



**THE PHARMACEUTICAL SOCIETY OF IRELAND**

**ANNUAL REPORT OF THE PRELIMINARY PROCEEDINGS COMMITTEE 2017**

## Foreword

The Preliminary Proceedings Committee (the “**PPC**”), established under the Pharmacy Act 2007 (the “**Act**”) is pleased to present its eighth annual report covering the calendar year of 2017.

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 2017. Over this period, 57 complaints were considered by the PPC compared to 29 complaints in 2016.


The PPC took part in three training sessions on 23 February, 9 May and 18 May 2017. During such training the PPC considered issues which arise during decision-making, learnings from regulatory complaint processes and the application of the new PSI Mediation Guidelines.

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 2017. 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.

The PPC would also welcome a review of the current legislative framework in which it considers complaints. The PPC would be pleased to consider all potential options in order to enhance the complaints process, which could include further powers being provided to it. The PPC are of the view that such a review would assist in improving the complaints process and in dealing with the range of complaints it considers in an appropriate manner.

On behalf of the PPC, I would like to thank former PPC members who retired during the year, Ms Maeve Barry, Mr Liam Farmer MPSI, Ms Anne Murphy MPSI and Ms Aoife O’Rourke MPSI for their valued contribution to the PPC during their tenure.

As I retire as chair of the PPC this year, I would like to thank the Council for their support of the PPC over the past nine years. I would like to express my appreciation to the current and previous PPC members for their efforts, diligence and commitment in dealing with the complaints at each meeting. Their work continues to be characterised by professionalism and social responsibility allied to a strong sense of collegiality and trust between PPC members. I would like to thank both alternate chairs, Ms Anne-Marie Taylor and Ms Oonagh O'Hagan for the numerous times they took over as chair of the PPC. I express the PPC's continued thanks to the Executive of the PSI for their commitment, excellence and professional administrative assistance throughout the year. If I may, and also on behalf of the PPC, I would like to personally thank Ms Bernie Chamberlaine for her support to myself and the PPC throughout the past nine years. Her unhurried, thoughtful and calm efficiency was and is a continuing asset for the PPC.

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 2017 to 31 December 2017. 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 2017

### Non-Pharmacists

Ms Maeve Barry (completed term in October 2017)

Ms Margaret Barry

Ms Molly Buckley (appointed March 2017)

Mr Richard Hammond (appointed March 2017)

Ms Noreen Keane

Ms Jill Long (appointed December 2017)

Mr Shane McCarthy (Council representative)

Mr Michael McGrail (Chairperson)

Ms Elaine Quinlan

Ms Anne-Marie Taylor (alternate Chairperson)

### Pharmacists:

Mr Andrew Barber, MPSI

Mr Joseph Fahy, MPSI (appointed September 2017)

Mr Liam Farmer, MPSI (completed term in October 2017)

Ms Geraldine Hetheron, MPSI

Mr John Hillery, MPSI (appointed June 2017)

Mr Garvan Lynch, MPSI (appointed June 2017)

Ms Anne Murphy, MPSI (completed term in September 2017)

Ms Oonagh O’Hagan, MPSI (alternate Chairperson)

Ms Aoife O’Rourke, MPSI (completed term in October 2017)

### **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 2017, 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 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 Complaint<sup>1</sup>**

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.

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<sup>1</sup> 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.

### **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.

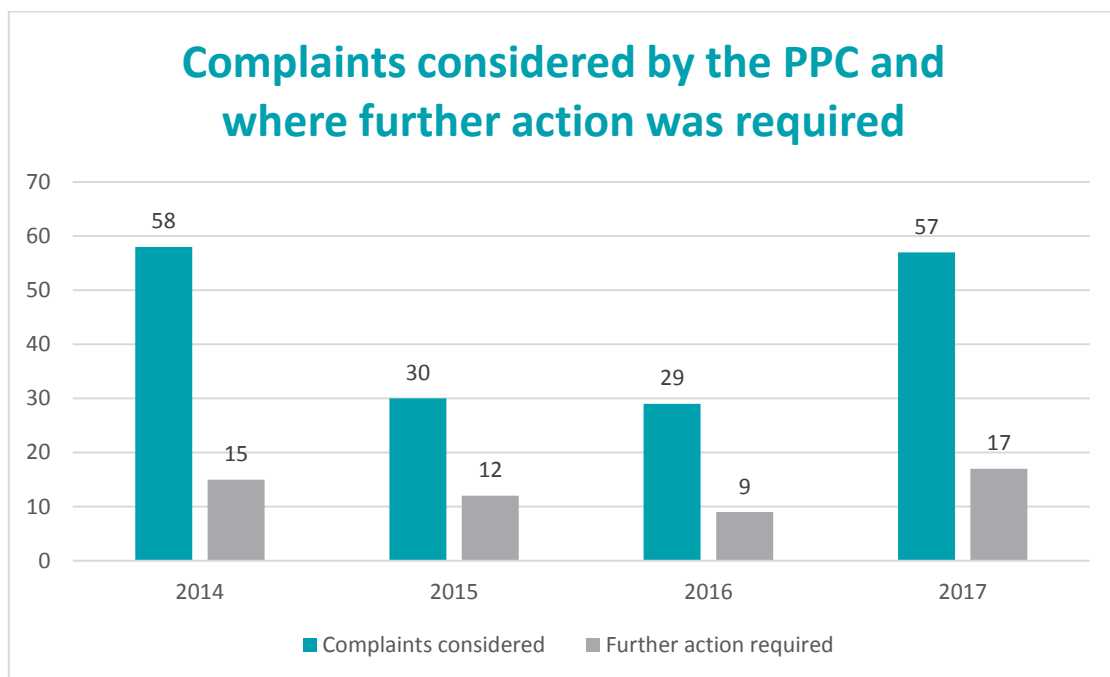
Where a complaint is made against two or more respondents, and the PPC has decided that there is a case for further action against one or more of the respondents but no case for further action against others, the Council will review the decisions in respect of which the PPC has decided there is no case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

### Activities from 1 January 2017 to 31 December 2017

In 2017 the PPC held eight meetings to consider complaints by members of the public, pharmacists, other healthcare professionals and the Registrar of the PSI against registered pharmacists and pharmacies.

The PPC considered a total of 57 complaints in 2017<sup>2</sup>. The chart at Figure 1 shows the number of complaints considered by the PPC since 2014 and the number of complaints where there was sufficient cause for further action being taken:

**Figure 1.**

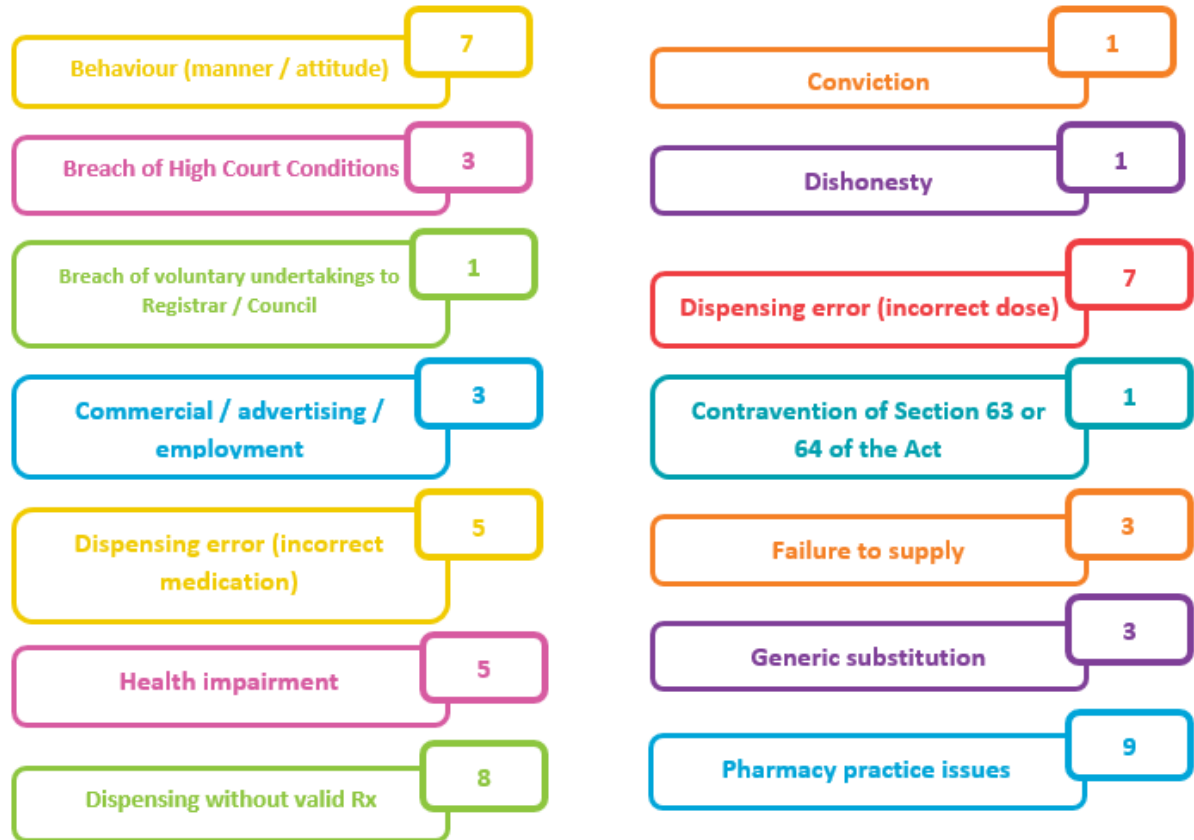


<sup>2</sup> Of the 57 complaints considered in 2017, 24 were received by the PSI in 2016 and referred to the PPC in 2017.

### Categories of Complaints Considered in 2017<sup>3</sup>

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

**Figure 2.**



### Timeframe

Of the complaints considered, 89% were dealt with within six months and almost half of these were dealt with within three months of being received by the PSI.

### Decisions of the PPC

The following is a summary of the PPC's decisions in relation to the 57 complaints considered:

- **Further Action**

The PPC sent 17 complaints forward for further action. Of these:

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

<sup>3</sup> Categories were revised in 2017 in order to provide greater insight into the types of complaints received. Therefore, the categories for a number of the complaints received in 2016 have been adjusted to reflect the new categories for 2017.



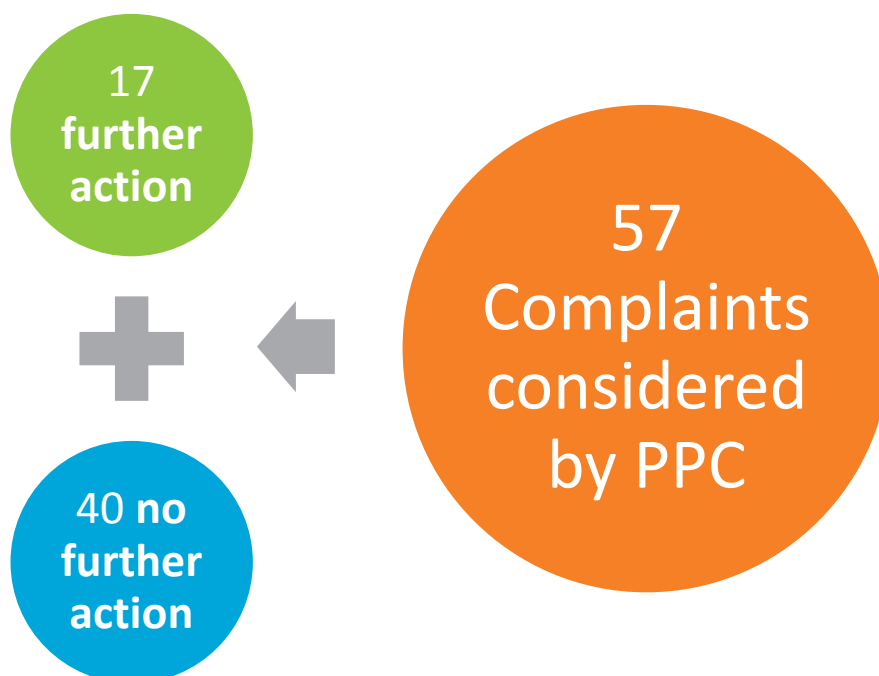
- **No Further Action**

The PPC advised the Council that 40 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 57 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 two complaints and to proceed as if the complaint had not been withdrawn in relation to one complaint<sup>4</sup>.

**Figure 3.**

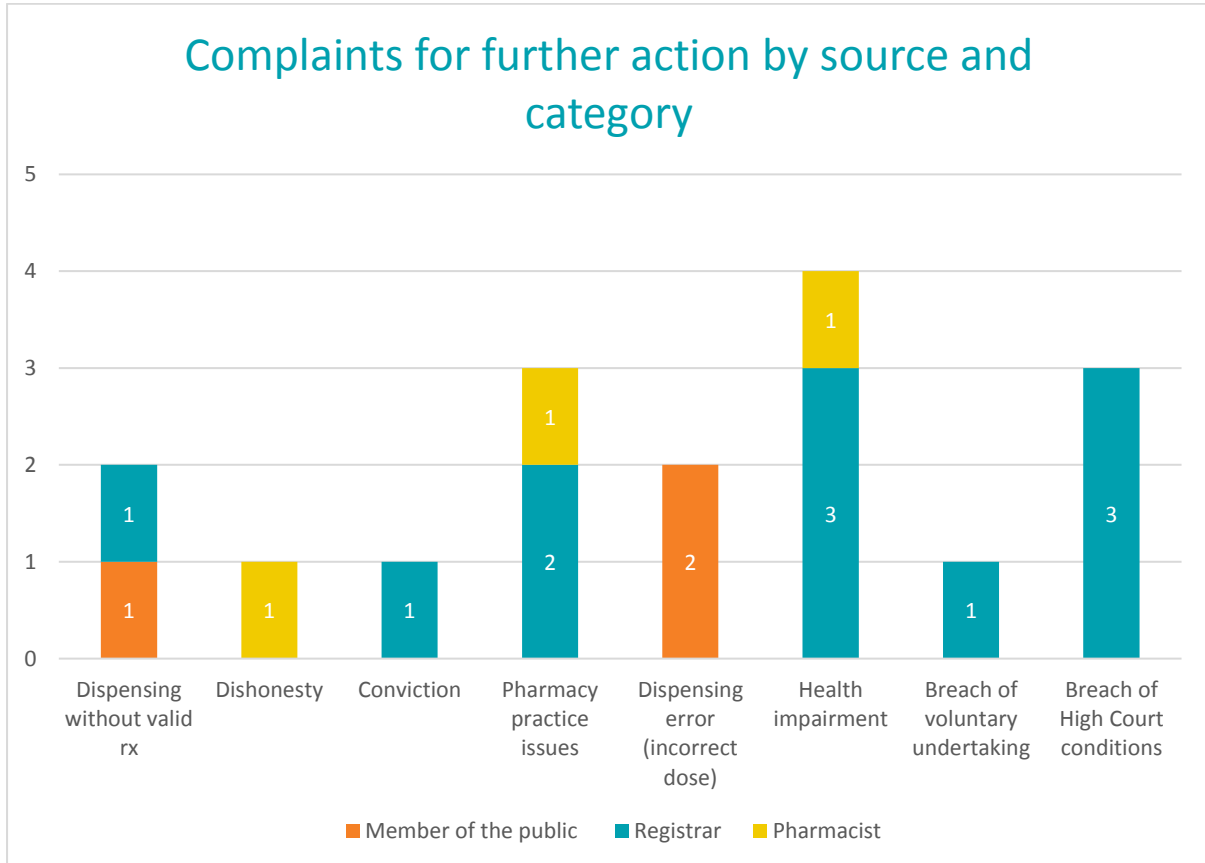


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<sup>4</sup> This complaint was considered by the PPC under Section 38 in 2018.

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 the committee noted a number of issues being raised as part of the complaints made to the PSI. Issues the PPC would like to highlight are listed below:

### **1. Dispensing of Non-Prescription Medicinal Products containing Codeine**

A number of complaints considered by the PPC relate to a patient's request for a non-prescription medicinal product containing codeine and the interaction with the pharmacist that follows. The PPC recognises the legislative and professional obligations on a pharmacist to ensure the supply of such medicines is safe and appropriate, as outlined in the [PSI's Guidance on the Safe Supply to Patients of Non-Prescription Medicinal Products containing Codeine](#). The PPC is of the view that the ability of a pharmacist to be able to exercise his or her professional judgment in such a situation is of paramount importance. However, the PPC would also like to highlight the importance of clear and sensitive communication with the patient as to the restrictions surrounding such medicines and that ultimately, any decision made by a pharmacist in relation to its supply is with the patient's best interests in mind. It is felt that clearer communication may assist in such interactions with the public.

### **2. Dispensing without a valid Prescription**

The PPC noted that a number of complaints related to the supply of prescription-only medicines without a valid prescription. Pharmacists are reminded to be vigilant in ensuring that the original prescription is physically present in the pharmacy and that this prescription is reviewed by the pharmacist, before a medicine is supplied, in order to have regard to the therapeutic and pharmaceutical appropriateness of the medicine therapy for the patient. The pharmacist must also ensure the prescription is within date. Ultimately, the above controls are to protect patient safety and enhance the continuity of care for the patient between the pharmacist and practitioner.

### **3. Monitored Dosage Systems**

The PPC would like to highlight the prevalence of issues arising in relation to the monitoring dosage systems ("MDS"). A standard operating procedure ("SOP") is an important way to review the operation of MDS within the pharmacy, establish better practices and minimise the risk for patients. The PPC would also like to emphasise the importance of training for staff in the preparation of the MDS.

### **4. Support for Locum Pharmacists**

The PPC would like to emphasise the importance of ensuring that sufficient support is provided to locum pharmacists in a pharmacy. The PPC appreciate that the pharmacy is a busy and demanding environment. Therefore, in order to assist with the efficient operation of a pharmacy, adequate time to review the pharmacies SOPs should be afforded to a locum pharmacist. Staff members of the pharmacy should be notified in the event a locum pharmacist is on duty, in order to assist with any queries the locum pharmacist may have.

## 5. Communication

The PPC has noticed that a number of complaints made during 2017 often contain poor communication issues. Where an issue arises, meaningful and clear communication between a pharmacist and a patient can often assist in resolving the issue before it escalates to a formal complaint to the PSI. The communication issues that have been raised include; failing to discuss discreetly a patient's medical care in the pharmacy and failing to provide clear information where the supply of a non-prescription medicinal products is refused. Pharmacists should consider their practice and whether it affords clear communication with patients. Where necessary, pharmacists could utilise the patient consultation area to afford more privacy to a patient where a detailed discussion regarding their care is required.

## Conclusion

This Annual Report covers the eighth 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).”*