

THE PHARMACEUTICAL SOCIETY OF IRELAND

ANNUAL REPORT OF THE PRELIMINARY PROCEEDINGS COMMITTEE 2015



AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Foreword

The Preliminary Proceedings Committee (the “PPC”), established under the Pharmacy Act 2007 is pleased to present its sixth annual report covering the calendar year 2015.

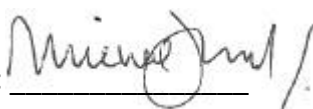
The PPC performs a vital function on behalf of the Pharmaceutical Society of Ireland (the “PSI”), the pharmacy profession and most importantly the public. The PPC considers whether further action is warranted when complaints are received concerning registered pharmacists and registered retail pharmacy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

There were eight meetings of the PPC during 2015. Over this period, 30 complaints were considered by the PPC. This represents a decrease of 28 from the number of complaints considered by the PPC in 2014. The PPC also participated in three training sessions (on 26 February, 4 June and 27 August) to assist in their 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 2015. 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 2015 in dealing with the complaints at each meeting. In particular, on behalf of the PPC, I would like to thank former PPC members Ms Joan Peppard, Mr Keith O’Hourihane, Mr Criofan Shannon and Dr Martin Duffy for their contributions to the PPC during their tenure. I would also like to welcome Mr Shane McCarthy (who replaced Mr O’Hourihane as PSI Council representative) and Mr Andrew Barber and Ms Anne Murphy who were appointed to the PPC in September 2015. Committee members, Ms Oonagh O’Hagan and Ms Anne Marie Taylor, were appointed as Acting Chairs in September 2015.

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

Signed: 

Michael McGrail

Chairperson of the Preliminary Proceedings Committee

Introduction

This report is prepared and approved by the PPC and covers the period 1 January 2015 to 31 December 2015. 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 (the “Act”). 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 2015

Non-Pharmacists appointed to represent public interest:

Ms Maeve Barry

Ms Margaret Barry

Dr Martin J Duffy (alternate Chairperson) (completed term in October 2015)

Ms Elaine Quinlan

Ms Noreen Keane

Mr Shane McCarthy (appointed 27 August 2015 as Council representative)

Mr Michael McGrail (Chairperson)

Ms Anne-Marie Taylor (alternate Chairperson)

Ms Marian Shanley

Pharmacists:

Mr Liam Farmer, MPSI

Ms Geraldine Hetherton, MPSI

Ms Oonagh O’Hagan, MPSI (alternate Chairperson)

Ms Aoife O’Rourke, MPSI

Ms Joan Peppard, MPSI (completed term in January 2015)

Mr Criofan Shannon, MPSI (completed term in October 2015)

Mr Keith O’Hourihane, MPSI (completed term in June 2015)

Mr Andrew Barber, MPSI (appointed September 2015)

Ms Anne Murphy, MPSI (appointed September 2015)

Secretariat

The PPC is supported in its work by an administrative team / Secretariat made up of trained PSI employees.

Legal Advisor to the PPC

In 2015, 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 go about its business expeditiously and in a manner that is 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 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.

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.

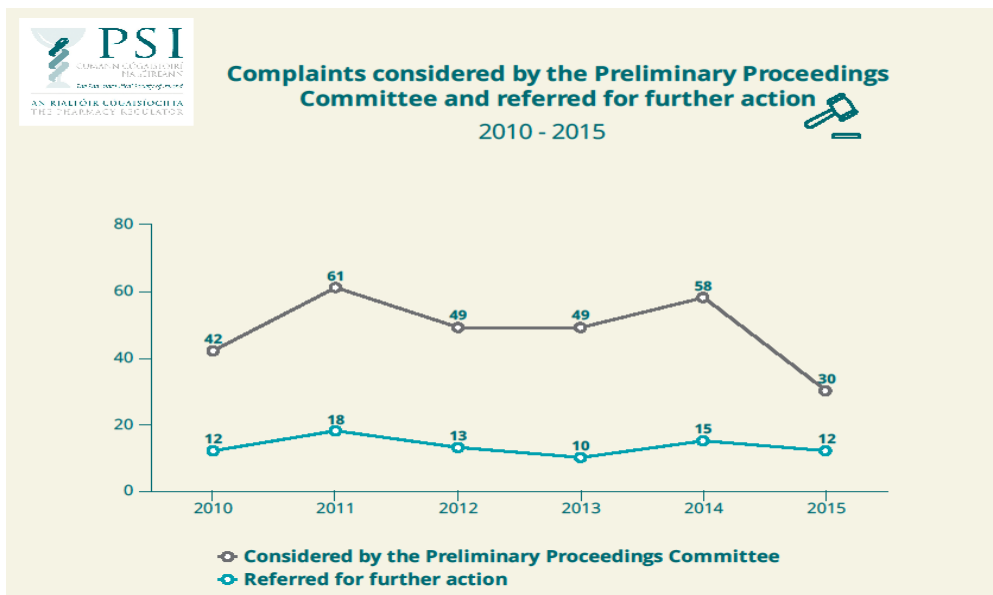
Not Sufficient Cause to Warrant Further Action

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 advice of the PPC 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 2010 and the number of complaints where there was sufficient cause for further action being taken:



As you will note from the graph above, the number of complaints considered by the PPC has decreased from 58 in 2014 to 30 in 2015. It is difficult to attribute a single cause for this decrease, however, there is a continued focus within the pharmacy profession to improve standards.

Activities from 1st January 2015 to 31st December 2015

In 2015 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 30 complaints in 2015². The complaints are broadly categorised in the table below.

Categories of Complaints³

Behaviour/Professionalism issue	9
Dispensing Error	6
Commercial/Advertising/Employment issue	5
Multiple Issues ⁴	5
Generic Substitution	1
Health Impairment/ other issues	3
Dishonesty	1

Total

30

Decisions of PPC

Of the 30 complaints considered, the PPC advised that there was:

- Sufficient cause to take further action in relation to 12 complaints:
 - 11 of these complaints were referred to the Professional Conduct Committee for inquiry. One complaint was 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 15 complaints; and
- 3 complaints were withdrawn pursuant to section 44 of the Act and the PPC, with Council's agreement, decided that no further action was to be taken on foot of the withdrawal.

² This figure includes 13 complaints received prior to 2015 and referred to the Preliminary Proceedings Committee in 2015

³ Some complaints related to more than one category but for the purpose of this table the primary category of complaint is recorded.

⁴ Complaints are classified as "*Multiple Issues*" in circumstances where complainants list more than one issue in their complaint form

Observations

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

Locum Staff

The PPC has noticed that where locum staff are working in pharmacies on a temporary basis, it is vital for the pharmacy to have well drafted and tailored Standard Operating Procedures in place regarding the safe operation of the pharmacy to assist the locum pharmacist in providing seamless and consistent care to patients. Locum pharmacists should be provided with concise information relevant to their role.

Legibility of Prescriptions

The PPC noted issues arising for pharmacists due to handwritten prescriptions and would again like to highlight this issue for both pharmacists and other medical professionals. In order for pharmacists to carry out their duties properly, they must be confident they are dispensing the appropriate medication and dosage in accordance with the prescription. In circumstances where there is any doubt, pharmacists should carry out additional checks, for example, ringing the prescribing doctor to clarify any uncertainty contained in the prescription⁵.

Patient Information

The PPC noted a number of complaints included references to patient information leaflets not being furnished with their medications. The PPC suggest that pharmacists should ensure that patient information leaflets are provided with the medication. Additional patient information leaflets can be printed from the Health Products Regulatory Authority's website. If a patient information leaflet is not available for a particular medicine, pharmacists should take extra time to ensure that they have provided all relevant information to the patient to enable the safe use of the product and answer any questions that they may have.

Variability in Generic Medicines

The PPC noted that pharmacists should be vigilant when they are supplying generic medicines as variability in the packaging, and tablet size and colour, of generic medicines can be confusing for patients. Pharmacists should discuss the generic medicine being supplied with the patient to ensure that they are familiar with the product and what a generic medicine is, as well as the correct use of the medicine.

⁵ The PSI and the Medical Council have convened a joint working group to examine issues of joint concern regarding safe prescribing and dispensing of medicines and in the course of exploring topics identified, the issue of legibility of prescriptions will be considered by the group.

Dispensing Errors

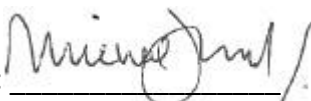
A number of complaints in 2015 related to dispensing errors. The PPC noted the importance of making sure that suitable remedial actions are put in place in a pharmacy where a dispensing error takes place to minimise the risk of an error of this nature occurring again.

Pharmacists should be extra vigilant in making sure that the dosage instructions on the dispensing label reflect the information on the prescription. This highlights the need for pharmacists to exercise particular caution when dealing with medicines which have a narrow therapeutic index. The PPC would like to emphasise the importance of having robust checking procedures in place in relation to the supply of all prescription medicines.

The PPC noted also the importance of good inventory management and suitable storage arrangements in minimising the risk of dispensing errors occurring especially where there can be confusion between different strengths of a particular medication and where medicines have similar packaging or similar sounding names.

Conclusion

This Annual Report covers the sixth 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).”