



THE PHARMACEUTICAL SOCIETY OF IRELAND

ANNUAL REPORT OF THE PRELIMINARY PROCEEDINGS COMMITTEE 2018

Foreword

The Preliminary Proceedings Committee (the “**PPC**”), established under the Pharmacy Act 2007 (the “**Act**”) is pleased to present its ninth annual report covering the calendar year of 2018.

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 before either the Health Committee or the Professional Conduct Committee.

There were eight meetings of the PPC during 2018. Over this period, 42 complaints were considered by the PPC compared to 57 complaints in 2017.

The PPC took part in three training sessions on 12 April, 30 April and 25 September 2018. These sessions included training on conscious and unconscious bias in decision-making, the new data protection and GDPR legislation and other topics relevant to the powers under Part 6 of the Act.

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 2018. 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 thank former PPC members who retired during the year, including the Chairperson Mr Michael McGrail and the two Acting Chairs Ms Anne-Marie Taylor and Ms Oonagh O’Hagan, who served on the Committee for nine years. Their commitment and dedication was crucial to the effective running of the Committee over that period.

I would also like to thank a number of other long serving members who retired during 2018 including Ms Geraldine Hetherton, Ms Margaret Barry, Ms Noreen Keane and Ms Elaine Quinlan, for their valued contribution to the PPC during their tenure.

Signed: 

Shane McCarthy

Chairperson of the Preliminary Proceedings Committee

Introduction

This report is prepared and approved by the PPC and covers the period 1 January 2018 to 31 December 2018. 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 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 2018

Non-Pharmacists

Ms Margaret Barry (completed term in May 2018)

Mr Hugo Bonar (Council representative) (commenced term in April 2018)

Mr James Bridgeman (commenced term in October 2018)

Ms Molly Buckley

Mr Richard Hammond (Acting Chairperson)

Ms Noreen Keane (completed term in January 2018)

Ms Jill Long (Acting Chairperson)

Ms Cindy J Mackie (commenced term in October 2018)

Mr John Murray (commenced term in March 2018)

Mr Shane McCarthy (Chairperson) (Council representative)

Mr Michael McGrail (Chairperson) (completed term in October 2018)

Ms Elaine Quinlan (completed term in October 2018)

Ms Anne-Marie Taylor (alternate Chairperson) (completed term in October 2018)

Pharmacists

Mr Andrew Barber MPSI

Mr Joseph Fahy MPSI

Ms Breda Heneghan MPSI (commenced term in October 2018)

Ms Geraldine Hetherington MPSI (completed term in October 2018)

Mr John Hillery MPSI

Mr Garvan Lynch MPSI

Ms Oonagh O'Hagan MPSI (alternate Chairperson) (completed term in 2018)

Ms Áine Shine MPSI (commenced term in October 2018)

Executive of the PSI

The PPC is supported in its work by the Executive made up of trained PSI employees.

Legal Advisor to the PPC

In 2018, independent legal advice was provided to the PPC by McDowell Purcell Solicitors (now known as Fieldfisher).

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 act in a considered and expeditious manner whilst ensuring its actions are 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.

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. For the purposes of this Annual Report, the PPC are only reporting the complaints where they made a final decision as to whether further action was required.

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. Refer the complaint for mediation subject to the consent of the complainant and the pharmacist(s) and / or pharmacy 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 the advice of the PPC in relation to the complaint 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 and the complaint concludes.

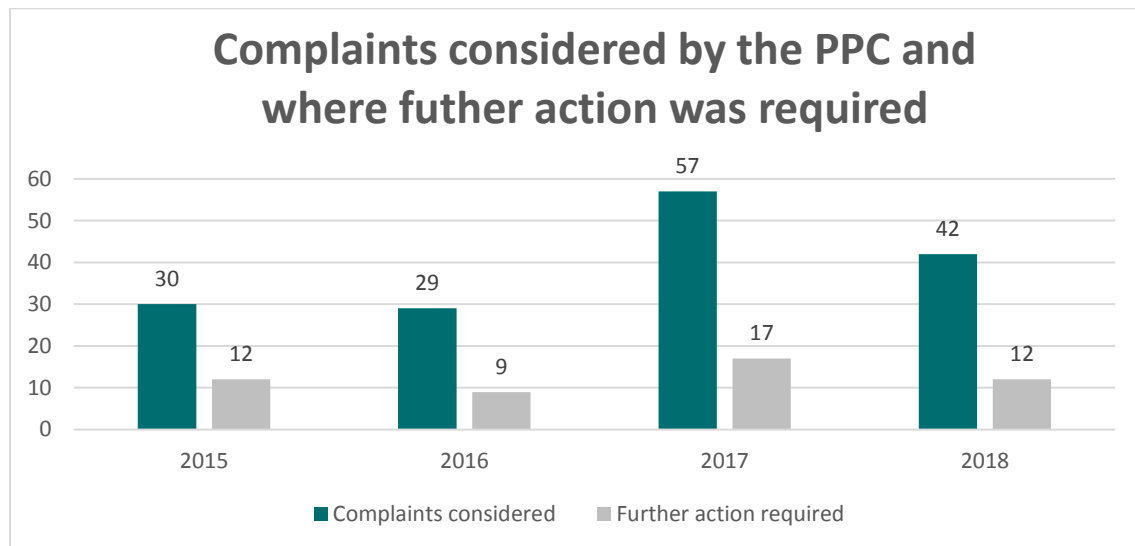
Where a complaint is made against two or more respondents, and the PPC has decided that there is a case for further action against one or more of the respondents but no case for further action against others, the Council will review the decisions in respect of which the PPC has decided there is no case for further action only.

Activities from 1 January 2018 to 31 December 2018

In 2018 the PPC held eight meetings to consider complaints by members of the public, pharmacists, other healthcare professionals and organisations and the Registrar of the PSI against registered pharmacists and pharmacies.

The PPC considered a total of 42 complaints in 2018². The chart at Figure 1 shows the number of complaints considered by the PPC since 2015 and the number of complaints where there was sufficient cause for further action being taken:

Figure 1.

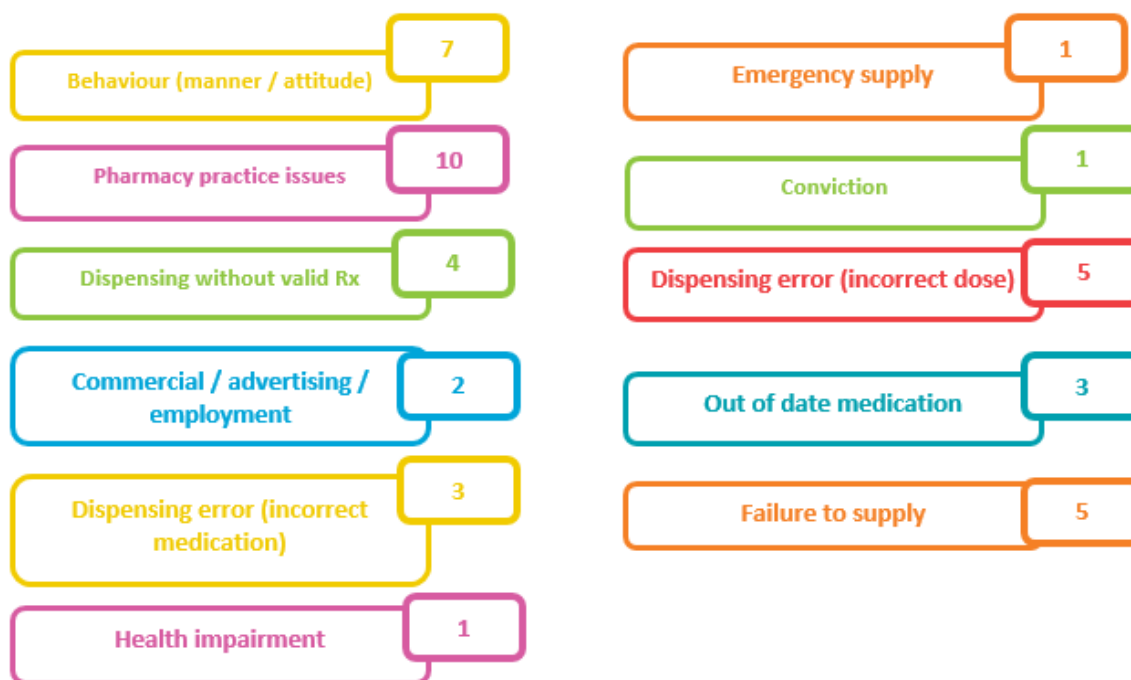


² Of the 42 complaints, 13 were received prior to 2018

Categories of Complaints Considered in 2018

The complaints are broadly categorised in the table at Figure 2 below:

Figure 2.



Timeframe

Of the 42 complaints considered, 86% were dealt with within six months.

Decisions of the PPC

The following is a summary of the PPC's decisions in relation to the 42 complaints considered:

• **Further Action**

The PPC sent 12 complaints forward for further action. Of these:

- Ten complaints were referred to the Professional Conduct Committee for inquiry;
- One complaint was referred to the Health Committee for inquiry; and
- One complaint was referred for resolution by mediation.

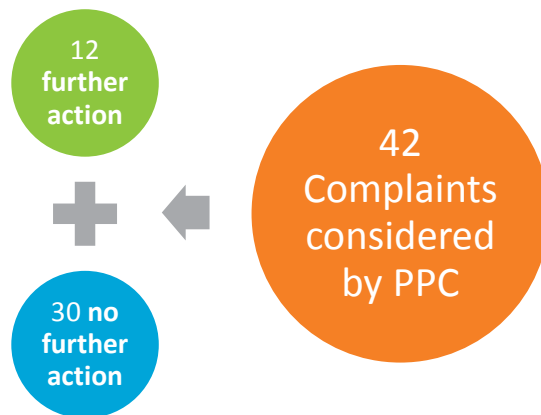
• **No Further Action**

The PPC advised the Council that 30 complaints did not warrant further action. The Council agreed with the advice of the PPC in relation to all of these complaints.

- **Withdrawal of Complaint**

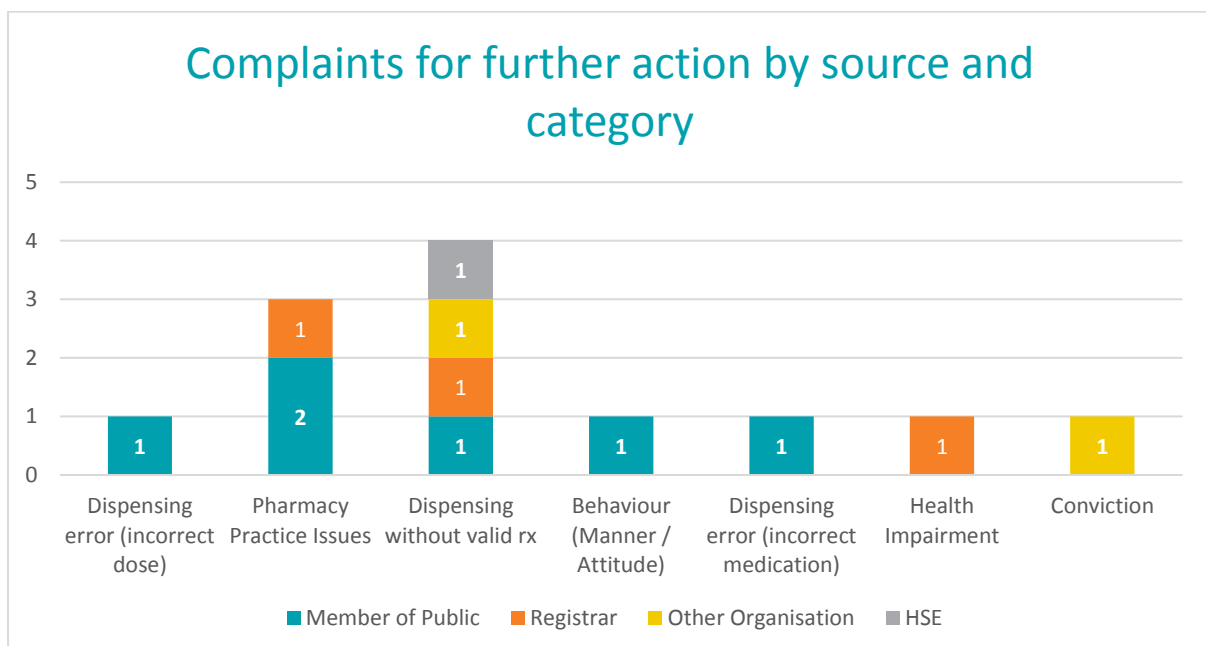
Three of the 42 complaints were withdrawn by complainants pursuant to Section 44 of the Act. The PPC decided, with Council’s agreement, to take no further action in relation to all of these complaints.

Figure 3.



The chart at Figure 4 below illustrates the category and volume of complaints with sufficient cause for further action including the source of that complaint.

Figure 4.



Observations

During the course of the PPC's work in 2018 the committee noted a number of issues being raised as part of the complaints made to the PSI. The PPC would like to highlight the following:

1. Dispensing Errors

The complaints relating to dispensing errors can be categorised broadly into three main categories:

- **Incorrect Strength of the Correct Medication**

A number of the dispensing errors complained of related to the incorrect strength of the correct medication being supplied. This type of error can lead to either an under-dose or overdose of medication, which can potentially put patient safety at risk. Particular care should be given to the storage location of different strengths of the same medicinal product to avoid potential confusion.

- **Incorrect Medication**

Some of the dispensing errors related to incorrect medication being supplied. It is important to ensure that assembly areas are clean and clutter-free to avoid potential errors.

- **Incorrect Labelling**

In some cases the medication supplied to a patient was labelled with incorrect details. Pharmacists should be extra vigilant in making sure that the details on the dispensing label reflect the information on the prescription. This is particularly important with regard to dosage instructions.

2. The Importance of Checking Procedures

The PPC would like to emphasise the importance of having thorough and robust checking procedures in place in relation to the supply of all prescriptions. In particular, the PPC would like to highlight the need for a double-check system to be carried out by the pharmacist and another member of the pharmacy team, where possible.

When checking a prescription (particularly in situations where the pharmacist did not personally enter the prescription into the Patient Medication Record), pharmacists should refer back to the patient history at the point of checking in order to complete the therapeutic review. The final check should involve reviewing the original prescription, against the label and against the product. If the pharmacist is working on their own, they should ensure that they have a mental break between the assembly and labelling of the medicinal products and doing the final check, to reduce the risk of errors.

3. Non Prescription Medicines

The PPC noted a number of complaints considered in 2018 related to the refusal to supply pharmacy only medicines such as Solpadeine, Nurofen Plus or cough bottles. Patients raised complaints with regard to the manner in which they say they were dealt with at the pharmacy.

Members of the public should be aware that pharmacists are expected to use their professional judgement when deciding whether a supply of a non-prescription medicinal product is in the best interests of the patient. If a medicinal product is deemed to be unsafe or inappropriate for a patient, the supply should not be made.

However, it is important that pharmacists communicate the reasons for their decision not to supply the medicines clearly and respectfully to the patient and relevant advice should be provided which includes referring the patient to another healthcare professional or service as appropriate.

Conclusion

This Annual Report covers the ninth 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: 

Shane McCarthy

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).”