



AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

**ANNUAL REPORT OF THE
PRELIMINARY PROCEEDINGS COMMITTEE 2016**

Pharmaceutical Society of Ireland
PSI – The Pharmacy Regulator
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Foreword

The Preliminary Proceedings Committee (the PPC), established under the Pharmacy Act 2007 (the Act) is pleased to present its seventh annual report covering the calendar year of 2016.

The PPC performs a vital function on behalf of the Pharmaceutical Society of Ireland (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 by either the Health Committee or the Professional Conduct Committee.


There were seven meetings of the PPC during 2016. Over this period, 29 complaints were considered by the PPC. The PPC made a decision in relation to 28 of the complaints and a decision was made in relation to one complaint in early 2017.

The PPC took part in two training sessions (on 9 June 2016 and 17 October 2016) in order to consider common issues which arise during the PPC's decision-making. As Chairperson of the PPC I was appreciative to be asked to represent the PPC in the Mediation Guidelines Working Group which led to updated Mediation Guidelines being published in December 2016. These guidelines are beneficial in considering the facility of mediation during PPC decision-making.

This Annual Report is prepared in order to outline the work of the PPC and to highlight 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 2016. It is also the intention of this report to inform the public and the profession on the role and the learnings of the PPC arising from the performance of its statutory functions.

I would like to express my appreciation to the PPC members for their continued effort, diligence and commitment shown throughout 2016 in dealing with the complaints at each meeting. In particular, on behalf of the PPC, I would like to thank former PPC member Ms Marian Shanley for her contribution to the PPC during her tenure.

Finally, on behalf of the PPC, I would like to express our continued thanks to the Executive of the PSI for their commitment, excellence and professional administrative assistance throughout the year.



Michael McGrail

Chairperson of the Preliminary Proceedings Committee

Introduction

This report is prepared and approved by the PPC and covers the period 1 January 2016 to 31 December 2016. The purpose of this report is to provide the Council of the PSI, together with members of the profession and the public, with 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 the pharmacy profession.

Legislative Background

Provision for investigation of complaints and the holding of inquiries is set out in Part 6 of the Pharmacy Act 2007. Specifically, section 34 of the Act empowered the Council of the PSI to establish the PPC. Sections 38 and 40 of the Act set out the functions and powers of the PPC. Please see Appendix A which sets out the applicable sections of the Act.

Membership and Composition of the PPC during 2016

Non-Pharmacists

Ms Maeve Barry
Ms Margaret Barry
Ms Elaine Quinlan
Ms Noreen Keane
Mr Shane McCarthy (Council representative)
Mr Michael McGrail (Chairperson)
Ms Anne-Marie Taylor (alternate Chairperson)
Ms Marian Shanley (completed term in May 2016)

Pharmacists:

Mr Liam Farmer, MPSI
Ms Geraldine Hetherton, MPSI
Ms Oonagh O'Hagan, MPSI (alternate Chairperson)
Ms Aoife O'Rourke, MPSI
Mr Andrew Barber, MPSI
Ms Anne Murphy, MPSI

Executive of the PSI

The PPC is supported in its work by the Executive made up of trained PSI employees.

Legal Advisor to the PPC

In 2016, independent legal advice was provided to the PPC by O'Connor Solicitors.

Role of the PPC

The PSI is the statutory regulator of the pharmacy profession 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 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 whilst ensuring its actions are lawful, fair and in conformity with the principles of natural justice.

Consideration of the Complaint¹

When considering a complaint the PPC ensures that it has sufficient information to process the complaint. In order to do this, it may be necessary for the PPC to request a party to a complaint to provide further information. When the PPC is satisfied it has sufficient information to consider a complaint it will then establish whether the complaint is trivial, vexatious or made in bad faith. If the PPC is satisfied that the complaint is not trivial, vexatious or made in bad faith, it can decide that:

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

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. Refer the complaint for mediation subject to the consent of the person(s) making the complaint and the person(s) 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.

¹ In consideration of all complaints the PPC must adhere to the provisions of the Act which permits only a limited number of actions being taken by the PPC.

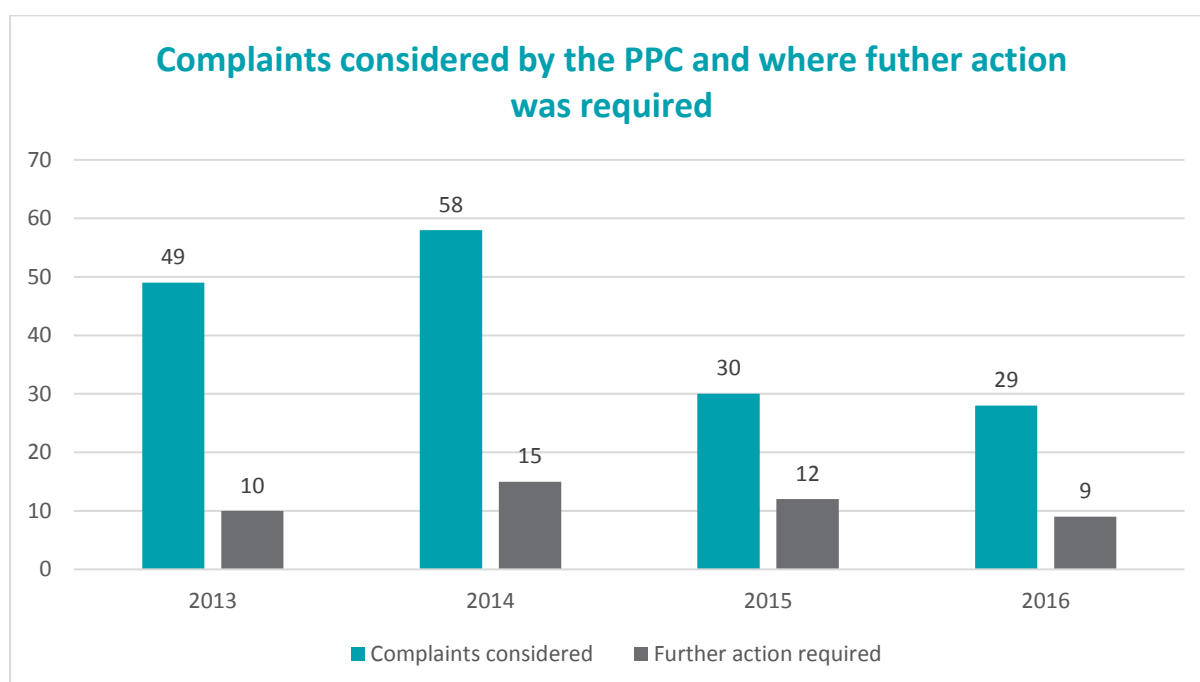
Not Sufficient Cause to Warrant Further Action

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

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

Where a complaint is made against two or more respondents, and the PPC has decided that there is a case for further action against one or more of the respondents but no case for further action against others, the Council will review the decisions in respect of which the PPC has decided there is no case for further action only.

The following chart shows the number of complaints considered by the PPC since 2013 and the number of complaints where there was sufficient cause for further action being taken:



Activities from 1 January 2016 to 31 December 2016

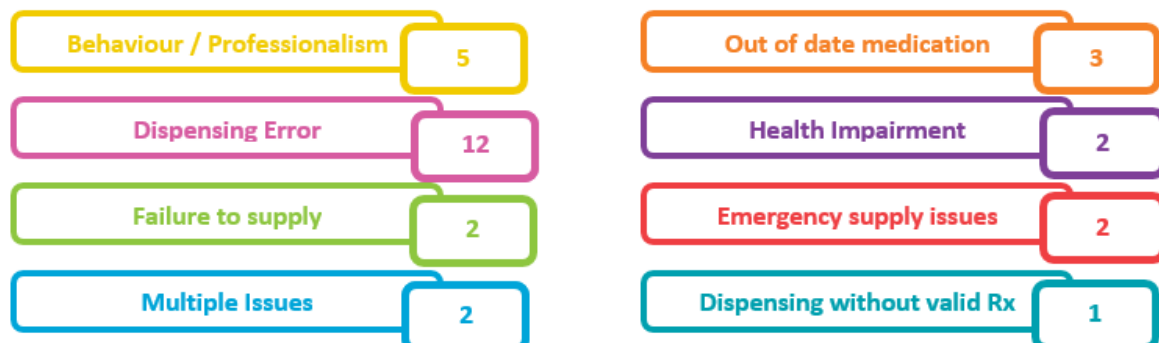
In 2016 the PPC held seven meetings to consider complaints by members of the public, pharmacists, other healthcare professionals and the Registrar of the PSI against registered pharmacists and pharmacies.

The PPC considered a total of 29 complaints in 2016. The PPC made a decision in relation to 28 of the complaints. Please note a decision was made in relation to one complaint in early 2017.



Categories of Complaints²

The complaints are broadly categorised in the table below.



² Some complaints related to more than one category but for the purpose of this table the primary category of complaint is recorded.

Timeframe

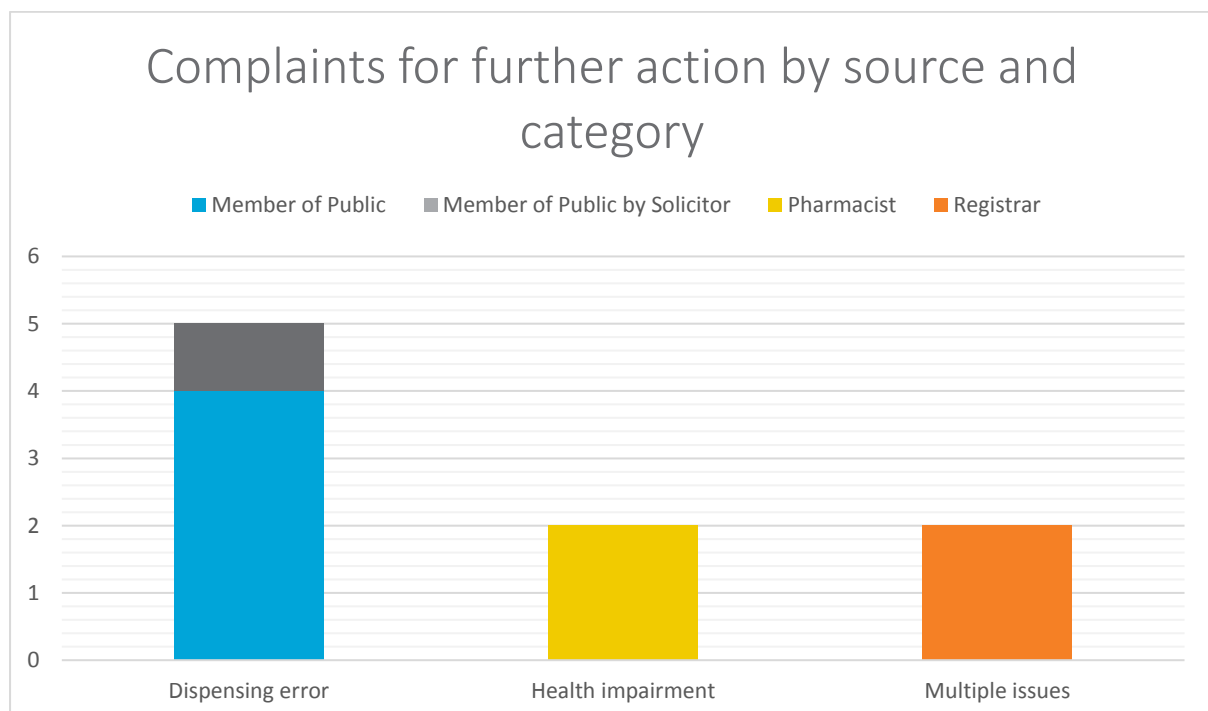
Of the complaints considered, 93% were dealt with within six months and almost half of these were dealt with within three months of being received by the PSI.

Decisions of the PPC

Of the 29 complaints considered, the PPC advised that there was:

- Sufficient cause to take further action in relation to 9 complaints:
 - 7 of these complaints were referred to the Professional Conduct Committee for inquiry.
 - Two complaints were referred to the Health Committee.
 - While there was no referral to mediation, the PPC considered the suitability of mediation in the case of each complaint where further action was taken;
- Not sufficient cause to take further action in 19 complaints; and
- A decision was also made in early 2017 in relation to one of the complaints considered by the PPC in 2016.

The chart below illustrates the category and volume of complaints with sufficient cause for further action including the source of that complaint.



Observations

During the course of the PPC's work the committee noted a number of issues being raised as part of the complaints made to the PSI. Issues the PPC would like to highlight are listed below:

1. Expired Medication

The PPC noted that a number of complaints concerned the supply of expired medication to members of the public. Pharmacists are reminded to be vigilant in checking the expiry date of medication prior to dispensing. A pharmacist must ensure that appropriate arrangements are in place to separate out-of-date and returned medicines and other waste medicines from active stock. The PPC suggests that pharmacists should review their current procedures and ensure they are in line with current legislation and guidelines, in particular, the PSI Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business. All staff should be trained on these procedures.

2. Dispensing Errors

The majority of complaints considered by the PPC in 2016 related to dispensing errors. These complaints fall broadly into three main categories:

i. Incorrect Strength of the Correct Medication

The PPC noted a considerable number of the dispensing errors complained of related to the incorrect strength of the correct medication being supplied. This led to an underdose or overdose of medication, potentially putting patient safety at risk. Particular care should be given to the storage location of different strengths of the same medicinal product to avoid potential confusion.

ii. Incorrect Medication

Some of the dispensing errors related to an incorrect medication being supplied due to its visual similarity to an entirely different medication. Particular care should be given to the storage location of different medication with similar packaging known as sound alike, look alike drugs ("**SALADS**"). The pharmacist should also ensure that assembly areas are clean and clutter-free to avoid potential errors.

iii. Incorrect Labelling

In one case the medication supplied to a patient was labelled with incorrect dosage instructions. Pharmacists should be extra vigilant in making sure that the dosage instructions on the dispensing label reflect the information on the prescription.

The PPC would also like to emphasise the importance of having thorough and robust checking procedures in place in relation to the supply of all prescriptions. In particular, the PPC would like to highlight the need for a double-check system to be carried out by the pharmacist and

another member of the pharmacy team, where possible. Where an error has occurred, robust procedures are necessary to manage the error and ensure that any impact to the patient is minimised and to reduce the risk of an error of this nature occurring again in the future. Pharmacists should ensure their procedures are implemented in accordance with legislation and guidance, in particular, the PSI's Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business and the Inspector's Advice on Medication Error Management.

3. Emergency Supply of Prescription-Only Medication

The PPC have also noted that some complaints related to the refusal to dispense an emergency supply of a prescription-only medicine, without a prescription. Such scenarios can be difficult when presented to a pharmacist. The PPC would like to emphasise that the pharmacist must be satisfied, amongst other matters, that there is an immediate need for the medicine to be supplied and that a pharmacist is aware of the potential risks to the patient where medicines are supplied in the absence of an original prescription. Pharmacists should also consider the consequences of not supplying a particular medicine in emergency circumstances to a patient. Along with the current legislation, pharmacists should ensure they are familiar with the guidance issued by the PSI which is available on the PSI website.

4. Impairment

While still in low numbers, the PPC have noticed an increase in relation to complaints regarding the impairment of a pharmacist's ability to practise as a result of a health matter. The PPC wish to emphasise the importance of a pharmacist seeking assistance where they are experiencing difficult periods in their lives including depression, anxiety or other conditions such as alcohol or drug misuse. In particular, the PPC wish to highlight the work of the Practitioner Health Matters Programme. This is a strictly confidential service which provides support and appropriate medical care for practitioners in Ireland who may be going through a difficult time due to mental health difficulties or alcohol or drug misuse problems. The website is <http://practitionerhealth.ie/>. They also have a confidential email and telephone line, confidential@practitionerhealth.ie or (01) 297-0356.

Conclusion

This Annual Report covers the seventh full year in operation of the PPC. It is hoped that the Council and indeed the public can have confidence in the manner in which the PPC discharges its functions. The PPC is acutely aware of the importance of its role in the protection of the public and in ensuring that all complaints are dealt with in a manner that is transparent and fair for all parties concerned. It is hoped that the PPC can continue to successfully fulfil this role in the coming years for the benefit of the public and the pharmacy profession.

Signed: 

Michael McGrail

Chairperson of the Preliminary Proceedings Committee

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).”