adjournments, with some complaints being considered at multiple meetings as additional information was required to consider some of the matters.

Decisions of the PPC

The following is a summary of the PPC's decisions in relation to the 50 complaints (and 88 respondents) that were considered at PPC meetings in 2024:



Further Action

The PPC sent 18 respondents, associated with 11 complaints, forward for further action in 2024. Of these:

- Seventeen respondents were referred to the Professional Conduct Committee for Inquiry.
- One respondent was referred to the Health Committee for Inquiry.

No Further Action

The PPC advised the Council that no further action was warranted against 62 respondents. The Council subsequently agreed with the advice of the PPC in relation to all these cases.

Timeframe & Key Performance Indicator (KPI)

In 2024, the PPC reviewed 50 complaints, with 40% resolved within six months of receipt by PSI. Delays in addressing the remaining complaints were primarily due to limited capacity or the complexity of the issues involved. To improve timeliness, additional PPC meetings have been scheduled for 2025 with the aim of increasing the proportion of complaints resolved within a target timeframe.

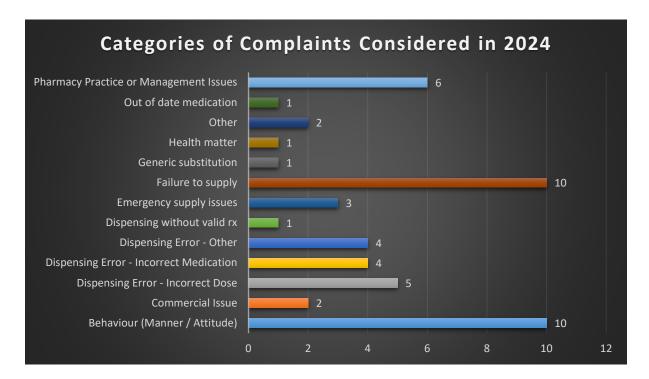
Withdrawal of Complaint

Four complaints considered by the PPC were withdrawn by complainants during the process. Pursuant to Section 44 of the Act, the PPC decided, with Council's agreement, to take no further action in relation to 4 of these complaints.

Categories of Complaints Considered by the PPC in 2024

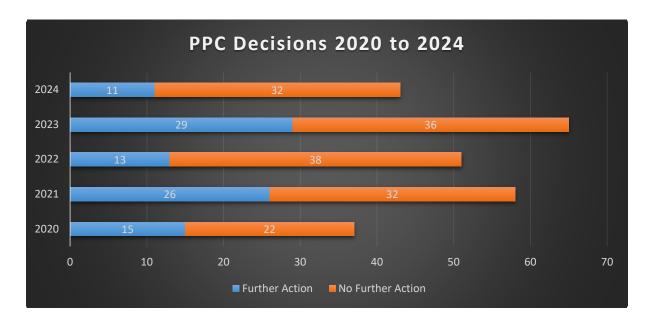
The chart at Figure 1 below shows the categories of the complaints that were considered by the PPC in 2024

Figure 1.



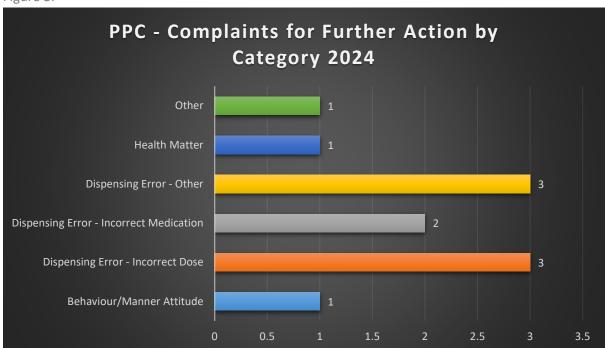
The chart at Figure 2 below shows the number of complaints considered by the PPC over the last five years and the number of these complaints where it was deemed that there was sufficient cause for further action to be taken:

Figure 2.



The chart at Figure 3. below illustrates the number of complaints, by category, that the PPC in 2024 considered to warrant further action.

Figure 3.



Observations

During their meetings in 2024, the PPC noted several recurring themes in the complaints being put before them for consideration or issues that were frequently at the heart of the complaints considered. The PPC would like to highlight the following:

Behaviour (Manner/Attitude)

The PPC noted again in 2024 that many of the complaints they considered related to how patients felt they were treated and spoken to by the pharmacist, and where a breakdown in communication appeared to have occurred between the complainant and the pharmacist. As stated in previous reports, when an issue arises, meaningful, respectful, and clear communication between a pharmacist and a patient can often help resolve the issue before it escalates to a formal complaint to the PSI. The private patient consultation area should be used to discuss sensitive or personal matters with patients.

Social Media

The PPC noted that several complaints also relate to the use of social media by the profession. The PPC believes that when expressing personal views in a public context, particularly on important or socially sensitive subjects, pharmacists should do so in a manner consistent with the <u>Guidance for Pharmacists on the use of Digital and Social Media</u> and the <u>Code of Conduct</u> for Pharmacists.

Hi-Tech Medicines

The PPC noted that a growing number of complaints relate to the supply of hi-tech medicines. There appears to be a poor understanding among some patients of how this scheme works, and this, together with occasional poor communication on the matter from the pharmacist, has led to complaints being submitted that may have been avoidable.

Medicines Shortages

The PPC also noted an increasing number of complaints relating to the unavailability of certain medicines. As worldwide shortages of certain medicines continue and are expected to persist for the foreseeable future, there needs to be ongoing awareness initiatives for the general public about these shortages., and in particular, how authorised medicines should only be prescribed for their approved use.

Conclusion

This Annual Report covers the 15th full year in the PPC's operation.

It is hoped that the Council, and indeed the public, can continue to have confidence in the way the PPC discharges its functions. The PPC is acutely aware of the importance of its role in the protection of the public and ensuring that all complaints are dealt with in a timely manner that is transparent and fair for all parties concerned.

Appendix A - Legislation

Section 34 of the Pharmacy Act 2007

- "(1) The Council shall establish the following disciplinary committees:
 - (a) a preliminary proceedings committee;
 - (b) a professional conduct committee;
 - (c) a health committee.
- (2) The President of the Society is not eligible to be appointed to a disciplinary committee.
- (3) A majority of the members of a disciplinary committee shall be persons other than registered pharmacists and at least one of those persons shall be appointed to represent the interest of the public.
- (4) At least one third of its members shall be registered pharmacists.
- (5) At least 2 of its members shall be registered pharmacists who are pharmacy owners.
- (6) The quorum of a disciplinary committee considering a complaint against a pharmacy owner shall include at least one registered pharmacist who is a pharmacy owner.
- (7) A person is not eligible to hold concurrent membership of more than one disciplinary committee.
- (8) The members of a disciplinary committee have, as such, the same protections and immunities as a judge of the High Court.
- (9) The Council shall appoint a registered medical practitioner with relevant expertise to advise the health committee in relation to each complaint referred to it.
- (10) The registered medical practitioner must be present at the meetings of that committee but may not vote.
- (11) The registered medical practitioner has, when advising that committee, the same protections, and immunities as a judge of the High Court."

Section 38 of the Pharmacy Act 2007

- "(1) As soon as practicable after receiving a complaint, the Council shall refer it to the preliminary proceedings committee for its advice on whether there is sufficient cause to warrant further action being taken.
- (2) The committee may –
- (a) require the complainant to verify, by affidavit or otherwise, anything contained on the complaint,
- (b) require the complainant to give, by statutory declaration or otherwise, more information relating to the matter raised by the complaint,
- (c) require the registered pharmacist or pharmacy owner to give such information in relation to the complaint as the committee specifies,
- (d) invite the registered pharmacist or pharmacy owner to submit observations.
- (3) A requirement under subsection (2)
 - (a) must be in writing,
 - (b) must specify a reasonable time within which it is to be met,
 - (c) may be made along with or after another such requirement.
- (4) The registered pharmacist or pharmacy owner may give the committee information although not required to do so and submit observations although not invited to do so.
- (5) Before arriving at its advice on whether there is sufficient cause to warrant further action, the committee shall consider –

- (a) any information given under this section, and
- (b) whether the complaint is trivial, vexatious, or made in bad faith."

Section 39 of the Pharmacy Act 2007

"(1) On receiving advice pursuant to section 38, the Council shall decide whether to take further action.
(2) If the Council decides to take no further action, it shall inform the registered pharmacist or the pharmacy owner, the preliminary proceedings committee and the complainant accordingly."

Section 40 of the Pharmacy Act 2007

"(1) If the preliminary proceedings committee advises, pursuant to section 38, that there is sufficient cause to warrant further action or the Council decides, under section 39, to take further action, the committee shall either –

- (a) refer the complaint for resolution by mediation under section 37, or
- (b) refer the complaint to whichever of the following committees ("committees of inquiry") it considers appropriate
 - (i) the professional conduct committee,
 - (ii) the health committee.
- (2) If informed by a mediator that a complaint referred for resolution by mediation-
 - (a) cannot be so resolved,
 - (b) can be so resolved but only after taking into account considerations which make the complaint more suitable for a committee of inquiry,

the committee shall refer the complaint to a committee of inquiry as if under subsection (1)(b)."

Section 44 of the Pharmacy Act 2007

"If a complaint is withdrawn, the committee considering it may, with the Council's agreement—

- (a) decide that no further action is to be taken, or
- (b) proceed as if the complaint had not been withdrawn."