General Pharmaceutical Council

Fitness to Practise Committee

Principal Hearing

General Pharmaceutical Council, 25 Canada Square, Canary Wharf, London E14 5LQ

23 to 25 May 2022

And

18 to 19 July 2022

Registrant name:	Genevieve Boateng
Registration number:	2212407
Part of the register:	Pharmacist
Type of Case:	Misconduct
Committee Members:	Philip Geering (Chair) Sam Stephenson (Registrant member) Anne Johnstone (Lay member)
Legal Adviser:	John Donnelly
Secretary:	Adam Hern, Lucy Eames and Gemma Walters
Registrant:	Present
General Pharmaceutical Council:	Represented by Ms Rayla Javaid, Case Presenter on 23 to 25 May 2022. Mr Mark Millin presented for the Council on 18 to 19 July 2022
Facts proved:	1a i, 2b, 2d, 2e, and 2f i.
Facts proved by admission:	1a ii & iii, 1b i, ii, iii & iv, 2a &c, 3**.**
Facts not proved:	2f ii.
Fitness to practise:	Impaired
Outcome:	Conditions of Practice for 12 months
Interim measures:	Interim Measure of Conditions of Practice imposed

This decision including any finding of facts, impairment and sanction is an appealable decision under our rules. Therefore, this decision will not take effect until 17 August 2022 or, if an appeal is lodged, once that appeal has been concluded. However, the interim conditions set out in the decision take effect immediately and will lapse when the decision takes effect or once any appeal is concluded

The Conditions are as follows:

1. You must:
    - tell the GPhC before you take on any position for which you must be registered with the GPhC
    - give the GPhC details of the role and the hours you will work each week, including locum or relief work
    - give the GPhC the contact details of your employer, superintendent pharmacist and/or pharmacy owner.

2. You must tell the following people in writing about the restrictions imposed on your pharmacy practice, if you are doing any paid or unpaid work for which you must be registered with the GPhC. You should do this within two weeks of the date this order takes effect:
    - all employers or contractors
    - agents acting on behalf of employers and locum agencies
    - superintendent pharmacists
    - responsible pharmacists
    - line managers
    - workplace supervisors
    - accountable officers for controlled drugs.

    You must send the GPhC a copy of this notification.

    If you are applying for work, you must tell any prospective employer about the restrictions imposed on your pharmacy practice when you apply.

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

4. You must:

    - find a workplace supervisor for each place of work (who must be a registered Pharmacist or GMC registered Doctor) and put yourself, and stay, under their remote supervision
    - ask the GPhC to approve your workplace supervisor(s) within 4 weeks of the date this order takes effect. If you are not employed, you must ask us to approve your workplace supervisor before you start work
    - give the GPhC your permission to exchange information with your workplace supervisor(s) about your efforts to improve your pharmacy practice.

5. You must arrange for your workplace supervisor(s) to send a report on your progress with regard to the development of your safe and effective clinical practice to the GPhC every 4 months, with a minimum of three reports prior to a review hearing, or when the GPhC requests one. The GPhC will act reasonably in how often reports are requested.

6. You must not work as a sole practitioner or superintendent pharmacist or responsible pharmacist.

7. You must not provide mail-order or online pharmacy services.

End of Conditions

DETERMINATION

Introduction

1. This is the written determination of the Fitness to Practise Committee following a Principal Hearing concerning the Registrant, Genevieve Boateng.

2. The Registrant is registered with the General Pharmaceutical Council ('the Council') as a pharmacist, registration number 2212407.

3. It is alleged that her fitness to practise is impaired by reason of misconduct.

4. These proceedings are held under the provisions of The Pharmacy Order 2010 ('the Order') and The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rule) Order of Council 2010 ('the Rules').

5. The Committee has also had regard to the Council's guidance contained in its document *"Good decision making: Fitness to practise hearings and sanctions guidance"* dated March 2017.

Preliminary Matters

6. Representation: the Registrant attended the hearing and confirmed her registration number. She was not legally represented. She explained that she had received legal advice including with regard to the submission of her bundle for the hearing, but was not in a position to be represented at the hearing. The Legal Adviser and the Council's representative spoke with the Registrant before and during adjournments of the hearing. During the hearing, the Committee took time to explain the process to the Registrant and gave her time to consider issues as the need arose.

7. The Council was represented by Ms Rayla Javaid on 23 to 25 May 2022. Mr Mark Millin represented the Council on 18 and 19 July 2022.

8. Service: the Committee was shown a copy of a letter dated 4 April 2022 headed 'Notice of Hearing', emailed to the Registrant.

9. No issue was taken on the Registrant's behalf regarding service.

10. In the light of the above, the Committee was satisfied that proper service within the relevant Rules had been effected.

11. Papers: prior to the hearing the Committee was provided with:

a. A bundle of documents prepared by the Council paginated to page 390 containing, amongst other documents, the Particulars of Allegation, witness statements and exhibits adduced on behalf of the Council, including documents the Registrant had provided to the Council;
b. A 'Combined Statement of Case and Skeleton Argument' on behalf of the Council, dated 12 May 2022; and
c. A bundle of documents prepared on behalf of the Registrant paginated to page 50. The bundle contained a 'Case Statement' presenting an indication of her anticipated admissions/denials along with further submissions regarding her fitness to practise, the Registrant's statement, a reflective statement, documentary exhibits and testimonials.

12. During the hearing the Registrant sought to provide the Committee with:

a. a copy email from herself to the Council's Inspector dated 13 May 2020 and a screen shot showing two items saved on a computer dated 16 November 2019; and
b. a copy email from herself to the Council's Inspector dated 22 November 2019 accompanied by several attached documents.

13. On behalf of the Council no objection was raised to the admission of the documents.

14. Having received the advice of the Legal Adviser, the Committee was satisfied that the documents were relevant to the proceedings and that it would be fair to admit them as evidence in the proceedings and for the Committee to consider them in the context of the case.

15. The Committee was unable to complete the hearing in the time originally scheduled, 23 to 25 May 2022. Having made findings of fact, the Committee adjourned the hearing, and recommenced on 18 July 2022. For the resumed part of the hearing, the Committee was provided with the following:

    a. an additional Hearing bundle on behalf of the Council indexed and paginated pages 1 to 44;

    b. a revised Registrant's bundle indexed and paginated pages 1 to 65; and

    c. an addition bundle for the Registrant prepared for the sanction stage paginated page 1 to 7.

The Allegation

16. The Allegation is presented as follows:

    You, a registered pharmacist, and the Responsible Pharmacist (RP), Superintendent Pharmacist (SI) and the Director/person with significant control of Maiden Consult Ltd 1.38 160 London Road, Barking IG11 8BB (the pharmacy), between 18 February 2019 and 20 November 2019, were responsible for the safe and effective delivery of services from the pharmacy. In relation to the dispensing and supply of high-risk drugs, containing codeine, dihydrocodeine, zopiclone and zimovane:

    1. You failed to ensure that the pharmacy had robust procedures in place:

a. *to ensure that sufficient checks were made when supplying medications, in that:*
    i. *You failed to audit the system which ensured patient identity was verified accurately;*
    ii. *you failed to audit the system used to prevent inappropriate supplies to patients who made repeat orders;*
    iii. *medications were sometimes supplied prior to relevant checks being fully completed.*
b. *to ensure that the medicines supplied were appropriate and safe in that:*
    i. *the pharmacy website allowed people to choose the medicine, strength and quantity prior to a consultation;*
    ii. *You supplied patients with high risk medicines without ensuring their regular doctor agreed with the supply and, in the absence of a GP or regular prescriber, did not ensure that the prescriber made a clear record to justify their decision to prescribe;*
    iii. *medicines, including high risk medicines, were supplied based on a questionnaire completed by the patient;*
    iv. *unlicensed medication including duloxetine and carbamazepine were advertised on your website.*

2. *You did not identify and manage all of the risks involved with the services provided in that:*
    a. *You did not ensure clinical audits and/or prescribing reviews were completed.*
    b. *your IT system did not prevent unauthorised personnel from accessing and/or creating and/or amending records*
    c. *you failed to ensure sufficient records were kept of discussions between patients and pharmacy staff*
    d. *You did not conduct regular audits of the number and nature of prescriptions which had been refused by the prescribers*
    e. *You did not audit the process for receiving responses back from patients' regular doctors*
    f. *You did not ensure prescribers*
        i. *followed UK national guidelines (including GMC guidance);*

ii. were appropriately registered in their home country.

3. You did not ensure all services, including for prescribers, were covered by appropriate indemnity insurance.

By reason of the matters above your fitness to practise is impaired because of your:

a) Misconduct

17. The Registrant made admissions to the following particulars of the Allegation: 1a ii & iii, 1b i, ii, iii & iv, 2a &c, 3. Whilst she made these admissions, she also made clear that she did so on a specific basis with regard to some particulars as is reviewed below.

18. By the application of Rule 31(6) of the Rules, the factual particulars admitted were found proved.

19. Accordingly, the Committee went on to receive evidence and submissions regarding the factual particulars of the Allegation that were not admitted.

Background

20. The Registrant first registered as a Pharmacist in August 2016.

21. In 2018 she set up Maiden Consult Ltd as a pharmacy which opened early in 2018 at 1.38 160 London Road, Barking IG11 8BB ('the pharmacy').

22. The Allegation concerns the period between 18 February 2019 and 20 November 2019. The Registrant was the Responsible Pharmacist (RP), Superintendent Pharmacist (SI) and the Director/person with significant control of Maiden Consult Ltd, a pharmacy. As such, the Registrant was responsible for the safe and effective delivery of services from the pharmacy.

23. It was an "online" pharmacy. As explained below, the pharmacy was subject to an unannounced inspection by inspectors from the Council. An inspection report dated 20 November 2019 provides a brief description of the pharmacy as follows:

> *"This is a distance selling pharmacy (www.mynetdoctor.co.uk) linked to an online prescribing service. The pharmacy dispenses private prescriptions only, generated by an online EU based prescriber in Romania. The vast majority of people using the pharmacy are based in the UK. The types of medicines mainly dispensed included: pain relief (codeine phosphate, dihydrocodeine, co-codamol) and sleep aids (zopiclone). The pharmacy is closed to the public and situated in a serviced office block and medicines are delivered to people via courier."*

24. In February 2019 the pharmacy was subject to an unannounced inspection by the Council which resulted in a finding that the performance of the pharmacy was satisfactory against the then existing expectations and there were no required actions.

25. In April 2019 the Council issued guidance entitled *"Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet"*, guidance that was relevant to the Registrant's business. Whilst it is described as "guidance" it is clear from the document that it is to be followed: see for example at the very start of the guidance:

> *"As the pharmacy owner, you are responsible for making sure this guidance is followed. Everyone in the pharmacy team, including managers with delegated responsibility and the responsible pharmacist, should understand the guidance and be aware of their responsibilities to follow it. If the registered pharmacy is owned by a 'body corporate' (for example a company or an NHS organisation) you should make sure the superintendent pharmacist understands it should be followed."*

26. On 20 November 2019 inspectors from the Council made an unannounced visit to the pharmacy. The Registrant was logged as the RP on duty at the time but was not present. She subsequently attended at the pharmacy and engaged with the inspectors during their visit to the pharmacy and subsequently.

27. During the visit the inspectors identified a range of concerns whereby the standards expected were not being met in a way that gave rise to patient safety issues.

28. It is noted here that the Council has statutory responsibilities for regulating both pharmacists as individual professionals, *and* pharmacy premises. The Council maintains a separate register for each, one for pharmacists and one for pharmacy premises.

29. As a consequence, three significant steps were taken by the Council:

    a. On 2 December 2019, the lead inspector emailed the Registrant a Notice of Conditions restricting the registration of the pharmacy premises with immediate effect;

    b. On the same date, 2 December 2019, the Registrant was provided with a draft Inspection Report on which she could, and did, comment; and

    c. On 20 February 2020, a finalised Inspection Report was issued, albeit the date remained unchanged from the draft, 20 November 2019, the Registrant's responses having been taken into account.

30. The Notice of Conditions restricting the registration of the pharmacy is issued by the Registrar when it is considered *"necessary … for the purpose of securing the safe and effective practice of pharmacy at those premises"* and is issued with immediate effect when *"giving reasonable notice would prejudice the health, safety or well-being of members of the public"* (as set out in the notice).

31. The Notice of Conditions provided the following summary of reasons for conditions being imposed:

    "A number of GPhC Standards for registered pharmacies have been failed following an inspection visit on 20 November 2019 including:
    •The pharmacy does not identify and manage all of the risks involved with its services.

•The pharmacy does not properly review its services to make sure that they are safe for people to use. For example, it does not do regular audits of how many prescriptions had been refused by the prescribers. And it does not audit its process for receiving responses back from people's regular doctors. This increases the risk that people with addiction problems go undetected by the pharmacy and are still supplied medicines.

•The pharmacy has not produced any evidence to demonstrate whether the prescribers, (who are based in the EU and are not registered with any UK regulatory bodies) are following UK national guidelines (including GMC guidance).

•The pharmacy's website allows people to choose the medicine, strength and quantity prior to receiving a consultation. This is contrary to GPhC Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet.

• The pharmacy does not always supply its medicines safely. It does not carry out enough checks to ensure medicines are appropriate for the individual patients it supplies. It supplies medicines that can be abused or misused to people without making sure that their regular doctor agrees with the supply. And in the absence of this agreement, the pharmacy does not ensure that the online prescriber has made a clear record to justify their decision to make the supply.

• The pharmacy has not provided assurances that it manages the risk that people may deliberately provide incorrect information via a questionnaire-based consultation to receive medicines that they want, despite it being clinically inappropriate. This is a particular issue for people seeking opioid pain killers and 'Z-drugs' (such as zolpidem or zopiclone). These people may have a history of substance abuse and it is more likely that the history they provide will be insufficient and unreliable, by the very nature of their condition.

•The pharmacy does not have adequate systems in place to safeguard the welfare of vulnerable people receiving its services. Particularly as many of the people who use the pharmacy are receiving high-risk medicines such as opioids and sleeping tablets.

•The pharmacy is not able to demonstrate whether the prescribers it works with are covered by appropriate indemnity insurance. The pharmacy is not able to demonstrate that its insurers are aware of the full scope of services provided, and therefore they cannot show that appropriate insurance or indemnity is in place.

Taken together, these matters indicate system wide failures in the operation of the pharmacy which presents a serious risk to patient safety. The risks are heightened by the nature of the services provided by the pharmacy, which involve the dispensing and supply of high-risk medicines, including opioids and Z-drugs, at a distance, against prescriptions issued by non-UK prescribers.

There are serious systemic failings in the governance and management of risk at the pharmacy and patients and members of the public continue to use its services. In the circumstances, the conditions need to be imposed without notice in view of the continuing risks as any delay would otherwise prejudice the health, safety or well-being of members of the public.

It is therefore necessary to make the pharmacy subject to conditions as it is necessary for the purpose of securing the safe and effective practice of pharmacy at these premises."

32. The Notice of Conditions imposed the following condition:

> *"The pharmacy must not sell or supply any controlled drugs from Schedule 1 to 5 (as detailed in the Misuse of Drugs Regulations 2001, as amended)."*

33. A subsequent email from the Council inspector required documentary proof of compliance with the Notice of Conditions by close of 6 December 2019 which the Registrant provided.

34. Whilst the above actions were taken within the context of regulating the pharmacy premises, these fitness to practise proceedings have been brought against the Registrant as the registered pharmacist responsible for the pharmacy.

Determination of the Facts

35. The Committee proceeded to receive evidence for the purpose of determining the facts that were not admitted. To do so the Committee considered both the documentary evidence

provided by both the Council and the Registrant, and oral evidence presented on behalf of the Council and the Registrant and the submission made on behalf of both parties.

36. On behalf of the Council, Witness A was called to give oral sworn evidence. She is a pharmacist and an inspector with the Council. She led the inspection of the Registrant's pharmacy on 20 November 2019, was responsible for liaising with the Registrant thereafter and for finalising the Inspection Report.

37. The Registrant gave oral sworn evidence, adopting her witness statement, the Case Statement and documentary exhibits. She was cross-examined on behalf of the Council and answered questions posed by the Committee and, at the request of the Committee, questions posed by the Legal Adviser in order to address the fact that she was unrepresented.

38. At the conclusion of the evidence, it was submitted on behalf of the Council that the particulars of the Allegation that were not admitted should, on the evidence, be found proved save for particular 2f ii which the Council conceded could not be proved.

39. The Registrant made submissions regarding the particulars she had not admitted, identifying evidence in support of her case and, regarding some particulars, making concessions.

40. The Legal Adviser gave advice to the Committee which was agreed by the parties and accepted by the Committee, in particular that the burden of proof was on the Council meaning that it was for the Council to prove the Allegation, it was not for the Registrant to disprove them, and that the standard of proof was the civil standard, namely on the balance of probabilities.

41. The Committee considered each of the disputed particulars of the Allegation in turn. In addition, and for completeness, the determination sets out background facts to the particulars that are admitted.

42. **Stem of the Allegation:** the Registrant admitted that she was the Responsible Pharmacist (RP) for the Pharmacy, the Superintendent Pharmacist (SI) and the Director/person with significant control of the pharmacy during the period of the allegation. She accepted that she was responsible for the safe and effective delivery of services from the pharmacy including the dispensing and supply of "high-risk drugs", containing codeine, dihydrocodeine, zopiclone and zimovane, these being high-risk drugs because they are susceptible to abuse, misuse, and addiction. To that list of drugs, the Registrant agreed she also supplied zolpidem as listed in the inspector's statement, amongst other medication.

43. The Registrant confirmed that no one else had been the pharmacy's Responsible Pharmacist, Superintendent Pharmacist or director/person with significant control of the pharmacy.

44. **Particular 1a i:** the Registrant denied that she failed to audit the system which ensured patient identity was verified accurate.

45. It is routine for pharmacists to check the identity of the person to whom drugs are to be supplied to check that they are the person to whom the drugs have been prescribed. This is for safe-guarding purposes and applies whether drugs are dispensed in person or at a distance through an online pharmacy.

46. Principle 4 of the April 2019 Guidance concerns the way pharmacies ensure online services are delivered in a way that *"safeguard the health, safety and wellbeing of patients and the public."* The Guidance requires the pharmacy owner

> *"to show the steps you have taken to minimise the risks you identify. This should include how you:*
> • *…*
> • *make sure your pharmacy staff can:*
> *− check that the person receiving pharmacy services is who they claim to be, by carrying out an appropriate identity check (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)"

47. Under Principle 1 of the Guidance (concerned with governance) the Guidance includes the following:

"The safety and quality of pharmacy services must be reviewed and monitored. You should carry out a regular audit, at an interval that you can show to be appropriate for your pharmacy services. The audit should be part of the evidence which gives assurance to people who use your pharmacy that it continues to provide safe pharmacy services."

And

"If you identify any issues, you should take action to put them right. This may lead to you carrying out a 'reactive' review. You should record this reactive review and say clearly when a new risk assessment needs to be carried out."

And

Pharmacy owners should make sure

"*a reactive review is carried out when any of the following happens:*

- *you identify any issues during your regular audit*
- *…*
- *there is a significant change in any part of the pharmacy service you provide, such as … a change in a third party, agent or contractor you use*
- *…*
- *there is a change in the technology you use*

48. The Registrant has provided evidence that in around April/May 2019, before the November 2019 inspection, she undertook an audit to identify patient records which did not have a proof of address and where the photo ID did not contain an address. The audit reviewed the first 20 prescriptions for the months January 2019 to April 2019. The results from the sample

of 80 prescriptions revealed that *"39% of records were missing proof of address and 21% were missing photo identification".*

49. The Registrant denied this allegation on the basis of having undertaken this audit.

50. The Registrant's oral evidence was that as a result of April/May 2019 audit the "ID3 global check system" was implemented through a contract with a third party. The system required patients to upload a form of ID containing a date of birth and a document confirming proof of address. Once the details were entered onto the system manually, the system would verify the patient's name, date of birth and address.

51. The inspector's evidence was that *"we were told that no checks had been carried out to verify or audit the system"*. The inspector further reports that during the inspection a prescription was seen where the date of birth on the prescription *"was around two weeks before the inspection"*, something that appeared to be an error but which had not been detected by the system or staff in the dispensing process.

52. The Registrant's evidence was that *"spot checks"* of the system were undertaken and that some patients were contacted *"to ensure the effectiveness of the identity checking process"*, that the date of birth error identified was *"a glitch"* on the system, and that a further audit was planned at the point the inspectors visited the pharmacy.

53. There was evidence to support the Registrant's assertion that an audit of the patient ID verification system was due. Sometime before the inspection visit on 20 November 2019, the Council wrote to online pharmacies and required them to produce evidence that they were compliant with the April 2019 Guidance. On 16 October 2019, the Council received documentation from the Registrant. This included a document headed *"Risk Assessment"* with the Registrant shown as the author. The document listed identified risks, the risk management measures in place, changes made, and a review date. The risks listed include a *"Customers may not be who they say they are"*, referred to the implementation of the ID3 system, and further intended improvements. Significantly, the Risk assessment document showed that this risk was to be again reviewed on 10 December 2019. The Registrant has

provided evidence that she undertook a very limited 'test run' of the planned audit on 16 November 2019: this evidence was provided after the inspection visit but nonetheless, in the context of the case, the Committee accepted that it showed the Registrant anticipated undertaking the review in December 2019.

54. In oral evidence, and in response to questions from the Committee, the Registrant stated that no audit of the patient identity verification process had been undertaken before the April/May 2019 audit, that no audit of the process had been undertaken between implementation of the ID3 process in May 2019 and the inspection visit on 20 November 2019, and that the planned review on 10 December 2019 *"was not soon enough"* and that she *"should have audited the ID3 process sooner"* after it was implemented in May 2019.

55. On the available evidence, the Committee has reached the following conclusions:

a. The verification of a patient's identification is an essential and important step to be undertaken, for the safe-guarding reasons outlined in the April 2019 Guidance;
b. The Registrant had not undertaken an audit of the patient identity verification process before April/May 2019;
c. The Registrant did undertake an audit of the process around April/May 2019 – it is unsatisfactory that the audit, as presented in manuscript and typed form, is not dated, but the Committee accepts the Registrant's evidence that she undertook the audit in response to the February 2019 inspection visit and the results of the audit were of sufficient concern to lead to the implementation of the ID3 identity verification system;
d. The Committee accepts the Registrant's evidence that she implemented the ID3 system in May 2019;
e. The Committee does not accept that the "spot checks" and contact with some patients to verify identification amounts to an audit: these steps were taken in the course of processing orders, not afterwards; no central record was kept of the results of the spot checks and contacts made, and no analysis of these steps was undertaken. These steps represent unstructured and informal actions when what was required was a structured, formal, process to check that the new system as a whole was functioning correctly;

f. The Committee concludes, in line with the Registrant's own evidence, that the implementation of the ID3 process should have led to a reactive review/audit as required by the April 2019 Guidance;
g. The Committee accepts the Registrant's evidence that no formal audit of the new ID3 system had been undertaken by the time of the inspection on 20 November 2019;
h. The Committee accepts that a further audit was due on 10 December 2019 given the documentary evidence that supports this.

56. Finally, the Committee concludes, in line with the Registrant's own evidence, that an audit of the ID3 system, implemented in May 2019, should have been undertaken before the inspection on 20 November 2019. The verification of patient identity is an important process central to safe-guarding measures, particularly in the context of high risk medication. The new ID3 system was implemented to address the very significant failings of the previous process. It was important the Registrant assured herself that the new system had indeed addressed those failings in a timely way, yet no audit of the new system had been undertaken by the time of the inspection approximately six months after implementation.

57. The Committee is therefore satisfied that this amounts to a failing to audit the patient identity verification system.

58. Accordingly, the Committee finds Allegation 1a i proved.

59. **Particular 1a ii:** the Registrant has admitted that she failed to audit the system used to prevent inappropriate supplies to patients who made repeat orders.

60. The April 2019 Council Guidance includes a reference to pharmacy owners taking steps to minimise risk including by way of being able to:

> *"identify requests for medicines that are inappropriate, by being able to identify multiple orders to the same address or orders using the same payment details – this includes inappropriate combinations of medicines and requests that are too large or too frequent"* (under Principle 4) and that this applies to a range of medicines including *"Medicines*

liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important."

61. The Council's guidance identifies the need to audit pharmacy processes and systems to ensure safeguarding process are working.

62. The Inspection Report, under the heading of *"Governance"*, reads in part as follows:

"The pharmacy does not identify and manage all of the risks involved with its services. People can purchase high-risk medicines on a regular basis without the knowledge of their GP. The prescribers are not based in the UK and the pharmacy cannot demonstrate that the prescribers are following UK prescribing guidance….The pharmacy does not properly review its services to make sure that they are safe for people to use. For example, it does not do regular audits of how many prescriptions had been refused by the prescribers. And it does not audit its process for receiving responses back from people's regular doctors. This increases the risk that people with addiction problems go undetected by the pharmacy and are still supplied medicines."

63. The inspector's statement reads:

"*There were no automated flags built into the system with the exception of a flag when people ordered more than in once in a month* [sic]. *When asked, we were told that the system could not be filtered to show this information. We were also told that by Miss Boateng there had not been any audits carried out to see the number of occasions that this had happened".*

64. The Registrant's written statement reads in part:

"For repeat medication liable to abuse, allegation 1 (a) ii, the system would block requests for orders of the same medication within a month. The pharmacy personnel and prescriber would not see a blocked order but would see the last order date for a medication. Just prior to the inspection, the permitted frequency of ordering opioids

was reduced to three times a year, but an alert had not been put in place for this at the time of the inspection.

No medication was found that had been issued within the prohibited time period, but I accept this system was not audited."

65. As noted above, the Registrant admitted Particular 1a ii and it is therefore found proved.

66. **Particular 1a iii:** the Registrant admitted that medications were sometimes supplied prior to relevant checks being fully completed.

67. It was clear during the hearing that there is an overlap between this particular and Particular 1b iii (checks being made with GP when supplying high-risk medicines). Applying the stem of the allegation *("in relation to the…supply of high-risk drugs…"*) it is clear that both particulars cover much the same ground. On behalf of the Council, the Committee had been referred to the April 2019 guidance under section 4.2 and this was referred to in reference to both particulars. Despite submissions on behalf of the Council, the Committee was not able to identify material difference between the two particulars.

68. Accordingly, the Committee's consideration of this particular is subsumed in its consideration of particular 1b ii.

69. The Registrant admitted this particular on the same basis as she admitted particular 1b ii.

70. Accordingly, this particular, 1a iii, has been found proved.

71. **Particular 1b i:** the Registrant admitted that the pharmacy website allowed people to choose medicines, strengths and quantity prior to a consultation.

72. The Council's April 2019 Guidance reads in part *"We expect you to make sure that your website and the websites of companies you 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".

73. Inspection Report reads in part: *"The pharmacy's website allowed patients to choose the medicine, strength and quantity prior to receiving a consultation for some medicines."* This was reiterated in the inspector's statement. The report further read that the Registrant, at the time of the inspection *"stated that high-risk medicines were blocked on the website at the time of the inspection. This had been done at the beginning of the week, however, it was noted that codeine could be selected the day before the inspection."*

74. Registrant's statement reads in part:

> *"In relation to allegation 1(b) i, it is important to note that at the time of the inspection changes had just been made to the pharmacy website and were continuing to be made. Immediately prior to the inspection, changes were made to the website that meant there could be no prior selection of high risk medication before a consultation. The website was changed again after the visit and a more robust system was put in place to block patients from any prior selection of medicine."*

75. The Registrant's evidence was that the ability of people to choose the nature, strength and quantity of medication was in the process of being changed at the time of the inspection but that this was work in progress with a change made with regard to some medication and changes regarding others yet to be made. She provided documentary evidence to support her case that this change was on-going at that time.

76. The Committee accepted the Registrant's account in this regard in part relying on documentation provided two days after the inspection visit that showed that the website had been changed so that patients could not choose the quantity/strength of co-dydramol.

77. As noted above, the Registrant admitted Particular 1b i and it is therefore found proved.

78. **Particular 1b ii:** the Registrant has admitted that she supplied patients with high-risk medicines without ensuring their regular doctor agreed with the supply and, in the absence of a GP or regular prescriber, did not ensure that the prescriber made a clear record to justify the decision to prescribe.

79. The April 2019 Guidance reads in part that online pharmacy owners who decide to work with an online prescribing service or prescriber, *"for medicines which are liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important, assured yourself that the prescriber has contacted the GP in advance of issuing a prescription, and that the GP has confirmed to the prescriber that the prescription is appropriate for the patient and that appropriate monitoring is in place"* and that *"if there are circumstances where the person does not have a regular prescriber such as a GP, or if there is no consent to share information, and the prescriber has decided to still issue a prescription, you should assure yourself that the prescriber has made a clear record setting out their justification for prescribing".*

80. The Inspection report reads (under Principle 4):

> *"The pharmacy mostly supplies medicines without waiting for a response from people's regular doctor to make sure that their regular doctor agrees to the supply. This is a risk because people's conditions might not be properly monitored, and their use of the medication may not be appropriately controlled. People's GPs are not contacted by the prescriber in advance of issuing a prescription. And in the absence of a response from the person's GP, prescribers are not making a clear record at the time explaining their justification for prescribing. This means that people may receive medicines which are not suitable for them."*

81. The Inspection Report included the following examples:

> *"There was one example where the prescription for a person for zolpidem had a comment written by the prescriber in retrospect as to why the prescription was issued without the regular GP's response. On this particular prescription GP contact was made at 10:27 on 11*

November 2019 and the prescription was changed to processing at 11:51. The pharmacy had previously said that the change in procedures had been made before this date, it was unclear as to why the order had been processed without providing the GP time to respond. Previously the pharmacy had waited for 24 hours to hear back from the GP, however, this had been increased to 48 hours. In the absence of hearing back from the GP within this timescale orders were still processed. A record seen where someone had been supplied with 100 codeine tablets, showed that the order had been received on 5 November 2019, the person's GP had been contacted on 8 November 2019 on the same day that the prescription had been approved by the prescriber. And was changed from 'on hold' to 'processed' by the RP. However, the records on the system showed that this change had been initiated by the IT personnel; the RP explained that this was because she shared the same account. The prescriber on 18 November 2019, had retrospectively made a note to say justify why the prescription had been issued. This person had also said that they were taking co-codamol tablets."

82. The inspector's statement reads in part:

"several other prescriptions were seen by us where high-risk medication was being supplied without GP consent, but this was before the change was made to the website. Miss Boateng said that approximately two prescriptions had been processed in the week commencing 11 November 2019. However, this did not match the number of prescription forms that were seen by us, as many more than two were found".

83. The Registrant's Case Statement reads in part: *"Procedures were in place to prevent supply without approval of a regular GP. Procedures were also in place for a prescriber to justify the decision to prescribe in the absence of a regular GP but it is accepted that regrettably on some occasions this did not happen."*

84. The Registrant's statement reads in part:

"In relation to allegation 1(b) ii, procedures were set up to ensure that a patient's regular doctor was given time to respond in relation to the supply. In addition, there were

procedures ensuring the prescriber made a note to justify a decision to prescribe. It is accepted that on some occasion this did not happen and I regret this. The GPhC inspector refers to an email timed 10:27am on 11 November being sent to a GP where the prescription was changed to 'processing' at 11:57. I have attempted to locate this email and prescription without success. However, my recollection is (although it was some time ago) that although it may have been changed to "processing", it would only have been dispensed at "completed" and I believe it could be held at "processing" for some time. I attach the emails sent at around this time as I believe they give a better picture of my general attitude to dispensing."

85. As it is, the Registrant's own evidence is that on 18 November 2019, she commenced an audit of 'Patient GP responses from September – October 2019'. The commencement of the audit involved data collection in which she reviewed approximately fifty orders processed over that period. She had not undertaken an analysis of that data by the time of the inspection two days later on 20 November 2019. However, she has referred the Committee to her witness statement dated 17 May 2022 prepared for this hearing. In that statement (section 11), she states as follows:

"my audit of the checks on notification to GP was that they [GPs] were contacted 100% of the time. However, 46% did not respond within the time given for a response."

86. As noted above, the Registrant admitted Particular 1b ii and it is therefore found proved.

87. **Particular 1b iii:** the Registrant has admitted as a matter of fact that medicines, including high risk medicines, were supplied based on a questionnaire completed by the patient.

88. The inspector's statement, repeating the contents of the Inspection Report, reads in part:

"Following selection of the medicine, people had to answer and submit a questionnaire prior to the medication being added to the basket. The questionnaire ranged from free text box, yes or no questions, or selecting answers that applied. The list of questions for pain was extensive and included questions such as 'Describe the diagnosis,' and

confirmation that a GP or specialist had made the diagnosis. It also included 'Are you under the care of a psychiatrist?', 'Do you believe you may be addicted to opiate/opioid-based painkillers?' ….. The decision to prescribe or not was based entirely on the answers provided on the questionnaire and there was no face-to-face or further interaction involved…"

89. The Registrant's statement reads in part:

"In relation to allegation 1 (b) iii, the questionnaire was carefully designed with input from the prescriber. I no longer have notes of calls with the prescribers in which we discussed the working of the questionnaire, but I can confirm risks and safeguards were discussed. The questionnaire was not the only means of communication between patient and prescriber or pharmacy. A significant proportion of patients also contacted the pharmacy to discuss their medication and prescriptions. They would do this by emailing, using the chat feature on the website or by telephoning. The prescriber's portal also allowed contact directly between the prescriber and the patient. The prescriber would record interventions and communications on the prescriber section of the Patient Medication Record."

90. The Registrant reiterated this in her oral evidence.

91. As noted above, the Registrant admitted Particular 1b iii and it is therefore found proved.

92. **Particular 1b iv**: the Registrant has admitted failing to ensure that medicines supplied were appropriate in that unlicensed medication including duloxetine and carbamazepine were advertised on the website.

93. The inspector's statement advises that this is a breach of Regulation 279 of the Human Medicines Regulations 2012 which prohibits advertising of medicines for which no marketing authorisation or registration is in force. The statement reports that *"number of medicines such as duloxetine and carbamazepine were seen on the website as unlicensed treatments"*

and that the Registrant had subsequently advised that these medicines had never been supplied and that they had now been removed from the website.

94. The Registrant's statement reads in part: *"In relation to 1 (b) iv, I accept that unlicensed medication was included in error on the website. No supplies of unlicensed medicines were made, and once the inclusion of the unlicensed medicine was identified on the website it was immediately removed."*

95. As noted above, the Registrant admitted Particular 1b iv and it is therefore found proved.

96. **Particular 2a**: the Registrant has admitted that she did not ensure clinical audits and/or prescribing reviews were completed.

97. The April 2019 Council Guidance relating to audits and reviews is referred to above (under Allegation 1ai. In particular, under Principle 1 of the Guidance (concerned with governance) the Guidance includes the following:

> *"The safety and quality of pharmacy services must be reviewed and monitored. You should carry out a regular audit, at an interval that you can show to be appropriate for your pharmacy services. The audit should be part of the evidence which gives assurance to people who use your pharmacy that it continues to provide safe pharmacy services."*

98. During oral evidence, the inspector explained that clinical audits are undertaken to assess whether prescribing is undertaken in a way that is consistent with relevant guidelines, whereas prescribing reviews assess the accuracy of prescriptions that have been issued.

99. The Inspection report reads in part: *"The RP confirmed that no clinical audits or prescribing reviews had been carried out. The RP was unsure if this had been carried out by EUdoctor24, the associated prescribing service. The RP was the clinical lead."* This is evidence reasserted in the inspector's statement.

100. The Registrant's statement reads in part: *"I was not fully aware of the extent to which I needed to audit the pharmacy's activities when I began operating the pharmacy and I accept the audits and reviews did not always provide a complete analysis of the activities."* The Registrant reiterated this evidence in her oral testimony.

101. During the hearing the Registrant provided the Committee with an updated version of the Risk Assessment she had undertaken in the autumn of 2019, before the inspection, and which she had provided to the Council on 16 October 2019 in response to a request sent to online pharmacies. She had updated the Risk Assessment immediately after the inspection visit and had sent the updated version to the inspector to demonstrate her commitment to improving the services provided by her pharmacy. The Risk Assessment identified risks, actions to address risk and gave review dates when the risk would be re-assessed. Of the seven process risks that had review dates, one review date pre-dated the inspection, had not been undertaken and had been given a new review date of a month after the inspection, one had changed because action had been taken to address risk, and the remainder remained unchanged and yet to be undertaken.

102. As noted above, the Registrant admitted Particular 2a and it is therefore found proved.

103. **Particular 2b**: the Registrant denied that her IT system did not prevent unauthorised personnel from accessing and/or creating and/or amending records.

104. The April 2019 Guidance reads: *"Your IT equipment should meet the latest security specifications and the security of data should be protected when it is in transit, by either wired or wireless networks, inside your business and outside it. You should also control access to records and how you store, keep and remove records"* (under Principle 5).

105. The Inspection report reads in part: "the RP was signed on using the log in details of an IT member. The trainee dispenser had her own individual account. Following the inspection, the RP confirmed that the account settings had been changed and she had her own individual account for which she had also changed the password." (under Principle 5).

106. The inspector's statement reads in part: *"The prescribing software was not secure; no evidence was provided that there were different levels of authorisation for prescribers or pharmacy staff including IT personnel who were based off-site. It was seen that prescriptions could be potentially generated by non-qualified staff. The responsible pharmacist and IT personnel's screen had commands to generate or delete prescriber signatures and apply the prescriber's approval on people's orders. This could mean that the prescriber's signature was not under their sole control…"*.

107. The Registrant's statement reads:

> *"In relation to unauthorised access to the system, allegation 2 (b), I had administrative access to enable me to oversee all functions as owner of the pharmacy. However, I would not have been able to sign prescriptions, not just because it would have been a complete breach of my professional ethics but because it would not have been technologically possible. The prescriber had to upload his signature each time he prescribed and there was no way for me to intercept his signature. Additionally, the doctor would screen the completed orders each month against the orders he signed (he kept a record for his own auditing purposes). If any unauthorised completion occurred, he would have picked it up. Also, every change made was recorded, so again if the doctor had not conducted the action, he would have picked this up. In practical terms therefore this was not a safety concern. In addition, the IT provider did not have full access, as I had changed the IT provider's password once they created the portal for me. No member of staff would have been able to write prescriptions. Following inspection, further steps were taken to ensure prescriber exclusivity. It was not the case that any unauthorised person could access, create, or amend records."*

108. In oral evidence, the Registrant said that she engaged a web developer to undertake the initial development of her web site. She said that when it was handed over to her the password was changed so that only she had access to it though the web developer was retained to provide IT services and had access to the 'back end' of the web site for coding purposes but not to the functionality of the web site.

109. Following questions, the Registrant explained that when an order was received it was given the status of *"On hold"*. As initial steps were taken the status would be changed to *"In progress"* and that once the order was approved the status could be changed again to *"Completed"* unless it was changed to *"Cancelled"*. She stated that only she and the prescriber could change the status of the order. Once an order was shown as *"Completed"*, her pharmacy assistant would present her with the order and the medicine for her to check, after which it was packaged and despatched to the customer using a delivery service. The Registrant was not, at that time, qualified as a prescriber.

110. She accepted that after the inspection, when concern about the IT system had been raised, she had made changes. In her response to the draft Inspection Report the Registrant wrote:

> *"We have now incorporated a signature function into our backend that only the prescriber can use. It is not available on other users."*

111. By a letter dated 23 April 2021, the Registrant's solicitors wrote:

> *"it is accepted that there was an error in the system that could potentially allow unauthorised access. However, the only person with this access was Miss Boateng herself. The IT provider did not have full access as our client had changed the IT provider's password. No member of staff would have been able to write prescriptions. As soon as the problem was detected, steps were taken to resolve it."*

112. The Committee has considered the evidence. It is apparent that there are complexities to the IT system that are not fully set out in the available evidence. However, the common ground is that the Registrant was, technically, in a position to progress an order to completion when she should not have done, not being qualified as a prescriber. Her evidence was also that whilst she could not insert Dr R-O's signature, she could, had she wished to do so, insert her own signature. There is no evidence to show that she either progressed an order when she should not have done so, nor evidence that she inserted her signature when she should not have done so. There is some evidence that had she done so the prescriber could have spotted the unauthorised completion had he checked his records as she assumed he would.

However, the terms of the Registrant's response to the draft Inspection Report, and the terms of the solicitor's letter, indicate an acceptance of the concern raised by the inspection, namely that the IT system was not secure against the Registrant having unauthorised access.

113. The Committee is not satisfied on the evidence that anyone else could have such unauthorised access.

114. For the safe-guarding reasons given in the April 2019 guidance, it is important that the IT system should be secure.

115. Accordingly, on the limited basis that the Registrant alone could, technically, have accessed and amended records on the IT system in a way that she was not authorised to do, the Committee finds Particular 2b proved.

116. **Particular 2c**: the Registrant has admitted she failed to ensure sufficient records were kept of discussions between patients and pharmacy staff.

117. The April 2019 Guidance reads in part:

> *"When there is no face-to-face contact, you should consider what information you and your staff record and keep to show that the pharmacy service you provide is safe. The records you keep are important evidence for the judgements you and your staff make. They can also be a powerful tool for service improvement and quality management."*

118. The Inspection report reads under Principle 4:

> *"Most prescriptions were supplied to people living in the UK. ….. Approximately 30% of people were counselled over the telephone. However, there was no record made of this or evidence available to confirm this. People could communicate with the pharmacy via telephone or email. The trainee dispenser was the first point of contact and would refer calls to the RP where she thought appropriate. Prescribers communicated with people using 'UberChats' which was built into the system. The RP could not see details of the*

conversations held. The pharmacy was looking into introducing face-to-face consultations."

119. The inspector's statement repeats the Inspection Report by reference to the Registrant saying that the pharmacy *"called around 30% of patients, but they did not keep any records of these calls or notes".*

120. The registrant's statement reads as follows:

"In relation to 2 (c), which relates to sufficient records being kept of discussions with patients, records were kept of discussions if they used the on-line chat function or emailed. It is accepted that insufficient records were kept of telephone counselling. Before the inspection I had drafted a confirmation of medication form and after the inspection I refined this and sent [the inspector] *an example of what I would send to patients."*

121. As noted above, the Registrant admitted Particular 2c and it is therefore found proved.

122. **Particular 2d**: the Registrant denied that she did not conduct regular audits of the number and nature of prescriptions which had been refused by the prescribers.

123. The April 2019 Guidance includes guidance on the need to undertake audits to ensure pharmacy processes are working to safeguard patient safety. It states that pharmacy owners are expected to make sure that regular audits are undertaken of "records of decisions to make or refuse sale" and the "activities of third parties, agents or contractors" which would include prescribers.

124. The Inspection report reads: *"The pharmacy does not properly review its services to make sure that they are safe for people to use. For example, it does not do regular audits of how many prescriptions had been refused by the prescribers."* The example given is then repeated in the inspector's statement.

125. The Registrant's statement reads:

"In relation to 2 … (d) (audits of prescriptions refused) …, I was not fully aware of the extent to which I needed to audit the pharmacy's activities when I began operating the pharmacy and I accept the audits and reviews did not always provide a complete analysis of the activities. However, I did audit:

● Prescriptions refused (see page 264 of the GPhC bundle. This audit was carried out on 4 November 2019, just before the inspection took place…."

126. Shortly after the inspection visit the Registrant provided the inspector with a copy of her audit of prescriptions refused by prescribers dated 4 November 2019. Whilst it is noted by the Committee that this was not produced by the Registrant on the day of the inspection, the Committee accepts it as evidence that she had undertaken an audit of this issue on 4 November 2019.

127. In her oral evidence, she stated that she had not previously undertaken an audit of prescriptions refused by prescribers, not since starting the pharmacy in early 2018 nor since the Council's guidance was published in April 2019 and that the audit of 4 November 2019 was the first time she had audited the issue.

128. She stated that she now accepted that she should have undertaken an earlier audit of the issue.

129. The Committee has considered the evidence. Particular 2d reflects the April 2019 guidance that sets out an expectation of "regular" audits of processes that are central to patient safety. Whilst it is to the Registrant's credit that she had undertaken an audit, the Committee's conclusion is that this is not evidence of "regular" audits of the issue.

130. This conclusion is underscored by the findings of the one audit of prescriber refusals that had been undertaken. Under the heading *"Results"* the audit reads:

"85 out of 270 prescriptions were cancelled by the Dr. The most common reason (74%) was that patients has ordered from another online source that month."

And under the heading *"Conclusion"* the audit reads:

> *"From the results we see that the most common reason for refusal of sale is that patients are ordering from online sources. This highlights the need to have robust safeguards in place to ensure that patients are not abusing the online method of ordering prescriptions. It also suggests that patients ordering from multiple sites may have an issue with abuse of medicines orders."*

and under the heading *"Recommendations"*, the audit records an intention to take further steps to address the risk, about which the Registrant gave oral evidence, and:

> *"This will be re-audited in 3 months to see if the number of cancellations due to patients ordering from other sites are reduced with implementation of this question."*

131. In addition, the Registrant identified a limitation to her audit of prescriber refusals that *"Some orders did not have the reasons for cancellations so we could not ascertain the reason for why the prescription was cancelled."* In the Committee's view this limitation demonstrated an inadequacy of record keeping highlighted by the audit and demonstrates the need for regular audits. None of the actins identified in the audit addressed this limitation.

132. Given the evidence as reviewed above, the Committee found the particular proved.

133. Accordingly, the Committee finds Particular 2d proved.

134. **Particular 2e**: the Registrant denied that she did not audit the process for receiving responses back from patients' regular doctors.

135. The April 2019 Guidance includes guidance on the need to undertake audits to ensure pharmacy processes are working to safeguard patient safety, as referred to above. Those

processes would include the process whereby a patient's regular doctor is contacted for their agreement for the medicines to be supplied.

136. The Inspection report summary reads in part under Principle 4:

> *"The pharmacy does not provide its services safely. It does not make sufficient checks to ensure that all the medication it supplies are appropriate for people. And it supplies some medicines which may not be suitable for supply via remote consultations. The pharmacy mostly supplies medicines without waiting for a response from people's regular doctor to make sure that their regular doctor agrees to the supply. This is a risk because people's conditions might not be properly monitored, and their use of the medication may not be appropriately controlled. People's GPs are not contacted by the prescriber in advance of issuing a prescription. And in the absence of a response from the person's GP, prescribers are not making a clear record at the time explaining their justification for prescribing. This means that people may receive medicines which are not suitable for them. The pharmacy does not fully review the safety of its prescribing and supply service effectively. Prescribers issue prescriptions by default without waiting to hear from the patient's GP or without carrying out necessary checks. And this is not in-line with the GMC prescribing guidance."*

137. The inspector's statement reads *"The Registrant also failed to carry out an audit of the process for receiving responses back from patient's regular doctors."*

138. The registrant's statement reads in part: *"I was not fully aware of the extent to which I needed to audit the pharmacy's activities when I began operating the pharmacy and I accept the audits and reviews did not always provide a complete analysis of the activities. However, I did audit: …. ● Responses from patients' regular GPs…. This audit was carried out on 18 November 2019."*

139. The Committee has been provided with a document headed *"Audit – Patient GP responses from September-October 2019"*. It lists a series of approximately fifty individual orders for medication, whether their GP was contacted, whether a response was received within 48 hours, a description of the response and action taken with that particular order.

140. The Registrant was questioned about this document and accepted that the document was a data collection document and did not include any analysis or recommendations for action as might be expected in an audit. Her oral evidence was that whilst she had collected the data two-days before the inspection visit, she had not undertaken the analysis of the data by the time of the inspection on 20 November 2019. She gave evidence that she did subsequently analyse the data and she referred the Committee to her witness statement dated 17 May 2022 prepared for this hearing. In that statement (section 11), she states as follows:

> *"my audit of the checks on notification to GP was that they [GPs] were contacted 100% of the time. However, 46% did not respond within the time given for a response."*

141. Whilst it is of some concern that the Registrant did not mention this audit that was under way at the time of the inspection, the Committee accepts her evidence that she was, at that time, undertaking an audit.

142. In answer to questions, the Registrant accepted that she had not previously undertaken an audit of GP responses since starting her pharmacy in early 2018 nor since the publication of the Council's guidance in April 2019 and that the data collection she had undertaken on 18 November 2019 was the start of her first audit on this issue.

143. In her oral evidence she accepted that she should have undertaken an earlier audit of the issue.

144. The Committee has considered the evidence. Particular 2e alleges that she had not undertaken a review of GP responses. Whilst there is evidence that she had started the process of an audit at the time of the inspection, she had not completed it in the time-frame set by the allegation, that is up until 20 November 2019. In these circumstances, the Committee concluded that the allegation was proved.

145. Accordingly, the Committee finds Particular 2e proved.

146. **Particular 2f i**: the Registrant has denied that she did not ensure prescribers followed UK national guidelines.

147. The April 2019 Council's Guidance reads in part:

> *"If you decide to work with an online prescribing service or prescriber, the above categories of medicines [which includes high-risk medications liable to abuse, misuse and addiction] should not be prescribed unless the safeguards below have been put in place:….*
>
> *the prescriber is working within national prescribing guidelines for the UK and good practice guidance. This would include following relevant guidance on prescribing a licensed medicine for an unlicensed purpose known as "off-label" use. For more information please see the 'Other useful sources of information' at the end of this document"*

148. At the end of the guidance document is a two-page list of websites from which further guidance is available. These include the GMC, NICE, CQC and the NHS, and include websites relevant to Wales and Scotland.

149. The inspector's statement reads:

> *"A Prescribing Policy ….. We were told the prescriber was expected to sign against the guidance…to acknowledge their compliance with it…There were no UK clinical guidelines listed in the document. When asked by us Miss Boateng said that the prescriber used NICE guidance but was unable to list any particular documents. The GPhC guidance for registered pharmacies providing pharmacy services at a distance including on the internet, required the pharmacy owner to carry out regular audits on activities of third parties, agents or contractors."*

150. The Committee has been provided with a copy of the Registrant's Prescribing Policy. It lists the following: '*A Competency Framework for all Prescribers'; 'Good Medical Practice'; 'Good*

practice in prescribing and managing medicines and devices (2013)'; 'Guidance for registered pharmacies providing pharmacy services at a distance including on the internet'; 'Maiden Consult Ltd Privacy Policy', against each of which is a signature in the name of Dr R-O (except for Good Medical Practice") and dated 1 July 2019. This list is followed by: *"I have read and am abiding by the following guidelines and guidance."* This is then followed by the following: *"I agree to use UK prescribing guidelines to inform my prescribing"* and this is then followed by a signature in the name of Dr R-O and dated 1 July 2019. On the reverse side of the page is a further page of text which includes: *"The doctor prescribes in line with UK prescribing guidelines and good practice guidelines…".* The document concludes by recording that it is version one of the Prescribing Policy, that it was developed by the Registrant, was produced in June 2019 and was to be reviewed two years later in May 2021.

151. The inspector's oral evidence was to the effect that she would have expected the Prescribing Policy to list specific guidelines relevant to medicines and illnesses including reference to NICE guidelines.

152. The registrant's statement reads:

> *"In relation to 2 (f), exhibit FD/01 in the GPhC bundle illustrates the documentation the prescribers signed to confirm that they would be working in accordance with UK prescribing guidelines. In addition, from my conversations with the prescribers when obtaining input into the questionnaire and other documents I was able to form a view that they were competent and knowledgeable about UK national guidelines. The doctor's registration documents were also available to me and information on how to confirm their registration was available to patients through the mynetdoctor website".*

153. The Registrant repeated this evidence in her oral evidence. She described how she had engaged in discussion with Dr R-O to develop a questionnaire to be used in consultations with patients and from those discussions she gained an understanding that he was aware of UK prescribing guidelines.

154. By an email dated 28 February 2020 the Registrant sent the inspector an action plan to address the concerns identified and supporting evidence. The supporting evidence included a document which commences: *"The purpose of this policy is to set out a prescribing procedure that ensures prescribers can prescribe safely…in line with the GMC Guidance…".* It includes reference to NICE guidelines and the BNF, provides specific guidance in relation to *"Medication of high potential of abuse and diversion"* and other guidelines.

155. The Committee has considered the evidence. The Committee is not satisfied that the two-page Prescribing Policy that was in place at the time of the inspection, signed by the prescriber, is sufficient evidence to demonstrate that the Registrant had ensured the prescriber would follow UK guidelines. It is very limited in scope and does not refer to, for example, NICE guidelines. Whilst the Registrant may have spoken with the prescriber the Committee is not satisfied that she could be assured of the prescriber's compliance with UK guidelines as a result. Without commenting on the adequacy of the new policy document produced by the Registrant, the contrast in detail between that document and the earlier Prescribing Policy document is stark.

156. Accordingly, the Committee finds Particular 2f i proved.

157. **Particular 2f ii:** the Registrant denied that she had not ensured prescribers were appropriately registered in their home country.

158. The April 2019 Council's Guidance reads that pharmacy owners are expected to make sure "*the prescriber is registered in their home country where the prescription is issued."*

159. Evidence indicated that the Registrant used a single prescriber, Dr R-O, based in Romania.

160. The Council's bundle included copy photographs of documents seen by the inspectors on the day of their inspection of the pharmacy. These included copy registration documents relating to Dr R-O in Romanian. In the course of the hearing, it also became apparent that the Council's bundle included versions of these registration documents translated into English in the form of photographs taken by the inspectors on the day of their visit.

161. The Registrant's evidence, in her statement and orally, was that she had obtained the prescriber's registration documentation in Romanian, that these were the documents that met the expectations of the GMC for the purposes of verifying a qualification, that she had, prior to the inspection, obtained English-language translations of the documents to assure herself that Dr R-O was suitably qualified, and in addition, her web-site informed patients how they could check Dr R-O's registration, a point the Council did not dispute. The documentation showed Dr R-O to have registration current at the time of the inspection with a speciality described as *"Family Medicine"* which appeared to equate with GP status.

162. In the circumstances outlined above, at the conclusion of the evidence, it was conceded on behalf of the Council that Particular 2f ii could not be proved.

163. The Registrant maintained her denial of the particular.

164. Having reviewed the evidence, the Committee was satisfied that this particular could not be proved.

165. Accordingly, Particular 2f ii was found not proved.

166. **Particular 3:** the Registrant has admitted she did not ensure all services, including for her prescriber, were covered by appropriate indemnity insurance.

167. The Council's April 2019 reads in part: *"you have sufficient indemnity insurance in place to cover: – your service that uses prescribers or prescribing services based outside the UK" under Principle 1 concerning governance arrangements."*

168. The Inspection report reads in part: "*The pharmacy is not able to demonstrate whether the prescribers it works with are covered by appropriate indemnity insurance."* The Inspection Report goes on as follows:

"The prescriber had provided the pharmacy with copies of individual indemnity insurance. However, these were in other languages. It was not clear from these what level of indemnity insurance cover the prescriber had and the staff were also unable to clarify that they had confirmed this themselves. The pharmacy's indemnity insurance did not cover any prescribing issues. In the risk assessment the pharmacy had said that they had sufficient indemnity insurance in place to cover prescribers who prescribe outside of UK…"

169. The inspector's statement reads in part: "*Miss Boateng said that the pharmacy used a European Union (EU) prescriber based in Romania; Dr* R-O, who *was recruited via a prescribing company EU Doctor 24 SRL. At the time of the inspection, Miss Boateng said that this company was owned by Dr T who was from India but was also based in Romania. We were also told that the prescriber was not registered with the General Medical Council (GMC)."* The inspector's evidence describes how the Registrant described Dr R-O as being insured with the Vienna Insurance Group and produced an Insurance Certificate, though these were in Romanian and the Registrant did not have an English-language translation. This led to exchanges of emails between the inspector and the Registrant following the inspection including the inspector seeking from the Registrant a translation of the full insurance documentation. The inspector's statement reads:

"Miss Boateng responded on the same day to say that she was waiting to receive this. I produce a copy of this email as Exhibit FD/08. On 22 January 2020, I received another email from Miss Boateng informing me that the prescriber had only been provided with the cover sheet. I produce a copy of this email as Exhibit FD/09. On 3 February 2020, I asked Miss Boateng if she had confirmed the terms with the insurance policy in the past; she responded the same day to confirm she had spoken to someone in Vienna who had confirmed that the prescriber's practice was covered by the policy. She added that she had requested the documentation for this but had never received it"

170. The Registrant's statement reads in part: *"In relation to allegation 3, indemnity insurance for the prescriber and the pharmacy was in place and documents were provided to GPhC. I was also given assurances regarding cover by the prescribers. The documents provided to me showing the extent of the prescriber's cover are in the GPhC bundle at pages 47 and 100*

(translated version). I am sorry I was not able to give a full explanation when asked by the inspectors."

171. The translations show that the documents were insurance cover certificates for the relevant period. The Registrant was not able to produce the policy documents which would detail the terms, conditions and extent of the insurance cover. As it was, the insurance cover note appeared to be for a maximum of 12,000 Euros. When questioned by the Committee, the inspector in oral evidence was hesitant to express a view regarding the insurance cover note but went as far to say *"If this* [12,000 Euros] *is the insurance cover for prescribing errors it does not appear to be adequate."* In her evidence, the Registrant described how, subsequent to the inspection, she had recruited a UK based prescriber who had a cover note to the value of £5million.

172. In her oral evidence, the Registrant reiterated her statement to the effect that the cover note was all she had been able to obtain, that she had sought further documentation before the inspection, including by way of telephoning the Vienna insurance company and had asked for further documentation but had not received it and she accepted that she had not chased up provision of the additional documentation. She expressed an understanding that registration as a doctor in Romania automatically came with insurance and referred the Committee to the doctor's registration certificate that referenced insurance. She gave evidence denying that she *"took a lax approach – the material I had was what I could obtain"*. However, she went on to state that *"Because I don't have the information, I have admitted it"* and that she fully accepted the particular without condition.

173. As noted above, the Registrant admitted Particular 3 and it is therefore found proved.

174. The above concludes the Committee's determination of the factual particulars of the Allegation. Before concluding this part of the determination, it is fair to record here that throughout her oral evidence, the Registrant was keen to express her regret at the failings she had admitted. She indicated she had been focused on patient safety. She outlined steps she had taken to improve the service provided by her pharmacy both before and after the inspection. This included prompting her insurance to set-up a network of pharmacists

responsible for online services which could offer mutual support and guidance. During her evidence she alluded to her reasoning for setting up the online service, namely to make pharmacy services available through digital technology that delivered the same level of care as in-person pharmacy services. She expressed that she had been "*horrified by the inspection's findings and the shock made me very eager to show remediation"* and referred to the steps she had taken immediately after the inspection to address the concerns that arose. These elements of her evidence given at this stage will be relevant at the next stage of these proceedings.

Grounds and Impairment

The Law and Guidance

175. Article 51(1) of the Order provides: *"A person's fitness to practise is to be regarded as impaired for the purposes of this Order only by reasons of (a) misconduct;…"*

176. If that ground is established, then by way of Article 54(1) of the Order the panel must then consider whether the Registrant's fitness is impaired.

177. The panel took account of the guidance given to the meaning of 'fitness to practise' in the Council's publication "Good decision-making" (Revised March 2017) Paragraph 2.11 states *"A pharmacy professional is 'fit to practise' when they have the skills, knowledge, character, behaviour and health needed to work as a pharmacist…safely and effectively. In practical terms, this means maintaining appropriate standards of competence, demonstrating good character, and also adhering to the principles of good practice set out in your various standards, guidance and advice."*

178. The Committee received and accepted the advice of the Legal Advisor.

Evidence and Submissions on grounds and impairment.

179. No additional evidence was called by the Council. The Additional Bundle provided by the Council for this stage of the proceedings contained some emails and file notes: these related to inquiries made by the Council concerning one of the references provided by the Registrant. Mr Millin advised that the Council would not be pursuing, referencing or relying on that matter for the purposes of this hearing.

180. The Registrant gave evidence on oath. In very brief summary, she highlighted the following:

a. That she was of good character, with no previous regulatory proceedings against her;

b. She emphasised her "passion" for her work as a pharmacist;

c. She accepted that in hindsight she had "leapt into" setting up the online pharmacy at a time when she was overly confident thinking she had relevant experience but "could have benefited from working alongside someone with more experience";

d. She acknowledged that supplying high-risk medication to patients through a process that did not ensure the safe supply gave rise to the risk of causing patients serious harm and even death;

e. At a time after the April 2019 guidance was issued, she recognised the challenges of running an online pharmacy, wanted to be compliant with standards, and had sought advice from the Council (the advice given was to direct the Registrant to her insurer); and, having engaged with her insurers, that led to the setting up of a network of those involved with online pharmacies;

f. She engaged with the inspectors and the Council and complied with the Conditions that were imposed on her pharmacy, and she expressed appreciation for the work of the Council in maintaining standards;

g. She had closed her online pharmacy. She had decided to take a step back to reflect. She had revisited CPD regarding record keeping and auditing. She had read and re-read the April 2019 Guidance relating to online pharmacies: she had "no desire" to open an online pharmacy but rather she wanted to understand her failings.

h. She referred to her time shadowing a Consultant Haematologist at the Whittington Hospital for 90 hours over the summer of 2021 as part of her Independent Prescribing course which she passed and from which she gained experience and learning;

i. she was apologetic and remorseful for what had occurred, accepting that it was her responsibility;

j. in cross-examination she accepted breaches of the Standards expected of her and accepted that appointing herself as SI for her own pharmacy was "not the best of ideas";

k. she referred to having undertaken a course to qualify as a Pharmacist Independent Prescriber;

l. she described her current working arrangements, referred to in more detail below, where no concerns had arisen;

m. she referred to her testimonials and emphasised her passion for her profession.

181. On behalf of the Council, it was submitted that standards had been breached, the breaches were such that members of the profession and the public would regard the conduct as deplorable, the conduct had put members of the public at risk. In these circumstances, it was submitted that serious misconduct was established. It was further submitted that whilst the Registrant may have shown some insight, the Committee could not be satisfied that it was full insight. It was further submitted the Committee could not be satisfied that, despite her evidence including that of CPD, experience and the testimonials, she had fully remediated her failings, and therefore there was a risk of repetition. It was submitted that the Committee should find the Registrant's fitness to practise to be impaired on the grounds that there was a risk of harm to members of the public, and on the ground of the wider public interest, being to maintain public confidence and professional standards.

182. The Registrant referred to the evidence she had given, including the fact that she had no past regulatory history, had engaged and complied, closed the business, had expressed genuine and sincere remorse, undertaken CPD and other learning to understand and address her failings so that there was now no risk of repletion, and had been working without complaint. In her submission, misconduct was not established and her fitness to practise was not currently impaired.

The Panel's decision on grounds

183. The Allegation brought by the Council relied on impairment being found by reason of misconduct.

184. The Committee has found, as matters of fact, that the Registrant had been responsible for running an online pharmacy when the systems and arrangements in place were deficient in a number of respects. The systems were deficient in checking patient identity; allowed patients to choose medication before a consultation; involved the supply of high-risk medication before any, or any proper consultation with the patient's GP when such consultation could have taken place; medications, including high risk medications, were supplied based solely on a questionnaire completed by the patient. The Committee has also found that the Registrant did not identify and manage all of the risks arising from the operation of an online pharmacy, in particular by failing to undertake relevant audits.

185. Whilst the pharmacy passed an inspection in February 2019, the Committee is particularly concerned with the period between April 2019 when the new guidance was issued to online pharmacies setting out expectations for the standards they should meet, and 20 November 2019 when the inspection was undertaken leading to this hearing. The expectation is that, as with all online pharmacies, the Registrant should have ensured that after April 2019 her pharmacy was up to standard. She has said that she was not initially aware of the standards. It is clear she knew of them by July 2019 when she wrote a policy document referencing the standards. By November, it is reasonable to expect that she should have ensured she understood the expectations of the guidance, assessed her pharmacy against the standards, and addressed any short comings that she found. Her evidence is that she sought the assistance of the Council, and, at the suggestion of the Council assistance from her insurers to understand the new standards. There is good evidence that she was proactive in this regard. However, what she had not achieved by late November 2019 was an adequate review of her pharmacy nor had she addressed the systemic failings within her pharmacy.

186. The consequence of this failing was to leave in operation a pharmacy that was operating unsafe procedures with the result that high-risk medication could, and was, supplied to members of the public over a number of months.

187. There is no evidence that actual harm was caused to any patient. However, the Registrant's failings gave rise to a risk of serious harm being caused. As she acknowledged, high risk medication not only gives rise to a risk of addiction, misuse and over-use, but also gives rise to a risk of death to individuals receiving medication from her pharmacy. The Registrant's failure in this regard is compounded by her failure to ensure the prescriber working for her was covered by appropriate indemnity insurance.

188. Given the above summary of the Committee's review of its findings of fact, the Committee is satisfied that the Registrant breached the standards expected of pharmacists, in particular:

a. Standard 1: pharmacy professionals must provide person centred care;
b. Standard 5: Pharmacy professionals must use their professional judgement; and
c. Standard 9: Pharmacy professionals must demonstrate leadership.

189. The Committee bore in mind that the Standards may be taken into account when considering the issue of misconduct but that a breach of the Standards does not automatically result in a finding of misconduct.

190. However, in the circumstances of this case, as assessed and summarised above, the Committee is satisfied that the Registrant's conduct would be regard with a degree of opprobrium by members of the public and would be deplored by other pharmacists. It is fundamental to the role of being a pharmacist that they put patient's first and ensure their actions are designed to protect patients, particularly vulnerable patients. The Registrant's conduct did not meet this fundamental expectation.

191. **Accordingly, the Committee finds that the ground of misconduct is made out.**

The Panel's decision on Impairment

192. The panel went on to consider what are referred to as the Personal and Public Components of impairment.

193. The Personal Component: the Committee has considered whether the Registrant has insight in relation to the circumstances of her misconduct.

194. She has admitted the greater part of the allegations and accepted the Committee's findings of fact that were against her. Having heard and tested her written and oral evidence, the Committee is satisfied she understands that she failed to run a safe practice which gave rise to a risk of serious harm to patients.

195. She has expressed regret and remorse. The Committee is satisfied that her regret and remorse are genuine.

196. In this regard it is helpful to review her motivations in setting up the online pharmacy. Her explanation is that she is passionate about providing care through her work as a pharmacist and had wanted to combine the patient-centred benefits of community-based pharmacy with the benefits of digital technology, so that she could deliver care to a wide number of people. The Committee is alert to the potential with online pharmacies to generate significant profits and that the potential for significant profits may well be a major motivation for some pharmacists. It is clear that the Registrant intended to run her pharmacy as a business, but there is good evidence that her interest in providing care was the greater motivating factor. The Registrant has given oral evidence to this effect which has impressed the Committee. More particularly, her evidence, supported by the testimonials demonstrate that the Registrant has, over an extended period of time, invested her own time and money in a community enterprise to help under-privileged individuals get on in life. This evidence demonstrates a more positive motivation than one that is focused on significant profits. In addition, there is evidence that she wanted to run a safe pharmacy, for example by prompting the setting-up of a support network to help online pharmacist meet standards; this does not suggest that she was meaning to cut corners to enhance profit.

197. Against that background, the Committee accepts her evidenced that she was *"shocked"* and *"surprised"* when the inspectors in November 2019 found that she was not meeting standards.

198. The Registrant has also given evidence of reflection as to how she came to fail. She has acknowledged that, approximately 18 months after first registering as a pharmacist, she was not sufficiently experienced to set-up an online pharmacy and to take on the roles of Superintend Pharmacist and responsible Pharmacist together; she has acknowledged that her earlier work at another online pharmacy led to her being overly confident; that she *"leapt into"* setting up the online pharmacy, trying to *"run before I could walk"*.

199. The Committee agrees with her analysis. It takes the view that she was naïve and lacked judgement in the setting up and running of the online pharmacy, albeit she was genuinely "passionate" about her work and progressed her ambition for an online pharmacy with a positive motivation.

200. For example, the Committee is concerned that she could ever have thought it was safe to be prescribing and supplying high risk medication to unseen patients based on a questionnaire completed by the patient and without cross-checking with the patient's GP when that could have been done. The risks were something that should have been relatively obvious to a pharmacist, not least of all after the April 2019 guidance was issued. It does not take a significant leap of imagination to be concerned that a vulnerable patient, who may be desperate to get hold of high-risk medication, perhaps because of addiction or thoughts of self-harm, might provide misleading or false information in a questionnaire. Yet the operation the Registrant was responsible for allowed high-risk medication to be supplied after taking the information on questionnaires at face-value and without questioning or cross-checking with a GP when that could have occurred. The Committee's conclusion is that the failings are not only indicative of a lack of business skills but also indicative of a lack of judgement in her clinical skills.

201. The Committee gives the Registrant credit for the evidence she has produced about undertaking work as a pharmacist, undertaking CPD including with regard to record keeping and auditing, undertaking the Independent Prescribing qualification including 90 hours of shadowing a Consultant at the Whittington Hospital over the summer of 2021. The Committee acknowledges that her evidence is that she is currently engaged with an agency *"Virtual Pharmacist"* since early May and through that agency has been working for three weeks with the Linden Medical Centre/Group based in Northampton/Kettering where, to summarise her evidence, she is responsible for undertaking a pharmacy clinic where decision-making regarding medication is in part shared with a GP and is in part taken by her alone. She also gave evidence of having undertaken locum work on approximately six occasions with a pharmacy in East London over the past month where she acts as Responsible Pharmacist.

202. However, the Committee has to avoid falling into what might be termed 'wishful thinking'. For the Committee to be satisfied that the Registrant has remediated her failings, the Committee would need to be assured that she had not only undertaken learning, and had opportunities to gain experience, but that there is reliable independent evidence that she has put that learning and experience into practice and demonstrated safe practice.

203. The Committee does not have that evidence. In particular, the Committee does not have the following:

a. A C.V. from the Registrant – the Committee remains unclear when and where the Registrant has been working over the years since she registered. Some detail of her current working arrangements was elicited after extensive questioning by the panel to expand on the limited information initially given by the Registrant. The testimonials show she has worked in various places over the years but the complete picture remains unclear;
b. The Committee does not have a reference from the Consultant or other staff at the Whittington hospital to confirm the experience and learning about which the Registrant has given evidence;

c. It has no reference from the Virtual Pharmacist agency with which she is currently registered;
d. It has no reference from the GP clinic in Northampton/Kettering with which she is currently working; and
e. It does not have the CPPD/CPD certificates confirming the learning she has undertaken.

204. In addition, the Committee notes that the testimony from the pharmacist in east London with whom the Registrant undertakes locum work ('SA') is brief and does not assure the Committee about the Registrant's professionalism. It is note-able that the pharmacist providing the testimony states that she has *"read the particulars of the allegation"* but not that she has seen the Committee's written determination from May 2022 setting out not simply allegations but admitted and proved findings of fact.

205. The Committee has testimonies from other pharmacists and healthcare professionals. They all speak well of her professionally. Not all of the testimonials refer to having seen the allegation brought against her. Given the failings that have been found, the broad statements in her favour can carry only limited weight when the Committee's focus must be on its statutory overarching objectives of protecting the public and the wider public interest.

206. In the absence of significant up-to-date evidence of the Registrant's practice, and with the limitations of the testimony from the pharmacist who provides locum work, the Committee cannot be assured that the Registrant has remediated her failings. The Committee remains concerned that she lacks judgment not only with regard to the risks and challenges of running an online pharmacy but also in her clinical skills given that the clinical risks presented by the short-comings of her pharmacy should have been obvious to her.

207. The Committee is therefore not satisfied that she yet has the skills, understanding and judgement that would enable her to avoid repeating her failings and it is concerned that this could arise in two respects:

a. <u>Within the setting of an online pharmacy:</u> the Registrant's evidence is that she has no current intention of returning to working within the setting of an online pharmacy. The

Committee accepts her sincerity in this regard. However, unless she is subject to restrictions, she could change her mind at any time. Were she to do so, the Committee is concerned that she may well repeat the failings shown when she was running her own online pharmacy;

b. Outside of the setting of an online pharmacy: the Committee is concerned that the registrant's misconduct demonstrated a lack of clinical judgement in not acting on the risks in supplying high-risk medication to patients. Her current work involves patient medication reviews. The Registrant's evidence is that she has had training, has access to Patient Medical Records, and that there is a mix of shared decision-making with a GP and decision-making that she undertakes alone. Her evidence is that her work involves her deciding when to consult others and when she decides matters for herself, depending on her assessment of whether the decision is within her scope of practice or not. The Committee's concern is that her judgement about what is within her scope of practice and what is not cannot be adequately relied upon. This leaves open the risk that she may make a wrong decision which could lead to harm. The Committee's concern is underscored by the fact that she acts as Responsible Pharmacist in her locum work.

208. Thus, while the Committee is satisfied that the Registrant has shown some insight, and has taken steps to start remediating her failings, it remains concerned that she has not fully remediated her failings and could repeat the same or similar failings again whether she is in the role of a pharmacist responsible for running a pharmacy, or as a front-line pharmacist prescribing or supplying medication.

209. Two aspects of the evidence underscore the Committee's concerns about the Registrant's judgement:

a. With regard to her engagement with the agency 'Virtual Pharmacist' her evidence is that she joined the agency in early May 2022, and that about two weeks before the start of the Principal Hearing (start date: 23 May 2022) she used social media *"chats"* to inform her manager at Virtual Pharmacy, 'LS', of this hearing and her need for time-off to attend.

LS's testimonial indicates that she has only seen the allegations, not the Committee's written determination of the facts;

b. With regard to the Northampton/Kettering GP Clinic, she *"does not think that anyone knows"* about this hearing at the clinic.

210. The Committee is not aware of any obligation on the Registrant to have fully informed either the agency or the clinic of this hearing. However, good judgement might suggest that she should have done so, particularly given the Committee's findings of fact which were available. Without knowing of the fitness to practise concerns, the clinic in particular cannot manage its business to assure itself that any risk to patients that might arise is appropriately mitigated.

211. The Public Component: the Public Component requires, in line with the statutory objectives of this regulatory regime, the panel to consider whether the Registrant presents a risk of causing harm to others and to consider the other wider public interest considerations of maintaining public confidence in the profession and the maintenance of professional standards.

212. Having concluded that the Registrant could repeat the same or similar failings by the poor exercise of judgement, including clinical judgement, the Committee also concludes that there is a risk to members of the public. Drugs may well have medicinal properties, but they can also present a risk of serious harm if mis-prescribed or mis-supplied. This is all the more so with Controlled Drugs, and more generally high-risk drugs that give rise to a risk of addiction, misuse and overuse. The Committee's concerns about the Registrant's capabilities and short-comings in her judgement give rise to a risk of serious harm in the event that she fails to identify the risks in individual cases or in the systemic procedures adopted when prescribing, dispensing or reviewing medication.

213. The Committee is therefore satisfied that the Registrant's fitness to practise is currently impaired by reason of a risk of serious harm to the public.

214. The Committee is also satisfied that a finding of impairment is necessary to uphold public confidence in the profession and the regulator. The public would be concerned if a registrant who was found to present a risk of serious harm to others though her work was not restricted in the work that could be undertaken.

215. The Committee is also satisfied that public confidence in the profession and the regulator would be undermined were there not to be a finding of impairment irrespective of the risk of future harm. The Registrant's past misconduct is serious and the public would expect a clear statement to this effect.

216. The Committee is also satisfied that a finding of impairment is required to uphold professional standards. The roles of Superintendent Pharmacist and Responsible Pharmacist are onerous. Their roles were created very much to maintain high standards in the work conducted by pharmacists and to ensure safe practices. They are roles that should not be taken on lightly. The Registrant was first registered as a Pharmacist in August 2016 yet in early 2018 she set up the online pharmacy and gave herself those roles. The Committee has already concluded that the Registrant was naïve given her inexperience. Her naïvety has led to her running a pharmacy that did not meet the basic standards required to deliver a safe service. A finding of impairment is therefore necessary to uphold professional standards, so that there is a statement to express the seriousness of what has occurred and to emphasise to the profession about the weight of responsibility that comes with being a pharmacist and with the roles of Superintendent Pharmacist and Responsible Pharmacist.

217. **Accordingly, the Committee finds the Registrant's fitness to practise to be impaired not only because of a risk to the public but also for the wider public interest considerations of maintaining public confidence in the profession and regulator, and for the upholding of professional standards.**

Sanction

218. Having found impairment, the Committee has gone on to consider the matter of sanction.

The Law and Guidance

219. The Committee's powers are set out in Article 54(2) of the Order.

220. In determining the appropriate sanction, the Committee must consider the range of sanctions in Article 54 in ascending order from the least restrictive to the most restrictive to identify the appropriate and proportionate sanction that meets the circumstances of the case.

221. The Committee must also have regard to the Council's 'Good decision making: Fitness to practise hearings and sanctions guidance' to inform its decision.

222. The Committee is entitled to give greater weight to public interest over the consequences to the Registrant of the imposition of any particular sanction. Sir Thomas Bingham MR (with whom Rose and Waite LJJ agreed) said in Bolton v Law Society (1994) 1 WLR 512:

> *'The reputation of the profession is more important than the fortunes of any individual member. Membership of a profession brings many benefits, but that is part of the price'.*

223. The Committee received and accepted the advice of the Legal Advisor.

Council's submissions on sanction

224. On behalf of the Council, having identified aggravating and mitigating features, it was submitted that the Committee should consider a sanction of suspension for a minimum of six months to reflect the seriousness of the findings made against the Registrant.

Registrant's submissions

225. On her own behalf, the Registrant repeated that she accepted her responsibility for the failings, understood the gravity of the matter, was remorseful and had engaged, and had shown a commitment to remediating her failings. She accepted that a sanction was required.

She invited the Committee not to suspend her highlighting the financial impact this would have on her and those in her life given that she was the sole earner in her household and that there were others she supported through her charitable work. She also highlighted the impact on her professional reputation. She invited the Committee to impose a Conditions of Practice Order which would meet the seriousness of the case whilst enabling her to continue building on her learning and development and to pursue the profession about which she was passionate. In support of her submission, the Registrant provided a seven-page bundle consisting of CPPE certificates from over the period August 2021 to May 2022, reflecting the courses she had informed the Committee about, and what was presented as an extract of a report by her supervisor, Dr ED, at the Whittington Hospital in 2021 which included positive comments about the Registrant's clinical skills.

The Committee's decision on sanction.

226. In considering sanction, the Committee recognised the need to act proportionately, that any sanction should be no more restrictive than it needs to be to achieve its aims. The Committee was mindful that the purpose of sanction in regulatory proceedings is not to punish the registrant but to protect patients and the wider public interest.

227. The Committee bore in mind the Council's publication 'Good decision-making: fitness to practise hearings and sanctions guidance' (revised March 2017).

228. The Committee identified a number of aggravating factors:

a. The Registrant was the owner and SI of an online pharmacy that operated with systemic failings;
b. The failings gave rise to a risk of serious harm;
c. This continued over a number of months leading up to November 2019; and
d. The online pharmacy sector was, and remains, relatively new and she should have had heightened alertness to the complexities, challenges and risks that came with this new way of delivering pharmacy services.

229. The Committee identified a number of mitigating factors:

a. The Committee has accepted as genuine and sincere the Registrant's regret and remorse in respect of what occurred. She largely admitted the allegations, made appropriate concessions during the hearing, and has had the time to accept the Committee's findings of fact;
b. She engaged fully with the Council at the time of the Inspection, and was compliant with the Conditions placed on her pharmacy;
c. She chose to close the pharmacy as a result of the Inspection;
d. She has engaged with these regulatory proceedings including by attending this hearing and giving evidence;
e. She has demonstrated making sustained efforts over time to learn from her failings and has started to address them through reflection, courses, learning and through experience.

230. The Committee also records here contextual information that is relevant to its consideration of sanction:
a. There is no evidence that actual harm was caused to any patient;
b. The Registrant's online pharmacy was of a relatively limited scale and there has been no evidence of her undertaking steps to do what might be regarded as 'hard-selling' or 'targeted-selling' of her online pharmacy to boost profits;
c. The Committee has concluded that the Registrant has demonstrated a significant "passion" for her profession;
d. The Committee is satisfied that her motivation for setting up the online pharmacy was a positive one, driven by a wish to help people rather than what might otherwise have been the case to make significant profits;

231. Overall, the Committee concluded that whilst the Registrant's conduct must be regarded as serious, it is not at the most serious end of the spectrum when it comes to the possibilities with online pharmacies.

232. The Committee approached the issue of sanction by considering, in turn, each available sanction in ascending order.

233. The Committee first considered whether it should take no action. The Committee concluded that this would not be appropriate as it would not address the risk of future harm it had identified, nor would it be adequate to maintain confidence in the profession or the regulatory process, nor would it be sufficient to declare and uphold professional standards.

234. The Committee next considered whether a warning would be appropriate. It concluded that a warning would not be appropriate as it would not address the risk of repetition and the risk of future harm it had identified, nor would it be adequate to maintain confidence in the profession or the regulatory process, nor would it be sufficient to declare and uphold professional standards.

235. The Committee next considered the imposition of conditions.

236. The Committee first concluded that there are appropriate and workable conditions that could adequately manage the risk presented by the Registrant. She has shown some insight. She has described having her awareness of risk to patients "heightened" by the inspection and regulatory experience, and to adopting a more cautious approach. There is some evidence that she is alert to patient safety issues and has acted appropriately in recent times. In addition, the testimonies, albeit limited as the Committee has described above, indicate that she is currently engaged in pharmacy work in a way that has not identified any complaint. The Committee has concluded that whilst there is a risk of repetition of poor judgement and therefore a risk of serious harm being caused, the level of risk is one that is manageable in the workplace. Conditions that prohibited her from working within an online pharmacy setting, from being an SI and RP would both reduce the risks and mean that she is subject to supervision, supervision that is reinforced by a condition. The Committee is also satisfied that the Registrant would be compliant with any conditions imposed, as evidenced by her positive engagement with the inspection process and this regulatory process.

237. The Committee has gone on to consider whether a Conditions of Practice Order would adequately meet the public interest. The sanction should be appropriate to convey a clear message that reassures the public and reminds the profession of expected standards. The message from this case is clear: those who contemplate setting up an online pharmacy, and

particularly those who go on to actually set up an online pharmacy, should only do so when they are assured they have a good understanding of the complexities, challenges and risks involved, a good understanding of the standards that are expected, and who have the skills, knowledge and depth of experience to run safely and effectively an online pharmacy. The responsibilities of being an owner, Superintendent Pharmacist and/or Responsible Pharmacist of such a pharmacy, are onerous and are not to be taken on lightly.

238. The Committee is satisfied that the proportionate and appropriate means for delivering this message in the context of this case, and without losing the measure of the seriousness of the case, is a Conditions of Practice Order. The Committee is satisfied that such an order would adequately manage the risk to the public whilst also sending a proportionately clear message to the public and the profession about the seriousness with which it takes this case.

239. To complete its assessment of the appropriate sanction, the Committee has gone on to consider whether a Suspension Order would be appropriate. Having done so, the Committee is satisfied that in the particular circumstances of this case, a Suspension Order would not be appropriate or proportionate.

240. The Committee makes it clear that the conditions it has selected are not intended to prevent the Registrant from continuing her work through Virtual Pharmacy (where she is providing the services of a pharmacy clinic within the setting of a GP clinic, albeit remotely, as distinct from the services of an online pharmacy), nor prevent her from continuing her work as a locum, including with the community pharmacy in east London.

241. The Committee has concluded that the period of the Order should be 12 months. It reaches this conclusion taking account of the seriousness with which it regards the failings in this matter and the need for a clear message to the public. In addition, the Committee is satisfied that this is the minimum length of time required for the Registrant to be able to gather appropriate evidence to demonstrate that she is able to practise without restriction.

242. In reaching this conclusion, the Committee has balanced the public interest with the Registrant's own interest. The Registrant's evidence, which the Committee accepts for these

purposes, is that she and those around her would be significantly and adversely impacted if she, the sole-earner in her household, were suspended. The Committee has also borne in mind the impact on the Registrant's professional reputation were she to be suspended.

243. In these circumstances, the Committee is satisfied that a Conditions of Practice Order is the appropriate sanction.

244. Before concluding this part of the determination, the Committee notes as follows. The Registrant has given evidence of running an online educational platform whereby she shares 'hints and tips' primarily to trainee pharmacists and, separately, undertakes mentoring. This reflects the evidence of her "passion" for the profession, her enthusiasm for helping others, and her concern for enabling the next generation of pharmacists. The Committee has not seen any material from the online platform nor her mentoring (save for possibly for one testimony). Neither her online platform nor her mentoring have been a part of the allegation brought against her. The Council has not made any submissions on the issue. The Committee's remit is limited. However, the Committee does invite the Registrant to consider the appropriateness and wisdom of engaging with the online platform and the mentoring whilst she is subject to Conditions of Practice.

245. The Committee therefore directs the Registrar to impose Conditions of Practice on the registration of Miss Genevieve Boateng (registration number 2212407).

246. The Conditions are as follows:

1. **You must:**
    - **tell the GPhC before you take on any position for which you must be registered with the GPhC**
    - **give the GPhC details of the role and the hours you will work each week, including locum or relief work**
    - **give the GPhC the contact details of your employer, superintendent pharmacist and/or pharmacy owner.**

2. **You must tell the following people in writing about the restrictions imposed on your pharmacy practice, if you are doing any paid or unpaid work for which you must be registered with the GPhC. You should do this within two weeks of the date this order takes effect:**
    - **all employers or contractors**
    - **agents acting on behalf of employers and locum agencies**
    - **superintendent pharmacists**
    - **responsible pharmacists**
    - **line managers**
    - **workplace supervisors**
    - **accountable officers for controlled drugs.**

    You must send the GPhC a copy of this notification.

    If you are applying for work, you must tell any prospective employer about the restrictions imposed on your pharmacy practice when you apply.

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

4. **You must:**

    - **find a workplace supervisor for each place of work (who must be a registered Pharmacist or GMC registered Doctor) and put yourself, and stay, under their remote supervision**
    - **ask the GPhC to approve your workplace supervisor(s) within 4 weeks of the date this order takes effect. If you are not employed, you must ask us to approve your workplace supervisor before you start work**
    - **give the GPhC your permission to exchange information with your workplace supervisor(s) about your efforts to improve your pharmacy practice.**

5. **You must arrange for your workplace supervisor(s) to send a report on your progress with regard to the development of your safe and effective clinical practice to the GPhC every 4 months, with a minimum of three reports prior to a review hearing, or when the GPhC requests one. The GPhC will act reasonably in how often reports are requested.**

6. **You must not work as a sole practitioner or superintendent pharmacist or responsible pharmacist.**

7. **You must not provide mail-order or online pharmacy services.**

End of Conditions

247. The Committee directs that this sanction should be reviewed before it terminates. It is a matter for the Registrant to determine what if any evidence she wishes to present at the review. The Committee has already referred to documents that it had not seen. The Conditions of Practice also direct additional material that should be made available to the reviewing Committee panel.

Interim Measure

248. The Committee's substantive decision will not take effect for 28 days, or until any appeal has been determined.

249. On behalf of the Council the Committee was invited to impose an interim measure, pursuant to Article 60(2) of the Pharmacy Order 2010, to cover the appeal period. It was submitted that the interim measure was required to protect the public and in the wider public interest.

250. Mr Millin and the Legal Advisor had spoken with the Resistant to alert her to the possibility of an Interim Measure application and what this could mean.

251. The Registrant indicated that she in general terms understood the concept and had no observations to make about the application.

252. The Committee received and accepted the advice of the Legal Advisor.

253. The Committee considered the application and had in mind the Council's guidance of March 2017.

254. The Committee decided that an Interim Measure was required. It was satisfied that an Interim Measure was necessary both to protect the public and otherwise in the public interest. It reached this conclusion given its earlier findings of a risk of repetition, the consequential risk to patient safety, the seriousness of the Registrant's misconduct and the potential impact on public confidence and professional standards.

255. Accordingly, the Committee grants the application and orders an Interim Measure of Conditions of Practice (in the same terms as set out above in the substantive order) to be imposed on the Registrant's registration.

256. This order takes immediate effect. The interim measure will lapse and be replaced with the substantive order 28 days after the Registrant is given formal notice of the panel's decision if there is no appeal or at the conclusion of any appeal process.

257. That concludes this determination.