

Annual Report of the Scrutiny Committee 2020

It was a privilege to be appointed as Chair of the Scrutiny Committee on the 1st of October 2020. Along with the rest of the Committee panel members, I look forward to continuing the Committee's work to act in the interests of the public to ensure the protection of members of the public by upholding proper standards of conduct and maintaining public confidence in the profession.

As Chair of the Scrutiny Committee, I have compiled the eighth annual report of the Committee's work in compliance with Regulation 7(1) of the Council of the Pharmaceutical Society of Northern Ireland (Statutory Committee, Scrutiny Committee and Advisers) Regulations (Northern Ireland) 2012.

The legislation states as follows at Regulation 7(1)

7(1) The Scrutiny Committee has the following additional functions—

- (a) providing an annual report to the Council in respect of each calendar year, by a date specified by the Council, which is to include
 - (i) trends, patterns and learning points observed from cases considered by the Scrutiny Committee,
 - (ii) details of the numbers of fitness to practise and disqualification allegations which were disposed of by the Scrutiny Committee by means of warnings and undertakings during that year, and
 - (iii) the reasons why the allegations referred to in sub-paragraph (ii) were not referred to the Statutory Committee.

The work of the Committee was challenged by several factors during 2020 including COVID-19 government restrictions which necessitated the development of remote working and training and a move to online meetings of the Committee. Further, the Pharmaceutical Society commissioned an independent report on a number of matters to aid learning and which has resulted in improved processes for the Committee. The work of the Committee was suspended by agreement of the Chair and the Pharmaceutical Society NI for four weeks pending the development of new processes in compliance with the COVID-19 restrictions and the consideration of the independent report. The Committee's membership also changed during 2020 due to the resignation of the Chair, Mr John Gibbons and the tenure of several experienced members, including the Deputy Chair, Rosemary Connolly, finishing on the 30 September 2020.

I would like to record the Committee's appreciation of the extraordinary efforts of the staff of the Pharmaceutical Society NI and the understanding of all those involved in the fitness to practise processes to ensure the continued

effectiveness, fairness and transparency of the Committee's work during this past year.

This eighth annual report, while covering the calendar year of 2020, also includes one 2019 case, which was concluded in 2020 and was not reported in the last Scrutiny Committee annual report.

Composition of the Scrutiny Committee

The Scrutiny Committee which sat during 2020, consisted of a publicly recruited panel, trained in fitness to practise proceedings.

Composition of the Scrutiny Committee until 30 September 2020

Chair and legally qualified member	Mr. John Gibbons (resigned June 2020)
Deputy Chair and legally qualified member	Ms. Rosemary Connolly*
Lay member	Mr. Andrew Popplewell
Lay member	Mr. Colin Kennedy
Pharmacist member	Ms. Bronagh White*
Pharmacist member	Mr. James Taggart*
Pharmacist member	Ms. Anita Lawther
Pharmacist member	Ms Patricia Holden

* Retired due to time served on 30 September 2020.

Composition of the Scrutiny Committee from 1 October 2020

Chair and legally qualified member	Ms Nicole Lappin**
Deputy Chair and legally qualified member	Ms. Louisa Fee**
Lay member	Mr. Andrew Popplewell
Lay member	Mr. Colin Kennedy
Pharmacist member	Ms. Rachel Lloyd**
Pharmacist member	Mr. Andrew Dawson**
Pharmacist member	Ms. Anita Lawther
Pharmacist member	Ms Patricia Holden

** New Committee member.

Membership of Scrutiny Committee panels in 2020

The Chair assigns members to panels on a rota basis unless the member is unavailable or another reason determined by the Chair exists, for example, a potential conflict of interest in a particular case.

	Member	Number of Panels
Chair and legally qualified member	Mr. John Gibbons (resigned June 2020)	1
Deputy Chair and legally qualified member	Ms. Rosemary Connolly*	4
Lay member	Mr. Andrew Popplewell	2
Lay member	Mr. Colin Kennedy	3
Pharmacist member	Ms. Bronagh White*	1
Pharmacist member	Mr. James Taggart*	0
Pharmacist member	Ms. Anita Lawther	3
Pharmacist member	Ms. Patricia Holden	1

* Retired due to time served on 30 September 2020.

During the reporting period, the availability and attendance of members at them was impacted by Government Covid-19 restrictions and the development of improved processes and training for the Committee following the independent report.

On behalf of the Committee, I want to thank the members who left during 2020 for their collective service. All the members brought enthusiasm and expertise to the Committee and were committed to ensuring that the Committee's work to act in the interests of the public to ensure the protection of members of the public by upholding proper standards of conduct and maintaining public confidence in the profession were carried out with fairness, respect and transparency.

On behalf of the Committee I would particularly like to thank its former Chair, John Gibbons and Deputy Chair, Rosemary Connolly for their leadership through this challenging year and to highlight the Deputy Chair's assistance during the preparation for the appointment of the new Committee members. Their legal background and experience of both regulation and procedure greatly enhanced the Committee's role and I thank them for their many years of service.

Background

Following the enactment of new legislation in October 2012, additional powers enable the Fitness to Practice Committees of the Pharmaceutical Society NI to take more proportionate approaches to the management of fitness to practise case outcomes, than simply removal from the register.

The Committees are empowered to.

- Give advice,
- Issue formal warnings,

- Agree undertakings,
- Place conditions on the practise of a pharmacist,
- Impose suspension,
- Issue interim orders and
- Remove Registrants from the register.

Fitness to Practise Committees

Under the legislation, two Committees have been established which determine allegations regarding fitness to practise.

Scrutiny Committee (Initial Proceedings)

This Committee considers initial allegations on a paper-based format and it has the power to dismiss a case, give advice, issue warnings and agree undertakings if appropriate and refer more serious cases to the Statutory Committee (subject to threshold criteria).

Statutory Committee (Hearings Committee)

This Committee considers allegations at hearings of misconduct of registered pharmacists. Registrants are invited to make representations with legal support should they so wish. The Statutory Committee deals with all categories of alleged impairment referred to it by either the Registrar or the Scrutiny Committee and may utilise the full range of fitness to practise sanctions i.e. Give advice, issue formal warnings, agree undertakings, place conditions on the practice of a pharmacist, impose suspension and remove Registrants from the register. It also deals with interim orders, restoration applications and review hearings.

The Work of the Scrutiny Committee in 2020

The Committee sat on five occasions during the reporting period, dealing with a total of four cases. One of these cases was part of a complex multi-Registrant case in 2019 which at the request of one of the Registrants, the Committee agreed to deal with separately by a different panel which occurred during this reporting period.

A table outlining the date of the meeting, the Registrar's recommendation in each case and the method of disposal by the Committee is shown below at **Table 1**. A short summary of those cases is attached hereto at **Appendix 1**.

During the period of this report, the Council of the Pharmaceutical Society NI adopted new Threshold Criteria for referral to the Scrutiny Committee effective from the 30th of June 2020, which was applicable to one of the four cases, Registrant D. To better understand the Scrutiny Committee's reasoning in all cases, the previous Threshold Criteria for referral to the Scrutiny Committee which was applicable to three of the

reported cases (Registrants A, B and C), due to the date of referral to the Scrutiny Committee along with the new 30th June 2020 Threshold Criteria, which were applicable to Registrant D, are set out in full at **Appendix 2** (before 30th June 2020) and **Appendix 3** (from 30th June 2020).

These criteria guide the Scrutiny Committee as to how to assess which cases meet the criteria for referral to the Statutory Committee. In each of the four cases, the Legal Chair supplied a full written determination setting out how these criteria have been applied in each case, following the Committee's deliberation.

The Scrutiny Committee must not refer any fitness to practise allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registered person's fitness to practise is impaired. The Scrutiny Committee also must not refer any disqualification allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will give a direction for disqualification.

The 'real prospect' test applies to both the factual allegations and to the question whether, if found proved, the facts could support a finding of impairment. Where there is doubt as to whether the real prospect test is met, case law indicates that the Scrutiny Committee should err in favour of referral to the Statutory Committee.

The Scrutiny Committee concluded that in two of the cases before it, (Registrants C and D), the threshold for referral to the Statutory Committee had been met and these cases are not further reported on. The Scrutiny Committee dealt with the remaining two cases (Registrants A and B), using the powers granted to it by the legislation. Further information on those cases is provided later, in the section of this report that deals with Regulation 7(1)a(iii).

Table 1: Table showing the Recommendation of the Registrar compared to the method of disposal by the Scrutiny Committee.

Registrant	Date of meeting	Registrar's recommendation for disposal	Disposal by the Scrutiny Committee
A	10/1/2020	Warning / Advice	Advice
B	18/11/2019 then 21/1/2020	Referral to Statutory Committee	Undertaking

C	25/8/20	Referral to Statutory Committee	Referral to Statutory Committee
D	21/9/2020	Referral to Statutory Committee	Referral to Statutory Committee

THE STATUTORY PURPOSE OF THIS REPORT:

Regulation 7(1) a(i): “Trends, Patterns and Learning Points”.

As required by legislation, the key purpose of this report is to identify “trends, patterns and learning points” and bring these to the attention of the Council of the Society, with a view to enabling issues to be identified at as early a stage as possible.

Trends and Patterns:

Of the four cases dealt with by the Scrutiny Committee during the reporting period, two met the statutory criteria and were referred to the Statutory Committee. Of the remaining cases disposed of by the Scrutiny Committee, one case involved an alleged dispensing error and in the other case a Registrant was reported to the Scrutiny Committee as part of a complex multi-Registrant case. In this last case it was alleged that the Registrant, while undertaking the role of pre-registration tutor, had failed to properly and satisfactorily observe the standards prescribed by the Pharmaceutical Society of Northern Ireland Standards for Pre-Registration Training (July 2012).

The cases which come before the Committee highlight a diverse mix of cases, but given the low numbers of cases, again this year, it was impossible to discern any pattern of concern.

Learning Points

Each panel considering a case comprises of a Legal Chair, a Lay member and a Pharmacist member. The Pharmacist members were asked to comment on any learning points which had arisen in each case they were involved in, as they are best placed to comment on what may or may not be the considered view of the average member of the profession. Other members were asked to put forward any points they felt may be relevant, from their more general experience.

Below is a summary of the points made by Committee members, as to what could be considered learning points, which were considered and gathered from the panel members at the end of each meeting, on the dates given. These are issues which

may already be addressed in training and guidance given to the profession, but as they have arisen in the context of the Committee's caseload, these may be areas where further emphasis may be needed. That would be a matter for the Pharmaceutical Society to consider.

Learning points for the profession – recorded at the Scrutiny Committee meetings in 2020.

Meeting date 10-01-2020

- i. Registrants must fully comply with all aspects of the Standard Operating Procedure when dispensing, including specifically that section which states that when the final accuracy check is complete that the label must be signed with the checker's initials.
- ii. Registrants must, if they fail to fully adhere to Standard Operating Procedures, as part of any remedial action consider any learning outcomes and reflect on their duties in respect of these issues as contained in the Code of 'Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland'.

Meeting date 21-01-2020

- i. Tutors must comply with the instructions issued by the Pharmaceutical Society NI which is vital for the development of trainees. If difficulties arise, then it is incumbent on tutors to inform the Pharmaceutical Society NI at the earliest opportunity.
- ii. Learning points for the Scrutiny Committee and the Pharmaceutical Society NI

As reported in the 2019 Scrutiny Committee annual report, following the conclusion of this complex, multi-Registrant case, issues were identified in relation to operational processes and procedures that required further examination. In February 2020, Council commissioned a lesson learned report and following the presentation of the report, certain procedural changes are continuing to be made and refresher training was given to Committee members and relevant staff. At no stage were the decisions or conclusions of the Committee called into question and the learnings of this case informed the basis of induction and ongoing training in 2020.

Regulation 7(1)a(ii): “Details of disposals by warnings and undertakings”

As required by the legislation mentioned earlier, the second purpose of this report is to identify those cases where the Scrutiny Committee was able to dispose of the case by way of warnings and/or undertakings, rather than refer the case onto the Statutory Committee.

One case presented to the Scrutiny Committee which was disposed of in this way related to Registrant B who agreed to an undertaking as set out by the Committee.

An additional case involving Registrant A, resulted in advice being given by the Committee.

These cases are identified and summarised in the report at **Appendix one** hereto.

Regulation 7(1)a(iii): Reasons for non-referral to Statutory Committee

No relevant cases.

Conclusion

As Scrutiny Committee Chair, I can report that Committee members have found the work they have been tasked with to be challenging, varied and interesting. Along with colleagues I have already benefited from training offered to us at the beginning of our terms of appointment along with refresher training for all members. I am also grateful to the support which has already been shown to me by Pharmaceutical Society staff in enabling me to fulfil the role. In particular, I would like to commend Simon McClenahan the Scrutiny Committee Secretary for his assistance in the preparation of this report. I look forward to working further with him and others as the Committee carries out its role to protect the safety of patients and maintain the reputation of the profession.

I trust that this report will again provide a useful insight into the work of the Scrutiny Committee in the past year, and reassurance to the Society that these important issues are being addressed in accordance with the legislation in a satisfactory and proportionate way. As the newly appointed Chair I look forward to working with colleagues in 2021 to ensure this important work continues to be carried out.

Accordingly, I commend this report to you.

Nicole Lappin
Chair
Scrutiny Committee of the Pharmaceutical Society NI

5 March 2021

Details of disposals by warnings and undertakings

1. Registrant A (10/01/2020)

In this case it was alleged that a dispensing error occurred at a community pharmacy whereby Amlodipine was dispensed in an Amitriptyline box instead of Amitriptyline tablets. The complainant had reported that they took the Amlodipine and became ill as a result.

It is also alleged that the Registrant who dispensed the tablets had failed to follow the Standard Operating Procedures (SOPs) established in the pharmacy in relation to Assembling and Labelling Prescriptions and Accuracy Checking in that the 'dispensed by' / 'checked by' boxes on the dispensing label were not signed by the accuracy checker who assembled the medicines or the Registrant who carried out the final check.

It was further alleged that the Registrant failed to acknowledge that something went wrong with a pharmacy service and they failed to properly deal with the complaint that was raised.

It was submitted on behalf of the Society that the relevant Threshold criterion in this case was as follows:

Criterion 3(b) – There is evidence of behaviour on the part of the registered person which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Following consideration of the evidence, the Scrutiny Committee found that sufficient *prima facie* evidence existed to ground the allegations against the person concerned in the following respects.

It was clear that the relevant medication did not bear the accuracy checker's initials as required by the Standard Operating Procedures applicable at the relevant time and that the Registrant did not at an early stage recognise that the Standard Operating Procedures had not been fully adhered to and had not accepted that there are learning outcomes.

In accordance with paragraph 6(1) of Schedule 3 to the 1976 Order, the Scrutiny Committee considered whether the allegation ought to be considered by the Statutory Committee. The Scrutiny Committee must not refer any fitness to practise allegation to the Statutory Committee, unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registered person's fitness to practise is impaired (Regulation 10(8)(a) of FtP Regulations 2012). Having considered all the evidence, the decision of the Scrutiny Committee was that, given the facts of the matter there was no real prospect of such a finding by the Statutory Committee.

Following consideration of the options available to it, the Committee concluded that the matter should be dealt with by way of advice to the Registrant and recommended that:

As the responsible Pharmacist, the Registrant must fully comply with all aspects of the Standard Operating Procedure, including specifically that section which states that when the final accuracy check is complete that the label must be signed with the checker's initials.

The Committee also expressed its disappointment that the Registrant had not recognised at an earlier stage that the Standard Operating Procedure had not been fully adhered to and had not accepted that there are learning outcomes. Further, that the Registrant should reflect on their duties in respect of these issues as contained in the Code of 'Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland'.

2. Registrant B (18/11/2009 then 21/1/2020)

Following the Registrant's request, this case, part of a complex, multi-Registrant case was considered by a different Committee than that considering the other cases. It was alleged that Registrant B, while undertaking the role of pre-registration tutor, had failed to properly and satisfactorily observe the standards prescribed by the Pharmaceutical Society of Northern Ireland Standards for Pre-Registration Training (July 2012).

It was alleged that that by their acts and/or omissions, the Registrant acted in a manner that was dishonest, misrepresented proper compliance with due processes, caused, allowed or permitted an impression to be created which they knew to be false, inaccurate and misleading and also caused, allowed or permitted pre-Registrants to become registered with the Society without them having properly or satisfactorily completed their pre-registration training in accordance the Standards for Pre-Registration Training (July 2012). The Registrant also failed in their duty as a pre-registration tutor causing harm to two pre-Registrants.

It was submitted on behalf of the Society that the relevant Threshold criteria in this case were as follows:

Criterion 2 (e): There is evidence of a course of conduct which is likely to put patient safety at risk or undermine public confidence in the profession generally, if not challenged.

Criterion 3 (b): There is evidence of behaviour on the part of the registered person which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Criterion 3 (c): There is evidence that the registered person failed to demonstrate high standards of personal and or professional conduct.

The Registrar recommended that the case be referred to the Statutory Committee.

The Registrant, through their legal representative, made an application to the November 2019 Scrutiny Committee that the case be put before a different Committee than the Committee considering the other cases concerned in these matters. Following discussion this was agreed by the Committee.

The new Scrutiny Committee, on considering the information, documents and recommendations placed before it by the Registrar and the Registrant was satisfied that there was sufficient evidence within the papers to meet the Threshold Criteria and therefore that the case had been properly referred to it. It further concluded that sufficient *prima facie* evidence existed to ground the allegations against the Registrant.

Having considered all the evidence, the decision of the Scrutiny Committee was that, given the facts of the matter, there was not a real prospect that the Statutory Committee would make a finding that the registered person's fitness to practice was impaired.

The Committee, then considered, in ascending order, the various methods of disposal available to it and determined that the appropriate method of disposal was by way of obtaining undertakings from the Registrant.

Summary of Reasons

The Scrutiny Committee was satisfied that the Registrant had failed to properly and satisfactorily observe the standards prescribed by the Pharmaceutical Society NI in relation to acting as a pre-registration training tutor.

The Scrutiny Committee considered mitigating factors and in that regard the Scrutiny Committee accepted that the following factors were particularly relevant:

The Scrutiny Committee noted the remorse and regret expressed by the Registrant and that the seriousness of what he had done was now fully appreciated.

The Scrutiny Committee noted that there was no evidence of any patient harm as result of the Registrant's action or omissions.

The Scrutiny Committee noted the significant pressure the person concerned was under as an employed Registrant in a busy pharmacy; and

The Scrutiny Committee noted that some insight and learning had been shown by the Registrant and the Scrutiny Committee believed that they had the capacity to learn from the experience.

The committee proposed the following Undertaking to which the Registrant agreed.

- i. Not to perform the role of a tutor until I have successfully retaken the Pharmaceutical Society NI's full day new tutor accreditation Tutor Course.

Threshold Criteria for referral to Scrutiny Committee to 29 June 2020

Cases are not to be referred to the Scrutiny Committee unless one of the following statements is true:

Principle 1: Make the safety and welfare of patients your prime concern.

- There is evidence that the registered person's conduct or performance caused moderate or severe harm or death, which could and should have been avoided.
- There is evidence that the registered person deliberately attempted to cause harm to patients and the public or others.
- There is evidence that the registered person was reckless with the safety and well-being of others.

Principle 2: Respect and protect confidential information.

- There is evidence that the registered person failed to respect the confidentiality of information or misused confidential information acquired in the course of professional practice to an extent likely to undermine public confidence in the profession if not challenged by the regulatory body.

Principle 3: Show respect for others.

- There is evidence that the registered person failed to respect the human rights of patients or demonstrated in their behaviour attitudes which are incompatible with registration as a pharmacy professional.
- There is evidence that the registered person failed to maintain appropriate professional boundaries in their relationship with patients and/or others.

Principle 4: Exercise professional judgment in the interests of patients and public

- There is evidence that the registered person put their own interests, or those of a third party, before those of their patients.
- There is evidence that the registered person culpably failed to act when necessary in order to protect the safety of patients.

Principle 5: Encourage patients (and/or their carers as appropriate) to participate in decisions about their care.

- There is evidence that the registered person damaged or put at significant risk the best interests of patients by failing to communicate appropriately with patients or others.

Principle 6: Maintain and develop professional knowledge and competence.

- There is evidence that the registered person practised outside of their current competence.
- There is evidence that the registered person failed to maintain their knowledge and skills in a field relevant to their practice.
- There is evidence of a course of conduct, which is likely to undermine public confidence in the profession generally or put patient safety at risk, if not challenged by the regulatory body.
- There is evidence of adverse physical or mental health which impairs the registered person's ability to practice safely or effectively.

Principle 7: Act with honesty and integrity

- There is evidence that the registered person behaved dishonestly.
- There is evidence of behaviour on the part of the registered person which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Principle 8: Provide a high standard of practice and care at all times.

- There is evidence that the registered person has practised in a way that was systematically unsafe, or has allowed or encouraged others to do so, where he or she has responsibilities for ensuring a safe system of working.

if the Registrar is in doubt as to whether the above criteria have been met, he shall refer the case to the Scrutiny Committee.