

THE PHARMACEUTICAL SOCIETY OF IRELAND

**ANNUAL REPORT OF THE PRELIMINARY PROCEEDINGS
COMMITTEE 2013**



AN RIALTÓIR CÓGAIŚÍOCHTA
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 fourth annual report covering the calendar year 2013.

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 8 meetings of the committee during the year 2013. During this period, 49 new complaints under Part 6 of the Act were considered by the PPC. This was the same number of complaints considered by the PPC in 2012. The committee also participated in a training session together with the Council of the PSI in September 2013.

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 inform the public and the profession on the learnings arising from the performance of the committee’s 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 James O’Connor, for his contribution to the PPC during his tenure and wish him the best in his future endeavours.

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 also like to express sincere thanks to the PPC’s legal advisor in 2013, Ms Jeanne Kelly, for her valued 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 2013 to 31st December 2013. 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 recommendations for important learning for the 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 16 members with a non-pharmacist majority appointed to represent the public interest up to September 2013. Following Mr James O'Connor's departure from the Committee in September 2013 the PPC's membership has consisted of 15 members, a non-pharmacist majority remains.

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*¹

Ms Margaret Barry

Mr Harry Cooke*

Dr Martin J Duffy* (Alternate Chairperson)

Ms Elaine Quinlan

Ms Noreen Keane

Mr Michael McGrail* (Chairperson)

Mr James O'Connor (resigned 26 September 2013)

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

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 2013, independent legal advice was provided to the PPC by Ms Jeanne Kelly, Solicitor.

¹ The PPC members identified above with an accompanying asterisk* were re-appointed to the PPC in November 2013 for a term expiring in October 2015.

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 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 2013 to 31st December 2013

In 2013 the PPC held 8 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 2013². It was noted that the complaints could be categorised as set out below. Note that 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	12
Dispensing Error	10
Commercial/Advertising/Employment issue	5
Restricted from Practising Pharmacy in another Jurisdiction	2
Refusal to supply medicinal products containing Pseudoephedrine and Paracetamol / refusal to supply medicinal product containing Codeine	3
Pricing	2
Generic Substitution	2
Complaints made following inspection by the PSI for failures to comply with medicines and pharmacy legislation	2
Prescription Levy	4
Pharmacy providing Influenza Vaccination Service	1
“Short supply” in quantity of medication	1
Supply of unlicensed medication	3
Health Impairment	1
Supplying out of date medication	1

Total

49

² Please note this figure includes 18 complaints received in 2012 and referred to the Preliminary Proceedings Committee in 2013.

Decisions of PPC

Of the 49 cases considered the following are the decisions of the committee.

- | | |
|---|----|
| • Sufficient Cause to take further action | 10 |
| • Not Sufficient Cause to take further action | 35 |
| • Complaint withdrawn under section 44 of the Act | 4 |

In relation to the 35 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 the complaints.

Of the 10 complaints, where the PPC decided that there was sufficient cause to warrant further action, 8 were referred to the Professional Conduct Committee for inquiry. 1 complaint was referred to the Health Committee and 1 complaint was referred to Mediation.

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.

Dispensing Errors

In 2013, the PPC considered 10 complaints relating to dispensing errors. The PPC acknowledges that while unfortunately dispensing errors do occur, it is important that the risk of errors occurring is minimised.

The following are observations from complaints on dispensing errors considered by the PPC. The PPC believes that these issues should be highlighted to the profession and may be of assistance to the Council in the on-going development of guidance in this area to help improve practice, patient safety and mitigate the risk of a similar incident occurring again.

- The committee has noted with concern that a number of dispensing errors involved medication being dispensed from the Patient Medication Record (PMR) on the computer as opposed to the original prescription. The committee noted that filling prescriptions from the PMR often compounds a dispensing error made on the first dispensing.
- The committee has noted that errors occurred when an appropriate label was prepared but the wrong medication was selected. This highlights the importance of ensuring that the pharmacist carries out a final check between the label, the medicinal product and the

prescription and that a second member of staff should be involved in the dispensing procedure where at all possible. It also highlights the need for good organisation and risk management to be used in the pharmacy dispensary.

- The committee has noted that the supply of a different medication to that prescribed due to the prescribed medication being out of stock can give rise to a dispensing error if the pharmacist fails to take account of the dosage adjustment required as a result of the change i.e. medicinal product *prescribed* at a dose of 50mg twice daily, medicinal product *supplied* at a dose of 100mg twice daily.
- The committee has noted the occurrence of Patient Returned Medications being dispensed to a different patient. This highlights the importance of clearly segregating patient returned medication until they can be destroyed.
- The committee has noted the occurrence of date expired medicines being supplied to patients. Expiry dates of medicines and medical devices should be checked as part of the dispensing process. Systems and procedures should also be in place in the pharmacy to ensure the expiry date of stock is checked when it comes in from the wholesaler and there is a system for stock rotation and date checking all stock on a regular basis.
- The committee has noted the occurrence of dispensing errors where the pharmacist has supplied the incorrect strength and/or provided incorrect dosage instructions in circumstances where the directions on the prescription were unclear. If a pharmacist is unclear about the directions of a prescriber, the pharmacist must clarify the prescription with the prescriber.
- It was also noted that appropriate handling of an error once discovered is very important to patient safety and satisfaction. The committee would like to recommend the development of guidance to advise pharmacists of the appropriate patient safety considerations to take into account and the procedure to follow if a dispensing error is reported to them.

Paediatric Dispensing Errors

In 2012, the PPC considered 11 complaints involving dispensing errors, 5 of which concerned errors made during the dispensing of medication for children.

As outlined in the 2012 Annual Report the PPC welcomed the fact that the PSI in its November/December 2012 E-Newsletter took account of these statistics and issued advice to the profession addressing the matter. The PPC also notes that the PSI in its March 2013 E-Newsletter highlighted the risk of paediatric paracetamol overdose and issued guidance to Pharmacists on the steps that should be taken to minimise the potential for these errors.

In 2013 none of the dispensing errors considered by the PPC concerned medication for children. Notwithstanding this the PPC continues to be concerned by the potential for errors

occurring when dispensing prescriptions for infants and children. The PPC would respectfully suggest that the Council continue to issue guidance regularly to the profession reminding them to remain extra vigilant in the dispensing of paediatric medicinal products by ensuring that the appropriate product and correct dosage is supplied and that the parent/carer has been adequately counselled on the safe and appropriate use and storage of the product.

Methotrexate

The PPC is concerned by the potential for errors occurring in the supply of methotrexate. Medication errors arising from the prescribing, dispensing or the use of methotrexate can result in significant adverse effects which have the potential to cause serious harm to patients. Pharmacists play a vital role in ensuring the safe supply and use of methotrexate, through their participation in the risk management, safe dispensing of the medication, and in the educating, counselling and monitoring of patients.

The PPC notes that Guidance for Pharmacists on Safe Supply of Oral Methotrexate was issued in June 2012 and respectfully suggests that the Council consider issuing a reminder to pharmacists about this guidance and the actions that should be taken in a Pharmacy when a dispensing error in relation to Methotrexate is discovered.

Communication Issues

The PPC notes that complaints capable of being resolved at local level may have been so resolved if appropriate complaint handling policies and procedures were in place. The PPC observed poor communication may have contributed to these matters escalating to formal complaints. The PPC noted patients complained of being aggrieved in the following situations:

- The manner in which information was communicated to a patient by the Pharmacist / or member of staff.
- Conversations being conducted in the public area of the pharmacy.
- Patients expressed concern that confidential health matters could be overheard by other persons.
- The inability of the Pharmacy to provide information when requested.
- Telephone call not being returned when indicated it would be.

In light of these observations, the Council may wish to consider issuing guidance to superintendent and supervising pharmacists to review any relevant policies or procedures in the pharmacies under their control to see if any improvements in practices or in patient care can be made to address these concerns. In particular the guidance might address whether the competence and training requirements of pharmacists and other staff in dealing with in-pharmacy patient complaints needs to be addressed. Finally the Council may wish to

consider highlighting to the profession again the importance of the patient consultation area and that it is being utilised to facilitate patients and the pharmacist in their required counselling of the patient as regards their medication.

Codeine Observations

2011: 22% of complaints considered by the PPC involved either a refusal to supply codeine or a failure to adhere to PSI issued codeine guidance.

2012: 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.

2013: 4% 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.

Miscellaneous Observations

The PPC also observed that the following miscellaneous matters gave rise to complaints in 2013: -

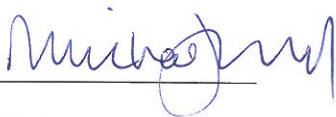
- Inconsistent pricing of medication supplied against a private prescription.
- 28 tablets being supplied on foot of a prescription where 30 tablets were prescribed.
- A generic medicine dispensed against a prescription for a branded product without consulting the patient.

Intermediate Level Below "Sufficient Cause"

In 35 of the 49 complaints considered by the PPC during 2013, there was not “sufficient cause to warrant further action”. In a number of these cases the PPC felt that whilst it was not appropriate to refer the complaint for mediation or a full inquiry there was still learning that could be acquired from the complaint and highlighted to the registrant, pharmacy owner or profession to improve practice and patient safety. The Act does not provide that the PPC may communicate such learnings to the individual pharmacist or pharmacy owner who is subject to the complaint.

Conclusion

This Annual Report covers the fourth 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).”