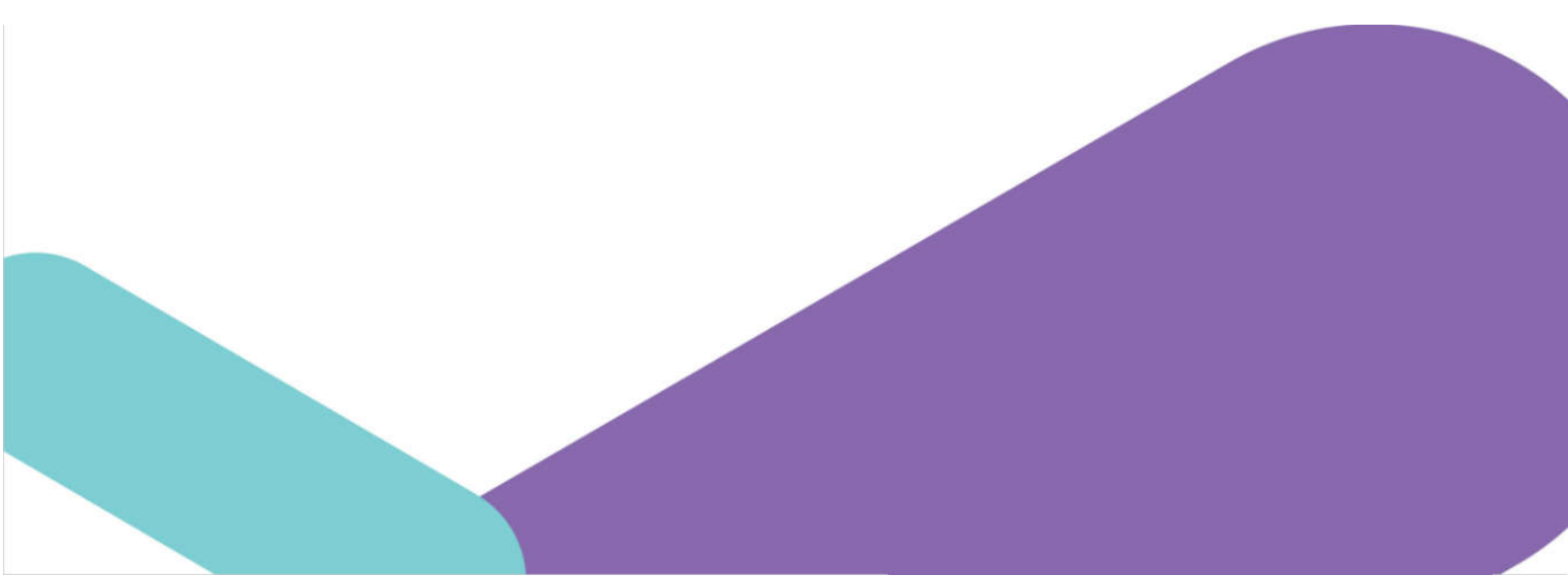




Annual Report of the Preliminary Proceedings Committee 2019



Foreword

The Preliminary Proceedings Committee (the “**PPC**”), established under the Pharmacy Act 2007 (the “**Act**”) is pleased to present its tenth annual report covering the calendar year of 2019.

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 Professional Conduct Committee or Health Committee.

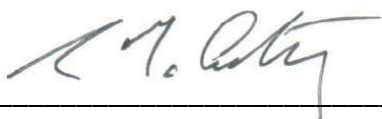
There were eight meetings of the PPC during 2019. Over this period, 74 complaints were considered by the PPC compared to 42 complaints in 2018.

The PPC took part in training on 27 June 2019. This session included training on right touch regulation, the grounds for judicial review, the principles of natural justice, rationale and reasons for decisions, governance matters, conflicts of interest, bias and the importance of collective decision making, and other topics relevant to the powers under Part 6 of the Act.

This Annual Report outlines the work of the PPC and highlights 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 2019. 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.

Finally, I would like to thank Mr Joseph Fahy MPSI, who resigned as a Committee member during the year, for his valued contribution to the PPC during his tenure.

Signed: _____



Dr Shane McCarthy

Chairperson of the Preliminary Proceedings Committee

Introduction

This report is prepared and approved by the PPC and covers the period 1 January 2019 to 31 December 2019. The purpose of this report is to provide to the Council of the PSI, together with members of the profession and the public, 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 pharmacy practice in Ireland.

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, 40 and 44 of the Act set out the salient functions and powers of the PPC in relation to the hearing of complaints. Please see Appendix A which sets out the applicable sections of the Act.

Membership and Composition of the PPC during 2019

Non-Pharmacists

Mr Hugo Bonar (Council representative)

Mr James Bridgeman SC

Ms Molly Buckley

Mr Richard Hammond (Deputy Chairperson)

Ms Jill Long (Deputy Chairperson)

Ms Cindy J Mackie

Mr John Murray

Dr Shane McCarthy (Chairperson) (Council representative)

Pharmacists

Mr Andrew Barber MPSI

Mr Joseph Fahy MPSI (resigned in April 2019)

Mr Derek Fehily MPSI (commenced term in December 2019)

Ms Breda Heneghan MPSI

Mr John Hillery MPSI

Mr Garvan Lynch MPSI

Ms Fiona Rowland MPSI (commenced term in April 2019)

Ms Áine Shine MPSI

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 2019, independent legal advice was provided to the PPC by Fieldfisher Ireland.

Role of the PPC

The PSI is the statutory regulator for pharmacists and pharmacies in Ireland 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 of the PSI 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, amongst other matters, 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. Once the PPC is satisfied that it has sufficient information to consider a complaint it will decide whether:

- (a) There is sufficient cause to warrant further action; or
- (b) There is not sufficient cause to warrant further action.

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 In considering complaints the PPC must do so in accordance with the provisions of the Act which sets out the actions it is authorised to take. For the purposes of this Annual Report, only complaints in which a final decision was given by the PPC in 2019 are reported on.

1. Refer the complaint for mediation, if appropriate and 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 following a complaint against a respondent the following steps will be taken:

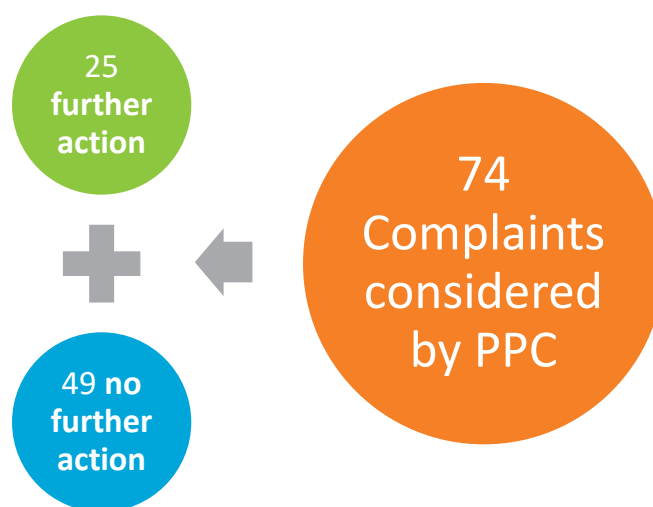
1. The PPC refers the complaint and the advice of the PPC in relation to the complaint to the Council;
2. The Council will consider the advice of the PPC;
3. If the Council disagree with the PPC's advice and decide to take further action in relation to a complaint, the matter is referred back to PPC 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.

Activities from 1 January 2019 to 31 December 2019

In 2019 the PPC held eight meetings to consider complaints made by members of the public, pharmacists, other healthcare professionals, other organisations and the Registrar of the PSI against registered pharmacists and pharmacies. The PPC considered a total of 74 complaints in 2019².

Decisions of the PPC

The following is a summary of the PPC's decisions in relation to the 74 complaints considered:



Further Action

The PPC sent 25 complaints forward for further action. Of these:

- Sixteen complaints were referred to the Professional Conduct Committee for inquiry;
- Four complaints were referred to the Health Committee for inquiry; and
- Five complaints were referred for resolution by mediation.

Of the five complaints that were referred to mediation, the complainant did not consent to this process in three of these cases and accordingly these cases were referred to a Committee of Inquiry.

No Further Action

The PPC advised the Council that 49 complaints did not warrant further action. The Council agreed with the advice of the PPC in relation to all of these complaints.

² Of the 74 complaints, 20 were received prior to 2019.

Withdrawal of Complaint

Four of the 74 complaints considered 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 three of these complaints and to proceed as if the complaint had not been withdrawn in relation to one complaint. This complaint was subsequently referred to a Committee of Inquiry.

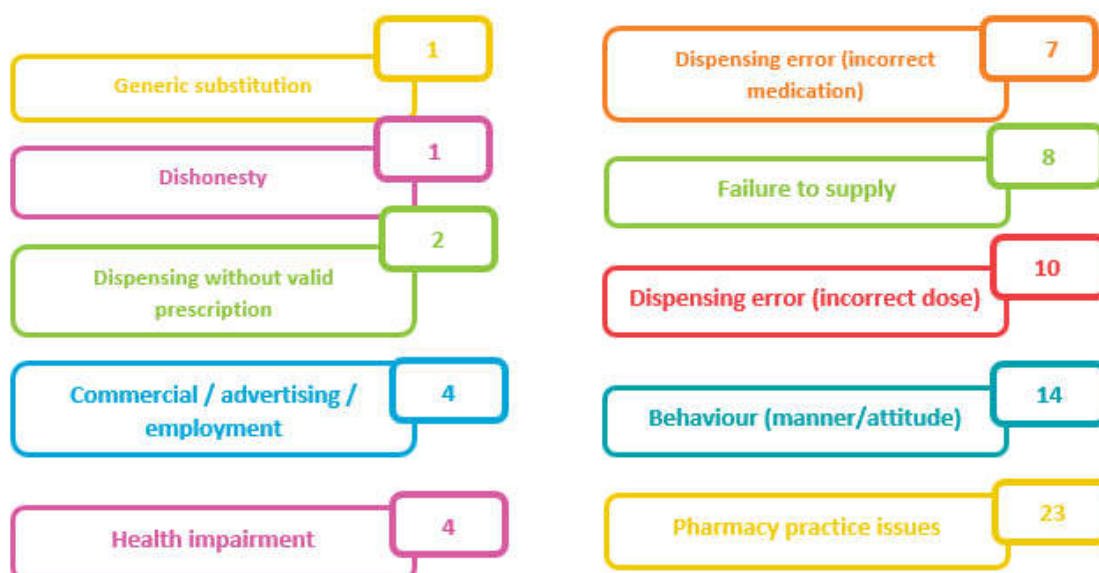
Timeframe

Of the 74 complaints considered by the PPC, 92% were dealt with within six months.

Categories of Complaints Considered in 2019

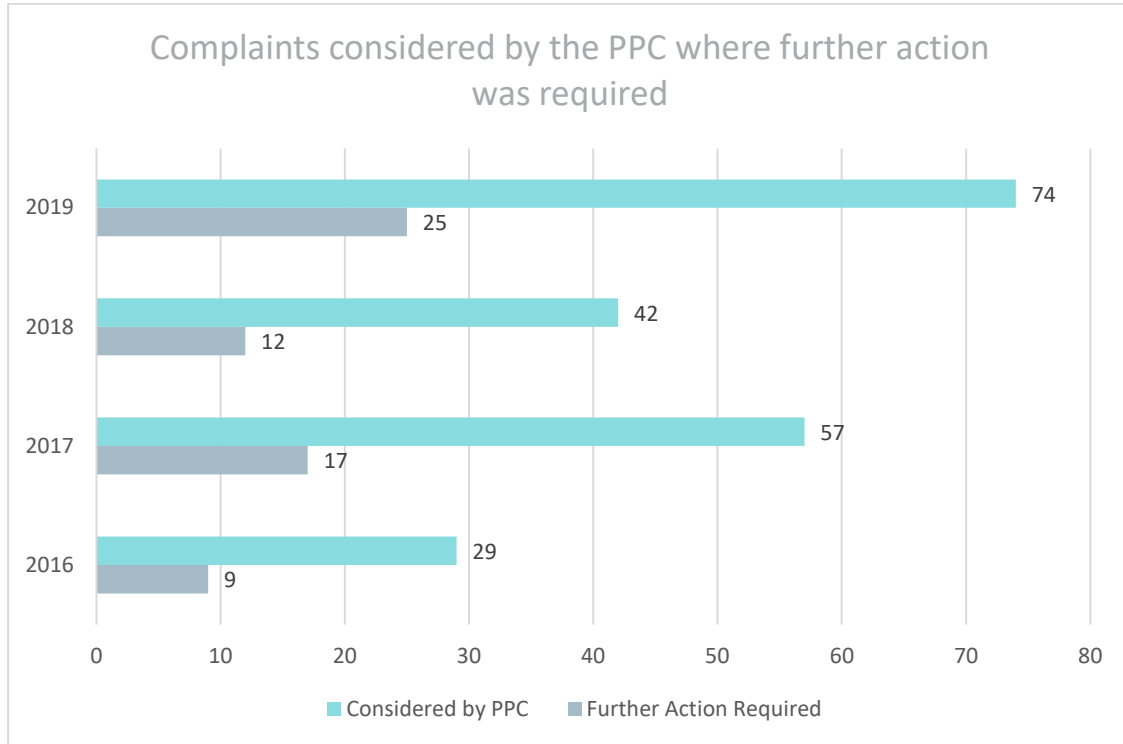
The complaints considered are broadly categorised in the table at Figure 1 below:

Figure 1.



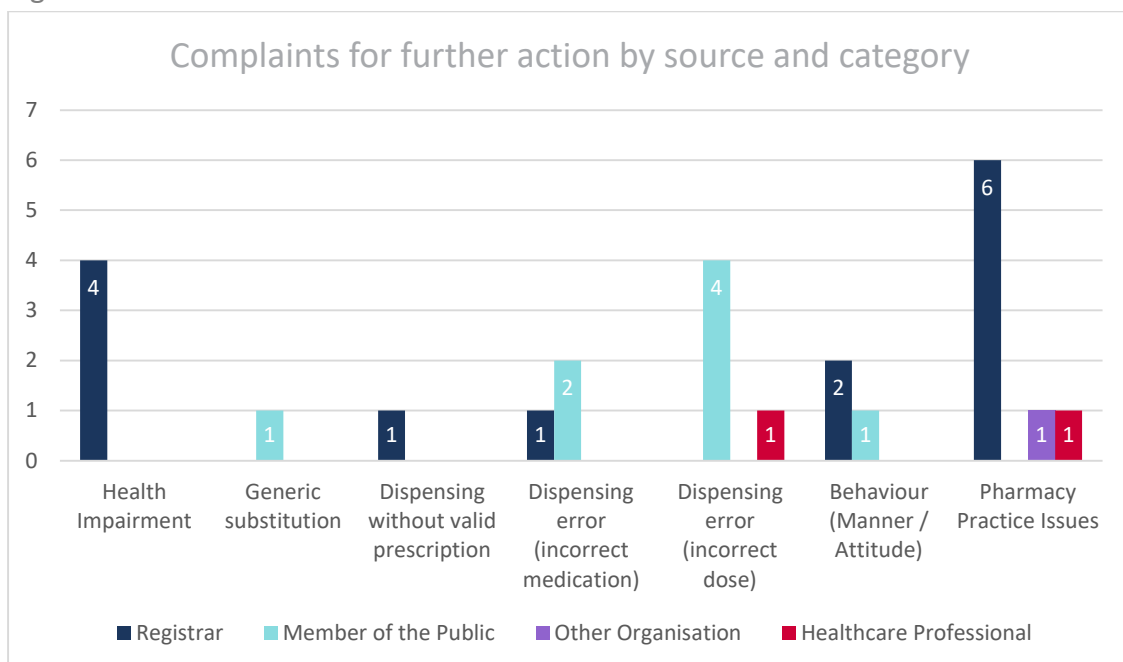
The chart at Figure 2 shows the number of complaints considered by the PPC since 2016 and the number of complaints where there was sufficient cause for further action being taken:

Figure 2.



The chart at Figure 3 below illustrates the category and volume of complaints with sufficient cause for further action including the source of that complaint.

Figure 3.



Observations

During the course of the PPC's work in 2019 the PPC noted a number of issues being raised as part of the complaints made to the PSI. The PPC would like to highlight the following:

Pharmacy practice issues

The majority of complaints considered by the PPC in 2019 related to a variety of pharmacy practice issues including:

- The sale and supply of benzodiazepines;
- Failure to supply the full quantity of medication on the prescription meaning that patients had to return to the pharmacy a number of times to collect their medication. In those instances, the PPC recognised that there may be shortages in some medication from time to time. In such cases, the PPC highlighted the importance of counselling and consulting with patients about those medicines;
- The supply of veterinary medications/animal remedies in the absence of a prescription from a veterinary practitioner;
- Lack of information provided to patients on the safe storage of vaccines.

Dispensing errors

A number of complaints considered related to dispensing errors. The types of errors noted and the PPC's observations set out below are consistent with those noted in previous years:

(a) Incorrect medication

Some of the dispensing errors related to an incorrect medication being supplied due to its visual similarity to an entirely different medication. The PPC considers that particular care should be given to the storage location of different medication with similar packaging known as sound alike, look alike drugs ("SALADS").

(b) Incorrect strength of 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. The PPC considers that particular care should be given to the storage location of different strengths of the same medicinal product to avoid potential confusion.

(c) Incorrect labelling

In some cases, the medication supplied to a patient was labelled with incorrect details or did not contain adequate directions for use. The PPC considers that 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.

(d) Paediatric dispensing errors

Two complaints related to the supply of medication to children. The PPC continues to be concerned by the potential for errors to occur when dispensing prescriptions for infants and children. The PPC have identified the need for ongoing messaging and guidance from the PSI to regularly remind the profession to be extra vigilant in the dispensing of paediatric medicinal products by ensuring that the appropriate product and correct dosage is supplied, directions for use are clear and that the parent/carer has been adequately counselled on the safe and appropriate use and storage of the product. Particular attention should be paid where a calculation has been required to obtain or check the dose. If possible, the calculation should be checked by another appropriately trained member of staff.

The PPC reminds pharmacists of the importance of a thorough and robust checking system to prevent dispensing errors. It recognises the need for a double-check to be carried out by the pharmacist and another member of the pharmacy team, where possible. If a pharmacist is working on their own, he/she 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.

The PPC also noted the importance of following up with the prescriber where a pharmacist is unsure of the details on the prescription or any aspect of the patient's therapy. In particular, where a pharmacist is unclear about the directions of a prescriber, the PPC underscored the need to clarify the prescription with the prescriber before supplying the medicines.

Communications/Counselling

A number of the complaints considered by the PPC in 2019 related to communications or counselling.

- In dealing with vulnerable people, the PPC noted the importance of communicating effectively so that patients receive safe and appropriate care. It recognised the need for a pharmacist to ask relevant questions, listen carefully and respect confidentiality and to communicate in a manner that enables patients to make decisions that are informed and right for them;

- The PPC noted a number of complaints related to the manner in which patients felt they were dealt with by the pharmacist, where they felt they were not being supplied in accordance with their prescription or their requirements. The PPC notes the importance of pharmacists counselling patients on the use of medications and any contraindications to their use each time medication is supplied;
- The PPC noted how a pharmacist's satisfactory and respectful engagement with a patient at the pharmacy level could reduce the likelihood of a formal complaint being made.

Data Protection/GDPR

The PPC noted patients' awareness of the new Data Protection/GDPR rules and patients' concerns regarding privacy such as:

- Conversations being conducted in the public area of the pharmacy and personal details and health information being overheard by other customers;
- Personal details and health information shared with others.

The PPC recognised the need for patients to be treated in a sensitive and courteous way, which respects them, their beliefs and their privacy. The PPC highlighted the importance of being able to speak to a pharmacist in confidence, in a private consultation area and the need for personal records to be kept confidential.

Social media posts

An increase in complaints relating to the material contained in social media posts made by pharmacists was noted. The PPC recognises that social media has become part of daily life for many pharmacists and it can be a powerful way for pharmacists to collaborate with peers and colleagues, as well as patients and the public. The PPC wishes to remind pharmacists of the need to exercise good judgement when using social media and in expressing any personal opinions or views which may conflict with their professional duties and responsibilities.

Increase in complaints relating to Health impairment

The PPC noted an increase in the number of complaints relating to the impairment of a pharmacist's ability to practise due to issues including alcohol or drugs. The PPC wish to emphasise the importance of a pharmacist seeking appropriate assistance and supports where they are experiencing difficult periods in their lives including depression, anxiety or other conditions such as alcohol or drug misuse. The PPC would like to highlight the work of the Practitioner Health Matters Programme. This programme is an independent

organisation that provides support to health practitioners including pharmacists and pharmaceutical assistants in Ireland who may have a concern about a mental health or substance abuse problem.

Details and contact information can be found on the website www.practitionerhealth.ie. The programme can be contacted on a confidential telephone line 01 278 9369 or emails sent to confidential@practitionerhealth.ie for an expert clinical advice service.

Conclusion

This Annual Report covers the tenth 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: _____



Dr 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).”

Section 44 of the Pharmacy Act 2007

“If a complaint is withdrawn, the committee considering it may, with the Council’s agreement—

(a) decide that no further action is to be taken, or

(b) proceed as if the complaint had not been withdrawn.”