

<b>Case Number</b>	2013/03
<b>Name</b>	Fiona Mary Collins
<b>Registration Number</b>	4664
<b>Date of Hearing</b>	19 <sup>th</sup> and 21 <sup>st</sup> June 2013
<b>The Notice of Allegation</b>	
<p>The particulars of the alleged impairment are set out as follows.</p> <p>1. You pleaded guilty to and were convicted of 13 summary charges relating to the period of investigation which was between January 2010 and October 2010 within which you were the responsible pharmacist on the occasions when medication was dispensed to the named patients without the authority of prescriptions. The details of the charges are as follows:</p> <p>Between the 1st day of March 2010 and the 30th day of April 2010, in the County Court Division of Belfast, supplied a prescription drug namely Temazepam to Patient A in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).</p> <p>Between the 14th day of June 2010 and the 31st day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely Temazepam to Patient A in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).</p> <p>Between the 1st day of February 2010 and the 31st day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely Amlodipine to Patient A in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).</p> <p>Between the 4th day of January 2010 and the 29th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely Lanzoprazole to Patient A in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).</p>	

Between the 28th day of June 2010 and the 25th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely Tramadol to Patient B in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 1st day of June 2010 and the 26th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely SERC, a brand name for Betahistine, to Patient C in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 16th day of July 2010 and the 11th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely Fosamax to Patient D in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied only 8 tablets of the said dn1g when 20 tablets should have been dispensed contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 17<sup>th</sup> day of May 2010 and the 11th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug namely Bumetanide to Patient E in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug instead of Furosemide which should have been supplied in accordance with the corresponding prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 28th day of June 2010 and the 11th day of October 2010 in the County Court Division of Belfast, supplied a prescription drug namely Pantoprazole to Patient E in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug instead of Omeprazole which should have been supplied in accordance with the corresponding prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 17th day of May 2010 and the 11th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug, namely Temazepam, 20mg tablets, to Patient E in circumstances corresponding to a retail sale in contravention to section 58(2)(a) of the Medicines Act 1968, in that you supplied the said drug at the incorrect strength instead of supplying Temazepam, 10mg tablets, in accordance with the corresponding prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 17th day of May 2010 and the 11th day of October 2010, in the County Court Division of Belfast, supplied a prescription drug, namely Quinine Sulphate 300 mg tablets to Patient E in circumstances corresponding to a retail sale in contravention of section 58(2)(a) of the Medicines Act 1968, in that you supplied the said drug at the incorrect strength instead of supplying Quinine Sulphate 200 mg tablets in accordance with the corresponding prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 8th day of February 2010 and the 11th day of October 2010, in the County Court Division of Belfast supplied a prescription drug, namely Atorvastatin Patient F, in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

Between the 8th day of February 2010 and the 29th day of October 2010, in the County Court Division of Belfast supplied a prescription drug, namely Lansoprazol to Patient F, in circumstances corresponding to a retail sale in contravention of section 58(2) (a) of the Medicines Act 1968, in that you supplied the said drug without prescriptions contrary to Section 67(2) of the Medicines Act 1968(4802011SB).

2. That you failed to comply with the following principles and associated obligations of the Pharmaceutical Society of Northern Ireland's Code of Ethics and Practice 2009;

2.1 The general principle of Registration as a Pharmacist that requires you to act to promote and maintain public confidence in the Pharmacy profession.

2.2 The Code to maintain patient safety and public confidence in the profession.

2.3 Principle 1 – Make the safety and welfare of patients your prime concern and associated obligation.

Obligation 1.1 *“Act in a manner that promotes well being and safeguards the health welfare of patients.”*

Obligation 1.2 *“Take steps to safeguard the wellbeing of vulnerable individuals, both adults and children”.*

Obligation 1.3 *“Ensure the provision of high standard of professional service by you or those working under your direct supervision”.*

Obligation 1.11 *“Undertake regular reviews, audits and risk assessment”*

2.4 Principle 4 – Exercise professional judgement in the interests of patients and public and the associated obligation.

Obligation 4.1 *“Consider and act in the best interests of individual patients and the public”.*

2.5 Principle 6 - Maintain and develop professional knowledge and competence and the associated obligations.

Obligation 6.3 *“Apply your knowledge and skills appropriately to your professional responsibilities”*

2.6 Principle 7 - Act with Honesty and Integrity and the associated obligations.

Obligation 7.1 *“Maintain public trust and confidence in your profession by acting with honesty, integrity, and professionalism.”*

Obligation 7.2 *“Demonstrate high standards of personal and professional conduct at all times.”*

2.7 Principle 8 – Provide a high standard of practice and care at all times and the associated obligations.

Obligation 8.4 *“Take responsibility for all work done by you or under your supervision. Ensure that individuals to whom you delegate tasks are competent and fit to practise and have undertaken, or are in the process of undertaking, the training required for their duties.”*

Obligation 8.7 *“Be satisfied that appropriate standard operating procedures (SOPs) exist, are adhered to and are monitored and revised as appropriate, and that clear lines of accountability and verifiable audit trails are in place”.*

Obligation 8.8 *“Take all reasonable steps to ensure that both you and those you employ or supervise comply with all legal and professional requirements and best practice guidance”.*

Obligation 8.10 *“Make sure that your actions do not prevent others from complying with their legal or professional obligations, or present a risk to patient care or public safety”.*

3. By your acts or omissions you may (a) have brought the profession into disrepute, (b) have failed, on a professional basis, to observe the principles set out above and (c) have undermined public confidence in the profession.

<b>Admissions</b>
The registrant admitted misconduct on charges one two and three
<b>Impairment</b>
<p>The committee determined the registrant is currently impaired. See determination below</p> <p>Chair;" In respect of impairment the Committee has made the following decision in respect of Fitness to Practise. The Committee has considered all of the evidence adduced to date in the Hearing and has taken into account the following in reaching a decision:</p> <ol style="list-style-type: none"> <li>1. The statement of agreed facts.</li> <li>2. The admitted criminal convictions.</li> <li>3. The admission by Ms. Collins of current impairment.</li> <li>4. The submission prepared by Council for the Pharmaceutical Society of Northern Ireland in the matters of the charges made.</li> </ol> <p>And finally, the oral submissions made on behalf of Ms. Collins by her counsel.</p> <p>The Committee notes that in the case of CHRE &amp; Grant, the Grant case, Cox J states:</p> <p><i>"In determining whether a practitioner's Fitness to Practise is impaired by reason of misconduct, the relevant Panel should generally consider not only whether the practitioner continues to present a risk to members of the public in his or her current role, but also whether the need to uphold proper, professional standards and public confidence in the profession would be undermined if a finding of impairment were not made in the particular circumstances".</i></p> <p>So in addition the Committee considered:</p> <ol style="list-style-type: none"> <li>(a) the criminal convictions covered a period of approximately 10 months and involved six patients.</li> <li>(b) it is noted that this was not an isolated, one off incident, but a continuing failure to observe appropriate standards</li> <li>(c) the convictions relate exclusively to the preparation of MDS cassettes.</li> <li>(d) there is no evidence that Ms. Collins failed to observe appropriate standards in any other aspect of her pharmacy practise.</li> <li>(e) it is not asserted that the behaviour was either premeditated or deliberate, more that the Registrant allowed herself to fall into bad practise, that she did not appreciate required rectification.</li> <li>(f) the errors involved dispensing to vulnerable patients.</li> <li>(g) the convictions relate to the Registrant's profession and her professional ability, and were committed on pharmacy premises - there is a direct link between the behaviour that led to the convictions and the Registrant's professional life.</li> <li>(h) the Registrant failed to properly update the PMR after prescriptions were received or ensure that this was done.</li> <li>(i) the Registrant routinely prepared MDS cassettes from the PMR without reference to a valid prescription.</li> </ol> <p>The Committee has had regard to Regulation 4(2) of the Fitness to Practise Regulations</p>

(Northern Ireland) 2012 and to the 2009 Pharmaceutical Society of Northern Ireland Code of Ethics. The Committee finds the conduct of Ms Collins to be impaired for the following reasons:

(a) That she failed to properly check the MDS cassettes with the relevant prescriptions and that she has breached her duty to maintain public safety.

(b) That the Committee has regard to the criminal convictions in respect of her conduct and that these convictions are likely to have an adverse impact on public confidence in the pharmacy profession.

(c) That the respondent, Ms. Collins, has breached fundamental principles of the professional Code of Ethics of 2009 being specifically:

The general principle of Registration As a Pharmacist that requires you to act and maintain public confidence in the Pharmacy profession, more specifically

2.2 The Code to maintain patient safety and public confidence in the profession.

2.3 Principle 1 - to make the safety and welfare of patients your primary concern and associated obligation.

Obligation 1.1. To *"act in a manner which promotes wellbeing and safeguards the health, welfare of patients"*.

Obligation 1.2. *"Take steps to safeguard the wellbeing of vulnerable patients, both adults and children"*.

Obligation 1.3. *"Ensure the provision of a high standard of professional service by you or those working under your direct supervision"*.

Obligation 1.11. *"Undertake regular reviews, audits and risk assessment"*.

2.4 Principle 4 - Exercise professional judgment in the interests of patients and the public and the associated obligation, being

Obligation 4.1. *"Consider and act in the best interests of individual patients and the public"*.

2.5 Principle 6 - Maintain and develop professional knowledge and competence and associated obligations, specifically

Obligation 6.3. *"Apply your knowledge and skills appropriately to professional responsibilities"*.

2.6 Principle 7- Act with Honesty and Integrity and the associated obligations, specifically

Obligation 7.1. *"Maintain public trust and confidence in your profession by acting with*

*honesty, integrity, and professionalism".*

Obligation 7.2. *"Demonstrate high standards of personal and professional conduct at all times".*

2.8 Principle 8 - Provide a high standard of practice and care at all times and the associated obligations, specifically

Obligation 8.4. *"Take responsibility for all work by you or under your supervision. Ensure that individuals to whom you delegate tasks are competent and fit to practise and have undertaken, or are in the process of undertaking, the training required for their duties".*

Obligation 8.7. *"Be satisfied that appropriate standard operating procedures (SOPs) exist, are adhered to, and are monitored and revised as appropriate, and that clear lines of accountability and verifiable audit trails are in place."*

Obligation 8.8. *"Take all reasonable steps to ensure that both you and those you employ or supervise comply with all legal and professional requirements and best practice guidance."*

Obligation 8.10. *"Make sure that your actions do not prevent others from complying with their legal or professional obligations, or present a risk to patient care or public safety."*

The Committee notes that the 2009 Code of Ethics has statutory effect by Paragraph 1(3) of Schedule 3 of the Pharmacy (Northern Ireland) Order 1976 as amended and Regulation 26(1) of The Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012.

And having regard to A to C above that I have read and for those reasons the Committee finds Ms. Collins is not currently fit to practise. "

### **Sanction**

The committee opted to make conditions on the continued registration of the registrant. See determination.

CHAIR: "In coming to our decision we have taken into account all of the evidence before us, including the agreed facts, the testimonials received, and the evidence of the Registrant, and the submission of counsel.

In particular the Committee has considered the detailed submissions of counsel on behalf of the Society and on behalf of the Registrant in relation to the course of action which the Committee should adopt in this matter.

The Committee has considered what is appropriate and necessary in the present instance in order to preserve public confidence in the Pharmacy Profession and the maintenance of professional standards.

The Committee is mindful that it should come to a conclusion that is the minimum necessary to achieve these goals.

We have been invited to consider the agreement of Undertakings under Regulation 28 of the Fitness to Practise Regulations 2012 as an alternative to the imposition of conditions under Paragraph 7 Schedule 3 of the Pharmacy Order 1976 as amended.

We have taken into account the representations on behalf of the Pharmacy Society for Northern Ireland (PSNI) that:

1. There was routine contravention of proper procedures and statutory requirements.
2. The period of contravention lasted for a prolonged period of over 10 months.
3. Patient safety was compromised, although no actual harm was suffered by any patient.
4. The Registrant was aware that she was failing to update patient medical records to reflect the prescriptions that were either received or which should have been received for the patients.
5. The Registrant has admitted that she did not have or did not look at prescriptions she received.
6. The Registrant admitted she was convicted of criminal offences in relation to all of the matters at issue in this Hearing.
7. The Registrant had lost control of the administration of the proper management of the branch over which she had been appointed manager and for which she was the Responsible Pharmacist.
8. The Committee has been invited to accept the proposition that for The Committee to accept Undertakings in this instance would be to send the wrong message to the General Public and to the Profession.
9. We have been invited to form the view that the acceptance of Undertakings would wrongly shift the focus of these proceedings from its duties to the Public and the Profession to the rehabilitation of the Registrant.
10. We are mindful that both Undertakings or Conditions imposed by this Committee must be workable to be effective but that at the same time that if the Committee was to accept either of these as appropriate in this case that in doing so they incorporate an appropriate level of supervision whilst being certain and enforceable.
11. We note that the undertakings as proposed to the Committee amount to a significant restriction on the Registrant and we have considered whether these undertakings are sufficient to dispose of this matter having regard to our obligations to the Public and to the Profession.
12. The Committee notes that a staged approach to resolving this matter may be appropriate with an initial period of direct supervision followed by a longer period



thereafter of supervision that might be appropriate.

We have been invited to consider all sanctions in an ascending order of severity, however the Committee has decided to give due consideration to all remedies available to it in order to reach a proportionate and balanced decision. We bear in mind the necessity of imposing the minimum necessary in order to achieve a proportionate and balanced result in this particular instance.

We have carefully weighed up the particular factors identified by the Society and the Registrant and have looked at whether striking off from the Register is appropriate in this case. Having regard to all of the circumstances in this case the Committee does not find this to be an appropriate case for striking off for the following reasons:

There was no actual harm suffered by the patient.

The Registrant has shown insight as to their shortcoming in this matter.

The Registrant has cooperated with the investigation

There was no dishonesty or fraud in this matter

There was no actual material advantage to the Registrant or her Employer

The departure from the Code of Ethics of the Pharmacy Society is not considered so serious as to merit striking off.

In relation to whether the Committee should suspend in the present instance it finds that:

The Registrant has no previous undertakings or conditions

The matter can be resolved by a lesser sanction than suspension

The Registrant has shown insight into her shortcomings in her professional practice and has shown a willingness to remedy same.

That in this instance the imposition of a lesser sanction than suspension will not damage the reputation of the Pharmacy Profession in Northern Ireland or undermine public confidence in same and the upholding of professional standards behaviour.

The Committee has considered the remaining options open to it of whether to accept Undertakings as opposed to the imposition of conditions.

In looking at whether Undertakings are an acceptable means of dealing with this matter the Committee has considered the draft undertakings proposed by the Registrant to the Committee and the concerns expressed by the PSNI in relation to same.

We consider that Undertakings are not an acceptable means of disposing of this matter

for the following reasons:

The deviation from accepted professional standards in this instance was serious and prolonged.

There was substantial or potential risk of harm to patients, although no harm was actually sustained in this case.

The matter was the subject of criminal proceedings which resulted in the conviction of the Registrant on 13 counts.

That undertakings would send the wrong message to the general public and to the profession that deficient professional performance committed by the Registrant in charge of a pharmacy premises is not a serious matter.

The undertakings would be difficult to regulate by the PSNI and would impose an unreasonable burden on the Society.

Finally, the Undertakings as offered included insufficient detail as to the identity of a mentor or supervising pharmacist so as to be workable and effective. It was noted that Regulation 47 of the Regulations offers a means of supervision by PSNI of such undertakings but the Committee did not consider this to offer sufficient oversight in the present instance.

In order to protect the general public and to maintain public confidence in the profession and maintain proper standards of behaviour in these circumstances the Committee has decided that registration of the Registrant be made subject to the following conditions. In considering what conditions would be appropriate the Committee is mindful of the following aggravating factors:

- Deficient professional performance over a prolonged period of time involving six patients
- Patient Safety was potentially compromised
- The Registrant failed to update PMRs in each instance.
- The Registrant admits the deficient performance.

In mitigation the Committee notes:

- No prior disciplinary record of the Registrant with the Society
- No dishonesty or fraud on the part of the Registrant.
- There was open and frank admissions by the Registrant at an early stage demonstrating insight
- No benefit to the Registrant or her employer resulted from the conduct
- Full cooperation on the part of the Registrant at an early stage.

### **Sanctions**

Therefore the Committee imposes the following conditions on the registration of the Registrant:

1. To notify the following people, in writing, in relation to any work (whether paid or unpaid) for which registration with the Pharmaceutical Society of Northern Ireland is required, of the restrictions imposed on your pharmacy practice.

- All employers or contractors
- Prospective employers or contractors
- Agents acting on behalf of employers and locum agencies
- Health and Social Care Board
- Accountable officer for Controlled drugs or your employer
- Superintendent Pharmacist
- Responsible Pharmacist
- Line Manager
- Workplace supervisor

In the case of prospective employers this notification must be given at the time of application.

2. To notify the Pharmaceutical Society of Northern Ireland before undertaking any position for which registration with the Pharmaceutical Society is required, and which requires you to act as a responsible pharmacist/superintendent pharmacist/pharmacist owner in the course of your duties, and to provide the Pharmaceutical Society of Northern Ireland with the contact details of your employer, superintendent pharmacist or pharmacist owner.

3. To consent to the Pharmaceutical Society of Northern Ireland exchanging information with your employer, any locum agency, Health and Social Care Board, or other person or organisation for whom you provide services that require registration with the Pharmaceutical Society of Northern Ireland.

4. To inform the Pharmaceutical Society of Northern Ireland if you apply for work as a pharmacist/pharmacy technician outside of Northern Ireland.

5. To work with a nominated registered pharmacist to formulate a personal development plan specifically designed to address deficiencies in the following areas of your practice; prior to returning to work as a pharmacist, to participate in the Northern Ireland Centre for Pharmacy Learning and Development Return to Practice Course, or its equivalent, and to notify the Society of any successful completion of that course; also training and compliance with the Medicines Act 1968 and the supply of medications via a Monitored Dosage System.

6. To forward a copy of your personal development plan to the Pharmaceutical Society of Northern Ireland within three months of the date on which these conditions become effective.

7. To inform the Pharmaceutical Society of Northern Ireland of the name and contact details of the person named in condition 5 and to consent to the Pharmaceutical Society of Northern Ireland exchanging information about the standard of your professional performance and your progress towards achieving the aims set out in your Personal Development Plan with the person nominated to formulate your personal development plan, and any other person involved in your retraining and supervision.

8. To nominate a suitable pharmacist to act as your mentor. Such nomination shall be provided to the Pharmaceutical Society of Northern Ireland within three months from the date that this order takes effect.

To seek advice from and retain regular contact with your mentor in relation to the following:

To arrange for your mentor to write to the Pharmaceutical Society of Northern Ireland every three months to confirm that meetings are taking place.

To consent to your mentor reporting any concerns/issues to the Pharmaceutical Society of Northern Ireland.

9. When the Registrant returns to work as a Pharmacist to consent to the Pharmaceutical Society of Northern Ireland exchanging information with Superintendent Pharmacist/line manager about your efforts to improve your knowledge/pharmacy practice.

10. When the Registrant returns to work as a Pharmacist to place yourself and to remain under the direct supervision of a workplace supervisor (who shall be a registered pharmacist), such person to be approved by the Pharmaceutical Society of Northern Ireland.

11. To arrange for your workplace supervisor to send a report on your progress and development directly to the Pharmaceutical Society of Northern Ireland every three months, or on reasonable request.

12. To consent to the Pharmaceutical Society for Northern Ireland to exchange information with your workplace supervisor in relation to your efforts to improve your pharmacy practice.

13. To maintain a log recording use of Monitored Dosage Systems and to provide a copy of this log to the Pharmaceutical Society of Northern Ireland every three months or, alternatively, confirm that there have been no such cases of Monitored Dosage Systems.

14. Not to work as a sole practitioner/superintendent pharmacist/responsible pharmacist until all requirements in condition 1 have been met.

15. Not to carry out Monitored Dosage Systems unless directly supervised by a pharmacist.

16. To refrain from completing Monitored Dosage Systems until you have provided satisfactory evidence to the Pharmaceutical Society of Northern Ireland that you have completed appropriate up to date training in this area and that you are competent to provide such a service safely.

17. The conditions outlined above are to be implemented on the following timetable:

- i. The personal development plan is to be approved by the Pharmaceutical Society of Northern Ireland no later than three months from the effective date of this order.
- ii. The Registrant has a further period of 12 months thereafter to implement and complete the said development plan.
- iii. All the conditions set out above shall continue in force throughout this 15 month period from the date of this order and shall lapse thereafter unless a further order of the Committee is made on the application of the Registrar. “

<b>Costs</b>	
Costs were not awarded	
<b>Time Scale for Enactment</b>	28 days from 26 <sup>th</sup> June 2013 the date of notification of determination, subject to any appeal by the registrant
<b>Chair of Committee</b>	Mr Kevin Neary [legal chair]
<b>Members of the Fitness to Practise Committee</b>	Mrs Sheelagh Hillan [registrant member] Mr Eoin Doyle [lay member]
<b>Society Counsel</b>	Mr Jon Paul Shields, instructed by Patrick Fleming (Cleaver Fulton Rankin)
<b>Registrant Counsel</b>	Mr Gerard Boyle, instructed by Leigh Linton (Carson McDowell)
<b>Clerk of Committee</b>	Ms Claire Wilkinson