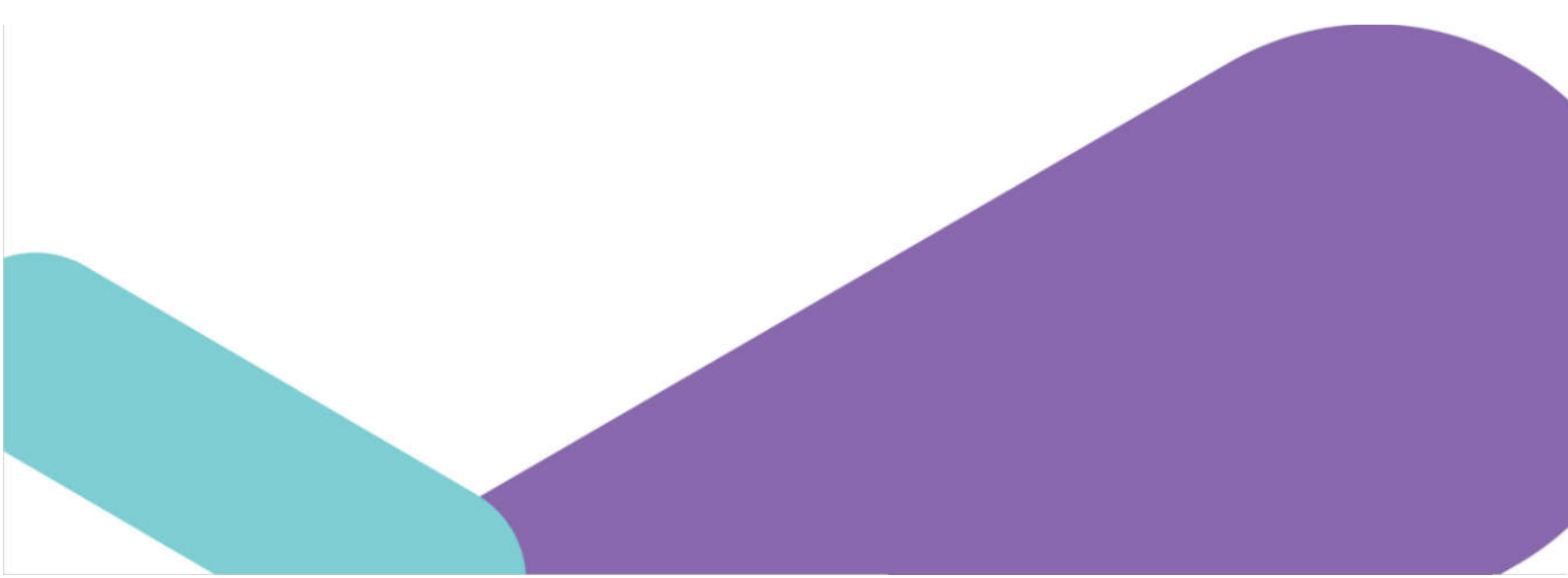




# **Annual Report of the Preliminary Proceedings Committee 2020**



## Foreword

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The Preliminary Proceedings Committee (the “**PPC**”) established under the Pharmacy Act 2007 (the “**Act**”) is pleased to present its eleventh annual report covering the calendar year of 2020.

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 six meetings of the PPC during 2020 in comparison to the typical schedule of eight meetings per annum. This was due to the fact that, following the Government announcement of a public health emergency arising from the Covid-19 pandemic, the PSI was very conscious of the many challenges being faced by pharmacists and pharmacy teams at that time. Therefore, the PSI suspended many of its regulatory activities, which included the processing of complaints between March and May 2020. During this suspension period the PPC did not sit to consider complaints.

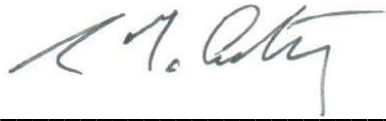
The PSI, along with many other public sector and private sector bodies, were required to redeploy their workforce to a remote working environment and implement technology solutions to allow for continuity of business at PSI staff level, but also that of the work of its Council, Advisory and Disciplinary Committees. Therefore, four of the six meetings held in 2020 were held remotely, with the first fully remote meeting taking place on 25 June 2020.

During 2020, 37 complaints were considered by the PPC compared to 74 complaints in 2019. This decrease is due, in part, to the temporary suspension of the complaints process as referenced above.

An important function of the PPC is to keep its knowledge and information up to date regarding professional regulation and the PPC received training during the course of 2020 in this regard.

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 2020. It also aims to inform the public and the profession on the role and the learnings of the PPC arising from the performance of its statutory functions.

As Chairperson, I would like to commend the PPC for its response in adapting to working in an online environment and I would also like to thank the Executive for its support in this respect.



Signed: \_\_\_\_\_

**Dr Shane McCarthy**

**Chairperson of the Preliminary Proceedings Committee**

## Introduction

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This report is prepared and approved by the PPC and covers the period 1 January 2020 to 31 December 2020. 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 consideration of complaints. Please see Appendix A which sets out the applicable sections of the Act.

### Membership and Composition of the PPC during 2020

#### Non-Pharmacists

Mr Hugo Bonar (Council representative)

Mr James Bridgeman SC

Ms Molly Buckley

Mr Richard Hammond SC (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 Derek Fehily MPSI

Ms Breda Heneghan MPSI

Mr John Hillery MPSI

Mr Garvan Lynch MPSI

Ms Fiona Rowland MPSI

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 2020, 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 Complaint<sup>1</sup>

Before arriving at its advice to the Council on whether there is sufficient cause to warrant further action in relation to a particular complaint, the PPC will consider whether the complaint is trivial, vexatious or made in bad faith.

When considering a complaint, the PPC will also ensure, amongst other matters, that it has sufficient information to process the complaint. 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.

In deciding whether there is sufficient cause for further action, and the complaint relates to a once-off error or failing, the PPC will consider whether it meets the threshold of “seriousness” as set down in the case of ***Corbally v Medical Council & Ors [2015] IESC 9***.

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<sup>1</sup> 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 2020 are reported on.

### 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, 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:

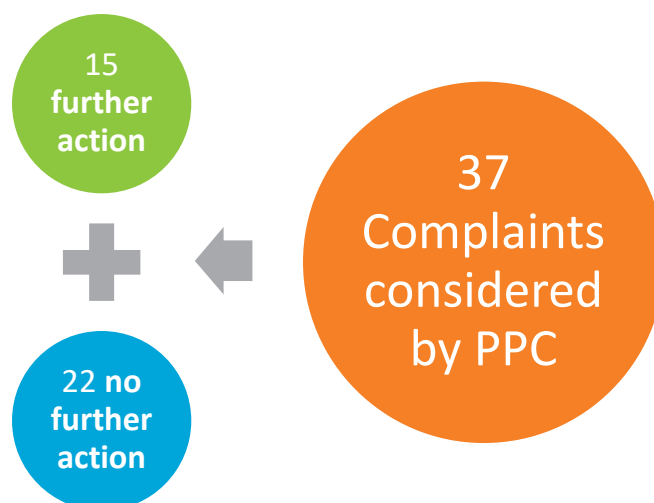
1. The PPC refers the complaint and the advice of the PPC in relation to the complaint to the Council.
2. The Council will consider the advice of the PPC.
3. If the Council disagree with the PPC's advice and decide to take further action in relation to a complaint, the matter is referred again to the PPC who must then refer the complaint 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 2020 to 31 December 2020

In 2020 the PPC held six meetings to consider complaints made by members of the public, pharmacists, other organisations and the Registrar of the PSI against registered pharmacists and pharmacies. The PPC considered a total of 37 complaints in 2020<sup>2</sup>.

## Decisions of the PPC

The following is a summary of the PPC's decisions in relation to the 37 complaints considered:



## Further Action

The PPC sent 15 complaints forward for further action. Of these:

- Thirteen complaints were referred to the Professional Conduct Committee for inquiry.
- Two complaints were referred for resolution by mediation. However, one complainant withdrew consent to mediation, and the other complaint could not be resolved by mediation and ultimately both complaints were referred to the Professional Conduct Committee for inquiry.
- No complaints were referred to the Health Committee for inquiry in 2020.

## No Further Action

The PPC advised the Council that 22 complaints did not warrant further action. The Council agreed with the advice of the PPC in relation to all 22 of these complaints.

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<sup>2</sup> Of the 37 complaints considered, 7 were received prior to 2020.

### Timeframe

Of the 37 complaints considered by the PPC in 2020, 95% were dealt with within six months from date of receipt by PSI, the currently agreed KPI.

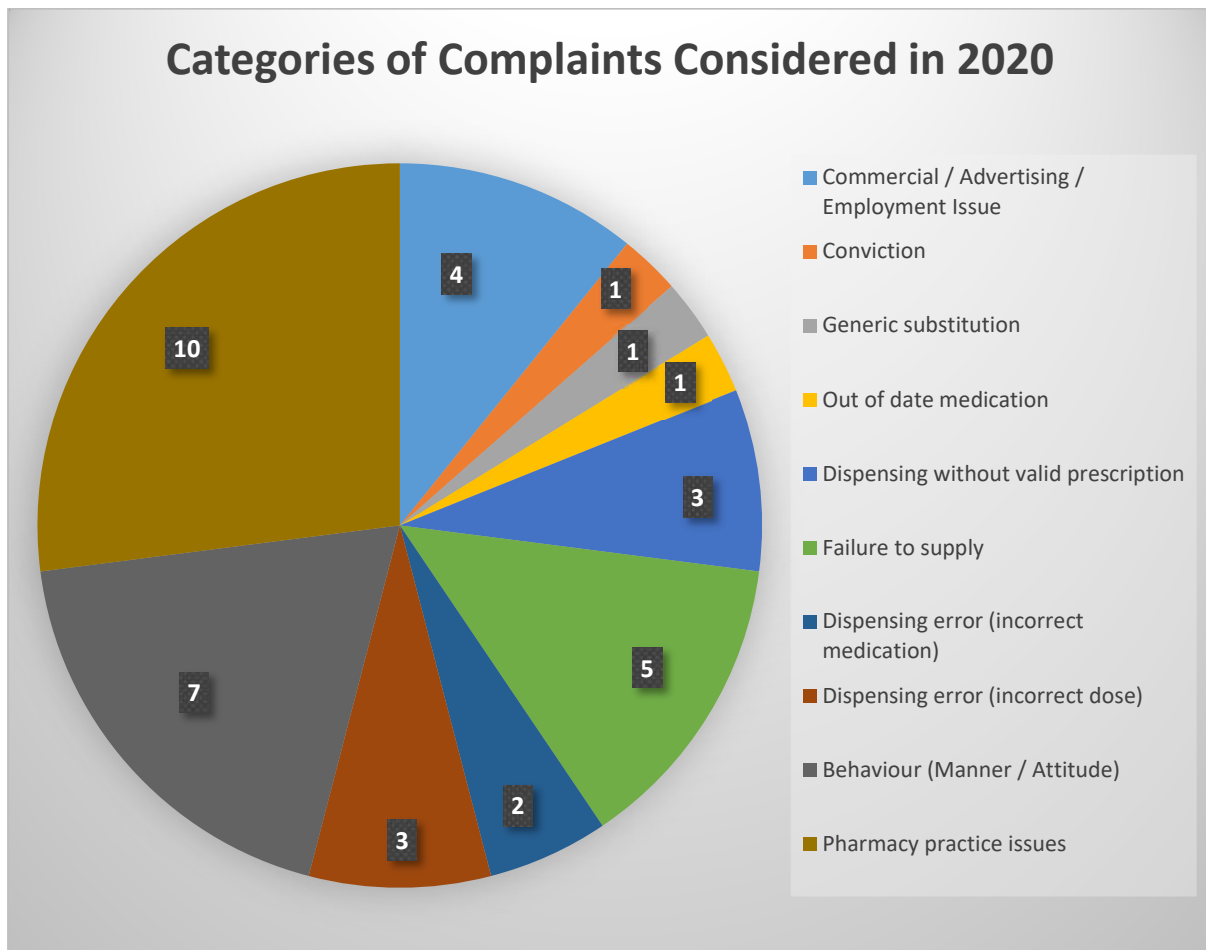
### Withdrawal of Complaint

Nine complaints considered by the PPC 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.

### Categories of Complaints Considered in 2020

The complaints that were considered by the PPC during 2020 are broadly categorised in the table at Figure 1 below:

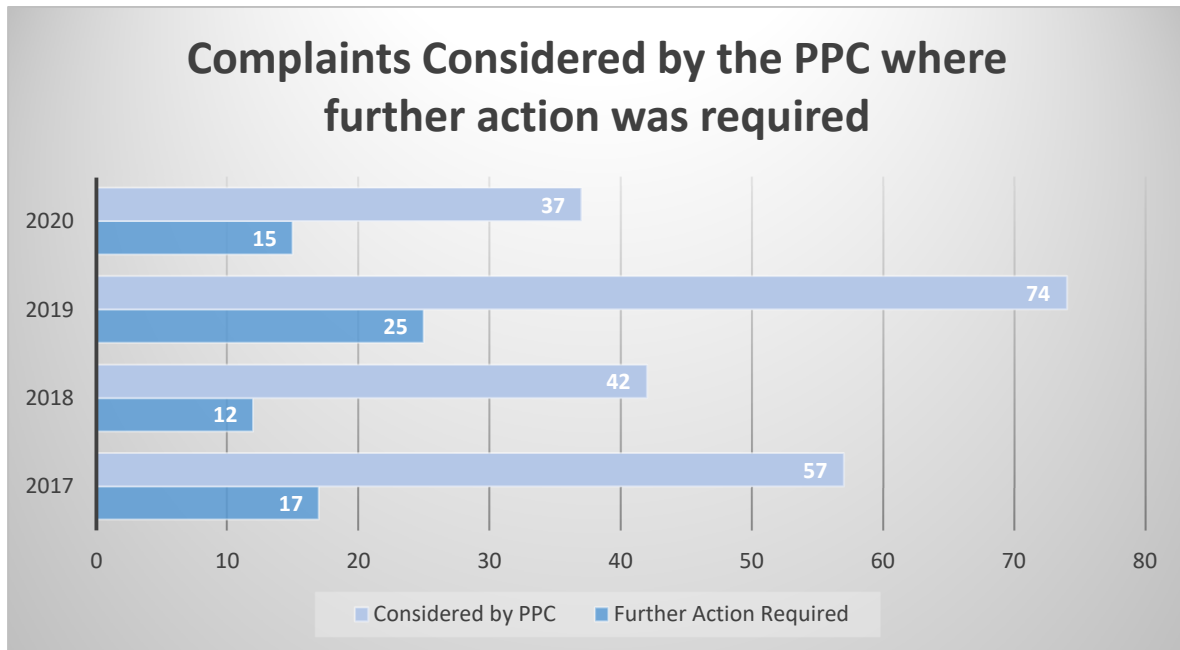
Figure 1.





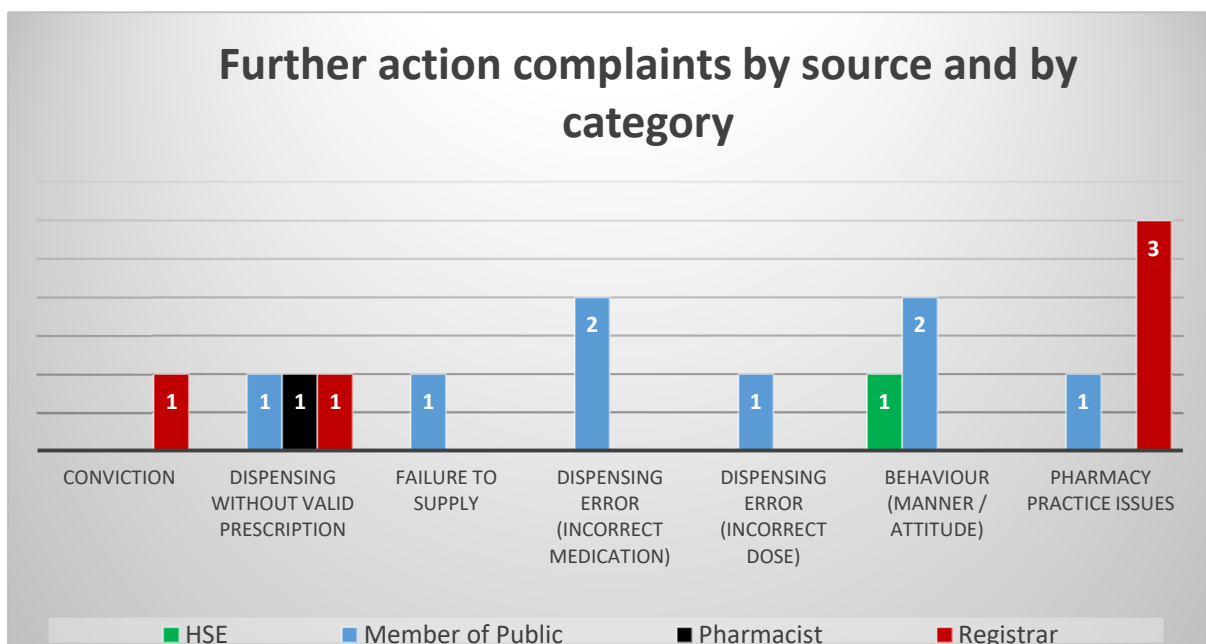
The chart at Figure 2 below shows the number of complaints considered by the PPC since 2017 and the number of these complaints where there was sufficient cause for further action being taken:

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

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During the PPC's work in 2020 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 largest category of complaints (27%) considered by the PPC in 2020 related to pharmacy practice issues including:

- The supply of a non-prescription medicine to a minor.
- The supply of methadone otherwise than in accordance with PSI 'Guidance for Pharmacists on the Safe Supply of Methadone'.
- The supply of a pharmacy-only medicine without a pharmacist on duty in the pharmacy.
- The supply of halved tablets to achieve the correct dosage, in circumstances where the original strength was in short supply/unavailable and not providing any or adequate information or advice to the patient on the change to their dispensed medicines.
- Changing dispensing cycle from one month to two weeks.

### Behaviour (Manner/Attitude)

The next highest number of complaints (19%) considered related to the behaviour of pharmacists in terms of manner or attitude.

The PPC noted several complaints related to the manner in which patients felt they were dealt with and spoken to by the pharmacist, and where a breakdown in communication appears to have occurred between the complainant and pharmacist. As stated in previous reports, where an issue arises, meaningful, respectful 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.

### Dispensing errors

The PPC noted a reduction in the number of complaints relating to dispensing errors compared to the previous year. The percentage of complaints considered as a result of dispensing errors reduced from 23% in 2019 to 13% in 2020.

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 incorrect medication being supplied. One complaint involved the dispensing of medication from a patient's Patient Medication Record (PMR) as opposed to the prescription. The PPC noted the importance of pharmacists reviewing prescriptions to ensure that they are legally valid and therapeutically appropriate for the patient, as well as reviewing the original prescription against the label and dispensed products as part of the final check, prior to supply to the patient.

#### (b) Incorrect strength of correct medication

One of the complaints related to the supply of medication to an infant. The PPC continues to be concerned by the potential for errors to occur when dispensing prescriptions for infants and children. Particular attention should be paid 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 of the product.

### Patient requests for supplies of medicines in emergency circumstances related to the Covid-19 pandemic

The PPC noted that a number of complaints related to the refusal by the pharmacist to provide an early supply or further medication in the absence of a prescription in emergency circumstances arising during the Covid-19 pandemic.

In response to the outbreak of Covid-19, certain changes were made to the relevant medicines legislation (including extending the validity period of prescriptions in some cases) to facilitate how prescription only medicines were to be supplied to patients to ensure continued care and treatment for patients. The pharmacist is required to use their professional judgement, in consultation with the patient, and if needs be the prescriber, to ensure that it is safe, appropriate and necessary to provide additional supplies of a medication for the patient's continued treatment and care.

Some of the complaints considered by the PPC related to circumstances where pharmacists refused to supply the requested medication in emergency circumstances. In other cases, the issue related to whether the validity of the prescription for the particular medicine could be extended.

While the PPC are aware that these situations can be challenging, the PPC believes it is important that pharmacists communicate the reasons for their decision not to supply the medicines clearly and respectfully to the patient while at all times being guided by the Statutory Code of Conduct for Pharmacists. Relevant advice should also include referring the patient to another healthcare professional or service as appropriate.

## Conclusion

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This Annual Report covers the eleventh full year in operation of the PPC during an unprecedented national and global health crisis which saw the management of complaints moved to a completely remote environment.

It is hoped that the Council and indeed the public can continue to 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 timely 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.”*