

**STATUTORY COMMITTEE OF THE PHARMACEUTICAL SOCIETY OF
NORTHERN IRELAND**

In the matter of: Michael Dorman (2001)

Location: This hearing was held in a hybrid format, with participants attending both online and at the Pharmaceutical Society NI, 73 University Street, Belfast, BT7 1HL.

Date: 28 August 2024

Committee: Mr Gary Potter, KC (Chair), Mr Paul Archer (Lay), Dr Mark Timoney (Registrant)

Persons Present and Capacity: Michael Dorman (Registrant), Mr Dennis Hamill Barrister, instructed by Michael Grant Campbell & Grant Solicitors, JonPaul Shields, Barrister, instructed by Ms Chloe Williams Fieldfisher Solicitors (PSNI's Legal Representatives) Mr Alan Goleac, Paralegal.

Service

1. There were no issues about service.

PRELIMINARY LEGAL ARGUMENT

2. There were no preliminary legal arguments.

ALLEGATIONS

The Registrant faced the following allegations:

- (i) On and between 1st January 2020 and 13th January 2022, as Superintendent, the Registrant failed to ensure that Dorman Healthcare Limited was organised or operated in such a way that the extemporaneous manufacture and preparation of unlicensed medicines complied with the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (section 4).
- (ii) On and between 1st January 2020 and 13th January 2022, as Superintendent, the Registrant caused, allowed or permitted an unlicensed medicine, namely, "The Tonic", to be manufactured and supplied by Dorman Healthcare Limited without adequate manufacturing records being kept with respect to all such preparations contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (section 4) in that he supplied 1,511 bottles of "The Tonic" whilst only having 120 manufacturing records.
- (iii) On and between 1st January 2020 and 13th January 2022, as Superintendent, the Registrant caused, allowed or permitted unlicensed medicines, namely, "Nappy Ointment", "Hack Cream" and "Japanese 35% Peppermint Oil Cream", to be manufactured, offered for sale and supplied by Dorman Healthcare Limited without any manufacturing records being kept contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (section 4).
- (iv) On and between 1st January 2020 and 13th January 2022, as Superintendent of Dorman Healthcare, the Registrant failed to ensure that the standard operating procedure for "Preparation of 'The Tonic'" was

adhered to with respect to record-keeping for the manufacture and supply of an unlicensed medicine.

- (v) As Superintendent, the Registrant failed to ensure that Dorman Healthcare Limited had a relevant standard operating procedure with respect to the manufacture and supply of the following unlicensed medicines, namely, “Nappy Ointment”, “Hack Cream” and “Japanese 35% Peppermint Oil Cream”.

3. The Registrant through his Counsel admitted each of the allegations.

4. The Registrant also admitted the facts of this case as set out in the Society’s statement of case.

- a. The Registrant is currently registered as a pharmacist with the Pharmaceutical Society of Northern Ireland (“the Society”) having first registered with the Society on 4th October 1977.*
- b. On and between 1st January 2020 and 13th January 2022, the Registrant was director and superintendent of Dorman Healthcare Limited which owned and operated Dorman Healthcare at 6 Lineside, Coalisland, Dungannon.*
- c. An inspection of the pharmacy on 13th January 2022 by a Pharmacy Inspector revealed that a number of unlicensed medicines were being extemporaneously manufactured in the pharmacy. A reconciliation was undertaken between sales recorded in the Patient Medication Record (PMR) and extemporaneous manufacturing records between 1 January 2020 and 13 January 2022. In general terms, concerns were raised about record keeping in relation to the extemporaneous manufacture and preparation of unlicensed medicines.*
- d. An extemporaneously prepared medicinal product refers to the process by which a registered pharmacist, using traditional compounding techniques,*

produces a medicinal product to meet the particular needs of a patient, or group of patients. An extemporaneous preparation should be undertaken having regard to published standards, namely Section 4 of the Professional Standards and Guidance for the Sale and Supply of Medicines. In particular, Section 4.9 refers to making and keeping manufacturing records.

e. The findings of the Inspector can be summarised, for the period between 1 January 2020 and 13 January 2022, as follows:

- (i) An unlicensed medicine called “The Tonic” was manufactured, offered for sale and supplied by Dorman Healthcare Limited without adequate manufacturing records being kept. There was a supply of 1,511 bottles of “The Tonic” with only 120 manufacturing records.*
- (ii) An unlicensed medicine known as “Nappy Ointment” was manufactured, offered for sale and supplied by Dorman Healthcare Limited without any manufacturing records being kept. Sales records were kept for Nappy Ointment showing 31 supplies.*
- (iii) An unlicensed medicine known as “Hack Cream” was manufactured, offered for sale and supplied by Dorman Healthcare Limited without any manufacturing records being kept. Sales records were kept for Nappy Ointment showing 45 supplies.*
- (iv) An unlicensed medicine known as “Japanese 35% Peppermint Oil Cream” was manufactured and offered for sale by Dorman Healthcare Limited without any manufacturing records being kept. There were. No sales records for this product.*

f. As Superintendent, the Registrant failed to ensure that Dorman Healthcare Limited was organised or operated in such a way that the extemporaneous manufacture and preparation of unlicensed medicines complied with the Pharmaceutical Society of Northern Ireland’s Professional Standards and Guidance for the Sale and Supply of Medicines (section 4).

g. At the time of the inspection, the Registrant had a Standard Operating Procedure (SOP) for the preparation of “The Tonic” which included a requirement for record keeping. The Registrant did not ensure that this SOP was properly followed within the Pharmacy.

h. At the time of the inspection, the Registrant had no Standard Operating Procedure (SOP) for the preparations known as “Nappy Ointment”, “Hack Cream” and “Japanese 35% Peppermint Oil Cream”.

5. Both the Counsel for the Society and for the Registrant acknowledged that the questions of misconduct and impairment of fitness to practice are ultimately a matter for this Committee. The Committee noted that the Registrant accepted that the facts giving rise to the allegations amount to serious misconduct. The Committee also noted that the Registrant accepted that his fitness to practise is impaired.
6. In making its decision in relation to the question of impairment the Committee took into consideration the relevant case law, and the relevant factual circumstances, and the aggravating and mitigating factors in this case.
7. As is clear from the papers, the Registrant had been manufacturing, or allowing the pharmacy of which he was superintendent and therefore responsible to manufacture, extemporaneous medicines for at least a two-year period. Manufacturing records are required to be kept by Professional Standards and Guidance. During this time, very few manufacturing records were maintained.
8. Not all manufacturing of extemporaneous medicines was covered by Pharmacy SOPs, and the SOP for “The Tonic” which was in place, was not adhered to.
9. The production and manufacture of unlicensed extemporaneous medicines is inherently more risk laden than the sale or supply of licensed medicines. Suitable and reviewable procedures needed to be established and readily available within the pharmacy environment, alongside appropriate record keeping, adequate training, and adherence to SOPs.

10. The Registrant co-operated with the investigations undertaken by the Pharmacy Inspector and the Society. He ceased the manufacture of some of the extemporaneous medicines immediately and of all such medicinal preparations within about 2 weeks of the Inspector's visit.
11. No adverse incidents were reported relating to any of the unlicensed medicines sold.
12. An aggravating feature in this case is that there had been previous inspections in 2012 and 2014 which identified issues with extemporaneous preparations and record keeping. Following the 2014 inspection, which highlighted that a manufacturing record for nostrums was to be maintained, the Registrant e-mailed the Inspector and assured him that manufacturing records for the tonic nostrum were in place. This position was not maintained by the Registrant.
13. The Registrant has now sold the business and is no longer owner or superintendent. His clear intention is to retire from pharmacy and not continue to practise.
14. The Committee was satisfied on the evidence that the Registrant had shown demonstrable insight, and he had taken prompt steps to remedy the omissions relating to a small and discreet element of his business. As the Registrant has sold his business, and has indicated that he has no intention of seeking to continue or return to work as a Registered Pharmacist at the age of 71, the Committee is satisfied that the risk of repetition is minimal in the particular circumstances of this case.
15. The Committee considers that the Registrant's fitness to practise is impaired. However, the Committee noted that the Registrant had a long and successful career providing services to his local community, and that no adverse harm arose from the sale and supply of these medications. The Registrant has no regulatory history with the Society. He has no criminal convictions, and is a man of otherwise good character.

16. The next question for the Committee is how to dispose of this case given the particular facts and circumstances of it, and the Registrant's admission of impairment. The Committee's attention was drawn to the provisions of Regulation 28 (1) of the 2012 Regulations which provides:

“28.—(1) The Statutory Committee may, if it thinks fit, dispose of fitness to practise proceedings by agreeing undertakings with the registered person concerned (that is, that the registered person will comply with such undertakings as the Statutory Committee considers appropriate) where they admit that their fitness to practise is impaired.

17. The Registrant invited the Committee to dispose of this case by way of undertakings. The Committee can agree undertakings where the Registrant has admitted that their fitness to practise is impaired. Here, the Registrant has admitted the facts, the allegations and that his behaviour amounts to serious misconduct. He has also admitted that his fitness to practice is impaired. Accordingly, it is open to the Committee to dispose of this case by way of undertakings, if it considers it appropriate, and this method of disposal is consistent with the public interest and the regulatory objectives.

18. Undertakings proposed by the Registrant are as follows:

The Registrant intends to leave the Register of Pharmaceutical Chemists maintained pursuant to Article 6 of the Pharmacy (NI) order 1976. He does not intend to apply to re-join the Register. To that end, the Registrant:

- (i) **UNDERTAKES** to make an application to voluntarily leave the Register pursuant to Regulation 7 of the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012 within 14 days from the date of this undertaking;*
- (ii) **UNDERTAKES** not have any involvement in the provision of pharmacy or healthcare services or engage in any activity that would require him*

to be registered with the Society from the date of this undertaking until his removal from the Register by the Registrar;

- (iii) **UNDERTAKES** not to engage in the provision or management of pharmacy and healthcare services; and*
- (iv) **UNDERTAKES** to inform the Registrar (with reasonable notice and not less than 4 weeks) should he intend to make an application for Registration.*

19. The Society has considered those undertakings and notwithstanding the Committee's own independent decision, the Society informed the Committee that it was content with disposal of this case by way of the four undertakings proposed by the Registrant.

DECISION

20. The Committee was reminded that any agreement of undertakings should be in the public interest and consistent with the Committee's regulatory objectives.

21. The Committee is reminded that any decision has to be proportionate. The Committee noted the Registrant's acceptance of responsibility and his acceptance of his impairment of fitness to practise. The Committee considered it to be relevant that the Registrant has retired, has ceased practice, and has sold his business. The Committee noted that the Registrant has fully acknowledged responsibility for his actions.

22. The undertakings proposed make it clear that the Registrant intends to apply voluntarily to have his name removed from the register. It is likely that the Registrar will agree to this application. The public are further protected in the interim by the second undertaking not to have any involvement in the provision of pharmacy or health care services, or to engage in any activity that would require him to be registered with the Society between the date of these undertakings and until his removal from the register has been formally made by the Registrar. The Committee also noted the third undertaking that in terms of the future he has undertaken not to

engage in the provision or management of pharmacy and healthcare services in the future.

23. Given the facts, the admission made, and the terms of the proposed undertakings, the Committee considers that disposing of this case by way of these undertakings is appropriate and proportionate. The undertakings provide a protection of the reputation of the profession, they align with the public interest, and meet the regulatory objectives.
24. It remains possible that the Registrant might apply for registration in the future. At the age of 71, the fact that he has sold his business and given his proposed undertakings, the Committee considers that such an application is probably unlikely. However, if such an approach is taken by the Registrant in the future, the Counsel for the Society made it clear at the hearing, on the record, that appropriate steps would be taken by the Society to deal with any such application in accordance with the legal framework. The public would be protected by the steps that could be taken by the Society in accordance with the relevant legislation.
25. In conclusion, the Committee considers it appropriate to dispose of these fitness to practise proceedings by agreeing the four undertakings proposed by the Registrant in circumstances where he has admitted that his fitness to practise is impaired.

UNDERTAKINGS

The Registrant intends to leave the Register of Pharmaceutical Chemists maintained pursuant to Article 6 of the Pharmacy (NI) order 1976. He does not intend to apply to re-join the Register. To that end, the Registrant:

1. **UNDERTAKES** to make an application to voluntarily leave the Register pursuant to Regulation 7 of the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012 within 14 days from the date of this undertaking;
2. **UNDERTAKES** not have any involvement in the provision of pharmacy or healthcare services or engage in any activity that would require him to be registered with the Society from the date of this undertaking until his removal from the Register by the Registrar;
3. **UNDERTAKES** not to engage in the provision or management of pharmacy and healthcare services; and
4. **UNDERTAKES** to inform the Registrar (with reasonable notice and not less than 4 weeks) should he intend to make an application for Registration.

COSTS

26. No costs application was made by the Society.

Gary Potter, KC

Chair of the Statutory Committee

28 August 2024