OUTCOME OF FITNESS TO PRACTISE HEARING

Case Number	2013/02
Name	Lynette Mary O'Hagan
Registration Number	5232
Date of Hearing	13th and 14th June 2013

The Notice of Allegation

The particulars of the alleged misconduct were set out as follows:

1. That on the 12th of December 2011 at the Four Winds pharmacy you did dispense:

(i) Captopril Oral Solution 5 mg/ml TID, (three times a day) and

(ii) Furosemide Oral Suspension - 20 mg/5 ml 100 ml 4.5 mls (4.5 mg) twice a day. In circumstances corresponding to a retail sale in contravention of Section 58(2)(a) of the Medicines Act 1968, in that you sold the medicinal product which was not of the nature or quality demanded by the purchaser contrary to section 64(1) of the Medicines Act 1968.

2. That you failed to:
(a) recognise the dispensing errors when concerns were raised by Miss B.
(b) take the opportunity to remediate dispensing errors when concerns were raised by Miss B.
(c) follow standard operating procedures in relation to extemporaneous preparations.
(d) complete, whether properly or at all extemporaneous dispensing worksheets.
(e) exercise a sufficient level of supervision over subordinate staff.
(f) properly and accurately check the dispensing label against the prescription.
(g) deal properly with a complaint raised by Mr B on 13th January 2011.

3. That by your acts and omissions you created a clear risk to the safety of patient A.

4. For the purposes of paragraph 1(3) of Schedule 3 of the Pharmacy (Northern Ireland) Order 1976, as amended, and Regulation 26(11) of The Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012, the following principles and obligations (contained in the Pharmaceutical Society of Northern Ireland's Code of Ethics and Practice 2009) are regarded by the Society as relevant to the proceedings.

Further, the Society alleges that the Registrant is in breach of these principles and obligations by reason of the misconduct particularised above.

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

Obligation 1.1. 'Act in a manner that promotes wellbeing and safeguards the health, welfare of patients'.

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

Obligation 1.6. 'Promote the safe, effective and rational use of medicines by controlling the sale or supply of all medicinal and all related products, especially those with the potential for abuse or dependency'.

Obligation 1.11. 'Undertake regular reviews, audits and risk assessment'.

Principle 4 - Exercise professional judgment in the interests of patients and public and the associated obligation.

Obligation 4.1. 'Consider an act in the best interests of individual patients and public'.

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

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

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'.

Obligation 7.4. 'Respond to complaints and criticism with honesty, transparency and courtesy'.

3.7. 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 are supervised, 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'.

Obligation 8.12. 'Ensure your place of work has an effective complaints procedure and follows it at all times'".

Admissions

The registrant admitted misconduct on charges one two and three

Impairment

The committee determined the registrant is not currently impaired. See determination below

CHAIR. There is no definition of fitness to practice. Impairment of fitness to practise can be demonstrated in a number of ways. In this matter the relevant provision is found at paragraph 4(1)(a) of Schedule 3 to the Pharmacy (NI) Order 1976, as amended, which provides that a person's fitness to practice can be regarded as impaired by reason of misconduct. In addition, when considering whether fitness to practice requirements are met we must have regard to the Fitness to Practice criteria set out in Regulation 4(2) of the Fitness to Practice and Disqualification Regulations. Although impairment is not defined we have noted the approach to impairment set out in Meadow-v-GMC 2006:

"*... the purpose of [fitness to practice] proceedings is not to punish the practitioner for past misdoings but to protect the public against acts or omissions of those who are not fit to practise. The [fitness to practice panel thus looks forward and not back. However, in order to form a view as to the fitness to practice of a person to practice today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past".*

The Statutory Committee is also obliged to consider the risk of repetition by the registered person and any steps taken to mitigate against that risk. In our consideration of that we must take account of evidence or submissions on whether the failing is easily remediable and/or whether it has already been remedied. Case law reminds us that some types of misconduct, for example, involving clinical issues, may be more capable of remedy than others, for example, dishonesty. Furthermore, in some cases due to the serious nature of the allegations we may still find impairment regardless of the action taken by the registered person to remedy the failing - see Yeong-v-GMC 2010.

In contemplating this issue we must also keep in mind the fundamental public interest requirements:

'... the need to protect the public and ... to declare and uphold proper standards of conduct and behaviour so as to maintain public confidence in the profession'.

And to consider.

'... not only whether the Registrant continued to present a risk to members of the public but whether the need to uphold proper professional standards and public confidence in the Registrant and in the profession would be undermined if a finding of impairment of fitness to practice was not made' - see CHRE-v-Nursing & Midwifery Council, (Grant) case [2011]".

Consideration

This is a matter involving admitted misconduct arising from dispensary errors made in respect of two medicines prescribed for a vulnerable child patient who suffered from complex congenital heart disease and who at the time of the incident was two months old. The opportunity to avoid and/or remedy the dispensing errors was missed in consequence of the failure of the Registrant to follow standard operating procedures for the safe and effective preparation of medicines, including the adequate completion of an extemporaneous worksheet.

A further opportunity to remedy the error was missed by the Registrant when she failed to understand the concerns raised by the child's mother on her examination of what had been dispensed. The Registrant's misunderstanding mistakenly led her to reassure the mother that the medicines had been properly dispensed.

Although these errors have the potential to make the child very unwell the alertness of his parents and the advice received on their inquiry from the Royal Belfast Hospital For Sick Children thankfully ensured that the dispensed medicines were not given. Counsel on behalf of the Society drew our attention to a number of factors which he contended were particularly relevant. These were:

1. The errors involved a vulnerable patient.
2. There was a clear risk to the patient's safety.
3. The dispensing errors were made in relation to two separate medicines.
4. There was a clear failure of oversight by the Registrant when concerns were raised by Ms .
5. The SOPs for extemporaneous medicines was not followed.
6. Extemporaneous worksheets were not properly completed.
7. There was a deficient level of supervision of subordinate staff.
8. There were deficiencies in the complaint handling process.

He highlighted the failure of the Registrant to follow procedures. Her failure to draw the parents' attention to the Society's complaint procedures and he questioned the Registrant's response and actions when initially informed by the mother of the error. He specifically drew our attention to the entitlement to have regard to the public interest in the form of maintaining public confidence in the pharmaceutical profession generally and in the

individual pharmacist when determining whether particular misconduct on the part of that pharmacist qualified as misconduct which currently impaired the fitness to practice of that practitioner.

Counsel for the Registrant referred us to the need to focus on the current fitness to practice of the Registrant but had acknowledged that she had accepted her misconduct which was in the past. In mitigation he noted the following:
1. The Registrant's full cooperation with the investigation.
2. Her full and frank acknowledgment of her error.
3. The Registrant had displayed insight into her alleged misconduct at the time and since.
4. The misconduct was capable of being remedied.
5. It had been remedied.
6. The Registrant had shown remorse and her performance and conduct since December 2011 demonstrated this.
7. There was a serious but isolated mistake and one that should be regarded as a single incident.
8. The Registrant had initiated contact with the parents immediately when she became aware of her mistake. She had recognised her error and apologised and invited them to come into the pharmacy and see her and/or her manager.
9. The Registrant recognised that other avenues of redress should have been advised to the parents but at no time was there any concealment of what had happened. 10. The Registrant's counsel drew attention to the fact that she had almost immediately after the accident sought and undertaken training, including course involving 21 contact hours completed in February 2012 and described as an 'Introduction to Paediatric Pharmaceutical Care' delivered by NICPLD. She had also undergone internal training on dispensing calculations. 11. The Registrant has remained in employment since December 2011 with no suggestion of any other difficulty in any aspect of her pharmacy practice.
12. Counsel for the Registrant highlighted the contemporary references received on behalf of the Registrant, including in particular those from Mr Corry and Mr McNamara, her most recent and current employers. He said that all of the persons who had given references had been made aware of the allegations against the Registrant.

Counsel for the Registrant urged the Committee to conclude that there was no current impairment and that this was not a case where the public interest was so strong as to make a finding of current impairment necessary on that basis (referring to the case of Grant 2011).

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

We have carefully weighed up the particular factors identified by the Society and also the fact that this was a serious, but nonetheless isolated incident, and was not misconduct continuing over a period of time.

We consider that the nature of the misconduct was such that it could be remedied. We have seen and heard evidence that satisfies us that it has in fact been remedied and that the risk of repetition of the dispensing errors and the associated procedural failures is minimal. We are

also satisfied that the Registrant has shown proper insight and remorse.

In considering the requirements of Fitness to Practice we have taken into account the provisions of Regulation 4(2) of the Fitness to Practice and Disqualification regulations. We have concluded that whilst this was a serious but isolated clinical error it is not one for which the wider public interest would demand a finding of current impairment. We have conclude therefore that the Registrant's fitness to practice is not currently impaired.

Sanction

The committee opted to give advice to the registrant. See determination.

CHAIR: We recognise that the Registrant is a young pharmacist who should have learned a salutary lesson from this experience. We accept the sincerity of her apology to the child and his family for the distress and concern she has caused them.

Although we have determined that the Registrant's fitness to practise is not currently impaired, we have a discretion whether or not to give a warning to the Registrant in connection with any matter that we consider necessary or desirable taking into account our findings and, if so, to give a direction that details of the warning be recorded in her entry on the Register.

As a lesser option we may give her advice in connection with any such matter.

We consider that it would be disproportionate in all the circumstances to impose a warning on the Registrant, and that the public interest does not require us to do so.

However, we have decided to advise the Registrant in the following terms. This is advice and not conditions but we feel that it is desirable in all of the circumstances of this case.

We advise the Registrant:

1. Whenever she is working as a pharmacist, wherever and in whatever capacity, she should satisfy herself that Standard Operating Procedures exist, that they are appropriate, and that she is and remains familiar with them.

2. We also encourage her, irrespective of the nature of her employment or the level of her responsibility, to formally record her acknowledgment of Standard Operating Procedures.
And that is the decision of the committee.

Costs

Costs were not awarded

Time Scale for Enactment	28 days from 24th June 2013 the date of notification of determination, subject to any appeal by the registrant
Chair of Committee	Mr Michael Wilson [legal chair]
Members of the Fitness to Practise Committee	Ms Mary Jane Biggart [registrant member] Ms Miriam Karp [lay member]
Society Counsel	Mr Jon Paul Shields, instructed by Patrick Fleming Moore (Cleaver Fulton Rankin)
Registrant Counsel	Mr Jonathan Millar BL, instructed by Leigh Linton (Carson McDowell)
Clerk of Committee	Mrs Claire Williamson