

THE PHARMACEUTICAL SOCIETY OF IRELAND

ANNUAL REPORT OF THE PRELIMINARY PROCEEDINGS COMMITTEE 2011



PSI

THE PHARMACEUTICAL
SOCIETY OF IRELAND

Cumann Cógaisearí na hÉireann

THE PHARMACY REGULATOR

Foreword

The Preliminary Proceedings Committee (established under the Pharmacy Act 2007 and hereinafter called the “PPC”) is pleased to present its second annual report covering the calendar year 2011. The committee was appointed on 29th September 2009 and 2011 was its second full year of operation. 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 “RPBs”) and where appropriate to refer complaints for mediation or for inquiry by either the Health Committee or the Professional Conduct Committee.

There were 8 meetings of the committee during the year. The committee also participated in a training meeting together with the Council of the Pharmaceutical Society of Ireland. During the period 61 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.

On a personal note I would sincerely like to thank the effort, diligence and commitment shown by members of the PPC in dealing with the various complaints that are put before each PPC meeting. 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.

Finally, on behalf of the PPC, I would like to express our appreciation of the work of the PSI Secretariat and staff for their assistance throughout the year and I would also like to express sincere thanks to the PPC’s legal advisor, Dominic Dowling, for his assistance.

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 2011 to 31st December 2011. The purpose of this report is to provide the Council of the PSI with information with regard to the day to day running of the PPC and other matters relating to the discharge of its functions.

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 (appointed 11 May 2011)

Mr Harry Cooke

Mr Stephen Driver (resigned 29 November 2011)

Dr Martin J Duffy (Alternate Chairperson)

Ms Caitriona Griffin

Ms Noreen Keane (until 10 May 2011) (appointed to Health Committee 11 May 2011)

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 Gary Smyth, MPSI (until 10 May 2011) (appointed to Professional Conduct Committee 11 May 2011)

Mr Eoghan Hanly MPSI, (11 May 2011 to 29 September 2011)

Mr Keith O'Hourihane, MPSI (appointed 29 September 2011)

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 RPBs. 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 2011 to 31st December 2011

In 2011 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 RPBs. The PPC considered a total of 61 complaints in 2011¹ 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

Total

Behaviour/professionalism issue	10
Codeine – refusal to supply	12
Codeine – failure to comply with PSI guidance	2
Commercial/Advertising/Employment issue	9
Contravention of Section 63/64	2
Dispensing error	9
Failure to comply with medicines and pharmacy legislation	7
Complaints made following inspection by PSI	4
Short supply of medication	1
Supply of medication no prescription	2
Convicted of a criminal offence	1
Health Impairment	1
Supplying out of date medication	1

Grand Total

61

Decisions of PPC

• Sufficient Cause to take further action	18
• Not Sufficient Cause to take further action	40
• Complaint withdrawn under section 44 of the Act	1
• Consideration of complaint deferred	<u>2</u>
	61

¹ Please note this figure includes 15 complaints received in 2010 and referred to the Preliminary Proceedings Committee in 2011.

In relation to the 18 complaints where the PPC decided that there was sufficient cause to take further action Council overturned one of those decisions and decided that there was not sufficient cause to warrant further action in respect of that complaint in light of the revised advertising guidance.

Of the remaining 17 complaints:

- | | |
|--|----|
| - Referred to Professional Conduct Committee for inquiry | 16 |
| - Referred to the Health Committee for inquiry | 1 |

In relation to the 40 complaints where the PPC decided that there was not sufficient cause to warrant further action, the Council decided to take further action in two cases and these were then referred by the PPC to the Professional Conduct Committee for inquiry.

In total 19 complaints were referred to a Committee for Inquiry in 2011:

- | | |
|--|----|
| - Referred to Professional Conduct Committee for inquiry | 18 |
| - Referred to the Health Committee for inquiry | 1 |

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 LLB, FCA, BL (Head of Unit)

Siobhan Shanahan B.Corp. Law, LLB (Solicitor) (from 12 April 2011)

Brendan Curran BCL (Solicitor) (5 July 2010 to 15 April 2011)

Bernie Chamberlaine (Administrator)

Independent Legal Advice

Independent legal advice is provided to the PPC by Dominic Dowling, Solicitor.

Observations

1. The PPC has the following observations in relation to issues that arose during their consideration of complaints and respectfully suggest that the Council might consider referring them to the Practice of Pharmacy Development Committee for review:

- (i) **Dosage instructions for liquid Medicines**

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) **Codeine**

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.

2. Intermediate Level Below "Sufficient Cause"

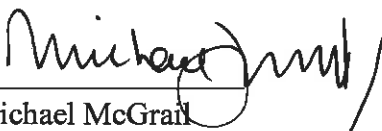
In 39² of the 61 complaints considered by the PPC during 2011, there was not "sufficient cause to warrant further action". This occurred in circumstances where in most cases the complainant clearly felt they had a genuine grievance. The PPC are of the view that the Council might, in such circumstances, explore the possibility of engaging in a more meaningful way with the complainant 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.

² Please see detailed breakdown of decisions made by the PPC and the Council of the PSI on pages 6 and 7 of this report

Conclusion

This Annual Report covers the second 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).”