

THE PHARMACEUTICAL SOCIETY OF IRELAND

**ANNUAL REPORT OF THE PRELIMINARY PROCEEDINGS
COMMITTEE 2014**



**AN RIALTOIR CÓGASÍOCHTA
THE PHARMACY REGULATOR**

Foreword

The Preliminary Proceedings Committee, appointed on 29th September 2009 and established under the Pharmacy Act 2007 (hereinafter called the “PPC” and/or the “committee”) is pleased to present its fifth annual report covering the calendar year 2014.

The PPC performs a vital function on behalf of the Pharmaceutical Society of Ireland (hereinafter called the “PSI”), the pharmacy profession and most importantly the public. It is the function of the PPC to decide whether further action is warranted when complaints are received about registered pharmacists and registered retail pharmacy businesses (hereinafter called “pharmacies”) and where appropriate to refer complaints for mediation or for inquiry by either the Professional Conduct Committee or the Health Committee.

There were eight meetings of the committee during the year 2014. During this period, 58 complaints under Part 6 of the Act were considered by the PPC. This represents an increase of nine from the number of complaints considered by the PPC in 2013. The committee also participated in a training session together with the Council of the PSI on 16 January 2014. Mr JP McDowell of McDowell Purcell solicitors briefed the committee on the judgment of the High Court in *Corbally –v- Medical Council & Ors* on this date.

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. 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 in dealing with the complaints before each meeting. In particular, on behalf of the PPC, I would like to thank former PPC member Mr Harry Cooke for his contribution to the PPC during his tenure and wish him the best in his future endeavours. I would also like to welcome Ms Marian Shanley, who was appointed to the PPC in May 2014.

Finally, on behalf of the PPC, I would like to express our thanks to the PSI Secretariat and staff for their administrative assistance throughout the year. I would particularly like to thank Ms Ciara McGoldrick, former Head of the Fitness to Practise and Legal Affairs Unit and Ms Siobhan Shanahan, solicitor, who have both departed from the PSI to take up new roles, for all their assistance to the PPC.

Signed: 

Michael McGrail

Chairperson of the Preliminary Proceedings Committee

Introduction

This report is prepared and approved by the PPC and covers the period from 1st January 2014 to 31st December 2014. 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 concerns or errors observed by the committee over the course of the performance of its statutory functions, and to make recommendations for important learning that may improve the pharmacy profession.

Legislative Background

Provision for complaints, inquiries and discipline 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, amongst other committees, the PPC.

The PPC consisted of 15 members, with a non-pharmacist majority appointed to represent the public interest, up to May 2014. Ms Marian Shanley was appointed to the committee in May 2014 and thereafter the committee maintained a membership of 16 members up to September 2014. Following Mr Harry Cooke's departure from the committee in September 2014 the PPC's membership consisted of 15 members to 31 December 2014, and a non-pharmacist majority remained.

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

Non-Pharmacists appointed to represent public interest:

Ms Maeve Barry

Ms Margaret Barry

Mr Harry Cooke¹

Dr Martin J Duffy (Alternate Chairperson)

Ms Elaine Quinlan

Ms Noreen Keane

Mr Michael McGrail (Chairperson)

Ms Anne-Marie Taylor

Ms Marian Shanley²

Pharmacists:

Mr Liam Farmer, MPSI

Ms Geraldine Hetherton, MPSI

Ms Oonagh O'Hagan, MPSI

Ms Aoife O'Rourke, MPSI

Ms Joan Peppard, MPSI

Mr Criofan Shannon, MPSI

Mr Keith O'Hourihane, MPSI

Secretariat

The PPC is supported in its work by an administrative team or Secretariat made up of trained PSI employees. The members of the Secretariat are:

- Feena Robinson, Solicitor, BCL, Dip. Eur. Law, Dip. Emp. Law, (Acting Head of Unit)
- Zoe Richardson, B.B.L.S., L.L.M, (Solicitor)
- Bernie Chamberlaine, (Administrator)

¹ Mr Harry Cooke resigned from the PPC on 11 September 2014.

² Ms Marian Shanley was appointed to the PPC on 15 May 2014.

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. The PPC is the first port of call for complaints regarding registered pharmacists and pharmacies. The PPC advises the Council on whether there is sufficient cause to warrant further action being taken on foot of a complaint. It is not the function of the PPC to find that a complaint has been proven or otherwise.

When considering a complaint the PPC ensures that it has sufficient information to process the complaint. This may necessitate the PPC requesting a party to a complaint to provide further information. When the PPC is satisfied that it has sufficient information to consider a complaint it will then establish whether the complaint is trivial, vexatious or made in bad faith.

When considering a complaint, the PPC can decide that there is or is not sufficient cause to warrant further action.

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

1. refer the complaint for mediation subject to the consent of the person 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.

Where the PPC decides to advise the Council that there is not sufficient cause to warrant further action, the complaint and advice of the PPC is referred to the next meeting of the Council, who may agree or disagree with this advice. If the Council disagrees with the committee's advice and decides to take further action in relation to a complaint then the matter is referred to the next meeting of the PPC, which must then refer the case to mediation or for inquiry as set out above. The Council decided on 27 March 2014, 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 PPC is aware that it must go about its business expeditiously and in a manner that is lawful, fair and in conformity with the principles of natural justice.

Activities from 1st January 2014 to 31st December 2014

In 2014 the PPC held eight meetings to consider complaints by members of the public (which included pharmacists and other healthcare professionals) and the Registrar of the PSI against registered pharmacists and pharmacies.

The PPC considered a total of 58 complaints in 2014³. It was noted that the complaints could be categorised as set out below. Some complaints related to more than one category but for the purpose of this table the primary category of complaint is recorded.

<u>Categories of complaints</u>	<u>Total</u>
Behaviour/Professionalism issue	18
Dispensing Error	16
Commercial/Advertising/Employment issue	12
Multiple Issues	5
Generic Substitution	3
Health Impairment	2
Contravention of Section 63 or 64 of the Act	1
Supplying out of date medication	1

Total

58

Decisions of PPC

Of the 58 cases considered, the following were the decisions of the committee at screening stage, prior to the Council considering the complaints:

- Sufficient cause to take further action 15
- Not sufficient cause to take further action 43

In relation to the 43 complaints where the PPC decided to advise the Council that there was not sufficient cause to take further action, the Council agreed that there was not sufficient cause to warrant further action in relation to 39 of the complaints. In relation to four of the

³ This figure includes 18 complaints received in 2013 and referred to the Preliminary Proceedings Committee in 2014.

complaints, which were inter-related, the Council decided further action was warranted and referred the four complaints back to the PPC for referral to inquiry⁴.

Of the 19 complaints that the PPC referred forward for further action in 2014, 17 were referred to the Professional Conduct Committee for inquiry. Two complaints were referred to the Health Committee. There were no referrals to mediation.

No complaints were withdrawn pursuant to section 44 of the Act in 2014.

Observations

During the course of the committee's work the committee noted a number of practice issues occurring in complaints. Issues the committee would like to highlight are listed below.

Identification of Dispensing Pharmacists:

The PPC notes that on at least one occasion the Committee was unable to decipher from the documentation before them the identity of the registered pharmacist who had dispensed a prescription the subject of a complaint. Therefore, the Committee did not have the requisite information to pursue the complaint sufficiently to decide whether further action was warranted or not. It is suggested that the pharmacist performing a "double-check" of the medications being dispensed be required to place their initials on the label, for identification purposes.

Accuracy of Prescriptions

The PPC noted that on a number of occasions, problems arose for pharmacists, partly as a result of confusion from the wording of a prescription for a controlled drug written by the prescribing doctor. The PPC notes, unless the prescription is written correctly and legibly, pharmacists may not dispense controlled drugs to patients. The PPC notes that the PSI is liaising with the Medical Council on matters relating to prescribing and dispensing, with a view to considering what supports or actions may be developed to increase patient safety. The PPC suggests that, in the course of this engagement, the PSI stress the importance of prescriptions being correctly written, given the potential delay in medications being dispensed to patients if the prescription is incorrect.

Pricing

The PPC notes that a number of complaints have concerned price differences between pharmacies. The PPC suggests that perhaps more information is required to be provided to members of the public, informing them that such price differentials do occur between pharmacies, that these price differentials are not prohibited under the Pharmacy Act, and that customers may shop around and seek generic versions of particular drugs should they wish to. If providing a patient with a generic medication, pharmacists should ensure to counsel patients that the medication contains the same drug as the branded version.

⁴ The PPC referred 19 complaints forward to inquiry in total.

Counselling

The PPC notes the importance of pharmacists counselling patients on the use of medications and any contraindications to their use each time medication is dispensed.

High Tech Medications

A number of complaints considered by the PPC in 2014 related to the dispensing of high tech medications. The PPC suggests that the pharmacy profession may need to be reminded that dispensing of high tech medications is a “high-alert” matter and that when dispensing such high tech medications to patients, pharmacists should be mindful of the need to explain the treatment, dose and duration of dose to the patient.

Human Resource/Employment Relationship

The PPC notes that a number of complaints arose from situations where a pharmacist has left the employment of a retail pharmacy business and subsequently made a complaint about that retail pharmacy business or pharmacists employed therein.

Reduction in complaints relating to minors and the request for supply of codeine-based medications

In 2014 the PPC notes a significant reduction in the number of complaints relating to dispensing of medication to minors. The PPC also noted a reduction in the number of complaints related to the request for supply of codeine-based medications.

Communication

The PPC notes that a significant number of complaints related to a communication breakdown between the pharmacist/pharmacy staff and the complainant. It is suggested that some of these complaints could be resolved with better communication, prior to the formal complaints process. The PPC suggests that that PSI, through the Irish Institute of Pharmacy, consider facilitating some guidance and training for pharmacists on interpersonal communications and skills for developing a rapport with patients. The PPC would encourage pharmacists to partake in such training.

Dispensing of Veterinary Medications

The PPC suggests that pharmacists should be made aware of the practice guidelines for dispensing of veterinary medications.

Conclusion

This Annual Report covers the fifth 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).”