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:	Mr Marcus Breslin
Pharmacist Registration Number:	5345
Complaint Reference(s):	518.2019
Date of Inquiry:	2 May 2024
Public/Private Hearing:	Public
Meeting Format:	In-Person at PSI House
Members of Committee:	Mr Dermott Jewell Ms Rebecca Kilfeather MPSI Mr Thomas Finn
Legal Assessor:	Ms Lorna Lynch SC
Appearances:	
For the Registrar:	Mr Eoghan O'Suillivan, BL Ms Aisling Ray, Solicitor, Fieldfisher LLP
For the Registrant:	Ms Maria Dillon Horan & Son Solicitors
Registrant in attendance:	Yes
Witnesses (if applicable):	Mr Shane McGlynn, PSI
Other Attendees:	Deirdre O' Malley D. O'Malley Stenography
In Attendance from the PSI:	Mr Des Butler, Solicitor, PSI Ms Clara O'Reilly, Regulatory Executive, PSI

1. Subject Matter of the Complaint and Proceedings

The complaint was made by the Registrar in respect of Mr Marcus Breslin MPSI, Registration No. 5345 on 19 June 2019. The complaint was referred by the Preliminary Proceedings Committee on 17 October 2019 to this Committee pursuant to Section 35(1)(a) and/or 35(1)(b) of the Pharmacy Act 2007, on the grounds of professional misconduct and/ or poor professional performance.

2. Applications

Application 1:

Mr. O'Sullivan, for the Registrar, made a preliminary application regarding the privacy for three patients, two of whom were deceased and whose medical conditions would be referenced in proceedings. There was no objection to the application by the registrant. Following advice from the legal assessor the Committee directed that the identities of all three would be anonymised and that nothing, in print or in any other medium, would be published which could identify any of the three patients.

Application 2:

Ms. Dillon, for the registrant advised that there had been discussions in advance of the hearing where a proposed position had been agreed, subject to the Committee. Ms Dillon indicated that proposed undertakings had been drafted and the Registrar was supportive of the matter being dealt by way of undertaking. It was agreed that Mr. O'Sullivan would present evidence to the Committee and thereafter, the detail of the undertakings would be presented to the Committee for consideration.

3. Allegations in the Notice of Inquiry

While you were a Registered Pharmacist and/or Superintendent Pharmacist at Portarlington Pharmacy, Eglington House, Park Lane, Portarlington, County Laois (hereinafter referred to as "the Pharmacy"):

1. Supplied and/or caused to be supplied and/or permitted to be supplied a High Tech medicinal product, namely Humira 40mg/0.4mls solution for injection, to the following patients otherwise than in accordance with a valid prescription:

    i. Patient A ([redacted] on or about one or more of the

dates set out in Schedule 1 to this Notice of Inquiry; and/or

ii. Patient B [redacted], on or about one or more of the dates set out in
Schedule 2 to this Notice of Inquiry; and/or

iii. Patient C [redacted], on or about one or more of the dates set out in
Schedule 3 to this Notice of Inquiry; and/or

2. Failed to ensure, prior to the supply of Humira 40mg/0.4mls solution for injection to Patient B on or about 22 February 2018, that a registered pharmacist reviewed the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for Patient B; 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 contained at 1 and/or 2 above, when taken individually, you are guilty of professional misconduct in that you acted in a manner that is in breach of one or more of the following principles of the Code of Conduct for Pharmacists:

i. Principle 1; and/or
ii. Principle 5; and/or
iii. Principle 6; and/or

AND FURTHER, by reason of one or more of the allegations and/or sub-allegations contained at 1 and/or 2 above when taken cumulatively and/or in combination, you are guilty of professional misconduct in that you acted in a manner that is in breach of one or more of the following principles of the Code of Conduct for Pharmacists:

i. Principle 1; and/or
ii. Principle 5; and/or
iii. Principle 6; and/or

AND FURTHER, by reason of one or more of the allegations and/or sub-allegations contained at 1 and/or 2 above when taken individually, 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.

AND FURTHER, by reason of one or more of the allegations and/or sub-allegations contained at 1 and/or 2 and/or 3 and/or 4 above, when taken 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.

4. Evidence

Mr. O'Sullivan advised that he would present evidence from one factual witness who was an authorised officer of the PSI and he proposed that the Committee consider the reports of two experts, one on behalf of the Registrar and one on behalf of the Registrant. It was confirmed that, should the Committee deem it necessary, both experts were present and available to give evidence.

It was confirmed to the Committee that Mr. Breslin was between December 2016 and March 2018 the Superintendent Pharmacist of Portarlington Pharmacy Limited. Mr Breslin did not work frequently in that particular pharmacy and primarily worked in another pharmacy that was owned by the same business.

Mr. O'Sullivan brought the Committee's attention to the provisions of relevant Regulations regarding the obligations of a Supervising Pharmacist in context of the allegations.

The Inspection Report of **Mr. McGlynn,** the authorised officer of the PSI, was opened to the Committee and it referred to an inspection which raised concerns regarding 31 supplies of Humira, a High-tech medicine. Mr O'Sullivan outlined that High-tech medicines are highly specialised and novel that can only be prescribed by consultants. He stated that they are very expensive, they tend to be funded by the State under the High Tech Medicines Scheme and they cannot be prescribed by a GP. The Inspection Report referred to 31 supplies, to three patients between December 2016 and March 2018, which were dispensed without prescriptions to authorise their supply. The pharmacist on duty, Mr Behan, explained to the inspector that he would contact the GP practice next door to get verbal authorisation before dispensing.

Mr. Breslin, in subsequent correspondence with the PSI confirmed that this should not have happened and that, while he did not dispense the items, it was neither his nor the Pharmacy's policy to dispense medicines without a valid current prescription. He added that the medicines in question were being used correctly in the treatment of long-term conditions under the supervision of the patients' GP and consultant. Mr Breslin referred to the difficulty in getting the patients to provide the correct paperwork but felt that it would be unethical not to provide them with the medicines. (*see Transcript 240502 Page 30 Line 13 to Page 32 Line 11)*

In a statement, **Mr. Behan**, currently the Director and Supervising Pharmacist at Portarlington Pharmacy and Mr. Breslin's business partner, advised that there were inefficiencies around

the dispensing system at the time of the inspection, which had now been corrected by the PSI and the HSE. He stated that there had not been a clear pathway to consultants for prescription renewal and the onus was on the patient. It was stated that clearance would be provided by the GP regarding current validity or otherwise of the prescription but the process and system was now improved and was centralised through the HSE. The Committee was provided with details of dispensing and issues which are set out in the *Transcript Page 37 Line 29 to Page50 Line 13 onwards.*

A statement from **Patient B's widow** was opened by Mr. O'Sullivan. She described Humira as the miracle drug for her late husband which had first been prescribed for him in 2004 and, at that time, the cost was €20,000. She stated that the prescription was issued through St. Vincent's hospital. She outlined significant difficulties in having the prescription renewed indicating that they were passed "*from Billy to Jack"* as no one there knew which program her husband was on.

Ultimately, while there were no prescriptions produced by the Pharmacy at the time of the inspection or subsequently, the Medical Records for Patient B and Patient C did indicatethat there appeared to be prescriptions from relevant Consultants for certain of the supplies made.

In regard to the **two expert's reports** Mr. O'Sullivan advised the Committee that he was not opening them but that the Committee members could read these for themselves. He identified a dispute between **Mr. Kerr's** opinion and that of **Mr. Stenson** in relation to the extent of Mr. Breslin's responsibility as a Superintendent Pharmacist for these supplies. Mr. Kerr was of the opinion that the Superintendant Pharmacist is ultimately responsible for ensuring robust and appropriate policies and procedures are in place and implemented. Mr. Stenson considered the responsibility lay elsewhere as Mr. Breslin had appropriately delegated what was required to the Supervising Pharmacist who was in whole-time charge of the Pharmacy.

Mr. Shane McGuinn, authorised officer of the PSI, subsequently gave detailed oral evidence in relation to matters set out in his Inspection Report of the 22nd of March 2018 and he was cross-examined by **Ms. Dillon.**

5. Submissions

Ms. Dillon outlined the detail of the proposed undertakings to the Committee. She confirmed that the proposed undertakings had been discussed in advance and were offered in the context of the early and open admissions made by Mr. Breslin as soon as he became aware of the situation in Portarlington Pharmacy. Ms Dillon stated that Mr Breslin had immediately

taken steps to remedy the situation. He accepted that, as Superintendent Pharmacist, he had a role of governance and oversight. Ms Dillon reflected on how a situation had arisen over time due to some over-familiarity or an excess of sympathy or empathy with patients that was misplaced. Mr. Breslin recognised the issues that had arisen regarding the supplies of High-tech medicines within the Pharmacy and Ms Dillon respectfully submitted that the undertakings put forward would provide comfort and assurance to the Committee.

Mr. O'Sullivan advised that the Registrar's view was that the undertakings proposed encompassed further education, a number of audits over a lengthy period of time and a consent to censure which in combination provided recognition of wrongdoing that was robust, comprehensive and that would protect the public. He noted that the system for the supplies of these medicines had been replaced under a robust HSE managed programme. Mr O'Sullivan stated that the Registrar was supportive of the application that the matter to be dealt with by way of the undertaking.

6. Legal Assessor's Advice

Ms. Lynch provided legal advice to the Committee regarding the decision available to it under Section 46 (1) of the Act and the matters the Committee should consider in making its decision. Ms Lynch outlined how, in this matter, Ms Dillon had set out carefully the terms of the undertakings that Mr. Breslin would be willing to give to the Committee if requested to do so. Mr. O'Sullivan, on behalf of the Registrar, indicated that the Registrar was supportive of that approach being taken.

Ms Lynch advised the Committee that it must initially decide if it was in a position to make an informed decision in the circumstances. The Committee must then consider whether it was an appropriate case to request an undertaking having regard to the evidence presented before moving to consider the particular wording of the undertaking that had been proposed.

7. Decision of the Committee

The Committee having considered this matter, the Core Book, the medical records, the evidence by Mr. McGlynn, the submissions by Mr. O'Sullivan and Ms Dillon and the legal advice by Ms Lynch, decided that it had sufficient information before it to enable the Committee to reach a decision about whether or not to request an undertaking in this case and the terms of any undertaking requested.

The Committee considered the circumstances of the case and noted in particular the following:

1. The Committee noted the very important role of a superintendent pharmacist and the responsibility that is attached to that role under the 2007 Act and the 2008 Regulations.
2. The Committee was concerned at the lack of proper governance in the Pharmacy and the responsibility that rested with Mr. Breslin in that regard.
3. The Committee was of the view that the Notice of Inquiry raises serious matters and that there was a pattern of medication being supplied without a valid prescription over an extended period. The Committee noted that it was an inspection that prompted changes and were concerned about what practices may have continued if an inspection had not taken place.
4. This practice concerned High-tech medications and the Committee had regard to Mr. McGlynn's evidence referring to the fact that these medications are carefully controlled, costly, carry an increased risk of harm, are specialised in nature and are generally consultant prescribed.
5. It was now shown that there were some valid prescriptions in place in respect of Patient B and C for certain periods. However, they were not available in the pharmacy and were not relied upon as the basis of the supplies of medication at the relevant times.
6. The medical records revealed some vulnerabilities and complex medical histories on of part of the patients but this was not an excuse for the supply of High-tech medication without a valid prescription and the Committee noted that it was not put forward by Ms Dillon as an excuse.
7. It is relevant to note that there is no evidence of any harm resulting to any patient.
8. The Committee noted the prompt steps taken by Mr. Breslin after the inspection and the level of engagement with the PSI.
9. The Committee noted the changes in the prescribing system for High-tech medications, which significantly reduces the possibility of these medications being supplied without a valid prescription.

The Committee decided that this was an appropriate case to request an undertaking pursuant to Section 46 of the Pharmacy Act 2007 as amended. The Committee considered the wording proposed and was satisfied that the wording was appropriate to meet the seriousness of the issues raised subject to one amendment.

The Terms of the Undertaking and Consent

Mr. Marcus Breslin, MPSI, pursuant to Section 46 of the Pharmacy Act, 2007, undertakes as follows:

1. *to consent to censure by the Council of the Pharmaceutical Society of Ireland (PSI);*

2. *to complete the following Irish Institute of Pharmacy courses within six months of the date hereof:*

    a. *Pharmacy & Medicines Legislation, 2024;*
    b. *Polypharmacy & Medication Review, 2024;*
    c. *Biosimilars: Supporting your Patients;*
    d. *Managing Quality & Pharmacy Practice;*

3. *engage with Mr. Noel Stenson, MPSI to conduct four unannounced Pharmacy Audit Inspections over a period of two years at both Retail Pharmacy Businesses - Breslin's Pharmacy, Unit G8, Parkside Shopping Centre, Portlaoise, Co. Laois and Portarlington Pharmacy, Eglington House, Portarlington, Co. Laois,: - and will provide a report to the Registrar within three months of the date of each inspection with such report to address the system of governance in place in the pharmacies and in particular the roles and responsibilities of the superintendent and supervising pharmacists.*

The full detail of the amended undertakings and consent were read to Mr. Breslin who confirmed the terms of same to the Committee.

SIGNED: 

Dermott Jewell, Chairperson

DATE: **17 June 2024**