General Pharmaceutical Council

Fitness to Practise Committee

Principal Hearing

Remote videolink hearing

10-12 May 2023

Registrant name:	Mohmed Hasan Moosa
Registration number:	2027682
Part of the register:	Pharmacist
Type of Case:	Misconduct
Committee Members:	David Bleiman (Chair)
	Bukky Giwa (Registrant member)
	Stephen Greep (Lay member)
Legal Adviser:	Ralph Shipway
Secretary:	Zainab Mohamad
Registrant:	Not present and not represented
General Pharmaceutical Council:	Represented by Gareth Thomas, Case Presenter
Facts proved:	1a, 2a, 2c, 2d, 3
Facts proved by admission:	None
Facts not proved:	2b
Fitness to practise:	Not impaired
Outcome:	Warning

Introduction

1. This Principal Hearing relates to Mr Mohmed Hasan Moosa ("the Registrant") a pharmacist first registered on 26 July 1982 and now registered with the General Pharmaceutical Council ("the Council") with registration number 2027682. Mr Moosa faces an allegation of impairment of fitness to practise by reason of misconduct. In summary, it is alleged that, when owner, superintendent and/or responsible pharmacist at Livesey Pharmacy ("the pharmacy") he did not adequately manage the risks associated with the sales of Codeine Linctus or ensure that Standard Operating Procedures ("SOPs") were updated and reviewed.

2. This hearing is governed by the *Pharmacy Order 2010* ("the Order") and we followed the procedure set out in Rule 31 of the *General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) of Order of Council 2010* ("the Rules").

3. The hearing took place by means of a remote videolink. The Council was represented by Gareth Thomas. Mr Moosa did not attend nor was he represented at the hearing. In his absence Mr Thomas confirmed the Registrant's name in accordance with Rule 31(3)(b).

4. We received a hearing bundle prepared by the Council (92 pages) and a Statement of Case and Skeleton Argument submitted by the Council (21 pages). There was no submission from Mr Moosa but a telephone file note dated 24 April 2023 recorded his responses in the course of a conversation with a paralegal calling him on behalf of the Council. On the morning of the hearing we received a Proof of Service bundle and a Proceeding in the Absence bundle. On the second day of the hearing we were provided with extracts from the *Medicines Act 1968* in relation to business carried on by body corporate (including requirements in relation to a superintendent and a responsible pharmacist) and duties of the responsible pharmacist. These extracts were from the versions in force at the time of the September 2020 inspection of the pharmacy.

5. Before we could proceed with hearing the substantive case, we dealt with a number of preliminary matters.

Notice of hearing

6. We examined a copy of a Notice of Hearing sent to Mr Moosa by email on 4 April 2023. The notice was sent to the email address which we confirmed is that contained in the Council's Register. The notice was sent more than 28 days before the start of this hearing and states the date, time and that the hearing will take place via a Zoom link.

7. Having accepted legal advice, we determined that there had been good service of notice in accordance with Rules 3 and 16.

Proceeding in the absence of the Registrant

8. Mr Thomas submitted that Mr Moosa was aware of this hearing and had voluntarily absented himself from the hearing. He referred to comments made by Mr Moosa in the course of a telephone call with the Council's paralegal on 24 April 2023 in which he stated that he does not plan to attend the Principal Hearing. Mr Thomas referred to a number of attempts by the Council to engage Mr Moosa in the process.

9. We accepted legal advice on the approach to be adopted in exercising our discretion under Rule 25 to proceed in Mr Moosa's absence.

10. We considered this matter, as advised, with the utmost care and caution. We find that Mr Moosa plainly has no intention of participating in a hearing on this or any other date. In a phone conversation of 16 March 2023 Mr Moosa said that he had not worked in a pharmacy for 3 years and no longer wished to be a registrant pharmacist. In a phone conversation with a Council's paralegal on 24 April 2023, he confirmed that he won't be attending the Principal Hearing. He stated that he retired on 1 October 2021. He expressed some frustration that he had not been allowed to take himself off the Register, his application for voluntary removal having been refused two and a half years ago. He stated that he won't be looking at any future correspondence.

11. In the light of Mr Moosa's decision to essentially disengage from the Fitness to Practise process and his clear intention not to attend a hearing, we decided that there was no prospect of securing his attendance by an adjournment and that, given the public interest in concluding this already somewhat historic matter in a timely manner, it would be fair to both parties to proceed in Mr Moosa's absence.

Allegations

12. The Committee Secretary read the allegations, as follows:

That you, a registered Pharmacist:

1. Were the owner, the Superintendent Pharmacist, and / or Responsible Pharmacist for Livesey Healthcare Limited, trading as Livesey Pharmacy in Blackburn ("the Pharmacy");

2. Between July 2017 and September 2020, did not adequately manage the risks associated with sales of codeine linctus and minimise the potential for patient misuse or addiction in that:

(a) Large volumes of codeine linctus were ordered into the Pharmacy and supplied to customers;

(b) You did not ensure that adequate controls were in place to:

i. monitor such purchases;
ii. monitor sales to customers;
iii. identify sales to repeat customers;

(c) You did not ensure that there was a record of refused requests, such that the Pharmacy had
no way of identifying potentially vulnerable patients;

(d) You did not audit and / or ensure that audits were carried out of refused requests, such that
the Pharmacy had no way of identifying potentially vulnerable patients;

3. Between October 2017 and October 2021, did not ensure that the Pharmacy's Standard Operating Procedures were updated and / or reviewed in respect of self-care and signposting and medicines liable to abuse;

And by reason of the matters set out above, your fitness to practise is impaired by reason of your misconduct.

Opening submission for the Council

13. Mr Thomas submitted that Mr Moosa was, at the time, the owner of the Pharmacy and bought it over 30 years ago. An extract from the Council's database confirmed that he was the superintendent pharmacist of Livesey Healthcare Limited.

14. Mr Thomas referred to the relevant statutory framework as set out in the provisions of the *Medicines Act 1968* in force at the time of the alleged facts. Where a retail pharmacy business was carried on by a body corporate, the *"keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list"* must be under the management of a superintendent pharmacist (s.71(1)(a) *Medicines Act 1968*). In addition, each premises from which the business was carried was required to have a responsible pharmacist ("RP") in charge of the business. Where the RP was not the Superintendent Pharmacist ("SI"), the RP was to be a manager or assistant *"subject to the directions"* of the SI (s.71(4)(b) *Medicines Act 1968*).

15. Section 72A(1) of the 1968 Act (prior to amendment) stated:

"It is the duty of the responsible pharmacist mentioned in sections 70, 71 and 72 of this Act to secure the safe and effective running of the pharmacy business at the premises in question so far as concerns–

(a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and

(b) the supply at those premises of such products in circumstances corresponding to retail sale."

16. Mr Thomas outlined the evidence set out in the witness statements of two witnesses: Ms Helen Jackson, pharmacist and Inspector for the Council, and Mr Ambrosios Paschalides, pharmacist and Inspections Operations Manager employed by the Council. Ms Jackson provided two witness statements dated 2 December 2020 and 27 May 2022. Mr Paschalides provided one statement dated 4 January 2021.

17. Mr Thomas explained that, in relation to the timeframe set out in allegation 2, the Council did not suggest that this was a continuing failure to adequately manage the risks throughout the period July 2017 to September 2020. Rather, the Council submitted that there were such failures at times within that period. In relation to allegation 3, the next review date of October 2017 was on the face of the SOP and October 2021 was the date on which the pharmacy changed hands.

18. Mr Thomas, in fairness to Mr Moosa, set out a number of qualifications to the Council's case. In summary, these were as follows:

- There was no evidence of actual harm to patients.
- There was no evidence of a specific inappropriate supply of codeine linctus.
- Codeine linctus can be sold lawfully over the counter ("OTC") without prescription.
- No prescriptive guidance was available which could be used as a checklist to evaluate the adequacy of systems and controls to manage the risks associated with the sale of codeine linctus. The case for the Council relied on the core standards of the profession, relating to the provision of safe and effective care and the roles of Superintendent and Responsible pharmacists under the Medicines Act 1968.
- The standards for registered pharmacies which formed the basis of the Council's inspections were not irrelevant but could not be simply "imported" into a judgement of the actions of an individual pharmacist in these proceedings. We should not import the conclusions of the inspections team.
- We should put out of our minds parts of the inspection report which made criticisms about matters not concerning codeine linctus and forming no part of the allegations, though we could take into account that some of the standards for registered pharmacies were found to have been met.
- Though Mr Moosa had not responded formally to the allegations, we should take into account that he appeared to have been cooperative with the inspection and compliant with the conditions imposed on the pharmacy. The Council did not place great weight on the file note of a conversation on 24 April 2023, in which Mr Moosa had not been advised that it might be used in evidence at this hearing. However, we should have regard to parts of that conversation in which Mr Moosa

explained his own position including that he sold 5 to 6 bottles of codeine linctus a week to people he had spoken to and that "he did all that he could diligently and ethically".

Evidence of Helen Margaret Jackson

19. Ms Jackson confirmed and adopted her witness statements of 2 December 2020 and 27 May 2022, the associated exhibits and additional documents in the case bundle including her inspection report of 14 September 2020, notice of conditions imposed on the pharmacy of 16 September 2020 and further inspection report of 11 November 2021 (of which, she confirmed, she was again the author).

20. Ms Jackson offered one correction to her first witness statement. The exhibit of a photo of the Standard Operating Procedure ("SOP") was incomplete, for reasons she could not explain but thought may be her own error in taking the photo. The photo did not include the section referencing codeine. She referred to her own manuscript notes in the inspection notebook in support of her statement that there had not been a specific reference to codeine linctus in the SOP. We found that the photocopy of the relevant page of the notebook in the case bundle was itself cut off at the right hand margin and the text was in note form, for example codeine referred to as "c". We invited Ms Jackson to read the relevant section aloud and we are satisfied that her notes confirm that she found that the SOP did reference how requests for products containing codeine should be handled but that there was no specific reference to codeine linctus.

21. Ms Jackson confirmed that Codeine Linctus is normally used for a dry or painful cough. It is a pharmacy-only ("P") medicine (and also a Schedule 5 Controlled Drug). As a P medicine, this can be bought 'over the counter' ("OTC") from a pharmacy under supervision of a pharmacist where the product has a marketing authorisation.

22. Ms Jackson undertook an unannounced intelligence-led inspection of the Pharmacy on 14 September 2020. The inspection took place following receipt of data from the Medicines and Healthcare products Regulatory Agency ("the MHRA") in February and July 2020 regarding high volumes of Codeine Linctus 200ml being purchased by pharmacies.

23. Ms Jackson set out the volume of Codeine Linctus being purchased by the Pharmacy (from one wholesaler) in Excel spreadsheets received by the Council from the MHRA.

24. Ms Jackson carried out an inspection of the Pharmacy on 14 September 2020. The key factual findings of her inspection report, with some clarifications provided by Ms Jackson in response to questions, were as follows:
    - Eight bottles of 200ml Care Codeine Linctus were found under the pharmacy counter and 12 bottles of 200ml Care Codeine Linctus were found in the stock room rear to the dispensary. No stock bottles of Codeine Linctus were found in the dispensary.
    - Mr Moosa told Ms Jackson that 24 bottles of 200ml Codeine Linctus were sold as OTC sales every week and the bottles were purchased from the wholesaler "Alliance". Ms Jackson, in oral evidence, acknowledged that this figure was in excess of that provided by MHRA and that she had not clarified this discrepancy with Mr Moosa. She wasn't aware that the MHRA data came from a different wholesaler, which Mr Paschalides told us was the "Converse Pharma Group (Testerworld)". She had not clarified with Mr Moosa where he sourced the codeine linctus.
    - Ms Jackson requested invoices for the purchases of 200ml Codeine Linctus, but these were not available at the time. She told us that it was "not a concern that the invoices weren't there."
    - Mr Moosa informed Ms Jackson that he knew that Codeine Linctus was liable to abuse. In an attempt to try and reduce the number of people buying Codeine Linctus, he had increased the price of 200ml bottle from £2.80 to £6.99 but this did not deter purchasers.

- No records were kept of OTC sales of Codeine Linctus or when requests for it were refused. The Pharmacy's tills did not provide specific information about the OTC products sold. Ms Jackson told us that the till wasn't sophisticated enough to even print off and show sales. Mr Moosa had in the past asked people to sign a record when they had purchased a 200ml bottle of Codeine Linctus, but he had stopped doing this and did not give a reason for doing so. Ms Jackson told us that she had not asked why, nor had she asked to see records of the OTC sales previously kept by Mr Moosa.
- Mr Moosa stated that the sales were always for people asking for Codeine Linctus to treat a dry cough and that on most occasions the request was from a person who had not used the Pharmacy before. He did not provide an example of when he had refused a sale.
- Ms Jackson pointed out to Mr Moosa that, without records of sales of Codeine Linctus and of refusals to sell it, other pharmacists working at the Pharmacy would not have the information needed to determine whether the person requesting it had used it before or if their request had been refused. This meant that other pharmacists would not be able to verify any information provided by the person seeking to buy Codeine Linctus.
- The SOP covering self-care and signposting was dated 24 October 2016 and was signed by Mr Moosa with a review date of 24 October 2017. There was no evidence of a review having taken place. No members of the Pharmacy Team had signed the SOP but the members of staff who were spoken to during the inspection confirmed that they had read all the SOPs. A flowchart within the SOP outlined the "Who/What/How/Action/Medication"("WWHAM") questions for selling OTC medicines but did not cover what staff were expected to do when a sale specifically for Codeine Linctus was refused nor the recording of refused sales.
- Mr Moosa said he had seen an increase in requests for Phenergan elixir in February and March 2020 and as a result he had stopped selling this product. Ms Jackson discussed with Mr Moosa that Phenergan and Codeine Linctus can be mixed together to form a product known as 'purple dank' or 'lean'. The Registrant was not aware of either of these products.

25. Ms Jackson did observe and note in her report some aspects of good practice. The summary judgement under the heading of "Principle 4 – Services" started with the statement that "the pharmacy has processes that mostly support it to manage its services safely." This was followed by a statement that the pharmacy "does not have adequate safeguards in place to manage the safe supply of codeine linctus which is a medicinal product liable to abuse." In the course of her visit, Ms Jackson observed the actions of a dispenser and a pharmacist on duty when a customer requested a product containing codeine. She also discussed with the dispenser how she would handle a request for codeine linctus. (We refer to this in more detail in our findings.)

26. A condition was imposed on the Pharmacy on 16 September 2020 which stated that the Pharmacy must not sell or supply any codeine linctus preparations, with the exception of supplying these medicines against an NHS prescription. Ms Jackson issued this by email to Mr Moosa at 17.21 on 16 September 2020 and posted it on 17 September 2020.

27. Ms Jackson informed us of Mr Moosa's response to the notice as follows:

" On 16 September 2020 at 2150 I received an email from Mr Moosa informing me he had received the notice of conditions. On 17 September 2020 around 0930 I spoke to Mr Moosa who confirmed receipt of the notice and stated he had stopped selling codeine linctus. Mr Moosa informed me that just before my call a person had presented asking for a bottle of codeine linctus and after informing the person he no longer sold it he asked the person what help he could provide them to which the person replied none, they were going off to work. Mr Moosa explained in the past he had asked the local drug team to provide information leaflets on support available for people and he would contact them again to ask for this information so the team could provide this to people asking for codeine linctus. Mr Moosa stated he was going to speak to all team members that day to inform them that codeine linctus was no longer sold."

28. We asked Ms Jackson whether she considered Mr Moosa's response to the notice to have been satisfactory. This was not relevant to the facts stage of the case but Mr Thomas had clarified that the Council's witnesses would only be called once and could be asked questions relevant to potential later stages of the case.

29. Ms Jackson replied that she did find Mr Moosa's response satisfactory. He was no longer selling codeine linctus. He was able to give an example of refusing a sale and was obtaining information about being able to signpost customers to other services.

30. A follow up unannounced Pharmacy inspection took place on 11 November 2021. The Inspection Report produced by Ms Jackson is dated 11 November 2021. The Pharmacy had changed ownership at the beginning of October 2021. Ms Jackson confirmed that since the first inspection on 14 September 2020, the Pharmacy had stopped selling Codeine Linctus and that there was no stock of it in the Pharmacy. The new pharmacist owners were aware of the conditions imposed.

Evidence of Ambrosius Paschalides

31. Mr Paschalides explained that Codeine Linctus is liable to abuse, misuse and overuse. He further explained that it is for this reason that many pharmacies choose not to stock it at all, and those that do sell it would be expected to take reasonable care to ensure that it is being used appropriately and responsibly.

32. He described the growing concerns in 2019/2020 regarding the issue of large quantities of codeine linctus being ordered from wholesalers. The Council had asked the regulatory agency, the MHRA, to provide data and in February 2020 the MHRA sent through a spreadsheet showing codeine linctus sales to nearly 2,000 pharmacies. A further spreadsheet was sent in July 2020. However, these related to wholesalers in just one group, "Converse Pharma Group (Testerworld)", representing "a small slice of the available wholesalers". The data was analysed internally by Council staff. Our interpretation as a Committee is that the analysis showed that the vast majority of

pharmacies ordered 1, 2 or no bottles in an average month. A much smaller number of pharmacies were ordering in excess of 10 bottles a month.

33. In response to questions, Mr Paschalides said that it would be up to a pharmacy whether to list codeine linctus separately in an SOP. He said: " I wouldn't have thought that they would need to mention it specifically. If they sell it they may want to include it separately. It would be up to them. We don't specify how they write their SOPs." He confirmed that if the SOP states codeine that should cover codeine linctus.

Closing submissions

34. Mr Thomas summarised the key evidence we had heard which, he submitted went to prove the allegations. He invited us to keep in mind throughout the nature of the risks associated with codeine linctus, as set out by Mr Paschalides. He also asked us to bear in mind that pharmacists were under a general duty to provide safe and effective care and that we should evaluate against that background whether Mr Moosa's risk management had been adequate in all the circumstances of the case. He accepted that Ms Jackson had found some evidence of some good practice but reminded us that Mr Moosa was a pharmacist in a leadership position and the case was about the adequacy of systems and controls.

35. Mr Thomas clarified the way that the Council put the case in relation to the wording of the allegations.

36. Mr Thomas acknowledged that we might consider the evidence somewhat weaker in relation to allegation 2 (b) (i).

Legal advice

37. We accepted legal advice on the approach we should adopt to finding the facts including the evaluation of the credibility and reliability of witnesses, the evaluation

of documentary evidence and the need to consider each charge and sub-charge separately.

Findings of fact

38. We found both Council witnesses to be credible. They were at all times helpful witnesses who answered questions with care and when they did not know the answer, said so. For example, Ms Jackson was careful to clarify her witness statement so as to point out to us a gap in the photographic evidence of the SOP and she admitted that this was probably the result of her own error in taking the photograph.

39. We had more concern regarding the quality and reliability of some of the Council's evidence. The main evidence arose from an inspection lasting about 3 or 4 hours which provided a snapshot of daily practice in the pharmacy. While this had the advantage of being unannounced, that had, in our view, two disadvantages.

40. One was that Mr Moosa would not have had time to collect together potentially relevant documents such as wholesaler invoices. But another was that, as Ms Jackson explained, an inspection was not an investigation, so that her report and evidence left a number of factual matters unresolved. One was a discrepancy between the volume of codeine linctus suggested by the MHRA data and the much larger volume (24 bottles a week) stated by Mr Moosa to Ms Jackson. Ms Jackson had not clarified this with Mr Moosa. Nor had she asked him why he had stopped asking people to sign a record when purchasing a 200ml bottle of codeine linctus. Nor had she been aware that the wholesaler named by Mr Moosa ("Alliance") was not the wholesaler whose data had been used by the MHRA, conveyed to the Council and led to the inspection.

41. There was a more general difficulty arising from the status of codeine linctus and the emerging concerns about potential for misuse and abuse. Although, as Mr Paschalides explained, the general risks had been well known for many years, in December 2019 the Council became alert to the issue of large quantities of codeine linctus being ordered and some time in 2019 he became aware that it was being mixed with

Phenergan to produce a recreational drug. The Council obtained wholesaler data from the MHRA. But the data related to only one supplier, representing in Mr Paschalides' words, a "small slice" of the available wholesalers. At or around the same time that the Council initiated its intelligence led inspections, including that of the pharmacy and others in the Blackburn area, NICE, we were told, had identified codeine linctus as a potential treatment for symptoms associated with Covid 19. Finally, despite all the known risks associated with the medication, codeine linctus remained (and remains) a 'P' product, available OTC in pharmacies, so that customers could request it without a prescription nor having to identify themselves, making it challenging for any pharmacist to manage the risks. Although pharmacists are well aware of the risks associated with all products containing codeine, including codeine linctus, there was no specific guidance from the Council regarding governance including monitoring and managing risk tailored for codeine linctus. Ms Jackson and Mr Paschalides both confirmed that there was no guidance as to whether or not codeine linctus should be specifically mentioned in an SOP. The Council had issued a statement reminding pharmacy owners to have governance arrangements in place in relation to codeine linctus but the evidence we heard indicates that this was issued after the inspection of the pharmacy.

Allegation 1

42. We found that the evidence before us all points to Mr Moosa being the owner of the pharmacy at the relevant time. We accept Ms Jackson's evidence that he was the pharmacy owner and had bought the pharmacy 30 years before her inspection. In the record of a conversation with the Council's paralegal, dated 24 April 2023, Mr Moosa said that at the time of the alleged conduct, he was in the process of selling the pharmacy. The Council's database records Mr Moosa as being the Superintendent from 2 September 2013 to 30 September 2021. Any pharmacist in charge of the pharmacy on a particular date would be the Responsible Pharmacist and it was clear that, at times, Mr Moosa acted in this capacity. It follows that Mr Moosa was under a duty, in accordance with the Medicines Act 1968 to provide "safe and effective care."

43. **Allegation 1 is proved.**

Allegation 2

44. One challenge for us in determining this allegation was the combination of a general allegation of inadequate management of risks associated with sales of codeine linctus with specifics which were said to substantiate the allegation. We accepted Mr Thomas's submission that we should bear in mind throughout our deliberations the nature of the risks associated with codeine linctus and the general duty of a pharmacist to provide safe and effective care. We take into account that in the Council's *Standards for pharmacy professionals*, May 2017 ("the Standards") there are nine detailed standards but all fall within a general concept of "safe and effective care" which features in the centre of a summary diagram on page 7 of the Standards. This accords also with the provisions of the Medicines Act 1968, already cited. We accepted the evidence of Mr Paschalides and Ms Jackson regarding the risks associated with codeine linctus. We first considered the individual particulars before addressing the summative allegation regarding adequacy of management of risks.

Allegation 2 (a)

45. We accept the submission of Mr Thomas that this allegation does not allege excessive volumes of codeine linctus. We accept the documentary evidence from the data provided by the MHRA to the Council as well as Ms Jackson's evidence based on her own experience as a pharmacist and a Council inspector, that the pharmacy was ordering "large volumes" of codeine linctus and supplying these to customers. For the sake of clarity we do not find that large volumes were supplied to *individual* customers, nor is that alleged.

46. **Allegation 2 (a) is proved**

Allegation 2 (b)

47. We found that, on the evidence of Ms Jackson, there was some good practice in the pharmacy in respect of dealing appropriately with customers who wished to purchase medications containing codeine. Ms Jackson reported that "The pharmacy had procedures for the team to follow when people asked to buy over-the-counter medicines including medication that could be misused such as codeine linctus." She personally witnessed, in the course of her inspection, a dispenser asking the pharmacist on duty (not Mr Moosa) to speak to a customer who asked for a product containing paracetamol and codeine (Solpadeine). She observed the pharmacist asking several questions and providing advice before selling the medicine. The dispenser on duty also confirmed that she would follow the procedures listed when a person asked to buy codeine linctus. And she would provide the pharmacist with the information given by the person asking for the codeine linctus in response to the questions she had asked. This included whether the person had the codeine linctus before. She would ask the pharmacist to speak to the person before codeine linctus was sold. Ms Jackson told us that the dispenser concerned, who was herself part-time, worked closely with her full-time dispenser colleague and "it was cohesive". The dispenser told her that she had discussed codeine linctus with her dispenser colleague and a locum pharmacist. Ms Jackson considered that the way that the dispenser she observed had handled the request for solpadeine was satisfactory and her response to the hypothetical request for codeine linctus was "equally satisfactory".

48. Ms Jackson reported that the procedures listed codeine as a medicine requiring referral to a pharmacist but did not mention codeine linctus specifically. We accept Mr Paschalides' evidence that it would be optional for a pharmacy as to whether to name codeine linctus specifically when codeine is listed in the SOP.

49. We find that there were controls in place and that the question is the adequacy of such controls. The evidence as Ms Jackson was able to gather on an inspection on a single afternoon, which she explained was not an investigation, points in different directions. Ms Jackson told us that staff understood their roles and what they had to ask and followed appropriate procedures when customers asked to buy products containing codeine. There was an SOP for self-care and signposting which did include

codeine, albeit not naming codeine linctus and which contained a flowchart including WWHAM questions which were being followed appropriately by staff observed during the inspection. However, the SOP had not been updated nor reviewed since 2016. Mr Moosa had the overall responsibility and this evidence suggests that he had put appropriate procedures in place with which staff were familiar although he had not ensured the updating of the SOP. More generally, the documentation was lacking. There were no invoices available in the pharmacy recording purchases from wholesalers. There was no record of sales to customers, whether one-off or repeat customers for codeine linctus. Nor was there a record of refusals.

50. In relation to (i) monitoring of purchases, we accept Ms Jackson's evidence that while invoices were not on the site on the day of the inspection, there was nothing improper about this. Ms Jackson told us that she was not able to ascertain who in the pharmacy was responsible for ordering codeine linctus. She did not find any evidence of monitoring of orders from the wholesalers but she did not pursue that line of enquiry. We note that Mr Thomas did not point to strong evidence in support of this particular allegation. We conclude that the Council has not discharged its burden of proof.

51. In relation to (ii) monitoring of sales to customers, we accept that Mr Moosa told Ms Jackson that he used to sign a record when a sale was made but he had stopped doing this. He did not provide a reason why but Ms Jackson did not enquire further, explaining to us that she was not conducting an investigation. We accept that the pharmacy was not keeping a record, at the time of inspection, of sales of codeine linctus to customers. The Council's witnesses did not describe what would have been an adequate means of monitoring one-off sales of a medication to a customer who had no prior connection with the pharmacy and would be entitled to purchase codeine linctus OTC. Ms Jackson referred to some potential difficulties including that new customers would not be on the pharmacy's PMR and that keeping patient identifying details would involve navigating the requirements of GDPR legislation. There was also the difficulty that the pharmacy did not have a sophisticated till which might have recorded the item purchased. As she had not pursued her enquiry into the earlier

record kept by Mr Moosa we are not in a position to know whether that was an adequate system, when or why it ceased. We take into account also that Mr Moosa told Ms Jackson that most of those purchasing codeine linctus were from a person who had not used the pharmacy before and often stated it was for another person such as a relative.

52. We have found it difficult to evaluate the limited evidence in relation to monitoring of sales to customers and, on balance, conclude that the Council has not discharged its burden of proof. This is primarily because it would be necessary to have a clear idea of how, in practice, a community pharmacy could monitor sales to a variety of customers unknown to them, coming in for a single OTC purchase of codeine linctus. That would have provided us with a benchmark against which to evaluate the practice in the pharmacy. We also took into account that there was evidence of a pharmacist intervention when the pharmacy was selling codeine containing analgesics.

53. While the pharmacy staff would get to know their local customers and might well discuss with colleagues any concern about an evident repeat customer, this allegation concerns whether, in the absence of record keeping, adequate controls were in place. Identifying sales to repeat customers in a formal written record raises the same difficulties as discussed above in relation to sales generally. If it is not clear how a one-off customer's purchase would be properly recorded for monitoring purposes, it is further unclear how a repeat visit by the same person could be logged. We find that the Council has not discharged its burden of proof.

54. **Allegation 2 (b) is not proved.**

Allegation 2 (c)

55. The SOP states that where a customer chooses not to follow advice an entry should be made in the referral/intervention book or on the PMR. This does not include a situation where sale of a medication such as codeine linctus is refused. Nor does the flowchart detail what to do when a sale was refused and the recording of refused

sales. Mr Moosa informed Ms Jackson that the pharmacy did not record when requests from people to buy codeine linctus were refused. We find that Mr Moosa did not ensure that there was a record of refused requests and that this resulted in the pharmacy not being in a position to identify potentially vulnerable patients, who might be overusing or misusing codeine linctus.

56. **Allegation 2 (c) is proved.**

57. As there was no record of refused requests, there was nothing available to audit. As such Mr Moosa did not audit or ensure that audits were carried out of refused requests.

58. **Allegation 2 (d) is proved.**

Allegation 2 in its totality

59. The way that allegation 2 is worded, having found some of the particulars proved, we were obliged to evaluate whether this amounted to an overall inadequacy of Mr Moosa's risk management in relation to codeine linctus. We reminded ourselves of the risks of codeine linctus, in particular the potential for misuse, overuse, addiction or abuse. We also reminded ourselves that there was evidence of some good practice by pharmacy staff and that this was to Mr Moosa's credit as the SI. We concluded that while there were elements of risk management and some good practice, the paperwork was lacking in respect of record-keeping and this meant that auditing could not take place and potentially vulnerable patients could not be identified. For these reasons we find that, on balance, Mr Moosa did not adequately manage the risks.

60. **Allegation 2 is found proved, on the basis of 2 (a),(c) and (d).**

Allegation 3

61. We confirm that, in accordance with the submission of Mr Thomas, this allegation is to be interpreted as referring only to the SOP regarding "Support for self-care and signposting" in place at the pharmacy at the relevant time.

62. We accept Ms Jackson's evidence that the SOP she found on her first inspection in September 2020 is that provided in the Council's bundle. On the face of the document is stated, against the heading "Date of next review" the date 24 October 2017. The box in which the review date should be entered and initialled is blank. We find that at the time of the first inspection the review had not taken place. We accept Ms Jackson's evidence that at the time of her follow-up inspection in November 2021, she found that the same SOP remained in place, that the pharmacy was under new owners and that the SOP had still not been reviewed. The new owners had not reviewed it but, as they had only had the pharmacy for a few weeks, she had not held this against them.

63. We find that from October 2017, when the SOP should have been reviewed, and October 2021, when he sold the pharmacy, Mr Moosa had not ensured that the SOP in respect of self-care and signposting, which was the relevant SOP covering medicines liable to abuse, had been updated and/or reviewed.

64. **Allegation 3 is proved**.

65. Having found allegations 1, 2 (a) (c) (d) and 3 proved, we are required to move to stage 2 of this case, in which we consider whether Mr Moosa's proven actions amounted to misconduct and, if so, whether his fitness to practise is impaired.

Misconduct and impairment

Submissions

66. Mr Thomas submitted that Mr Moosa's conduct was serious enough to reach the threshold of misconduct. Codeine linctus was a high risk medication. Mr Moosa was himself aware of the risks and on notice of a potential problem in his pharmacy. As owner/SI and RP he had a distinctive leadership role. Large quantities of codeine linctus had been sold by the pharmacy over a number of years. He pointed to a number of the Standards which he submitted had been breached by Mr Moosa.

67. Mr Thomas submitted that Mr Moosa's fitness to practise was impaired by reason of risk to the public, his breach of fundamental principles of the profession in relation to providing safe and effective care, and to uphold the reputation of the profession. He submitted that although Mr Moosa had complied with the notice prohibiting the sale of codeine linctus, there had been inadequate reflection or acceptance of wrongdoing on his part.

68. Mr Thomas submitted, in the alternative, that if we did not find impairment of fitness to practise, we should consider issuing a warning.

Legal advice

69. We heard and accepted legal advice on the relevant case authorities, the way in which the concept of "misconduct" should be understood and how we should assess impairment, were we to find misconduct. He confirmed our powers to issue a warning, if we were not to find impairment of fitness to practise.

Findings on misconduct

70. This is a case in which we have found, at the facts stage, that Mr Moosa fell short of what he should have done to manage the risks associated with the sale by his pharmacy of large volumes of codeine linctus. He also failed to ensure that the relevant SOP was reviewed, nor updated in a timely manner.

71. However, the Council's inspector found that, in practice, pharmacy staff were dealing appropriately with requests for products containing codeine and would likewise have

dealt with a request for codeine linctus appropriately including by use of the WWHAM questions set out in a flowchart within the SOP. Although we do not condone the fact that the SOP was not reviewed for several years beyond the planned date, we accept that the SOP mentioned codeine and that there was no obligation to specifically name codeine linctus.

72. There is no suggestion that any patient came to harm. Nor is it suggested that there was any inappropriate supply of codeine linctus to a patient.

73. Mr Moosa was cooperative with the inspector during the inspection and shared his own concerns about the level of supply of codeine linctus. He was open about his attempts to reduce sales and that these had been ineffective.

74. We find that Mr Moosa did breach certain Standards. He breached Standard 2 which includes that people receive safe and effective care when pharmacy professionals make and use records of the care provided. We have found a failure to keep records, in particular in relation to refused requests for codeine linctus. For similar reasons he breached Standard 5, which refers to having the information needed to provide appropriate care. He breached Standard 8 to the extent that, although open about his concerns during the inspection, he had not at an earlier date spoken up when he noticed a worryingly large volume of sales of codeine linctus and his attempts to control that by raising the price proved ineffective. Because of his particular responsibilities as owner, SI and RP, he also failed to show leadership by the sort of exemplary approach to reviewing the SOP which is required by Standard 9.

75. We considered the seriousness of these breaches of the Standards and whether, taking everything into account, including all of our findings of fact, Mr Moosa had committed misconduct. This was not an easy matter and we were very careful to evaluate his actions and omissions. We were minded of the threshold as set out in the relevant case authorities. Ultimately and on balance, we do not find that Mr Moosa's failings could be said to be "serious professional misconduct" having regard to *Meadow v General Medical Council [2007] 1 ALL ER 1 ("Meadow")*. We do not consider that fellow pharmacists, although they would be concerned, would regard

his conduct as "deplorable" having regard to *Nandi v General Medical Council [2004] EWHC 2317 (Admin)* as cited with approval in *Meadow*. We consider that members of the public would not be so concerned as to regard his conduct as "morally blameworthy" having regard to *Shaw v General Osteopathic Council [2015] EWHC 2721 (Admin).*

76. For all of these reasons we find that there has not been misconduct by Mr Moosa.

77. We are therefore not able to find impairment of fitness to practise but, in accordance with the legal advice, we are able to consider whether to give advice or issue a warning.

Warning

78. Our finding of no misconduct is not the end of the matter. We have found concerning omissions by Mr Moosa, amounting to a breach of the Standards. We consider that this needs to be marked. We might issue him with advice but that would not be adequate to address his failings and would not be recorded on the Register. We consider that a public declaration is necessary. A warning is partly for Mr Moosa, even though he may not intend to practise in the future, as he has informed the Council that he has retired. But a warning, in our view, is particularly necessary as a declaration for the pharmacy profession and the public, in view of the serious risks associated with codeine linctus and the need for pharmacists, especially those in a leadership role, to be alert to the need to keep procedures up to date to safeguard the public.

79. We direct that a warning be issued to Mr Moosa in the following terms:

You have been found to not adequately manage the risks associated with the sale of codeine linctus and minimise the potential for patient misuse or addiction. You also failed to ensure that your pharmacy's Standard Operating Procedures (SOPs) were updated and/or reviewed in respect of self-care and signposting and medicines liable to be abused.

It was not alleged that any patient came to harm, nor that there was any inappropriate supply of codeine linctus and there was some good practice in your pharmacy in relation to the supply of products containing codeine.

However, you breached some of the Council's Standards for Pharmacy Professionals. The Standards you breached are:

- *Standard 2 which includes that people receive safe and effective care when pharmacy professionals make and use records of the care provided.*
- *Standard 5, which refers to having the information needed to provide appropriate care.*
- *Standard 8 as, although open about your concerns during the Council's inspection of your pharmacy, you did not speak up at an earlier date when you noticed a worryingly large volume of sales of codeine linctus and your attempts to control that by raising the price proved ineffective.*
- *As owner, Superintendent and Responsible Pharmacist, you also failed to show leadership by the sort of exemplary approach to reviewing and updating the SOP which is required by Standard 9.*

It has not been found that your failings are of such a level of seriousness as to amount to misconduct and, for that reason, your fitness to practise is not impaired. However, we consider that a warning is necessary to publicly mark your failings and in order to declare and uphold standards and thereby ensure public confidence in the profession. In the light of the particular risks associated with codeine linctus, which remains available over the counter without prescription in pharmacies, it is especially important that all pharmacists are vigilant about governance procedures and record keeping to manage these risks.

This warning will be published on the Register and will be available for 12 months.