General Pharmaceutical Council

Fitness to Practise Committee

Principal Hearing

Remote videolink hearing

Monday 18 March 2024 to Tuesday 19 March 2024,

Monday 29 April 2024 to Tuesday 30 April 2024,

Wednesday 8 May 2024, and

Tuesday 28 May to Thursday 30 May 2024

Registrant name:	Alison Lesley Cooper
Registration number:	2040218
Part of the register:	Pharmacist
Type of Case:	Misconduct
Committee Members:	Philip Geering (Chair) Vaishally Patel (Registrant member) Andrew Popat CBE (Lay member)
Legal Adviser:	Ralph Shipway
Committee Secretary:	Gemma Staplehurst / Adam Hern
Registrant:	Present and represented by Martin Hadley, VHS Fletchers and accompanied by a person to provide personal support.
General Pharmaceutical Council:	Represented by Carl Buckley on behalf of Counsel, Case Presenter
Facts proved by admission:	1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, and 22, each in their entirety to include all sub-particulars.
Facts not proved:	2

Fitness to practise:	Impaired
Outcome:	Suspension Order for 12 months
Interim measures:	Interim Measure of Suspension order made

This decision including any finding of facts, impairment and sanction is an appealable decision under *The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010*. Therefore, this decision will not take effect until 2 July 2024 or, if an appeal is lodged, once that appeal has been concluded. However, the interim suspension set out in the decision take/s effect immediately and will lapse when the decision takes effect or once any appeal is concluded.

The Allegation

Particulars of Allegation

You, a registered Pharmacist, during the course of your engagement as an Independent Prescribers with Instant E-Care Ltd, 307 Forgeside House, Cardiff Bay Business Centre, Forgeside Close, Cardiff, CF24 5FA ("the pharmacy") between March 2015 and May 2019:

General Allegations

1. You failed to prescribe within the limits of your competency and/or scope of prescribing practice in that you prescribed medicines for the treatment of conditions without having completed and/or being able to provide evidence of relevant courses and/or training in the following areas of treatment:

1.1. chronic pain of musculoskeletal, nerve and visceral origin;

1.2. long-term insomnia;

1.3. dental Infections;

1.4. anxiety;

1.5. endometriosis.

2. Between June 2017 and June 2018 you issued approximately 11,850 prescriptions for opioids – amounting to approximately 32 prescriptions for each day of the previous 12 months.

3. You failed to prescribe medicines in accordance with and/or pay due regard to the 'GMC Good Practice in Prescribing and Managing Medicines and Devices Guidance' in that you prescribed in circumstances where you:

3.1. failed to obtain adequate information;

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

3.3. failed to determine capacity to provide consent to treatment;

3.4. failed to contact patients directly to obtain details of their physical health;

3.5. failed to contact patients directly obtain details of their mental health;

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

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

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

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

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

3.11. failed to put adequate safeguards in place.

4. Failed to prescribe medication in such a way as to safeguard patients and minimise the risk of medication being misused, overused, or abused in that you prescribed to patients in circumstances where:

4.1. there was no system of peer review;

4.2. no face to face or other virtual consultation took place other than the use of a questionnaire;

4.3. patients were allowed to pre-select the medicine, strength, and quantity they desired;

4.4. patients provided information primarily through a questionnaire;

4.5. the questionnaire at 4.4 above could be easily manipulated by patients as it highlighted to them answers which could prevent the supply of the medication they desired and permit the patient to change their answer;

4.6. you did not have access to the patient's full medical records;

4.7. you did not contact patients seeking Emergency Hormonal Contraception ("EHC") to ensure there were no safeguarding concerns;

4.8. you did not ensure that the patients were aware that efficacy of EHC reduced over time;

4.9. there were insufficient identity checks to ensure medicine was prescribed to the correct patient.

Specific Patients

Patient 3

5. On 27 May 2019 you prescribed and/or issued a supply of Co-codamol, 30mg/500mg, to the patient in circumstances where:

5.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

5.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

5.3. patient 3 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

5.4. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

5.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

5.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

5.6.1.physical Health; and/or

5.6.2.currently prescribed medication; and/or

5.6.3.patient medical and drug history.

5.7. you issued prescriptions to Patient 3 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 57

6. On 16 May 2019 prescribed and/or issued supplies of Dihydrocodeine, 30mg, to the patient in circumstances where:

16.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

6.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

6.3. patient 57 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

6.4. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

6.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

6.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

6.6.1. physical Health; and/or

6.6.2. currently prescribed medication; and/or 6.6.3.patient medical and drug history.

6.7. you issued prescriptions to Patient 57 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 65

7. On 29 May 2019 prescribed and/or issued supplies of Dihydrocodeine, 30mg, to the patient in circumstances where:

7.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

7.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

7.3. patient 65 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

7.4. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

7.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

7.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

7.6.1. physical Health; and/or

7.6.2. currently prescribed medication; and/or

7.6.3. patient medical and drug history.

7.7. you issued prescriptions to Patient 65 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 70

8. On 28 May 2019 prescribed and/or issued supplies of Dihydrocodeine, 30mg, to the patient in circumstances where:

8.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

8.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

8.3. patient 70 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

8.4. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

8.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

8.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

8.6.1. physical Health; and/or

8.6.2. currently prescribed medication; and/or

8.6.3. Patient medical and drug history.

8.7. you issued prescriptions to Patient 70 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 104

9. On 1 May 2019 prescribed and/or issued supplies of Co-codamol, 30mg/500mg, to the patient in circumstances where:

9.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

9.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

9.3. patient 104 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

9.4. you failed to contact or attempt to contact the Patient's GP so as to contact the Patient's GP so as to undertake necessary clinical checks;

9.5. you failed to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

9.5.1.physical Health; and/or

9.5.2.currently prescribed medication; and/or

9.5.3.patient medical and drug history.

9.6. you issued prescriptions to Patient 104 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 135

10. On 24 April 2019 and on 24 May 2019 prescribed and/or issued supplies of Codeine Phosphate, 30mg, to the patient in circumstances where:

10.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

10.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

10.3. patient 135 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

10.4. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

10.5. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

10.5.1. physical Health; and/or

10.5.2. currently prescribed medication; and/or

10.5.3. patient medical and drug history.

10.6. you issued prescriptions to Patient 135 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 138

11. On 7 April 2019 and on 3 May 2019, prescribed and/or issued supplies of Codeine Phosphate, 30mg, to the patient in circumstances where:

11.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

11.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

11.3. patient 138 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

11.4. Your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

11.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

11.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

11.6.1. physical Health; and/or

11.6.2. currently prescribed medication; and/or

11.6.3. patient medical and drug history. 22 11.7. you issued prescriptions to Patient 138 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 150

12. On 24 May 2019 prescribed and/or issued supplies of Dihydrocodeine 30mg to the patient in circumstances where:

12.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

12.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

12.3. patient 150 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

12.4. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

12.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

12.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

12.6.1. physical Health; and/or

12.6.2. currently prescribed medication; and/or

12.6.3. patient medical and drug history.

12.7. you issued prescriptions to Patient 150 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 164

13. On 16 May 2019 prescribed and/or issued supplies of Dihydrocodeine 30mg to the patient in circumstances where:

13.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

13.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

13.3. patient 164 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

13.4. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

13.5. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

13.5.1. physical Health; and/or

13.5.2. currently prescribed medication; and/or

13.5.3. patient medical and drug history.

13.6. you issued prescriptions to Patient 164 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 166

14. On 1 May 2019 prescribed and/or issued supplies of Dihydrocodeine 30mg to the patient in circumstances where:

14.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

14.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

14.3. patient 166 presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

14.4. you failed to contact or attempt to contact the Patient's GP so as to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

14.4.1. physical Health; and/or

14.4.2. currently prescribed medication; and/or

14.4.3. patient medical and drug history.

14.5. you issued prescriptions to Patient 166 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient 202

15. On 14 May 2019 prescribed and/or issued supplies of 14 Zopiclone tablets, 7.5 mg to the patient for long-term insomnia, in circumstances where:

15.1. you issued prescriptions to Patient 202 otherwise than in accordance with and/or against, relevant prescribing guidelines;

15.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

15.3. you failed to contact or attempt to contact Patient 202 in order to:

15.3.1. assess the need for cognitive behavioural therapy as an alternative and/or more clinically appropriate treatment;

15.3.2. adequately consider the possibility of misuse/abuse and/or risk of dependency;

15.4. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

15.4.1. physical Health; and/or

15.4.2. currently prescribed medication; and/or

15.4.3. patient medical and drug history.

Patient 163

16. On 23 December 2018 prescribed and/or issued supplies of Metronidazole, 400mg, to the patient for symptoms of painful gums/ 'pus' coming out of a tooth in circumstances where:

16.1. you did not have the knowledge and/or competency to prescribe for dental conditions;

16.2. you issued prescriptions to Patient 163 otherwise than in accordance with and/or against, relevant prescribing guidelines.

Patient P

17. On 28 January 2018 prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to the Patient (under her own name) in circumstances where:

17.1. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

17.2. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

17.3. you failed to ensure that you knew the Patient's identity was correctly checked;

17.4. you failed to seek consent and to contact the Patient's GP to carry out the necessary clinical checks;

17.5. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

17.6. you failed to select the most appropriate treatment for the patient and their condition(s);

17.7. you issued prescriptions to Patient P otherwise than in accordance with and/or against, relevant prescribing guidelines.

18. On 8 January 2018 prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to the Patient (under her first alternative name) in circumstances where:

18.1. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

18.2. you failed to consider possible misuse/abuse of weak and/or risk of dependency opioids;

18.3. you failed to ensure that you knew the Patient's identity was correctly checked;

18.4. you failed to seek consent and to contact the Patient's GP to carry out the necessary clinical checks;

18.5. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

18.6. you failed to obtain sufficient information to make and/or confirm a diagnosis;

18.7. you failed to select the most appropriate treatment for the patient and their condition(s);

18.8. you issued prescriptions to Patient P otherwise than in accordance with and/or against, relevant prescribing guidelines.

18.9. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

18.9.1. physical Health; and/or

18.9.2. currently prescribed medication; and/or

18.9.3. patient medical and drug history.

19. On 12 February 2018 prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to the Patient (under her first alternative name) in circumstances where:

19.1. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

19.2. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

19.3. you failed to ensure that you knew the Patient's identity was correctly checked;

19.4. you failed to seek consent and to contact the Patient's GP to carry out the necessary clinical checks;

19.5. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

19.6. you failed to obtain sufficient information to make and/or confirm a diagnosis;

19.7. you failed to select the most appropriate treatment for the patient and their condition(s);

19.8. you issued prescriptions to Patient P otherwise than in accordance with and/or against, relevant prescribing guidelines.

19.9. You failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

19.9.1. physical Health; and/or

19.9.2. currently prescribed medication; and/or

19.9.3. patient medical and drug history.

20. On 5 February 2018 prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to the Patient (who was using her partner's identity) in circumstances where:

20.1. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

20.2. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

20.3. you failed to ensure that you knew the Patient's identity was correctly checked;

20.4. you failed to seek consent and to contact the Patient's GP to carry out the necessary clinical checks;

20.5. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

20.6. you failed to obtain sufficient information to make and/or confirm a diagnosis;

20.7. you failed to select the most appropriate treatment for the patient and their condition(s);

20.8. you issued prescriptions to Patient P otherwise than in accordance with and/or against, relevant prescribing guidelines.

20.9. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

20.9.1. physical Health; and/or

20.9.2. currently prescribed medication; and/or

20.9.3. patient medical and drug history.

21. On 29 April 2018 prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to the Patient (under her second alternative name) in circumstances where:

21.1. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

21.2. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

21.3. you failed to ensure that you knew the Patient's identity was correctly checked;

21.4. you failed to seek consent and to contact the Patient's GP to carry out the necessary clinical checks;

21.5. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

21.6. you failed to obtain sufficient information to make and/or confirm a diagnosis;

21.7. you failed to select the most appropriate treatment for the patient and their condition(s);

21.8. you issued prescriptions to Patient P otherwise than in accordance with and/or against, relevant prescribing guidelines.

21.9. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

21.9.1. physical Health; and/or

21.9.2. currently prescribed medication; and/or

21.9.3. patient medical and drug history.

Patient Q

22. You failed to provide safe and effective care to Patient Q in that on or around 11 April 2019 you prescribed Co-Codamol, 30mg/500mg in circumstances where:

22.1. you used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

22.2. you failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

22.3. patient Q presented with a chronic but not acute condition, which is outside of the scope of the service that was provided;

22.4. your training and/or competency did not extent to management of chronic pain of musculoskeletal, nerve and visceral origin;

22.5. you failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

22.6. you failed to contact or attempt to contact the Patient's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of their:

22.7. physical Health; and/or

22.8. currently prescribed medication; and/or

22.9. patient medical and drug history.

22.10. you issued prescriptions to Patient Q otherwise than in accordance with and/or against, relevant prescribing guidelines.

By reason of the above acts and/or omissions, your fitness to practise was and is impaired amounting to misconduct.

End of Allegation

Documentation

Document 1- GPhC hearing bundle (indexed and paginated 1 to 975)

Document 2- GPhC Statement of Case dated 8/3/2024

Document 3- Registrant's bundle (indexed and paginated 1 to 154)

Document 4- Registrant's Skeleton and Statement of Case dated 12/3/2024

Document 5- An exchange of two emails dated 13/3/2024 between the parties concerning the admissibility of Dr Campbell's report

Document 6- the Allegation (Particulars 1 to 22 inclusive)

Document 7- Case Management Directions dated 8/3/2024 issued by the Chair concerning the provision of papers to the committee.

During the hearing, the following documents were provided:

Document 8 - Committee's written determination dated 19/3/2024 adjourning the hearing to April 2024.

Document 9 - Committee's written determination dated 29/4/2024 dismissing Allegation Particular 2 following a submission of no-case to answer under Rule 31(8).

Document 10 - Registrant's early admissions to allegation (undated).

Document 11 – Letter from an NHS Foundation Trust dated 22/8/2023 regarding the registrant's health, considered in private by the committee.

Note: the GPhC hearing bundle contained a report by Dr Campbell dated 15/3/2023, an expert relied on by the GPhC. As agreed between the parties, the report was held back from

the panel at Stage 1, fact finding, and provided to the panel at the start of Stage 2, determining grounds and impairment.

End list of documents

Witnesses

Witness A, Chief Pharmaceutical Office's Clinical Fellow at the Council who provided written statements as part of the Council's case.

Witness B, GPhC Inspector, who provided written statements as part of the Council's case.

Witness C, GPhC Case Officer, who provided a written statement as part of the Council's case.

Witness D, GPhC Case Officer, who provided written statements as part of the Council's case.

Witness E former husband of Patient P, who provided a statement as part pf the Council's case.

Witness F, Superintendent Pharmacist at the relevant pharmacy at the relevant time, gave oral evidence at facts stage.

Witness G, Director and Chief Executive Officer of the relevant pharmacy - gave oral evidence at facts stage

The Registrant gave evidence at Stage 2, giving evidence relevant to Stage 2 (determining grounds and impairment) and Stage 3 (Sanction).

Determination

Introduction

1. This is the written determination of the Fitness to Practise Committee at the General Pharmaceutical Council ('the Council').

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

3. The statutory overarching objectives for these regulatory proceedings are:

   a. To protect, promote and maintain the health, safety and well-being of the public;

   b. To promote and maintain public confidence in the professions regulated by the Council; and

   c. To promote and maintain proper professional standards and conduct for members of those professions.

4. The Committee also has regard to the guidance contained in the Council's *Good decision making: Fitness to practise hearings and sanction guidance* as revised March 2017 and also the Council's *Good decision-making: Fitness to practise hearings and outcomes guidance*, issued "Revised March 2024".

5. A Principal Hearing has up to three stages:

   Stage 1. Findings of Fact – the Committee determines any disputed facts.

   Stage 2. Findings of ground(s) of impairment and impairment – the Committee determines whether, on the facts as proved, a statutory ground for impairment is established and, if so, whether the registrant's fitness to practise is currently impaired.

   Stage 3. Sanction – the Committee considers what, if any, sanction should be applied if the registrant's fitness to practise is found to be impaired.

Conflict of Interests

6. On behalf of the Committee Members and the Legal Adviser, the parties were advised of historical matters, including past involvement with cases involving online pharmacies, not including Instance E-Care (the online pharmacy involved in the present case). On behalf of the Council and the registrant, the advocates confirmed that no issue was taken.

Service of Notice of Hearing

7. The Committee has seen a letter dated 16 February 2024 from the Council headed 'Notice of Hearing' addressed to the registrant.

8. Mr Hadley, on behalf of the registrant, confirmed that no issue was taken with service of the Notice of Hearing. The Committee was satisfied that there had been good service of the Notice in accordance with Rules 3 and 16.

Hearing by video link

9. Both parties confirmed that they were content for the hearing to proceed by way of video link.

Application to amend the particulars of allegation

10. There was no application to amend the Allegation.

Parts of Hearing to be held in Private

11. Two matters arose relating to parts of the hearing being held in private.

12. First, the mother of Patient Q attended parts of the hearing. The committee Chair spoke to her directly during the hearing and referred to her by name as did others.

13. Having heard from the two advocates, and received legal advice, the committee gave **a direction:**

    DIRECTION: that any reference to <u>the name of Patient Q's mother</u> should be regarded as having been spoken at a time when the hearing was held in private in order to protect the privacy of her and her family.

14. Secondly, an application was made on behalf of the registrant to give part of her evidence in private, namely evidence relating to her health. The application was supported by the Council. The panel received and accepted legal advice.

15. The application was **granted**.

16. In both instances, the panel Chair, exercising powers in the rules, **granted** observer status to the registrant's personal support to remain in the hearing when in private on the understanding that what was said was confidential (Rule 2(2)(a)(vi)).

Application to admit further evidence

17. Before the hearing, the Committee was provided with a number of papers including the Council's main bundle of evidence insofar as it was agreed.

18. What was not agreed at the start of the hearing, and which was removed from the Council's bundle before it was provided to the committee, was a document referred to by the advocates as Dr Campbell's report. On behalf of the registrant the report was objected to given that it relied on guidance issued to the profession after the period covered by the Allegation.

19. Discussions were held outside of the hearing between the parties.

20. The Committee was advised that the parties had agreed the following approach:

    a. That the report of Dr Campbell would not be provided to the Committee for the fact-finding stage of the hearing;
    b. It would be provided to the Committee at Stage 2 of the hearing (determining grounds and impairment) as it may assist the committee in determining whether the registrant has remediated any impairment.

21. The committee accepted this approach.

22. Other documents were subsequently also provided to the committee during the hearing. With the agreement of the parties the committee admitted those items in concluding that it was relevant and fair to do so (Documents 10 and 11 listed above).

Registrant's response to Particulars of Allegation

23. The registrant denied Particular 2 but otherwise admitted all remaining particulars (1, 3 to 22 inclusive) including all sub-particulars. The admissions were made by Mr Hadley on behalf of the registrant. The registrant confirmed the admissions made.

24. The registrant also confirmed her registration number as required by the rules.

25. In the light of the above, and by the application of Rule 31(6) of the Rules, the admitted factual particulars were found proved.

26. It is recorded here that right at the very start of the hearing the registrant spoke, addressing her comments to the mother of Patient Q who was observing the hearing at that time, expressing her regret at what had happened, her regret at her own involvement and her regret given the consequences that followed.

Application by Mr Buckley to be released

27. Mr Buckley disclosed that he had a professional conflict in that during the first afternoon of the regulatory hearing he was also expected to attend a one-hour hearing at the local County Court requiring his absence for approximately 90 minutes. Mr Hadley expressed disquiet about Mr Buckley absenting himself in this way given the potential impact progressing the hearing and the circumstances of the hearing. The panel Chair, exercising Case Management powers, released Mr Buckley, expressing concern, given the sensitivities of the regulatory hearing, the potential impact on the hearing, and that the matter had not been resolved beforehand. As it was, Mr Buckley was able to return in the hour, effectively over the mid-day adjournment and without adversely impacting on the hearing.

Applications to adjourn the hearing

28. Application on behalf of the Council to adjourn. On the first day of the hearing, Mr Buckley applied under Rule 37(2) to adjourn the hearing until 12 noon the following day. The application arose for the following reasons: in the light of the admissions made, a single particular remained which was disputed and the Council wished to call a single witness, Witness G, to give oral evidence regarding that particular. Witness SH had originally been warned to attend at a later stage of the scheduled hearing, though it had also been understood that he would be available over the period of the start of the hearing. As it was, Witness G had, the committee was told, emailed the Council on the first morning to advise that he was not currently available until 12 noon on the second day. Mr Buckley's submission was that an adjournment for this period would not adversely affect the completion of the case. Mr Hadley, on behalf of the registrant, opposed the application on the basis that the case had been scheduled for the convenience of the parties, that pleas had been indicated in advance of the hearing, and that an adjournment risked adversely impacting on the progress of the case which would not be acceptable given the age of the case and the sensitivities involved.

29. Having received legal advice, the committee initially postponed adjudicating on the application given that there were remaining other preliminary matters to resolve, the case had yet to be opened on behalf of the Council, the hearing was shortly to adjourn overnight and the possibility that Witness G may be available sooner than noon the following day.

30. The following morning, Mr Buckley confirmed that Witness G would not be available until 12 noon and re-applied for an adjournment of the case until then, save that he would first open the case on behalf of the Council. Mr Hadley repeated his concerns about delay. The committee received legal advice regarding Rule 37 and considered the matter. The committee determined that it would be appropriate to hear the opening on behalf of the Council and to then adjourn for what would then be a very short while by when Witness G would be available to give evidence.

31. Mr Buckley then commenced to open the case on behalf of the Council.

32. Application on behalf of the registrant to adjourn. An issue arose during the opening of the case that led to Mr Hadley to apply for the hearing to be adjourned either to the following morning or to the next dates scheduled for this case in late April 2024.

33. The issue concerned the Council's evidence that had been provided to Mr Hadley, which included a statement by Witness F (it was not resolved whether Witness F's statement had been formally served as part of the Council's case or simply disclosed). Due to an error, not detected in pre-hearing communications between the parties, a misunderstanding had arisen as to what evidence the Council was relying on (which included Witness F) and what was agreed by the registrant (which had not included Witness F's statement). As a result, Witness F was not warned to attend the hearing but would now be required and an adjournment would be required for this to be achieved. The application to adjourn was opposed by the Council.

34. Having received legal advice, the committee considered the matter. The committee was satisfied that fairness required the application to adjourn to be granted. It was evident that there had been a miscommunication between the parties and it would not be fair to visit the consequences of that miscommunication on the registrant. The circumstances and fuller reasons for granting the adjournment were set out in a written determination produced at that time and provided to the parties.

Application to dismiss Particular 2 of the Allegation under Rule 31(8)

35. At the resumed hearing commencing on 29 April 2024, the Council re-commenced opening the case and the hearing continued to consider Particular 2, the particular not admitted by the registrant.

36. Particular 2 alleged: "*Between June 2017 and June 2018 you issued approximately 11,850 prescriptions for opioids – amounting to approximately 32 prescriptions for each day of the previous 12 months.*"

37. The Council presented both written and oral evidence in order to prove Particular 2.

38. At the end of the Council's evidence, an application was made on behalf of the registrant to dismiss Particular 2 on the basis that there was insufficient evidence for the committee to safely consider it further. The application was opposed by the Council.

39. **The committee granted the application and dismissed Particular 2**.

40. A full written determination was produced by the committee and provided to the parties. In summary, the committee found that:

    a. Proof of Particular 2 depended entirely on an email dated 20/6/2018 from Witness F;

b. The number given in the particular, 11850, appeared in that email;

c. The number was produced as a result of a search of the pharmacy IT database;

d. It was unclear who conducted that search;

e. There is no evidence of exactly what question was put to the database that led to the figure being given, nor evidence as to how medicines were categorised within the database, and as a result it is difficult to know with any sense of reliability what the figure 11850 relates to;

f. It was not established whether the figure was a total given by the database or whether it was a total derived by an unknown person adding up sub-totals provided by the database;

g. Whilst of less significance, it was unclear exactly when the database search was undertaken nor the exact twelve-month period under review;

h. Given the uncertainties, it would be unsafe to place any reliance on the figure 11850.

Background

41. The registrant, Mrs Alison Cooper, is a Pharmacist. She first registered on with the Royal Pharmaceutical Society (RPS) on 3rd August 1992 with her professional registration subsequently transferring over to the General Pharmaceutical Council ('the Council'). Her registration number is 2040218.

42. Between December 2014 and May 2019, the registrant worked as a Pharmacist Independent Prescriber ('PIP') at Instant E-Care Ltd ('the Pharmacy').

43. The Pharmacy provided an online prescribing and pharmacy service through Instantecare.co.uk, operating from two postal addresses:

    a. 307 Forgeside House, Cardiff Bay Business Centre, Forgeside Close Cardiff, CF24 5FA, registration number 1124966; and

    b. S12 Forgeside House, Cardiff Bay Business Centre, Forgeside Close, Cardiff CF24 5FA, registration number 9010773.

44. The Pharmacy was inspected by the Council in 2015 and 2018, being rated poor on both occasions. The registrant's evidence is that she did not have access to, and had no means to have access to, the inspection reports, but that she was led to understand the inspection outcomes were largely satisfactory with attention needed in limited respects.

Patient P

45. On 18 June 2018 Mr P, the husband of Patient P submitted a concern to the Council regarding online pharmacies.

46. His concerns arose from the fact that his then wife, Patient P, was seemingly able to purchase dihydrocodeine on multiple occasions from multiple pharmacies using different ordering accounts. Dihydrocodeine is a drug susceptible to abuse, misuse and addition. Mr P described Patient P's ongoing battle with addiction which had a very harmful impact on her health and their family life and had the consequence that their child was born addicted to opiates.

47. As a result of the concern submitted by Mr P, the Council commenced an investigation. This included an investigation of Patient P's contact with Instant E-Care.

48. Evidence provided by the Pharmacy's Superintendent Pharmacist shows that the registrant prescribed dihydrocodeine to Patient P on five occasions over a period in the first part of 2018. The patient used four different names, email addresses and two different mobile numbers to create four accounts.

49. The five occasions, set out in the Allegation at Particulars 17 to 21, were (in chronological order):

    a. On 8 January 2018 the registrant prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to Patient P (under Patient P's first alternative name) (Particular 18);

    b. On 28 January 2018 the registrant prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to Patient P (under Patient P's own name) (Particular 17);

    c. On 5 February 2018 the registrant prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to Patient P (who was using her partner's identity) (Particular 20);

    d. On 12 February 2018 the registrant prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to Patient P (under Patient P's first alternative name for a second time) (Particular 19); and

    e. On 29 April 2018 the registrant prescribed and/or issued a quantity of Dihydrocodeine, 30mg, to Patient P (under Patient P's second alternative name) (Particular 21).

50. In summary, it was alleged, and the registrant has admitted, that on the occasions when she prescribed the Dihydrocodeine to Patient P she:

    a. failed to conduct the required clinical assessment so as to establish the clinical justification for that same medication;

    b. failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

    c. failed to ensure that she knew the Patient's identity was correctly checked;

    d. failed to seek consent and to contact the Patient's GP to carry out the necessary clinical checks (in particular, as specified in some of the particulars relating to

Patient P, failed to contact Patient P's GP to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of Patient P's physical health and/or currently prescribed medication and/or medical and drug history);

e. had not extended her training and/or competency to the management of chronic pain of musculoskeletal, nerve and visceral origin as presented by Patient P;

f. failed to obtain sufficient information to make and/or confirm a diagnosis;

g. failed to select the most appropriate treatment for the patient and her condition(s); and

h. issued prescriptions to Patient P otherwise than in accordance with and/or against, relevant prescribing guidelines

Generic concerns

51. Concerns of a generic nature were also identified, set out in Particulars 1, 3 and 4, to include:

a. Failing to prescribe within the limits of the registrant's competency and/or her scope of prescribing practice by prescribing medicines for the treatment of conditions such as long-term insomnia without having completed relevant study or training (Particular 1);

b. Failing to prescribe medicines in accordance with GMC guidance including by failing to obtain adequate information including about patient physical and mental health, without contacting directly patients or their GP or obtaining medical records, and failing to adequately consider the possibility of medication dependence and misuse (Particular 3); and

c. Failing to prescribe medication in such a way as to safe-guard patients and minimise the risk of medication being misused, overused or abused including by not undertaking a consultation with patients, relying primarily on a questionnaire completed by patients which could be manipulated by patients, without accessing patient medical records, and without undertaking steps to address safe-guarding or efficacy when prescribing Emergency Hormonal Contraception (Particular 4)

Concerns regarding Specific Patients

52. In addition to the general concerns about the registrant's practice concerns were identified in relation to specific patients. These, set out in Particulars 5 to 16 inclusive, concerning twelve patients. The specific concerns about the registrant's practice include that the registrant:

a. relied on generic questionnaires to assess different types of pain related to different medical and surgical conditions;

b. failed to conduct the required clinical assessment so as to establish the clinical justification for medication;

c. prescribed medication to patients presenting with health conditions outside of the scope of the service that was provided by the pharmacy;

d. did not have the training and/or competency to manage health conditions presented by patients (this sub-particular does not apply to all patients referred to in the particulars);

e. failed to consider possible misuse/abuse and/or risk of dependency of weak opioids (this sub-particular does not apply to all patients referred to in the particulars);

f. failed to contact or attempt to contact the GP of patients so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of patient health, current medication or medical and drug history;

g. issued prescriptions to patients otherwise than in accordance with and/or against, relevant prescribing guidelines including NICE guidelines and PHE guidelines.

53. The twelve patients involved were (in chronological order):

a. on 23 December 2018, Patient 163 to whom Metronidazole 400mg was prescribed for painful gums and 'pus' coming out of a tooth (Particular 16)
b. on 7 April 2019 and then again on 3 May 2019, Patient 138 to whom Codeine Phosphate 30mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 11)
c. on 24 April 2019 and then again on 24 May 2019, Patient 135 to whom Codeine Phosphate 30 mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 10)
d. on 1 May 2019, Patient 104 to whom Co-codamol 30mg/500mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 9)
e. on 1 May 2019, Patient 166 was prescribed Dihydrocodeine 30mg for a chronic not acute condition which was outside the scope of the pharmacy service
f. on 14 May 2019, Patient 202 to whom 14 Zopiclone tablets, 7.5mg was prescribed for long-term insomnia (Particular 15)
g. on 16 May 2019, Patient 57 to whom Dihydrocodeine 30mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 6)

h. on 16 May 2019, Patient 164 to whom Dihydrocodeine 30mg was prescribed for a chronic but not acute condition outside the scope of the pharmacy service (Particular 13)
i. on 24 May 2019, Patient 150 to whom Dihydrocodeine 30mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 12)
j. on 27 May 2019, Patient 3 to whom Co-codamol 30mg/500mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 5)
k. on 28 May 2019, Patient 70 to whom Dihydrocodeine, 30mg, was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 8)
l. on 29 May 2019, Patient 65 to whom Dihydrocodeine 30mg was prescribed for a chronic but not acute condition which was outside the scope of the pharmacy service (Particular 7).

Patient Q

54. Patient Q died on 9 August 2020 aged 38 years. On 2 February 2021, a Coroner conducted an inquest into her death. The Coroner concluded that her death was drug related.

55. Using statutory powers, the Coroner issued a statutory report dated 17 February 2021 to prevent future deaths. The report was addressed to the Minister of State for Patient Safety and also to the Care Quality Commission. Based on the circumstances of Patient Q's death the report identified areas of concern and the need for action to address those concerns to prevent future deaths. The concerns included the provision of services by on-line pharmacies.

56. By letter dated 8 March 2021 the Coroner sent a copy of the report to the Council. The letter identified on-line pharmacies used by Patient Q to obtain drugs. These included Instant E-Care.

57. The Coroner's letter to the Council included the following:

> *"What was established in evidence at the inquest was that neither a doctor nor any dispensing pharmacist checked with the registered GP whether it was appropriate to dispense these prescriptions which include opiate medication. Had any check been made, it would have been established that* [Patient Q] *had an opiate addiction…"*

58. The Allegation against the registrant at Particular 22, which she has admitted, sets out that the registrant failed to provide safe and effective care to Patient Q in that, on or around 11 April 2019, she prescribed Co-Codamol, 30mg/500mg in circumstances where the Patient Q presented with a chronic but not acute condition, which was

outside of the scope of the service provided by the pharmacy. Particular 22 identifies that the registrant:

a. failed to provide safe and effective care in that she used generic questionnaires to assess different types of pain related to different medical and surgical conditions;

b. failed to conduct the required clinical assessment so as to establish the clinical justification for the medication;

c. had not extended her training and/or competency to management of chronic pain of musculoskeletal, nerve and visceral origin as presented by Patient Q in the questionnaire;

d. failed to consider possible misuse/abuse and/or risk of dependency of weak opioids;

e. failed to contact or attempt to contact Patient Q's GP so as to obtain relevant or any GP medical records and/or relevant or any specialist clinical records in order to have a full picture of Patient Q's physical Health and/or currently prescribed medication; and/or patient medical and drug history; and

f. issued prescriptions to Patient Q otherwise than in accordance with and/or against, relevant prescribing guidelines.

59. The registrant's evidence, unchallenged by the Council, is that she left the pharmacy in May 2019 because of her concerns about patient safety and practices at the pharmacy. The committee notes that she has admitted issuing prescriptions through May 2019, including 29 May 2019 – Particular 7.

60. On 16 August 2021, the Pharmacy stopped trading, and was voluntarily removed from the Council's register on 24 August 2021.

Witness A – expert witness for the Council

61. Witness A is the Chief Pharmaceutical Officer's Clinical Fellow at the Council. He has provided statements reviewing evidence in this case and expressing opinions regarding the evidence, opinions that underpin many of the Particulars set out in the Allegation.

62. His conclusions included the following.

a. A Pharmacist acting as an Independent Prescriber, as the registrant was, must only prescribe within the scope of their practice. A prescriber's scope of practice is based on their experience (including training) and competencies. The expert witness was provided with records of training undertaken by the registrant from before she became an Independent Prescriber and subsequently. The expert concluded that the evidence was of training that was not intended for accrediting a specific prescribing scope of practice, but provided training for general level pharmacy services and general knowledge around prescribing and did not

demonstrate competency in prescribing for patients who suffer from arthritis. The expert commented that the evidence indicated that the registrant's experience and competencies were around dermatological conditions and managing minor ailments with no experience in managing patients with arthritis and chronic pain conditions.

b. That in relation to patients reporting arthritis, the questionnaires used by the registrant did not provide sufficient clinical information to elicit which type of arthritis the patient had and therefore could not have determined the appropriate management and treatment for the patient. The result was that in prescribing medication the registrant was not providing safe and appropriate care. The appropriate action would have been to refer the patient to their GP.

c. Specifically in relation to Patient P, the expert witness concludes that the registrant was not competent to assess or diagnose the condition described by Patient P in the questionnaire (namely arthritis and other pain-related complaints) nor competent to prescribe medication to treat the condition

d. That dihydrocodeine may be prescribed for arthritis in appropriate cases but is commonly used for short periods of time, in combination with other non-opioid painkillers (e.g. Paracetamol and Ibuprofen) to alleviate acute pain that is not controlled by non-opioid pain killers, and in cases of spinal arthritis Dihydrocodeine is only mentioned in official guidance as the fourth line of therapy options in relation to osteoarthritis. With regard to the registrant's patients there was no record of other painkillers being used, what dosage controls the pain, or why the patient has previously had repeated prescriptions from their GP.

e. As a prescriber, the registrant only dealt with a patient when orders were received and was not the patients' main healthcare provider such as a GP. The expert describes as *"paramount"* the need for communication with the patients' GP to gain information about the patient and their history to inform the clinical assessment used to justify the provision of a prescription and to ensure continuity of care after a prescription is provided. Without such communication with the GP patients are put at risk of harm through misdiagnosis, mistreatment, safeguarding failures and misuse.

f. The expert comments that *"The main reason for refusing the supply is solely because of the local* [pharmacy] *opioid policy which is not based on any appropriate clinical reasoning. The process is merely a transactional one and does not elevate to the level of a well conducted consultation to provide safe and effective care."*

g. GMC (2013) and RPS (2016) prescribing guidance and the Council's January 2018 guidance on providing pharmacy services at a distance was not followed, in particular:

i. Guidance on prescribing within the limits of the pharmacist's competency

ii. Only prescribing when there is adequate knowledge of the patient's health

iii. That to assess a patient the prescriber should access all available and relevant patient records, to gain an understanding of the conditions being treated and to consider differential diagnosis,

iv. Prescribes after having made an assessment of risks and benefits

v. The need to apply relevant guidelines including NICE guidelines

vi. To consider the potential for misuse of medicines

vii. To identify the risks associated with remote prescribing and take steps to mitigate them.

h. That there were no pharmacy clinical governance arrangements in place to support and monitor the prescribing process, including that the registrant did not receive peer review feedback to work as part of a multi-disciplinary team, the value of which is recognised in professional guidance; that the pharmacy Standard Operating Procedures ('SOP') introduced over time were in places weak and in places not consistent with national guidance; and that readily available good practice guides were not adopted. The witness refers to a SOP prepared by the registrant (SOP3 Process Contacting GP) as *"appears well drafted"* but that at the time of the inspection (1/10/2019) *"there was no evidence that this SOP or other policies were followed or even implemented and there was no monitoring of compliance."*

i. No evidence of sharing prescribing information: as a prescriber, the registrant relied on patient GPs to provide other aspects of care such as monitoring, follow-up and determination of the duration of treatment. The witness concluded *"there was no evidence that* [the registrant was] *communicating or sharing information* [on prescriptions issued] *with the patients' local GPs"* that could have ensured continuity of care.

63. The expert witness evidence was that ultimately, the registrant was responsible for the prescriptions she issued, and that as a pharmacist independent prescriber, the registrant had an extra level of responsibility and accountability towards the patients.

Misconduct and Impairment

64. Having found all particulars of allegation proved by admission, except for Particular 2 which has been dismissed, the committee went on to consider whether the particulars found proved amounted to misconduct and, if so, whether the registrant's fitness to practise is currently impaired.

65. On behalf of the Council, it was submitted that the committee should find misconduct and impairment. It was submitted that impairment should be found under Rule 5(2) (b) and (c) (bringing the profession into disrepute and breaching a fundamental principle of the profession). It was further submitted that the committee could find impairment under Rule 5(2)(a) (presenting a risk to patients). On behalf of the council no reliance was placed on Rule 5(2)(d) (lack of integrity).

66. On behalf of the registrant, it was accepted that the committee was likely to find misconduct. It was submitted that the committee should not find impairment under any of the factors listed in Rule 5(2). In particular, it was submitted that the registrant's fitness to practise may well have been impaired at the time the facts of the case occurred, but that since then five years had passed, the registrant has admitted the facts and did so at an early stage of the regulatory process, has shown considerable remorse, has shown understanding of what she did wrong and how it came about, has undertaken very considerable reflection which, along with her CPD work and testimonials provided, shows that she has addressed the failings she was responsible for as identified in Dr Campbell's report. It was further highlighted that she has worked as a prescriber without any concerns being raised, and has been trusted by a University to teach undergraduate pharmacy students including in relation to their responsibilities when prescribing.

67. The committee accepted the advice of the legal adviser with which both legal representatives agreed.

68. The committee took account of all the documentary evidence available to it, both from the Council and the registrant, and also took account of the oral evidence of the registrant who gave evidence having affirmed. The committee also took into account the submissions made by Mr Buckley on behalf of the Council, and the submissions by Mr Hadley on behalf of the registrant.

Decision on misconduct

69. The committee is in no doubt that the facts admitted and found proved amount to misconduct.

70. Pharmacists are colloquially described as 'gate-keepers'. Medicines can do much good for patients, but can cause significant harm if they are not used as intended which is why they are kept within a secure supply chain. It is pharmacists who act as the custodians of medication, ensuring safe and effective use, only releasing it to patients when it is safe and appropriate to do so. This characterisation of the role also extends to pharmacist prescribers. It is for this reason that every pharmacist prescriber should know that whatever their work environment they personally carry professional responsibility and accountability for the prescriptions they issue.

71. This characterisation of pharmacist prescribers is reflected in the standards expected of them. The committee has considered the two pharmacy professional standards documents covering the period that the registrant worked with Instant E-Care:

72. Standards of conduct, ethics and performance dated July 2012, and

73. Standards for Pharmacy professionals dated May 2017.

74. Of the 2012 Standards, the committee finds that the registrant breached the following standards:

> Standard 1: Make patients your first concern.
>
> In particular under this standard, to make sure that the services provided are safe, take action to protect the well-being of patients, get all the information required to assess a person's needs in order to give the appropriate treatment and care, and if needed refer patients to other health professionals.
>
> Standard 2: Use your professional judgement in the interests of patients and the public.
>
> In particular under this standard, consider and act in the best interests of the individual patient and public, and be prepared to challenge the decisions of others if there is reason to believe their decisions could affect the safety or care of others.
>
> Standard 4: Encourage patients and the public to participate in decisions about their care.
>
> In particular under this standard, communicate effectively with patients, work in partnership with patients and other professionals to manage the treatment and care, and make sure information is appropriately shared with other health professionals involved in the care of individual patients.
>
> Standard 5: Develop your professional knowledge and competence.
>
> In particular under this standard, to recognise the limits of professional competence, and maintain the quality of practice by keeping knowledge and skills up to date and relevant to roles and responsibilities – which would include maintaining an understanding of relevant guidance and how it should be applied.
>
> Standard 7: Take responsibility for your working practices.
>
> In particular under this standard, to be satisfied that appropriate standard operating procedures are in place and to make sure legal and professional responsibilities are kept and that the working conditions do not present a risk to patient care or public safety.

75. Of the 2017 standards, the committee finds that the registrant breached the following standards:

Standard 1: Provide person-centred care.

In particular under this standard involve and enable every person when making decisions about their health, listen to the person and understand their needs, and make the best use of the resources available.

Standard 2: Work in partnership with others.

In particular under this standard to work with the person receiving care, identify and work with the individuals and teams who are involved in the person's care, contact and work with relevant local and national organisations, take action to safeguard people, and work with others to make sure there is continuity of care.

Standard 3: Communicate effectively.

In particular under this standard overcome barriers to communication, and communicate effectively with others involved with the care of the person.

Standard 4: Maintain, develop and use professional knowledge and skills.

In particular under this standard to work within the limits of knowledge and skill, and refer to others when needed, and use up-to-date evidence to deliver care (which would include using relevant guidance).

Standard 5: Use professional judgement.

In particular under this standard, to provide safe and effective care to make the care of the person the first concern and act in their best interests, have the information needed to provide appropriate care, and recognise the limits of their competence.

Standard 8: Speak up when they have concerns or when things go wrong.

In particular under this standard to challenge poor practices and behaviours, raise a concern even when it is not easy to do so, and promptly tell employers and all relevant authorities including the GPhC about concerns they may have.

Standard 9: Demonstrate leadership.

In particular under this standard to take responsibility for pharmacy practice, assess the risks in the care provided and do everything possible to keep risks as low as possible.

76. The committee bore in mind that the Standards may be taken into account when considering the issues of grounds and impairment but that a breach of the Standards does not automatically result in a finding of misconduct (Rule 24(11) of the Rules).

77. Before working with Instant E-Care the Registrant had over 20 years of experience including as a community pharmacist. The evidence indicates that over that time she well-understood her role as a pharmacist, acting as gate-keeper - she confirmed that she recognised and understood this description of the role of pharmacists. Her own evidence indicates that she had considerable knowledge of the risks that can come with medication, particularly with opioid-based medication: she had seen those who had become addicted to opioid-based medication and the desperate lengths they could go to in order to feed their addictions. She gave evidence that she had challenged doctors when she had experienced repeat opioid prescriptions issued in a way that raised, for her, concern about patient care. Her evidence is that she had alerted doctors when she was concerned patients may need monitoring, for example when patients had made excuses for having lost medication or sought repeat opioid prescriptions earlier than might have been expected.

78. In addition, in qualifying as a prescriber she had had to shadow a medical Doctor and repeatedly experienced the Doctor undertaking face-to-face consultations with patients when the doctor could assess the patient's presentation, physically examine the patient, delve further with them in discussion their medical history and presenting symptoms. She experienced doctors having access to patient medical records when confirmation and clarification of their medical history may be more accurately understood and concerns identified. Her evidence was that she understood the value of these things as part of the process of decision-making leading to the issuing of a prescription.

79. The insights gained by the registrant as a pharmacist and in training to be a prescriber were then underscored by her first experience employed as a pharmacist prescriber with BARDOC as a "triage pharmacist adviser". Whilst in this role she did not have face-to-face consultations with patients but she did have telephone consultations with patients, enabling her to undertake clinical assessments with direct experience with patients, and she had access to medical records of patients. In addition, she could readily require patients to attend in person for face-to-face consultations with other healthcare professionals with relevant skills and experience. She gave as an example that she would not prescribe antibiotics on the basis of a telephone consultation but would require patients to attend in person for face-to-face consultations. She gave evidence to the effect that she understood the value of direct consultation with patients and access to their health records to enable safe and effective prescribing decision.

80. The evidence is, and her admissions acknowledge, that she largely disregarded her previous insights and understandings when she took on her role as a prescriber with Instant E-Care. At Instant E-Care she had no interaction with patients. She relied on the Questionnaire completed by the patient. She could not see them to assess their presentation, or discuss with them their condition and needs to delve further to understand the detail of the information given in the Questionnaire. She gave evidence that she adopted an approach that patients would be honest in the

information given without considering that patients may give incomplete and/or inaccurate information or even dishonest information. Even when consent was given for a patient's GP to be contacted this was only infrequently done. Without contact with GPs she could not confirm and clarify what the patient had written in the Questionnaire, could not be alerted to factors that could impact on the decision to prescribe, and could not ensure that arrangements were in place for follow-up care.

81. How and why she came to act as she did is considered later in this determination. What is clear is that she failed to provide safe and effective care, over-rode the value she had previously experienced in face-to-face consultations and access to medical records, over-rode her understanding of the risks that come with medications, particularly the opioid medications, and over-looked her understanding that some patients may in desperation lie and mislead to obtain drugs. In the registrant's own words she *"opened up the gateway"* and that she did so without considering the consequences. She accepted in evidence that even if it had only been a repeat prescription service as, in her evidence, it had been *"sold"* to her as being, the professional obligations on her about the care required to issue a prescription did not change. She acknowledged that she was aware of the RPS guidelines for prescribers but that *"it was almost forgotten"*, that she considered the Questionnaire sufficient consultation, that by not contacting patient GPs she was respecting patient confidentiality and she was improving accessibility to health care.

82. An expert witness for the Council described her approach in issuing prescriptions as *"transactional"*: a patient order medication and she issued a prescription for its supply. The committee agrees with this description given the evidence, not least of all the registrant's own evidence. She was issuing prescriptions on request in a similar manner in which medication is dispensed according to a prescription, *"blurring"* the roles of a prescribing and a dispensing pharmacist. Her evidence was that she *"lost the patient in the journey"* and that she "*saw the patient Questionnaire as the patient in front of her"*. She could not have undertaken meaningful consultations or clinical assessments required when prescribing medicines that brought with them significant risks, including opioid based medicines. As evidenced by the expert, there were instances when orders for medication were refused but that this occurred because of policies adopted by the pharmacy rather than as a result of a clinical assessment of a patient.

83. **Accordingly, the committee concluded that, in its judgement, the ground of misconduct is established.**

84. The committee therefore did go on to consider whether the Registrant's fitness to practise is impaired.

Decision on Impairment

85. Having found that the particulars of allegation amounted to misconduct, the committee went on to consider whether the registrant's fitness to practise is currently impaired. In doing so the committee considered (as required by Rule 5(2)) whether the particulars found proved show that actions/omissions of the registrant that:

a. present an actual or potential risk to patients or to the public

b. has brought, or might bring, the profession of pharmacy into disrepute

c. has breached one of the fundamental principles of the profession of pharmacy

d. means that the integrity of the registrant can no longer be relied upon

86. In the circumstances of this case, the committee considered these factors in reverse order, as follows.

87. Integrity: a lack of integrity is not alleged in this case. The Council has not relied on this factor in support of a finding of impairment. On behalf of the registrant, it was submitted that this is not a case concerning a lack of integrity. The committee agrees with this submission. The evidence indicates that the registrant has been a conscientious and well-meaning pharmacist who has sought to perform her role in the interests of patients, albeit in a misguided manner whilst at Instant E-Care. The committee is satisfied that her failures were not motivated by greed or financial gain. In this regard, there is evidence that she earned well from her employment with Instant E-Care but that she (a) capped her income at £3,000 a month when it could have been more, and (b) on her account chose to leave Instant E-Care when she concluded the practices there were not safe.

88. Accordingly, the committee did not find current impairment on the grounds of a lack of integrity.

89. Public Confidence and Professional Standards: the committee is satisfied that the registrant's misconduct is so serious that it has brought the profession of pharmacy into disrepute and has breached fundamental principles of the profession. The committee is further satisfied that there needs to be a finding of current impairment in order to promote and maintain both public confidence and professional standards.

90. In terms of the seriousness of the misconduct the committee has found that the registrant failed to meet five of the seven standards set out in the Council's 2012 Professional Standards document, and seven of the nine standards set out in the Council's 2017 Professional Standards document. That so many standards have been breached, and breached repeatedly over time, affecting multiple patients and in ways that gave rise to a significant risk of harm, and evidence of actual harm, that the misconduct can only be regarded as serious.

91. Further, in reaching a conclusion on the seriousness of the misconduct, the committee takes into account the following:

a. Over an extended period of time registrant was issuing prescriptions for high-risk drugs

b. She was prescribing substantially outside her competency or scope of practice

c. She was doing so on a transactional basis without undertaking the required clinical assessment

d. She was not following relevant guidance relating to the medication and the treatment of relevant conditions including NICE guidance

e. She was not following the relevant guidance for the practice of prescribing, including the guidance of her own profession, the RPS 2016 guidance

f. The admissions cover twelve specific patients involving opioid medications and Z drugs which alone make the matter serious

g. In addition to the twelve specific patients, she prescribed on five occasions opioid medication to Patient P, giving rise to a risk of very serious harm. The evidence shows that Patient P and her family suffered very substantially as a result of the drugs Patient P was able to obtain

h. In addition, the registrant provided on one occasion to Patient Q who, over a year later, died. Her death was held to be drug related. Plainly, there is a significant passage of time between the registrant's involvement and Patient Q's death, during which other prescribers and pharmacists may well have engaged with Patient Q. Nonetheless, the registrant's failings in prescribing opioid medication was a link in a chain that ended with Patient Q's death. The registrant failed to conduct the required clinical assessment, failed to contact Patient Q's GP, failed to consider the possibility of drug misuse/abuse/dependency and acted outside the scope of her competence and the scope of the pharmacy service, and failed to follow professional guidance. The registrant has herself, on a number of occasions during the hearing, voiced her own sense of responsibility for her failings towards Patient Q and the events that followed.

Individually and collectively, these factors make the misconduct more serious.

92. Furthermore, what emerges from the evidence is that the circumstances in which the registrant prescribed high risk medication to the patients listed in the Allegation reflected her prescribing practice more generally at the time, in particular, the reliance on the Questionnaire, the failure to contact GPs for clinical records, the failure to ensure follow-up care was in place when required, and the failure to comply with relevant guidance. Practicing in this way inevitably gives rise to a risk of causing harm to patients who may be inappropriately prescribed medication. The precise number of patient's effected in this way is not established on the available evidence. However, in the registrant's own evidence it was "most days" when she

was prescribing opioids and it was “not a rarity” but “day-to-day say five or six or so” when she was prescribing opioid based medications. In her evidence, in reference to Patient P and Patient Q, the registrant acknowledged that she “opened a gateway without consideration for vulnerable patients like Patient Q” and that there would have been other patients “some genuine patients but there have been plenty for whom avenues opened and I was part of that”. The committee is clear that on the facts of the Allegation alone the misconduct is serious. However, what emerges from the evidence is the wider scale of the misconduct which goes to underscore the committee’s conclusion that the misconduct is serious and in need of marking by way of a finding of impairment both to maintain public confidence and professional standards.

93. A finding of impairment sends a clear and unambiguous message to the public. The public must be re-assured that such serious failings are unacceptable. The public must be reassured that the fundamental principle of the profession, to put patient interests first, is properly understood and applied faithfully. It is not in the interests of patients to expand access to health care whilst failing to apply fundamental standards that protect patients from harm. It is not in the interests of patients to prescribe high-risk drugs without appropriate access to medical records on the basis of respecting patient privacy. It is not in the interests of patients to prescribe medication when there has not been an appropriate clinical assessment justifying the prescription nor appropriate follow-up care put in place. It is not in the interests of patients to fail to comply with professional guidance. It can be in the interests of patients not to prescribe medication even when a patient asks for the medication.

94. The message to the profession must be that if a pharmacist takes on the role of being a prescriber, the pharmacist has personal responsibility for each and every prescription issued: it is no answer to claim compliance with an organisation’s processes when it ought to be obvious to a pharmacist that the processes are not safe. Professionals must be familiar with and apply professional standards and relevant guidance. This applies to compliance with guidance about both the practice of prescribing such as the RPS guidance and guidance about specific medication/treatments such as NICE guidance. Pharmacists who are qualified to prescribe must stay within their scope of practice and assure themselves that any extension to their scope of practice is supported by training, experience and demonstrable competence. The standards make it clear that they “are professionally accountable for [their] practice” and “responsible for what [they] do or do not do, no matter what advice or direction your manager or another professional gives [them]” (2012 Standards document page 7). The professional expectations are personal to each pharmacist: “Pharmacy professionals are personally accountable for meeting the standards and must be able to justify the decisions they make” (2017 Standards document, paragraph 13). Pharmacists must understand that they are held in public trust to act as gate-keepers, managing the appropriate release of medication from the secure supply chain into the community, and that when they fail in this role they are accountable.

95. In reaching the conclusion that a finding of current impairment is needed to maintain public confidence and professional standards, the committee has taken full account of the submissions made on behalf of the registrant. In particular, the committee has taken into account the passage of time since the facts that led to this hearing, that she has continued to work both in a clinical setting and as an academic teaching to undergraduate pharmacy students, and that there have been no further concerns reported. However, the committee is satisfied for the reasons given above that the failures are so serious and extensive that a finding on impairment on the grounds of professional standards is needed in order to send a clear and unambiguous message of reassurance to the public and of the need to adhere to standards to other professionals.

96. Risk to patients or the public. The committee has considered the final factor listed in Rule 5(2)(a). Having given this issue particularly anxious and careful consideration, the committee has reached the following conclusions:

a. It is clear from the evidence that at the time of the facts of this case, between March 2015 and May 2019, the registrant presented a very significant risk of causing serious harm to patients given her approach to prescribing high risk medication both in respect to the patients listed in the Allegation and in her prescribing practise more generally.

b. There is evidence that the risk presented by the registrant has reduced over time.

c. However, the committee is not satisfied that there is enough evidence to conclude that she has reduced risk sufficiently to the extent that she no longer presents an actual or potential risk to patients or the public.

97. The reasoning that she presented a risk at the time of the misconduct is set out in the reasoning given above. The evidence shows that the registrant's approach to prescribing high risk drugs was transactional, failed to undertake required clinical assessments, failed to follow guidance and failed to put in place follow-up care when appropriate. The tragic consequences for Patients P and Q and their families evidence the very substantial harm that can follow when registrants do not adhere to standards in the way the registrant failed to adhere while working at Instant E-Care.

98. There is evidence that the registrant has made progress in rehabilitating herself to recover her professionalism and compliance with standards. This evidence comes from a number of sources:

a. The registrant's oral evidence and her written statements, reflective writings and written case studies. These clearly show that the registrant has an understanding of how she failed and what the consequences are. There is evidence that maps the registrant's current understanding of what is expected against the expectations set out in Dr Campbell's report describing the circumstances in which safe and effective prescribing may occur. This includes the vale of face-to-face consultations, the importance of accessing medical records, the importance

of following professional guidance and the importance of establishing 'safety-netting' procedures to ensure continuity of follow-up care where required.

b. Evidence from the University where the registrant is employed to lecture pharmacists on matters including the law, ethics and practice of being a pharmacist and prescriber. As Mr Hadley submitted, the University has risked its reputation by engaging her to lecture but has done so on the basis that senior academics, aware of the allegations against the registrant, have assured themselves about her abilities. The registrant's bundle includes testimonials from senior academics who write highly of their impression of her as a pharmacist, prescriber and educator, including the fact that she has (to some degree) been open with students about her own failings in order to impress upon students the lessons that follow from her failings.

c. Evidence from her current employers at E-Med (formerly Babylon) where she practices as a pharmacist prescriber and has done so for some years now. Testimonials refer to her *"adhering to best practice"*, *"provided care by risk assessing patients and managing them alongside relevant local and national guidance"*, and in which she is regularly audited *"With an impressive notes audit score of 99%, compared to the pharmacist average of 90%"* and *"showcases her commitment to meticulous documentation and ensuring comprehensive patient records".*

d. It is now five years since she left Instant E-Care in May 2019 with no further concerns being recorded against her. She joined Babylon (now E-Med) as a prescriber in July 2019 (according to the reference of an Associate Director of Pharmacy at Babylon, KP) and remains working there. Over that time no complaints about her prescribing practices have been brought to the committee's attention.

99. Taken collectively, this evidence is indicative of the registrant having learnt lessons from her misconduct and put them into practice in a way that would reduce risk of harm to patients. That she has, to some degree, been able to recover her professionalism is underscored by the fact that before she worked at Instant E-Care she had many years of experience as a Community Pharmacist unblemished by any regulatory concern.

100. However, the committee concluded that there are limitations to the evidence of the progress she has made to recover her professionalism.

a. The registrant's own evidence is inevitably self-serving. The registrant had over twenty years of experience as a pharmacist in clinical settings before joining Instant E-Care. The standards expected of her to practice professionally were understood by her before she joined Instant E-Care. As referred to below, it is not clear why she failed to adhere the standards whilst at Instant E-Care. As it is, the committee anticipates that had she been asked at the time she was working at Instant E-Care whether or not she was complying with standards she would have

replied “Yes” – her evidence to the committee is that she believed at the time she was at Instant E-Care that she was meeting professional standards. At that time she thought she was putting patients first, was working within her competencies, and was undertaking appropriate clinical reviews. Since stepping away from Instant E-Care it is evident that she has reflected on her misconduct and now articulates the standards in a more developed way. What is less clear, is the degree of risk of her relapsing again in her professionalism despite having gained additional insights on what the standards actually require of her.

b. The evidence from the University is in the form of testimonials rather than sworn statements, written or oral. Nonetheless, the committee accepts the contents of them as reflecting the registrant’s performance at the University, albeit the contents of the statements have not been tested. The testimonials indicate that the registrant is able, within an academic setting, to articulate the standards expected of pharmacists and pharmacist prescribers. This again reflects what the committee would expect of the registrant given her experience and her evident reflection since her misconduct. However, being able to articulate standards in an academic setting is not necessarily the same as applying those standards in a clinical setting.

c. The evidence of colleagues at her current, clinical, place of work is also in the form of testimonials rather than sworn evidence, written or oral. Nonetheless, the committee accepts the contents of them as reflecting the registrant’s performance at E-Med (formerly Babylon), albeit the contents of the statements have not been tested which may have been of assistance to the committee. The testimonials indicate that the registrant is able, within a clinical setting, to apply the standards expected of pharmacists and pharmacist prescribers. This again reflects what the committee would expect of the registrant given her experience and her evident reflection since her misconduct. However, there are just three testimonials from E-Med (formerly Babylon), her current clinical place of work. Her own evidence, supported to a limited degree by the testimonials, is that: her work there is within relatively limited parameters of her scope of prescribing practice, only rarely involving opioids; where there is an established peer group within which she works and can seek advice; has had a mentor, and is regularly audited for the quality of her work; where she can readily refer patients to others when their presenting condition is outside her limited scope of practice for example referring dental patients to dentists; and where she readily has access to patient medical records. The evidence is indicative of her undertaking safe practice and that the risks she presents are reduced. However, the committee’s concern is not just that the evidence from her clinical work place is limited to three untested testimonials, but it may also simply indicate that she can meet standards when supported rather than because of her own professional abilities and can meet standards in relatively unchallenging work. The committee is therefore concerned about whether the evidence from her clinical work place actually demonstrates she has remediated her failings or whether she could again

relapse into poor practices if she were to work in a clinical setting with less support or operating less safe practices.

d. Finally, whilst it is positive that no concerns have been expressed to the regulator about her practice over the past five years, it is unclear whether her professionalism has actually been tested to a significant degree. It appears that her work within the clinical setting at E-Meds is undertaken within a safe working environment with appropriate governance arrangements (so far as this committee can assess) and she undertakes a relatively limited scope of practice. It may therefore be unsurprising that no concerns are recorded, but not necessarily indicative of risk having been sufficiently addressed.

101. In addition to the above, the committee has two further concerns.

102. First, the committee remains unclear about how the registrant, an experienced pharmacist, came to fail in her professional obligations over an extended period of time whilst working at Instant E-Care. The registrant was an experienced community pharmacist at the time she joined Instant E-Care. Through her experience she had seen the value of face-to-face consultations and telephone consultations with patients; seen the benefit of having access to medical records; understood the need for clinical aftercare; was aware of relevant guidance; and knew about the dangers with high-risk drugs including opiates and the risks that patients may be misusing and abusing drugs to a degree that they be desperate enough to lie or mislead in order to get more drugs.

103. She has suggested that she was “naïve” whilst working at Instant E-Care, but she was not naïve in ways that mattered given her many years of experience and previous application of standards that she subsequently breached at Instant E-Care. She has suggested that she was “excited” about being involved in “innovative and groundbreaking” ways of delivering pharmacy services, yet in this scenario the professional response would be to proceed with care with a new model of delivering services, not to abandon previous practices that underpinned patient safety. She has suggested that she placed over-reliance on the systems and processes put in place by the SI and the SI’s assurances when challenged. Yet, the committee notes, that the registrant was more qualified and more experienced than the SI and was well placed to question and challenge the SI’s assurances or to leave sooner than she did given the unsafe practices adopted.

104. Remediation is the process of putting right what has gone wrong so that the wrong is not repeated. Remediation will often start with an acceptance that things have gone wrong and an understanding of how that came about so that the causes can be addressed. The registrant accepts that she did wrong. It is not clear that the registrant fully understands how she came to fail as significantly as she did – she refers to her “excitement” at joining Instant E-Care and her naivety and other matters referred to above. However, in an early response to the allegations brought by the council she wrote: “I reflect back and still cannot understand how I was drawn in to

such an awful situation." This was reflected in her oral evidence to the committee: when pressed to explain how she came to fail in the ways that she did, she had, in the committee's judgement, no substantive and comprehensive explanation. The committee remains unclear as to how she came to act as she did. The committee is satisfied that understanding how things went wrong is not a necessary pre-curser to achieving remediation, but the committee does hesitate to conclude that sufficient remediation has been achieved when that understanding of 'how' is not yet as clear as may be wished for. It may be that 'how' such an experienced pharmacist came to fail to the extent that she did will never be fully clear but in this instance, the committee will take particular care before concluding that the failings have been remediated, especially when the risks of harm are so serious and significant.

105. Secondly, and linked to the above, the registrant has described herself as a *"people pleaser"*, and that this characteristic in part explains how she came to fail. The context of this case is that she was excited to be part of a new model of delivering pharmacy services, a model that she believed would increase accessibility to health care. The committee understands her *"people-pleasing"* characteristic led her to be pleased to help the SI when asked to work for Instant E-Care, and pleased to write prescriptions for patients who sought medication. Her evidence is that she now recognises this trait in her as a weakness and that she has learnt to say *"No"*, to challenge others when appropriate and that she teaches this as part of her lecturing to students. In her oral evidence she acknowledged that her 'people pleasing' traits remained a *"threat"* to her. The panel accepts that to a degree recognising a weakness is a significant step towards managing it. There is evidence in her own evidence and reflections, and to a lesser degree in the testimonials from her clinical colleagues, of her managing her work within her restricted scope of practice including by declining to assist patients but by arranging for them to be served by other healthcare professionals with the relevant skills. The committee gives the registrant credit for this evidence. However, the committee is not satisfied that it has sufficient evidence of her willingness now to say *"No"* has been adequately tested and would be deployed when under greater pressure or in less managed circumstances.

106. Taking the above analysis overall, the committee concludes that it is not satisfied that the registrant has now reduced the risks she presented at the time of the misconduct to a degree that there is no meaningful actual or potential risk to the public. The committee concludes that there remains a risk to the public albeit reduced from what it previously was.

107. In these circumstances, the panel does make a finding of current impairment on the basis that the registrant presents an actual or potential risk to patients or the public.

108. Finally, the committee records here that in reaching its conclusions on impairment, the committee has taken account of a number of matters for which the registrant deserves some credit. These include:

a. That aside from this matter, the registrant has had a long an unblemished career spanning the time that she was with Instant E-Care and is well-regarded by those she currently works with both in her academic setting and in her clinical setting. She attracts credit or this when assessing current impairment, though this is significantly off-set by the seriousness of her misconduct.

b. There is evidence that she was misled by the registration of the pharmacy with the regulator and her awareness of the regulator's engagement with the SI. However, her evidence is that she allowed herself to be misled by the SI as to the significance of the regulator's engagement and did so to a degree that over-rode the safety issues that should have been apparent to her given her experience, including the limitations of prescribing from a questionnaire without being able to consult patients in a meaningful way or being able to access GP records.

c. There is evidence, from the registrant, that the registrant challenged the SI as to the clinical practice at the pharmacy but that overall she allowed herself on her evidence, to be rebuffed, and continuing to practice in an unsafe model for the delivery of the prescribing service when her considerable previous experience as a pharmacist should have alerted her to the safety issues and to take action other than continuing to engage with an unsafe model. There is evidence that after the concerns regarding Patient P came to light in 2018, the registrant chose to stop issuing prescriptions for opioids being concerned about patient safety issues. The registrant deserves credit for this. However, on her account she allowed herself to be reassured and subsequently resumed issuing prescriptions for opioid medication right up to the time she left at the end of May 2019, on her account because she was concerned for patient safety. She ought to have realised sooner that the model continued to be unsafe given the reliance on the questionnaire, the absence of access to GPs and medical records, and the fact that clinical aftercare was not being arranged.

d. The committee gives the registrant credit for the very considerable remorse she has demonstrated, remorse for her failings and the impact this has had on patients, the profession and the wider public.

e. The committee has also taken into account, when appropriate, the very considerable amount of time since the misconduct occurred and that she has been under the regulatory process.

109. **Accordingly, for all these reasons, the committee finds that the registrant's fitness to practise remains currently impaired.**

110. The committee therefore continued to the next stage of these proceedings, namely to consider what if any sanction should be imposed.

Decision on Sanction

111. Having found impairment, the committee has gone on to consider the matter of sanction. The committee's powers are set out in Article 54(2) of the Order. The

committee should consider the available sanctions in ascending order from least restrictive, namely to take no action, to most restrictive, namely removal from the register, in order to identify the appropriate and proportionate sanction that meets the circumstances of the case.

112. The purpose of the sanction is not to be punitive, though a sanction may in fact have a punitive effect. The purpose of the sanction is to meet the overarching objectives of regulation, namely the protection of the public, the maintenance of public confidence and to promote professional standards. The committee is therefore entitled to give greater weight to the public interest over the Registrant's interests.

113. The committee had regard to the Council's 'Good decision making: Fitness to practise hearings and outcomes guidance' March 2024 to inform its decision.

114. On behalf of the registrant, the committee was provided with a letter from an NHS Foundation Trust dated 22 August 2023 providing a summary of the registrant's engagement with the specialist services provided by the Trust. The contents of that letter, relating to the registrant's health was considered in private by the committee.

115. The committee took into account the submissions made by Mr Buckley on behalf of the Council and by Mr Hadley on behalf of the registrant.

116. On behalf of the Council, Mr Buckley submitted that the facts of the case and the findings of the committee established that this is a serious matter. He identified aggravating and mitigating features. In his submission, the appropriate sanction was of the maximum period of 12 months suspension from the register.

117. On behalf of the registrant, Mr Hadley submitted that the registrant had acknowledged the seriousness of the case, had done so from early on in the process, accepted that her practice at the time gave rise to a risk of harm, referred to the evidence that this occurred at a difficult time in her life, referred to the committee's finding that the risk of her repeating her failings and of again putting others at risk of harm had reduced and referred the committee to the evidence of insight and remediation. He submitted that the misconduct needed to be seen in the context of an otherwise unblemished career including the five years since the facts arose when she has undertaken a prescribing role and no concerns have been reported about her practice. Mr Hadley referred the committee to the testimonials given by professionals who valued her work as a pharmacist, the impact the five years has had on her, her engagement with the regulatory process, and referred the committee to the public interest in not ending the career of an otherwise competent professional. Mr Hadley invited the committee to consider all the sanctions available to it save that in his submission this was not a case that needed the ultimate sanction of removal.

118. The committee received and agreed the advice of the Legal Adviser.

119. The committee first considered what, if any, aggravating and mitigating factors there may be.

120. The committee identified the following aggravating factors, including:

a. The misconduct affected a number of patients, fourteen on the face of the Allegation. The registrant's own evidence was that "plenty" more patients could have been affected.

b. The misconduct endured over a period of time. The evidence indicates that opioids were only available from Instant E-Care from late-2017. The Allegation concerns prescriptions issued by the registrant, including for opioids, between 8 January 2018 (Allegation Particular 18) and 29 May 2019 (Allegation Particular 7), about the time that she left Instant E-Care. The committee acknowledges that there was a period when, on her account, she chose to stop prescribing opioids following the reported concern involving Patient P in June 2018 and her concerns about patient safety, but that she subsequently returned to prescribing opioids for a period before she left the pharmacy – the Allegation relates to her issuing prescriptions, including for opioids throughout April and May 2019. The relevant period therefore appears to be the first half of 2018 and the two months of April and May 2019 when the registrant was issuing prescriptions for opioids. The registrant's evidence was that she was prescribing opioids "most days". On this analysis, the misconduct can be described as prolonged and repeated.

c. The medication she was prescribing involved high-risk drugs, drugs that may be subject to misuse/overuse/abuse and dependency, and drugs that required follow-up care to ensure safe use.

d. Given her experience, it ought to have been obvious to her that the systems used at Instant E-Care did not enable safe clinical assessments to be undertaken. She ought to have known not to place reliance on the Questionnaire in the way she did. It ought to have been obvious to her the risks that arose when there was no direct consultation with patients, no engagement with GPs to enable access to medical records and to ensure continuity of care.

e. She ought to have had in mind the significant risks with high-risk drugs such as opioids, in particular the risks of misuse, overuse, abuse and dependency, yet she gave no thought to these matters.

f. She ought to have followed the existing guidance both in relation to working within the online setting and prescribing medicines and treatments. Her evidence was that the Royal Pharmaceutical Society 2016 guidance was *"almost forgotten".*

g. The evidence is that she gave no real thought to the risks of prescribing high-risk drugs through the online pharmacy. This is an aggravating feature. Pharmacists must put patient interests first. Patient safety is a priority. To give no sufficient thought to the obvious patient safety issues, and to continue issuing prescriptions, is a serious matter.

h. The registrant's conduct amounts not only in a failure to meet her professional obligations, but a breach of public trust in pharmacists.

121. On the issue of harm caused, the submission on behalf of the council was that the registrant's misconduct led to potential and actual harm. Mr Hadley's submission was that there was no evidence that the registrant's misconduct had led to actual harm. The committee does not entirely accept Mr Hadley's submission. In relation to the twelve patients listed in the Allegation under the heading "Specific Patients", the registrant's prescribing practice was dangerous and gave rise to potential harm to patients. In relation to Patient P, her addiction to opiates was ongoing and causing her and her family actual harm: the registrant issued five prescriptions to Patient P without undertaking an appropriate clinical assessment; had she done so, she may not have issued the prescriptions. There is evidence that five prescriptions issued by the registrant were dispensed and dispatched to Patient P. It is reasonable to conclude that the prescriptions issued by the registrant contributed to the ongoing actual harm suffered by Patient P and her family. In relation to Patient Q, the committee has already held that the registrant's failings in prescribing opioid medication to Patient Q was a link in a chain that ended with Patient Q's death over a year later, albeit that the registrant's responsibility is not a direct cause of her death. The registrant has expressed her own sense of responsibility for events that led to Patient Q's death. Taken overall, the committee is satisfied that the registrant's prescribing practice was dangerous because it gave rise to a risk of serious harm being suffered by patients and, to a limited but significant degree, actual harm.

122. The committee identified the following mitigating factors, including:

a. The evidence indicates that aside from the concerns that arose in this case, the registrant is a caring pharmacist who has worked over a long and otherwise hitherto unblemished career of 31 years to help patients.

b. The committee has concluded that her misconduct was not motivated by greed or financial gain.

c. There is evidence that the registrant challenged the pharmacy SI about the safety of its practices, and stepped back from prescribing opiates for a period after the concerns about Patient P arose, and did ultimately leave the pharmacy because of her concerns.

d. The registrant has admitted her failings, did so fully and from an early stage of these regulatory proceedings, and shown that she takes responsibility for them.

e. She has engaged fully and right from the beginning with the regulatory process and this hearing.

f. Her sense of remorse has been evident during this hearing.

g. She has apologised for her failings in writing, orally to this committee, and directly to the Mother of Patient Q who attended the early stages of this hearing.

h. It is also to the registrant's credit that she has been open with others about her failings, including at her places of work.

i. The registrant has undertaken a very significant amount of reflective work in an effort to understand how and why she failed and how she can ensure that she does not fail again. Her written reflective pieces evidence significant insight and work to address the issues of concern identified in Dr Campbell's report.

j. The many testimonials from a range of professionals, including pharmacy professionals, and the evident support that she had from the University is to her credit.

k. The committee has concluded that the risk of her repeating these failings has reduced.

l. It is a fact that she has been practicing as a pharmacist prescriber for the past five years since leaving Instant E-Care and has done so without any reported complaint or concern.

123. In addition, the committee does, to a limited degree, find as a mitigating factor, the adverse impact of these regulatory proceedings have had on the registrant. That adverse impact has been apparent to the committee during the hearing, and is evidenced by medical reports available to the committee. However, insofar as the impact may be a mitigating factor it is limited in weight. Had the purpose of these proceedings been to punish the registrant for her misconduct, the adverse impact may have weighed more. However, the purpose is not to punish. The purpose of these proceedings is the protection of the public, the maintenance of public confidence in the pharmacy profession and to promote professional standards. In this context, the adverse impact of the time taken to bring this matter to a resolution is of limited weight.

124. Mr Hadley submitted that the committee should take account of the fact that her misconduct occurred following the death of her mother in June 2013, her father having died some years earlier. The registrant gave evidence of a "rebellious" phase in her life following the death of her mother. The registrant's evidence was that this "rebellious" phase contributed to her decision to join the online pharmacy in 2015 but that rebelliousness was not part of her decision-making when issuing prescriptions in the years with which this hearing has been concerned, 2017 - 2019. Given this evidence, the committee does not attach significant weight to the personal circumstances of the registrant at the time of her misconduct.

125. The committee also noted its earlier finding that 'why' the registrant misconducted herself as she did remains unclear. The committee does not regard this as an aggravating or mitigating factor: it is a factor that went to the risk of repetition which is a matter the committee should take into account when considering sanction.

126. The committee went on to consider the options available to it, starting with the least restrictive.

127. To take no action. The committee is satisfied that to take no action would not be an appropriate outcome given the seriousness of the findings made against the registrant and that it had identified a risk of repetition.

128. Warning. The committee is satisfied that to issue a warning would not be an appropriate outcome given the seriousness of the findings made against the registrant, that it had identified a risk of further harm and the need to give a clear and unambiguous message to both the public and the profession that professional standards are to be adhered to and failings to do so that give rise to a significant risk of harm will be taken seriously.

129. Conditions of Practice. The committee next considered the imposition of conditions of practice. A Conditions of Practice Order would allow the Registrant to practise albeit with restrictions. The committee must determine whether a Conditions of Practice Order would be appropriate given the concerns identified regarding the Registrant's practice, in particular whether conditions would protect the public from harm, be sufficient to mark the seriousness of the matter so as to maintain public confidence in the Registrant, the profession and the regulator, and sufficient to promote professional standards within the profession.

130. The committee was unsure whether it may be possible to formulate conditions of practice that would manage the risk of repetition. However, the committee was satisfied that a Conditions of Practice order would not be sufficient to mark the seriousness of the committee's findings against the registrant or be sufficient to send an unequivocal message of reassurance to the public or an unequivocal message to the profession about the importance of adhering to professional standards.

131. Accordingly, the committee was satisfied that a Conditions of Practice order was not appropriate in this case, given the seriousness of the misconduct.

132. Suspension Order. The committee next considered whether suspension would be a proportionate sanction. The committee noted the Council's guidance which indicates that suspension may be appropriate where:

"The committee considers that a warning or conditions are not sufficient to deal with any risk to patient safety or to protect the public, or would undermine public confidence."

And

"When it is necessary to highlight to the profession and the public that the conduct of the profession is unacceptable and unbefitting a member of the pharmacy profession. And when public confidence is the profession demands no lesser outcome."

133. The committee is satisfied that a suspension order would manage the risk of repetition.

134. The committee is, after anxious consideration, also satisfied that a suspension order would be sufficient to mark the seriousness of the registrant's misconduct and to

send an unequivocal message to both the public and the profession about the seriousness of this matter and the importance of pharmacists adhering to professional standards.

135. In reaching this conclusion, the committee has weighed the aggravating and mitigating factors. The registrant's failure to adhere to professional standards, to not follow existing guidance, and to adopt a dangerous prescribing practice that has led to potential harm and actual harm, is very serious.

136. Balanced against this, the committee weighs her early admissions, the evident sense of responsibility she has for her failings and not trying to blame others, and her apology to those affected. In addition, having accepted responsibility early on, she has been able to spend a substantial amount of time undertaking reflective practice: reflecting on what she did wrong and the impact, reviewing the areas of concern identified in Dr Campbell's report and challenging herself about them, and gaining significant insights on how to avoid a repeat of her failings. She has been able to work over the past five years without a concern being reported about her. The testimonials about her are positive. The committee is satisfied that the substantial work she has undertaken has reduced the risk of repetition. The committee is satisfied that she was not motivated by greed and financial gain.

137. The committee also acknowledges that there is a public interest in maintaining pharmacists who can provide safe services to the public. The evidence suggests that in due course the registrant may be able to do so.

138. The committee has considered the time period for the suspension order. Given the seriousness, the committee is satisfied that the maximum period of 12 months is warranted.

139. Removal from the register. To ensure the committee reaches a proportionate conclusion, it is required to consider the next available sanction, which would be removal. The committee is satisfied that removal in this case would not be a proportionate and appropriate sanction.

140. The committee makes it clear that the registrant has avoided the ultimate sanction of removal by the narrowest of margins.

141. In reaching this conclusion, the committee has balanced the public interest against the registrant's own interests. The public interests include the protection of the public, the maintenance of public confidence and the promoting of professional standards. The committee has set out above the significant degree to which each of these public interests are engaged in this case. With regard to the registrant's interests, the committee has in mind her interest in pursuing her chosen profession, the financial impact on her of a sanction – and in this regard the committee notes the evidence regarding the significance of her income in her family life – and takes into account the significant impact the sanction may have on her personal life. The committee is entitled to give greater weight to the public interest than the

registrant's own interests and in this case the committee is satisfied that the public interest significantly outweighs the registrant's interests given the seriousness of the findings in this case and took proportionate account of this when deciding the sanction.

142. **Accordingly, the committee directs the Registrar to suspend the name of Alison Lesley Cooper (registration number 2040218) from the register for a period of twelve months.**

Review Hearing

143. The committee directs that this sanction must be reviewed by the committee before it expires.

144. When reviewing the matter the committee may be assisted by:

a. Further reflective writings from the registrant, that may include application of professional standards and professional guidance.

b. Evidence that she has maintained her skills and knowledge through CPD.

c. It is a matter for her, but she may wish to seek additional evidence from her current clinical place of work to evidence her safe practice and the means by which her employers have assured themselves about her prescribing practice.

d. Updated references.

e. Evidence of any additional training, mentoring or coaching she has undertaken.

Interim Measures

145. Interim measures are provided for under Article 60 of the Order. Interim measures may only be imposed after an order for removal, suspension or conditions of practice. The purpose of an Interim Measure is to manage risk between the making of the substantive sanctions order and it coming into effect after the 28-day appeal period or at the conclusion of any actual appeal, depending on the outcome of such an appeal.

146. On behalf of the Council an application was made for an Interim Measure of Suspension to be imposed. The application was made on the basis of risk to the public and the wider public interest given the seriousness of the case and the findings of the committee.

147. On behalf of the registrant Mr Hadley indicated that the registrant did not oppose the application.

148. The committee accepted the advice of the Legal Adviser and took account of the Council's relevant guidance.

149. The committee acknowledges that the registrant has been working for the past five years in a role requiring her registration and has done so without a concern being reported against her. However, at the conclusion of this case, the committee has found that she presents a risk of harm, albeit reduced from the time of the misconduct, and that her misconduct is so serious it needs to be marked by way of a suspension order for the maximum period possible.

150. Those findings apply now, and it would be inconsistent of the committee not to now impose an interim measure of suspension, which it does, in order to protect the public and that to do so is otherwise in the public interest.

151. **The committee therefore grants the application for an Interim Order of Suspension order.**

152. The interim measure of suspension comes into effect immediately. It ends either at the end of the 28 day appeal period if there is no appeal, at which time the substantive order of suspension will come into effect, or it will come to an end at the conclusion of any appeal process, when the substantive suspension order will either come into effect or not depending on the outcome of the appeal.

Concluding observations

153. Before concluding this determination, the committee has two observations to record.

154. First, the time span between a concern being first expressed (Patient P's husband reported his concern to the Council on 18 June 2018) and this hearing starting in March 2024 but only ending in June 2024. The remit of this committee has been to review the registrant's conduct; it has not been to review the conduct of the case being brought. The committee acknowledges that it does not know the 'ins and outs' of what has occurred over that time span. Nonetheless, the committee does express concern about how long it has taken to reach a resolution of the case. Regulation, to be effective, needs to be timely.

155. Related to this, it remains unclear to the committee how or why the Council *"unilaterally"* cancelled the original dates scheduled for this hearing in October 2023 (as Mr Hadley has described it and unchallenged by Mr Buckley who advised the committee that he did not have instructions to explain either the legal basis on which the Council cancelled a hearing nor the reasons for doing so). The effect, however, is that the registrant had to wait a further six months for the hearing to commence. The adverse impact on the registrant of the time taken to resolve this matter has been obvious and is evidenced by reports seen by the committee. The committee makes it clear that any concerns that arise about this time span and the impact of it

are not directed at Mr Buckley who was more recently instructed to represent the Council at this Principal Hearing.

156. Secondly, it may well be that the provision of pharmacy services online brings benefits to society. However, as the Council's guidance acknowledges, it also brings with it risks. The circumstances of this case highlight those risks and the very great harm that can follow if risks are not adequately managed, and services not delivered safely. Plainly, managers and pharmacists engaged with the provision of online services carry a responsibility for managing risk and ensuring safe practices. Overarching them is the regulator which sets the regulatory framework within which online pharmacies operate. The regulator has a responsibility to ensure that regulatory processes are in place to manage risk and promote safe and effective practice. This can include the training and education of pharmacists, the provision of guidance, and the enforcement of standards.

157. In the committee's view, every senior leader of the Council should read the statement made to the police by the Mother of Patient Q dated 19 August 2019 and read the statement made to the Council by Witness E, husband to Patient P. Those statements are heartbreaking to read. They act as powerful reminders of the importance of effective regulation and the grievous harm that may follow when pharmacists do not meet professional standards.

158. The committee has heard during this hearing that within the near future it is planned that every pharmacist will have the ability to prescribe. The regulator will want to ensure that the most effective regulatory arrangements are in place, and every pharmacy professional will need to ensure that they live up to the standards expected of them, if further tragedies are to be avoided.

159. This concludes the determination.