

**THE PHARMACEUTICAL SOCIETY OF
IRELAND**

**ANNUAL REPORT OF THE PRELIMINARY
PROCEEDINGS COMMITTEE 2012**



AN RIALTÓIR CÓGÁISÍOCHTA
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 third annual report covering the calendar year 2012.

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 10 meetings of the committee during the year. The committee also participated in a training session together with the Council of the Pharmaceutical Society of Ireland in May 2012. During the period 49 new complaints under Part 6 of the Act were considered by the PPC.

This Annual Report is prepared in order to outline the work of the PPC and to highlight to the Council of the Pharmaceutical Society of Ireland any comments and observations that the PPC may have. It is also the intention of this report to educate the public and the profession alike on the role and the learnings of the PPC arising from the performance of its statutory functions.

On behalf of the PPC, I would like to acknowledge the recent death of Mr Dominic Dowling who sadly passed away in January 2013. Dominic was the trusted and valued legal advisor to the PPC since its conception under the Pharmacy Act 2007, and through his careful legal guidance assisted the committee in considering the various complaints before the PPC over the last three years. I would like to extend our deepest sympathies to Dominic’s family on his passing. Dominic’s brilliant legal mind and witty humour will be greatly missed by all on the PPC and I’m sure by all of those who had the privilege of knowing him.

I would like to reiterate my appreciation to the PPC members for their continued effort, diligence and commitment shown in dealing with complaints. In particular, on behalf of the PPC, I would like to thank former PPC member Ms Catriona Griffin, for her contribution to the PPC during her tenure and wish her the best in her future endeavours. I also wish to formally welcome new PPC member Ms Elaine Quinlan who was appointed to the PPC in 2012 and welcome back Ms Noreen Keane who was re-appointed to the PPC in 2012.

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.

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 2012 to 31st December 2012. The purpose of this report is to provide the Council of the PSI, together with members of the profession and the public, with information as regards the day to day running of the PPC and other matters relating to the discharge of its functions. It is also used as the mechanism to report any observations made by the committee over the course of the performance of its statutory functions during 2012.

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 consists of 16 members with a non-pharmacist majority appointed to represent the public interest.

Sections 38 and 40 of the Act set out the functions and powers of the PPC. Please see Appendix A which sets out 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 Cooke

Dr Martin J Duffy (Alternate Chairperson)

Ms Caitriona Griffin (resigned 25 October 2012)

Ms Elaine Quinlan (appointed 25 October 2012)

Ms Noreen Keane (re-appointed 31 January 2012)

Mr Michael McGrail (Chairperson)

Mr James O'Connor

Ms Anne-Marie Taylor

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

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 process 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 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 2012 to 31st December 2012

In 2012 the PPC held 10 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 49 complaints in 2012¹ and the categories of complaints considered are set out below. Note that some complaints may relate to a number of categories but for the purposes of this table the primary category of complaint is recorded.

Categories of Complaints

<u>Categories of Complaints</u>	<u>Total</u>
Behaviour/professionalism issue	9
Codeine – refusal to supply	3
Codeine – failure to comply with PSI guidance	0
Commercial/Advertising/Employment issue	9
Contravention of Section 63/64	0
Dispensing error	13
Failure to comply with medicines and pharmacy legislation	5
Complaints made following inspection by PSI	6
Short supply of medication	2
Supply of medication no prescription	2
Convicted of a criminal offence	0
Health Impairment	0
Supplying out of date medication	0

Grand Total

49

Decisions of PPC

• Sufficient Cause to take further action	13
• Not Sufficient Cause to take further action	33
• Complaint withdrawn under section 44 of the Act	3

In relation to the 33 complaints where the PPC decided to advise the Council that there was not sufficient cause to take further action, the Council too decided that there was not sufficient cause to warrant further action in relation to all of the complaints respectively.

Of the 13 complaints, where the PPC decided that there was sufficient cause to warrant further action, all were referred to the Professional Conduct Committee for inquiry. For the avoidance of any doubt no complaints were referred to the Health Committee in 2012 and no complaints were referred to mediation in 2012.

¹ Please note this figure includes 20 complaints received in 2011 and referred to the Preliminary Proceedings Committee in 2012.

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:

Ciara McGoldrick LL.B, FCA, BL (Head of Unit)

Siobhan Shanahan B.Corp. Law, LL.B (Solicitor)

Bernie Chamberlaine (Administrator)

Independent Legal Advice

In 2012, independent legal advice was provided to the PPC by Mr Dominic Dowling, Solicitor. *Ar dheis Dé go raibh a anam.*

Paediatric Dispensing Errors

In 2012, the PPC considered 13 complaints involving dispensing errors, 5 of which concerned dispensing errors made during the dispensing of prescriptions for children. The PPC notes that this emerging trend was considered by the Practice of Pharmacy Development Committee (“the PPD Committee”) and welcomes the fact that the PSI in its November/December 2012 Pharmacist E-Newsletter took account of these statistics and issued advice to the profession addressing the issue. The PPC is assured that the learnings observed from the fitness to practise process provided for under Part 6 of the Act are being communicated to the profession at large which in turn maintains and improves the standards in the profession.

2011 Annual Report

The PPC in its 2011 annual report made two particular observations in relation to issues that arose during the consideration of complaints during that year and respectfully suggested in that report that the Council might consider referring them to the PPD Committee for review: The 2 observations were as follows: -

- (i) That dosage instruction for liquid measures should be documented in both words and figures. *Give 2.5ml (half a 5ml spoonful)* is recommended over *Give 2.5ml*. The decimal should always be checked since it may not be clear on the label leading to a risk of a tenfold or other significant overdose. This level of overdose may lead to serious adverse consequences.
- (ii) 12 out of the 61 complaints (almost 20%) considered by the PPC in 2011, related to issues surrounding the refusal of the supply of codeine. The PPC observed that for the most part the complaints did not arise from the actual refusal of the product but related to how the patient felt they were treated when the codeine product was requested and refused and the manner in which the refusal was communicated to the patient.

The Council noted the two observations made by the PPC and both were referred by the Council to the PPD Committee for review. The PPC is pleased to note that following consideration of the matter by the PPD Committee, the PSI in its October 2012 Pharmacist E-Newsletter, Superintendent and Supervising pharmacists were specifically informed of these 2 observations and requested to review any relevant policies or procedures in the pharmacies under their control to see if any improvements in practices or in patient care need to be made.

Further as regards dosage instructions for liquid medicines, the newsletter advised, that given liquid formulations are more commonly prescribed and dispensed for infants and children, who are often at greater risk of harmful consequences of over-dosage, the need for clear and legible labels is critical, along with clear and practical counselling for parents or carers administering medicines to children.

The newsletter also pointed out, in terms of managing codeine consultations that robust local complaint handling procedures should be in place in a pharmacy so that complaints which may be amenable to local resolution are resolved at the pharmacy level and these procedures should provide for complaints to be escalated to the supervising and/or superintendent pharmacist where necessary. Pharmacists are increasingly engaging in more complex consultations with patients and should therefore reflect on their existing individual confidence and competence in dealing with patient consultations, particularly in relation to what they feel may be challenging scenarios.


The PPC saw a marked reduction in complaints involving codeine before them in 2012. Approximately 22% of complaints considered by the PPC in 2011 involved either a refusal to supply codeine or a failure to adhere to PSI issued codeine guidance. In 2012, only 6% of all complaints considered by the PPC related to the refusal to the supply of codeine. The committee did not consider any complaints relating to non-compliance with PSI issued codeine guidance.

Intermediate Level Below "Sufficient Cause"

In 33 of the 49 complaints considered by the PPC during 2012, there was not "sufficient cause to warrant further action". This occurred in circumstances where in most cases the complainant clearly felt they had a genuine grievance. The PPC respectfully suggests that the Council might give consideration, where it deems it appropriate to do so, to exploring the possibility of engaging with the complainant in a more meaningful way after the decision has been made that there is not sufficient cause to warrant further action in relation to the complaint whilst at the same time endeavouring to ensure that the respondent pharmacist / pharmacy owner / profession "learns" from the complaint experience. The Act does not permit the PPC to behave in such a way in relation to a complaint.

Conclusion

This Annual Report covers the third 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 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).”