General Pharmaceutical Council

Fitness to Practise Committee

Principal Hearing

Remote hearing online

2-13 September 2024; 25-27 February 2025; & 3 March 2025

Registrant name:	Mr Anees Khoda
Registration number:	2067807
Part of the register:	Pharmacist
Type of Case:	Misconduct
Committee Members:	Manuela Grayson (Chair)
	Surinder Bassan (Registrant Member)
	Wendy Golding (Lay Member)
Legal Adviser:	2-13 September 2024 & 27 February 2025: Michael Levy, Counsel;
	Wildinger Levy, Couriser,
	25-26 February 2025:
	Ralph Shipway, Solicitor
	3 March 2025:
	Asif Khan, Counsel
Committee Committee	Camacan Aharad
Committee Secretary:	Sameen Ahmed
Registrant:	Present
Registrant's representative:	Anthony Haycroft, Counsel
General Pharmaceutical Council:	Represented by Guy Micklewright, Counsel
Facts proved:	1 (in part); 3.1; 3.2; 3.3; 3.7; 3.8; 3.9; 3.10; 3.11; 4.1;

4.2; 5; 6.1; 6.2; 6.3; 6.4; 8; 9; 10; 12; 14

Facts proved by admission: 2; 11.2

Facts not proved: 3.4, 3.5, 3.6; 7; 13

Fitness to practise: Impaired

Outcome: Suspension, eight months with review

Interim measures: Interim measure of suspension

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 April 2025) or, if an appeal is lodged, once that appeal has been concluded. However, the interim suspension set out in the decision takes effect immediately and will lapse when the decision takes effect or once any appeal is concluded.

Particulars of Allegation (as amended)

You, a registered pharmacist, between October 2018 and April 2021, as director and/or owner of Pronto Healthcare Limited, Suite 8a, 1-3 The Courtyard, Calvin Street, Bolton, Greater Manchester, BL1 8PB ('the pharmacy'); and between August 2020 and April 2021, as the Superintendent Pharmacist and regular Responsible Pharmacist of the pharmacy, provided services at a distance through ukpharmacymeds.com in circumstances where:

- 1. You failed to ensure that the pharmacy and/or the Prescribers 1 and/or 2 ("the EU prescribers") carried out any or any adequate identity checks on all patients requesting:
- 1.1 antimicrobials
- 1.2 medicines liable abuse, overuse of misuse
- 1.3 medicines requiring ongoing monitoring and/or management.

[PROVED IN PART]

2. You failed to audit and/or ensure audits were carried out on cancelled and/or refused requests for the supply of medication.

[ACCEPTED]

- 3. You allowed and/or failed to prevent the EU prescribers prescribing contrary to the General Medical Council ("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 their physical health;
- 3.5 failed to contact or attempt to obtain details of their mental health;
- 3.6 failed to access and/or attempt to access patients' GP medical records and/or specialist clinical records;
- 3.7 failed to request a face-to-face consultation with patients;
- 3.8 failed to adequately consider the possibility of medication dependence and misuse;
- 3.9 failed to query with the 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/or
- 3.11 failed to put adequate safeguards in place.

[3.1, 3.2, 3.3, 3.7, 3.8, 3.9, 3.10, 3.11 PROVED; 3.4, 3.5 and 3.6 NOT PROVED]

- 4. You failed to ensure that the pharmacy operated in a safe and effective manner in that:
- 4.1 the pharmacy's website was arranged so that a person could choose a POM and its quantity before there had been an appropriate consultation with a prescriber; and
- 4.2 patients were able to change their answers to consultation questions without any auditable log of any changes being kept.

[PROVED]

5. You failed to ensure that the EU prescribers obtained all the information they would need to prescribe safely and appropriately in that the EU prescribers relied primarily on the information supplied by the patient in the sign-up form and consultation questionnaire with no opportunity for the prescribers to have a face to face consultation with the patient.

[PROVED]

- 6. Your failed to ensure that the pharmacy and/or the EU prescribers:
- 6.1 managed the risk that people may deliberately provide incorrect information to receive medicines that they wanted, despite them being clinically inappropriate;
- 6.2 shared relevant information about the prescriptions with other relevant healthcare professionals, including their GP;
- 6.3 contacted the patient's GP in advance of issuing a prescription for high-risk medicines to confirm that the medicine was appropriate for the patient and/or that appropriate monitoring was in place; and/or
- 6.4 recorded adequately their justification for prescribing in circumstances where the person did not have a GP or did not consent to share information with their GP.

[PROVED]

7. You failed to ensure that the EU prescribers were competent in their prescribing and/or able to prescribe legally in the UK.

[NOT PROVED]

8. You failed to ensure that the EU prescribers had any, or any adequate, indemnity cover.

[PROVED]

9. You failed to ensure that the EU prescribers followed national prescribing guidance for the UK including the GMC 'Good practice in prescribing and managing medicines and devices' and the GPhC 'Guidance for registered pharmacies providing pharmacy services at a distance'.

[PROVED]

10. You failed to ensure that the services the pharmacy provided at a distance, including the prescribing service, had been adequately risk assessed.

[PROVED]

- 11. You failed to ensure that the Pharmacy website had the following details on display:
- 11.1 [deleted]
- 11.2 the prescriber's name, registration details and regulatory body.

[ACCEPTED]

12. Having agreed to amend the pharmacy website on or around 10 July 2019 to prevent a patient selecting medicines before a consultation had been completed, on or around 7 August 2019 you caused and/or allowed the pharmacy website to revert back to allowing patients to select medicines before a consultation was completed.

[PROVED]

- 13. Your conduct at 12 above lacked integrity in that:
- 13.1 you had agreed the change in order to ensure the pharmacy met the pharmacy standards; and
- 13.2 the change was made to increase remuneration for the pharmacy and did not take account of patient safety concerns.

[NOT PROVED]

- 14. Whilst working as Responsible Pharmacist dispensed dihydrocodeine to Patient A on occasions stated in Schedule A in circumstances in which you:
- 14.1 failed to ensure you and/or the prescriber had all of the necessary information to ensure that the supplies to be made were clinically appropriate and safe for the patient;
- 14.2 failed to ensure that the patient's GP or other treating healthcare professionals were consulted before the supply was made; and
- 14.3 failed to refer the patient back to their GP for appropriate assessment.

[PROVED]

By reason of the matters above, your fitness to practise is impaired by reason of your Misconduct.

SCHEDULE A

Date (s)	Medicine/quantity
29 October 2018	112 tablets of dihydrocodeine 30mg
18 December 2018	200 tablets of dihydrocodeine 30mg
29 January 2019	112 tablets of dihydrocodeine 30mg
12 February 2019	56 tablets of dihydrocodeine 30mg
4 March 2019	112 tablets of dihydrocodeine 30mg
21 March 2019	112 tablets of dihydrocodeine 30mg
3 April 2019	112 tablets of dihydrocodeine 30mg
29 April 2019	112 tablets of dihydrocodeine 30mg

Documentation

Document 1 – Agreed bundle of documents prepared by the Council, (1461 digital pages)

Document 2- Council's Statement of Case and Skeleton Argument, 22 August 2024

Document 3- Defence Skeleton Argument, 27 August 2024

Document 4- Council's Skeleton argument regarding hearsay evidence application

Document 5- Defence Skeleton argument regarding hearsay evidence application

During the hearing the following documents were provided:

Document 6- Ms 1 notebook entries 7 August 2019

Document 7- part of typed notes of Ms 1 in relation to follow up visit, undated

Document 8- two emails set by Ms 1 to the Registrant dated 22 June 2019 and 7 July 2019

Document 9- bundle of emails on behalf of the Registrant (20 pages)

Witnesses

- Dr C, expert witness gave sworn evidence at facts stage on behalf of the Council
- Ms 1, GPhC Inspector gave sworn evidence at facts stage on behalf of the Council

Witness statements from the following witnesses were agreed:

- Ms 2, Lead Clinical Advisor and Specialist Inspector at the Council
- Mr 1

The Registrant gave evidence at the facts stage

Determination

Introduction

- 1. This is the written determination of the Fitness to Practise Committee at the General Pharmaceutical Council ('the Council').
- 2. The 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").
- 3. The statutory overarching objectives for these regulatory proceedings are:
 - a. To protect, promote and maintain the health, safety and well-being of the public;
 - b. To promote and maintain public confidence in the professions regulated by the Council; and
 - c. To promote and maintain proper professional standards and conduct for members of those professions.
- 4. The Committee also had regard to the guidance contained in the Council's *Good decision* making: Fitness to practise hearings and outcomes guidance as revised March 2024.
- 5. A Principal Hearing has up to three stages:
 - Stage 1. Findings of Fact the Committee determines any disputed facts;
 - Stage 2. Findings of ground(s) of impairment and impairment the Committee determines whether, on the facts as proved, a statutory ground for impairment is established and, if so, whether the Registrant's fitness to practise is currently impaired;
 - Stage 3. Sanction/Outcome the Committee considers what, if any, outcome should be applied if the Registrant's fitness to practise is found to be impaired.

Service of Notice of Hearing

6. The Committee has seen a letter dated 26 July 2024 from the Council headed 'Notice of Hearing' addressed to the Registrant. No issue was taken by the Registrant regarding notice. The Committee concluded that good service had been effected in accordance with the Rules.

Applications to amend the Particulars of Allegation

At the start of the Hearing

- 7. The Committee heard an application from Mr Micklewright on behalf of the Council under Rule 41 to withdraw particular 11.1 of the Allegation, and to amend particular 10 by adding "adequately".
- 8. Mr Micklewright accepted on the Council's behalf the evidence of Ms 1 to the effect that the Pharmacy registration number was available on the Pharmacy website. He submitted that withdrawal or discontinuance of particular 11.1 would not lead to under-prosecution of the case as a whole.
- 9. In relation to the proposed amendment of particular 10, Mr Micklewright submitted that insertion of "adequately" would better reflect the evidence of Ms 1 including her exhibits, and that the Registrant had been on notice as to the nature of the Council's case since the case had been served on him. The proposed amendment would cause no prejudice to the fairness of the case.
- 10. Mr Haycroft confirmed on behalf of the Registrant that he did not oppose the proposed amendments.
- 11. The Committee accepted the advice of the Legal Adviser.
- 12. The Committee was satisfied that the amendments could be made without causing prejudice to the Registrant, for the reasons submitted by Mr Micklewright.
- 13. Accordingly, the Committee granted the Council's application to withdraw particular 11.1, and to amend particular 10 as proposed by Mr Micklewright.

After closing submissions on the facts

14. During its questions following closing submissions on behalf of both parties, the Committee asked for clarification in relation to sub-particulars 3.4 and 3.5, which were unclear and incomplete. After obtaining instructions, Mr Micklewright made an application to amend both particulars s to read (amendments in bold):

- "3.4 failed to contact **the patients and/** or attempt to obtain details of their physical health;
- 3.5 failed to contact **the patients and/** or attempt to obtain details of their mental health".
- 15. Mr Micklewright acknowledged that this application was somewhat late but submitted that there would be no procedural unfairness nor unfairness to the Registrant who, it was clear from his defence, had always understood the Council's intended meaning.
- 16. Mr Haycroft submitted that this was an example of the charges being too vague to be understood; all the evidence had been heard; and it would be unfair to the Registrant to make the proposed amendments at this stage.
- 17. The Committee, having accepted the advice of the legal adviser, determined that it would be unfair to the Registrant to amend the particulars at this stage, since his defence had been prepared and argued on the basis of the unamended particulars. It therefore declined to amend sub-particulars 3.4 and 3.5 as proposed by Mr Micklewright on behalf of the Council.
- 18. Mr Micklewright confirmed that he had no instructions to withdraw the sub-particulars.

Application for the hearing to be held in Private

19. At the direction of the Committee, where the Registrant referred in his oral evidence to private matters of heath and/or family, those parts of his evidence were held in private under Rule 39(3). Both parties' representatives agreed to this procedure, and the Committee heard and accepted legal advice on this matter.

Registrant's response to Particulars of Allegation

- 20. The Registrant denied the entirety of the Allegation, save for particulars 2 and 11.2, which he accepted.
- 21. In the light of the above, and by the application of Rule 31(6) of the Rules, the Chair announced that the accepted and thus admitted factual particulars were found proved by the Committee.
- 22. The Committee then proceeded to receive evidence and submissions regarding the remaining particulars of the Allegation.

Background, according to the Council as set out in its Statement of Case and Skeleton Argument

23. The Allegation in this case relates to the Registrant's practice at the Pharmacy between October 2018 and April 2021.

<u>Pronto Healthcare Ltd ("the Pharmacy")</u>

- 24. Prior to his involvement with the Pharmacy, the Registrant was director, Superintendent Pharmacist ("SI") and Responsible Pharmacist ("RP") of EU Healthcare Limited ("EU Healthcare") between November 2017 and April 2019. The Pharmacy was incorporated on 12 September 2018 with the Registrant as sole director, a position he held until 9 September 2020. On 1 June 2019, the Registrant assumed the role of superintendent ("SI"). Prior to that date, Moses Kolapo Ajayi was SI. The Registrant became director of Digital Health Ltd on 2 June 2020, a position he resigned from on 30 November 2022. Digital Health Ltd is described by the Registrant as taking over Pronto Healthcare in April 2021. On 19 August 2021, the Registrant completed a form to voluntarily remove the Pharmacy from the Register. That application was eventually approved on 31 January 2022.
- 25. The Pharmacy delivered services to patients online via the website www.ukpharmacymeds.com ("the Website"). The business model of the Pharmacy was entirely an online/distance selling pharmacy. No medication was dispensed to patients attending the Pharmacy in person. Patients would request medication via the Website. The Website offered a variety of prescription medications but mainly supplied opiate pain killers and sedative sleeping tablets. Patients would request the medication and the amount of medication they wanted and provide information via an online questionnaire. That information would then be passed on to two prescribers. One of those prescribers was based in Spain and one in the Czech Republic. Neither was registered with the General Medical Council ("GMC"), and the prescribing service itself was not registered with the Care Quality Commission ("CQC"). No face-to-face consultations would take place with patients. Once a prescription had been produced, the order would be dispensed and then sent by post or courier to the address nominated by the patient.

Pharmacy Inspection 16 May 2019

- 26. As a result of a complaint submitted by Mr 1 concerning Patient A on 2 May 2019, an inspection of the Pharmacy was undertaken. Ms 1 carried out the inspection accompanied by another GPhC Inspector, Sharon Monks. At that point the Registrant was the RP of the Pharmacy and, as the SI was not playing an active role in the daily operation or management of the Pharmacy, the Registrant was the person with operational management and oversight of the systems and procedures in place.
- 27. The Inspection report, dated 16 May 2019, prepared by Ms 1, raised the following concerns:
 - (i) Not carrying out identity checks on all patients requesting prescription only medications ("POMs"), oral contraceptives and emergency hormonal contraception ("EHC");
 - (ii) The Pharmacy did not have adequate safeguards to ensure supplies of opiates and sleeping tablets are appropriate and are not being abused by the patient;
 - (iii) The Pharmacy could not demonstrate that the prescribing service is safe and that the prescribers are competent;
 - (iv) The Pharmacy could not demonstrate that the prescribers had adequate indemnity cover;
 - (v) The Pharmacy's systems did not ensure that patients received the most appropriate treatment because the Website is arranged so that a patient can choose a POM and its quantity without a consultation with a prescriber, as well as change answers to consultation questions, without any record being retained, in order to circumvent the system (questions would indicate which individual answer would prevent a prescription from being issued);
 - (vi) There were inadequate safeguards to prevent selling POMs to patients who may abuse them, for example that the prescriber will proactively share information with other health professionals, such as the patient's GP, contact the GP in advance of prescribing, and recorded the reasons for prescribing where the patient either does not have a GP or refuses to consent to information being shared with their GP;

- (vii) The Pharmacy had failed to ensure that the prescribers' names, registration details and regulatory bodies were on the Website; and
- (viii) The Pharmacy had not fully identified and managed all of the risks to patients.

Improvement Notice 18 June 2019

- 28. Following an enforcement action meeting on 7 June 2019, a decision was made to issue an Improvement Notice ("the Notice") under Art. 13 of the Pharmacy Order 2010. The Notice was served on 18 June 2019. The Notice required the following to be done by 16 July 2019:
 - a) You must provide evidence that the prescribers you work with are appropriately registered and qualified, and able to lawfully prescribe for people who are resident in the UK
 - b) You must provide evidence that the prescribers you work with are operating within their spheres of competence and working within UK national prescribing guidelines and good practice guidance
 - c) You must provide evidence that the prescribers you work with are covered by appropriate indemnity arrangements
 - d) You must provide evidence to show that the pharmacy effectively monitors and reviews all prescriptions to prevent over-ordering or misuse
 - e) The pharmacy website must not allow people to choose the medicines they want before they have had an appropriate consultation with a prescriber
 - f) The consultation questions must not indicate which individual answer prevents a prescription from being issued, or allow answers to be subsequently altered without the alteration being visible to the prescriber
 - g) The pharmacy must carry out an appropriate identity check of the patient (for example by keeping to the Identity Verification and Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services) before medicines are supplied
 - h) You must demonstrate that the pharmacy gets all of the information it needs about people who use its services to check that the supply is safe and appropriate. This will include the patient's age, gender, other medicines and other relevant issues
 - i) You must provide evidence that the prescribers you work with:

- proactively share all relevant information about the prescriptions they issue with other health professionals involved in the care of the patient (for example their GP)
- that the prescriber contacts the GP in advance of issuing a prescription to confirm that the prescription is appropriate for the patient and that appropriate monitoring is in place
- that the prescriber makes a clear record setting out their justification for prescribing, in circumstances where the patient does not have a GP, or does not consent to share information.
- 29. On 10 July 2019, the Registrant emailed Ms 1 with details of "all required changes and evidence". The material was contained in two emails. The first email dealt with points (a) to (d) and the second email with points (e) to (i).
- 30. On 26 July 2019, Ms 1 emailed the Registrant. She considered that the Pharmacy had still not taken adequate steps to meeting the requirements of the Notice, and set out what was still required in respect of each point, asking that the additional information was provided by 7 August 2019:
 - a) Evidence that the prescribers are authorised to prescribe to UK patients via online consultations;
 - b) Evidence that regular repeat prescribing of opioid painkillers and sleeping tablets to patients residing in the UK is undertaken with NICE, BNF, GMC and other good practice guidance, for example by clinical audits or risk assessments of prescribing decisions, and details of any specific training carried out by the prescribers to provide assurance that they are competent to prescribe these drugs;
 - c) Verification from the prescribers' insurance companies that their indemnity arrangements cover their remote prescribing activities and, given that the level of insurance cover is lower than that offered by prescribers in the UK, what steps have been taken to ensure that patients and/or families may be adequately recompensed in the event of medical malpractice, harm and/or death;
 - d) Evidence to demonstrate how the control systems within the software and operating systems manage the risk of over-ordering or misuse, which is currently reliant on

- personal vigilance alone, and what processes are in place to enable a prescriber to inform their decision to issue a prescription where a request has previously been denied because it has been made too soon;
- e) Further information regarding the input from the prescriber at the consultation stage on the Website, whether there is two-way communication with the patient, what information the Pharmacy provides the prescriber with and whether repeat customers bypass the consultation;
- f) Details of how the Pharmacy is managing the risk that patients would enter incorrect information into the Website to get the medication they want when it is clinically inappropriate to prescribe it;
- g) Details of whether Equifax has been introduced (for the purposes of checking patient ID) and at what point of the process it will be used; whether it is to be used for all patients or only those requesting certain types of medicines; and whether it will be used only for new patients;
- h) Whether the Registrant is still requesting a copy of a previous prescription when prescribing opioid painkillers and sleeping tablets and whether that will be extended to all medications supplied; and
- i) When a patient gives consent to contact their GP or doctor, whether there is a delay in the supply of the medication until the doctor has confirmed that the prescription is appropriate. The Registrant was asked what his Standard Operating Procedures are and whether records of communication with the GP are kept.
- 31. In that email, Ms 1 said that she was, "particularly interested to see real-life examples of the systems and processes, and to see the new arrangement of the website" at the visit on 7 August 2019 with Ms 2.
- 32. The Registrant did not provide any of the requested evidence or information by 7 August 2019.

Pharmacy Inspection 7 August 2019

33. At this inspection Ms 1 was not satisfied that the requirements of the Notice had been met and the Registrant was continuing to supply opioids and 'Z drugs' despite the patient safety

concerns identified in the Inspection report. Ms 1 was of the impression that the Registrant appeared to lack insight into the risks involved in continuing to supply patients with high-risk medication while operating as he was.

- 34. Of particular note was the fact that the Website had changed on or around 10 July 2019 so that the consultation was completed prior to the selection of a medicine by the patient.

 However, Ms 1 says that when she checked the Website on 6 and 7 August 2019 in advance of the inspection, the Website had reverted to allowing for the selection of the medicine first.
- 35. [The following elements of the background according to the Council were found Not Proved by the Committee:] [When asked about this, the Registrant said that he had changed it back due to an increased number of queries from customers and because "business had fallen".
- 36. It remained the case that the Pharmacy and the prescribers could only see the final version of the online questionnaire and could not see if any of the answers have been altered. No answer was provided by the Registrant as to how the Pharmacy managed the risk of incorrect information being entered.
- 37. The Registrant said that he had not been checking IDs since July 2019 due to him investing in a new ID checking system: Equifax. He said that in order to install it the old system could not continue on the Website.]
- 38. During the 16 May 2019 inspection, very few patients were giving consent to share information with their own GP. Out of 27 patients reviewed, only one had given consent to share information and the Registrant was unsure whether the GP in question had been contacted by the Pharmacy in relation to the supply. On 7 August 2019, of the 31 prescriptions randomly checked only two patients had provided GP consent. All 31 patients were nevertheless supplied. Ms 1 states that in such circumstances she would expect the Pharmacy either to put the order on hold pending GP consent or to reject the order if the patient failed to provide their GP details. If the prescriber wanted to go ahead and prescribe the medication, then the justification for doing so would need to be appropriately recorded. The Registrant confirmed, however, that the prescribers were not recording their clinical

assessment and justification for prescribing medication. The reason given by the Registrant is that the prescribers were not yet trained on the new system and so were unaware of how to record their clinical notes.

39. Following the 7 August 2019 inspection, the GPhC considered that there remained a failure to comply with the Notice and so the GPhC imposed conditions on the Pharmacy's registration on 13 August 2019. The condition was that the Pharmacy "must not dispense any controlled drugs from schedule 1 to 5".

Relevant Standards and Guidance

- 40. A number of regulatory standards and guidance documents were referred to in this matter and include the following:
 - a. Standards for pharmacy professionals, May 2017;
 - b. Standards for registered pharmacies, June 2018;
 - c. General Medical Council ("GMC"), 2013, Good practice in prescribing and managing medicines and devices ("the GMC Guidance");
 - d. Royal Pharmaceutical Society ("RPS"), 2016, A Competency Framework for all Prescribers;
 - e. General Pharmaceutical Council (GPhC), April 2015, Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet ("the 2015 Guidance");
 - f. General Pharmaceutical Council (GPhC), January 2018, Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet ("the 2018 Guidance");
 - g. General Pharmaceutical Council (GPhC), June 2018, discussion paper on making sure patients and the public obtain medicines and other pharmacy services online;
 - h. NHS guidance: Identity Verification and Authentication Standard for Digital Health and Care Services, 21 June 2018;

- General Pharmaceutical Council (GPhC), April 2019, Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet ("the 2019 Guidance");
- j. General Pharmaceutical Council (GPhC), November 2019, In practice: Guidance for pharmacist prescribers;
- k. Schedule 3, Misuse of Drugs Regulations 2001.

Expert Evidence of Dr C

- 41. Dr C, expert witness on behalf of the Council, provided a witness statement dated 15 May 2023 which discussed online prescribing in general terms: she did not give evidence in relation to the facts of this particular case. She also gave oral evidence to the Committee. She explained that her statement made reference to the guidance in force at the time she wrote it.
- 42. The Committee noted that she referred in detail to the guidance set out in the GMC's "Good Practice in Prescribing and Managing Medicines and Devices", issued in 2021, whereas the GMC guidance in force at the time of the events set out in the Allegation was the previous edition, from 2013; and to the GMC's "Good medical practice" of 2019, which came out towards the end of the relevant period, replacing an earlier version also from 2013; and to the RPS's "A Competency framework for all Prescribers" 2019, which replaced the version issued in July 2016.
- 43. In relation to the GPhC <u>"Guidance for online pharmacies working at a distance including on the internet"</u> Dr C made detailed reference to the 2019 Guidance which came out one month before Ms 1's inspection of the Pharmacy.
- 44. The Committee took these factors into account in assessing the weight of Dr C's evidence.

- 45. The Committee also took into account, in assessing the weight of her evidence, that Dr C was not a pharmacist but a GP, and that whilst she had experience of prescribing within traditional health settings, she did not have experience of prescribing in an online setting.
- 46. The Committee bore in mind that Mr Haycroft had submitted that great care should be exercised in accepting Dr C's evidence due to these and other factors which he set out.
- 47. However, it was of the view that her opinion in relation to the principles of safe prescribing, and of what would be required for the online prescribing model to operate safely, could properly be relied on.

Council's Application to Admit hearsay evidence

- 48. Prior to the Committee hearing evidence from Ms 1, Mr Micklewright made an application for the following hearsay evidence to be admitted:
 - Third witness statement of Ms 1, para 30
 - Third witness statement of Ms 1, paragraphs 43 and 44;
 - Exhibit Ms 1/10, being a file note made by Ms 1 dated 7 June 2019, consisting
 of an account of what Ms 1 says she was told by an underwriter at the
 Registrant's professional insurer.
- 49. Mr Micklewright submitted that the evidence was demonstrably relevant; it was reliable; and it would be fair to admit it. He said a decision had been made by the Council that it was not proportionate to take a witness statement given the length of time the investigation had taken at the point the progress of the investigation was reviewed by a senior lawyer.
- 50. Mr Haycroft objected to the application on the basis that it would be unfair to admit the proposed evidence because he would have no way of testing it on the Registrant's behalf. He submitted that the Council were *not* relying upon a statement of an insurer via a witness statement (first hand hearsay) but the recollection of Ms 1 of a conversation with someone from an insurance company (second hand hearsay). It was demonstrably unreliable. He

further submitted that Ms 1 was not an expert on insurance; and the individual spoken to was not an independent witness into insurance matters and should not be relied upon in any event first hand let alone second hand. No sufficient reason had been given for the Council not having sought a relevant expert as a witness. He submitted that the Council had deliberately chosen not to obtain admissible and proper evidence.

51. The Committee heard and accepted legal advice. It took into account Rule 24(2) of the Rules, which provides, as follows:

"24(2) Subject only to the requirements of relevance and fairness, the Committee may receive—

- (a) subject to paragraph (3), any documentary evidence; and
- (b) where a hearing is held, any oral evidence,
 whether or not such evidence would be admissible in any subsequent civil proceedings
 if the decision of the Committee were appealed to the relevant court."
- 52. The Committee also applied the principles set out in relevant case law, which had been helpfully summarised in the skeleton arguments of both counsel and was not disputed.
- 53. The Committee accepted that the hearsay evidence from Ms 1 about the conversation she had with the insurer was relevant, however it was of the view that it would not be fair in all the circumstances for the evidence to be admitted. Whilst there was no suggestion other than that Ms 1 believed she had faithfully recorded what she was told, there was no way in fact to test what the insurer had said as the Council had not provided a statement from him nor was he available as a witness at the hearing.
- 54. The Committee therefore refused the application insofar as it contained references to the content of the telephone conversation which Ms 1 had with the insurer. It therefore admitted all of paragraph 30 save for one sentence; all of paragraph 43 save for the last sentence of that paragraph; and only the second sentence of paragraph 44. As for exhibit Ms 1/10, Ms 1's file note of the conversation, the Committee resolved not to admit all of the first paragraph of the note, that is, Ms 1's hearsay record of the conversation she had with the Registrant's

insurer. In relation to the second paragraph, the Committee did not admit words from the first sentence which referred to contents of Ms 1's conversation with the insurer, so that the first sentence was admitted to read as follows:

"I then called Anees Khoda and [redacted] I explained [redacted] he told me had...[etc]".

Decision on Facts

- 55. In reaching its decisions on facts, the Committee considered the documentation listed at the start of this determination and all of the oral evidence. The Committee also took account of the submissions, both written and oral, made on behalf of the Council and the Registrant.
- 56. The Committee accepted the advice of the Legal Adviser.
- 57. When considering each particular of allegation, the Committee bore in mind that the burden of proof rests on the Council and that particulars are found proved based on the balance of probabilities. This means that particulars will be proved if the Committee is satisfied that what is alleged is more likely than not to have happened. The Committee bore in mind submissions which had been made by Mr Haycroft to the effect that it must take care not to allow the burden to be "reversed by stealth" such that it becomes a burden upon the Registrant to disprove any alleged particular. Mr Haycroft submitted that this caveat applied especially in relation to particulars 7-10 and 14.

Preliminary Matters

58. Before reviewing the individual particulars, the Committee turned first to consider the various regulatory documents it had been provided with and to assess the extent of the Registrant's professional duties – if any- under them.

- 59. Under the <u>Pharmacy Order 2010</u>, there were two sets of standards which the Registrant was expected to comply with: (i) the <u>Standards for pharmacy professionals</u> (May 2017); and (ii) the <u>Standards for registered pharmacies</u> (June 2018). It should be noted that whilst they are mandatory in nature, failure to comply with the standards is not, of itself, to be taken to constitute misconduct on a registrant's part, but is to be taken into account in any fitness to practise proceedings (Article 48(3) of the Order).
- 60. The Registrant accepted throughout that he had a professional duty to abide by the GPhC Standards in force at the relevant times.
- 61. In relation to the various guidance documents issued by the GPhC from time to time, the Committee took into account that, unlike the Standards, the guidance is not mandatory, however, it is intended to support pharmacists to maintain those Standards, and support pharmacy owners to make decisions.
- 62. Both the 2015 Guidance and the 2018 Guidance state as follows:

"We expect this guidance to be followed. However, we also recognise there are a number of ways to meet our standards and achieve the same outcomes for patients and people who use pharmacy services – that is, to provide safe treatment, care and services. If you do not follow this guidance you must be able to show how your own ways of working:

- safeguard patients and users of pharmacy services
- identify and manage any risks, and
- meet our standards."
- 63. The Committee observed that this wording clearly set out that if the Registrant diverged from following guidance which he had the right to do in principle it would nevertheless be incumbent on him "to show" how such divergence safeguarded patients etc, as set out above.
- 64. The 2019 Guidance contained different wording, which is set out below:

"Following this guidance is an important part of making sure you meet our standards for registered pharmacies...We therefore expect this guidance to be followed.

Not following this guidance, or not taking the appropriate steps to achieve a desired outcome under our standards, could mean that you fail to meet one or more of the standards for registered pharmacies. This could result in our taking enforcement action."

- 65. Whilst the wording in the 2019 Guidance set out in no uncertain terms the Council's expectation that it would be followed, it also allowed for registrants to take alternative "appropriate steps" to comply with the standards.
- 66. It had been argued for the Registrant that although the "Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet" from time to time in force did apply to him as Pharmacy owner and, after he took over on 1 June 2019, also as SI of the Pharmacy, (and day-to-day as RP), the Committee should exercise caution as to the weight it gave to guidance in two respects:
 - (i) it was "unfair and unreasonable" to expect him to have fully complied with the 2019 Guidance in the short period of time given to him by Ms 1 after her May 2019 inspection (one month from the Improvement Notice issued on 18 June 2019) because it was far more rigorous than the earlier guidance and had come into force only a month before the inspection. Moreover, Pronto had only begun trading in February 2019. The Registrant referred the Committee to the GPhC's general communications including a letter to all pharmacy owners and SIs of internet pharmacies dated 17 September 2019 which, he said, gave them until 16 October 2019 to inform the GPhC as to how they were complying with the 2019 Guidance on managing the risks of their internet pharmacy businesses; and
 - (ii) The EU prescribers were not "staff" within the meaning of the GPhC's guidance. The Registrant stated in his witness statement that he believed there had been "a clear"

misunderstanding by the GPhC of [his] business model... The doctor's service was a separate entity from Pronto healthcare and completely different business. Pronto was an affiliate of the doctors' company". In oral evidence, the Registrant said this arrangement was similar to the way Amazon works: he simply put the patients in contact with the prescribers who, in return, sent him the prescription to dispense. His lawyers explained that "Pronto Healthcare Ltd did not employ the doctors nor did it offer a prescribing service. It simply connected the patients to the doctors. The doctor was responsible for undertaking the consultation from the questionnaire, using their clinical expertise and competencies in accordance with the NICE and BNF guidelines".

- 67. Mr Haycroft submitted that the 2019 Guidance clearly distinguished between "staff" and "EU prescribers" when referring to the additional risks involved when using EU prescribers, and if the intention was for such prescribers to be treated as "staff" of the Pharmacy, the Guidance would have said so.
- 68. In relation to (i) above, the Committee could have had some sympathy with the Registrant's submissions in relation to the new content in the 2019 Guidance, if the first time he had been notified of the more detailed nature of that guidance had been on 16 May 2019; however, this was not the position in relation to this Registrant.
- 69. This Registrant had many years of experience of internet pharmacy. He had been the SI of an internet pharmacy (HR Healthcare Ltd) from 2010 to 2017 and in November 2017 he moved to become SI and RP of another internet pharmacy, EU Healthcare, where he was also a director. That pharmacy was inspected by Ms 1 on 28 September 2018, and whilst it was on the whole found to be 'satisfactory', Ms 1 found that it had "not met" a number of Standards. The Registrant was required to deal with Ms 1's concerns by way of an Action Plan. The Committee was provided with both the Inspection Report from that visit and, by the Registrant, also with the Action Plan. The report set out for example that:

"There is no evidence of risk assessment to provide assurance that high risk activities are being appropriately managed. This would include: using non-UK regulated prescribers; supplying addictive medicines without the knowledge or agreement of the patient's GP; the patient entering incorrect information during the online consultation."

In relation to patient ID, the report stated: "It was a mandatory requirement for patients requesting sedatives and opioids to upload personal identification (ID) but this was not necessary for other POMS such as emergency contraceptives (EHC), contraceptives and antibiotics. The SI accepted admitted [sic] that there might be a risk that EHC and contraceptives were supplied to third parties, which might be a safeguarding concern".

The Committee was of the view that these comments summed up clearly and concisely the essential concerns which Ms 1 had in relation to the systems and procedures the Registrant was overseeing in his pharmacy at that time.

- 70. In the event, Ms 1 told the Committee, the improvements process in relation to EU

 Healthcare was never completed because the Registrant left that business soon after, to set

 up Pronto, whose registration he applied for on 1 December 2018.
- 71. Ms 1 told the Committee that she planned to continue her monitoring of the Registrant's compliance with the <u>Standards for Registered pharmacies</u> (June 2018) and the relevant guidance when she visited this new business, which she did, on 16 May 2019. This visit, she explained, was prioritised because of the concern raised in relation to Patient A.
- 72. Ms 1's evidence was that she told the Registrant at the visit in late September 2018 to EU

 Healthcare, that the Council was in the process of reviewing its 2018 Guidance to make it

 clearer and more detailed, and that he should be looking to implement the changes proposed
 in the consultation document which was available on the GPhC's website.
- 73. Mr Haycroft submitted that the Registrant should not have been expected to make changes to his business model during the period of consultation in mere anticipation of what the updated guidance might require, because he could not have known what the final guidance would contain until it was published. It followed that it was unfair to hold him to a higher

- standard in terms of timing for compliance with the 2019 Guidance than was the case for others in the industry.
- 74. The Committee considered the 2019 Guidance. It was significantly more detailed than previous guidance in relation to how pharmacies should manage the risks of using non-UK based prescribers; it also contained new guidance to be followed where pharmacies have chosen to work with "an online prescribing service or prescriber".
- 75. However, this guidance imposed nothing new in relation to the basic responsibilities of pharmacy owners: they had always been responsible for making sure that the "culture and processes within the pharmacy deliver safe and effective care to patients and the public". As early as 2015, the Guidance had recognised that:
 - "Different ways of providing pharmacy services are becoming more common...because of changes in society and advances in technology, pharmacy services will continue to adapt and change. However the pharmacy service is delivered, the legal principles and regulatory standards aimed at quaranteeing safe outcomes for patients...must still be met".
- 76. The Registrant's position has been that he relied on Ms 1's assessment of EU Healthcare's performance against the principles as "satisfactory", albeit with "a limited action plan which was completed soon after the inspection". He told the Committee that when he moved from EU Healthcare to Pronto, he "mirrored the processes" at EU Healthcare: he retained the same website name and address ("ukpharmacymeds.com"); he was using the same patient questionnaire; he transferred the risk assessments he had written following ROC's inspection of 28 September 2018 from EU Healthcare to Pronto; and he even transferred his existing patients to the new company.
- 77. However, Ms 1's evidence was that the concerns she raised with the Registrant's prescribing model back in September 2018, when she told the Registrant that his model was "unprofessional and dangerous", were never satisfactorily dealt with by the Registrant. As far as Ms 1 was concerned, her inspection process in relation to this Registrant was a continuing one, albeit he had set up a new company to take over the business of EU Healthcare.

- 78. The Committee bore in mind in this regard, for example, the Registrant's evidence that the 2019 Guidance requiring pharmacy owners to "make sure that [their] website and the websites of companies they work with are arranged so that a person cannot choose a POM and its quantity before there has been an appropriate consultation with a prescriber" was, "to [his] knowledge...the first express statement of such an expectation". The Committee observed that the evidence before it did not support what he said on this point. The Inspection Report of September 2018 warned that "patients using the prescribing service are able to select medication and the quantity required before having a consultation with a ...prescriber which may increase the risk of inappropriate medicine being selected". The Registrant's Action Plan made no mention of this concern and according to the Registrant's own evidence, he did not amend the website until 10 July 2019 following, of course, Ms 1's repeat of the same concern when she visited Pronto.
- 79. Moreover, as was clear from the format of both Inspection Reports, the businesses were judged against the <u>Standards for registered pharmacies</u> (June 2018), and these did not change over the relevant period; the guidance, as has already been set out, was updated from time to time, to assist pharmacy owners and SIs to assure themselves, or where necessary, the GPhC, that they were indeed operating in accordance with those Standards.
- 80. Having reviewed all of the evidence in relation to point (i), the Committee was of the view that, due to the inspection history as set out above, this Registrant in fact had an advantage over other pharmacies: he had, in effect, been given what might be called a "heads up" by Ms 1 that new guidance was on its way and all internet pharmacies were going to be expected to show that they comply with it. Many, if not all, of the main changes made to the 2019 Guidance, dealt with concerns which Ms 1 had raised with this Registrant when she visited EU Healthcare on 28 September 2018. Her message was clear: there were serious risks associated with his business processes, which she specifically outlined in both Inspection Reports and various emails to him, and he needed to change them.
- 81. In summary, then, the Committee did not consider that it was unfair to have expected the Registrant to comply with the 2019 Guidance in the manner in which and the time in which, Ms 1 gave him though it accepted that the statutory 28 day period she allowed after her Improvement Notice of 18 June 2019 was one which she had no discretion to change.

- 82. The Committee next turned to consider point (ii) above: the submission on behalf of the Registrant that the EU prescribers were not "staff" of the Pharmacy, and therefore the Registrant's duties in relation to their standard of practice was less onerous than if they had been. Mr Haycroft had submitted that many of the Particulars of Allegation (1, 4-11, 14) were "fatally flawed" and "not proven, irrespective of the evidence", because there had been a fundamental misunderstanding on the part of the Council as to the nature of the Registrant's business. The Registrant, it was submitted, operated a dispensing business, he did not provide a "prescribing service". The prescribing was undertaken by independent EU-registered and regulated doctors, for whom he only provided an "affiliate" service.
- 83. The Committee considered the Guidance, all three versions of which require that "pharmacy owners and superintendents should make sure that all staff ...are familiar with" its contents.

 Both the 2015 and the 2018 Guidance state that 'staff' includes:
 - "any third party who helps the pharmacy provide any part of the pharmacy service, and deals with patients and people who use pharmacy services on behalf of the pharmacy owner."
- 84. The 2019 Guidance did not materially alter this definition. Just like the 2018 Guidance, the 2019 guidance alerted pharmacy owners to consider the particular risks entailed both in working with non-UK registered prescribers, and with prescribers who were online. It reminded pharmacy owners that it was their responsibility to "make sure" that such prescribers were "aware that some categories of medicines are not suitable to be supplied online unless further safeguards have been put in place to make sure that they are clinically appropriate". The safeguards which were then set out in the 2019 Guidance, simply echoed the basic rules of safe prescribing.
- 85. Furthermore, all three versions of the Guidance make clear that "due diligence" must be carried out when selecting contractors. The 2018 and 2019 Guidance go further and require the pharmacy owner to make sure that their regular audit includes the activities of third parties, agents or contractors.

- 86. Mr Micklewright submitted on behalf of the Council that the definitions in the guidance documents clearly encompassed the EU prescribers. He submitted that at all material times, as the Pharmacy owner and director, the Registrant had duties to ensure not merely that the dispensing function of the Pharmacy was properly managed, but also that the EU prescribers worked according to UK good prescribing practice.
- 87. The Committee carefully considered the Guidance, the submissions on behalf of both parties, and the evidence before it about the relationship between the Registrant and the EU prescribers.
- 88. The Committee observed that the Registrant managed and controlled the Website including the operation of the patient questionnaire, (albeit via an external IT service provider). Any limitations on the prescribers' ability to properly and appropriately clinically assess the patients caused by the Website functionality, would have been his responsibility. It followed therefore that the prescribers were operating under the direction and control of the Registrant and indeed, at no point did the Registrant seek to suggest that the prescribers could do anything other than depend on the processes he had set up via the Website to carry out their prescribing function.
- 89. The Registrant told the Committee that he had decided to use EU prescribers because it was too expensive and too complicated to use UK prescribers who, he asserted, had to be registered with and regulated by the GMC and the CQC. It was unclear to the Committee from the Registrant's evidence, whether one or both of the prescribers provided their service via an intermediary, and the Committee did not have sight of any contract between them, however the Registrant told the Committee that the prescribers received 25% of the profit made on each sale of medication, and he calculated that profit after accounting for such things as the cost of the medication and the cost of delivering it to patients.
- 90. Quite apart from the fact that this appears therefore to have been a business model in which the prescribers received payment or commission according to the number of prescriptions they issued and the Committee makes no finding in relation to this fact which emerged

during Committee questions and had not previously been raised by the Council – the Committee was satisfied, on the basis of the evidence before it of the relationship between the Pharmacy and the EU prescribers, and the way in which patients communicated with the prescribers via the Website which he controlled, that the Pharmacy was providing both a dispensing and a prescribing service. It followed that the Registrant, particularly as owner of the Pharmacy, but also when he became SI, and indeed at all times when he was the RP, was subject to the professional duties set out in the Guidance from time to time, to assure himself that their prescribing practice was safe.

91. In any case, as was made clear in the 2019 Guidance, the fact that the Registrant was working with the EU prescribers, that is, with "prescribers or prescribing services operating outside the UK", meant that he had a responsibility to "make sure...that they were working within national prescribing guidelines for the UK". This was indeed irrespective of whether or not they were engaged as a "prescribing service" by the Pharmacy.

Other preliminary observations

- 92. One further submission made by Mr Haycroft which it was appropriate for the Committee to consider before turning to consider the Particulars of Allegation, was that a "failure to ensure" as alleged in a number of the particulars, amounted, unfairly, to a charge of strict liability, or of vicarious liability by one professional the Registrant pharmacist, for the professional duties of others the EU doctors. The Council could have alleged failure "to take reasonable steps to ensure", but it had not done so. Mr Micklewright's submission was that the Committee was entitled to find a failure to ensure proven if: (i) It is satisfied that there was a duty to act; (ii) It is satisfied that duty required the Registrant to take all reasonably necessary and appropriate steps to produce or prevent the relevant outcome; and (iii) the Registrant did not do so.
- 93. The Committee approached these submissions by considering the Registrant's fundamental responsibility according to the <u>Standards for registered pharmacies (June 2018)</u>. As owner of the Pharmacy, he was "responsible for ensuring the safe and effective provision of pharmacy

services". This required him, among other things, to ensure that "The risks associated with providing pharmacy services [were] identified and managed" (Standard 1.1); "The safety and quality of pharmacy services [were] reviewed and monitored" (Standard 1.2); and, for example, that: "Appropriate indemnity or insurance arrangements [were] in place for the pharmacy services provided" (Standard 1.5).

- 94. The Committee accepted Mr Haycroft's submissions that it should not impose strict or vicarious liability upon the Registrant in relation to the standard of professional practice of the EU prescribers. However, it was satisfied that as owner of the Pharmacy, which provided both a dispensing and a prescribing service to patients who engaged with the Website he controlled, he was responsible for managing the "particular risks" (2019 Guidance), or "different risks" (2018 Guidance) involved in providing those services online.
- 95. The Committee resolved to consider the Particulars of Allegation only in relation to those responsibilities, or duties, directly imposed upon the Registrant as owner of the Pharmacy with overall management for the safe and effective provision of its services, (and, in addition, as SI and/or RP).
- 96. Having said the above, the Committee did accept and take into account the submissions of the Registrant to the effect that internet pharmacy was a fast developing area of pharmacy business and all those involved from the pharmacy owners to Council inspectors were learning as they went along. The Committee was in no doubt that as Ms 1 gained more experience of visiting and inspecting internet pharmacies operating with patient questionnaires, her understanding both of the risks involved and of the complex information technology ("IT") being utilised, would itself have been developing.
- 97. The Committee noted that in relation to a number of the particulars, the evidence from Ms 1 and the Registrant as to what was said at inspections, and as to how in fact the IT system operated, was in conflict.
- 98. The Registrant had vehemently maintained in his evidence to the Committee that he had found it difficult to explain to Ms 1 and her colleagues how his Website worked; he said they

did not seem to have much experience of similar websites; and he was not sure they properly understood it. In response to some Committee queries about the Website's contents, he said that even he himself had not read it through fully and had not checked all the information it contained; it had been developed by a specialist in the Ukraine: the Registrant himself was not an IT expert.

- 99. The Committee bore in mind throughout its decision-making that, despite best efforts, it was possible that the Registrant had not been able to explain clearly enough to Ms 1 and her colleagues how the IT system operated in certain respects, and they might have misunderstood it.
- 100. The Committee accepted the submission of Mr Haycroft that the Council did not interrogate the computer system from an IT perspective, so the only evidence before the Committee of how it operated was what Ms 1 and RN reported, or the Registrant was able to explain.
- 101. Having dealt with the above preliminary matters, the Committee turned to consider each of the particulars in turn.

Particular 1

You, a registered pharmacist, between October 2018 and April 2021, as director and/or owner of Pronto Healthcare Limited, Suite 8a, 1-3 The Courtyard, Calvin Street, Bolton, Greater Manchester, BL1 8PB ('the pharmacy'); and between August 2020 and April 2021, as the Superintendent Pharmacist and regular Responsible Pharmacist of the pharmacy, provided services at a distance through ukpharmacymeds.com in circumstances where:

- 1. You failed to ensure that the pharmacy and/or the Prescribers 1 and/or 2 ("the EU prescribers") carried out any or any adequate identity checks on all patients requesting:
- 1.1 antimicrobials
- 1.2 medicines liable abuse, overuse of misuse
- 1.3 medicines requiring ongoing monitoring and/or management.
- 102. In relation to the stem of particular 1, there was no evidence before the Committee that the prescribers themselves carried out identity checks however the Committee considered that it would in principle have been appropriate for the Registrant to carry them out on the

prescribers' behalf. In any event, he did have a separate professional duty to ensure on behalf of the Pharmacy, that the patients were who they said they were – this was a basic requirement of good professional practice as a pharmacist.

- 103. The Council's concerns, according to Mr Micklewright, were twofold: (i) Ms 1's evidence that no ID checks of any kind were carried out for patients requesting antimicrobials or medicine requesting monitoring or management; and (ii) her evidence that there was a period between 16 July 2019 and 7 August 2019, when the Registrant was not carrying out ID checks at all, because he was in the process of setting up third-party ID (Equifax) and during that period he was not able to continue with the previous system of checking.
- 104. In relation to (i) above, Ms 1 stated in her Inspection Report of 16 May 2019 that "the pharmacy does not always carry out appropriate identity checks before supplying POMs...it was a mandatory requirement for patients requesting sleeping tablets and opioids to upload personal identification (ID), confirmation of address and proof of previous GP prescription. But this was not necessary for any other POMs...".
- 105. Ms 2 reviewed the Website questionnaire consultation for modafinil. She stated that it did not request proof of ID, address or previous prescription. She commented that: "The drug also requires regular monitoring of blood pressure and recommendations suggest an ECG before initiation. It would also require dose adjustments in hepatic impairment and potentially renal impairment. The suitability of this drug being prescribed via an online consultation is questionable due to monitoring requirements, dose adjustments and potential for misuse as it is a stimulant."
- 106. Ms 1 repeated these concerns in all of her witness statements and in oral evidence.
- 107. The Registrant's evidence, throughout the inspection and regulatory process, was that Ms 1 had misunderstood the position. In his witness statement he stated that "Patients were required to submit proof of identification, proof of address, and proof of the repeat medicine required". There had been delays in integrating a third-party identification process (Equifax) on to the website, and "in the interim, patients were asked to upload the identification and proof

of address to enable their order to be processed". He repeated this in oral evidence, explaining that most of the patients were requesting repeat prescriptions anyway so he would not have needed to recheck their ID – however for new patients, he was still able to operate the manual system of uploading and personal checking which he himself carried out.

- 108. In his witness statement he further added that although it was his understanding that ID checks were not required in traditional pharmacies for certain medicines, "nevertheless, we assessed the risk and took it upon ourselves to require ID from every patient for any medication. This was made a default position on the questionnaire. The system would just not allow it". In oral evidence he explained that when he updated the Website, it was too complicated to set up ID for only some of the medicines (which was what he thought was required) so the IT developer advised that it was easier just to require ID from all patients and so that was what was put in place.
- 109. The Committee took into account that there was no evidence before it in the form of technological analysis which would have assisted it to understand the Website's functionality, in order to come to a conclusion as to the facts, and the evidence from Ms 1, Ms 2 and the Registrant was in direct conflict.
- 110. Having carefully considered the available witness evidence, the Committee was of the view that the Council had not discharged its burden to prove that the Registrant did not carry out "any" identity checks on all patients requesting medication, nor in relation to whether there was a short period in July/August 2019 in which no ID was required at all, as submitted by Mr Micklewright. The Committee therefore found particular 1 not proved in relation to the word "any".
- 111. As for the alternative word, "adequate", also set out in the particular, the Committee observed that no submissions had been made on behalf of the Council as to the adequacy of manual ID checking as described by the Registrant and outlined by Ms 1 in her Inspection Report. While the Registrant himself stated that she had told him that he needed to upgrade to a third-party system, there was no evidence in her Inspection Report that she considered manual ID checking to be inadequate in principle, although later correspondence showed that she was urging him to confirm that the Equifax system was in operation.

- 112. The Committee did however take into account that the 2019 Guidance requires the Pharmacy owner to assure themselves that the prescriber has "robust processes to check the identity of the person". It did not consider that manual uploading of ID and manual checking by the Registrant, in the context of the Pharmacy's Website questionnaire process, where there was no direct communication between the prescriber and the patient and no mandatory requirement for communication (for example by phone) with the Registrant, was at all robust because a person could upload anyone's personal ID and the Registrant would have no way of verifying it.
- 113. The Committee was therefore of the view that the Registrant's system of accepting manually uploaded personal ID was not "adequate" and therefore it found all of particular 1 proved in relation to the adequacy of the ID checks.
- 114. Accordingly, the Committee finds particular 1 proved in part, in that the Registrant failed to ensure that the Pharmacy carried out adequate identity checks on all patients requesting the medicines set out in particular 1. The Committee found particular 1 proved in its entirety in relation to prescribers 1 and 2.

Particular 2

- 2. You failed to audit and/or ensure audits were carried out on cancelled and/or refused requests for the supply of medication.
- 115. This particular was found proved by admission. The 2015, 2018 and 2019 Guidance all require that audits are carried out of cancelled and/or refused requests. The Registrant's position was that he did keep a 'Queries, interventions and signposting log', which was provided to the inspectors both at the inspection on 16 May 2019 and the visit on 7 August 2019, and also maintained a 'watch list' and a 'red list'. However he accepted that although checks were done, this was partial only and insufficient as no formal audits were conducted.

Particular 3

- 3. You allowed and/or failed to prevent the EU prescribers prescribing contrary to the General Medical Council ("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 their physical health;
- 3.5 failed to contact or attempt to obtain details of their mental health;
- 3.6 failed to access and/or attempt to access patients' GP medical records and/or specialist clinical records;
- 3.7 failed to request a face-to-face consultation with patients;
- 3.8 failed to adequately consider the possibility of medication dependence and misuse;
- 3.9 failed to query with the 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/or
- 3.11 failed to put adequate safeguards in place.
- 116. The questions for the Committee, in respect of this particular, as Mr Micklewright helpfully expressed in his closing skeleton on the facts, were:
 - (i) Whether there was a duty on the Registrant to ensure that the prescribers he was engaging were prescribing to UK guidance, or whether that was simply a matter he was entitled to delegate to them; (Mr Micklewright submitted that there was such a duty); and
 - (ii) Whether the prescribers did in fact prescribe in line with UK guidance or not; (Mr Micklewright submitted that they did not).

- 117. Mr Haycroft however submitted that there was no such duty: it was not clear that EU prescribers were "staff" within the meaning of the GPhC Guidance; and furthermore, the GPhC Guidance did NOT include an obligation to ensure the prescribers comply with GMC Guidance, it merely referred to the GMC guidance as "other sources of useful information". In considering this submission, the Committee noted that specific reference to the GMC was first made only in the Council's 2019 Guidance it was entirely omitted from the 2015 and 2018 Guidance. The 2018 Guidance did however provide a link to the Royal Pharmaceutical Society, (RPS) whose "Competency Framework for all Prescribers" (2016) would have or ought to have been known to the Registrant, and which contained very similar guidelines to those contained in the GMC guidance. Mr Haycroft also asked by way of a submission: "As a matter of common sense how can a pharmacist "prevent" a prescription being issued? At most they can refuse to dispense which is different".
- 118. The Committee carefully considered the facts in light of the submissions on behalf of both parties. It appeared to the Committee that the submissions of Mr Haycroft were for the most part based on the Registrant's professional role as a registered pharmacist. He accepted that, as such, the Registrant was of course under a duty to observe the professional standards and guidance from time to time in force applicable to registered pharmacists.
- 119. The Committee bore in mind Mr Haycroft's concern that it must not inadvertently impose a vicarious liability upon the Registrant for any breaches of their own professional standards by the prescribers. However, the Registrant was not just a responsible pharmacist in a traditional "bricks and mortar" pharmacy, dealing with the safe dispensing, supply and delivery of medication prescribed by others to their patients.
- 120. The Committee was satisfied that by virtue of his position as SI and RP, but also and independently by virtue of being the owner of the Pharmacy, the Registrant had specific responsibilities or duties in relation to the safe and effective practice of all the services provided

by the Pharmacy. This included the safe and effective delivery by the Pharmacy of its prescribing service.

- 121. It is in respect of those specific duties, which were to be found in the <u>Standards for registered</u> <u>pharmacies</u> (June 2018), and the relevant <u>Guidance for registered pharmacies providing</u> <u>services at a distance</u>, that the Committee considered the facts alleged at particular 3. (and also, for similar reasons, particulars 4, 5, 6, 7, 8 and 9).
- 122. The 2015, 2018, and 2019 Guidance documents all made it clear that the Registrant, as owner, was:

"responsible for the overall safe running of the pharmacy...mak[ing] sure that all staff involved in providing [its] services [were] familiar with the Guidance". This included "any third party who helps the pharmacy provide any part of the pharmacy service and deals with patients...".

And:

"Examples of the pharmacy services covered by this guidance include: (...)

- An internet pharmacy service, including ones linked to an online prescribing service whether or not the prescribing service is owned and operated by you, or by a thirdparty business".
- 123. Moreover, the 2018 Guidance stated:

"You must be able to show how you are assured that all prescribers...follow the relevant guidance on remote consultation, assessment and prescribing".

124. All versions of the GPhC Guidance highlighted that pharmacy staff must "get all the information they need from patients to check that the supply is safe and appropriate" and that "requests for medicines that are inappropriate, too large or too frequent" are identified.

- 125. In effect, the Guidance was reminding internet pharmacy owners that, as was surely obvious, the prescribers they worked with must follow UK good prescribing practice. If they were using non-UK prescribers, their business model might carry different risks from traditional pharmacies using UK-registered prescribers, in which case the pharmacy owners had a duty to make sure they were nevertheless complying with UK law and good practice.
- 126. Mr Micklewright referred the Committee to the following paragraphs of the GMC Guidance:

 14 You should prescribe medicines only if you have adequate knowledge of the patient's health and you are satisfied that they serve the patient's needs
 - 32 If you prescribe for a patient, but are not their general practitioner, you should check the completeness and accuracy of the information accompanying a referral. When an episode of care is completed, you must tell the patient's general practitioner about a) changes to the patient's medicines (existing medicines changed or stopped and new medicines started, with reasons) b) length of intended treatment c) monitoring requirements d) any new allergies or adverse reactions identified, unless the patient objects or if privacy concerns override the duty, for example in sexual health clinics.
 - 33 If a patient has not been referred to you by their general practitioner, you should also: a) consider whether the information you have is sufficient and reliable enough to enable you to prescribe safely; for example, whether: i) you have access to their medical records or other reliable information about the patient's health and other treatments they are receiving ii) you can verify other important information by examination or testing, b) ask for the patient's consent to contact their general practitioner if you need more information or confirmation of the information you have before prescribing. If the patient objects, you should explain that you cannot prescribe for them and what their options are;

60 Before you prescribe for a patient via telephone, video-link or online, you must satisfy yourself that you can make an adequate assessment, establish a dialogue and obtain the patient's consent in accordance with the guidance at paragraphs 20-29;

61 You may prescribe only when you have adequate knowledge of the patient's health, and are satisfied that the medicines serve the patient's needs. You must consider: a) the limitations of the medium through which you are communicating with the patient b) the need for physical examination or other assessments c) whether you have access to the patient's medical records"

- 64 If the patient has not been referred to you by their general practitioner, you do not have access to their medical records, and you have not previously provided them with face-to-face care, you must also:...c) follow the advice in paragraphs 30–34 on Sharing information with colleagues."
- 127. In addition, the Committee considered that the following paragraphs of the GMC Guidance were particularly relevant in this case:
 - 30 You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must share all relevant information with colleagues involved in your patient's care within and outside the team.
 - 51 Whether you prescribe with repeats or on a one-off basis, you must make sure that suitable arrangements are in place for monitoring, follow-up and review, taking account of the patients' needs and any risks arising from the medicines.
 - 53 Reviewing medicines will be particularly important where:... c) the patient is prescribed a controlled or other medicine that is commonly abused or misused d) the BNF or other authoritative clinical guidance recommends blood tests or other monitoring at regular intervals.
 - 55 You are responsible for any prescription you sign, including repeat prescriptions for medicines initiated by colleagues, so you must make sure that any repeat prescription you

sign is safe and appropriate. You should consider the benefits of prescribing with repeats to reduce the need for repeat prescribing.

- 128. The Committee accepted that the GPhC's 2019 Guidance was much more explicit and detailed than previous versions: it echoed many of the principles to be found in the GMC and RPS documents, which had not been included in earlier GPhC Guidance.
- 129. The Committee considered the evidence of Dr C in relation to the potential risks of the Registrant's business model which relied principally, (or indeed, solely, in the vast majority of cases examined by Ms 1 and her team), on consultation by way of an online questionnaire completed by the patient with no independent verification of what they said and no direct, let alone 2-way, contact between the prescriber and the patient.
- 130. Dr C pointed out that the model was not in accordance with the competencies as described in the Royal Pharmaceutical Society's Competency Framework of 2016 a framework which applied throughout the relevant period.
- 131. In her witness statement, commenting in general on pharmacies providing a prescribing service with consultations by way of online patient questionnaires, (that is, with no way to verify what the patient declared), Dr C opined as follows:

"in my opinion, online prescribing from self-reported questionnaires is insufficient to enable safe and appropriate, evidence based prescribing".

132. Dr C was of the view that online questionnaires were not safe for prescribing high risk medicines such as those the Pharmacy was supplying.In her opinion,

"...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".

- 133. She was of the view for example that patients with ongoing pain require regular face to face assessment in order that their condition is properly examined, and medication is either stopped, changed or optimised.
- 134. Dr C further opined that "...a prescriber should be aware of potential misuse of all opiates and needs to be aware of any past or current addiction issues (from medical records, rather than self-reported), needs to keep adequate records in order to check frequency of requests and amounts previously supplied."
- 135. In her opinion, prescribing without communicating with a patient's GP is unsafe and contrary to national guidelines. A GP should be consulted prior to any prescription being authorised and adequate clinical records sent to the GP after a prescribing episode.
- 136. In relation to opiates such as dihydrocodeine and other opiates which the Pharmacy supplied,

 Dr C commented that these medications:

"should be prescribed at the lowest dose and for the shortest period of time due to potential for tolerance and dependence. ..the long term risks of prescribing opiates from clinical information from an online questionnaire, are missed opportunities to review its efficacy, the potential to miss more serious pathology, tolerance and dependence. They are not suitable to be prescribed from an online questionnaire".

And in relation to modafinil:

"Modafinil, in the UK, is only indicated for the excessive sleepiness associated with narcolepsy. It is, however, a drug of misuse, commonly among students and shift workers...due to its potential for cardiac issues, any patient commencing on modafinil should have an electrocardiogram, and possibly liver and kidney blood tests to ensure no impairment. ECGs

should be repeated annually. ...It should also be used with caution in patients with a history of drug or alcohol misuse, mania, depression and psychosis. Without a full clinical history, a prescriber cannot safely prescribe modafinil... It is not suitable to be prescribed from an online questionnaire".

137. The Committee took into account the following notes from Ms 2 about her conversations with the Registrant and the Spanish prescriber on 30 and 31 May 2019:

"Counselling, safety netting and red flags:

[the Registrant] advised that the doctors notify him of the points and he would communicate it to the patients when asked how he said probably ring or text. He was vague about how he received the information from the doctors. He also felt that as prescriptions supplied were prescribed initially by a UK doctor, the patient would have already received counselling, safety nets etc. He stated several times the service is for repeat prescribing and not polypharmacy management. Upon discussing this with [the prescriber in Spain], she stated that they counsel through the platform where they receive the consultations. I struggled to understand what she was saying but it seemed they have an option of typing notes on the platform. She was unsure how information reached the patients but similar to [the Registrant] stated the role is to repeat prescribe...";

And:

"[the Registrant] felt he did not provide a clinical service and it was just a supply service";

And:

"[the Registrant] described the interface where consultations and prescriptions were transferred between the prescriber and the Pharmacy as a portal...The RP can allocate prescription request to each prescriber...The consultation is received by the doctor and they make a decision whether to approve or decline a prescription. If approved the platform switches to a system which dates and time endorses and provides an encrypted electronic signature. This is then received in the Pharmacy".

The Registrant said that he would then carry out his role as the RP and make any interventions if necessary, for example: "if a medication was ordered early he can intervene

and contact the patient and either delay until a later date or provide the patient with a refund. When asked about other interventions including interaction, [the Registrant] advised the patients are usually only on one medication...".

Ms 2's report of her conversation with the prescriber in Spain was that:

"She stated that her view was they were not obliged to notify the GP if the patient did not want this...She..made it clear that her expectation was that a GP had seen the patient first as she is not providing a clinical examination".

- 138. The Committee was of the view that the evidence from Ms 1 and Ms 2 was that due to the inherent limitations of the Registrant's online questionnaire model, the EU prescribers could not have had the ability to obtain adequate information (3.1); establish whether the patient had communication or support needs (3.2); determine capacity to provide consent to treatment a duty fundamental to the process of safe prescribing, which required more complex assessment of the patient's understanding and ability to comply than the question of capacity under the Mental Capacity Act 2005 (3.3).
- 139. The Committee was of the view that sub-particulars 3.4 and 3.5 were not capable of proof because, as drafted, they were too vague.
- 140. Turning to 3.6, the Committee had not been provided with evidence that there was a separate online question asking to access GP medical records and/or specialist clinical records. The questionnaire did however include a request for consent to contact the patient's GP, and that could have been a way for the prescribers to access or attempt to access records. Without any thorough audit of the Website, the Committee was of the view that the Council had not provided sufficient evidence to discharge its burden of proof in relation to 3.6.
- 141. In relation to sub-particular 3.7, it was clear that there was no possibility at all, given the limitations of the Website's functionality, of the prescriber being able to request a face-to-face consultation if for example this was necessary to obtain adequate information.

- 142. As for the remaining sub-particulars, 3.8, 3.9, 3.10 and 3.11, the evidence before the Committee, for example the record from RN above, suggested that the Pharmacy's processes for recording reasons for prescribing, particularly repeats or in the absence of consent to contact the GP, decisions for rejection and advising patients of those reasons, and review and monitoring of repeat medication were haphazard to say the least.
- 143. Neither the Registrant nor either of the prescribers (the Czech prescriber never engaged with Ms 2), demonstrated a proper (one might say, any) understanding of their professional duty to ensure the medications supplied by the Pharmacy were safe and appropriate for the patients to whom they were sold. It was clear to the Committee that the prescriber in Spain did not consider that she needed independently to assess the patients' clinical needs before prescribing medication, nor that she had a duty to ensure that any risks associated with the medications she prescribed, would be properly managed.
- 144. In summary, the Committee accepted Mr Micklewright's submission that it was clear from the evidence that the prescribers were <u>not</u> prescribing in accordance with the GMC's 'Good <u>practice in prescribing and managing medicines and devices' Guidance</u>. The system of patients choosing their medication, filling in an online questionnaire and then that forming the basis for the prescribing of, commonly, opioid and sedative medication, with no 2-way communication with the patients and/or their GPs, did not meet what is required by the GMC Guidance.
- 145. The Committee was satisfied that the EU prescribers failed to adequately consider the possibility of medication dependence and misuse (3.8); failed to query with the patients the frequency of requests for medication and/or the amounts requested (3.9); failed to refer patients back to their GP for appropriate assessment (3.10); and, altogether, failed to put adequate safeguards in place (3.11).
- 146. And as has been set out above, the Registrant bore direct personal and professional responsibility in relation to those failures.

- 147. Taking all of the above into account, the Committee was satisfied that all of particular 3 was proved, save for 3.4 and 3.5, which were too vague; and 3.6 in relation to which the burden of proof was not satisfied by the evidence available.
- 148. Accordingly, the Committee finds Particular 3 Proved in part, in that 3.4, 3.5 and 3.6 are Not Proved.

- 4. You failed to ensure that the Pharmacy operated in a safe and effective manner in that:
- 4.1 the Pharmacy's website was arranged so that a person could choose a POM and its quantity before there had been an appropriate consultation with a prescriber; and
- 4.2 patients were able to change their answers to consultation questions without any auditable log of any changes being kept.
- 149. Dealing first with the stem of particular 4, the Committee was satisfied, for the reasons set out in its "Preliminary Matters" section above, that the Registrant, as owner of the Pharmacy whose services included a prescribing service, had a duty to ensure that the service operated safely and effectively. He was in control of the Website; the EU prescribers worked for him.
- 150. The Committee first considered 4.1. This was an issue which was raised with the Registrant at EU Healthcare in September 2018, when Ms 1 commented that "Patients using the prescribing service are able to select medication and the quantity required before having a consultation with a qualified prescriber which may increase the risk of inappropriate medicine being selected". However, when Ms 1 inspected Pronto, in May 2019, she again found that "the Pharmacy website was arranged so that the patient chose the POM and the quantity before filling in the consultation questions. This means people may not always receive the most suitable medicines for their needs".
- 151. The Committee noted that the Registrant's lawyers in their response on 10 August 2023 stated that the 2019 Guidance warning about this process, was, to the Registrant's

knowledge, "the first express statement of such an expectation". That clearly was not the case for this Registrant.

- 152. The Registrant told the Committee that he spent over £36,000 on changes to the website following Ms 1's May 2019 inspection, and this included changing this pre-selection system.
- 153. (However, it had changed back when Ms 1 checked it on 6 and 7 August 2019). This matter is dealt with in more detail at the Committee's findings in relation to particulars 12 and 13.
- 154. It is self-evident however, that a system which allowed patients to select the medicine they wanted (mostly, moreover, medicines which were open to abuse, including addiction) before the prescriber had made a clinical assessment of its appropriateness, was open to significant risk in relation to safety and effectiveness. The Registrant had been alerted to this risk by Ms 1 in September 2018 but he did nothing to deal with it until after she raised the same concerns at the 16 May 2019 inspection.
- 155. In relation to Particular 4.2, the Registrant had submitted that it was not technically possible to create an auditable log no websites work that way and in any case, other businesses operated in the same way. However, the Committee took into account Ms 2's evidence, which was not disputed, that when she examined the website:

"If you answer yes to some questions that require a negative response. E.g. are you pregnant or breastfeeding? Or are you under the care of a psychiatrist? - a note appears which states...
"In view of your answer, to treat your condition, it would be best if you are treated with a face to face consultation with your own GP Doctor". ... However, the patient may be able to change the response to the answer and it is unlikely to be auditable as you do not need to log in or register to carry out the consultation".

156. Ms 1 explained that the patient could go back on the consultation and enter a different response. Neither the Registrant nor the prescribers could trace or audit such changes.

- 157. It appeared from the Registrant's (undated) "Proposed Changes" document which he had submitted to the Council following the Notice of conditions, that he considered the 'pop-up' messages were "safety alerts", and he stated that he would remove them.
- 158. However, whatever the Registrant's intention in using them, this was, in the Committee's view, an unsafe and ineffective way for the Pharmacy to operate.
- 159. Accordingly, the Committee finds all of Particular 4 Proved.

- 5. You failed to ensure that the EU prescribers obtained all the information they would need to prescribe safely and appropriately in that the EU prescribers relied primarily on the information supplied by the patient in the sign-up form and consultation questionnaire with no opportunity for the prescribers to have a face to face consultation with the patient.
- 160. For reasons summarised earlier in this determination, the Committee was satisfied that the Registrant was subject to a direct professional duty to ensure that the services provided by his Pharmacy were operated safely. This was separate from the professional duties of the prescribers themselves.
- As has been set out in this determination elsewhere, the online patient questionnaire consultation process managed and operated by the Registrant had no facility for the EU prescribers to hold a "dialogue" with the patients, whether by phone, or email and certainly not face to face. The prescribers had to rely on what the patient answered in the online questionnaire. They could not physically examine the patient, or independently verify anything the patient told them. In the rare cases where consent was given for a GP to be contacted, the system controlled by the Registrant allowed for a prescription to be issued even if the GP did not respond to contact from the Pharmacy.
- 162. The Committee accepted that this was before online face to face consultations became routinely possible, and that the Guidance does not *mandate*, even nowadays, face to face consultations for all online prescribing. However, the Registrant's Pharmacy was selling

mostly high- risk medications which were open to abuse including addiction, or which needed review and monitoring. He had asserted that he was "surprised" that the majority of the prescriptions requested were for these types of medication. As was clear from the 2018 Guidance, which was based on good prescribing practice as set out in the GMC Guidance and the RPS Guidance, (para.4.2), "Selling and supplying medicines at a distance including on the internet, brings different risks than those of 'traditional' pharmacy services". The Registrant had a duty to ensure that his systems and processes appropriately dealt with those risks. In circumstances where the system he operated was inadequate to enable the prescribing of high-risk medications to take place safely, according to good prescribing practice, he failed in that duty.

163. The Committee was satisfied that, given the limitations of the online consultation process managed and operated by the Registrant, he failed to ensure that the prescribers he was working with obtained all the information they would need to prescribe safely and appropriately.

164. Accordingly, the Committee finds particular 5 proved.

- 6. Your failed to ensure that the pharmacy and/or the EU prescribers:
- 6.1 managed the risk that people may deliberately provide incorrect information to receive medicines that they wanted, despite them being clinically inappropriate;
- 6.2 shared relevant information about the prescriptions with other relevant healthcare professionals, including their GP;
- 6.3 contacted the patient's GP in advance of issuing a prescription for high-risk medicines to confirm that the medicine was appropriate for the patient and/or that appropriate monitoring was in place; and/or
- 6.4 recorded adequately their justification for prescribing in circumstances where the person did not have a GP or did not consent to share information with their GP.

- 165. As has been stated at particular 2, the Registrant was responsible for making sure that the EU prescribers carried out their tasks safely and effectively. The <u>Guidance for registered</u> <u>pharmacies providing services at a distance, including on the internet</u>, made it clear that internet pharmacy carried "different" or "particular" risks, which it was his responsibility, as Pharmacy owner, SI and RP, to manage.
- 166. The responsibilities set out in 6.2, 6.3, and 6.4, were requirements of the <u>GMC Good practice</u> in prescribing and managing medicines and devices (2013) and were repeated in summary in the GPhC's 2019 Guidance. The Registrant's duties to ensure the systems he managed and oversaw were in line with that and the RPS Guidance, were also expressed, though not in so much detail, in earlier Council Guidance.
- 167. In relation to 6.1, Mr Haycroft submitted that no doctor or pharmacist could ensure that patients do not lie: the Registrant managed the risk as best he could. However, it was clear that, as has been said elsewhere in this determination, and as the GPhC Guidance warned, the systems and processes which the Registrant had in place at the Pharmacy were prone to different risks compared to traditional "bricks and mortar" pharmacies. This was a business model in which there was almost never an opportunity to obtain independent verification of anything the patient declared from the uploading of ID which could have been anyone's, to answers to questions on the questionnaire which a patient could adapt in order to obtain the medication they sought and including, despite the Registrant having been warned of the risks in September 2018, a process by which the patient could select their choice of medication.
- 168. The Committee considered that it was self-evident that although patients can deliberately provide incorrect information in a traditional pharmacy setting, it would be far easier to do so in an online pharmacy where the prescriber could not see or speak directly to the patient, could not ask questions based on the patient's presentation, could not physically examine the patient.
- 169. In relation to 6.2, 6.3 and 6.4, it was clear from the GMC document (see the paragraphs set out in the Committee's findings in relation to particular 3) and GPhC Guidance, as explained

by Dr C, that it is essential that the prescriber obtains the full clinical picture, particularly when dealing with "high risk medications", which includes contacting the patient's GP and any other relevant healthcare professionals in advance. If the prescribing continues in any event, then it is necessary to record the justification.

- 170. At the Registrant's Pharmacy, although the patient would be asked for permission to contact their GP, the evidence was that medication was nevertheless prescribed in the overwhelming majority of cases when patients refused which in fact they did, in the overwhelming majority of cases. The Registrant repeatedly made the excuse in his defence that it would be a breach of confidentiality to approach a GP in the absence of patient consent but he never demonstrated to the Committee that he understood all of the risks of prescribing without shared care. When Ms 2 asked him on 30 May 2019 about the previous day when 37 supplies had been made but only one patient had consented, his response was that "he felt that this was the service patients wanted and people don't want everyone to know everything'".
- 171. In his witness statement, 1 August 2024, the Registrant stated that "some patients were signposted to their GPs", and "the patients were not customers of Pronto healthcare. The patients who contacted us were passed on to the doctors' service for assessment. It was an affiliate service". Signposting alone, was not, in the Committee's view, sufficient, particularly in the context of prescribing medications which were open to abuse including addiction and/or required regular monitoring and review.
- 172. The Committee took into account that the Spanish prescriber had commented to Ms 2 that "her view was that they were not obliged to notify the GP if the patient did not want this".
- 173. In relation to the process when GP consent was given, the Registrant provided to the Committee examples of proforma emails and text messages which were automatically sent to GPs. The automated email informed the GP of the request and asked the GP to contact the Pharmacy if there were any issues. However, the Committee was concerned to note that the letters were drafted so as to assume that no response from the GP would imply they concurred with the proposed treatment. Moreover, if a GP did not respond, the medication would normally be prescribed nevertheless. The Committee did not consider that this

automated system fulfilled the requirements of the GMC's Guidance at paragraph 6.3, which implied two-way communication with the GP whereby the GP *confirmed* that the medicine was appropriate for the patient and/or that appropriate monitoring was in place.

- 174. In relation to 6.4, the evidence before the Committee from Ms 1 was that when she visited the Pharmacy in May 2019 there was no system at all in place requiring the EU prescribers to record their justification for prescribing where there was no GP or no consent, and later when Ms 1 visited again in August 2019, and there had been no change, the Registrant explained that the prescribers had not yet been trained on the new system he had installed.
- 175. The Registrant's comments on this requirement, in his letter to the Council's case officer on 24 September 2020, was: "Making clear justification of making records of medicine supply where patient had no doctor was unknown to us, thereafter we implemented this on a file".
- 176. Accordingly, the Committee finds particular 6 proved.

- 7. You failed to ensure that the EU prescribers were competent in their prescribing and/or able to prescribe legally in the UK.
- 177. The Registrant was responsible, as has been stated above, for meeting the <u>Standards for registered pharmacies</u>, (June 2018). Principle 2 of that document stated:

 "Staff members and anyone involved in providing pharmacy services, must be competent...".

 And, at standard 2.2: "Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out...".
- 178. The 2015 and the 2018 Guidance both set out as follows:

- "[at 1.4] If you contract out any part of your pharmacy service to a third party you are still responsible for providing it safely and effectively. You must carry out 'due diligence' in selecting any contractors...
- [at 2.1] You are responsible for creating a culture of patient-centred professionalism within your pharmacies... You must make sure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely."
- 179. Following the inspection in May 2019, the Registrant emailed the EU doctors and obtained confirmation from them that they were qualified and registered to practise in their own countries; and also that they were prescribing in accordance with the UK's NICE and BNF guidelines. The Registrant also provided Ms 1 with relevant Medicine, Ethics and Practice (MEP) guidance which confirmed that EU-registered doctors could (at the time) legally prescribe to patients in the UK.
- 180. It was submitted on behalf of the Council that since the evidence was provided by the Registrant only after Ms 1's inspection in May 2019, one could infer that he had not ensured that the doctors could legally prescribe in the UK before engaging them. However, the Registrant told the Committee that he had the documentation before engaging them, but that he had simply written again to the doctors for fresh confirmation of their status, in order to reassure Ms 1. The Committee took into account that Ms 1 did record in her Inspection Report that the Registrant informed her that he had checked the prescribers' credentials, photo ID and registration certificates.
- 181. In relation to the doctors' competence, it was submitted by the Council that there was no evidence to demonstrate that he had investigated this. Ms 2 reported a phone conversation with the Registrant on 30 May 2019 in which when asked how he ensures competency of the doctors: "he stated he doesn't have any assurance of this and doesn't believe he needs to. He thought it was the regulator's role of the country the prescribers worked in to revoke their license to practise where necessary".
- 182. Ms 1 told the Committee that she "never got to the bottom" of whether the EU prescribers were in fact qualified and competent to prescribe online in the UK.

- 183. The Committee considered all of the available evidence in relation to this particular.
- 184. The evidence before the Committee suggested that the doctors were, as a matter of fact, able to prescribe legally in the UK.
- 185. In terms of their competence, whilst the Registrant did not have any documentary evidence to show his due diligence, he told the Committee that he had met one of the doctors face to face; he had also engaged at least one of the doctors (the one from the Czech Republic) via an intermediary company, which, he said, had confirmed the doctor's credentials; he explained that the Spanish doctor worked or had worked in the surgical department of a hospital and was a GP; and the Czech doctor was a GP.
- 186. Whilst Ms 1 clearly found it hard to get to the bottom of the situation, and it may be that the Registrant ought to have been able to provide her with more organised records of his own due diligence, the Committee was mindful when considering the evidence in relation to this particular, not to inadvertently reverse the burden of proof, and not to infer more than was fair from the Registrant's rather haphazard approach.
- 187. In relation to competence, the Committee accepted that some of the medicines which the doctors were prescribing are usually or normally prescribed by specialists rather than by GPs but that is not always the case. It considered there was merit in the submission of Mr Haycroft that if an EU prescriber may prescribe in the UK and is qualified and registered abroad in the EEA then prima facie they are competent unless proven otherwise. There was no credible evidence before it from the Council that the prescribers were not in fact competent to prescribe.
- 188. Accordingly, the Committee finds particular 7 not proved.

- 8. You failed to ensure that the EU prescribers had any, or any adequate, indemnity cover.
- 189. Ms 1's comments in her Inspection Report, May 2019, were as follows:

"A current certificate of professional indemnity insurance was on display in the pharmacy. The [Registrant] confirmed that the insurance covered all the activities of the pharmacy apart from the prescribing. He said the prescribers arranged their own indemnity insurance for this. He was able to produce some documentation but it was not written in English...It was not clear if the prescriber's [sic] indemnity arrangements covered online prescribing for patients in the UK and the amount of indemnity cover looked relatively low compared to cover provided in the UK".

190. The Registrant, in his witness statement dated 1 August 2024, said:

"The doctors we used all had appropriate insurance in place...one of the doctors had insurance in place equivalent to £1.7m and the other doctor had insurance equivalent to Euros 300,000".

He said that he had asked Ms 1 for advice on appropriate levels but she told him she could not help him and he should seek legal advice.

- 191. Contrary to the contents of Ms 1's Inspection Report above, the Registrant sought to suggest to the Committee that the Pharmacy's own insurance would cover any claims against the prescribers. He said he had paid an extra premium to his insurers to cover the added risk of running a pharmacy on the internet. He had not however, he accepted, told his own insurers that the prescribers he was using were outside the UK because he had not been asked.
- 192. The Committee considered the evidence and submissions in relation to this particular.

- 193. It took into account that the 2019 Guidance was the first to contain details about the duties of a pharmacy owner to make sure they had sufficient indemnity cover in place when using "prescribers or prescribing services based outside the UK".
- 194. The Committee observed that in her report for EU Healthcare, which used a prescriber in Romania, Ms 1 had merely written: "Insurance arrangements were in place. A current certificate of professional indemnity insurance was on display in the pharmacy". It appeared to the Committee that this was one area in which perhaps both Ms 1 and indeed the Council itself had been developing their knowledge and concerns when it came to the increasing use of EU prescribers working with UK pharmacies online. There was no doubt, given the evidence before it of Ms 1's attempts to understand the position that she was not an expert when it came to insurance and she had to seek advice from Council colleagues, one of whom in an email response had warned her that he was not himself sure of the position. Mr Haycroft had submitted that insurance was a specialist area and the Committee ought not to find this particular proved in the absence of expert evidence.
- 195. Nevertheless, the Committee did not accept Mr Haycroft's submission. It was clear that the Registrant was fully aware of his responsibility to ensure that the Pharmacy was properly insured, and whether or not he accepted that he was managing a prescribing service, he was fully aware that he needed to satisfy himself that the EU prescribers were themselves indemnified he had their (untranslated) certificates of indemnity in his green folder to prove it when Ms 1 visited him on 16 May 2019.
- 196. The Committee considered that his duty extended beyond merely obtaining untranslated copies of the prescribers' foreign indemnity cover. He needed to have exercised sufficient care or due diligence- to assure himself that he was working with prescribers who were properly and adequately indemnified to prescribe the medicines for patients of the Pharmacy. The evidence before the Committee was that he really had no idea whether they were properly insured, nor whether his own insurance covered them and in respect of the Czech-based prescriber, he had miscalculated the sum allegedly insured so as to mistake an actual sum of Krona equivalent to £170,000, for £1.7m.

- 197. The Committee therefore was satisfied that the Registrant had failed in his duty as owner of the Pharmacy, as SI and as RP, working with EU prescribers, to ensure that they had any, or any adequate, indemnity cover.
- 198. Accordingly, the Committee finds particular 8 Proved.

- 9. You failed to ensure that the EU prescribers followed national prescribing guidance for the UK including the GMC 'Good practice in prescribing and managing medicines and devices' and the GPhC 'Guidance for registered pharmacies providing pharmacy services at a distance'.
- 199. The Registrant provided evidence from the EU prescribers to confirm that they were following the NICE guidance and prescribing in accordance with the BNF. He also provided various UK guidance. These included: Greater Manchester Medicines Management Group's Neuropathic pain Guideline (March 2014); Southern Health NHS FT's Guidelines for Treatment of Primary Insomnia (September 2016); NICE Summary of antimicrobial prescribing guidance managing common infections (October 2019). In connection with specific medication including opioids, he provided NICE Bites Opioids in palliative care June 2012; and for modafinil MHRA's December 2014 drug safety update. These he said he had sent to the prescribers. However, there was no evidence that he had ever drawn their attention to the GMC 'Good practice in prescribing and managing medicines and devices' guidance nor the GPhC 'Guidance for registered pharmacies providing pharmacy services at a distance'. Nor had he, for example, drawn their attention to the RPS's Competency Framework for all Prescribers.
- 200. The Committee has set out its findings in relation to whether the EU prescribers in fact prescribed according to the GMC guidance above at particular 3. It is not repeated here, save to say that the patient questionnaire- based consultation system which he had in place did

not allow them properly to carry out their prescribing tasks in accordance with the relevant guidance.

- 201. As Pharmacy owner, (and as SI and RP), the Registrant was responsible for providing them with a culture and processes which enabled them to do so.
- 202. The Committee was satisfied that due to the deficiencies in the online questionnaire-based consultation system which have been identified above, the Registrant failed to ensure that the EU prescribers followed national prescribing guidance for the UK including the GMC 'Good practice in prescribing and managing medicines and devices' and the GPhC 'Guidance for registered pharmacies providing pharmacy services at a distance'.
- 203. Accordingly, the Committee finds Particular 9 Proved.

Particular 10

10. You failed to ensure that the services the pharmacy provided at a distance, including the prescribing service, had been adequately risk assessed.

204. The 2018 Guidance stated at 1.1:

"1.1 There are different risks with providing any pharmacy service at a distance, including on the internet. Before you start providing the service, you should gather evidence that you have identified and managed the risks, and checked that the arrangements you have in place meet the requirements of principle 1 [The governance arrangements safeguard the health, safety and wellbeing of patients and the public]....A risk assessment...is a careful and thorough look at what in your work could cause harm to patients and people who use pharmacy services, and what you need to do to keep the risk as low as possible....it should cover the whole service...you should ...review your risk assessment regularly...".

- 205. The 2019 Guidance contained a new section relating to the "significant extra risks" created when working with prescribing services not based in the UK, and listed such matters as indemnity insurance, making sure the prescriber is registered in their country, and working within national prescribing guidelines for the UK. Whilst these matters had not been set out in the previous GPhC Guidance, they did not introduce new responsibilities; rather they spelled out, for the avoidance of doubt, some of the issues that a pharmacy owner needed to assure themselves about, when starting up an internet pharmacy business using non-UK prescribers.
- 206. As for this Registrant, he was on notice about the need for a "comprehensive risk assessment" in accordance with the 2018 Guidance, from Ms 1 since the inspection in September 2018. She had found Standard 1.1 "not met" because:

"There is no evidence of risk assessment to provide assurance that high risk activities are being appropriately managed. This would include: using non-UK regulated prescribers; supplying addictive medicines without the knowledge or agreement of the patient's GP; the patient entering incorrect information during the online consultation".

- 207. The Registrant told the Committee that, as a result of the September 2018 inspection of EU Healthcare, he prepared some risk assessments and then he transferred them, exactly as they were, to Pronto. He did not review or change them at all at that point. He did not review or update them throughout the period that he owned Pronto either, for example to bring them in line with the 2019 Guidance.
- 208. The Committee considered the risk assessment documentation which the Registrant provided. The Registrant drew the Committee's attention during the hearing to numerous typed documents relating to medications and their indications and associated risks, as examples of his comprehensive risk assessments, however there were only three handwritten pages which dealt with "the services the Pharmacy provided at a distance, including the prescribing service". Those were the pages he sent to Ms 1 when she requested evidence of risk assessment, and those are the only assessments relevant to this particular.

- 209. The Committee has dealt earlier in this determination (in the "Preliminary Matters" section) with the submission that the Registrant was not providing a "prescribing service": it has found as a matter of fact, that he was.
- 210. The pages list seven risks, only two of which have a heading ("Online EU Doctor" and "Address verification"); there was no date; no date for review; no document version; no named owner of the risk documents (this would, the Committee understood, have been the Registrant himself).
- 211. Where the Registrant identified the risk of "Patients over prescribing", and the cause as "Addiction", the only additional control measure specified was "Patients must adhere to the Opioid policy which determines the maximum amount they can be prescribed per month. If abused, then blacklisted. 28 day supply". There was no mention of medication review; no mention of ensuring a full clinical assessment in relation to diagnosis and treatment; nothing at all in the documentation about the risks of prescribing in the absence of consent to contact the patient's GP; and nothing about the risks inherent in a process whereby patients could select their choice and quantity of medicine prior to the online consultation.
- 212. In relation to the identified risk of "patient ordering medication and pretend to be someone else e.g EHC", the "Additional control measures required" simply stated: "Patient I.D must be uploaded and address of patient. This will ensure the person ordering is legitimate". No consideration of the simple possibility that the person ordering may have uploaded false ID.
- 213. Overall, the Committee considered that the documentation contained insufficient and therefore wholly inadequate consideration of all of the risks associated with the Pharmacy's business model, or what had been done to minimise them.
- 214. The Committee was satisfied that the Registrant, who had a duty in this respect, as owner of the Pharmacy and also as SI, failed to ensure that the services the pharmacy provided at a distance, including the prescribing service, had been adequately risk assessed.
- 215. Accordingly, the Committee finds Particular 10 Proved.

- 11. You failed to ensure that the Pharmacy website had the following details on display:
- 11.1 [deleted]
- 11.2 the prescriber's name, registration details and regulatory body.
- 216. The website had a link providing access to the GPhC website and it stated that the Pharmacy used prescribers who were registered in the UK (which was not the case|), and in the EU.

 However the address, registration number and country of registration of the prescribers were not clear on the Website.
- 217. The Committee had found particular 11.2 Proved by admission.

- 12. Having agreed to amend the pharmacy website on or around 10 July 2019 to prevent a patient selecting medicines before a consultation had been completed, on or around 7 August 2019 you caused and/or allowed the pharmacy website to revert back to allowing patients to select medicines before a consultation was completed.
- 218. Mr Micklewright submitted, in relation to particulars 12 and 13, that having originally agreed to amend the operation of the Website to prevent patients selecting medications themselves prior to a consultation being completed, the Registrant, motivated by seeking to avoid the adverse impact on income this change had caused, reverted the Website back to its preinspection operation.
- 219. Ms 1's evidence in relation to this particular was that when she checked the Website on 6 and 7 August 2019 it had reverted to allowing the patient to select the medication they wanted before proceeding to the consultation stage. She said RN also checked it on her mobile during

the visit on 7 August 2019. She produced a screenshot of the Website from 6 August 2019 which had pictures of boxes of co-codamol, co-dydramol, codeine phosphate and dihydrocodeine, each of which had a link below inviting the purchaser to "Proceed to consultation".

- The Registrant's position was that he did make the change on 10 July 2019 as required by MsHe did not deny that the Website had reverted as described however he said he wasunaware that it had done so until Ms 1 alerted him to the change.
- 221. The Committee finds particular 12 proved on the basis that the Registrant allowed the pharmacy website to revert back to allowing patients to select medicines before a consultation was completed.

- 13. Your conduct at 12 above lacked integrity in that:
- 13.1 you had agreed the change in order to ensure the pharmacy met the pharmacy standards; and
- 13.2 the change was made to increase remuneration for the pharmacy and did not take account of patient safety concerns.
- 222. Ms 1's recollection was that the Registrant said he had changed the Website back due to an increased number of queries from customers about how to select their medicines, and because business had fallen (Ms 1 second witness statement, 14 February 2022). In her fourth witness statement she states that the Registrant changed it because business had "dropped dramatically". She explained to the Committee that the Registrant said patients were complaining because they could no longer select their choice of medication.

- 223. The Registrant's consistent position in relation to this concern was that he changed the system on 10 July 2019 as required by Ms 1, and he was not aware it had reverted back until she told him. He stated that "there was an IT glitch which occurred when there was a period of update on the server which reverted the software back to its original code". He told the Committee he had spent nearly £37,000 on changes to the Website to comply with what Ms 1 had required (the Committee was taken to the relevant invoice), so it would have made no sense for him to have altered the system on purpose, especially during the inspection process when he knew Council inspectors would be likely to follow up on his progress. The Committee noted, in this regard, that Ms 1 wrote to him giving him notice of her intended visit on 7 August 2019: it was not unannounced.
- 224. During cross examination, Ms 1 accepted that the Registrant had made a number of comments during that visit about bugs in the IT her handwritten note recorded "lots of bugs" and though she was sure he had not mentioned bugs as a possible explanation for this particular change, she accepted that it was possible that it had been caused by a bug.
- 225. In considering this particular, the Committee took into account the screen shot provided by Ms 1 dated 6 August 2019 and also her handwritten notes of the meeting, as well as her four witness statements. Her handwritten note did not record a comment about business falling, however it did record the issue with bugs yet, as Mr Haycroft submitted, that was nowhere set out in her four statements.
- 226. The Committee took into account Ms 1's recollection of comments made by the Registrant about customer complaints and reduction in business and also that these observations had also been made by the member of staff who was present at the visit, however the Registrant had also been consistent in his denial that he had made the system revert on purpose. In balancing the conflicting evidence, the Committee considered credible the Registrant's point that it would have made no sense for him to change the system back during the Council's inspection process, and having spent a significant sum changing it to deal with Ms 1's concerns.

227. It also took into account that in her third witness statement of 10 May 2023, Ms 1 stated that when she raised the matter at the visit on 7 August 2019, "the Registrant stated that the prescriber only sees that the patient had requested 'pain relief' rather than a specific medicine". This appeared to be what the Registrant was explaining in his "Proposed changes" document, where he stated:

"We believe the inspector has misunderstood on this particular point as once the website was amended on the 10/07/2019, since this date the online consultation has always remained active. The change that occurred was in regards to the consultation button as the button was placed at the bottom of the page, which was confusing customers. Therefore, the developer placed a button on each medication on the site to make it user friendly. This button took them to the consultation page....only the doctor recommends...Since the change was implemented the consultation has never been removed".

- 228. It was also aware, as Mr Haycroft had submitted, that it should take particular care in relation to the standard and burden of proof where an allegation was more serious, such as here where the Registrant's integrity was called into question.
- 229. This was one example, the Committee concluded, where it would have benefitted from evidence of full interrogation or investigation by the Council of the way the Website worked, to ascertain for example, whether there was a difference between what the customer thought they were requesting and what the prescriber saw.
- 230. In the absence of such evidence, the Committee was of the view that it could not reconcile the conflicts in the evidence and it was therefore of the view that the Council had not discharged its burden of proof.
- 231. Accordingly, the Committee finds Particular 13 Not Proved.

- 14. Whilst working as Responsible Pharmacist dispensed dihydrocodeine to Patient A on occasions stated in Schedule A in circumstances in which you:
- 14.1 failed to ensure you and/or the prescriber had all of the necessary information to ensure that the supplies to be made were clinically appropriate and safe for the patient;
- 14.2 failed to ensure that the patient's GP or other treating healthcare professionals were consulted before the supply was made; and
- 14.3 failed to refer the patient back to their GP for appropriate assessment.

SCHEDULE A

Date (s)	Medicine/quantity
29 October 2018	112 tablets of dihydrocodeine 30mg
18 December 2018	200 tablets of dihydrocodeine 30mg
29 January 2019	112 tablets of dihydrocodeine 30mg
12 February 2019	56 tablets of dihydrocodeine 30mg
4 March 2019	112 tablets of dihydrocodeine 30mg
21 March 2019	112 tablets of dihydrocodeine 30mg
3 April 2019	112 tablets of dihydrocodeine 30mg
29 April 2019	112 tablets of dihydrocodeine 30mg

232. The Committee was provided with evidence in the form of some prescription records and an email from the Council's senior case officer demonstrating that eight supplies of dihydrocodeine tablets were dispensed between 29 October 2018 and 29 April 2019, as alleged in Schedule A. There was no evidence that the prescriber or the Registrant had raised any queries in relation to Patient A's repeated ordering of medication which is known to be open to abuse. The prescriber had no access to GP or other health provider's clinical notes, they had had no opportunity to communicate directly with Patient A; it appeared that they

had simply taken it on trust that whatever she had written on her patient questionnaire in relation to any diagnosis or condition was the truth and had continued to prescribe quantities of medication without any verification that it was clinically appropriate and safe to do so. The Registrant had simply continued to supply the medication without any questioning or concerns.

- 233. Moreover, it was clear from the emails provided to the Committee that it was only due to the intervention of Mr 1 that the Pharmacy placed Patient A on the 'red list'.
- 234. The Committee accepted the submissions of Mr Micklewright to the effect that this was a specific example of the general prescribing model in operation at the Pharmacy: it did not manage the risks of a patient potentially lying to obtain dangerous and addictive medication; and it did not make it possible for prescribers to undertake their own independent clinical assessment, as was required by the rules of the GMC 2013 Guidance and the RPS 2016 Guidance, to determine that supplies made to Patient A were clinically appropriate.
- 235. In relation to sub-particulars 14.2 and 14.3, the Committee first observed that the Registrant never had contact details for Patient A's GP. She told him in emails that she didn't have one because she was moving home and later that she was in the process of getting a new one.
- 236. The Committee was satisfied that the Registrant as owner and as RP was responsible for the safe running of the Pharmacy and this involved prescribers or himself having access to and contacting Patient A. He ought to have been concerned at the repeated nature of Patient A's requests and he had a duty to take action as set out in 14.2 and 14.3.
- 237. The Committee took into account that the Registrant did not dispute that he had a professional duty in this respect, however he stated that he did refer Patient A to her GP. He maintained he had no concerns because the dose, and hence the quantity, supplied were within the BNF guidelines.

- 238. The Registrant had provided the Committee with emails evidencing his communications both with Patient A and with Mr 1, which showed that after he was alerted to the concern by Mr 1, the Registrant wrote to patient A on 29 April 2019 saying "before any medication is sent out we would require the name and number of your GP". He wrote on 1 May 2019 asking her to notify the Pharmacy of contact details for her new doctor, and wrote "we need to clarify and need your permission to notify your G.P". On 8 May 2019 the Registrant again wrote "Please get your GP to give the pharmacy a call in regards to your medication order".
- 239. The Registrant also provided the Committee with a patient record which stated: "Do NOT SEND UNTIL CONFIRMATION FROM HER DOCTOR: 2 May 2019".
- 240. However, it is plain from the email correspondence that, while the Registrant did ask for permission to speak to Patient A's GP, he did not refer her back to her GP for assessment.
- 241. Accordingly, the Committee finds Particular 14 Proved.

THE IMPAIRMENT STAGE

- 242. Having made its determination in relation to the facts, the Committee went on to consider whether those facts amount to misconduct and, if so, whether the Registrant's fitness to practise is currently impaired by reason of his misconduct.
- 243. "Misconduct" has been termed a "gateway" which may lead to a finding of current impairment. Article 51(1) of the Pharmacy Order 2010 provides that:

"A person's fitness to practise is to be regarded as "impaired" for the purposes of this Order only by reason of:

(a) misconduct

[various other grounds...]".

244. Article 54(1) of the Pharmacy Order 2010 provides:

"The Fitness to Practise Committee must determine whether or not the fitness to practise of the person in respect of whom the allegation is made (referred to in this article as "the person concerned") is impaired".

245. The Council's <u>Good decision making</u>: Fitness to practise Hearings and Outcomes Guidance (March 2024), Paragraph 2.12 states:

"2.12 A pharmacy professional is 'fit to practise' when they have the skills, knowledge, character, behaviour and health needed to work as a pharmacist or pharmacy technician safely and effectively. In practical terms, this means maintaining appropriate standards of competence, demonstrating good character, and also keeping to the principles of good practice set out in our various standards, guidance and advice."

Evidence

246. The Registrant provided document bundle of 67 pages for stage 2 of the hearing. This included a reflective account dated 31 October 2024; a record of a peer discussion on the same date; "Reflection of Incident" dated 19 February 2025; character references from three colleagues including two who were pharmacists and all of whom attested to his good clinical practice; information about an incident where he helped a person who had an allergic reaction having been stung by a bee; numerous certificates confirming attendance at training; and evidence of planned and unplanned Continuing Professional Development (CPD).

Submissions

247. Mr Micklewright, on behalf of the Council, referred the Committee to his skeleton argument and the relevant law. He submitted that the conduct which the Committee had found proved was in breach of Standards 1, 2, 3, 5, and 9 of the <u>Standards for pharmacy professionals</u> (2017), and whilst the Council did not seek to submit that the facts at 11.2 and 12 amount to

misconduct, the remaining conduct fell far below the standards of practice to be expected of registered pharmacists and would be considered deplorable by members of the public and fellow professionals; it therefore met the threshold for a finding of misconduct.

- 248. Turning to current impairment, Mr Micklewright submitted that limbs (a), (b) and (c) of Rule 5(2) of the Rules were engaged. He drew the Committee's attention in particular to the case of <u>Cohen v General Medical Council [2008]</u> EWHC 581 (Admin) and submitted that whilst the Registrant's conduct was remediable, it had not, in fact, been remediated. He submitted that the Registrant had shown some understanding of the issues relating to the benefits of face to face contact but the full extent of the risks within his business model had not been fully explored in his mind. The Committee could not be assured that he would not in future decide to return to online pharmacy; the factual findings touched on the fundamentals of being an SI or Director of a pharmacy, not just online business, in particular risk- assessing and auditing. He submitted that nothing in the Registrant's stage 2 bundle provided could satisfy the Committee that the conduct was [in the words of the principle set out in the <u>Cohen</u> case] "highly unlikely to be repeated"; there remained therefore a risk to public protection.
- 249. Mr Micklewright also submitted that the Committee should find the Registrant impaired in the wider public interest, citing in support the case of *Fopma v GMC*, [2018] EWHC 714 (Admin).
- 250. Mr Haycroft, on behalf of the Registrant, provided written submissions at this impairment stage. He reminded the Committee that for a finding of misconduct, a Registrant's conduct has to have fallen far short of what would be expected in the circumstances: it has to have been seriously reprehensible or deplorable. He submitted that whilst all of the facts found proved (except 11.2 and 12) could be regarded as negligent, and one or two of the particulars, for example, particulars 8 and 14 could be perceived to be "on the cusp" of misconduct, or, in the case of particular 8, might nowadays amount to misconduct when proper weight is given to the context in that online pharmacy was a developing area in which the guidelines were repeatedly being updated the facts found proved were not sufficiently serious to amount to misconduct.

251. In relation to current impairment, Mr Haycroft accepted the principles in <u>Cohen</u>. He submitted that the bar would be set too high if the requirement for a finding of no impairment was that there was no risk of repetition in future. The Registrant had reflected very long and hard on his practice: because he now understood the risks involved, he had not worked in online pharmacy since 2019. The Registrant's conduct should be judged by reference to the guidelines in place at the time of the events and not as at today's date. The Registrant had demonstrated his understanding of the risks involved through the documentation contained within his 67 page bundle which included reflections from real life experiences, he realised that the online pharmacy business model though lawful was fraught with difficulties and he now had a settled intention never to return to work as an SI or Director in online pharmacy.

The Committee's Decision

- 252. The Committee took into account the submissions on behalf of both parties, the relevant law and guidance, including reference to the Council's "Good Decision- making: fitness to practise hearings and outcomes guidance" (March 2024), and the Registrant's 67 page bundle. It accepted the legal advice of the legal adviser. It bore in mind that it was a matter for its own professional judgement whether the conduct it had found proved was so serious as to amount to misconduct; and whether if so, the Registrant's fitness to practise is currently impaired.
- 253. It took into account the Council's overarching objective which is the protection of the public, by:
 - protecting, promoting and maintaining the health, safety and wellbeing of the public
 - promoting and maintaining public confidence in the profession
 - promoting and maintaining proper professional standards and conduct for members of the profession.

- 254. The Committee accepted the submissions of Mr Micklewright in relation to the Council's "Standards for pharmacy professionals (May 2017). It determined that there had been breaches of the following Standards:
 - a. Standard 1: pharmacy professionals must provide person-centred care: the Committee has found that the Registrant's business model did not adequately and safely manage risks to patients who could order medications based on questionnaires with no face to face or other direct communication between the patient and prescriber, and this subjected the patients to a risk of harm.
 - b. Standard 2: pharmacy professionals must work in partnership with others: the Registrant did not have robust processes in place to communicate with patients' other healthcare providers for example their GPs: if a patient withheld consent to contact their GP, the doctors could nevertheless issue prescriptions for medications which had the potential to be harmful.
 - c. **Standard 3: pharmacy professionals must communicate effectively:** the Registrant's business model did not require him to communicate effectively with other professional colleagues including GPs.
 - d. Standard 5: pharmacy professionals must use their professional judgement: the Registrant breached this standard by omitting to observe basic and fundamental expectations of his profession. As SI, he failed to use his professional judgement to put in place and manage safe processes. Rather, he was managing a business which, as the Committee has found, did not, in a number of respects, provide safe and effective care to the patients who accessed its services via the internet.
 - e. **Standard 9: pharmacy professionals must demonstrate leadership:** the Registrant in his role as SI and RP of the business and Director of the Pharmacy, did not demonstrate leadership in that he failed in his responsibility to manage the business safely and effectively.
- 255. The Committee bore in mind that the Standards may be taken into account when considering the issues of grounds and impairment but that a breach of the Standards does not automatically result in a finding of misconduct (Rule 24(11) of the Rules).

- 256. The Committee carefully considered its findings of facts. It accepted, as acknowledged by the representatives for both the Council and the Registrant, and has been emphasized in all iterations of the Council's guidelines since at least 2013, that the business model the Registrant was operating providing pharmacy services at a distance was inherently risky.
- 257. Mr Haycroft had reminded the Committee at this stage, as he had at the facts stage, that it must not hold the Registrant responsible vicariously for the failings of others, and the Committee has taken this submission fully into account. The Committee has also taken into account that the provision of pharmacy services at a distance was growing as an area of pharmacy practice, giving pharmacists and those who ran pharmacies new business opportunities. Online pharmacies were and are, as emphasised by Mr Haycroft, in principle, legal.
- 258. The Committee also took into account the submissions of Mr Haycroft and the comments of the Registrant in his stage two bundle, to the effect that the Registrant had been running his business, to the best of his knowledge, in accordance with the Council's guidance as it existed at the time. It was submitted on the Registrant's behalf that the Committee should be careful not to judge the Registrant's conduct by today's standards, which, Mr Haycroft submitted, are stricter and more specific today than they were in 2018-21.
- 259. The Committee did not however accept those submissions. The Registrant, as Director and SI of the business, was directly responsible for ensuring that the systems and processes of his business were safe and effective, and that his practice as a registered professional complied with the principles of good practice. Those standards and professional responsibilities did not change over time, and were the same whether the business was a bricks and mortar business, or one that was online.
- 260. The Committee has found that, in a number of respects, the Registrant failed to act in accordance with those standards and professional responsibilities. He failed to ensure that is, to properly satisfy himself that the prescribers were appropriately insured, and that the patients were who they said they were; he set up and managed a business which did not

provide the prescribers he engaged, with all the information they needed, both in relation to UK professional standards and prescribing guidance and also to the patients for whom they were prescribing medications; there was no or insufficient communication with other health care providers; no requirement for access to medical notes; and very little risk assessment and auditing of the processes as a whole nor of individual patient outcomes.

- 261. The Committee was satisfied from the evidence it had seen and heard that the Council had been engaging with the Registrant since at least September 2018, when he was SI of a previous enterprise: the Council's inspector, Ms 1, had provided him with significant advice as to her concerns and encouragement for him to improve his processes.
- 262. The Committee was of the view that the Registrant's failings went to the heart of the role of SI and Director of a pharmacy business, whatever its nature. If running a pharmacy at a distance was inherently more risky than a traditional pharmacy, then it was down to the Registrant to ensure his processes were sufficiently rigorous to maintain professional standards in the delivery of that pharmacy service.
- 263. The Committee did not accept that the failings it has found amounted merely to negligence which was not serious enough to amount to misconduct. In the Committee's view the Registrant's breaches of his professional standards were seriously reprehensible. His conduct fell below acceptable and expected standards for pharmacy professionals, and would be considered deplorable by his fellow practitioners, and also by patients and the public.
- 264. For all of the reasons above, the Committee is satisfied that the ground of misconduct is found proved.

Impairment

265. Having found misconduct proved, the Committee went on to consider whether the Registrant's fitness to practise is currently impaired. Rule 5 of the Rules sets out the criteria which the Committee must consider when deciding, in the case of any Registrant, whether or not the requirements as to fitness to practise are met.

266. Rule 5(2) of the Rules states:

"In relation to evidence about the conduct or behaviour of the Registrant which might cast doubt on whether the requirement 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."
- 267. Guidance on this issue, (echoed the Council's <u>Guidance</u> (2024) at Paragraph 2.15), was set out by Mr Justice Silber in <u>Cohen v General Medical Council</u> [2008] EWHC 581 (Admin) at paragraph 65:

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

- 268. The Committee was of the view that the Registrant's conduct which led to the charge was in principle remediable.
- 269. As for whether the Registrant had, in fact, remediated his conduct, the Committee carefully considered the evidence he had provided in relation to current impairment.
- 270. The Registrant had in his reflective document stated the following:

"In summary, reflecting back on the past 5 years and from reading the updated guidelines on providing pharmacy services online including online prescribing, I feel there are a number of important factors which I would have implemented to improve patient safety and to prevent unintentional harm, had they been issued prior to 2018.... I would have tried to prevent potential

hazards by gathering more detailed, accurate patient information through effective verbal and written communication with patients and healthcare professionals involved in their care. Also, I would have accessed patient SCR medical records (after gaining informed patient consent) to help confirm the patient information presented was adequate and reliable for the safe prescribing and dispensing of medicines...contemplating back I would have tried to make sure that rather than using only online questionnaires, prescribers would carry out confidential consultations over the phone or by video...".

The Registrant also commented:

"In conclusion, all this has given me an insight of how important face to face consultation is along with keeping up to date with new guidelines as they come out. These types of experiences have played a key role in me considering my decision to never do online business again. This is due to the fact that many of my experience[s] have indicated this level of patient care and safety cannot be done online".

271. In relation to professional standards expected of him at the time of the events, the Registrant offered the following observations:

"I feel the GPhC did not acknowledge the efforts and tasks, I had implemented within 28 days to meet all the points stated in the improvement notice. The GPhC along with the inspector did not offer any clear cut support or advice to help me to achieve the best outcome. They only went on to issue updated guidelines for online pharmacies many years later...I believe GPhC still has a lot of work to do and issue a complete absolute robust guidelines and it will still take a number of years for them to do this...".

272. His hopes for the future are to continue to work in a community setting:

"My future goal is to focus on my clinical knowledge and professional development and I aspire to undertake a more clinical role in either a general practice or hospital setting after this ordeal is placed aside".

273. In conclusion, the Registrant stated:

"I feel sorry and have remorse that even after all efforts I made whilst conducting my online pharmacy business, there may have been safety concerns, which as a result I decided to close the business 5 to 6 years ago, although no patient complaint or no patient harm had occurred. In hindsight had I known, what I know now and by evaluating the standards produced only a couple of weeks ago, I would have had a better understanding of what is actually required from a distance selling pharmacy to ensure patient safety. Though I do believe the business did try to operate to the best of its ability with the limited information pharmacies had at our disposal at the time prior to April 2019 quidelines".

- 274. The Committee accepted that there was evidence before it that the Registrant's practice as a clinician was of a good professional standard and that he had diligently completed his CPD as required to maintain his registration. He expressed remorse for his conduct in his reflective document and set out his developed understanding in relation to the advantages of face to face or direct communication with patients; and the fact that online pharmacy carries inherent risks.
- 275. However, the Committee was not satisfied that the Registrant had sufficiently demonstrated an understanding of the specific risks posed by the particular way in which he had set up his online business. His reflections demonstrated a persisting conviction that the Council's inspectors had not been helpful enough; or had judged him too harshly; that the Council's guidance was not detailed enough and kept changing; that he was operating his business in the same way as other online businesses at the time: in effect, that he had done his best and the failings, for the most part, were not his fault.
- 276. The Committee was of the view that the Registrant had not demonstrated a sufficiently developed understanding of his own direct or personal and professional responsibility as the SI and Director of the business to ensure that the Pharmacy operated safely and effectively and in the best interest of his patients.
- 277. The Committee acknowledged that the Registrant had said he does not intend to return to online pharmacy or certainly not in the role of SI or Director. However, the Committee

considered that there was a possibility that he could change his mind in the future. It also observed that the failings it had found, including inadequate risk assessment and auditing, and lack of communication with fellow healthcare professionals, related to fundamental aspects of safe practice as a pharmacist, and not just to online pharmacy.

- 278. Taking all of the evidence into account, the Committee was not persuaded that the Registrant had remediated his misconduct nor that it was highly unlikely to be repeated.
- 279. The Committee next considered Rule 5(2) of the Rules. The Committee accepted the submissions of Mr Micklewright in that (a) the Registrant currently presents an actual or potential risk to patients or to the public; (b) he has brought the profession of pharmacy into disrepute; (c) he breached not just one but a number of the fundamental principles of the profession of pharmacy. The Committee did not consider that Rule 5(2)(d) was engaged by the facts of this case.
- 280. The Committee therefore is of the view that the Registrant's fitness to practise is currently impaired on the personal component.
- 281. Turning to the wider public interest, the Committee bore in mind the case of <u>CHRE v NMC and</u>

 <u>Grant [2011] EWHC 927 (Admin) in which it was said:</u>

"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 professional standards and public confidence in the profession would be undermined if a finding of impairment were not made in the particular circumstances."

282. It also took into account the case of <u>Fopma v GMC</u> [2018] 714 (Admin), in which the Judge stated: "A failure to find impairment in any given case, whilst warnings as to future conduct can still be issued, is tantamount to an indication on behalf of the profession that conduct of the kind need not have regulatory consequences. If that, depending on the nature of the

conduct in question, would itself be an unacceptable conclusion, then that can in any given case be a sufficient basis in itself to justify or indeed compel a conclusion of impairment".

- 283. The Committee was of the view that its findings of fact and the misconduct involved were serious and particularly so, given that more and more pharmacies are providing services online, in a business model which carries inherent risks which may be greater than in a bricks and mortar business. In this context, a failure to find impairment, being tantamount to an indication that conduct of the kind found in this case need not have regulatory consequences, would assuredly been an unacceptable conclusion. It is therefore of fundamental importance that the Committee makes a finding of current impairment in the wider public interest to send a message to pharmacy professionals and to the public that no matter how pharmacy businesses are organised and delivered, they must provide their services to patients safely and effectively, in accordance with professional standards.
- 284. The Committee is satisfied that the need to uphold professional standards and public confidence in the profession would be undermined if a finding of impairment were not made in the particular circumstances of this case.
- 285. The Committee therefore finds that the Registrant fitness to practise is currently impaired, both on the personal component, and also on the public component, that is, in order to uphold and maintain professional standards and maintain public confidence in the profession and in the regulator.

Decision on Outcome

- 286. Having found impairment, the Committee went on to consider the appropriate outcome.
- 287. The Committee's powers in relation to sanction are set out in Article 54(2) of the Pharmacy Order 2010.
- 288. Article 54(2) of the Order provides:

"If the Fitness to Practise Committee determines that the person concerned's fitness to practise is impaired, it may—

- a. give a warning to the person concerned in connection with any matter arising out of or related to the allegation and give a direction that details of the warning must be recorded in the person concerned's entry in the register,
- b. give advice to any other person or other body involved in the investigation of the allegation on any issue arising out of or related to the allegation;
- c. give a direction that the person concerned be removed from the register;
- d. give a direction that the entry in the Register of the person concerned be suspended, for such period not exceeding 12 months as may be specified in the directions; or
- e. give a direction that the entry in the Register person of the person concerned be conditional upon that person complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interest of the person concerned."

The Committee may also make no order.

- 289. The Committee was aware that it should consider the available outcomes in ascending order from the least restrictive, taking no action, to the most restrictive, removal from the register, in order to identify the appropriate and proportionate outcome that meets the circumstances of this case. It bore in mind that the purpose of the outcome is not to be punitive, though an outcome may in fact have a punitive effect. The purpose of the outcome is to meet the overarching objectives of regulation, namely the protection of the public, the maintenance of public confidence and to promote and uphold professional standards. The Committee is therefore entitled to give greater weight to the public interest over the Registrant's interests.
- 290. The Committee had regard to the GPhC's guidance, entitled: <u>Good decision making: Fitness</u> to practise hearings and outcomes guidance (March 2024), ("the Good decision making Guidance") which reminds the Committee that it must consider the full range of outcomes.

Submissions

- 291. Mr Micklewright referred the Committee to his skeleton argument and submitted that the Registrant's conduct was fundamentally incompatible with continued registration and so the only appropriate and proportionate order was removal. He submitted that in accordance with case law, the Registrant's personal circumstances, whilst relevant, should take second place to the public interest considerations. He submitted that the Registrant's reflections show a failure to understand and accept his professional standards: he still seeks to duck fulsome responsibility for his actions and to criticise his regulator rather than fully reflecting on those actions himself. He submitted that the Registrant was responsible for the safe and effective running of the Pharmacy and as such, it was his duty to mitigate risks to patients- especially so when working in an area which was itself inherently risky.
- 292. Mr Haycroft, on behalf of the Registrant, provided written submissions on outcome in which he summarised the relevant law and guidance, setting out how the guidance should be applied to the facts of this case. He emphasised that the Committee must consider the full range of outcomes available to it. He reminded the Committee that the Registrant has worked for four years in community pharmacy since the relevant events without further concerns being raised against him and drew the Committee's attention to case law which states that there is a public interest in retaining an otherwise good clinician in practice so that they can continue to provide a service to the public.
- 293. Mr Haycroft submitted that an order for conditional entry for a period of 12 months would be appropriate and proportionate in this case, and any more restrictive outcome would be disproportionate.
- 294. Mr Haycroft also informed the Committee of the Registrant's personal family and financial circumstances which he submitted must be taken into account in weighing up the appropriate outcome.

The Committee's Decision

- 295. The Committee had regard to the relevant law and to the Council's <u>'Good decision making:</u>

 <u>Fitness to practise hearings and outcomes guidance</u> (March 2024)' ("the Good decision making Guidance"), to inform its decision. It took into account the submissions made by Mr Micklewright and Mr Haycroft.
- 296. The Committee first considered what, if any, aggravating and mitigating factors there may be.
- 297. The Committee identified the following aggravating factors:
 - The medications concerned included prescription only high risk medications;
 - The conduct was sustained over a period of time;
 - Patients were not appropriately assessed or managed;
 - The transactional nature of the Registrant's practice.
- 298. The Committee identified the following mitigating factors:
 - There was no dishonesty found in this case.
 - The Registrant has demonstrated remorse for his conduct;
 - The Registrant provided testimonials from professional colleagues who attested to his good quality of work as a community pharmacist.
- 299. The Committee next turned to consider the sanctions available to it in ascending order.
- 300. <u>Take no Action:</u> The Committee first considered where it would be appropriate to take no action, however it was of the view that this outcome would not protect the public nor would it be sufficient to reflect the seriousness of the Registrant's misconduct.
- 301. <u>Warning:</u> The Committee next considered whether issuing a warning would be appropriate but it decided that a warning would not be appropriate for the same reasons as above,

namely that a warning would not protect the public nor sufficiently mark the public interest.

The Committee also was of the view that a warning would not be proportionate to the seriousness of the Registrant's failings.

- 302. <u>Conditions of Practice.</u> The Committee next considered whether to impose conditions of practice. The Good decision making 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 where there is not a significant risk posed to the public by the imposition of conditions.
- 303. The Committee bore in mind that Mr Haycroft had submitted that conditions would be an appropriate outcome in this case, and carefully considered this outcome. The Committee acknowledged that it had found at the impairment stage that his misconduct was in principle remediable. It considered that conditions could have been formulated which would prevent the Registrant from working in the role of SI and/or RP and/or a director, in a distance-selling pharmacy business for a period of time. Indeed, the Registrant had been working, the Committee was informed, as a community pharmacist since he had stopped working in his online business.
- 304. However, this was a case in which the Committee had found, that, in a number of specific respects, the Registrant had failed to abide by his basic professional responsibility to set up and manage his distance selling business so as to ensure safe and effective care for patients. Distance selling is a growing area of pharmacy practice (though it has of course been in place for a significant number of years), and as has been explicitly and repeatedly set out in the Council's guidance since at least 2013, it carries specific risks.
- 305. The Registrant's business model failed to deal satisfactorily with those risks, not because it was in and of itself an online business, but because of the significant weaknesses in the processes which he set up. As has been set out by this Committee at earlier stages of this hearing, the business model which the Registrant set up, owned and managed and which

included a prescribing service, did not give the prescribers, doctors based outside the UK, the ability to communicate directly and effectively with the patients who accessed the service. They were prescribing, in the majority of cases, potentially harmful medications based solely on the word of those who wanted to purchase them, with no system in place to verify whether the medications were clinically appropriate.

- 306. In these circumstances the Committee is of the view an order for conditions would not be sufficient to mark the seriousness of the matter and send a clear message to the Registrant's professional colleagues and to the public so as to maintain public confidence in the profession and the regulator.
- 307. <u>Suspension Order.</u> The Committee next considered whether suspension would be a proportionate sanction.
- 308. It took into account that Mr Micklewright had submitted that suspension would not be proportionate, to the seriousness of the case, whilst Mr Haycroft had submitted that it would be disproportionately severe.
- 309. The Committee carefully considered the Council's <u>Good decision making guidance</u> which indicates 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. 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".

310. The Committee took into account that the Council's <u>Good decision making guidance</u> states at paragraph 5.7 and 5.8 that in reaching a decision on what outcome to impose, the Committee should give appropriate weight to the wider public interest. The Committee is entitled to give

greater weight to the public interest, than to the consequences for the professional. Even if an outcome will have a punitive effect, it may still be appropriate.

- 311. The Committee was satisfied that the public would be protected from any risk of harm whilst the Registrant was suspended from the register. It therefore turned to consider whether a suspension would be adequate and proportionate to maintain public confidence in the profession and proper standards of behaviour.
- 312. The Committee took into account all of the mitigating factors of the case which it had identified. It bore in mind that the Registrant has been working as a pharmacist for several years since the events came to light with no concerns raised against him. It also took into account his family and financial circumstances and his expressed intention not to return to work as a SI or owner in a distance- selling pharmacy, because of the inherent risks involved in doing so, which it considered, demonstrated some degree of recognition of the seriousness of his misconduct and the inherent risks involved in distance selling pharmacy. The Committee also properly weighed its earlier conclusion that the misconduct it had found proved in this case was capable in principle of being remedied.
- 313. After careful consideration, the Committee concluded that a period of suspension would satisfactorily mark the seriousness and nature of its findings. It was satisfied that members of the public, were they to be appraised of all the evidence in this case, would consider it appropriate, reasonable and fair that this Registrant should be suspended from working as a pharmacist for a period of time so as to send an important message to the profession, to patients and to the public, about the seriousness of this Committee's findings. This will make clear the fundamental need for pharmacists working in a distance-selling context to abide by their professional standards and their responsibility to make sure they have done all they reasonable can to mitigate the inherent risks involved in this type of pharmacy service.
- 314. The Committee considers that a period of eight months' suspension is appropriate and proportionate to reflect the seriousness of this case.

- 315. The Committee considers that this is a case in which a review ought to be held before the expiry of the period of suspension, so that the Registrant can demonstrate to a reviewing committee that he has developed his insight further and fully into his failings, and demonstrate how he will guard against repeating his conduct in future.
- 316. The Committee considers that the reviewing committee would be assisted by the Registrant providing the following:
 - i) A reflective document demonstrating the Registrant's full insight into the seriousness of his misconduct, explaining that he understands what he should have done at the time and what he would do in future to avoid repeating his failings. He may find it helpful to refer specifically to each of the Committee's factual findings in turn and to the relevant guidance;
 - ii) Evidence of any training he may undertake, for example shadowing an SI working in a distance-selling context;
 - iii) Testimonials in relation to relevant work, whether paid or unpaid.
- 317. Removal. Having concluded that a period of suspension would satisfactorily deal with the issues of public protection and public interest which it has identified, the Committee considered whether removal was in fact more appropriate. The Committee took into account that removal is reserved for the most serious conduct. The Sanctions Guidance states that:

"Removing a professional's registration is reserved for the most serious conduct... The committee should consider this outcome when the professional's behaviour is fundamentally incompatible with being a registered professional".

318. Taking all of the evidence into account, the Committee has come to the view that the Registrant's conduct is not fundamentally incompatible with being a registered professional and therefore removal of his name from the register would be disproportionate.

- 319. The Committee therefore directs that the entry in the Register of Mr Anees KHODA whose registration number is 2067807, be suspended from the register for a period of eight months.
- 320. That concludes this determination.

Decision on Interim Measure

- 321. Mr Micklewright made an application on behalf of the Council for an interim measure of suspension to be imposed on the Registrant's registration, pursuant to Article 60 of the Pharmacy Order 2010, pending the coming into force of the Committee's substantive order. He submitted that given that the sanction imposed by the Committee, the public would consider it perverse for an interim measure of suspension not to be imposed to cover the duration of the appeal period.
- 322. The Registrant did not oppose the application.
- 323. The Committee carefully considered the Council's application. It took account of the fact that its decision to order the suspension of the Registrant's name from the register will not take effect until 28 days after the Registrant is formally notified of the outcome, or until any appeal is concluded. The Committee also took into account the Council's Good Decision making guidance of 2024.
- 324. The Committee was satisfied that an interim measure of suspension ought to be in place from today's date, as it is necessary for the protection of the public and is otherwise in the public interest, given the seriousness of its findings in relation to the Registrant's conduct.
- 325. The Committee therefore hereby orders that the entry of the Registrant in the register be suspended forthwith, pending the coming into force of the substantive order