PSI
The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Professional Conduct Committee to the Council of the Pharmaceutical Society of Ireland in relation to a complaint made pursuant to Part 6 of the Pharmacy Act 2007.

Introduction - Summary Details

Registered Pharmacist:	Ms Andrea Palfi
Pharmacist Registration Number:	12170
Complaint Reference(s):	555.2020
Date of Application:	14 & 27 July 2023
Public/Private Hearing:	Public
Meeting Format:	MS Teams
Members of Committee:	Mr Dermott Jewell
	Ms Rebecca Kilfeather MPSI
	Mr John Naughton
Legal Assessor:	Ms Lorna Lynch S.C
Appearances:	
For the Registrar:	Hugh McDowell B.L
	Aisling Ray, Solicitor, Fieldfisher LLP
For the Registrant:	Not represented
Registrant in attendance:	Yes
Witnesses (if applicable):	Not applicable
Other Attendees:	Deirdre O'Malley, D. O'Malley Stenography
In Attendance from the PSI:	Des Butler, Solicitor, PSI
	Anna Malone, Regulatory Executive, PSI
Documentation:	Core Book

1. Subject Matter of the Complaint and Proceedings

The complaint was received from in respect of Ms Andrea Palfi MPSI, Registration No. 12170 on 27 February 2020. The complaint was referred by the Preliminary Proceedings Committee on 13 August 2020 to this Committee on the grounds of professional misconduct and/or poor professional performance within the meaning of Sections 35(1)(a) and 35(1)(b).

The proceedings were progressed throughout with consideration to the Registrant that she was not represented and to ensure that every effort was made to facilitate a full understanding by her of all matters engaged with.

The proceedings were progressed under the new provisions, which provided that, following presentations and submissions, the Committee adjourned to determine findings. These were determined and advised on Day 1 of the Inquiry and distributed in detail to all parties in advance of Day 2 of the Inquiry proceeding at which submissions were made as to sanction.

2. Allegations

"That you, whilst you were a Registered Pharmacist at Sam McCauley Chemists, Kilkenny Shopping Centre, Loughboy, Kilkenny ("the **Pharmacy**"), on or about 12 May 2019, in respect of ("**Patient A**"):

1. Supplied and/or caused to be supplied and/or permitted to be supplied for Patient A, a bottle containing 10mg/ml of Monotrim® (trimethoprim) with dosage instructions of "*GIVE 9ML AT NIGHT*", in circumstances where this:

    (a) was otherwise than in accordance with the prescription dated 8 May 2019 ("**the Prescription**") which provided for the supply of "*Trimethoprim 9mg PO nocte 6/12*"*"; and/or*

    (b) was provided to mother of Patient A without any, or any adequate counselling and/or advice; *and/or*

    (c) was not clinically appropriate; *and/or*

2. By reason of one or more of sub-allegations 1(a) – 1(c) above, you failed to comply with one or more of the following Standard Operating Procedures which were in place in the Pharmacy;

    a. Pharmaceutical Assessment; *and/or*
    b. Assembly and Labelling of Prescriptions: *and/or*
    c. Accuracy Checking; *and/or*
    d. Handing out Prescriptions to the Patient; *and/or*

3. Such further or other allegations as may be notified to you in advance of the Inquiry.

AND FURTHER by reason of one or more of the allegations and/or sub-allegations as set out at 1 and/or 2 above, when considered individually and/or cumulatively and/or in combination, you are guilty of poor professional performance in that you failed to meet the standards of competence that may be reasonably expected of a Registered Pharmacist".

2. Applications

Mr. McDowell, by way of preliminary matters, admitted the Core Book as Exhibit A noting that there had been prior engagement with Ms. Palfi regarding content and the approval of it.

Mr. McDowell also made application for anonymisation of the names of the child and parents the subject of the Inquiry.

Ms. Lynch, noting that the Registrant was not represented, sought and received confirmation from Ms. Palfi that the documents contained within the core book had been and were now agreed. This included the removal of a document to which Ms. Palfi had raised an objection, which was confirmed to be removed.

Ms. Lynch also outlined the detail of the application that references to the parents and child would be referred to Patient A and Patient A's Mother/Father throughout the Inquiry.

Ms. Palfi confirmed her understanding of the application and that she had no objection to it or to the Committee considering making such a decision.

The Committee Members had no objection and confirmed acceptance of the application for anonymisation.

3. Nature of the Complaint

Mr. McDowell advised that the allegations were of poor professional performance and within the definition found in Section 33 of the Act. He also advised that the burden of proof rested with him at all times and that it was the criminal standard of proof beyond reasonable doubt that applied.

Ms. Lynch engaged further with Ms. Palfi to ensure she fully understood the process as outlined.

Mr. McDowell brought the Committees attention to the Notice of Inquiry and Ms. Palfi's registration detail. Ms. Palfi was of Hungarian nationality, had qualified in that country and was first registered in Ireland in July 2017.

Patient A's mother made a complaint on the 25th of February 2020 in relation to an incident that occurred on the 12th of May 2019 at Sam McCauley Pharmacy, Loughboy, Co. Kilkenny. The incident complained of was in relation to a dispensing of antibiotics to a 4-week-old boy that was 10 times the prescribed dose. The prescribed dosage was for 9mg per night while the direction on the label provided with the medicine advised a dosage of 9ml per night. In addition this was a 6-month duration prescription. It may assist Council by noting the engagement in specific relation to this on page 71 of the transcript.

The incident caused great concern to the parents of Patient A and resulted in the child being admitted to and kept overnight in hospital with a number of follow-up appointments required to monitor his condition.

Ms. Palfi sent her observations to the complaint on June 4th 2020 and this can be referenced at pages 18 to 21 of the transcript.

At the time of the incident, in May 2019, Ms. Geraldine Ramage MPSI, the superintendent Pharmacist for McCauley's Pharmacy, conducted an investigation. In the course of this investigation Ms. Palfi accepted that she had made an error, apologised and undertook to use CPD to reflect upon her practice and ensure a similar dispensing error would not occur.
In her response Ms. Palfi expressed her confusion at the gap of time that had elapsed between the incident in May 2019 and the complaint of February 2020.

Patient A's mother, in evidence, advised that she had not made a complaint as emotions were elevated at that time. She and her husband took time to reflect and sought legal advice. In that period, matters were resolved with the pharmacy and the legal advisor assisted in preparation of Parent A's statement. This provided the detail of the complaint to the PSI. Throughout that time Patient A's mother had no engagement with Ms. Palfi of any kind.

Patient A'a mother, in evidence, advised how she had not given the medication to Patient A on the first night. She tried to do so the next day but realised the amount was too much for the infant and stopped. She sought advice from the pediatric ward in St. Luke's Hospital She further advised that Patient A did not suffer any long-term consequences from what occurred. Detail was read into the record of the incident Report compiled by McCauley's Chemist and can be referenced at pages 41 to 47 of the transcript.

Ms. Caroline Hogg had prepared an expert report and was called to give evidence.
It was her opinion that Ms Palfi, failed to label the dispensed medicines in accordance with the prescription dosing instructions, which she considered to be clear, unambiguous and easy to interpret.

In doing so she provided ten times the prescribed dose.

This was a serious failure and it was her opinion that Ms Palfi failed to meet the standards of competence that may be reasonably expected of a pharmacist.

In context she outlined her opinion that:
"There's a lot of elements when you are prescribing for young children, extra precautions should be taken. When you are talking about a baby, a four-week old baby, they require very low doses and it is very easy for a dose to be inappropriate or toxic. So extra precautions should be taken there and all pharmacists would be aware of that.
Also, it is quite a significant error to dispense a product with ten times the prescribed dose."

While agreeing that everyone can make a mistake, Ms Hogg referred to the requirement under the provision of the SOP in operation at the time in McCauley's Pharmacy that required that a pharmacist, when making calculations for minors, should check that dosage with a pharmacist in another pharmacy.

Significant detail surrounding SOP's at the pharmacy, the licensing of medicines and their toxicity, (Pages 72-76 of the Transcript) assessment procedures in dispensing and counselling requirements and protocols were engaged with, in the course of Ms. Hogg's evidence. This can be reviewed for context within the transcript.

It was Ms. Hogg's opinion that the matters, the subject of the complaint, reflected poor professional performance on behalf of the Registrant.

4. Submissions

Mr. McDowell brought the Committee through the evidence as presented in reference to the allegations. He outlined the position of the Registrar that Allegation1 and Allegation 2 individually and cumulatively amounted to Poor Professional Performance.
Following Ms. Palfi's submission, he fairly brought the Committee's attention to a series of documents within the Core Book regarding CPD training undertaken by her and references from current employers.

Ms. Palfi reflected upon the years that had elapsed since the dispensing error. She had apologised at the time for what she described as her shock to see that the label had been incorrect.

She had since ensured that all possible steps were taken to ensure no re-occurrence.

She reflected that the safety of the patient was the most important consideration. In this instance she re-stated how it was her opinion that *" The patient safety is the most important and the child wasn't sick.'*

Council is recommended to note her full submission at (Pages 84 to 97 of the transcript) and notably as there was legal discussion and clarifications sought regarding HSE and BNF guidelines regarding dosage of anti-biotics.

Submissions as to Sanction

Mr. McDowell advised the Committee of his instructions that the Registrar was taking a neutral approach to the question of sanction.
He brought the Committee's attention to certain relevant factors that he suggested the Committee might consider when considering sanction.

Ms. Palfi advised that she had understood the position at this point in proceedings and had no further comment or submission to make.

5. Legal Assessors Advice

Ms. Lynch advised the Committee of the decisions available to it under the provisions of the Act and the matters it must consider in making those decisions. The advice given is recorded in the transcript.

6. Decision of the Committee

Allegation 1 (a)

1. Supplied and/or caused to be supplied and/or permitted to be supplied for Patient A, a bottle containing 10mg/ml of Monotrim® (trimethoprim) with dosage instructions of "*GIVE 9ML AT NIGHT*", in circumstances where this:

> ***(a)*** **was otherwise than in accordance with the prescription dated 8 May 2019 ("the Prescription") which provided for the supply of "*Trimethoprim 9mg PO nocte 6/12*"*"; and/or***

Allegation 1(a) - Proven as to fact – YES

The Committee has had regard to the following evidence and documentation in coming to its decision:-

- Certain admissions made by Ms Palfri in her observation document (point 5, page 60 of Core Book) and also, during her closing submission, about the labelling error which resulted in dosage instructions otherwise than those on the prescription dated 8 May 2018.
- The original prescription and the copy provided to the Committee.
- The label affixed to the medication as supplied.
- The evidence of Patient A's mother regarding the dosage instruction on the label of the medication which was different to the prescription.

- Extracts from the electronic medication dispensing records.

Allegation 1(a) - Proven as to Poor Professional Performance - YES

The Committee has had regard to the following evidence and documentation in coming to its decision:-

- Expert Report and oral evidence of Ms Hogg

The PCC accepts the evidence of Ms Hogg that irrespective of the nature of the mistake, a pharmacist is required to label a medication in accordance with the prescription dosing instructions. The Committee is satisfied that even though this was a single error, there was a level of seriousness attached to the error having regard to the age of Patient A and the higher risks associated with incorrect dosage instructions for babies of that age. The Committee finds that this amounts to poor professional performance.

Allegation 1 (b)

1. Supplied and/or caused to be supplied and/or permitted to be supplied for Patient A, a bottle containing 10mg/ml of Monotrim® (trimethoprim) with dosage instructions of "*GIVE 9ML AT NIGHT*", in circumstances where this:

(b) was provided to mother of Patient A without any, or any adequate counselling and/or advice; *and/or*

Allegation 1(b) - Proven as to fact – YES - IN PART

The Committee does not find the allegation that the medication was supplied to the mother of Patient A without any counselling or advice proven as to fact. The Committee does find the allegation that the medication was supplied to the mother of Patient A without any adequate counselling or advice is proven as to fact.

The Committee has had regard to the following evidence and documentation in coming to its decision:-

- Undisputed evidence of Patient A's mother that she had limited advice regarding the medication which was about administration by syringe and how long the dose would last. Patient A's mother was clear that this advice was not given Ms Palfri. In her submissions, Ms Palfri stated that she could not remember her interactions on the day in question.

Allegation 1(b) - Proven as to Poor Professional Performance - YES

The Committee has had regard to the following evidence and documentation in coming to its decision:-

- Expert Report and oral evidence of Ms Hogg

The Committee accepts the evidence of Ms Hogg about the pharmacist's legal responsibility of counselling and advising the patient's mother. The Committee accepts the evidence of Ms Hogg that this would have provided an opportunity for discussion which may have identified the error. The Committee agrees with the evidence of Ms Hogg that Ms Palfri's failure in this regard is serous and finds that this amounts to poor professional performance.

Allegation 1 (c)

1. Supplied and/or caused to be supplied and/or permitted to be supplied for Patient A, a bottle containing 10mg/ml of Monotrim® (trimethoprim) with dosage instructions of "*GIVE 9ML AT NIGHT*", in circumstances where this:

(c) was not clinically appropriate;

Allegation 1 c - Proven as to fact – YES

The Committee has had regard to the following evidence and documentation in coming to its decision:-

- The fact that the medication supplied had dosage instructions which were 10 times the dosage on prescription.
- The fact that this was a prophylactic dose prescribed over the course of 6 months as opposed to a treatment dose.
- Patient A's weight and age.
- Ms Palfri stated that she checked the HSE website at the relevant time but the HSE website does not list the dosage instructions as supplied as being clinically appropriate for a baby of the age and weight of Patient A.
- Ms Palfi also referred to the maximum dose in the BNFC but the BNFC does not list the dosage instructions as supplied as being clinically appropriate for a baby of the age and weight of Patient A

Allegation 1(c) - Proven as to Poor Professional Performance - YES

The Committee has had regard to the following evidence and documentation in coming to its decision:-

- Expert Report and oral evidence of Ms Hogg

The Committee notes Ms Hogg's evidence about the checks that should have been undertaken to ensure that the dosage instructions were clinically appropriate and Ms Hogg's evidence that these checks may have prevented the error which occurred. The Committee accepts Ms Hogg's evidence that the failure to supply a clinically appropriate dose is a serious matter and finds that this constitutes poor professional performance.

Allegation 2

2. **By reason of one or more of sub-allegations 1(a) – 1(c) above, you failed to comply with one or more of the following Standard Operating Procedures which were in place in the Pharmacy;**

    a. **Pharmaceutical Assessment; *and/or***
    b. **Assembly and Labelling of Prescriptions: *and/or***
    c. **Accuracy Checking; *and/or***
    d. **Handing out Prescriptions to the Patient; *and/or***

Allegation 2 – Proven as to fact - YES

The Committee finds proven as to fact that by reason of allegations 1(a), 1(b) and 1(c), Ms Palfri has failed to comply with Standard Operating Procedures as follows:-

a. Pharmaceutical Assessment – Stage of procedure: Box 4, p.120, Box 1, page 121, Box 13 page 121
b. Assembly and Labelling of prescriptions: Box 4 and 5 page 126, Box 5 page 127
c. Accuracy Checking: Box 1,2,3 page 129
d. Handing out prescriptions to the Patient: Box 2 and 3, page 130

The Committee has had regard to the following evidence and documentation in coming to its decision

- The copy SOPs as provided to the Committee. It is not disputed by Ms Palfi that the SOPs were in place in the relevant pharmacy at the relevant time and that she was aware of same.

Allegation 2 - Proven as to Poor Professional Performance - YES

The Committee has had regard to the following evidence and documentation in coming to its decision

- Expert Report and oral evidence of Ms Hogg

The Committee accepts the evidence of Ms Hogg that the failure to comply with the relevant elements of the SOPs is serious and finds that this amounts to poor professional performance.

7. Recommendation as to Sanction

Reasons

- The Committee is of the view that this was a serious error and because Ms Palfi did not follow the appropriate procedures. A number of opportunities to identify the error were missed.
- While the Committee is of the view that Ms Palfi has shown some insight, there remains a concern about a gap in insight regarding the extent of the incorrect dosage, the age of Patient A, the fact that Patient A was admitted to hospital and the potential for harm.
- The Committee were of the view that Ms Palfi was somewhat dismissive about the fact that the prescribed medication was an antibiotic and the extent of the incorrect dosage.
- In terms of mitigating factors, the Committee accepts Ms Palfi's evidence that this was an honest error and Ms Palfi has apologised for the error.
- There are no previous issues regarding Ms Palfi's practice and this must be viewed as an isolated error.
- Ms Palfi has provided evidence of additional training she has engaged in and numerous courses she had undertaken.
- She has a very impressive CV and is very committed to enhancing her professional practice.
- The Committee accept Ms Palfi's evidence that she has not made an error of this type since this incident and the PCC had regard to the two very positive references from two other pharmacists who are supportive of Ms Palfi.

Recommended Sanction

The Committee is of the view that an admonishment is not sufficient to meet the seriousness of the findings and is of the view that the appropriate and proportionate recommendation is Censure.

SIGNED: _____

Dermott Jewell, Chairperson

DATE: 26 September 2023