General Pharmaceutical Council

Fitness to Practise Committee

Principal Hearing

Remote hearing via Zoom

23 September 2024 - 3 October 2024

Registrants name:	Vishal Sood, Mohammed Yusuf Shabbir & Afreen Afzal
Registration number:	2080859, 2078725 & 2212896
Part of the register:	Pharmacist
Type of Case:	Misconduct
Committee Members:	Sarah Hamilton (Chair) Raj Parekh (Registrant Member) Sara Atkins (Lay member)
Secretary:	Sameen Ahmed – 23-24 September Gemma Staplehurst- 25-27 September Chelsea Smith - 30 September - 4 October
Registrants:	Present and represented by Stephen McCaffrey and Catherine Stock
General Pharmaceutical Council:	Represented by Tom Hoskins
Facts proved by admission:	Vishaal Sood - All except 4.2 Mohammed Yusuf Shabbir - All except 4.2 Afreen Afzal - All except 4.2
No case to answer:	Vishal Sood - 4.2

	Mohammed Yusuf Shabbir - 4.2
	Afreen Afzal - 4.2
Fitness to practise:	Vishal Sood - Impaired
	Mohammed Yusuf Shabbir - Impaired
	Afreen Afzal - Impaired
Sanction:	Vishal Sood - Conditions of Practice 12 months
	Mohammed Yusuf Shabbir - Conditions of Practice 12 months
	Afreen Afzal - Conditions of Practice 12 months
Interim measures:	Vishal Sood - Conditions of Practice
	Mohammed Yusuf Shabbir - Conditions of Practice
	Afreen Afzal - Conditions of Practice

This decision including any finding of facts, impairment and sanction is an appealable decision under *The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010*. Therefore, this decision will not take effect until 1 November 2024 or, if an appeal is lodged, once that appeal has been concluded. However, the interim conditions set out in the decision take/s effect immediately and will lapse when the decision takes effect or once any appeal is concluded.

Documentation

Document 1- Council's hearing bundle - Mr Sood

Document 2- Council's hearing bundle - Mr Shabbir

Document 3- Council's hearing bundle - Ms Afzal

Document 4- Council's skeleton argument

Document 5- Registrant's witness statement re facts - Mr Sood dated 20 September 2024

Document 6- Registrant's witness statement re facts- Mr Shabbir dated 19 September 2024

Document 7 - Registrant's witness statement re facts - Ms Afzal dated 21 September 2024

Document 8 - Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (March 2022)

Document 9- Registrant's written reflection re impairment - Mr Sood dated 24 September 2024

Document 10- Registrant's written reflection re impairment - Mr Shabbir dated 24 September 2024

Document 11 - Registrant's written reflection re impairment - Ms Afzal dated 24 September 2024

Witnesses

Dr C, Council's expert- gave evidence at facts stage

Ms M- Council Inspector -gave evidence at facts stage

Mr Sood, Registrant - gave evidence at impairment stage

Mr Shabbir, Registrant - gave evidence at impairment stage

Ms Afzal, Registrant - gave evidence at the impairment stage

DETERMINATION

Introduction

1. This is a Principal Hearing in respect of Mr Vishal Sood, Mr Mohammed Yusuf Shabbir and Ms Afreen Afzal ("the Registrants"), all Pharmacists registered with the General Pharmaceutical Council ("the Council"). The Registrants' registration numbers are 2080859, 2078725 and 2212896 respectively. The Registrants are present and are represented by Stephen McCaffrey and Catherine Stock. The Council is represented by Tom Hoskins.

2. In advance of the hearing the Committee had read a statement of case and skeleton argument on behalf of the Council, together with the Council's three bundles of evidence (one for each Registrant) running to 961, 962 and 951 pages respectively. The Committee also read the Registrants' witnesses statements which were served on the first day of the hearing and their written reflections which were served on day three. The Committee heard oral evidence under affirmation from two Council witnesses, and from the Registrants. The Committee heard oral submissions from Mr Hoskins, Mr McCaffrey and Ms Stock.

3. This hearing is governed by The Pharmacy Order 2010 ("the Order") and The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010 "'the Rules").

4. The statutory overarching objectives for these regulatory proceedings are:
    - To protect, promote and maintain the health, safety and well-being of the public;
    - To promote and maintain public confidence in the professions regulated by the Council; and
    - To promote and maintain proper professional standards and conduct for members of those professions.

5. The Committee also had regard to the guidance contained in the Council's *Good decision making: Fitness to practise hearings and sanction guidance* as revised March 2024.

6. A Principal Hearing has up to three stages:
    - Stage 1. Findings of Fact – the Committee determines any disputed facts.
    - Stage 2. Findings of statutory ground(s) and impairment – the Committee determines whether, on the facts as proved, a statutory ground for impairment is established and, if so, whether the Registrants' fitness to practise is currently impaired.
    - Stage 3. Sanction – the Committee considers what, if any, sanction should be applied if the Registrants' fitness to practise is found to be impaired.

The allegations (as amended)

7. The Particulars of Allegation, as amended, against Mr Sood are as follows:

    "Between around 1 August and around 14 December 2020 you, the Superintendent Pharmacist and registered pharmacist, whilst acting as a responsible pharmacist ("RP") of Vishyus Pharma Limited trading as PharmacyOnline.co.uk ("the Pharmacy"):

    1. In relation to supplies of high-risk medicines liable to abuse, misuse or overuse including Codeine Linctus (approximately 3533 bottles) and/or Phenergan (approximately 1015 bottles

and 9142 packs) and/or Cyclizine (approximately 522 packs) and/or Collis Browne (approximately 80 bottles) you failed to ensure there was robust risk management including:

1.1. monitoring supplies patients

1.2. keeping a record of OTC medicines interventions

1.3. Identifying repeat sales

1.4. preventing repeat sales and/or sales in breach of the Pharmacy's opioid policy

1.5. safeguarding vulnerable patients

1.6. managing the risks associated with the pharmacy's services against medicines liable to abuse or misuse.

2. You failed to confirm and/or ensure that the GP prescriber and/or Dr Felix service prescribers:

2.1 Followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

2.2 Were appropriately registered if necessary, with Health Improvement Scotland before prescriptions were dispensed by the Pharmacy.

3. You allowed and/or failed to prevent the GP prescriber and/or Dr Felix service prescribers prescribing contrary to the GMC Good practice in prescribing and managing medicines and devices guidance in that they prescribed in circumstances where the prescriber:

3.1 failed to obtain adequate information

3.2 failed to establish whether the patient had communication or support needs

3.3 failed to determine capacity to provide consent to treatment

3.4 failed to contact or attempt to obtain details of patients' physical health

3.5 failed to contact or attempt to obtain details of patients' mental health

3.6 failed to access and/or attempt to access patients' GP medical records and/or specialist clinic records in order to have a full picture of their physical and/or mental health, current prescribed medication and/or addiction history

3.7 failed to request a face-to-face consultation with patients in order to adequately examine the clinical need for medication

3.8 failed to adequately consider the possibility of medication dependence and misuse

3.9 failed to query with patients the frequency of requests for medication and/or the amounts requested

3.10 failed to refer patients back to their GP for appropriate assessment; and

3.11 failed to put adequate safeguards in place.

4. In relation to the PharmacyOnline's prescription service:

4.1 you failed to ensure that patients using the Pharmacy could not select a medicine and/or quantity before they had completed an appropriate consultation with the prescriber

4.2 you failed to ensure that patients were unable to amend their answers within the questionnaire when prompted to do so

4.3 you failed to ensure that you and/or the Pharmacy and/or the prescribers made an adequate record setting out how a patient not consenting to share information with their GP had been taken into account

4.4 you failed to keep and/or failed to ensure that any, or any adequate, records were kept of communications with the prescriber and/or the patients and/or other healthcare professionals.

5. In relation to the GenderGP prescriptions dispensed by the Pharmacy:

5.1 you failed to confirm and/or ensure that GenderGP was regulated in the United Kingdom

5.2 you failed to ensure that any adequate risk assessment had been carried out

5.3 you failed to ensure the Pharmacy had confirmed that the prescribers were competent to prescribe the medicine which you and/or the Pharmacy dispensed to patients

5.4 you failed to confirm and/or ensure that the prescribers followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

5.5 you failed to confirm and/or ensure that advice and/or counselling and/or monitoring was provided to patients using the GenderGP service for medicines

dispensed by the Pharmacy

5.6 you failed to ensure before entering into an agreement to dispense GenderGP prescriptions that you and/or the Pharmacy had the requisite knowledge and/or experience in gender dysphoria medication such as to dispense such medication safely and effectively.

5.7 you failed to ensure that there was a safeguarding policy in place in relation to the GenderGP patients

5.8 you failed to confirm and/or ensure that the patients had consented to their GP being contacted.

6. You failed to ensure that the services the Pharmacy provided at a distance, including the prescribing service, had been adequately audited.

7. You failed to ensure that patient records held by the Pharmacy were accessible to and/or accessed only by those with a clinical justification for doing so.

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

8. The Particulars of Allegation, as amended, against Mr Shabbir are as follows:

"Between around 1 August and around 14 December 2020 you, a registered pharmacist, whilst acting as a responsible pharmacist ("RP") of Vishyus Pharma Limited trading as PharmacyOnline.co.uk ("the Pharmacy"):

1. In relation to supplies of high-risk medicines liable to abuse, misuse or overuse including Codeine Linctus (approximately 3533 bottles) and/or Phenergan (approximately 1015 bottles and 1942 packs) and/or Cyclizine (approximately 522 packs) and/or Collis Browne (approximately 80 bottles) you failed to ensure there was robust risk management including:

1.1. monitoring supplies to patients

1.2. keeping a record of OTC medicines interventions

1.3. Identifying repeat sales

1.4. preventing repeat sales and/or sales in breach of the Pharmacy's opioid policy

1.5. safeguarding vulnerable patients

1.6. managing the risks associated with the pharmacy's services against medicines liable to abuse or misuse.

2. You failed to confirm and/or ensure that the GP prescriber and/or Dr Felix service prescribers:

2.1 Followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

2.2 Were appropriately registered if necessary, with Health Improvement Scotland before prescriptions were dispensed by the Pharmacy.

3. You allowed and/or failed to prevent the GP prescriber and/or Dr Felix service prescribers prescribing contrary to the GMC Good practice in prescribing and managing medicines and devices guidance in that they prescribed in circumstances where the prescriber:

3.1 failed to obtain adequate information

3.2 failed to establish whether the patient had communication or support needs

3.3 failed to determine capacity to provide consent to treatment

3.4 failed to contact or attempt to obtain details of patients' physical health

3.5 failed to contact or attempt to obtain details of patients' mental health

3.6 failed to access and/or attempt to access patients' GP medical records and/or specialist clinic records in order to have a full picture of their physical and/or mental health, current prescribed medication and/or addiction history

3.7 failed to request a face-to-face consultation with patients in order to adequately examine the clinical need for medication

3.8 failed to adequately consider the possibility of medication dependence and misuse

3.9 failed to query with patients the frequency of requests for medication and/or the amounts requested

3.10 failed to refer patients back to their GP for appropriate assessment; and

3.11 failed to put adequate safeguards in place.

4. In relation to the PharmacyOnline's prescription service:

4.1 you failed to ensure that patients using the Pharmacy could not select a medicine and/or quantity before they had completed an appropriate consultation with the prescriber

4.2 you failed to ensure that patients were unable to amend their answers within the questionnaire when prompted to do so

4.3 you failed to ensure that you and/or the Pharmacy and/or the prescribers made an adequate record setting out how a patient not consenting to share information with their GP had been taken into account

4.4 you failed to keep and/or failed to ensure that any, or any adequate, records were kept of communications with the prescriber and/or the patients and/or other healthcare professionals.

5. In relation to the GenderGP prescriptions dispensed by the Pharmacy:

5.1 you failed to confirm and/or ensure that GenderGP was regulated in the United Kingdom

5.2 you failed to ensure that any adequate risk assessment had been carried out

5.3 you failed to ensure the Pharmacy had confirmed that the prescribers were competent to prescribe the medicine which you and/or the Pharmacy dispensed to patients

5.4 you failed to confirm and/or ensure that the prescribers followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

5.5 you failed to confirm and/or ensure that advice and/or counselling and/or monitoring was provided to patients using the GenderGP service for medicines dispensed by the Pharmacy

5.6 you failed to ensure before entering into an agreement to dispense GenderGP prescriptions that you and/or the Pharmacy had the requisite knowledge and/or experience in gender dysphoria medication such as to dispense such medication safely and effectively.

5.7 you failed to ensure that there was a safeguarding policy in place in relation to the GenderGP patients

5.8 you failed to confirm and/or ensure that the patients had consented to their GP being contacted.

6. You failed to ensure that the services the Pharmacy provided at a distance, including the prescribing service, had been adequately audited.

7. You failed to ensure that patient records held by the Pharmacy were accessible to and/or accessed only by those with a clinical justification for doing so.

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

9. The Particulars of Allegation, as amended, against Ms Afzal are as follows:

"Between around 1 August and around 14 December 2020 you, a registered pharmacist, whilst acting as a responsible pharmacist ("RP") of Vishyus Pharma Limited trading as PharmacyOnline.co.uk ("the Pharmacy"):

1. In relation to supplies of high-risk medicines liable to abuse, misuse or overuse including Codeine Linctus (approximately 3533 bottles) and/or Phenergan (approximately 1015 bottles and 1942 packs) and/or Cyclizine (approximately 522 packs) and/or Collis Browne (approximately 80 bottles) you failed to ensure there was robust risk management including:

1.1. monitoring supplies to patients

1.2. keeping a record of OTC medicines interventions

1.3. Identifying repeat sales

1.4. preventing repeat sales and/or sales in breach of the Pharmacy's opioid policy

1.5. safeguarding vulnerable patients

1.6. managing the risks associated with the pharmacy's services against medicines liable to abuse or misuse.

2. You failed to confirm and/or ensure that the GP prescriber and/or Dr Felix service prescribers:

2.1 Followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

2.2 Were appropriately registered if necessary, with Health Improvement Scotland before prescriptions were dispensed by the Pharmacy.

3. You allowed and/or failed to prevent the GP prescriber and/or Dr Felix service prescribers prescribing contrary to the GMC Good practice in prescribing and managing medicines and devices guidance in that they prescribed in circumstances where the prescriber:

3.1 failed to obtain adequate information

3.2 failed to establish whether the patient had communication or support needs

3.3 failed to determine capacity to provide consent to treatment

3.4 failed to contact or attempt to obtain details of patients' physical health

3.5 failed to contact or attempt to obtain details of patients' mental health

3.6 failed to access and/or attempt to access patients' GP medical records and/or specialist clinic records in order to have a full picture of their physical and/or mental health, current prescribed medication and/or addiction history

3.7 failed to request a face-to-face consultation with patients in order to adequately examine the clinical need for medication

3.8 failed to adequately consider the possibility of medication dependence and misuse

3.9 failed to query with patients the frequency of requests for medication and/or the amounts requested

3.10 failed to refer patients back to their GP for appropriate assessment; and

3.11 failed to put adequate safeguards in place.

4. In relation to the PharmacyOnline's prescription service:

4.1 you failed to ensure that patients using the Pharmacy could not select a medicine and/or quantity before they had completed an appropriate consultation with the prescriber

4.2 you failed to ensure that patients were unable to amend their answers within the questionnaire when prompted to do so

4.3 you failed to ensure that you and/or the Pharmacy and/or the prescribers made an adequate record setting out how a patient not consenting to share information with their GP had been taken into account

4.4 you failed to keep and/or failed to ensure that any, or any adequate, records were kept of communications with the prescriber and/or the patients and/or other healthcare professionals.

5. In relation to the GenderGP prescriptions dispensed by the Pharmacy:

5.1 you failed to confirm and/or ensure that GenderGP was regulated in the United Kingdom

5.2 you failed to ensure that any adequate risk assessment had been carried out

5.3 you failed to ensure the Pharmacy had confirmed that the prescribers were competent to prescribe the medicine which you and/or the Pharmacy dispensed to patients

5.4 you failed to confirm and/or ensure that the prescribers followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

5.5 you failed to confirm and/or ensure that advice and/or counselling and/or monitoring was provided to patients using the GenderGP service for medicines dispensed by the Pharmacy

5.6 you failed to ensure before entering into an agreement to dispense GenderGP prescriptions that you and/or the Pharmacy had the requisite knowledge and/or experience in gender dysphoria medication such as to dispense such medication safely and effectively.

5.7 you failed to ensure that there was a safeguarding policy in place in relation to the GenderGP patients

5.8 you failed to confirm and/or ensure that the patients had consented to their GP being contacted.

6. You failed to ensure that the services the Pharmacy provided at a distance, including the prescribing service, had been adequately audited.

7. You failed to ensure that patient records held by the Pharmacy were accessible to and/or accessed only by those with a clinical justification for doing so.

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

Preliminary matters

Application to amend the particulars of allegation

10. Mr Hoskins applied to slightly amend four of the Particulars of Allegation which were minor grammatical alterations pursuant to Rule 41. He submitted that these amendments could be made without prejudicing the fairness of the proceedings, as required by Rule 41 but instead sought to provide greater clarity prior to the issue of admissions being addressed. The Registrants had been put on notice of these proposed amendments and made no objection.

11. In addition, having now seen the Registrants' witness statements, Mr Hoskins applied to amend Particular 1.3, which originally pleaded *"identifying and/or keeping a record of, repeat sales."* He applied to delete the words "*and/or keeping a record of",* as he accepted the Registrants' submission that they had kept records of repeat sales, and they had provided those records to the Council. The Registrants did not oppose that proposed amendment either.

12. The Committee agreed to the proposed amendments, noting that these were fair and better reflected the evidence in this case.

Application for joinder

13. Mr Hoskins also made an application to join all three fitness to practise cases pursuant to Rule 27, which provides that unless there is a risk of prejudice to the fairness of proceedings,

fitness to practise allegations against two or more persons may be considered at the same hearing where:

- the allegation against each person concerned arises out of the same circumstances; or
- in the view of the Committee, a joint hearing is necessary or desirable.

14. Mr Hoskins submitted that the allegations plainly arise out of the same circumstances and the charges faced by each Registrant are identical save that in respect of Mr Sood there is the additional fact of his occupying the Superintendent Pharmacist ("SI") position. He said that evidentially the case advanced by the Council is identical for each Registrant and arises factually from a single Pharmacy at which each Registrant worked, and a series of inspections and interventions conducted by the Council. Mr Hoskins said that the witnesses to be called are the same for each Registrant.

15. Mr Hoskins further submitted that a joint hearing is both necessary and desirable, to prevent the resources of the Council, Registrants and witnesses being expended three times over; to easily ensure consistency in decision making across identical cases; and to avoid delay where valuable hearing time has been set aside together with the wider public interest in expeditious disposal of cases.

16. Mr McCaffrey indicated that his clients consented to the joinder application.

17. For all of the reasons set out by Mr Hoskins, the Committee agreed that the three cases should be joined and heard together.

Hearing partially in private

18. The Committee agreed that any reference to personal and family matters pertaining to Mr Shabbir and Ms Afzal would be heard in private. The remainder of the hearing would be heard in public.

Admission

19. At the start of this hearing Mr McCaffrey confirmed that the Registrants admitted all of the Particulars of Allegation except Particular 4.2, and the Committee therefore announced those parts of the Allegation proved by way of admission in accordance with the Rules.

Background

20. Mr Hoskins then opened the case for the Council and outlined the background. The allegations against the Registrants arise from their roles working at a new online pharmacy with the web address PharmacyOnline.co.uk ("the Pharmacy"). It was first registered with the Council on 1 August 2019 and, following a period of preparation to commence operations, began trading in August 2020. The Pharmacy's monthly turnover had increased from £2,500 in August to £89,000 by November 2020. The directors and owners of the company were Mr Sood and Mr Shabbir. Ms Afzal, although the wife of Mr Shabbir, did not occupy any corporate office within the Pharmacy. The Pharmacy also employed one member of staff to work on their IT resources, but he did not fulfil any pharmaceutical role within the Pharmacy at the relevant time.

21. Mr Sood was the SI of the Pharmacy, responsible for ensuring safe systems were in place. As the SI, Mr Sood would check the orders and prescriptions and confirm ID checks remotely from a location off-site. There were also times when he was the Responsible Pharmacist ("RP") undertaking dispensing duties on-site. Although not physically present on site at the point of the Council's unannounced inspection on 14 December 2020, thereafter Mr Sood played an active role in corresponding with the Council's Inspector Ms M regarding the concerns arising from the inspection. Mr Sood left the company in September 2021 and is now employed at a pharmacy in Liverpool working full time as a locum pharmacist.

22. Mr Shabbir was one of the RPs at the Pharmacy. He was most commonly responsible for the dispensing of medications as he was physically located most often at the site and was present during the various visits from Ms M. Today he remains an owner of the business and is practising as a pharmacist at the Pharmacy one to two days a week, alongside other business activities.

23. Ms Afzal is married to Mr Shabbir. She occupied the role of RP at the Pharmacy part-time and, like both Mr Shabbir and Mr Sood, dispensed medication from the site in Clydebank. [PRIVATE].

24. The Pharmacy had three main streams of work. Firstly, it sold over the counter ("OTC") medications to customers who had completed an online request. Secondly, it dispensed prescription-only medication ("POMs") according to private prescriptions issued by the Pharmacy's own online prescribing service by a single GP (who mainly worked at an aesthetic clinic also based in Glasgow). Thirdly, the Pharmacy also dispensed to UK based patients according to private prescriptions issued from around October 2020 by another online entity called GenderGP based in Bucharest, Romania, which was an organisation dealing with conditions such as gender dysphoria.

25. Prior to commencing trading in August 2020, the Pharmacy had commissioned an external doctor to produce an assessment questionnaire for its prescribing service and had purchased assessment forms and policies for OTC medications from an external provider, but which were approved by Mr Sood and Mr Shabbir. Ms Afzal had no role in the design or construction of the systems or forms in place at the Pharmacy. Customers seeking OTC medication would complete a product-specific questionnaire via the Pharmacy website which would then be reviewed, generally off site by Mr Sood. Historical checks of the client's previous orders as well as ID checks were supposed to be carried out and at some stage a Sales of Opioid Policy was introduced, which stated that no repeat orders within a six-month period would be permitted. The Pharmacy also had a Standard Operating Procedure ("SOP") called "*Monitoring Fraudulent Activity in Opioid Order*" and a blacklist of people who it was said would not be permitted to supply medicines. The Pharmacy's systems were supposed to be designed so as to block repeat orders, orders in too high a multiple or combinations of orders such as opioids (including codeine linctus) and promethazine (including Phenergan). Once the checks were completed the RP would assemble and check the order for dispatch via the post.

26. For prescription medication, none of these Registrants were Pharmacist Independent Prescribers ("PIPs"). As with OTC medications, customers would access the prescribing

service online via a questionnaire. They would select the desired medication and quantity of the required medication and then fill out a product specific questionnaire. They were asked whether they gave consent for the Pharmacy to contact their GP, which in the majority of cases was withheld. The questionnaire went straight to the GP prescriber. If the medication was authorised, the prescriber would send an electronically generated prescription to the Pharmacy, which would then dispense the medication.

27. The Council received information from the Medicines and Healthcare products Regulatory Agency ("MRHA") that the Pharmacy had been ordering high volumes of both codeine linctus (a controlled opioid drug known to be liable to abuse and addiction but is provided to relieve the symptoms of a dry cough) and Phenergan (a brand of promethazine), an antihistamine medication used to treat allergies or motion sickness also known to be liable to abuse. These two medications can be mixed together to create a commonly abused substance called "Purple Drank", which Mr Shabbir was aware of. The Pharmacy's ordering patterns were the reason for the Council's unannounced visit on 14 December 2020.

28. As part of the inspection process the Council looked at 7,602 transactions and found that the amount of rejected orders for OTC medication was small, that the sale of codeine linctus and Phenergan in combination was not prevented, that codeine was sold repeatedly and that medications risked being sold in excessive quantities. Ms M considered that the Pharmacy did not have adequate systems in place to appropriately manage or monitor the sales and supply of these sorts of medications, and there were no risk assessments or audits in place. Ms M also identified that the Pharmacy's online-prescribing service was not registered with Health Improvement Scotland ("HIS") as it was required to be.

29. In addition, during the 14 December 2020 inspection Ms M was told by Mr Shabbir that he was under the impression that GenderGP was regulated by the Care Quality Commission ("CQC"), when it was, in fact, not. Mr Shabbir told Ms M he had requested details of policies, procedures and prescribing practices of GenderGP, but these had not been received.

30. On 17 December 2020, the Council issued the Pharmacy with a Notice of Conditions restricting it from supplying codeine linctus, medicines containing promethazine and any

medicines containing cyclizine (a medication used to treat and prevent nausea, vomiting and dizziness due to motion sickness or vertigo.) That notice remains in force today.

31. The inspection report which was created following the 14 December 2020 visit stated that the Pharmacy had not met the following Standards for Registered Pharmacies:

    - *1.1 - The risks associated with providing pharmacy services are identified and managed*
    - *1.2 - The safety and quality of pharmacy services are reviewed and monitored*
    - *1.6 - All necessary records for the safe provision of pharmacy services are kept and maintained*
    - *1.8 - Children and vulnerable adults are safeguarded*
    - *2.2 - Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training*
    - *3.1 - Premises are safe, clean, properly maintained and suitable for the pharmacy services provided*
    - *4.2 - Pharmacy services are managed and delivered safely and effectively*
    - *4.3 - Medicines and medical devices are:*
      • *stored securely*
      • *disposed of safely and securely*

32. An Improvement Notice was served on the Pharmacy on 29 January 2021, citing:
    "*A system wide failure in the governance and management of risk at the pharmacy. This includes gaps in required policies and procedures including safeguarding. And there is no evidence that the policies they do have are implemented into the day-to-day running of the pharmacy*".

33. The Improvement Notice required an action plan of seven elements be undertaken by the Pharmacy. During the period February 2021 to 4 May 2021, the Pharmacy worked with Ms M to remedy the identified failings, including engaging external consultants and PIPs to improve

governance. The Pharmacy is now under the new ownership of Express Healthcare Limited with a different SI.

Witness evidence

Dr C

34. The Council called Dr C as its medical expert. She had provided two reports to the Council dated 15 May 2023 and 11 January 2024. Dr C gave oral evidence in line with her reports. Her first report had the subject matter "*Safety of Prescribing Prescription Only Medications from Information Provided by Patient SelfReported Online Questionnaires and Potential Risk to Patients"* and within the report Dr C stated that in the past five to six years she had written several reports for the General Medical Council, ("GMC") on a variety of topics including Remote Prescribing. She contributed to the GMC's updated Guidance on Remote Prescribing in 2020. Dr C provided a useful summary to the background for her report, which read as follows:

"*The Council's concerns in this case…centre on a remote prescribing model operated by online pharmacies, which involve a questionnaire-based assessment operating through a web-based platform. The Council are currently investigating a large number of cases that involve online pharmacies. These companies often own a registered pharmacy premises and operate a website through which the prescribing and dispensing services are accessed. Members of the public access the website and complete an on-line questionnaire, supplemented in some instances by standardised self-reporting scales. The completed documentation is then passed to a prescriber who makes a prescribing decision. Where a prescription is issued, the medication is then dispensed and dispatched to the patient by post or courier. The Council are concerned that medication is routinely being prescribed and issued without any discussion with the patient and without any access to information from the patients GP or other objective evidence of their diagnosis or condition. These online pharmacies provide a wide range of medications which, include medicines liable to abuse, overuse or misuse, or where there is a risk of addiction and ongoing monitoring is important, and medicines that require ongoing monitoring or management. Prescribers do not have access to the patient's General Practice records.*

Patients are usually asked to consent to information being shared with their General Practitioner. The Council are concerned that, if consent to share data was refused, it is common for prescriptions to be issued, nonetheless. Although there is often a facility for prescribers to email or call patients, there is evidence, gathered by the Council, that this happens very infrequently. The evidence obtained by the Council's Inspection teams has demonstrated that it is very common for medication to be prescribed and dispensed based solely on the completed questionnaire and without any discussion between prescriber and patient, or clinical lead and patient. The Council are concerned that these systems present an inherently weak model that puts patients at risk of harm."

35. This first report was a generic report commenting on the practices of remote prescribing. Dr C summarised her opinion as follows:
"*In my opinion, the model used by these online pharmacies is unsafe insofar as prescribing within the requirements and limits of the framework was not in accordance with the competencies as described in the Royal Pharmaceutical Society's Competency Framework."*

36. In her first report Dr C warned against prescribing in situations where an online self-reported questionnaire is used, especially one which can prompt responses. She also highlighted the risks associated with a lack of face-to-face interaction between patient and prescriber, a lack of access or interaction with the patient's own GP's notes, together with a lack of ongoing monitoring which includes the sorts of drugs prescribed by the Pharmacy.

37. Dr C's second report dated 11 January 2024 had the subject matter "*Doctors prescribing with Pharmacists dispensing within, or overseeing, online pharmacy models that rely on questionnaires in order to prescribe.".* She stated:
"*I have written a number of Expert Reports on remote prescribing and have had access to several different online questionnaires. These questionnaires tend to have YES/NO answers, drop down boxes, and rely wholly on a patient honestly and competently giving a full and clinically accurate account of their medication conditions and current prescriptions. Patients are often asked if they are seeing or have seen their own GP or a secondary care specialist, if they are currently under any investigations, the results of previous investigations, previous medications tried and current medication including frequency and dosage.*

It is not possible to see a patient's GP notes, assess capacity and competence, (through observation and history taking), examine patients to see if signs and symptoms stated fit the clinical history given, assess any possible drug interactions or addiction and mental health issues as the prescriber can only rely on the information in front of them which has been provided by the patient and therefore not corroborated.

In my opinion, the self-populated questionnaires do not give sufficient clinical information to allow for an adequate patient assessment. In order for such an assessment, in my opinion, the Clinician requires access to the medical records or a discussion with the patient's own GP/Specialist as well as potential face to face patient assessment to confirm current physical or mental health, by video-link or, at least, by discussion over the telephone.

38. The majority of Dr C's written evidence dealt with online prescribing, by both doctors and PIPs. In the present case the Registrants were not prescribing themselves. However, Dr C was asked by the Council to specifically comment on the role of the SI/RP in relation to online prescribing. In her second report, Dr C stated:

"*Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, Including on the Internet sets out guidance to SIs/RPs when providing online services and recommends a number of risk assessments that need to be carried out."*

39. However, during cross-examination, Dr C conceded that the Council's guidance she was referring to from April 2019 (which is the only guidance she was aware of when she wrote her reports) did not actually refer at all to the SI or RP, but instead to the duties of pharmacy owners. The guidance stated:

"*As the pharmacy owner, you are responsible for making sure this guidance is followed. Everyone in the pharmacy team, including managers with delegated responsibility and the responsible pharmacist, should understand the guidance and be aware of their responsibilities to follow it".*

40. Dr C maintained that:

"*In my opinion, SI/ RP have a large and important role in ensuring that the prescribing doctor follows UK prescribing guidance including the GMC Good practice in prescribing and managing medicines and devices as Council guidance echoes GMC guidance."*

41. In her oral evidence Dr C said that as a GP she would never prescribe from a self-populated online questionnaire due to the "*complete lack of dialogue with the patient".* She would also be concerned as she would not understand the patient, their medication history (including possible mental health and addiction issues) and would not have received informed consent from them. At the very least Dr C would want the patient to give consent so that their doctor could be told what medication had been prescribed. She is of the opinion that this online model of prescribing is unsafe and has come across cases where this model has led to patient deaths (although there is no such evidence in this case).

42. Dr C was also of the opinion that the duty on pharmacists to check the doctor's prescribing decision is even more important with the online model in light of the absence of any patient assessment.

43. During cross-examination by Mr McCaffrey, Dr C said that she was not aware of the Council's updated guidance regarding online pharmacies from 2021 or 2022. She conceded that a lot of her answers to the Council's questions in her second report were based on the Council's guidance regarding prescribing at a distance. She agreed that her second report was about prescribing, and not dispensing. She agreed to McCaffrey's points that the majority of the questions posed by the Council were all about RP/SI responsibilities. Initially she said that the April 2019 guidance referred to duties of the SI and RP, but she later conceded that she was mistaken about this, and there was no specific mention of them in the document.

Ms M

44. Ms M is an inspector for the Council and also gave oral evidence at this hearing. Her witness statement is dated 4 August 2022. She confirmed that she had only inspected one online pharmacy prior to this one. The trigger for the inspection was the MHRA's information regarding the sales of codeine, and that was Ms M's main focus during the inspection. She said that she would expect an online pharmacy to have a risk assessment regarding its activities, produce policies and procedures based on the risks it identified, and then have monitoring and audit systems in place to ensure that the risks were being dealt with. She called this the "*cycle of clinical governance".*

45. Ms M said that in December 2020, the main difference between community and online pharmacies was that the community risks were well known. She said that the online service model was not well established, which is why she would have expected any pharmacy opening up online to undertake a risk assessment, especially with regards to its prescribing service.

46. Ms M confirmed that the Pharmacy was registered in August 2019. The Council's guidance had come into force in April 2019, but Ms M does not know how well publicised or visible it was, other than being on the Council's website. She accepted that there was a lack of awareness amongst pharmacists regarding this guidance. Generally, pharmacists/pharmacy owners thought that opening an online pharmacy would be quite a straightforward process, and there was a lack of awareness of the risks involved from moving from a community to an online model. She said that updated guidance was issued by the Council in April 2021 and then again in March 2022 as the Council was learning about the risks involved and wanted to support this sector.

47. Ms M clarified that the RP is responsible for the day to day safe running of the pharmacy, ensuring a safe system of work and responding to incidents. The pharmacy owner has a duty to support the SI, who is "*ultimately accountable".*

48. In her witness statement Ms M gave details of the data provided to the Council by the MHRA. This included that the Pharmacy had purchased the following:
    - codeine linctus formulations (sugar containing and sugar free):
        - In July 2020, 25 bottles;
        - In September 2020, 104 bottles.
    - Phenergan elixir bottles:
        - In August 2020, 12 bottles;
        - In September 2020, 11 bottles.
    - Phenergan 25 mg tablets:
        - In August 2020, 14 bottles; (containing 56 tablets);
        - In September 2020, 10 boxes (containing 56 tablets).

49. Ms M explained that codeine linctus is used to treat a dry, unproductive cough and is classified as a 'pharmacy' (P) medicine, which means it can only be sold from registered pharmacy premises under the supervision of a pharmacist (the Committee is aware that this has now changed and codeine linctus is now a POM). Codeine linctus is known to be liable to misuse and addiction. She said that, for this reason, many pharmacies choose not to stock it, and if they do, it is not usually visible on the shelves in a pharmacy. She was not aware of any guidance on clinical use of codeine linctus for Covid. She was not aware that it was regularly being given as a treatment for "Covid cough" in 2020, as has been suggested by the Registrants in their witness statements.

50. Ms M was aware during the inspection in December 2020 that HIS had carried out a regulatory visit the preceding month and had requested that certain policies be drafted by the Pharmacy, including safeguarding, GDPR, online prescribing and consent. Mr Shabbir told her that he was still developing these at the time of the Council's inspection.

51. Following the inspection, Mr Shabbir provided Ms M with details of the Pharmacy's sales of codeine linctus, Phenergan tablets, Phenergan liquid and cyclizine tablets with a total of 7,602 transactions. Codeine linctus, Phenergan 25mg tablets Phenergan elixir 1014 (100ml), and cyclizine 50mg tablets (100) were in the top six OTC medications sold. The data showed that since August 2020, the Pharmacy had sold:
    - 2,281 bottles of sugared codeine linctus,
    - 1,252 bottles of sugar-free codeine linctus,
    - 1,942 x 56 Phenergan 25mg tablets,
    - 1,014 Phenergan elixir.
    - 522 x 100 cyclizine 50mg tablets, and
    - 80 x Collis Browne, (which contains morphine and peppermint oil.)

52. Ms M said that her colleagues at the Council analysed the sales records provided by Mr Shabbir, which confirmed that there were:

- Five transactions where both codeine and Phenergan (either tablets or linctus) had been supplied to the same person and/ or to the same address. This was out of a total of 445 transactions.
- 13 repeat transactions of codeine linctus seen for the same person/ or the same address in the 445 transactions. There were no transactions of more than one codeine linctus being supplied at one time. Repeat sales were made after days, weeks or months apart and not in line with the Pharmacy's opioid policy of no less than six monthly intervals.
- Two instances of multiple transactions on the same SAGE payment card number but for different people/and or at different but similar addresses. The emails submitted were similar but not the same.
- Instances where the person had attempted to purchase two bottles/packs of either Phenergan or codeine linctus and whilst this was rejected, they had been able to make a purchase of one bottle at a later date.
- Instances where the person had attempted to purchase Phenergan and codeine linctus together, where one of the quantities was two bottles/packs and the other one pack. The quantity of two was rejected but the quantity of one still went through as approved.
- 20 attempts between August 2020 and December 2020 to purchase cyclizine tablets by two people living next door to each other. There were eight orders rejected due to two packs being requested with 12 packs being supplied.
- The number of rejections by the Pharmacy was 564, so 7.42%, but this was only orders of two bottles/packs. 100% of these orders were rejected.

53. Ms M's main findings from her inspection were as follows:

- The Pharmacy's governance arrangements and management of risk were inadequate.
- The Pharmacy was unable to provide the Council with the assurance that the supplies of medicines it was making to patients on prescriptions from the overseas on-line provider were always safe and appropriate;
- The Pharmacy's website was arranged so a person could choose a prescription only medicine ("POM") and quantity before an appropriate consultation with a prescriber;

- The Pharmacy did not have the necessary safeguards in place to prevent inappropriate sales of OTC medicines, in that it did not adequately restrict the sales of medicines liable to abuse and misuse;
- The Pharmacy did not have adequate safeguards to ensure it always provided its services safely.

54. Ms M said that the Pharmacy website linked sales using “Google analytics”. The RP, Mr Shabbir, told her that he was not aware that this happened. On the page for codeine linctus there were links to buy Phenergan 25mg tablets and Phenergan elixir, (i.e. there would be a picture of codeine linctus, and underneath there would be a picture of Phenergan with a message to indicate that the customer may also be interested in purchasing Phenergan.) Mr Shabbir told Ms M that he was aware of ‘Purple Drank’, which is produced when mixing codeine linctus and Phenergan together. The Pharmacy charged £19.99 for codeine linctus. Mr Shabbir stated that the high price was intended to act as a deterrent. In her oral evidence Ms M explained that Purple Drank is highly sought after on the streets, as it gives people a euphoric high and is very addictive.

55. Ms M was told that Mr Sood worked off-site and carried out the review of individual assessment forms submitted by patients for 'P Medicine' sales. Mr Shabbir stated that he reviewed the person’s user history. The form was product specific and provided the pharmacist with the information that the customer had confirmed. Mr Shabbir stated that the history check provided the pharmacist with information about the requested product as well as previous sales for other products. The pharmacists could either approve or reject the orders. The RP assembled and checked the orders that the SI, Mr Sood, had approved.

56. Ms M was told that the Pharmacy had an ‘Opioid’ policy. It stated that there would be no authorised repeat orders for opioid based products within a six-month period, and opioid products should not be sold alongside any products containing promethazine. The Pharmacy used blockers to restrict access to high-risk products including codeine and Phenergan. Ms M found that there was no evidence that the Pharmacy was monitoring sales to ensure that it was complying with the Opioid policy.

57. Ms M was told that Mr Shabbir spent two hours every day verifying the ID checks as per the 'Monitoring Fraudulent Activity on Opioid Orders SOP'. She was told that the Pharmacy had spent £10,000 purchasing software from LexisNexis to assist with this. However, she found that the Pharmacy was not monitoring the ID check results.

58. Mr Shabbir told Ms M that they had a 'blacklist' of people who regularly failed the checks they had in place. The list was located above the dispensing bench. The list provided in the Council's bundle contained the names of 11 customers.

59. Ms M was told that one GP provided the online prescribing service. He mostly worked at a private aesthetics clinic in Glasgow. Mr Shabbir referred to a prescribing policy that was being updated in response to an HIS inspection which had taken place on 13 November 2020. It was not available at the time of Ms M's inspection. Mr Shabbir explained that HIS had asked them to improve or introduce other policies and procedures by the end of December 2020.

60. Ms M stated in her written statement that the Pharmacy's website enabled patients using the prescribing service to select the medicine and its quantity before having a consultation with a prescriber. Individuals were asked to complete the assessment questionnaire form. When asked, the individual selected their blood pressure level from a drop-down menu; High/Normal/Low. Mr Shabbir did not believe the prescriber verified the readings that were provided. Ms M said that individuals could also change their answers on the assessment questionnaire form when prompted to do so, and there was no audit trail of this. If individuals tried to submit a form for a second time, it would show on the Pharmacy's system and the pharmacist would message them. The pharmacists did not keep records to show that they had contacted people. In her oral evidence Ms M clarified that when she was referring to amending patient questionnaires, she was referring to OTC medications, and not POMs. At the inspection she was concentrating on codeine linctus and Phenergan. It was the clinical specialist at the Council who later started looking at the prescribing service. Ms M could not remember how she came to the conclusion in her report that patients could change their answers on the assessment questionnaire form regarding the prescribing service.

61. The forms asked patients if they would like the Pharmacy to inform their GP of their treatment. Mr Shabbir believed that only around five to ten percent of people said 'yes'. The Pharmacy could not produce records to verify this, and they did not monitor the people who said 'no'. They did not investigate why people did not allow the Pharmacy to inform their GP.

62. Mr Shabbir advised Ms M that the Chief Operating Officer at GenderGP contacted the Pharmacy to arrange private prescriptions for dispensing. The Pharmacy had been dispensing prescriptions for two months since the middle of October 2020. One prescriber, who was based in the EU, in Bucharest, wrote the prescriptions. The Pharmacy had dispensed 260 prescriptions from GenderGP. 170 supplies were for children under 18 years of age. Samples showed that six supplies had been made to children aged nine, ten and 11. The pharmacists did not see treatment summaries. Medicines prescribed included Triptolerin injection, Synarel nasal spray and Testogel gel.

63. Mr Shabbir had asked GenderGP for an information pack to include the prescriber's and counsellors' details. This had not been received by the Pharmacy. Mr Shabbir also produced a 'Service Level Agreement'. This was a template with another pharmacy's name on it. It had not been populated with the relevant information. The Pharmacy did not have any information about GenderGP's policies or guidelines.

64. The Pharmacy had not carried out any risk assessments of the GenderGP clinic or the medicines that were prescribed and dispensed. Mr Shabbir stated that he believed the service to be safe, as the CQC regulated the service (this was not correct). He also believed the medication regimes to be safe and appropriate. Ms M considered that Mr Shabbir did not have any specialist knowledge about gender dysphoria. The Pharmacy had not identified knowledge gaps or completed any relevant training, although Ms M was not able to say what training was available in 2020 for gender dysphoria. Nevertheless, she was concerned that the Pharmacy was dispensing items such as Synarel "*outside of its licensed indication"*, so for a condition it was not usually prescribed for, without any insight into this topic - "*they were simply making supplies at face value".* Prescriptions were not being challenged and there was no discussion between the pharmacist and the prescriber, including the issue of consent.

65. In her oral evidence Ms M said that during the inspection she was told by Mr Shabbir that they intended to stop dispensing for GenderGP. Ms M confirmed that the Monitoring Fraudulent Activity Flowchart was dated 17 November 2020, yet the sales data provided by Mr Shabbir showed that sales of codeine linctus and Phenergan continued up until 13 December 2020, the day before the inspection. Ms M also confirmed that the Pharmacy was not able to produce any records showing when requests for medication were rejected or that the pharmacists were challenging the prescriber's decisions.

66. Shortly after the inspection the Council imposed conditions, preventing the Pharmacy from selling medication which contained codeine linctus and promethazine. Ms M said that this was necessary due to the volumes being sold and the seriousness of the breaches of policies.

67. Ms M said that the only pharmacist she met on the day of the inspection was Mr Shabbir, and he engaged fully, and was open and honest. She received an email from Mr Sood shortly afterwards where "*there was some challenge initially",* but thereafter he engaged and provided some documentation, but this had not been completed for all services. Ms M said that there were no policies for the dispensing of the prescriptions for GenderGP, including the risk of off-licence prescribing or a safeguarding policy. The Pharmacy stopped dispensing for GenderGP. By February 2021 an updated OTC sales procedure/policy had not been submitted, even though the Pharmacy was subject to conditions and had also made the decision to stop sales of Collis Browne mixture. No training records were provided as evidence that the policies/procedures had been read by all staff. The Pharmacy had employed a PIP but had not provided any evidence of induction or whether the PIP had read the Pharmacy's policies and procedures. The Pharmacy had not submitted updated procedure documentation relating to monitoring the quality of services, even though it stated that it had implemented a wider range of audits. Audit information relating to the supply of OTC and POM medicines had been provided but it was incomplete.

68. Ms M also stated that the Pharmacy had said that it had reviewed its safeguarding policy but had not provided evidence of an up-to-date policy to safeguard children and vulnerable adults. In addition, the Pharmacy had made changes to obtaining people's GP details for the online prescribing service and stated that if they did not have these details then they would

no longer supply any “long-term monitored POM”. The Pharmacy had not provided an updated policy /procedure with further details of this. It did not provide information about what those medicines were and how it would audit and monitor compliance with its own policy. Ms M was told that an audit identified that the medical prescriber was not meeting the needs of “pharmacovigilance” and the Pharmacy employed a PIP to replace them.

69. The Council held an internal meeting on 8 March 2021 and noted that the Pharmacy did not seem to have grasped what they needed to do. Ms M said that there appeared to be a lack of understanding and lack of progress towards achieving the requisite standards set out in the Improvement Notice. In cross-examination Ms M said that the first risk assessment which the Pharmacy produced after the inspection did not make sense and did not meet the Council’s standards.

70. On 26 March 2021, a virtual meeting took place with Mr Sood (the SI/RP), Mr Shabbir (the RP), a Clinical Governance Pharmacist who had been appointed by the Pharmacy, Ms M and two of her colleagues. The meeting was arranged to discuss progress against the Improvement Notice, and to provide an opportunity for the Pharmacy's staff to ask questions. Following this meeting Ms M received additional documentation from the Clinical Governance Pharmacist. Ms M said that by that stage the Pharmacy had become proactive in getting support by bringing onboard external entities including the Clinical Governance Pharmacist, as they realised that they needed help. The Clinical Governance Pharmacist was able to produce a risk assessment very quickly once she came onboard which impressed Ms M.

71. On 23 April 2021, Ms M conducted a follow-up visit to the Pharmacy. She said that by that stage the external support had had a significant impact. They had gone back to basics, had produced the necessary policies and had started implementing them. They were doing a significant amount of auditing. Ms M said that “*it really turned around after that point”.* The Pharmacy was focusing on the completion of new risk assessments for the individual services it provided. The new risk assessments were documented, and high-risk medicines and the conditions they were being used to treat were being prioritised.

72. By the time she wrote her witness statement in August 2022, Ms M considered that the mitigating actions were appropriate and were managing the risks to an acceptable residual level. The Pharmacy was implementing extra safeguards into its practices to make sure that identified risks were being managed. Team members had been trained to follow the policies and procedures according to their roles and responsibilities. This included the new PIP and team members that carried out administrative tasks. The Pharmacy had updated its policies to show the methodology and sampling protocols for the proactive and regular review of the quality of services it was providing. It was keeping records of completed audits and the actions taken to improve the safety of its services. The sample size and scope of auditing had improved and was more proportionate for the volume and risk profile of medicines supplies made. The ongoing monitoring of services included records of near miss errors, incidents and complaints and the learning taken from these.

73. The Pharmacy had recurring clinical governance meetings where issues regarding prescribing were discussed. Ms M gave one example where there was evidence from the meeting minutes that issues relating to treatment reviews of Saxenda (weight loss medication) had been highlighted and actions assigned to mitigate these issues. In response, the prescribing platform had been programmed to automatically send review questionnaires via email at four, eight and 12 weeks to patients using Saxenda which were then assessed by the pharmacist to ensure patients were appropriately managed. The Clinical Governance Pharmacist had planned an audit to ensure that responses to the review questionnaires were captured, recorded and patients' answers were appropriately assessed to determine whether the treatment should continue or not. The planned audit report would include patients' response rate, quality of record keeping and the pharmacist reviews. In cross-examination Ms M said that there was no definition of "regular" with respect to audit, and it would depend on the volume of sales. For example, in community pharmacy the accepted practice is that near miss audits are carried out monthly.

74. Ms M noted that the Pharmacy had an up-to-date policy to safeguard children and vulnerable adults which was relevant to the services it provided. All pharmacy team members had been trained to follow the policy. This included administrative staff who answered the phone and carried out non-dispensing tasks.

75. The Pharmacy could show that it had restricted access to the prescribing platform and was meeting the requirements of the Human Medicines Regulations for a prescriber's electronic signature. The Pharmacy had implemented measures to manage risks associated with the supply of medicines which required ongoing monitoring. For example, obtaining a patient's consent to sharing information with their GP was mandatory for the supply of asthma inhalers to ensure that the patient's condition and response to treatment were being monitored appropriately.

76. Ms M carried out a further inspection in December 2022 and found that the Pharmacy was showing full compliance with all standards.

Registrants' half-time submission of no case to answer

77. At the close of the Council's case Mr McCaffrey, on behalf of the Registrants, made a submission of no case to answer pursuant to Rule 31(8) regarding Particular 4.2 of the Allegation, which reads:

    "4. In relation to the PharmacyOnline's prescription service:
    4.2 you failed to ensure that patients were unable to amend their answers within the questionnaire when prompted to do so".

78. Mr McCaffrey submitted that the stem of this allegation makes it clear that it relates to the prescribing service. He relied upon Ms M's oral evidence at this hearing where she said that when she was talking about the ability of patients to amend their answers on the questionnaire, she was referring only to OTC medication, and not POMs. On this basis, Mr McCaffrey submitted that it would be impossible for the Committee to find Particular 4.2 of the Allegation proved. He referred to the relevant case of *R v Galbraith [1981] 1 WLR 1039.*

79. Mr Hoskins, on behalf of the Council, indicated that it did not oppose the application. He took the Committee through the relevant passages of Ms M's written evidence and the inspection report following the inspection on 14 December 2020. He conceded that none of this evidence specifically referred to patients being able to amend their answers when

prompted in relation to the prescribing service, so for POMs. In her oral evidence at this hearing, Ms M had clarified that during the inspection she does not believe that she accessed the questionnaire for the POMs, and she does not know how she came to the conclusion that the criticism regarding amending the questionnaire referred to POMs. She said that her focus during the inspection was the OTC medication, including codeine linctus.

80. Mr Hoskins said that there was some evidence in the Council's bundle regarding Particular 4.2 but, in accordance with the test in *Galbraith*, taken at its highest it was so weak or tenuous that a tribunal could not find it proved, taking into account Ms M's oral evidence.

Decision

81. Rule 31(8) states that after the Council has closed its case on facts:
"*The registrant may make submissions regarding whether sufficient evidence has been adduced to find the facts proved or to support a finding of impairment, and the Committee must consider and announce its decision as to whether any such submissions should be upheld."*

82. The case of *Galbraith* considered the circumstances where (in that case a criminal court) a party may make an application to stop the case, and referred to two distinct limbs:

- Limb 1 - there is no evidence upon which the jury could convict; or
- Limb 2 - there is some evidence, but it is so poor that it would be unsafe to leave it to the jury, it is of a tenuous character, for example because of inherent weakness or vagueness or because it is inconsistent with other evidence.

83. It is not for this Committee to find facts at this stage, but to consider, when taking the case at its highest, the tests in *Galbraith* and Rule 31(8) are made out in relation to Particular 4.2

84. The Committee considered a full review of all of the evidence received so far in relation to Particular 4.2. It also noted that all three Registrants have always denied this allegation. In his written response to the Council, Mr Sood stated "*We have never allowed this to happen for medical questions – only the disclaimer which had to be ticked. If the form was submitted and*

it was not ticked it would identify that it did need to be ticked and allow the form to be submitted again."

85. In her oral evidence, Ms M confirmed that in the inspection report she wrote:
"*The pharmacy uses a questionnaire to assess whether sales of medicines are appropriate. But this informs the customer when an answer they have given will prevent the sale, which may mean the person completing the questionnaire is more likely to change their response in order to obtain the medicine they want."*

86. However, she clarified that she had in mind the OTC medication when she wrote that part of the report and was not referring to the POMs. So, although there was some evidence in the Council's bundle to support Particular 4.2, taken at its highest, having heard Ms M's oral evidence, it was so inherently weak, this Committee could not find it proved.

87. In light of this, the Committee therefore found that, when applying the tests in *Galbraith* and Rule 31(8), there was insufficient evidence which had been adduced to find Particular 4.2 proved.

88. Accordingly, Mr McCaffrey's application was granted, and the Committee found no case to answer for Particular 4.2

Decision on facts

89. The Committee has already found the majority of the Particulars of Allegation proved by way of admission. However, it has set out below all the Particulars as Dr C and Ms M gave evidence (both written and oral) in relation to each Particular, which may be relevant at a later stage in these proceedings.

Particulars 1.1-1.6 - admitted

1. In relation to supplies of high-risk medicines liable to abuse, misuse or overuse including Codeine Linctus (approximately 3533 bottles) and/or Phenergan (approximately 1015 bottles and 1942 packs) and/or Cyclizine (approximately 522 packs) and/or Collis Browne (approximately 80 bottles) you failed to ensure there was robust risk management including:

1.1. monitoring supplies to patients

1.2. keeping a record of OTC medicines interventions

1.3. Identifying repeat sales

1.4. preventing repeat sales and/or sales in breach of the Pharmacy's opioid policy

1.5. safeguarding vulnerable patients

1.6. managing the risks associated with the pharmacy's services against medicines liable to abuse or misuse.

90. This Particular of Allegation reflects the concerns that were identified at and following the inspection on 14 December 2020 in relation to the functioning of the systems designed to prevent the risk of dispensing high risk OTC medicines such as codeine linctus and Phenergan, together with Cyclizine (an anti-nausea medication which is liable to abuse due to its euphoric effects and is dangerous in combination with alcohol), and Collins Browne, which contains morphine and peppermint oil.

91. Sales data revealed that these made up the vast majority of 7,602 transactions in terms of both volume and value (from around £630 in August 2020 to £57,000 by the time of the inspection).

92. In her witness statement Ms M analysed the sales data in detail. She noted that the amount of rejected orders for OTC medication was small. Ms M noted that the sale of codeine linctus and Phenergan in combination was not prevented. There were 15 transactions of the 445 transaction sub-set involving different people in which both codeine and Phenergan were sold to the same person or same address. Additionally, there were instances where simultaneous orders of both medications were submitted where one medicine was being bought in quantities of greater than one. The order would be rejected but only to the extent of the multiple quantity aspect of the order, the single quantity order proceeding, notwithstanding the motives of the customer would be clear. She said that this was aggravated by the fact that on the Pharmacy's website page for codeine linctus there were links to buy Phenergan.

93. Ms M said that codeine was sold repeatedly: there were 13 repeat sales of codeine linctus to the same person or address of the 445 transaction subset examined, not simultaneously but days, weeks or months apart, and contrary to the Pharmacy's own opioid policy. The Registrants say that these sales occurred during the time of Covid, when codeine linctus which was recommended for treatment of covid cough. However, the Committee notes the NICE guidance which said that the first line of treatment should be home remedies such as honey, and codeine linctus should only be supplied where the cough is very distressing, and even then the pharmacist should consider the addiction potential of the medication. Ms M did not have any data to say whether there had been a substantial increase in the supply of codeine linctus in 2020 due to covid cough, although anecdotally she had heard that there was an increase in demand for the online sale of it. The Committee considered that the risk management for the sale of codeine linctus was not sufficient as the Pharmacy was selling large quantities of the medication without any monitoring or audit findings.

94. Ms M also noted that medications risked being sold in excessive quantities. Following efforts by customers to purchase multiple codeine linctus or Phenergan that were rejected, the Pharmacy still dispensed lower quantities to the same customers at a later date. There were 20 attempts by two people with adjacent addresses to purchase Cyclizine of which 12 orders were fulfilled, the eight rejected were because multiple quantities were requested, rather than because of the similarity of addresses or repeat orders.

95. The Registrants state that there were some systems in place but accept that those systems were not robust enough with respect to risk management. They say that they were attempting to address this pre-inspection in December 2020 and continued to do so post-inspection. Ms M gave clear and cogent evidence that the improvement did not really start to take place until the Clinical Governance Pharmacist was appointed in 2021.

Particulars 2.1-2.2 - admitted

2. You failed to confirm and/or ensure that the GP prescriber and/or Dr Felix service prescribers:

2.1 Followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

2.2 Were appropriately registered if necessary, with Health Improvement Scotland before prescriptions were dispensed by the Pharmacy.

96. Ms M identified at the point of the 14 December 2020 inspection that the Pharmacy's online-prescribing service was not registered with HIS, as it was required to be. She was told by Mr Shabbir that HIS had conducted an inspection on 13 November 2020 and had required that the Pharmacy make improvements.

97. Ms M stated that there was no effort to ensure that the prescribing done by the GP and/or Dr Felix (where the prescribing GP also worked) was within national prescribing guidance for the UK. Such obligations are set out in the evidence of Dr C who warned against prescribing in situations where an online self-reported questionnaire is used, there is a lack of face-to-face interaction between patient and prescriber and a lack of access or interaction with the patient's own GP's notes, together with a lack of ongoing monitoring. During cross-examination Dr C accepted that it was permitted for prescribers to prescribe online without a face-to-face consultation. Her main concern was that the Pharmacy's model meant that there was virtually no interaction between the patient and the prescriber, the patient could self-select the medication including dosage, and there was no requirement for the patient to consent to information being sent to their GP.

98. The Registrants admitted these Particulars of Allegation, stating that they under-estimated the need to ensure that the prescribers were following UK prescribing guidance including GMC Good practice. They applied a community setting approach and realise now that this was not enough for the online setting.

99. Although Dr C gave evidence that she would never prescribe based on an online questionnaire alone, the Committee acknowledges that this is not unlawful. However, pharmacists must ensure that the prescribers are following UK prescribing guidance, including *the General Medical Council guidance for Good practice in prescribing and*

managing medicines and devices ("GMC guidance"), which advises against this method without any further safeguards.

Particulars 3.1-3.11 - admitted

3. You allowed and/or failed to prevent the GP prescriber and/or Dr Felix service prescribers prescribing contrary to the GMC Good practice in prescribing and managing medicines and devices guidance in that they prescribed in circumstances where the prescriber:

3.1 failed to obtain adequate information

3.2 failed to establish whether the patient had communication or support needs

3.3 failed to determine capacity to provide consent to treatment

3.4 failed to contact or attempt to obtain details of patients' physical health

3.5 failed to contact or attempt to obtain details of patients' mental health

3.6 failed to access and/or attempt to access patients' GP medical records and/or specialist clinic records in order to have a full picture of their physical and/or mental health, current prescribed medication and/or addiction history

3.7 failed to request a face-to-face consultation with patients in order to adequately examine the clinical need for medication

3.8 failed to adequately consider the possibility of medication dependence and misuse

3.9 failed to query with patients the frequency of requests for medication and/or the amounts requested

3.10 failed to refer patients back to their GP for appropriate assessment; and

3.11 failed to put adequate safeguards in place.

100. These Particulars of Allegation specify the areas where, in the context of the dispensing following the online prescriptions provided by the Pharmacy's external GP and/or acting on behalf of Dr Felix, the system in place in the Pharmacy fell short. These shortcomings were highlighted in Ms M's witness statement and in Dr C's reports. Ms M noted that the Pharmacy had no facility to obtain information from the customer's GP or other relevant healthcare professionals. There was no access to Emergency Care Records or Summary Care Records and the Pharmacy did not have any other way of verifying the information provided

in the questionnaire. There was no facility for face-to-face consultations and any communication between the prescriber and patient was not habitually recorded.

101. The Registrants said that they underestimated the need for a greater level of scrutiny with respect to prescribers' decisions.

Particular 4.1, 4.3 and 4.4 - admitted

4. In relation to the PharmacyOnline's prescription service:

4.1 you failed to ensure that patients using the Pharmacy could not select a medicine and/or quantity before they had completed an appropriate consultation with the prescriber

4.3 you failed to ensure that you and/or the Pharmacy and/or the prescribers made an adequate record setting out how a patient not consenting to share information with their GP had been taken into account

4.4 you failed to keep and/or failed to ensure that any, or any adequate, records were kept of communications with the prescriber and/or the patients and/or other healthcare professionals.

102. During her inspection Ms M found that customers could pre-select the medication and quantity they sought prior to the information being sent to the prescriber, which was contrary to the Council's guidance. The form asked if the prospective customer gave consent to contact their regular GP which, according to Mr Shabbir, was refused in between 90-95% of cases without any further enquiry.

103. The Council stated that any further discussions between the Pharmacy and the customer were not recorded. Mr Sood and Mr Shabbir asserted that records were made but not with every customer in line with usual practice in the community setting. Ms M said that no evidence was provided by the Pharmacy to show that the pharmacists were recording their own interventions or conversations between prescriber and pharmacist.

Particular 4.2 - no case to answer

4. In relation to the PharmacyOnline's prescription service:

4.2 you failed to ensure that patients were unable to amend their answers within the questionnaire when prompted to do so

Particulars 5.1-5.8 - admitted

5. In relation to the GenderGP prescriptions dispensed by the Pharmacy:

5.1 you failed to confirm and/or ensure that GenderGP was regulated in the United Kingdom

5.2 you failed to ensure that any adequate risk assessment had been carried out

5.3 you failed to ensure the Pharmacy had confirmed that the prescribers were competent to prescribe the medicine which you and/or the Pharmacy dispensed to patients

5.4 you failed to confirm and/or ensure that the prescribers followed UK prescribing guidance including GMC Good practice in prescribing and managing medicines and devices

5.5 You failed to confirm and/or ensure that advice and/or counselling and/or monitoring was provided to patients using the GenderGP service for medicines dispensed by the Pharmacy

5.6 you failed to ensure before entering into an agreement to dispense GenderGP prescriptions that you and/or the Pharmacy had the requisite knowledge and/or experience in gender dysphoria medication such as to dispense such medication safely and effectively.

5.7 you failed to ensure that there was a safeguarding policy in place in relation to the GenderGP patients

5.8 you failed to confirm and/or ensure that the patients had consented to their GP being contacted.

104. From October 2020, the Pharmacy had been fulfilling the prescriptions generated to UK customers of a Romanian based website offering gender confirmation prescriptions and

treatment for gender dysphoria. Over the period relevant to the allegations, the Pharmacy dispensed 260 prescriptions, including 170 to children as young as nine. The prescriptions (samples of which were provided at the time of the inspection) were issued in the EU.

105. During the 14 December 2020 inspection, Ms M was told by Mr Shabbir that he was under the impression that GenderGP was regulated by the CQC, when it was in fact not, contrary to the Council's guidance to ensure the appropriate regulation of that business. The Registrants produced a Service Level Agreement for a different pharmacy and no information about the policies, procedures or prescribing practices of GenderGP. Mr Shabbir had indicated to Ms M that this sort of information had been requested together with information about the prescribers and counsellors, but that this had not been received. There was no evidence of risk assessments having been undertaken. Ms M noted that there was no expertise on the part of the staff in respect of the specialised and complex conditions being addressed by GenderGP. In respect of counselling, the information from GenderGP indicated that this was entirely optional on the part of the patient, and although the prescriptions each indicated that counselling had been received there was no evidence of this being checked. In fact, each prescription stated that the Pharmacy should not contact the patient.

106. Although the prescriber in the EU was not GMC registered, the oversight of prescribing service was part of the Registrants' role as the RP, and they had a duty to ensure that any prescribing to patients was safe. The RP had a duty to ensure that the prescribers were not prescribing in a manner which was contrary to the principles set out in the GMC guidance.

Particular 6 - admitted

6. You failed to ensure that the services the Pharmacy provided at a distance, including the prescribing service, had been adequately audited.

107. The Council's guidance required that when providing services at a distance, regular audits should be undertaken. Ms M said that there was generally an absence of evidence of this having taken place and the audits that had been done (namely a single sample of 20 POMs) had no apparent rationale or logic to the sample size or approach. She conceded that there was no definition of "regular" in the April 2019 guidance, and it would depend on the volume

of POMs being supplied. However, the Committee notes that there do not appear to have been any audits at all undertaken prior to the December 2020 inspection other than for the 20 POMs.

Particular 7 - admitted

7. You failed to ensure that patient records held by the Pharmacy were accessible to and/or accessed only by those with a clinical justification for doing so.

108. Ms M found that there was unrestricted access to sensitive, confidential information. Mr Shabbir knew the doctor's log-on credentials and could access the system under the doctor's name. She said that the audit trail to show who was accessing and using the different parts of the system was not robust. There was a non-healthcare professional (IT) who also had unrestricted access.

Impairment

109. Having found the majority of the facts proved, the Committee now turns to the issue of impairment by reason of misconduct. At this stage of the proceedings there is no burden or standard of proof.

110. At this stage in the proceedings the Registrants gave oral evidence. A summary of their written evidence is set out below.

Mr Shabbir

111. Mr Shabbir gave oral evidence under affirmation. His written statement is dated 19 September 2024, and he also provided a written reflection dated 24 September 2024. He accepted that there were failings in the design and implementation of the governance systems around Pharmacy Online and that, as an owner and an RP, he had obligations to make sure that these systems were implemented and were effective. While the 2019 guidance did not specifically mention the responsibilities of an RP, Mr Shabbir accepted that the spirit of the guidance applied to all professionals working in the organisation. He said that he failed in meeting these obligations and made this clear to Ms M from the outset.

Although he believed that there was a lack of clarity about exactly how these systems should work and what meets the criteria for terms such as '*frequency', 'regular'* and *'adequacy*' he said that the responsibility lay with him to sort these issues out - "*But at that time trying to figure out what was a legal matter, what was a guidance matter and how everything blended together was extremely difficult. Colleagues all seemed to have differing views on the application of the principles and what they meant in practice".*

112. Mr Shabbir's experience had been as a locum pharmacist for Boots since he qualified in 2012. He realises now that he was entirely naïve about the very different model of online pharmacy. He believed that he had the skills, knowledge and experience to run this new business, but quickly realised that he was out of his depth.

113. Mr Shabbir said that prior to Ms M's visit in December 2020 they knew they were struggling - they had been visited by HIS in November 2020 and their systems and procedures were found wanting. He said that the Pharmacy did not anticipate the *"huge and exponential demand"* for online services. They thought that following the process adopted by the large multiples like Boots would be the best way forward. He realises now that this only worked if the way they operated was the same as Boots. They failed to adapt those processes to their own business model.

114. Mr Shabbir wished to point out that he sought to engage fully with the inspection on 14 December 2020. He handed over everything he could that day to Ms M including sales data, access to all areas and broken-down sales and stock details. He said that he was open and honest with Ms M and conceded that the service was not up to the standard he wanted.

115. Mr Shabbir stated that after the initial inspection in December 2020, rather than seeking to put things right whilst continuing to trade, they should have stopped the service, corrected the problems and then put it back online, but *"we really did think we were managing and coping better than we were."*

116. Regarding the sales of codeine linctus, Mr Shabbir said that they knew this had dramatically increased. If it had not been for Covid this would have been of far greater concern than it

was, given the risks associated with it. He said that the medication was being actively promoted (prior to them operating) as a recommended medication for Covid cough. He relied upon an article entitled "*Covid 19: managing symptoms in the community"* dated 22 July 2020 which discussed the advice from the National Institute for Health and Care Excellence ("NICE"). This included advice that "*First line management is with home remedies such as honey, and only if the cough is very distressing should we consider options like codeine linctus."* The Table accompanying the advice for treatments warned "*consider addiction potential for codeine linctus".*

117. Mr Shabbir said that the high number of sales of codeine linctus in and of itself, during Covid and soon after starting operations, did not flag as it otherwise clearly would have. However, due to the risks, they knew that they needed to have a more robust system so that they could assure themselves and others that those seeking it were doing so because of Covid advice and not using that as an excuse. In his witness statement he said that they did implement a policy and it worked. There was a sharp decline in approvals and an incline in rejections in the first two weeks of November 2020, prior to the Council's visit.

118. Regarding the GenderGP work, Mr Shabbir stated that this was also addressed by the Pharmacy prior to the Council's visit. When they began fulfilling prescriptions, they were given assurances around GenderGP's setup and their expertise. They sought advice from Dr Helen Webberley, director of GenderGP, who was a "*recognised specialist GP in the field at the time"*. However, Mr Shabbir accepts that more specific information was not forthcoming as time went on and he failed to conduct proper checks and ask probing questions about others involved in GenderGP (e.g. the actual prescriber and the counsellors.) He accepts that he failed with respect to the Service Level Agreement, and the policies they requested did not materialise. Among other concerns was an inability to get any training for themselves in the field. Following a Board Meeting they decided they had not received the assurances they had sought and in November 2020 they ceased dispensing the prescriptions as they did not feel comfortable continuing. Mr Shabbir accepts that he was not satisfying the guidance of 2019. Although they were insured and had assured themselves as to the main GP's expertise *"we lost sight of our own need to be satisfied of our actions.*"

119. On 4 May 2021 Mr Shabbir was advised that the requirement of the Council's Improvement Notice had been met. He said that in August 2021 they were tasked with further changes to the website. Guidance from the Council was becoming clearer and more updated and the April 2019 guidance had been replaced with new guidance in April 2021, which he said was getting clearer and more prescriptive which was of a huge benefit to the Pharmacy. In September 2021 the dedicated Clinical Governance Pharmacist took over as the SI in place of Mr Sood, who left the business at that point.

120. In December 2021 the company sought new premises in a larger warehouse and moved there in January 2022, having taken time to make sure that everything was in place. Focus remained on safe practice and good governance standards. In September 2022 they hired an ex-Council inspector to act as an independent check on all policies, SOPs and compliance/governance issues - "*the idea was to stop group think and maintain an 'independent' check on our operations*". In December 2022 they had a Council inspection by two inspectors including Ms M. All standards were met and there were no issues. That same month they purchased an NHS distance selling pharmacy in Manchester as they continued to expand, "*always replicating what we had learned and looking for ways to improve and develop.*" In October 2023 they purchased a physical pharmacy in Stirling to keep a balance with community pharmacy – not just online pharmacy. In April 2024 they purchased a physical pharmacy in Glasgow and an NHS Hub in Glasgow. The latter had failed an inspection when they took it over. Using their experience and knowledge from their own mistakes it passed re-inspection in July 2024 and is operating safely and in compliance.

121. Mr Shabbir highlighted one important change to their business - any prescribers who worked with the company could not be based solely in private practice. They must have a post in an NHS setting too to make sure they are fully regulated and up to date with all regulations and changes.

122. In his written reflection Mr Shabbir accepted that his actions had the potential to cause harm, due to the lack of governance. He said that in respect of OTC medication, which was considered high risk, clearly the lack of systems could have led to a risk of harm to users. At the time, he placed too much reliance on codeine linctus being the recommended choice for

covid cough and that this had caused such an increase in purchases. He said that their policies and systems were not robust enough to prevent potential misuse. He also accepted that his failings could potentially impact on the reputation of his profession and in turn lead to a loss of public trust and confidence in pharmacists.

123. In terms of remediation, Mr Shabbir said that he has undertaken continuous CPD, and has received in-person training on how to manage the risks associated with prescribing remotely and the decision making on which medicines are appropriate for supply on the internet. In July 2023, he joined the Digital Clinical Excellence Network ("DICE"), which works closely with the Council, MHRA, GMC and other professional bodies to help shape the future of digital healthcare.

124. Mr Shabbir said that if he could go back to 2019, before launching the project into the public domain, he would have brought on board/worked with an experienced team in the online pharmacy field to help with all aspects of running an online pharmacy, such as SOPs, policies and risk assessments. He now knows that liaising with his regulator is extremely important in such a new sector. He would not hesitate to seek help and feedback from individuals more experienced than he when venturing into a field in which he had limited experience.

125. In his written reflection, Mr Shabbir said that his action plan for the future is:

- *Ensure regular reminders on new guidance*
- *Signed up to notifications from the specialist inspectors – for example he is now aware that a few days ago, the GPHC has proposed extra safeguards for online services and that a consultation is taking place*
- *Annual CPD to address gaps in knowledge – he prefers in person training from experts as online is such a niche field*
- *Mentorship from experience individuals*
- *Planning proactively*
- *Embracing feedback*
- *Working with the correct people who have the correct knowledge*

126. In his oral evidence Mr Shabbir said that he had been *"pretty naive"* to think that he could take his skill set from community pharmacy and replicate it for online pharmacy.

127. Regarding the NICE Covid guidance, Mr Shabbir said that codeine linctus was "first line" treatment. He said that the online questionnaire would have asked customers what else they had tried but admitted that even if they said nothing (including honey) the Pharmacy would still have probably sold them codeine linctus anyway.

128. Regarding GenderGP, Mr Shabbir said that he should have been more probing about its set up. He treated it just like a community pharmacy. He accepts now that this was a specialised area of care. Although each private prescription stated that the patient had had counselling, Mr Shabbir said that he did not carry out any check to satisfy himself that this was correct; he accepts that there were no safeguards in place.

129. With regards to CPD, Ms Shabbir explained that he received one training session from the external consultant Jackie Peck in 2021, and one session from an ex-Council inspector in 2022 regarding online risks and which medicines are safe to sell online. He said that he has found the Council's specialist inspector really helpful, and he is not afraid to pick up the phone to the Council's inspectors (including the specialist inspector) and ask for advice nowadays. DICE has created guidelines for online pharmacies, and he has been to about five or six of their meetings.

130. During cross examination Mr Shabbir said that he studied at University with Mr Sood, but they had never worked together before this business venture. Two versions of the website were built but scrapped during the planning phase as they did not provide a good customer experience. They then bought an "*out of the box"* solution which was already used by other pharmacies.

131. Regarding the Council's April 2019 guidance, Mr Shabbir said that he read it and tried to interpret it; he now accepts that it was his interpretation which was wrong. He accepts that it gave advice including that he should review his risk assessment regularly, or when there was a significant change in circumstances (such as taking on the prescriptions for GenderGP.) He

also accepts that the guidance said he should carry out audits regularly, and the frequency of these would depend on the activity. He believed that they did carry out a “reactive review/audit” of the sales of codeine linctus (whereas Mr Sood agreed with the Council that no such audit took place prior to the December 2020 inspection).

132. Regarding HIS, Mr Shabbir maintained that there was confusion - HIS approved the Pharmacy's policies whereas the Council said they were not good enough. Mr Shabbir was asked about risk assessments. Mr Hoskins referred him to Ms M’s evidence and her inspection report which stated that there were no risk assessments at the time of the inspection. Mr Shabbir said that they did have a risk assessment, but it was not available in paper form to give to Ms M at the time of the inspection. He said it was online, and if Ms M had asked to see it, he would have printed it off for her. He was unable to explain why he did not send her a copy on receipt of her draft report, or comment on this issue, although he accepted that, in any event, the risk assessment they did have was not good enough.

133. Mr Shabbir said that they introduced the Monitoring Fraudulent Activity Flowchart SOP because they became aware that customers were committing fraud in order to purchase codeine linctus. In his witness statement he had said that this was effective, and the number of approvals went down once it was introduced and the number of rejections increased. However, in his oral evidence he admitted that following the first week after the introduction of the policy the number of rejections started decreasing and the approval rate also started on an upwards trajectory again. He was also unable to explain why the total number of sales dropped at the time the policy was introduced. He said that they just could not cope with the volumes; he was getting up around 5am most days and was spending at least two hours a day going through the data, but it was not enough.

134. Mr Shabbir said in his statement that he was grateful that no patients came to any harm as a result of his actions. He assumes that if they had, the patient or GP would have reported this to the Pharmacy. He accepts that these were high-risk medicines being supplied, and that there was the potential for significant harm.

135. Finally, Mr Shabbir said that they have not requested for the condition regarding codeine linctus to be lifted (although the Council has said they would do so if asked), as he never intends to sell that medication again.

Mr Sood

136. Mr Sood's witness statement is dated 20 September 2024 and replicates Mr Shabbir's statement to a large extent. He gave oral evidence for over two hours. He also accepts that whilst the 2019 guidance did not specify the responsibilities of an SI, the spirit of the guidance must apply to all professionals working in the organisation and they clearly applied to owners and the SI. He referred to Mr Shabbir's detailed statement and said that this "*present[s] a fair and accurate assessment of my position as co-owner and I too accept my responsibility for both the failings and the remedial actions undertaken."*

137. In September 2021 Mr Sood left the company for several reasons. Firstly, he was geographically separate from the central hub of the business (he lived in Liverpool) and recognised that this had been a factor in their failings. While it was an online business, he formed the view that to maintain the high standards of governance they had by then achieved, the SI and governance posts needed to be on site, and he could not do this. Secondly, he felt that it was in the best interests of the business for there to be a fresh start moving forward with a new SI. They had achieved robust levels of governance by that stage and made the decision to bring in dedicated governance posts. He felt that he had no choice but to relinquish his interests. Mr Sood moved back to community pharmacy and now works as a locum for five days a week at Central Pharmacy in Liverpool.

138. Mr Sood's written reflection dated 24 September 2024 also largely mirrors that of Mr Shabbir's. Mr Sood also accepted that the lack of systems in respect of high-risk OTC medication could have led to a risk of harm, and they did not ensure that the GPs were prescribing within guidelines in regard to the online service. Similarly, with GenderGP, they were over reliant on the expertise of the prescriber and did not have enough focus on their own knowledge and experience.

139. Mr Sood said that he has reflected a great deal both professionally and personally. He has specifically turned his attention and energy to scrutiny of SOPs at all the companies he has been engaged with and has realised how they differ from one organisation to another. He said that an SI has a particular duty to manage compliance with SOPs, and this is not simply a paper exercise, but a responsibility to ensure that they are live working documents which, if adhered to, ensure safe and effective practice and are invaluable tools to audit and evaluate risk.

140. Mr Sood has also been responsible for the supervision of a pharmacy student who is sitting their professional registration exam next year. He believes that this has been a good learning experience for him to "*get back to basics".* This is his third pre-registration student. He has not, as yet, undertaken any further superintendent roles since leaving Pharmacy Online. He feels that he underestimated his role and whilst he believes that he had a wealth of knowledge and experience going into the project, he fell short at times. He said that this has had a profound effect on him. He felt that he needed to consolidate his skills and knowledge over a prolonged period of time, which is what he has done over the last few years.

141. Mr Sood said that through research and study, he has realised that the role of SI is not a "ceremonial one", but requires a vast amount of experience, knowledge and confidence. He has made a point of studying more modules via the Centre for Pharmacy Postgraduate Education ("CPPE") to further enhance his knowledge. Having reflected on this issue, Mr Sood has decided that he would not undertake a superintendent role again *"until I am ready."* In his oral evidence he said that he does not think he would apply for another SI role in the next five years, partly because he still feels he is lacking in knowledge, but also due to the commitments [PRIVATE].

142. Mr Sood's action plan is as follows:

- *Keep his knowledge up to date with all things related to regulation e.g. The new update proposed by the GPhC on regulation for online pharmacies and safeguarding*
- *Keep up to date with all his CPD needs and gaps in knowledge that he identifies through forward planning*

- *Continue to guide and mentor his pre-registration student and give back to the pharmacy community*
- *Continue to talk to professionals in the pharmacy world and actively engage with regulators*
- *Accepting critical and constructive feedback in all areas of his practice*

143. In his oral evidence Mr Sood said that he felt that he let himself and the Pharmacy down as the SI. He conceded that he now realises there were "*glaring"* gaps in his knowledge, and he did not have the skill set needed to be an SI. He left the company in September 2021 as he realised that he was not in a position to lead it, and they got someone more suitable to replace him. He accepts that when he first responded to the inspection findings, he was slightly more challenging with Ms M than Mr Shabbir was, which he attributes to his "ego".

144. Mr Sood acknowledged in his oral evidence that he was not present in the Pharmacy enough, partly due to Covid restrictions, and partly due to [PRIVATE]. He probably went there once or twice a month between August and December 2020. He was quite reliant on Mr Shabbir to point out the deficiencies "*on the ground".*

145. Regarding GenderGP, Mr Sood said that he never spoke to Dr Webberly, the director of the company. The extent of his research was reading online about the company. He accepts that he did not do his due diligence on the clinic and he did not research the condition of gender dysphoria.

Ms Afzal

146. Ms Afzal's witness statement is dated 21 September 2024. She gave oral evidence under affirmation for around two hours. She is married to Mr Shabbir. Her witness statement is shorter than the other Registrants, which to some extent reflects her lesser role in the company. She qualified in 2014 and worked as a locum for around five pharmacies on a regular basis up until 2020. She worked as an RP at the Pharmacy from September 2020 up until [PRIVATE] in December 2020, but was never an owner of the business, and she did not get involved in setting it up. She worked there to allow her husband Mr Shabbir to "*sort out the governance issues".* [PRIVATE] by that stage she did not work there full time - probably a

total of 10 days, and then only part of each day. She was really there to do the tasks which Mr Shabbir had not got round to, such as endorsing prescriptions and putting orders away.

147. Nevertheless, Ms Afzal accepts that as a pharmacist, she had a responsibility to ensure safe and effective care for her service users. She also appreciates that as an RP she had a duty and responsibility to ensure the safe and effective running of the service on that day and to further ensure that the dispensing of medication was safe and that accurate records were kept.

148. Ms Afzal said that she is now back working as a locum around twice a month [PRIVATE].

149. Ms Afzal's written reflection was somewhat shorter than the other two Registrants. She says that she was not involved in the business after December 2020. In terms of remediation, since her career break from pharmacy, she has read and reviewed the up-to-date guidance for online pharmacies and reflected on her role as an RP in an online setting and in the community.

150. Ms Afzal's action plan reads as follows:

• *She will ensure that she keeps up to date with all new guidance related to community and online pharmacy and to include this in her CPD as a learning experience .*

• *She has signed up to frequent updates which gives her all the latest developments in the pharmacy, and she also participates in pharmacy group chats with other pharmacists which helps her keep up to date with the pharmacy world*

151. In her oral evidence Ms Afzal said that she had a large gap in her knowledge of online pharmacy when she started working at the Pharmacy in September 2020. She had not read the April 2019 guidance issued by the Council and assumed that the policies and procedures which Mr Sood and Mr Shabbir had in place were sufficient. If she were to ever work again in online pharmacy she would check that appropriate risk assessments, audits and folders were in place. When she worked as a locum in community pharmacy before 2020, she never had the need to raise clinical concerns regarding governance as those pharmacies were compliant.

152. During cross-examination Ms Afzal was asked about GenderGP. She agreed that around 140 of the 256 prescriptions inspected by Ms M had her signature on them but said that she was "*just endorsing them*" - it was Mr Shabbir who had dispensed the medication. She had seen private prescriptions for treatment for gender dysphoria before when she worked in community pharmacy. She accepted Mr Hoskins' suggestion that a private prescription for this "*challenging"* condition which came from abroad should have raised red flags, and she should have scrutinised the prescriptions more. Instead, she just took them at face value, although she did think to herself that she had not realised there was so much demand for this medication. She believes that pharmacists in this country should have guidelines and training on this topic.

153. Ms Afzal was also asked about codeine linctus. She had not come across "Purple Drank" in 2020, but knew about the risks of codeine, that it was addictive in nature. She said that she did question the owners about the fact that there were so many orders for codeine linctus (she was concerned about this), but they told her that this was due to customers requiring medication for covid cough. She said that she had the blacklist of customers in front of her on the bench and she checked this every time she dispensed codeine linctus. She was not given a copy of the Monitoring Fraudulent Activity Flowchart and did not know anything about that. She knew that Mr Shabbir and Mr Sood were working in the background to catch fraudulent customers, but she now accepts that the system had major flaws. She did not realise how bad things were until they got the letter from the Council following the December 2020 inspection.

154. Following her yearlong [PRIVATE] Ms Afzal returned to working as a locum for the regular community pharmacies where she had worked prior to 2020, doing a couple of shifts a month. She said that she much prefers community work, including the patient contact and interaction with GPs. She has no plans to ever return to online pharmacy as she does not enjoy it.

155. Regarding the impact of her conduct, Ms Afzal said that there was the potential to cause harm, including drug misuse, overdose and addiction. She also accepted that her actions would have damaged the reputation of her profession.

Decision

156. In reaching its decision on impairment the Committee considered all the evidence and information before it at this stage and the previous stage of the proceedings, together with the written submissions of Mr Hoskins and Mr McCaffrey.

157. The Committee considered the question of impairment in two separate stages. Firstly, it considered whether the Registrants' actions which have been found proved constitute the statutory ground of misconduct for the purposes of the fitness to practise criteria.

158. The case law is clear that not every failing amounts to misconduct: it has to be serious, the type of behaviour that other members of the profession would regard as well below the expected standards. In the case of Roylance *v GMC (No.2) [2000] 1 AC 311* by Mr Walker, Lord Clyde said that 'misconduct' was:

"a word of general effect, involving some act or omission which falls short of what would be proper in the circumstances. The standard of propriety may often be found by reference to the rules and standards ordinarily required to be followed…in the particular circumstances…And such falling short must be serious."

159. Further, in the case of *Remedy UK Ltd v General Medical Council [2010] EWHC 1245 (Admin)* it was said that:

"Misconduct is of two principal kinds. It may involve sufficiently serious misconduct in the exercise of professional practice such that it can properly be described as misconduct going to fitness to practise. Second, it can involve conduct of a morally culpable or otherwise disgraceful kind which may, and often will, occur outside the course of professional practice, but which brings disgrace upon the doctor and thereby prejudices the reputation of the profession."

160. In this case it is the first type of misconduct that is alleged, as it involved the Registrants' exercise of professional practice.

Council's submissions on misconduct

161. It is submitted by the Council that the Registrants breached the following of the Council's Standards for pharmacy professionals dated May 2017:

- Standard 1: Pharmacy professionals must provide person centred care
- Standard 2: Pharmacy professionals must work in partnership with others
- Standard 3: Pharmacy professionals must communicate effectively
- Standard 5: Pharmacy professionals must use their professional judgement
- Standard 8: Pharmacy Professionals must speak up when they have concerns or when things go wrong.

162. It is further submitted that the Council's guidance for registered pharmacies providing pharmacy services at a distance, (April 2019) provided within Principle 1 significant duties in respect of governance including risk assessments, audit and record keeping. Principle 2 required staff to be properly trained and competent to provide medicines safely. Mr Hoskins submitted that this was breached by the Registrants due to the combinations and excess of the OTC medications and, more specifically, in relation to the sorts of conditions and high-risk patient profiles arising from the prescriptions from GenderGP. Principle 3 requires pharmacy owners to ensure appropriate regulation of linked entities and ensure the work of prescribers. Principle 4 requires the safe management of medicines including specific safeguards for medicines liable to abuse or misuse. Principle 5 requires the controlled access to records.

163. Mr Hoskins also relied upon the relevant guidance and guidelines cited by Dr C together with her linking the GMC (Good Practice in Prescribing and Managing Medicines and Devices (2013) to the work of pharmacists. He said that these set out the threshold for misconduct in this case.

164. In terms of how far below the standards the Registrants' conduct fell, Mr Hoskins highlighted the following:

- The allegations taken together demonstrate not a few lapses but a broad range of integral failures in the fundamental systems in operation at the Pharmacy. These were properly regarded as wholesale and, as late as January 2021, regarded by Ms M as *"A system wide failure in the governance and management of risk at the pharmacy. This includes gaps in required policies and procedures including safeguarding. And there is no evidence that the policies they do have are implemented into the day-to-day running of the pharmacy*";
- The patient profile, particularly in respect of the GenderGP dispensing, included vulnerable and young patients;
- The breakdown in the systems of OTC and prescription medication dispensing were not academic or of no demonstrable effect, given that dispensing errors did in fact occur in respect of high-risk medication liable to abuse and misuse
- Although the failings exhibited by the Registrants at the Pharmacy occurred in its first three to four months of trading, this came after a year post regulation and ample time to prepare adequate governance structures and embed them in an operation of this size.
- The sorts of failings at the heart of the mischief identified in the charges were basic and uncomplex. For example, the lack of any risk assessments, meaningful audit or safeguarding policies and late introduction of measures to prevent fraudulent or oversupply months after trading commenced, when it was an obvious concern, demonstrates complete ignorance and remedial failings at the Pharmacy with demonstrable effect.
- But for the intelligence led action of the Council, there is no clarity that the Pharmacy would itself have improved in a timely fashion without intervention in the context of exponential growth in sales.

Registrant's submissions on misconduct

165. Mr McCaffrey said that Mr Shabbir and Mr Sood accept that the allegations admitted are capable of amounting to serious misconduct. He submitted, on behalf of Ms Afzal, that the particular circumstances of her case do not amount to serious misconduct.

166. Mr McCaffrey made detailed submissions in relation to the Council's evidence in this case. With respect to Dr C, he submitted that during her oral evidence it was quickly established that she knew nothing of the specifics of this case and gave evidence generally - she did not get the inspection report for this case and had not seen the website or the questionnaire she was critiquing. Mr McCaffrey submitted that "*There is no rational or plausible explanation for commissioning these reports other than the Council expressing concerns about the regulatory landscape in 2023 and 2024. This is a clear indication of the state of mind of the regulator at the time – contrary to their position in this case that the situation was entirely clear from their 2019 guidance."*

167. Mr McCaffery also submitted that Dr C's understanding of her role as an independent expert was "exposed" during the hearing when she said "*Well I must have told [the Council] what they wanted to hear, and they paid me, and didn't question anything*." He submitted that it was entirely inappropriate for the Council to instruct Dr C in this case and more inappropriate for her to have accepted the instruction, and she had absolutely no knowledge, let alone expertise, on the role of SIs and RPs. Mr McCaffrey highlighted that during her evidence Dr C failed at times to understand the distinction between prescribing and dispensing in this case. As a final global point, Mr McCaffery said that it was perfectly plain that Dr C was fundamentally against online developments and does not believe they can ever be safe – contrary to the view in 2019 and to this day of the Council who instructed her. He submitted that her evidence, taken as a whole, fundamentally undermined the way the Council sought to present this case and the misconduct within it.

168. In relation to Ms M, Mr McCaffrey said that her evidence was more measured and balanced. He noted that when asked about the sales of codeine linctus and whether Covid was a justifiable explanation for the increase, she admitted that she could not answer the question.

She stated: "*We as inspectors were very limited. I do not have the information to make that comparison. I can only say that the other inspection also saw a huge increase in Codeine Linctus but cannot compare that to community pharmacy…anecdotally I have heard it going around that there was an increased demand for online sale. I do not have data to support that.*"

169. Mr McCaffrey submitted that the Council cannot rely on the sales data in its bundle to demonstrate that the excessive sales continued post November 2020 as her colleagues had carried out the analysis.

170. Mr McCaffrey submitted that Ms Afzal featured very little in the Council's evidence. She was a locum for a period of around ten days during the relevant time frame. He submitted that her conduct could never be described as deplorable by her peers, and therefore there should be no finding of serious misconduct in her case.

Decision on misconduct

171. Before dealing specifically with the issue of misconduct, the Committee will first deal with Dr C's evidence. The Committee agrees with Mr McCaffrey that she was not the appropriate expert to be called in this case; she was not qualified to give an opinion on the respective roles and responsibilities of the SI and the RP. In her report she erroneously referred to the Council's 2019 guidance as containing specific advice for the SI and RP. Her report was useful to the extent of providing details of the GMC guidance for prescribers, but beyond that her evidence was of limited assistance to the Committee.

172. Ms M's evidence was of more assistance. Although she did not personally analyse the sales data provided by the Pharmacy, the Committee could see for itself the individual dates of each mediation, and full details of to whom it had, or had not, been supplied. To that end the Committee was satisfied that the figures quoted by Ms M were accurate. In addition, the Registrants' own graph accords with the analysis regarding the increase in sales of codeine linctus.

Mr Shabbir and Mr Sood

173. In relation to Mr Shabbir and Mr Sood, the Committee considers that their failings were serious and could have resulted in harm to patients. The Council's guidance had been in place for well over a year when the Pharmacy started trading. This online pharmacy model had substantial risks. Although the Council's guidance regarding online pharmacies issued in April 2019 refers to "pharmacy owners", the RPs still had a responsibility to ensure that the processes and procedures were safe, and this included overseeing the prescribing service. The RPs statutory duty is to "*establish (if they were not already established), maintain and keep under review procedures designed to secure the safe effective running of the business including at a distance*". The Committee was satisfied that the 2019 guidance was sufficiently clear to provide advice to pharmacists who wished to move into the online business. It provided a checklist of areas which they should consider. The Committee makes no criticism of terms such as "regular" - clearly the term cannot be pre-defined as the frequency of, for example, an audit would depend on the results of the pharmacist's risk assessment. Although the Registrants say that the guidance was ambiguous, they accept that their risk management was insufficient and have admitted all of the allegations. They thought that they could take their knowledge of community pharmacy and apply it to an online model, which was entirely inappropriate.

174. The Committee also considers that the pharmacy owners failed in their duty to ensure that all RPs understood the risks involved in the online model. Ms Afzal was not shown the Monitoring of Fraudulent Sales flowchart SOP, and was not aware of "Purple Drank" or its dangers. She also did not know that there was Council guidance regarding online pharmacies.

175. The Committee has also taken very limited account of the Registrants' evidence regarding the interplay between HIS and the Council. At the time of the conduct in question the Registrants knew that their own conduct as pharmacists was regulated by their professional regulator, the Council, and to their credit they accepted this in their oral evidence.

176. In relation to the sales of codeine linctus, Mr Shabbir and Mr Sood failed to respond adequately to their own internal alarm bells. They were aware that there were a substantial

amount of orders for this medication, and it was increasing each month. The increase in sales may well have been justified by the pandemic, but they did not do enough research/checking to assure themselves and to keep records to demonstrate that this was the case. In his evidence Mr Shabbir was candid - he admitted that they knew there were fraudulent customers. He also accepted that even if customers had stated on their questionnaire that they had not tried the first line treatment for covid cough (e.g. honey), he probably would have dispensed codeine linctus to them anyway.

177. In relation to GenderGP and the UK prescribing service, although the GMC guidance states, *"the final decision will always be with the prescriber"*, in circumstances where the prescriber had no access to the patient's medical records, and did not carry out any consultation with the patient, the RP bore a degree of responsibility to check that the prescribing is safe.

178. Regarding GenderGP in particular, the Council's Guidance required pharmacy owners (so Mr Sood and Mr Shabbir) working with prescribers who are not appropriately registered with the UK professional regulator to ensure that they are registered in their home country where the prescription is issued. The pharmacy owner must ensure that the prescribers can lawfully issue prescriptions to people in the UK. There was no discussion with the prescriber regarding their understanding of the GMC guidance, or any of the Pharmacy's policies (such as they were at the time). The Registrants did not ensure that the prescriber based in the EU was prescribing in accordance with the GMC's guidelines. There was very little communication between the prescriber and the patient, and the prescriber did not have adequate information from the patient, such as a full medical history, or access to the patient's GP records. The Pharmacy was told specifically not to contact the patients of GenderGP. The Pharmacy did not assure itself that the patients had been appropriately counselled. This is important in the context of medication prescribed to patients as young as nine in relation to gender dysphoria. Mr Shabbir and Mr Sood were totally reliant on the prescriber, even though they still had a legal responsibility to check the appropriateness of the medicine. They should have carried out some research/CPD when products were being prescribed "*off-label",* particularly when the patients were children and/or vulnerable.

179. The RPs should have ensured that there were procedures in place to prevent inappropriate supplies of medication, including drugs which are open to misuse and abuse, to vulnerable members of the public. Most medicines were sent out to patients even though they had refused to give their consent for their GP to be informed. There were no adequate systems in place to audit either the supply of medication, or when a prescription had been refused.

180. The Committee agrees with the Council that the Pharmacy was not following the guidelines issued by the Council for providing pharmacy services at a distance. It was essentially run as a commercial, transactional model. There were not sufficient safeguards in place. It was possible for medication to be dispensed to patients with similar email addresses, postal addresses and using the same payment details. The ID checks were not robust enough. The Council's guidance requires that there should be robust systems in place for identification verification. The guidance sets out that categories of medications, including medicines liable to abuse or misuse (such as opioids), should not be prescribed until a number of appropriate safeguards have been put in place, such as ID checks, contact details of the patient's regular prescriber, and consent to contact that person. The "at distance prescriber" should proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP). The Council's guidance states that where the supply involves medicines which are liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important, steps should be taken to ensure that the prescriber has contacted the GP in advance of issuing a prescription, and that the GP has confirmed to the prescriber that the prescription is appropriate for the patient and that appropriate monitoring is in place. Where there is no regular GP, or there is no consent, there must be a clear record of justification for prescribing. The Committee appreciates that the Registrants were not prescribers but considers that they still had a responsibility to ensure that the medication they were dispensing was appropriately prescribed.

181. Clearly there were not adequate safeguards in place. Opioid medication (codeine linctus) was routinely being sent out to patients without any consultation with their GP. For POMs, there was a risk of harm to patients as the Registrants could not be assured that the

prescriber was not aware of the patient's full medical history, and therefore may not have sufficient information in order to prescribe safely.

182. Although there is no evidence that any patient came to actual harm, clearly the lack of safeguards put patients at risk of harm, as there was the potential for them to get hold of medicines liable to abuse, overuse or misuse (including the combination of codeine linctus and Phenergan). Tighter safeguards should have been put in place where there was a risk of addiction.

183. In terms of "blameworthiness", the ultimate responsibility for the risk management of the pharmacy lay with the SI. He had a statutory duty to ensure that the business was at all times carried on in ways that ensured its safe and effective running.

184. However, the Committee finds that both Mr Shabbir and Mr Sood breached the standards referred to above, which predominantly related to effective and safe professional practice. It considers that other members of the profession and the public would take a dim view of the Registrants' conduct. Their actions and failures fell well below the standards required.

185. For these reasons the Committee considers that the actions/failings of Mr Shabbir and Mr Sood amounted to serious misconduct.

Ms Afzal

186. The Committee then considered whether Ms Afzal's conduct also reached the threshold for serious misconduct. It is correct that she only worked as the RP on about ten occasions before the inspection and had no involvement thereafter. Her role when she was working was akin to a locum.

187. However, the Committee considers that even if only working on a locum-basis, Ms Afzal still had a duty to ensure that the dispensing to patients was safe, in line with her responsibilities as an RP, and to her credit she accepted this. The Committee noted that Ms Afzal gave evidence that she had concerns regarding the volume of sales of codeine linctus, and had highlighted this to Mr Shabbir. The Committee was also concerned that she endorsed a

substantial number of prescriptions from GenderGP which had been left in a pile by Mr Shabbir. She was therefore a party to this process and did not carry out any checks for herself that it was safe to prescribe medication such as puberty blockers to children, in circumstances where she had no access to or consultation with the patients, or access to the records that could assure her that the prescribing and dispensing of such medications was appropriate.

188. The Committee also noted that Ms Afzal had not undertaken any research herself regarding online pharmacies and was not even aware that there was Council guidance. Just because she was working in a locum-type capacity, to help out her husband, this did not abrogate her from her responsibilities as an RP.

189. For these reasons the Committee considers that Ms Afzal's conduct reached the threshold for serious misconduct.

Current impairment

190. The Committee next proceeded to the second part of the test, which is to consider whether the Registrants' fitness to practise is currently impaired by reason of their misconduct.

191. Rule 5 provides that the Committee must have regard to the criteria specified in that Rule when deciding in the case of any registrant whether or not the requirements of fitness to practise are met.

192. Rule 5(2) provides:

> "In relation to evidence about the conduct or behaviour of the registrant which might cast doubt on whether the requirements as to fitness to practise are met in relation to the registrant, the Committee must have regard to whether or not that conduct or behaviour—
>
> *(a) presents an actual or potential risk to patients or to the public;*
>
> *(b) has brought, or might bring, the profession of pharmacy into disrepute;*
>
> *(c) has breached one of the fundamental principles of the profession of pharmacy; or*

(d) shows that the integrity of the registrant can no longer be relied upon."

193. Although the Committee's determination must focus on the present position, that is to say whether fitness to practise is currently impaired, it is clear from leading cases such as *Cheatle v General Medical Council [2009] EWHC 645* that in order to form a view as to current impairment, it must take account of the way in which the Registrants have acted in the past, although a finding of misconduct in the past does not necessarily mean that there is impairment of fitness to practise today.

194. It was said in the case of *Cheatle:*

> "*the purpose of fitness to practise proceedings is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The Fitness to Practise Panel thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past...this means that the context of the doctor's behaviour must be examined. In circumstances where there is misconduct at a particular time, the issue becomes whether that misconduct, in the context of the doctor's behaviour both before the misconduct and to the present time, is such as to mean that his or her fitness to practise is impaired. The doctor's misconduct at a particular time may be so egregious that, looking forward, a panel is persuaded that the doctor is simply not fit to practise medicine without restrictions, or maybe at all. On the other hand, the doctor's misconduct may be such that, seen within the context of an otherwise unblemished record, a Fitness to Practise Panel could conclude that, looking forward, his or her fitness to practise is not impaired, despite the misconduct."*

195. In the case of *Cohen v General Medical Council [2009] EWHC 581* Silber J set out the following guidance:

"*It must be highly relevant in determining if a doctor's fitness to practise is impaired that first his or her conduct which led to the charge is easily remediable, second that it has been remedied and third that it is highly unlikely to be repeated.*"

196. In the case of Yeong v GMC [2009] EWHC 1923 (Admin) Sales J said:

"*in looking forward the Panel is required to take account of such matters as the insight of the practitioner into the source of his misconduct, and any remedial steps which have been taken and the risk of recurrence of such misconduct. It is required to have regard to evidence about matters that have arisen since the alleged misconduct occurred.*"

197. In addition, in *CHRE v (1) NMC and (2) Grant [2011] EWHC 927 (Admin*) Cox J considered the case of Cohen and stated:

"*In determining whether a practitioner's fitness to practise is impaired by reason of misconduct, the relevant panel should generally consider not only whether the practitioner continues to present a risk to members of the public in his or her current role, but also whether the need to uphold proper professional standards and public confidence in the profession would be undermined if a finding of impairment were not made in the particular circumstances...When considering whether fitness to practise is currently impaired, the level of insight shown by the practitioner is central to a proper determination of that issue.*"

Council's submissions on impairment

198. In his skeleton argument Mr Hoskins submitted that limbs (a)–(c) of the Rule 5 criteria above are engaged in this case and in respect of each Registrant. He said that taken together, the allegations demonstrate an almost wholesale failure concerning the fundamentals of dispensing medication by the delegation of the pharmacist's role to the patient seeking the medication, with no corroborating information and a derogation by each Registrant of their duties to external prescribers including those abroad, with no regard to the safety of the same. He highlighted that the actions were repeated over time, of reasonable and increasing

scale and liable to cause harm. As such, he submitted that the public interest alone demands a finding of current impairment on the past actions of the Registrants. Mr Hoskins said that members of the public would expect pharmacists to exercise their clinical judgement independently when dispensing medicines liable to abuse, and that the public must have confidence in the pharmacy profession to safeguard members of the public and vulnerable patients. However, Mr Hoskins indicated that in this case it was not just the public interest that was engaged, but there were also public protection issues which required a finding of current impairment.

Registrants' submissions on impairment

199. On behalf of the Registrants, Mr McCaffrey submitted that there should be no finding of current impairment for all three Registrants. He referred to the Council's *Good Decision Making* guidance and submitted that the conduct which led to the complaint can and has been addressed, and that it is not likely and has not been repeated.

200. Mr McCaffrey said it was important to look at the context in this case. He said that the 2019 guidance was applicable to owners, but to the Registrants' credit, they have not advanced a "technical case" on this basis and accepted that the spirit of the guidance applied to them whether an SI or an RP. He said that neither Mr Sood nor Mr Shabbir sought to exploit the fact that the Council chose not to include in the allegations their position as owners.

201. Mr McCaffrey said that it was relevant to look at the mitigating factors in this case, which he identified as follows:

• All three registrants have had a hitherto unblemished career. Mr Shabbir had been practising as a pharmacist for over 8 years, Mr Sood over nine years and Ms Afzal over six years.

"• All three registrants have continued to practise unrestricted and without issue for four years.

• The allegations cover a short four-month period

• All three registrants have expressed deep regret from the outset and are clearly embarrassed and distressed about this period in their careers.

• The registrants exhibited naivety rather any premeditated plan to work outside guidelines for gain

• This was a new and emerging fast changing sector

• There was a lack of clarity in respect of implementation of guidelines

• There was a lack of awareness across the profession about the 2019 guidance

• There was an unforeseen explosion in demand during the Covid pandemic affecting the way in which the public accessed pharmacists

• The Covid pandemic increased the need and demand for certain high-risk medication

• The GPhC imposed conditions only in respect of certain medications and those conditions could have been lifted since

• The GPhC did not impose conditions in respect of the online pharmacy in general but asked for certain improvements to be made which were implemented in a timely manner

• The GPhC did not impose conditions in respect of GenderGP however the pharmacy had themselves in 2020 made the decision to part company with Gender GP as required documentation had not been forthcoming

• At no point did the GPhC take action to prevent the registrants from practising nor put any restriction on their practise

• At no point did the GPhC seek to take action against the registration of the pharmacy itself.

202. In terms of insight, Mr McCaffrey submitted that from the very outset, even at the time of the December 2020 inspection, the Pharmacy fully accepted that they did not, across the board, have robust enough governance measures in place. He said that Mr Shabbir disclosed everything to the inspector on that day, and Mr Sood, following "*an initial knee jerk reaction of challenge*" (which Ms M had described as "*resistive"),* also wholly accepted what the inspector was telling them was inadequate.

203. Mr McCaffrey submitted that in early 2021, having recognised the limits of their skills and experiences, Mr Sood and Mr Shabbir employed a Clinical Governance Lead and by April 2021 had commissioned a consultant specialising in pharmacy support to work with them to dedicate time and funds on focusing on the higher-level governance issues.

204. Dealing first with Mr Shabbir, Mr McCaffrey said that he was integral in the improvements in the pharmacy following the December 2020 inspection and continues to be at the centre of maintenance of the expected standards until the present day. Mr McCaffrey submitted that the fact that Mr Shabbir recognised his failings and lack of expertise and took steps to seek external help is not something to be criticised but rather, as would be expected of any professional pharmacist, a professional approach to putting things right and gaining the necessary level of skills and knowledge moving forward.

205. With regards to Mr Sood, Mr McCaffrey submitted that his decision to leave the business in September 2021 was insightful and selfless, as he recognised that to maintain the high standards of governance that had been by then achieved, the SI and governance posts needed to be on site. Mr McCaffrey said that since that time Mr Sood has specifically targeted scrutiny of SOPs at all the companies he has been engaged with, and fully appreciates that an SI has a responsibility to ensure that SOPs are live working documents which, if adhered to, ensure safe and effective practice and are invaluable tools to audit and evaluate risk.

206. With regards to Ms Afzal, it was submitted that since returning to work she has reviewed the up-to-date guidance for online pharmacies and reflected on her role as an RP in an online setting. Although not specifically involved in the improvements implemented in the pharmacy since December 2020, it was submitted that Ms Afzal has watched and learned a great deal.

207. With regards to the public interest, Mr McCaffrey said that there does not need to be a finding of current impairment in order to declare and uphold proper standards of behaviour and/or maintain public confidence in the profession. He referred to the test for public interest set out in the case of *Patel v GMC [2012] EWHC 3688.* He also referred to the case of *Bijl v GMC [2001] UKPC 42; [2002] Lloyd's Rep Med 60*, where Lord Hoffmann said that proper concern with public confidence in the profession and its procedures for dealing with "*doctors who lapse from professional standards"* should "*not be carried to the extent of feeling it necessary to sacrifice the career of an otherwise competent and useful doctor who presents no danger to the public in order to satisfy a demand for blame and punishment".*

Decision on current impairment

208. The Committee finds that Rules 5 (2)(a) to (c) were engaged at the time of the misconduct in 2020 for all three Registrants.

209. The Registrants put patients at risk of harm by failing to ensure that there were proper procedures in place for the supply of OTC medication liable to misuse or abuse, or for the oversight of prescribing at a distance, although there is no evidence that any patients actually suffered harm. The risk for OTC medicines (codeine linctus and Phenergan) was that they could have been sent out to patients who had addictions and others for whom they may not have been safe or appropriate. The risk regarding the dispensing POMs was that the prescriber did not have sufficient information from the patient in order to prescribe safely, and the Registrants relied on the prescriber's actions, without any additional, separate checks or safeguards in place.

210. The Committee also finds that the Registrants brought the profession of pharmacy into disrepute, and breached a fundamental tenet of the profession, namely that Pharmacists should protect the public.

211. However, the Committee also took into account that the misconduct took place over three and a half years ago, and there has been no repetition since. It therefore considered carefully the evidence and submissions for each Registrant in turn, to decide if there was current impairment.

Mr Shabbir

212. Since the misconduct took place in August to December 2020, the Pharmacy has gone on to improve, so that by May 2021 the Council confirmed that it had reached the standards required by the Improvement Notice. Mr Shabbir has invested heavily in the recruitment of staff who have concentrated on governance, policies and procedures. He has bought other pharmacies, both online and physical entities, and the Council has "passed" these at subsequent inspections. Mr Shabbir was able to demonstrate that he understands the

importance of having competent prescribers, and now will not work with any prescriber unless they still have at least some NHS practice.

213. During his evidence Mr Shabbir displayed great remorse. He has engaged with the Council ever since the inspection in December 2020, showing a commitment to improving his practice. However, the Committee noted that in the early months following the inspection, before the external consultants came on board, Mr Shabbir struggled to remedy his failings. This was despite Ms M providing him with a detailed inspection report setting out the deficiencies and breaches of the Council's standards. It appears that it was the Clinical Governance Pharmacist who carried out the remedial work, drafting the updated policies and procedures to ensure regulatory compliance going forward. The Committee is not criticising Mr Shabbir for this - it was a sensible step for him to take, having acknowledged that he was out of his depth and struggling. It does, however, raise questions about the extent of Mr Shabbir's own remediation, as opposed to steps taken by his team as a whole.

214. In order to assess Mr Shabbir's own level of remediation and insight, the Committee therefore looked for evidence of what he has personally done since December 2020, and to this end unfortunately there is a lack of information/evidence. He said that he has attended one face-to-face training session with JP around risks assessments, and one with NC, the Ex-Council inspector regarding what medicines are safe to dispense online. However, there was no detailed reflection or CPD entry from Mr Shabbir about exactly what he learnt in those training sessions, and no written statement from the trainers explaining exactly what they taught during their session. Although the Clinical Governance Lead had been in correspondence with the Council in 2021 about looking into online CPD training, there is no evidence that this was ever arranged.

215. The Committee considered that this misconduct is capable of remediation. The Pharmacy's "track record" since 2020 shows that there have been no further concerns reported to the Council, and the Pharmacy has passed a subsequent inspection. However, the Committee also noted that Mr Shabbir has not sold codeine linctus or Phenergan since December 2020 (this restriction remains in place on the Pharmacy's registration). Mr Shabbir told the Committee that he had no intention of ever selling it again, even if the condition was lifted.

This does not, in the Committee's view, equate to "remediation", or evidence that there is no longer a risk of repetition. The Committee would have been more assured if Mr Shabbir had provided evidence of his training/CPD on this subject.

216. Likewise, Mr Shabbir has not provided any documentary evidence of his training/learning around dispensing for a prescribing service, either in the UK or abroad. He stopped working with Gender GP around the time of the inspection (the Committee was unable to establish exactly when that was), but for the Committee to be assured that there would be no risk of repetition, it would need to be satisfied that Mr Shabbir has undertaken relevant remediation, which could include reading research or training) and has reflected on his learning. He also said that he has attended meetings with DICE, but there was no detail provided about what he has learnt from those.

217. The Committee was also concerned that Mr Shabbir has not provided any testimonials from colleagues, patients or anyone who can comment on his current practice. Mr Shabbir is still operating an online pharmacy, but the Committee has no objective information/evidence showing that he understands the risks around the drugs he is now dispensing.

218. In light of the above, the Committee has decided that there remains a risk of repetition, due to Mr Shabbir's incomplete remediation and level of insight, and therefore his fitness to practise is currently impaired with regards to the "personal component."

Mr Sood

219. The Committee would repeat its comments regarding impairment above in relation to Mr Shabbir, to the extent that Mr Sood remained an active participant in the business until September 2021. By that time the Pharmacy had "passed" the Improvement Notice served by the Council and had almost been given a "*clean bill of health".* However, the same applies to Mr Sood - the Committee considers that these improvements were mainly down to the external people who were employed, rather as a result of Mr Sood's own substantial increase in skills and knowledge.

220. In addition to being an RP, Mr Sood was also the SI, so had ultimate responsibility for the safe and effective running of the Pharmacy. He acknowledged at this hearing that he was out of his depth and did not have the skills and knowledge required to be an SI. He left the Pharmacy in September 2021 without having remedied those failings. He indicated that he is in no hurry to be an SI again, although he hopes that one day in the future this may happen. This shows that he is willing to accept his limitations and is putting the interests of patients above his own interests, which is to be commended.

221. The Committee is not saying that Mr Sood would need to start practising again as an SI before it could be assured that his fitness to practise is no longer impaired. Instead, it is looking at what remediation he has undertaken, not only regarding his role as an SI but also as an RP and a pharmacy owner.

222. Mr Sood said in his written evidence regarding remediation that he has turned his attention to the SOPs in all the companies he has been engaged with, but he has not provided any further details in this respect, such as a written CPD around what he has learnt from them. He said that he has worked with other SIs and clinical governance leads, but there are no testimonials from them. It is unclear whether he was still working for the Pharmacy when the two face-to-face training sessions were provided. He did not mention them in his evidence. There is no documentary evidence before this Committee of any training/CPD which he has undertaken in the past four years.

223. Mr Sood is now employed as a full-time locum. He said that his employer is aware of these proceedings and is supportive of him. However, he has not provided any testimonials from his employer, colleagues or patients commenting on his practice since December 2020.

224. In light of the above, the Committee has decided that there remains a risk of repetition, due to Mr Sood's incomplete remediation and level of insight, and therefore his fitness to practise is currently impaired with regards to the "personal component."

Ms Afzal

225. Ms Afzal was never an owner of the Pharmacy and played no part in the running of the business. However, she did act as the RP, and has accepted that she should have ensured that the pharmacy service, including the remote prescribing, was safe and did not put patients at risk of harm.

226. It is fair to say that Ms Afzal's level of remediation is limited partly due to her personal circumstances. [PRIVATE] and when she did go back to work it has only been for approximately two shifts per month.

227. In her oral evidence Ms Afzal said that she was concerned about the level of codeine being supplied and raised this with the owners, who told her that it was due to Covid. She has not had the opportunity to raise any similar concerns since she returned to work as she said the pharmacies are well run and are compliant. The Committee noted that Ms Afzal did have concerns about the codeine linctus and reported these to her husband. The Committee would need to be assured that Ms Afzal would speak up in the future if she had similar concerns, and that she would have the courage to refuse to supply if she was not satisfied for herself that it was safe to do so.

228. The Committee considered that Ms Afzal did provide one good example of insight in her oral evidence, when she explained about the importance of record keeping. However, the Committee has not been provided with any documentary evidence such as CPD records or a detailed written reflection about what Ms Afzal has learnt since 2020. Without this, the Committee cannot be satisfied that her insight and remediation are well developed. Even though she is only working twice a month as a locum, she could still have done some reading or online training.

229. As with the other two Registrants, the Committee was disappointed that Ms Afzal had not provided any testimonial evidence.

230. In light of the above, the Committee has decided that there remains a risk of repetition, due to Ms Afzal's incomplete remediation and level of insight, and therefore her fitness to practise is currently impaired with regards to the "personal component."

Public interest

231. The Committee then considered the wider public interest criteria and the comments in the *Grant* case referred to above. The Committee acknowledged that there is no evidence of actual harm to patients. However, the Registrants' actions were serious, and they breached multiple standards. This was not an isolated incident but involved a substantial amount of irresponsible dispensing of POMs and selling OTC medicines without the appropriate safeguards in place. The Committee was not persuaded by the Registrants' assertion that they did not realise the extent of risks of selling so much codeine linctus because of Covid. Even Ms Afzal, who was only working limited shifts, noted the large amount of orders for the medication. There is no evidence that they went on to check that covid cough really was a valid explanation for such a high level of sales.

232. The Committee has decided that a reasonable member of the public, knowing all of the circumstances of this case, would consider that there needs to be a finding of current impairment in order to mark the public interest, and the seriousness of the misconduct. The "circumstances of the case" include that the Council's guidance had been in existence for over a year, and all three Registrants knew that they were operating in a new arena (online) for which they had no relevant training or experience. Despite this, Mr Shabbir and Mr Sood started trading without taking the time to first ensure that there were sufficient processes and safeguards in place. When they did realise that they were out of their depth, and that there were fraudulent customers, they pressed on, when they should have paused operations to put matters right. Ms Afzal continued to work as an RP to assist Mr Shabbir, despite having concerns about the level of codeine linctus sales.

233. For these reasons the Committee therefore finds that the Registrants' fitness to practise is currently impaired in order to mark the public interest.

Sanction

234. Having found that the Registrants' fitness to practise is currently impaired, the Committee now moves on to sanction.

235. In reaching the decision on sanction it has considered all of the evidence referred to in the determination of facts and impairment, together with the written submissions of Mr Hoskins and Mr McCaffrey. It also had in mind the Council's Fitness to Practise Hearings and Sanctions Guidance (revised March 2024).

236. The sanctions available to the Committee are those set out in Article 54 of the Pharmacy Order 2010. In summary, it may decide to take no action, issue a warning, direct that the entry on the register be conditional, order that the entry on the register be suspended for a period not exceeding 12 months, or make an order that the entry in the register be removed.

237. The Committee understands that the three-fold purpose of sanction is the protection of the public, the maintenance of public confidence in the profession and the maintenance and declaration of proper standards of conduct within the profession. It is not the purpose of sanctions imposed by this Committee to punish a registrant, although such a sanction may have a punitive effect.

238. In the case of *Bolton v Law Society* [1994] 2AER 486 it was said that the reputation of the profession is more important than the fortunes of any individual member. Thus it was observed that the Committee is entitled to give more weight to the public interest than to the consequences for any individual registrant. There is a need to demonstrate to the public, and to practitioners, the importance of adhering to the fundamental tenets of practice by declaring and upholding proper standards of professional behaviour. There is also a need to maintain public confidence in the profession and the regulatory process.

239. The Council's '*Good decision making: fitness to practise hearings and sanctions guidance*' invites the Committee to consider a number of factors, namely:

- the extent to which a registrant has breached the standards as published by the Council
- the interests of the Registrants, weighed against the public interest,

- the overarching objectives of the GPhC
- the personal circumstances of each Registrant and any mitigation they have offered
- that the decision is sufficient to protect the public
- any testimonials or character references given in support of the Registrants,
- relevant factors aggravating the conduct in the case,
- any statement or views provided to the Committee by a patient or anybody else affected by the conduct of the Registrants,
- submissions made by the Council's representative and by the Registrant or their representatives,
- the content of the sanctions guidance document, and
- any other guidance published by the Council

Council's submissions on sanction

240. The Council submitted that a warning would be insufficient to mark the seriousness of the Registrants' misconduct. It is the Council's case that the *Good decision making* guidance makes clear that a warning is best used in circumstances where there is no continued risk to patients or the public, but there is a need to publicly acknowledge that the conduct was unacceptable. Mr Hoskins said that this did not apply in this case.

241. Mr Hoskins also submitted that the Committee should refrain from imposing Conditions of Practice since there is no evidence that the Registrants will respond positively to retraining and/or supervision. He stated that they have not presented to the Committee areas they believe they would benefit from remedial training and have not evidenced clear and structured training since the end of the period of concern. Instead, Mr Sood and Ms Afzal have simply retreated from the sector of concern and, in Mr Sood's case, the level of seniority and consequent obligations he previously held. Furthermore, Mr Hoskins submitted that the extent of risk identified by the Committee cautions against a return to practice. He said that conditions of practice also do not directly remedy the damage to the public interest occasioned by the Registrants' actions.

242. The Council submits that the appropriate and proportionate sanction in this case is removal from the register, rather than a period of suspension, in light of the Committee's findings on

the scale of misconduct. Mr Hoskins said that this case falls within the cadre of cases that can properly be categorised as *"the most serious*". He conceded that the Committee has not to date identified that the Registrants' conduct is incompatible with remaining on the register (indeed it has found it is capable of remediation) but submitted that the deficiencies it has identified in terms of insight and remediation still remain almost four years since the time of the allegations. Mr Hoskins said that while the misconduct may, in principle, be remediable, the Committee is entitled to consider whether, given this passage of time, there is any realistic likelihood of remediation in practice.

Registrants' submissions on sanction

243. Mr McCaffrey submitted that there is a proper and justifiable basis for consideration of a conditions of practice order in this case, and that conditions are the appropriate and proportionate sanction in all the circumstances. He conceded that a warning is not appropriate as the Committee has clearly indicated that insight and remediation are still developing and has identified specific absences in evidence. He submitted that conditions of practice would be sufficiently severe so as to achieve the requirement to satisfy public interest and also allow the Registrants to reflect further on the Committee's findings and work towards satisfying a future committee that their current incomplete insight and remediation (as identified by this Committee) had in fact been remedied.

244. In his written submissions on sanction Mr McCaffrey helpfully summarised the areas of deficiency for the Registrants, which are as follows:

- Reflection and evidence of learning from the training with Jackie Peck around risk assessments.
- Reflection and evidence of learning from Nabila Chaudhri regarding safe online dispensing.
- Training/CPD with respect to the sale of codeine linctus and other like opioid medications online as opposed to in the community.
- Evidence of CPD regarding SOPs. (For Mr Sood)

- Documentary evidence of training/learning around dispensing for a prescribing service.
- Training in respect of dispensing for a prescribing service either in the UK or abroad.
- Relevant remediation and learning/research beyond this.
- Detail of learnings from meetings with DICE. (Mr Shabbir)
- Evidence of current practice as RP (Ms Afzal) and pharmacy owner. (Mr Shabbir)
- Evidence of learning and CPD with respect to the role of SI. (Mr Sood)

245. Mr McCaffery proposed the following conditions:

- To identify a mentor/supervisor within four weeks
- To create, with the above, a Personal Development Plan [PDP] specifically designed to deal with the shortcomings identified in their practice
- To forward the PDP to the Council within eight weeks
- To arrange for the mentor to provide a report on progress towards achieving the aims as set out in PDP every three months for 12 months
- To undertake training/retraining in the following areas and send evidence of completion to the Council

Mr Shabbir

- Operating an online pharmacy and risks associated
- Risks around dispensing high risk drugs
- Clinical governance
- Audit
- Record keeping
- Online dispensing

Mr Sood

- Role of SI
- SOPs
- Clinical governance
- Audit

- Record keeping
- Online dispensing.

Ms Afzal

- Role of RP
- Record keeping
- Escalation of risk

246. Conditions can be imposed for up to three years. Mr McCaffrey submitted that a period of 12 months would be appropriate to allow the Registrants sufficient time to reflect, develop further insight and remediate past failings, however this would be short enough to satisfy proportionality.

247. Mr McCaffrey submitted that while it might be argued that a period of suspension with a review would be appropriate, this lengthy fitness to practise process, coupled with a finding of impairment, has already marked for the profession and the public that the conduct of the Registrants was unacceptable. He submitted that the impact of suspension would be devastating and entirely counterproductive. He said that although the Committee has found a risk of repetition is still present, this is tempered by the continued unrestricted practice of all Registrants to date without repetition - and the engagement and attitudes of each Registrant.

248. Mr McCaffrey submitted that Mr Shabbir is closely governed by the standard of governance in place at the Pharmacy. Neither Mr Sood nor Ms Afzal have worked in the sector since and do not have any intention to do so, but both are governed by the governance systems where they work, and both have SIs as RPs.

249. Furthermore, Mr McCaffery submitted that the opportunity for real remediation would be lost should suspension be imposed, as no-one at a review hearing would be able to report or speak to the learning beyond an academic level and no-one, including the Registrants themselves, would be able to show that any learning had been successfully translated into practice.

250. In terms of proportionality, Mr McCaffery said that while a suspension would have negligible practical impact on Mr Shabbir (in that he could continue to run his business without registration) and on Mrs Afzal (who works minimal locum shifts in the community), it would have a devastating and disproportionate impact on Mr Sood both personally and professionally.

251. Having read Mr McCaffery's written submissions on sanction, the Committee asked him to clarify in the hearing the current position regarding Ms Afzal as to whether her current employers know about these proceedings, and whether they would be prepared to continue to employ her as a locum if the Committee were to impose conditions. Having taken a break in order to take instructions, Mr McCaffrey stated that the employers are aware of these proceedings. However, he also confirmed that Ms Afzal has not, in fact, practised at all for over a year [PRIVATE]. Prior to this she worked regularly for two pharmacies, but during [PRIVATE] one pharmacy had changed hands (i.e. a new owner) and the other had a new SI. She therefore cannot say for certain whether they would support conditions of practice, although she believes that they would.

Decision on sanction

252. The aggravating factors which the Committee identified were as follows:-

- The misconduct took place in the workplace, and over a period of approximately four months
- The case involved a substantial number of transactions involving medication which is liable to misuse and abuse
- There was a serious risk to patient safety, including the risks of overdose and addiction
- This case involved a significant breach of several professional standards
- Mr Sood and Mr Shabbir were aware that there were issues, including fraudulent customers trying to buy codeine linctus and Phenergan but despite this they carried on trading, instead of pausing the business whilst they addressed these concerns

- All three Registrants were experienced pharmacists
- The dispensing to GenderGP patients involved children and those who were vulnerable
- The supply of codeine linctus (controlled drug) included to customers who may have been vulnerable (i.e. had addictions) on a large scale

253. The Committee considered the following to be mitigating factors:-

- There is no evidence that any patient actually suffered harm
- The misconduct took place during the Covid pandemic, when pharmacies were experiencing greatly increased demand and were under significant pressures
- Ms Afzal's involvement in the online pharmacy was less - she only worked ten part time shifts
- The Registrants admitted all of the Particulars of Allegation at the start of this hearing
- There is no previous Fitness to Practise history for any of the Registrants
- Mr Shabbir and Mr Sood have been in full time practice for almost four years without any further incidents.
- Ms Afzal has been in part time practice (albeit very limited) for two years without any further incidents.
- Mr Shabbir has continued working in the field of online pharmacy ever since this misconduct, dispensing two days a week, and the Council has given his pharmacies a "clean bill of health".

254. In relation to Ms Afzal, the Committee was surprised to learn that she had not practised for over a year. In her written statement and written reflection, both signed with a statement of truth in September 2024, Ms Afzal had said that she was currently working as a locum. She repeated this in her oral evidence. The Committee had noted in its decision on impairment that Ms Afzal had worked without any further concerns for the past three years, whereas this is incorrect, as she did not practise for over a year during that period. The Committee was informed at the sanction stage that Ms Afzal in fact took a period [PRIVATE] for around a year during that time. The Committee accepts that [PRIVATE] is a private matter but is of the

view that Ms Afzal should have been clearer with it about her work experience in the period prior to this hearing.

255. Turning now to sanction, the Committee decided that taking no action or giving a warning would clearly be inadequate in response to a case involving serious breaches of professional standards. The 2024 guidance states that a warning may be appropriate where "*there is a need to demonstrate to a professional, and more widely to the profession and the public, that the conduct or behaviour fell below acceptable standards"* but "*there is no need to take action to restrict a professional's right to practise, there is no continuing risk to patients or the public, but there needs to be a public acknowledgement that the conduct was unacceptable."* In this case there is a risk of repetition, and the Committee has found that the Registrants' remediation and insight are insufficient. If a warning were to be given, there would be no review by a future committee in order to establish whether the current deficiencies had been addressed.

256. The Committee next considered whether a Conditions of Practice Order was appropriate here. The 2024 guidance states that conditions may be appropriate where *"There is evidence of poor performance, or significant shortcomings in a professional's practice, but the committee is satisfied that the professional may respond positively to retraining and supervision",* and also where "*There is not a significant risk posed to the public, and it is safe for the professional to return to practice but with restrictions".*

257. The Committee has decided that there is a risk of repetition in this case, but it would not assess that risk as "significant", taking into account that there was no evidence of patient harm, the Registrants do have some insight into their misconduct, and there has been no repetition since 2020.

258. The Committee has taken into consideration both the aggravating and mitigating factors referred to above. These were balanced evenly. The Committee has decided that Conditions of Practice could be devised which would address the concerns in this case. Conditions of Practice would allow the Registrants to continue to practise, and they would be able to translate their academic learning into their day-to-day practice. However, the Committee

decided that the conditions would need to be stringent enough to protect the public and mark the public interest in this case.

259. In terms of proportionality, the Committee was satisfied that this sanction was proportionate for all Registrants. Mr Sood's misconduct was serious due to his roles as pharmacy owner, SI and occasionally RP. Mr Shabbir's misconduct was serious due to his roles as pharmacy owner and RP, and also because he was the one who dispensed the majority of the medication in the Pharmacy. Although Ms Afzal's involvement was less, she has practised to a very limited extent since the misconduct occurred and therefore has had less opportunity to improve her practice (e.g. in the area of escalation). Overall, the Committee considered that the risks each Registrant currently poses is at the same level, so proportionally a sanction of Conditions of Practice is appropriate for each Registrant.

260. The Committee has decided that the conditions will apply as follows:

Mr Shabbir

1. You must:

• give the GPhC the contact details of your place of employment and anyone who is likely to be the manager or persons supervising you (employer, pharmacy owner, agency, superintendent pharmacist responsible pharmacist)

• tell the GPhC before you take on any position for which you must be registered with the GPhC

• give the GPhC details of the role and the hours you will work each week, including locum or relief work

• tell the GPhC if any of the above details change

2. You must notify the following people in writing of these conditions before you commence any work, in relation to any paid or unpaid work for which registration with the GPhC is required:

• All employers or contractors

• Agents acting on behalf of employers and locum agencies

• Superintendent Pharmacists

• Responsible Pharmacists

• Line Managers

• Workplace supervisors

• Accountable Officer for Controlled drugs

• Prospective employers (notification should be given at the time of applying)

You must provide the GPhC with a copy of the notification(s)

3. You must tell the GPhC if you apply for work as a pharmacist or pharmacy technician outside Great Britain

4. You must not work as a Superintendent Pharmacist

5. You must, within eight weeks of the date this order takes effect:

• find a workplace supervisor (who must be a Superintendent Pharmacist) and ask the GPhC to approve your workplace supervisor

• put yourself, and stay, under their remote supervision ("Remote" means the supervisor can work apart from you, but must be available for advice or assistance)

• give the GPhC your permission to exchange information with your workplace supervisor about your efforts to improve your pharmacy practice

If you are not employed, you must ask the GPhC to approve your workplace supervisor before you start work

Your supervisor must not be involved in any of your businesses

6. You must carry out a peer review on the appropriateness of a prescription of high-risk medication relevant to your area of practice and submit evidence of this to your supervisor in advance of your supervision meetings

7. You must send evidence of these peer reviews to the Council

8. You must work with your supervisor to draw up a personal development plan (PDP), specifically designed to deal with the shortcomings in the following areas of your practice:

- *Clinical governance*
- *Risk management, including*
    - *risk assessments*
    - *monitoring*
    - *audits*
- *Record keeping*

You must send a copy of your PDP to the GPhC within twelve weeks of the date this order takes effect.

9. You must meet with your supervisor at least once every two months to discuss:

- *Clinical governance*
- *Risk management, including*
    - *risk assessments*
    - *monitoring*
    - *audits*
- *Record keeping*
- *Your peer reviews*
- *Progress regarding your PDP*

10. You must arrange for your workplace supervisor to send a report on your progress and development directly to the GPhC every two months or when the GPhC asks for one, commenting on how you have changed your practice to ensure safe and effective care using your services in the following areas:

- *Clinical governance*
- *Risk management, including*
    - *risk assessments*
    - *monitoring*
    - *audits*
- *Record keeping*
- *Your peer reviews*
- *Progress regarding your PDP*

11. You must undertake training on supplying pharmacy only medicines that have potential for misuse or abuse (for example, the course offered by CPPE on "Addiction, Misuse and Dependency: A Focus On Over the Counter and Prescribed Medicines")

The training is to be paid for by you. You must send the GPhC evidence of completion within 10 days of the course.

12. You must provide to the Council prior to the review hearing a reflective account explaining how you meet the following standards for pharmacy professionals:

- *Standard 1 - Providing person centred care*
- *Standard 2 - Work in partnership with others*
- *Standard 3 - Pharmacy professionals must communicate effectively*
- *Standard 5 - Use professional judgement*
- *Standard 8 - Speak up when you have concerns or things go wrong*
- *Standard 9 - Demonstrate leadership*

Mr Sood

1. You must:

• give the GPhC the contact details of your place of employment and anyone who is likely to be the manager or persons supervising you (employer, pharmacy owner, agency, superintendent pharmacist responsible pharmacist)

• tell the GPhC before you take on any position for which you must be registered with the GPhC

• give the GPhC details of the role and the hours you will work each week, including locum or relief work

• tell the GPhC if any of the above details change

2. You must notify the following people in writing of these conditions before you commence any work, in relation to any paid or unpaid work for which registration with the GPhC is required:

• All employers or contractors

• Agents acting on behalf of employers and locum agencies

• Superintendent Pharmacists

• Responsible Pharmacists

• Line Managers

• Workplace supervisors

• Accountable Officer for Controlled drugs

• Prospective employers (notification should be given at the time of applying)

You must provide the GPhC with a copy of the notification(s)

3. You must tell the GPhC if you apply for work as a pharmacist or pharmacy technician outside Great Britain

4. You must not work as a Superintendent Pharmacist

5. You must, within eight weeks of the date this order takes effect:

• find a workplace supervisor (who must be a Superintendent Pharmacist) and ask the GPhC to approve your workplace supervisor

• put yourself, and stay, under their remote supervision ("Remote" means the supervisor can work apart from you, but must be available for advice or assistance)

• give the GPhC your permission to exchange information with your workplace supervisor about your efforts to improve your pharmacy practice

If you are not employed, you must ask the GPhC to approve your workplace supervisor before you start work

6. You must carry out a peer review on the appropriateness of a prescription of high-risk medication relevant to your area of practice and submit evidence of this to your supervisor in advance of your supervision meetings

7. You must send evidence of these peer reviews to the Council

8. You must work with your supervisor to draw up a personal development plan (PDP), specifically designed to deal with the shortcomings in the following areas of your practice:

- *SOPs*
- *Clinical governance, including audits*
- *Record keeping*
- *Online dispensing.*

You must send a copy of your PDP to the GPhC within twelve weeks of the date this order takes effect.

9. You must meet with your supervisor at least once every two months to discuss:

- *SOPs*
- *Clinical governance, including audits*
- *Record keeping*
- *Online dispensing.*
- *Your peer reviews*
- *Progress regarding your PDP*

10. You must arrange for your workplace supervisor to send a report on your progress and development directly to the GPhC every two months or when the GPhC asks for one, commenting on how you have changed your practice to ensure safe and effective care using your services in the following areas:

- *SOPs*
- *Clinical governance, including audits*
- *Record keeping*
- *Online dispensing.*
- *Your peer reviews*
- *Progress regarding your PDP*

11. You must undertake training on

- *supplying pharmacy only medicines that have potential for misuse or abuse (for example, the course offered by CPPE on "Addiction, Misuse and Dependency: A Focus On Over the Counter and Prescribed Medicines")*
- *the role and responsibilities of an SI*

The training is to be paid for by you. You must send the GPhC evidence of completion within 10 days of the course.

12. You must provide to the Council prior to the review hearing a reflective account explaining how you meet the following standards for pharmacy professionals:

- *Standard 1 - Providing person centred care*
- *Standard 2 - Work in partnership with others*
- *Standard 3 - Pharmacy professionals must communicate effectively*
- *Standard 5 - Use professional judgement*
- *Standard 8 - Speak up when you have concerns or things go wrong*
- *Standard 9 - Demonstrate leadership*

Ms Afzal

1. You must:

• give the GPhC the contact details of your place of employment and anyone who is likely to be the manager or persons supervising you (employer, pharmacy owner, agency, superintendent pharmacist responsible pharmacist)

• tell the GPhC before you take on any position for which you must be registered with the GPhC

• give the GPhC details of the role and the hours you will work each week, including locum or relief work

• tell the GPhC if any of the above details change

2. You must notify the following people in writing of these conditions before you commence any work, in relation to any paid or unpaid work for which registration with the GPhC is required:

• All employers or contractors

• Agents acting on behalf of employers and locum agencies

• Superintendent Pharmacists

• Responsible Pharmacists

• Line Managers

• Workplace supervisors

• Accountable Officer for Controlled drugs

• Prospective employers (notification should be given at the time of applying)

You must provide the GPhC with a copy of the notification(s)

3. You must tell the GPhC if you apply for work as a pharmacist or pharmacy technician outside Great Britain

4. You must not work as a Superintendent Pharmacist

5. Before you return to work as a pharmacist, you must:

• find a workplace supervisor (who must be a Superintendent Pharmacist) and ask the GPhC to approve your workplace supervisor

• put yourself, and stay, under their remote supervision ("Remote" means the supervisor can work apart from you, but must be available for advice or assistance)

• give the GPhC your permission to exchange information with your workplace supervisor about your efforts to improve your pharmacy practice

6. You must carry out a peer review on the appropriateness of a prescription of high-risk medication relevant to your area of practice and submit evidence of this to your supervisor in advance of your supervision meetings

7. You must send evidence of these peer reviews to the Council

8. You must work with your supervisor to draw up a personal development plan (PDP), specifically designed to deal with the shortcomings in the following areas of your practice:

• Monitoring of prescriptions

• Record keeping

• Escalation of risk/raising concerns

You must send a copy of your PDP to the GPhC within twelve weeks of the date this order takes effect.

9. You must meet with your supervisor at least once every two months to discuss:

• Monitoring of prescriptions

• Record keeping

• Escalation of risk/raising concerns

10. You must arrange for your workplace supervisor to send a report on your progress and development directly to the GPhC every two months or when the GPhC asks for one, commenting on how you have changed your practice to ensure safe and effective care using your services in the following areas:

• Monitoring of prescriptions

• Record keeping

• Escalation of risk/raising concerns

• Your peer reviews

• Progress regarding your PDP

11. You must undertake training on supplying pharmacy only medicines that have potential for misuse or abuse (for example, the course offered by CPPE on "Addiction, Misuse and Dependency: A Focus On Over the Counter and Prescribed Medicines")

The training is to be paid for by you. You must send the GPhC evidence of completion within 10 days of the course.

12. You must provide to the Council prior to the review hearing a reflective account explaining how you meet the following standards for pharmacy professionals:

- *Standard 1 - Providing person centred care*

- *Standard 2 - Work in partnership with others*
- *Standard 3 - Pharmacy professionals must communicate effectively*
- *Standard 5 - Use professional judgement*
- *Standard 8 - Speak up when you have concerns or things go wrong*

261. The Conditions of Practice will remain in place for 12 months. This will give the Registrants sufficient time to carry out the necessary training, develop their PDP and then put into practice their learning.

262. The Committee did go on to consider suspension. The 2024 guidance states that suspension may be appropriate where "*The committee considers that a warning or conditions are not sufficient to deal with any risk to patient safety or to protect the public, or would undermine public confidence"* and "*When it is necessary to highlight to the profession and the public that the conduct of the professional is unacceptable and unbefitting a member of the pharmacy profession. Also when public confidence in the profession demands no lesser outcome."*

263. The Committee considered that suspension would be unduly punitive, when the concerns it has identified can be addressed with conditions of practice. They will protect the public, as none of the Registrants will be permitted to act as an SI and will have stringent conditions in place to ensure that their practice is being supervised.

264. The Committee considered that conditions would be sufficient to mark the public interest, taking into account the mitigating factors in this case.

265. Finally, the Committee noted that the Council was asking for strike off for all three Registrants in this case, but the Committee considered that this would be a disproportionate response, and that the Registrants' behaviour is not fundamentally incompatible with being a registered professional. The public interest would not be served by permanently depriving the public of pharmacists who have developing insight and are willing to work on their remediation.

266. The Committee directs that there should be a review prior to the expiration of the order. This Committee cannot bind the reviewing committee, but considers that it is likely to be assisted by:

- Evidence that the Registrants have complied with their Conditions of Practice
- Testimonials from either paid or unpaid work

Interim measures

267. Mr Hoskins then applied for an interim measure to be imposed pursuant to Article 60 of the Pharmacy Order 2010 on the grounds of public protection and public interest. The decision of this Committee is an appealable one under Article 55(3) of the Pharmacy Order 2010. There will therefore be a period of 28 days before the Committee's direction comes into effect. Furthermore, during that 28-day period the Registrants could lodge an appeal and, if they did so, the Committee's substantive direction would not take effect until the appeal proceedings were concluded.

268. Mr McCaffrey indicated that his clients did not oppose the application.

269. This is a case where the Committee has found that the Registrants' conduct was so serious that the appropriate sanction is a 12-month Conditions of Practice order. The finding of impairment for all three Registrants was on the basis of public interest, but also due to the Registrants' insufficient remediation and insight, the Committee found that there remains a risk of repetition.

270. The Committee has therefore decided that interim measures are appropriate in order to protect the public. In addition, the public would be concerned if the Registrants were free to practise without restriction until the substantive order takes effect. It is therefore also in the wider public interest for there to be a Conditions of Practice order during the interim period before this Committee's direction comes into effect.

271. Ms Hoskins had suggested that some of the substantive conditions were more geared to the Registrants developing insight, and therefore not strictly necessary on an interim basis. The Committee decided that most of the conditions were still required during the appeal period

as they address the risks to the public but agreed that conditions around peer reviews and reflective accounts were not necessary. Both Counsel requested that the timing of the condition regarding appointing a supervisor should read within 12 weeks, rather than the eight weeks in the substantive conditions, so that the Registrants have the same overall time period to find a supervisor, allowing for the additional four-week period before the substantive sanction comes into effect. The Committee agreed to this.

272. The Committee therefore determined that the Registrant's registration be subject to Interim Conditions of Practice for 18 months. The conditions are as follows:

Mr Shabbir

1. You must:

• give the GPhC the contact details of your place of employment and anyone who is likely to be the manager or persons supervising you (employer, pharmacy owner, agency, superintendent pharmacist responsible pharmacist)

• tell the GPhC before you take on any position for which you must be registered with the GPhC

• give the GPhC details of the role and the hours you will work each week, including locum or relief work

• tell the GPhC if any of the above details change

2. You must notify the following people in writing of these conditions before you commence any work, in relation to any paid or unpaid work for which registration with the GPhC is required:

• All employers or contractors

• Agents acting on behalf of employers and locum agencies

• Superintendent Pharmacists

• Responsible Pharmacists

• Line Managers

• Workplace supervisors

• Accountable Officer for Controlled drugs

• Prospective employers (notification should be given at the time of applying)

You must provide the GPhC with a copy of the notification(s)

3. You must tell the GPhC if you apply for work as a pharmacist or pharmacy technician outside Great Britain

4. You must not work as a Superintendent Pharmacist

5. You must, within 12 weeks:

• find a workplace supervisor (who must be a Superintendent Pharmacist) and ask the GPhC to approve your workplace supervisor

• put yourself, and stay, under their remote supervision ("Remote" means the supervisor can work apart from you, but must be available for advice or assistance)

• give the GPhC your permission to exchange information with your workplace supervisor about your efforts to improve your pharmacy practice

If you are not employed, you must ask the GPhC to approve your workplace supervisor before you start work

Your supervisor must not be involved in any of your businesses

6. You must work with your supervisor to draw up a personal development plan (PDP), specifically designed to deal with the shortcomings in the following areas of your practice:

- *Clinical governance*
- *Risk management, including*
    - *risk assessments*
    - *monitoring*
    - *audits*
- *Record keeping*

You must send a copy of your PDP to the GPhC within twelve weeks of the date this order takes effect.

7. You must meet with your supervisor at least once every two months to discuss:

- *Clinical governance*
- *Risk management, including*
    - *risk assessments*
    - *monitoring*
    - *audits*
- *Record keeping*
- *Progress regarding your PDP*

8. You must arrange for your workplace supervisor to send a report on your progress and development directly to the GPhC every two months or when the GPhC asks for one, commenting on how you have changed your practice to ensure safe and effective care using your services in the following areas:

- *Clinical governance*
- *Risk management, including*
    - *risk assessments*
    - *monitoring*
    - *audits*
- *Record keeping*
- *Progress regarding your PDP*

9. You must undertake training on supplying pharmacy only medicines that have potential for misuse or abuse (for example, the course offered by CPPE on "Addiction, Misuse and Dependency: A Focus On Over the Counter and Prescribed Medicines")

The training is to be paid for by you. You must send the GPhC evidence of completion within 10 days of the course.

Mr Sood

1. You must:

• give the GPhC the contact details of your place of employment and anyone who is likely to be the manager or persons supervising you (employer, pharmacy owner, agency, superintendent pharmacist responsible pharmacist)

• tell the GPhC before you take on any position for which you must be registered with the GPhC

• give the GPhC details of the role and the hours you will work each week, including locum or relief work

• tell the GPhC if any of the above details change

2. You must notify the following people in writing of these conditions before you commence any work, in relation to any paid or unpaid work for which registration with the GPhC is required:

• All employers or contractors

• Agents acting on behalf of employers and locum agencies

• Superintendent Pharmacists

• Responsible Pharmacists

• Line Managers

• Workplace supervisors

• Accountable Officer for Controlled drugs

• Prospective employers (notification should be given at the time of applying)

You must provide the GPhC with a copy of the notification(s)

3. You must tell the GPhC if you apply for work as a pharmacist or pharmacy technician outside Great Britain

4. You must not work as a Superintendent Pharmacist

5. You must, within 12 weeks:

• find a workplace supervisor (who must be a Superintendent Pharmacist) and ask the GPhC to approve your workplace supervisor

• put yourself, and stay, under their remote supervision ("Remote" means the supervisor can work apart from you, but must be available for advice or assistance)

• give the GPhC your permission to exchange information with your workplace supervisor about your efforts to improve your pharmacy practice

If you are not employed, you must ask the GPhC to approve your workplace supervisor before you start work

6. You must work with your supervisor to draw up a personal development plan (PDP), specifically designed to deal with the shortcomings in the following areas of your practice:

- *SOPs*
- *Clinical governance, including audits*
- *Record keeping*
- *Online dispensing.*

You must send a copy of your PDP to the GPhC within twelve weeks of the date this order takes effect.

7. You must meet with your supervisor at least once every two months to discuss:

- *SOPs*
- *Clinical governance, including audits*
- *Record keeping*
- *Online dispensing.*
- *Progress regarding your PDP*

8. You must arrange for your workplace supervisor to send a report on your progress and development directly to the GPhC every two months or when the GPhC asks for one, commenting on how you have changed your practice to ensure safe and effective care using your services in the following areas:

- *SOPs*
- *Clinical governance, including audits*
- *Record keeping*
- *Online dispensing.*
- *Progress regarding your PDP*

9. You must undertake training on

- *supplying pharmacy only medicines that have potential for misuse or abuse (for example, the course offered by CPPE on "Addiction, Misuse and Dependency: A Focus On Over the Counter and Prescribed Medicines")*

  The training is to be paid for by you. You must send the GPhC evidence of completion within 10 days of the course.

Ms Afzal

1. You must:

• give the GPhC the contact details of your place of employment and anyone who is likely to be the manager or persons supervising you (employer, pharmacy owner, agency, superintendent pharmacist responsible pharmacist)

• tell the GPhC before you take on any position for which you must be registered with the GPhC

• give the GPhC details of the role and the hours you will work each week, including locum or relief work

• tell the GPhC if any of the above details change

2. You must notify the following people in writing of these conditions before you commence any work, in relation to any paid or unpaid work for which registration with the GPhC is required:

• All employers or contractors

• Agents acting on behalf of employers and locum agencies

• Superintendent Pharmacists

• Responsible Pharmacists

• Line Managers

• Workplace supervisors

• Accountable Officer for Controlled drugs

• Prospective employers (notification should be given at the time of applying)

You must provide the GPhC with a copy of the notification(s)

3. You must tell the GPhC if you apply for work as a pharmacist or pharmacy technician outside Great Britain

4. You must not work as a Superintendent Pharmacist

5. Before you return to work as a pharmacist, you must:

• find a workplace supervisor (who must be a Superintendent Pharmacist) and ask the GPhC to approve your workplace supervisor

• put yourself, and stay, under their remote supervision ("Remote" means the supervisor can work apart from you, but must be available for advice or assistance)

• give the GPhC your permission to exchange information with your workplace supervisor about your efforts to improve your pharmacy practice

6. You must work with your supervisor to draw up a personal development plan (PDP), specifically designed to deal with the shortcomings in the following areas of your practice:

• Monitoring of prescriptions

• Record keeping

• Escalation of risk/raising concerns

You must send a copy of your PDP to the GPhC within twelve weeks of the date this order takes effect.

7. You must meet with your supervisor at least once every two months to discuss:

• Monitoring of prescriptions

• Record keeping

• Escalation of risk/raising concerns

8. You must arrange for your workplace supervisor to send a report on your progress and development directly to the GPhC every two months or when the GPhC asks for one, commenting on how you have changed your practice to ensure safe and effective care using your services in the following areas:

- *Monitoring of prescriptions*
- *Record keeping*
- *Escalation of risk/raising concerns*
- *Progress regarding your PDP*

9.You must undertake training on supplying pharmacy only medicines that have potential for misuse or abuse (for example, the course offered by CPPE on "Addiction, Misuse and Dependency: A Focus On Over the Counter and Prescribed Medicines")

The training is to be paid for by you. You must send the GPhC evidence of completion within 10 days of the course.

273. This ends the determination.