Neutral Citation Number: [2025] EWHC 2270 (Admin)

Case No: AC-2024-LON-003354

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 05/09/2025

Before :

THE HONOURABLE MRS JUSTICE LAMBERT

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Between :

THE KING **on the application of** **(1) ANAESTHETISTS UNITED LIMITED** **(2) MARION CHESTERTON** **(3) BRENDAN CHESTERTON**	**Claimant**
- and –	
GENERAL MEDICAL COUNCIL	**Defendant**
- and –	
(1) BRITISH MEDICAL ASSOCIATION **(2) ASSOCIATION OF ANAESTHESIA ASSOCIATES** **(3) FACULTY OF PHYSICIAN ASSOCIATES** **(4) ROYAL COLLEGE OF ANAESTHETISTS**	**Interested Parties**

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Thomas de la Mare KC, Naina Patel KC and Emily MacKenzie (instructed by **Bindmans LLP**) for the **Claimants**
Rory Dunlop KC and Peter Mant KC (instructed by **the General Medical Council**) for the **Defendant**
Jenni Richards KC and Adam Boukraa (instructed by **TLT LLP**) for the **First Interested Party**
The Second, Third and Fourth Interested Parties were not represented

Hearing dates: Hearing dates: 14-15 May and 9 June 2025

Further submissions 24 and 25 July 2025

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Approved Judgment

This judgment was handed down remotely at 14:00 on 5th September 2025 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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THE HONOURABLE MRS JUSTICE LAMBERT

Mrs Justice Lambert DBE:

Introduction

1. Physician Associates (PAs) and Anaesthesia Associates (AAs) were introduced into the UK healthcare system between 2002-2004. In October 2017, the Department of Health and Social Care ("DHSC") described the medical associate role as "*part of the wider healthcare workforce… trained to the medical model to augment service delivery alongside doctors. They are competent to practise in a range of specialties and can offer continuity of care, particularly in acute settings and GP practices. As such they are dependent practitioners, working within their sphere of competence releasing doctors to focus on more complex patient pathways and care whilst bolstering the healthcare team*." Associates are not medically qualified but are able to practise clinically following completion of an undergraduate degree (typically but not necessarily in the biosciences) and two years of clinically based experiential training.

2. The number of associates working in the UK healthcare system has steadily increased: at the end of 2024 there were approximately 6,000 associates, with this number projected to rise to 16,000 by 2030. This growth has been accompanied by a series of consultations which initially identified the case for, and subsequently refined the details of, a regulatory framework for associates. At the time this claim was filed, associates were not a regulated profession; this changed with the coming into force of the Anaesthesia Associates and Physician Associates Order 2024 ('the 2024 Order') on 13 December 2024. The defendant is the statutory regulatory body which has historically been responsible for regulating doctors in the UK, pursuant to the Medical Act 1983 ('MA 1983'). By the 2024 Order, the defendant's regulatory remit was extended beyond medical doctors to include a new role as regulator of PAs and AAs.

3. The First Claimant is a doctors' advocacy body formed in 2023 by Dr Richard Marks and others; its purpose, as described in the Statement of Facts and Grounds ("SFG"), is to "*air concerns about the plans to increase exponentially the number of associates in the NHS without an adequate, patient-safety focussed regulatory framework*." The Second and Third Claimants are the parents of Emily Chesterton, who died tragically of a pulmonary embolus in November 2022 due to the failure by the PA working at Ms Chesterton's GP practice to refer her to hospital on two occasions. The First Interested Party in these proceedings is the British Medical Association ("the BMA"), the professional association and trade union for doctors and medical students across all branches of medicine across the UK. Its role is to represent and support UK doctors and medical students on issues impacting upon the medical profession. The Second, Third and Fourth Interested Parties were not represented and took no active part in the proceedings.

4. The claimants and the BMA challenge the defendant's ongoing failure to regulate associates in a manner which complies with the defendant's over-arching patient safety objective under s. 1(1A) MA 1983.

5. Underlying the application is the contention that the use of associates poses systemic risks to patient safety. Their training is shorter and far less comprehensive than even a

newly qualified doctor; there is no career structure for associates following their initial training and they may be deployed anywhere within the health service based on the employer's needs at the time. By contrast, it is said, doctors follow a career path of progressive specialisation. As Mr de la Mare KC for the claimants expressed it, there are no "tramlines" within which an associate works and therefore there can be no certainty or confidence in their training, skills and competence. The current regulatory position, which requires an associate to work within the limits of his or her competence, does not address the risk to public safety posed by associates because, unlike doctors, associates are unable to identify those safe limits and work within them. Further, although supervision by a doctor is required, in the absence of a defined career pathway, it is difficult for doctors to know the extent of the knowledge, skills and competence of the associate and delegate clinical tasks accordingly. Associates are therefore more likely to work outside their competence and to make mistakes with potentially very serious consequences. Those issues are compounded by the general public having little or no understanding of the associate role, and the assumption that they are being treated by doctors when in fact they are not. This ambiguity – which arises from the fact that associates are not required to explicitly state that they are not doctors before treating patients – means, it is alleged, that patients may not actually be giving informed consent to their treatment.

6. This claim was issued on 14 October 2024. Permission was granted on 13 January 2025. The SFG challenges the defendant's ongoing failure to produce guidance, policies or otherwise set standards (including potentially by adopting guidance or policies produced by others) whether for the doctors delegating to and supervising associates (in its capacity as regulator of doctors) or for the associates themselves which:

    (a) set any or any adequate limits on the tasks associates may undertake post qualification (ground 1(a));

    (b) ensure that informed patient consent is obtained for treatment by requiring associates to state unequivocally that they are not medically qualified (ground 1(b)); and

    (c) ensure that associates are safely supervised by doctors, including when delegating appropriate clinical tasks (and supervising them as those tasks are carried out) (ground 1(c)).

7. In respect of each limb of ground 1 it is alleged that the defendant acted irrationally both in its decision making process and the outcome of that process and/or was in breach of the *Padfield* principle (see *Padfield v Minister of Agriculture Fisheries & Food* [1968] AC 997) by its failure to exercise the statutory powers conferred upon it by the MA 1983 and the 2024 Order for their statutory purposes.

8. In ground 2, it is alleged that the defendant has failed to comply with its *Tameside* duty of inquiry (*Secretary of State for Education and Science v Tameside MBC* [1977] AC 1014), by failing to gather and consider sufficient information to address the question of whether it should introduce the safe and lawful practice measures.

Background

9. The regulation of associates developed following a series of consultations run by the DHSC. These consultations were separate from, but also informed and were in turn informed by, the defendant's own preparatory work in anticipation of its new regulatory responsibilities.

10. The DHSC's consultation process included the following:

    (a) In October 2017, a consultation document on the regulation of 'medical associate professions' (including PAs and AAs) in the UK was published. It sought views on proposals to introduce specific statutory regulation for associates. It recognised the increased use of these roles within multi-disciplinary teams, and the need to explore the options for statutory professional regulation and the appropriate healthcare regulator. Preparatory work done by Health Education England was incorporated into the 2017 consultation document and included the application of a risk assessment model devised by the Professional Standards Authority which concluded that PAs and AAs posed 'medium' to 'high' risks to patients. The consultation document explains the conclusions.

        (i) In respect of PAs, the high risk arose from: '*the wide ranging scope of the PA role including the provision of direct and interventional care to patients, the environments they work in (particularly primary care) and the level of direct supervision they are subject to.*'

        (ii) As to AAs, '… *the types of intervention [AAs] make on a routine basis are high risk … [W]e understand that a proportion of [AAs] work beyond the agreed scope of practice for the role, performing additional tasks with limited supervision … Although this extended practice is managed under local governance structures…there are no universal standards or training in these extended practices as part of the approved [AA] training course. This creates the potential for inconsistency across the profession and could pose a risk to patient safety.*'

    (b) The DHSC's response to the consultation was published in February 2019. It concluded that associates should be regulated but that more work was needed to identify whether the defendant or the Health and Care Professions Council (HCPC) would be the more appropriate regulator.

    (c) On 18 July 2019 the Minister of State for Health announced that the defendant had been selected to regulate associates across the UK, on the grounds that the GMC was "*best placed*" to regulate and "*regulation will enable these groups to work to their full potential and provide the very best care to patients as part of a multi-disciplinary team*."

    (d) In 2021, a further DHSC consultation ('*Regulating healthcare professionals, protecting the public*') was launched, which recognised that certain statutory changes would need to be made to reflect the expansion of the defendant's regulatory remit, and sought input from respondents on the proposed regulatory framework for associates. The DHSC's response was published on 17 February

2023, which largely reaffirmed what had been set out in the consultation document.

(e) In 2023, a third consultation, '*Regulating anaesthesia associates and physician associates*' was launched which invited views on the specific legislative provisions which would form the statutory framework for the defendant's regulation of associates. The Executive Summary provided an overview of the 'core functions' of a regulator, including (a) education and training, (b) registration requirements, (c) standards and guidance, and (d) fitness to practise. The response to this consultation was published on 11 December 2023, which reflected the government's view on the necessary elements of the regulatory framework, including a draft of the 2024 Order.

11. Following the announcement that the GMC was to regulate associates, the defendant established a work programme (the Medical Associate Professions or "MAPS" programme) to implement the regulatory framework for PAs and AAs. These included seven work streams covering various regulatory functions (professional standards, education, registration, fitness to practise), which reported to the MAPS Programme Board. The MAPS Programme sat alongside a wider Regulatory Reform Programme Board, which looked at issues relevant to regulatory reform in respect of all regulated medical professions. The MAPS programme regularly submitted reports on its work to the defendant's Executive Board and Council, the latter of which approved the current approach to regulating associates.

12. From late 2019 onwards, the MAPS programme took a number of steps as part of its information-gathering process. These steps included:

(a) between late 2019 and early 2020, a literature review to identify professional standards issues for associates and initial engagements with other key stakeholders including the Association of Anaesthesia Associates, Faculty of Physician Associates (FPA), and Royal College of Anaesthetists (RCA) to find out how the current regulatory guidance Good Medical Practice ("GMP") was being used by associates 'on the ground';

(b) a consultation process with other regulators to determine their approaches to regulation of ancillary professionals, including concerning the introduction of a scope of practice or some other form of limitation on the practice of associates or equivalent;

(c) in December 2019, the launching of a "community of interest" ("COI") via a blog post. Its purpose was to work closely with associates and those who worked with associates. In June 2020 the defendant undertook a survey of members of the community of interest. It received 1147 responses from associates, doctors, students, nurses and other healthcare professionals. 7 members of the public responded. A report setting out the survey results was published on the defendant's website;

(d) between December 2020 and January 2021, engagement with seven focus groups involving doctors and associates throughout the UK and across primary and

secondary care settings to develop thinking on professional standards that should apply to associates;

(e) the setting up of an External Advisory Group made up of the DHSC, BMA, Royal Colleges and other stakeholders. Its function was to "*advis[e] the GMC on the design of the regulatory framework for the Physician and Anaesthesia Associates and [to advise] on prioritisation, opportunities, risks and potential sensitivities within the overall development plan*." 18 meetings of the EAG were held between November 2019 and October 2024;

(f) the creation of an Advisory Forum of external experts to act as a 'critical friend and sounding board' for key decisions in the development of new core standards for Associates. Seven meetings were held between 8 September 2021 and 30 January 2023.

13. In addition to the MAPS programme's work, the defendant ran two public consultations on GMP:

(a) April-July 2022: A public consultation seeking feedback on proposals to '*have one set of core professional guidance for all medical professionals registered with us'* and to '*keep the guidance concise ... as high-level principles and duties*'. These subsequently led to the publication of a draft of new standards guidance on 22 August 2023, which came into effect on 30 January 2024.

(b) March 2024: A public consultation 'Regulating anaesthesia associates and physician associates: consultation on our proposed rules, standards and guidance." Following this consultation, the defendant approved a series of amendments to GMP on 7 November 2024.

14. On or around 11 April 2024, the defendant published on its website advice and guidance specific to the role of AAs and PAs. The materials covered:

(a) information for associates on registration, professional standards and revalidation;

(b) information for doctors about associates and working with associates including supervision and working within competence;

(c) information about patients about the role of associates, the benefits of regulation and how to raise a concern.

15. The 2024 Order came into force on 13 December 2024. Prior to this Order there had been no statutory regulation of associates. Under the 2024 Order, Article 19(1)(b), which relates to the use of the title anaesthesia or physician associate, does not take effect until 13 December 2026. There is therefore a two-year transition period for individuals with a relevant associate qualification who are practising as associates in the UK to gain registration. Any person who is not on the register of PAs and AAs by 12 December 2026 can no longer use the protected title of PA or AA.

16. The defendant produced amended rules setting out the procedural requirements for admission to the register and a Registration Evidence Framework describing the *"overarching approach"* to how associate applicants are able to demonstrate registration standards and information requirements. The Framework sets out the evidence requirements for education and training; knowledge and skills; experience and performance; conduct and ethics and language. Applicants are required to, amongst other things, provide evidence of their knowledge and skills which demonstrate that they are able to *"safely and effectively apply their learning within the context of UK practice and to the requisite standard."* The standard will be met by providing evidence of passing a GMC-approved registration assessment and by testing the core knowledge, skills and behaviours of applicants. Each of the approved registration assessments has two elements: a knowledge test and an assessment of clinical/practical skills.

17. The defendant issued updated advice and guidance on 16 December 2024 addressing (among other things) clinical governance, scope, supervision, working within competence and introductions.

18. In February 2025, the defendant published updated guidance on PAs and AAs in practice. In April 2025, the defendant published on its ethical hub "Supervision of physician associates and anaesthesia associates."

The Statutory Framework.

The MA 1983

19. The defendant's statutory purposes are set out in s 1 of the Act:

> (1) There shall continue to be a body corporate known as the General Medical Council (in this Act referred to as "the General Council") having the functions assigned to them by this Act.
>
> 1(A) The over-arching objective of the General Council in exercising their functions is the protection of the public.
>
> 1(B) The pursuit by the General Council of their over-arching objective involves the pursuit of the following objectives—
>
> (a) to protect, promote and maintain the health, safety and well-being of the public,
>
> (b) to promote and maintain public confidence in the medical profession, and
>
> (c) to promote and maintain proper professional standards of conduct for members of that profession.

20. Paragraph 9A of Schedule 1 to the MA 1983 specifies that, in exercising its functions, the defendant must have regard to '*the interests of persons using or needing the services*

of provisionally or fully registered medical practitioners in the United Kingdom', and to cooperate (insofar as appropriate and reasonably practicable) with public bodies and other persons concerned with the regulation of other health care professionals, the regulation of health services, and the provision, supervision or management of health services.

21. Section 2(1) MA 1983 requires the defendant to establish a register of '*medical practitioners*'.

22. Part II of the MA 1983 describes the defendant's responsibilities in relation to the medical education and registration of doctors. Part IIIA concerns licenses to practise. Part IV contains general provisions on registration. Section 29A(2) imposes a duty upon the defendant to make regulations with respect to the licences to practise of medical practitioners. Such regulations include the current Fitness to Practise Rules 2004 (as amended). That document should be read alongside other relevant guidance (including GMP and other subsidiary guidance) produced by the defendant. To that end, section 29G empowers the defendant to issue guidance to doctors for the purposes of obtaining a licence or revalidation; and s. 35 enables it to '*provide, in such manner as the Council think fit, advice for members of the medical profession on – (a) standards of professional conduct; (b) standards of professional performance; or (c) medical ethics*'.

The 2024 Order

23. On 13 March 2024, the 2024 Order was made pursuant to section 60(1)(b) of the Health Act 1999 ('the 1999 Act'). It provided for the regulation of professions not already regulated under the 1983 Act or any other legislation. The relevant provisions came into force on 13 December 2024. Prior to the 2024 Order coming into force, there was no statutory regulation of associates.

24. Article 3 of the 2024 Order imposes a duty on the defendant to determine standards applicable to associates following consultation and also to keep those standards under review. It provides as follows:

> "3 - Standards
>
> (1) The Regulator must determine standards applicable to associates.
>
> (2) The standards must relate to
>
> (a) education and training,
> (b) knowledge and skills,
> (c) experience and performance,
> (d) conduct and ethics,
> (e) proficiency in the English language, and
> (f) such other matters as the Regulator may prescribe in rules made under paragraph 2(2)(a) of Schedule 4.
>
> (3) Before determining a standard, the Regulator must consult such persons as the Regulator considers appropriate.

> (4) The Regulator –
>
> (a) must keep the standards under review, and
> (b) may vary or revoke a standard."

25. Article 4(1) permits the defendant to approve education, training and qualifications for the purposes of enabling a person to attain the standards determined under art. 3(1).

26. Paragraph 3 of Schedule 1 to the Order imposes new duties upon the defendant pertaining to associates which mirror those in s. 1 and para. 9A of Schedule 1 MA 1983:

> (1) The Regulator, in addition to its objectives and duties set out in section 1(1A) and (1B)(a) of, and paragraph 9A(1)(b) of Schedule 1 to, the Medical Act 1983 –
>
> (a) has the objective of promoting and maintaining –
> (i) public confidence in, and
> (ii) proper professional standards and conduct for members of, the anaesthesia associate and physician associate professions;
>
> (b) must have regard, in exercising its functions under this Order, to
> (i) the interests of persons using or needing the services of associates in the United Kingdom,
> (ii) any differing interests of different categories of anaesthesia associates and physician associates, and
> (iii) the principle that regulatory activity should be targeted only at cases in which action is needed.

27. Part 3 of the 2024 Order establishes an Associates register along the same lines as for doctors under the MA 1983. Article 7 requires the defendant to carry out a periodic assessment as to whether a registrant '*continues to meet the standards determined under article 3(1)*'. Article 8 enables the defendant to impose '*conditions on the practice of such descriptions of associate as may be prescribed in rules [made under powers in Schedule 4]*'.

28. Paragraph 5(1) of Schedule 3 to the 2024 Order obliges the defendant to publish, *inter alia*, standards determined under art. 3(1); a list of approvals given under art. 4(1); and guidance as to what amounts to impairment of fitness to practise. It is also under a duty to keep that guidance under review: paragraph 5(2). Paragraph 7 also imposes an evidence-gathering duty upon the defendant to '*take such steps as it considers necessary for the purpose of assessing whether … standards determined under Article 3(1) are met at any point in time, or a person's fitness to practise as an associate is impaired*'.

29. Paragraph 2 of Schedule 4 provides that the defendant may prescribe rules setting out the standards for the purposes of art. 3(1), and a description of 'associate' for the purposes of art. 8.

30. Art. 2(2)(a) of the 2024 Order defines impairment of fitness to practise as '*impairment by reason of – (i) inability to provide care to a sufficient standard, or (ii) misconduct*'.

Good Medical Practice and other guidance and advice issued by the GMC

31. Pursuant to its powers under the MA 1983 and the 2024 Order, the defendant amended GMP, its existing guidance and advice, and materials posted on its website. There is one set of unified guidance for all regulated professions. GMP contains high level guidance on ethics and conduct.

(a) Scope of Practice

32. Associates are prohibited from undertaking certain categories of work by legislation (eg. prescribing, requesting ionising radiation, signing death certificates). They are unable to work other than under supervision. The defendant has not issued policy or guidance further limiting the practice of associates by reference to the types of work that associates can perform. The standards set by the defendant require associates to act within their competence. Practice and actions which contravene those professional standards will be dealt with through the fitness to practise disciplinary process. As part of a five-year revalidation process, associates will keep up to date with any changes to those professional standards and guidance which is issued by the defendant (and any other relevant bodies including their employers). These expectations are set out in GMP.

33. Page 7 of the GMP is titled '*The duties of medical professionals registered with the GMC*' and states that '*[Y]ou must … meet the standards expected of you in all four domains*'. Domain 1 is titled '*Knowledge, skills and development*' and the first standard is to '*[p]rovide a good standard of practice and care, and* ***work within your competence'*** (emphasis added).

34. In the more detailed guidance for Domain 1, GMP provides as follows under the subheading '*Being competent*':

> 1. You must be competent in all aspects of your work including, where applicable, formal leadership or management roles, research and teaching.
>
> 2. You must recognise and work within the limits of your competence. You must only practise under the level of supervision appropriate to your role, knowledge, skills and training, and the task you're carrying out.
>
> 3. You must keep up to date with guidelines and developments that affect your work.

(b) Consent

35. Domain 2 of GMP, '*Patients, partnership and communication*', says this under the subheading '*Supporting patients to make decisions about treatment and care*'

> "24. All patients have the right to be involved in decisions about their treatment and care, and be supported to make informed decisions if they are able to. You must start from the presumption that all adult patients have capacity to make decisions about their treatment and care.
>
> 25. You must be satisfied that you have consent or other valid authority before examining or treating patients, or involving patients or volunteers in teaching or research. More detail about this is given in our guidance on *Decision making and consent* which you must follow.
>
> 26. You must be aware of your legal and ethical duties relating to consent and capacity. This means you must:
>
> a. be aware of the relevant law on capacity and mental health
>
> b. have regard to relevant codes of practice
>
> c. follow our guidance on *Decision making and consent*
>
> (…)
>
> 28. The exchange of information between medical professionals and patients is central to good decision making. You must give patients the information they want in a way they can understand."

36. As to how associates should approach how they introduce themselves and their role to a patient, GMP Domain 4 ('*Trust and professionalism*') states: "*You must always be honest about your experience, qualifications and current role. You should introduce yourself to patients and explain your role in their care*."

37. As GMP makes clear, the words "*you must*" are used for "*a legal or ethical duty you're expected to meet (or be able to justify why you didn't.)*" Whereas "*you should*" is used for "*duties or principles that either: may not apply to you or the situation you're currently in, or you may not be able to comply with because of factors outside your control.*"

38. *Guidance on PAs and AAs in practice* (published 16 December 2024) contains a section on "*Introductions*". It sets out that associates have a responsibility to communicate clearly who they are and their role in the team. It continues:

> "GMP requires….you should introduce yourself to patients and explain your role in their care. For example this includes PAs and AAs
>
> (i) Using and explaining their title in full before using any abbreviations
>
> (ii) Taking time to explain their role during clinical interactions

(iii) Remembering that role titles may not always be immediately clear to others

(iv) Offering patients and staff the opportunity to ask for more information about their role and taking sufficient time to explain."

39. The *Decision Making and Consent* guidance was updated on 13 December 2024. It is addressed to doctors and associates. It sets out a framework for decision making and the underlying principles of decision making. It does not require doctors or associates to provide information about their level of skills, qualifications or experience as a condition of informed consent.

(c) *Supervision*

40. GMP Domain 3 ('*Colleagues, culture and safety*') includes the following principles:

> 60. You must follow our more detailed guidance on *Leadership and management for all doctors*.
>
> 61. You must make sure that all colleagues whose work you are overseeing have appropriate supervision.
>
> (…)
>
> 66. You must be confident that any person you delegate to has the necessary knowledge, skills and training to carry out the task you're delegating. You must give them clear instructions and encourage them to ask questions and seek support or supervision if they need it.
>
> 67. If a task is delegated to you by a colleague but you're not confident you have the necessary knowledge, skills or training to carry it out safely, you must prioritise patient safety and seek help, even if you've already agreed to carry out the task independently.
>
> 68. You must follow our more detailed guidance on *Delegation and referral*.

41. Further detailed guidance on supervision and delegation is set out in *Leadership and management* and *Delegation and referral – professional standards*, both updated on 13 December 2024. The guidance provides high-level advice for doctors and associates on delegation of tasks and responsibilities which echo the principles in GMP.

42. In "*Guidance on PAs and AAs in practice*" (published 16 December 2024), under the section *Clinical Governance* the defendant explains that:

> "effective clinical governance systems are vital to make sure that PAs and AAs are properly and safely deployed. Organisations that employ PAs and AAs should make sure their governance arrangements take into account that these professionals are trained and will be registered on the basis that they will always work under

> supervision. We recommend that organisations identify an individual at board level who is responsible for PAs and AAs and that local processes are established governing how these professionals are deployed and supervised".

43. In the same document, under "*Supervision*" the defendant says:

> "Our clinical governance handbook sets out our expectation that organisations who employ PAs and AAs should make appropriate arrangements for their deployment and supervision….Many doctors already supervise colleagues or lead multi-disciplinary teams that include PAs and AAs. When it comes to good supervision, there isn't a one-size fits all approach. PAs, AAs and their named supervisors should agree a level of supervision appropriate to each individual's skill level, experience, role and the nature of the task.
>
> We recommend that organisations identify an individual at board level who is responsible for PAs and AAs and that local processes are established governing how these professionals are deployed and supervised. The aim of these processes should be to ensure high quality, safe care, and to support effective multi-disciplinary working.

44. On 24 April 2025, the defendant published "*Supervision Practice Advice*" on its online Ethical Hub. This is advice for doctors produced outside the suite of materials consulted upon as part of the changes to GMP. The Advice states that it '*does not set new professional standards and is not intended to replace the formal guidance*'; instead, it serves to draw together and signpost different resources to assist doctors.

45. The Supervision Practice Advice identifies the role of the 'named supervisor' to an associate. For PAs the named supervisor (usually a senior doctor or consultant) "*will have a clear understanding of their competences, skills and experience. If the named supervisor is not working directly with the PA themselves they will work with the PA to communicate this to the doctor who is responsible for overseeing the care of patients. This will enable that doctor to make sure all members of the team are working together*."

46. For AAs, the named supervisor "*will determine the range of activities an AA can do and with what level of supervision. This may be modelled on the supervisory approach set out by the Royal College of Anaesthetists in .. their Anaesthesia Associate Interim Scope of Practice 2024."*

47. The Supervision Practice Advice anticipates that the associate's named supervisor will be the doctor responsible for the patient's day to day care. The document also provides guidance to those doctors who are overseeing the clinical work of an associate but who are not the named supervisor. It sets out that that doctor will need to be aware of the range of tasks and the extent of the competence of the associate and ensure that there is the appropriate level of supervision. The doctor is referred to the:

> "*.. knowledge and skills expected at qualification… the job description which will outline what they are able to do and what knowledge, skills and experience is required for the post they undertake".* It continues *" more experienced PAs and*

AAs may have extended their safe scope of practice beyond this level shaped by their supervised training and experience and the clinical context of their work. Some royal colleges and PA and AA professional bodies have published interim guidance on post-qualification scope of practice Though there is no set consensus you may find them helpful as a starting point. The Leng Review is also likely to make recommendations in this area later in 2025."

48. The Supervision Practice Advice emphasises that associates are not able to work completely independently of supervision, that they cannot work as a sole practitioner or in settings where doctors are not present. The guidance draws attention to non-statutory guides from various Royal Colleges.

Claimants' Evidence of Risk to Patient Safety:

49. Dr Richard Marks is one of the founder members and directors of Anaesthetists United Ltd, an advocacy organisation for anaesthetists. He qualified as a doctor in 1979 and as a consultant anaesthetist in 1991. He describes himself as "semi-retired" though still undertakes some private practice work. In his first witness statement he describes how he has dedicated himself to helping his own patients and to enabling other doctors and colleagues to work to the high standards that patients are entitled to expect from the NHS.

50. Dr Marks sets out the background to the rollout of the associate roles, and the growing recognition of the risks posed by them. He explains how the concerns of the First Claimant and other bodies developed once the 2024 Order had been made and they became aware of how the defendant proposed to regulate associates; and their failed attempts to engage with the defendant as to the inadequacy of its proposed system (which then led the claimants to issue this claim). Dr Marks also points to various documents which, he says, support the view that the defendant would be responsible for imposing limits on associates' clinical tasks.

51. As further evidence of the systemic risks to patient safety arising from – and the concerns associated with – the use of associates, the claimants rely upon two main categories of material. The first category is the responses to a number of community surveys which were commissioned or issued by different bodies:

    (a) As noted above, in June 2020, the defendant issued a survey on professional standards to its COI Survey. The survey included questions concerning the safety and effectiveness of associates; public understanding of the role(s); and any specific issues which needed to be addressed when adapting GMP for associates. The free-text responses received indicated concerns over a lack of clarity on associates' scope of practice leading to them practising outside of their competence and a lack of understanding about the role amongst patients and the wider public who often mistook them for doctors.

    (b) In February 2024, the BMA published the results of its November 2023 Medical Associate Professions survey ('the BMA Survey'), which had collected over 18,000 responses from doctors in the UK. Around 80% of respondents were concerned that associates were occasionally or frequently working beyond their

competence; 87% believed that the way associates worked 'sometimes' or 'always' posed a risk to patient safety. Some respondents shared anecdotal experiences of PAs treating undifferentiated patients in primary care and GPs or A&E, leading to incorrect diagnoses. Some respondents stated that the introduction of associates had increased their workload due to their new supervision responsibilities.

(c) In November 2023, the Doctors' Association UK (DAUK) held a nationwide survey of doctors to gain insight into how concerns regarding associates were manifesting on the ground. Some 680 (mainly anonymous) responses were received which primarily focussed upon PAs, although some respondents commented upon AAs. These were summarised in the first witness statement of Dr Kneale dated 21 March 2025. The overarching concern was that patient safety was being compromised by the expansion of the PA role; and these included (i) a lack of transparency about PAs (which they were themselves contributing to by failing to adequately communicate their role with patients); (ii) PAs acting outside their competence; and (iii) a lack of clarity about supervisor responsibilities.

(d) Between April-May 2024, the Royal College of General Practitioners (RCGP) surveyed its members, receiving 5,000 responses which were published on its website in June 2024. The key findings were reproduced in Mr McAlonan's (for the BMA) first witness statement. They echoed the concerns expressed in the other surveys above. In particular, it noted that 24% of respondents said they were aware of the RCGP's 'red lines' (various principles relating to the use and deployment of PAs which the College had adopted) being breached. The survey findings led the RCGP to call for a halt to the recruitment of PAs into general practice until they could be better regulated and to issue a series of guidance documents for members including a scope of practice and guidance on supervision for PAs in general practice.

(e) In February 2025, the BMA undertook another survey of its members on associates and safety. Of 14,000 respondents, 95% agreed/strongly agreed that there should be nationally determined scope of practice for associates, 87.3% disagreed/strongly disagreed that restricting the range of tasks which associates could do and designating them as assistants would negatively impact patient care and 82.6% disagreed/strongly disagreed that PAs should be able to provide initial care to undifferentiated patients in primary care and in the Accident and Emergency Department.

52. It is the claimants' case that these surveys taken together demonstrate that the wider medical community holds serious concerns about the systemic risks posed by associates to patient safety which relate to Grounds 1(a)-(c). In the absence of a national scope of practice associates are alleged to frequently (sometimes intentionally) practise beyond their competence, including being the first point of contact for patients, sometimes leading to adverse clinical consequences. Doctors complained of the lack of guidance concerning, and difficulties associated with, delegating to and supervising associates. Patients themselves had little to no understanding of the associate roles, and often wrongly assumed that they were being seen by doctors. Some PAs failed to correct that assumption whilst others introduced themselves in misleading ways.

53. Dr Marks sets out the guidance on scope of practice which was issued by the RCA in 2016. The document provides guidance on supervision and the role and responsibilities of the supervising anaesthetist: for example, the supervising consultant anaesthetist must be present in the theatre suite and must be easily contactable and available to attend within two minutes; the supervising anaesthetist must directly supervise emergence from anaesthesia until the handover to recovery. The guidance does not set limits on the practice of AAs by reference to specific tasks save to remark that the nationally agreed curriculum leads to limits on scope of practice on qualification and that AAs are not qualified to induce regional anaesthesia, obstetric or paediatric anaesthesia or provide initial airway management of an acutely ill patient.

54. Dr Marks comments that, to the extent that he has been able to research the issue, the 2016 guidance on scope of practice (such as it is) is not uniformly followed by Trusts. In some instances it is ignored, in others it is "worked around." Trust practice is hugely variable with local protocols, policies and practices differing from Trust to Trust. The Royal Colleges have not so far delivered scopes of practice. Neither the Royal College of Physicians nor the Royal College of Surgeons has promulgated scopes of practice yet and are, according to Dr Marks, unlikely to do so soon. He remarks that the valuable work undertaken by the Fourth Interested Party is without teeth and unenforceable (absent its being formally adopted by the defendant).

Coroners' investigations and Prevention of Future Death reports

55. A further category of documents to which the claimants referred me were coroners' Records of Inquests and three Prevention of Future Deaths ('PFD') reports. The claimants assert that these documents (particularly the PFD reports) merit special attention because they are the product of an inquisitorial process specifically designed to identify the existence of systemic risks and call attention to them.

(a) Ms Emily Chesterton

56. Ms Emily Chesterton, the daughter of the Second and Third Claimants, died on 8 November 2022 from a pulmonary embolism. An inquest into her death was opened on 15 November 2022, and a hearing was held on 20 March 2023. The coroner issued a Record of Inquest, which recorded that:

> "[Ms Chesterton] attended her general practitioner surgery on the mornings of 31 October and 7 November 2022 with calf pain and shortness of breath, and was seen by the same physician associate on both occasions. She should have been immediately referred to a hospital emergency unit. If she had been on either occasion, the likelihood is that she would have been treated for pulmonary embolism and would have survived."

57. In her witness statement, Emily's mother explained that she had only learned that the person reviewing Emily was not a doctor at the inquest hearing itself. She set out her belief that Emily had not known that it was a non-medically qualified person who was reviewing her and that, had she known this, she would have sought a second opinion.

58. At the inquest, the coroner heard evidence that the GP surgery had conducted its own internal review into Emily's case and written a report. This documented a catalogue of failures, including that the PA failed to introduce herself or explain her status to Emily; failed to take an adequate history; failed to allow enough time for the appointment to conduct a thorough assessment; and failed to discuss the case with a doctor before sending her home. There had been earlier concerns about the PA's ability to recognise an unwell patient and escalate their case to a doctor. Multiple medical colleagues had raised concerns about this particular PA's overconfidence and lack of insight into the limitations of her clinical knowledge and practice. The PA herself seemingly continued to deny, even at the inquest, that she had acted outside of her competence. Throughout the appointments, the PA had not been directly supervised by a doctor, and she had never herself sought their input or discussed Emily's case with them. Although a GP signed off on the Propranolol prescription (as PAs are not allowed to prescribe medicine), this was based purely off the PA's (incorrect) notes and diagnoses. The GP in question said that she had hundreds of prescriptions to sign off, and this prescription had '*slipped through the net*'. Further, the PA's decision not to allow Emily's partner to join her during the appointment was contrary to the GP surgery's policy.

59. No PFD report was submitted by the coroner, nor was the case notified to the defendant by the coroner although the Second and Third Claimants brought their concerns to the attention of the defendant in writing in April 2024 and met with the Chief Executive, Mr Massey on 17 July 2024. During the hearing of this claim, a document prepared by the GP surgery was disclosed. The document was, in effect, a scope of practice for the associates working in Emily's GP surgery. It had been devised by the GP practice and had been in force when Emily had attended. It set out a list of conditions which the associates could see and those which were off limits. Had the document been adhered to by the associate she ought not to have seen Emily (at least, not on the second visit).

(b) Mr Benedict Peters

60. Mr Benedict Peters (aged 25 years) died on 12 November 2022 whilst staying at his parents' home. He had been discharged from hospital the day before having presented in the early hours of 11 November 2022 with chest pain, shortness of breath, a sore throat and an aching arm. He had been reviewed in hospital by a PA, who considered that Mr Peters' chest x-ray was normal and discussed his case with the duty consultant. Mr Peters was subsequently diagnosed with a panic attack/gastric inflammation and prescribed medication. The inquest into his death concluded that he had died from undiagnosed complications arising from an underlying heart defect. The coroner subsequently made a PFD report addressed to the Manchester University NHS Foundation Trust. The case was not notified to the defendant. The PFD report stated:

> "It is a matter of concern that despite the patient's reported symptoms, in view of his age and extensive family history of cardiac problems, Mr Peters was discharged from the Ambulatory Care Unit without being examined/reviewed in person by a doctor."

(c) Mrs Susan Pollitt

61. On 3 July 2023, Mrs Susan Pollitt was admitted to the Royal Oldham Hospital after collapsing at home. Whilst being treated, she subsequently developed ascites. On 11 July 2023, a junior doctor determined that an ascitic drain should be placed. The drain insertion was undertaken by PA who was unaware of the local hospital guidance on the insertion of ascitic drains, or the prohibition on drains remaining in place for any longer than six hours. Mrs Pollitt's drain remained in place for 21 hours before being removed. The PA also directed that the drain be clamped which was unnecessary given the moderate level of fluid that had been drained. The PA also failed to appreciate that clamping the drain would increase the risk of infection. Mrs Pollitt subsequently developed bacterial peritonitis and died on 11 July 2023.

62. In his witness statement dated 9 October 2024, Mr Pollitt set out that he did not know that the person treating his late wife was a PA. He had assumed they were a doctor. He stressed that at the time, he was wholly unaware that PAs even existed, much less the difference between their role and that of a doctor.

63. At the inquest, the Northern Care Alliance NHS Foundation Trust (which ran the Royal Oldham Hospital) admitted that the ascitic drain should have been removed within six hours of insertion, and that, if that had been done, Mrs Pollitt would have survived. The coroner subsequently returned a conclusion that Mrs Pollitt had died '*as a result of an unnecessary medical procedure contributed to by neglect*'. She issued a PFD report dated 31 July 2024 addressed to the DHSC, the defendant, and the FPA which listed the following Matters of Concern:

> "1. There is no regulatory body with oversight of Physician Associates. It is understood that this is currently the subject of a consultation by the General Medical Council.
>
> …
>
> 3. There is no national framework as to how Physician Associates should be trained, supervised and deemed competent. This is placing both patients, Physician Associates and their employers at risk. The court heard that since the death of Mrs Pollitt the Northern Care Alliance have put in place a local trust framework. Unlike all other clinical roles there is no national guidance save for very recent guidance issued by the British Medical Association (March 2024).
>
> 4. There remains limited understanding and awareness of the role of a Physician Associate both amongst medical colleagues, patients and their families. The lack of a distinct uniform and the title "Physician" gives rise to confusion as to whether the practitioner is a doctor.
>
> 5. In June 2022 the Physicians Associate had been signed off as competent for the insertion of ascetic drains. This sign off was completed by a liver nurse specialist using a competency form which was provided by the FPA. Whilst the competency form assessed the technical aspect of placing the drain, it did not include competency around the wider aspects of care such as taking consent, risk factors and after care."

64. The Royal College of Physicians (which managed the FPA at the time) responded to the PFD report on that same date. It noted that many of its fellows and members had '*significant concerns about the safe deployment of PAs, especially concerning regulation, scope of practice and supervision*'. It disagreed that PAs' scope of practice should be determined locally and suggested that the defendant should take a leading role in developing national-level scope of practice '*to reduce variation and enhance patient safety*'. It noted that '*[f]ailings in scope of practice and supervision*' were important factors in Mrs Pollitt's death.

65. Professor Melville for the defendant responded to the PFD report on 20 September 2024. The defendant noted that the absence of statutory regulation of PAs may have contributed to the circumstances of Ms Pollitt's death but that regulation by the GMC due to commence at the end of 2024 would address several of the issues raised. This should, in turn, bring benefits for patients, patient safety, PAs themselves and those that employ and work alongside them. Professor Melville noted, however, that there appeared to be "*wider concerns about the clinical governance arrangements at the Trust including the roles, supervision and relevant policies supporting the use of ascitic drains and the deployment of PAs*." He continued: "*Regulation is an important part of patient safety, but it alone cannot prevent future deaths. Good clinical governance by healthcare providers remains the most important factor. Your report raises significant questions that cannot be answered by those to whom the report is currently addressed, and are better explained by the trust*."

(d) Mrs Pamela Ann Marking

66. On 16 February 2024, Mrs Marking was admitted to the A&E at East Surrey Hospital after vomiting blood-stained fluid, with right-sided and suprapubic abdominal tenderness. She was diagnosed with a nosebleed and discharged home that afternoon without a medical review having been seen by an unsupervised PA who did not understand the significance of the symptoms and had undertaken an incomplete abdominal examination. Had Mrs Marking been examined properly, the presence of a femoral hernia would have been identified. She presented again to the A&E two days later with worsening symptoms and underwent emergency surgery that same evening. Owing to the initial misdiagnosis and subsequent failings in her care, Mrs Marking died on 20 February 2024.

67. A PFD report was issued by the coroner dated 24 February 2025 and addressed to NHS England, the DHSC, the defendant, the CQC, and the Surrey and Sussex Healthcare NHS Foundation Trust ('the Trust'). The coroner identified a number of concerns, of which the first five are relevant:

> "1. The term 'Physician Associate' is misleading to the public
>
> Mrs Marking's son was under the mistaken belief that the Physician Associate was a doctor by this title in circumstances where no steps were taken by the Emergency Department or the Physician Associate to explain or clearly differentiate their role from that of medically qualified practitioners.
>
> 2. Lack of public understanding of the role of Physician Associate

> Witnesses from the Trust gave evidence that a Physician Associate was clinically equivalent to a Tier 2 resident doctor without evidence to support this belief. This blurring of roles without public knowledge and understanding of the role of a Physician Associate has the potential to devalue and undermine public confidence in the medical profession whilst allowing Physician Associates to potentially undertake roles outside of their competency thereby compromising patient safety.
>
> 3. The right of patients and family to seek a second opinion
>
> The lack of public knowledge that a Physician Associate is not medically qualified has the potential to hinder requests by patients and their relatives who would wish to seek an opinion from a medical practitioner. It also raises issues of informed consent and protection of patient rights if the public are not aware or have not been properly informed that they are being treated by a Physician Associate rather than a medically qualified doctor.
>
> 4. Lack of national and local guidelines and regulation of the scope of practice for a Physician Associate
>
> A diagnosis … was made by the Physician Associate without appreciating the relevance of [Mrs Marking's symptoms] and in the absence of understanding the need to undertake … an abdominal examination in a patient who was unable to give a proper clinical history because of short term memory loss. No evidence was presented that the management of Mrs Marking was subject to a reflective practice review. Given their limited training and in the absence of any national or local recognised hospital training for Physician Associates once appointed, this gives rise to a concern they are working outside of their capabilities.
>
> 5. Lack of guidelines for direct supervision and consideration of an appropriate level of autonomy for Physician Associates
>
> Whilst there were discussions with the 'supervising' consultant the Physician Associate was effectively acting independently in the diagnosis, treatment, management and discharge of Mrs Marking without independent oversight by a medical practitioner. This gives rise to a concern that inadequate supervision or excessive delegation of undifferentiated patients in the Emergency Department to Physician Associates compromises patient safety."

68. Professor Melville, on behalf of the defendant, issued a response to the PFD report dated 17 April 2025.

    (a) In respect of Issues 1 and 2, Professor Melville cited paragraphs 2 and 82 of GMP which require registered professionals to '*always be honest about their experience, qualifications, current role, and they should introduce themselves to patients, and explain their role in patient care*'; and to '*recognise and work within the limits of their competence, and only practice under the level of [appropriate] supervision*'.

(b) On issue 3, '*PAs on our register must work in partnership with their patients to make decisions about treatment and care*' and must give patients the information they want and need. Professor Melville further referred to both GMP and the GMC's guidance 'Decision making and consent'.

(c) On issue 4, Professor Melville said that as with doctors, its standards did not impose ceilings on what individual associates could do once registered, because '*competence will vary by individual and is shaped by their supervised training and experience, and the clinical context of their work'*. Further, '*[i]t is an employer's responsibility, with the involvement of clinical leaders and supervisors, to determine which activities or specific tasks an individual can carry out and what level of supervision is required'*. He stressed the defendant's understanding that the Royal Colleges and other specialist professional bodies had the level of clinical expertise needed to provide more detailed national guidance on associates' scope of practice.

(d) On issue 5, Professor Melville explained that the professional standards relating to supervision, delegation and working with colleagues are set out in GMP, and also in other guidance issued by the defendant including 'Delegation and referral' and 'Leadership and management'. He foreshadowed a future website publication intended to bring together all of the relevant standards and expand on these with advice and referring to guidance issued by other bodies to support doctors with their supervising/delegating responsibilities. This document was published in April 2025.

69. The Surrey and Sussex Trust responded on 17 April 2025. It explained how, following the death of Mrs Marking, it had taken various steps and issued guidance to its PAs. PAs are now required to wear different-coloured scrubs with their title clearly embroidered on the front, along with distinct bright yellow lanyards. They are also required to always introduce themselves as "Hello, my name is xxx, I'm a Physician Associate. I am not a Doctor, but a senior doctor will be overseeing your care." The Trust issued a new scope of practice document for PAs working in the Emergency Department. Amongst other things, it prohibits PAs from seeing undifferentiated patients, and requires that for a patient to be discharged after seeing a PA, they must first be reviewed in-person by a senior doctor.

The Defendant's Evidence: Professor Melville

70. Professor Melville is a former consultant in emergency and intensive care medicine. He ceased clinical practice in January 2017 when he commenced his current role at the defendant as Lead for the GMC's Education and Standards Directorate. He has provided three statements in response to the claim.

Scope of Practice and Supervision

71. In summary, the defendant's position concerning scope of practice and supervision is this:

(a) The defendant has not produced guidance or policy which limits the practice of associates save to require them (in GMP) to work within their competence. It does not, currently, intend to do so.

(b) The defendant takes the view that patient safety is best protected by the imposition of core professional standards which are regulated via the fitness to practise regime. Those core professional standards require an associate to work within the limits of their competence.

(c) The defendant's education and training function involves the quality assurance of all courses leading to a qualification for associates. Accordingly when the period of transition closes in December 2026 all associates who have successfully obtained registration will have met the defendant's quality assured standards. They will be expected to comply with the core standards in the amended GMP. Specifically, says Professor Melville, having met the educational and training requirements for registration, the defendant would expect individual associates to understand the extent of their skills and appreciate the limits of their competence.

(d) The defendant's regulatory arrangements for appraisal and revalidation are still under development but it is anticipated that there will be an annual employer-led appraisal and review of the associate's job plan in line with clinical governance policies. The appraisal should establish that regulatory standards are met including the requirement to act within competence. The defendant will expect associates to discuss the types of work they are competent to undertake. The information provided in the revalidation process should pick up emerging concerns in any case in which an associate is or may be undertaking work beyond their skill base.

(e) The core standards in GMP are supplemented by more detailed guidance to which associates and supervising doctors must adhere. The suite of advice was updated and replaced on 16 December 2024. Further advice was issued in December 2024 (the guidance on PAs and AAs in practice) and April 2025 (the guidance on supervision of associates).

(f) As set out in GMP, all registrants must work within the limits of their competence. The defendant itself does not have the expertise to define those limits. Such limits are best addressed locally and individually. Competence and supervision should be seen together. It is for the employer to approve the scope of an associate's work which will vary depending upon the clinical context, competence and experience of the associate. The scope of practice of the associate, level of supervision and development of their competence in areas of patient care will be agreed with their named supervisor and relevant training and support given.

(g) The role of the employing healthcare organisation in ensuring patient safety is recognised by the DHSC. The DHSC emphasises the need for robust clinical governance processes and requires systems of oversight and supervision for their staff. In turn, NHSE has issued guidance to NHS providers on the role of associates (in March 2024) emphasising the need for NHS Trusts to have established policies and systems in place to ensure that associates are appropriately supported, supervised and integrated into the multi-disciplinary

team. Similar guidance has been issued by the defendant which recognises that, whilst regulation has an important role in public safety, good local clinical governance is equally important.

(h) The claimants raise concerns about variance in practice across different NHS Trusts and that financial pressures could lead to some Trusts permitting associates (or encouraging associates) to work outside their competence or without adequate supervision. The defendant does not accept that variance in scopes of practice itself presents a risk factor to patient safety. But in any event it is not for the defendant to address those issues. There are other bodies which have statutory duties to promote the safety and effectiveness of NHS services, including NHS England which issues guidance and oversees the work of NHS providers. The CQC has responsibility for inspections and assessments undertaken to ensure patient safety.

(i) The defendant does not have the expertise to devise scopes of practice, even high level, across many different specialist fields. Royal Colleges however do have the relevant expertise to devise limits of practice of national application. Any scopes of practice issued by Royal Colleges may be taken into account by a fitness to practise panel when deciding whether standards of conduct have been met. The defendant does not consider it appropriate to adopt formally Royal College guidance because:

(i) Royal Colleges are membership bodies not public authorities;

(ii) Parliament has not legislated for them to set professional standards and;

(iii) as Dr Marks has observed, Royal Colleges disagree (with each other) about what work may competently be carried out and adopting their practice guidance would lead, in practice, to contradictory rules for associates.

The Starting Point

72. Professor Melville says that the development of standards and guidance for associates was an iterative process and it is not possible to pinpoint a single date on which the GMC decided not to set limits on associate practice. However, the defendant is an experienced regulator and, when determining how to set professional standards for associates, it had regard to the approach which it had taken in respect of doctors: that is, the provision of generalised standards of professional conduct requiring doctors to work within their limits of competence rather than the imposition of ceilings upon the practice. This was the defendant's starting point. The regulation of doctors was well established and known to safeguard patients. Given the success of this approach, Prof. Melville said that "*compelling reasons*" would have been needed for the defendant to have taken a different and wholly untested approach to setting professional standards for associates. No such evidence emerged to suggest that a different approach was needed in the interests of patient safety

DHSC Intention

73. The validity of the initial approach was reinforced by a number of factors including the defendant's understanding of the intention of the DHSC concerning regulation and strands of work undertaken by the MAPs programme. The DHSC had not sought to legislate to restrict the activities that associates could perform beyond the existing legislation which specifies activities that only doctors may do. On 1 April 2022, the DHSC shared with the defendant an early draft of what became the 2024 Order with the "supporting commentary" that "*on review, we have not considered it necessary to make the duty to set standards wording any more specific. The GMC would satisfy this duty were it to set standards of the sort it currently sets using section 35 of the Medical Act (standards for professional conduct, professional performance and medical ethics).*"

Approach of Other Regulators

74. The MAPs programme included research into the approach taken to limiting the scope of practice of registrants by other healthcare regulators. None, save for the General Dental Council ("GDC"), set such limits. The Nursing and Midwifery Council (NMC) set common core professional standards of practice and behaviour for nurses, midwives and nursing associates and did not set limits on what could be done by, on the one hand, nurses or, on the other, by nursing associates. At a meeting with the GMC in October 2019, the NMC advised that it had not imposed any ceiling on the scope of practice of nursing associates in order not to fetter the development of the role. The HCPC guidance document "standards of conduct performance and ethics" sets common core standards for the fifteen professions regulated by that organisation.

75. The only healthcare regulator which has imposed limits is the GDC, which produced a "pared back" scope of practice for each separate profession setting out rules rather than high level principles. However, the GDC had commenced a review of its scope of practice guidance in 2019 and at its meeting with the defendant in October 2019 the GDC advised the defendant against defining the role of associate or its scope of practice as it had had the effect of inhibiting "growth of the profession and the role". It reported that one of the effects of the limit on scope of practice had been that registrants' focus was on not breaking the rules as opposed to acting in patients' best interests. The GDC launched a consultation on its existing practices in February 2023 with the commentary that the proposed changes to its approach to scope of practice aimed to better support dental professionals to use their professional judgement to make decisions. The commentary continued that the review of the current guidance showed that it was no longer being used as originally intended and that it was being "*widely interpreted by the dental professions as a comprehensive rather than indicative list of tasks*", which could "*limit and restrict*" a professional's practice and could impact patient care.

The COI Survey

76. Professor Melville said that the defendant's early focus was upon whether, and to what extent, the defendant should adapt the core professional standards for use by associates. But the defendant became aware of serious concerns relating to scope of practice and supervision when it analysed the COI survey results in mid-2020 and again when it consulted on the proposed rules standards and guidance in March 2024.

77. The defendant undertook a question by question analysis of the COI survey results. Professor Melville noted that 59.8% of respondents agreed or strongly agreed with the statement that "*PAs and AAs work safely for and effectively within a clearly defined scope of practice*". The responses suggested to the defendant that respondents understood that associates were working within a defined scope of practice agreed with their employers at the time. In addition 90% of respondents agreed with the question "do you think it is appropriate that PAs AAs adhere to the same professional standards as doctors in the four broad domains of GMP." Professor Melville said that the answers provided reassurance that a model for associates based upon high level standards with scope of practice determined locally could be safe and effective.

78. The defendant noted however the concerns which emerged from the COI survey relating to associates' scope of practice and their supervision.

79. Professor Melville says that:

    (a) the defendant did not have the clinical expertise to determine scope of practice (for example, the kinds of operation in which an experienced AA should not induce anaesthesia). The Royal Colleges had the requisite expertise and the defendant's fitness to practise process would if appropriate take relevant Royal College guidance into account. The defendant also placed considerable emphasis on local Trust-based processes for scope of practice and supervision.

    (b) Core standards in GMP required doctors to act within their competence and the defendant considered that the same standards ought to be applied to associates. The core standards were to be amended to apply to associates also and separate projects to develop rules and guidance about the pre-qualification standards of education and training for associates. The defendant judged that this was not a matter for the regulator but for local systems and processes together with advice from expert bodies.

    (c) Likewise, supervision was best addressed locally or individually. Supervision arrangements, appropriate to an individual associate, were best determined by the supervising doctor in discussion with the associate having regard to the associate's particular level of skill. The supervising doctors would be well placed to make judgements about supervision and delegation on a case by case basis. This is how supervision of, and delegation to, junior doctors currently operates. But the defendant recognised that there was a need for clarity regarding roles which was to be addressed by publishing advice and materials on the website.

80. Professor Melville concludes that the issues raised by respondents in the COI survey were carefully considered and resulted in amendments to the defendant's approach but the defendant remained of the view that it was not appropriate to set a ceiling upon the specific activities which could be performed by PAs and AAs. In addition "*to being contrary to our successful model for doctors, DHSC's intent, and the advice received from other multi-professional regulators, if we had done so this would have inhibited career development of the individual's role and of the AA and PA professional generally*." He said that the defendant did not have the expertise to set limits which were best set locally by employers with "*overall responsibility to ensure that the PAs and AAs they employ are competent to undertake the activities and tasks they perform*"

and that the medical Royal Colleges had the clinical expertise to provide advice on limits "across all specialties and general practice." He said that creating universal, hard and fast rules for all associates might restrict associates from undertaking work that they had the competence, experience and knowledge to perform which in turn would have a detrimental impact upon patient safety meaning, for example, that patients in the NHS have to wait longer for operations or treatment as associates would be limited in the assistance they could provide.

Pre-consultation engagement and the March 2024 public consultation

81. In November 2023 the defendant began the process of pre-consultation engagement on rules, standards and guidance for associates. Professor Melville says that the defendant spoke to 47 organisations including NHS employer organisations, associate representatives and doctor representatives. The public consultation was launched in March 2024 with the publication of "Regulating anaesthesia associates and physician associates, consultation on proposed rules, standards and guidance". The consultation document set out that scope of practice of associates was not being consulted upon "*because this depends on their skill and competence, which develop over time. We won't determine scope of practice for PAs and AAs beyond initial qualification competencies just as we don't for doctors….we know that NHS leadership, employer bodies and royal colleges have begun looking at how scope of practice may develop over time. We welcome those developments*" .

82. Concerns relating to the scope of practice were nonetheless recorded and addressed in the consultation report. The report documented that: "*although we do not set the scope of practice for associates as their regulator, we will set the learning outcomes that need to be achieved through education; standards that applicants must meet to enter the register, the registration requirements which must be passed by new graduates. Through these functions, we will ensure that only associates with knowledge skills and behaviours to work safely are entered on to the register. Once registered it is for employers to determine how best to deploy and utilise individuals safety to address local need*.

Concerns raised by Dr Marks

83. Professor Melville explains that the concerns raised by Dr Marks in his statement were the reason why the defendant decided to apply the same high professional standards to associates. Many of the concerns are directly addressed by the duties in GMP. The core standards in GMP are supplemented by more detailed guidance to which associates and doctors must adhere. On 11 April 2024 the GMC published advice and guidance specific to the associate role covering information for associates; for doctors working with associates, for patients (concerning the role of associates) and for employers and supervisors. The advice and guidance was updated and replaced in December 2024. Professor Melville indicates that the supervision advice was to be collated and brought together into a single document (published April 2025).

84. Professor Melville refers to the specific examples of misdiagnoses by associates which are referred to by Dr Marks. Those incidents occurred before associates were regulated. He commented that, following regulation, it will be possible for the defendant to scrutinise patient safety issues raised with it.

85. He places the PFD reports in context, pointing out that a significant number of such reports (in which the role of healthcare professionals is a relevant factor of concern) are issued each year. There were 10 such reports concerning hospital related deaths published in a one week period in March/April 2025.

86. Concerning Emily Chesterton, he observes that there was no PFD report and the coroner did not otherwise contact the GMC to raise concerns. It was not therefore brought to the attention of the defendant by the coroner.

87. As to Benedict Peters, a PFD report was sent to the Trust. The Trust responded making it clear that the PA involved in the treatment had acted appropriately, that he had discussed the clinical picture with the Consultant Physician in Acute Medicine, who agreed with the diagnosis and plan formulated by the PA and went on to prescribe the discharge medication himself. The Trust remarked that in doing so the consultant was acting in the same way as he would had the case been presented to him by a junior doctor or nurse clinician seeking approval for their diagnosis and management plan. The Trust response emphasised that it was the professional responsibility of the supervising consultant to ensure that they have confidence in the information provided by the practitioner (be they doctor, nurse or PA) and to seek any additional information they require directly from the patient should they believe it necessary before reaching a clinical decision.

88. Although not brought to the attention of the defendant by the coroner, having reviewed the response, Professor Melville concluded that it did not raise patient safety concerns about associates.

89. In relation to Susan Pollitt and Pamela Marking, Professor Melville responded to the PFD reports on behalf of the defendant. He points out that, whilst the Marking report was generated following the commencement of regulation, the events which led to the PFD report being issued occurred before the defendant became regulator and the core standards did not apply to associates at that time.

90. He says that the defendant has not reviewed its guidance and standards in the light of the deaths but it has reviewed its guidance as part of its preparation for the regulation of associates.

91. Professor Melville makes the following further points:

    (a) First, the EAG was aware of the defendant's approach to ceilings on practice and at no stage did any member suggest that the absence of hard-edged limits to the tasks that PAs and AAs could undertake would prove problematic or give rise to patient safety risks. He draws the court's attention to the minutes of the EAG meeting of July 2022 where some frequently asked questions and responses about associate regulation were discussed. One such question concerned whether, following regulation, the defendant intended to specify what associates could or could not do. The response to the FAQ was "*No, we'll be responsible for setting standards, outcomes and requirements that PAs and AAs must meet to gain and keep registration with us. But we won't place limits on PA or AA scope of practice beyond those existing in law… Instead we'll set out in guidance what it means to*

be a good PA or AA…including the requirement that they work within the limits of their competence, as we expect doctors do to now… they'll be expected to use their professional judgement to apply the principles set out in our guidance to the situations they face. Employers or other organisations such as national or specialist bodies and royal colleges, may specify training or certification requirement for carrying out certain procedures or activities. But that isn't a matter for us." At a further meeting of the EAG on 16 March 2023, the same point was made, namely that scope of practice was not a matter for the regulator but for local systems and processes together with advice from expert bodies.

(b) The defendant has not adopted Royal College guidance as binding or determinative of the limits of competence. The Colleges are membership bodies and not public authorities and Parliament has not legislated for them to set professional standards. Royal Colleges sometimes disagree and if adopted might lead to contradictory rules. Royal College guidance is however often considered at fitness to practise hearings.

(c) The concerns raised by the claimants all predate the regulation of associates. There are now standards of conduct and performance which address those patient safety concerns. Standards for pre-qualification training and education have been set and these are aligned to GMP. The defendant is introducing a system of appraisal and revalidation for associates. Guidance and advice documents have been updated and replaced. In April 2025 a comprehensive set of guidance concerning the supervision of associates was published. The defendant was aware that the concerns raised about scope of practice for associates related to unregulated professionals who had not been required to demonstrate relevant competencies and who could not be held accountable by any regulator if they failed to adhere to professional standards.

(d) Dr Marks' assertion that doctors are able to recognise their scope of practice and limits of competence but that associates are unable to do so is not borne out by Professor Melville's experience nor any objective evidence.

Informed Consent

92. Professor Melville says that the claimants' assertion that the GMC does not consider that a patient has a right to know that they are being treated by an associate "is simply wrong". The GMC has always been clear that associates are required to explain their role to patients and the amended version of GMP "puts this beyond doubt."

93. Professor Melville sets out that the 2024 Order does not place a duty on the defendant to issue guidance for associates on obtaining informed consent. The GMC guidance document "Decision making and consent" does however require associates to be satisfied that they have consent or other valid authority before examining or treating patients. The document is not intended to be a full account of the law.

Ground 1

94. I mention two preliminary points.

(a) First, the pleaded grounds allege "Abdication, Frustration of the statutory scheme established by the 2024 Order and Irrationality." The central argument advanced in the SFG was that, by reason of its limited response to the 2024 Order, the defendant had wholly failed to promote the purpose of patient safety for which the rule making power in the 2024 Order had been conferred. See *Padfield* and *R (Johnson v Secretary of State for Work and Pensions* [2020] EWCA Civ 778. In his oral submissions, however, Mr de la Mare focussed upon irrationality. He clarified that the *Padfield* challenge remains part of his case but only as another label for the irrationality challenge and on the basis that a metric of rationality is whether the decisions meet the risks that the statutory regime confers powers to address (see *Johnson v Secretary of State for Work and Pensions* [2020] EWCA Civ 778, [105]-[107]).

(b) Second, in his oral submissions, Mr de la Mare addressed grounds 1(a) and 1(c) together. I also deal with these grounds together, given the claimants' central submission that, absent limits on the practice of associates, neither safe practice nor safe supervision and delegation are possible.

Grounds 1(a) and 1(c): Scope of Practice and Supervision of Associates

Claimants' Submissions

95. The claimants' (and BMA's) case is that there has been, and continues to be, a failure by the defendant to exercise its powers in relation to the creation of the new regulatory regime lawfully. The regime requires the introduction by the defendant of safe and lawful practice measures. The claimants' pleaded case is that the only rational exercise of the regulatory powers contained in the 2024 Order is by the setting of nationally applicable limits on practice by reference to specific tasks which the associate profession are prohibited from undertaking even under supervision and irrespective of their post-qualification practice (and presumably experience). The limits should be set by the defendant or, if by a third party, then endorsed by the defendant.

96. The SFG sets out examples of the "*outer limits or ceilings*" beyond which it would never be appropriate for an associate to act instead of a qualified doctor. They include the prohibition on associates administering anaesthesia in paediatric or obstetric cases or other risky and complex cases such as major surgery on a patient with severe systemic disease (though provision could be made for genuine emergency situations). In oral submissions Mr de la Mare added the further example of a prohibition on associates seeing undifferentiated patients. These various prohibitions would remain even if the competency of associates evolves in their post-qualification practice.

97. Although the claimants' submissions do not differentiate between the two, the challenge encompasses both process irrationality and outcome irrationality. Mr Dunlop submits that the claimants' pleaded claim relates to the irrationality of the outcome, not the process by which it arrived at the outcome. The scope of the claimants' case is therefore an issue for me to resolve.

98. The claimants' main submissions (on both process and outcome rationality) are set out below. Many of the points which are made are derived from (or critique) the witness

statements of Professor Melville. As I understand the claimants' position, however, they do not accept that the reasoning and rationale in those statements is a true reflection of the defendant's thinking at the time. Mr de la Mare points out that there is no contemporaneous document or set of documents in which the defendant appears to have grappled with the central issues concerning limits of practice and supervision or the evidence bearing on those questions. Further, the defendant's initial response to the claim (in pre-action correspondence) challenged the existence of a power which would permit the defendant to impose limits of practice. Given this position, the claimants suggest that it is unlikely that the defendant gave any thought at all to the need for limits on practice and that from the outset the defendant adopted a "bright line" approach that such limits on scope of practice would not be part of the regulatory regime. The contents of Professor Melville's witness statements are after-the-event rationalisations for the purpose of this litigation. As such, it is submitted they are not admissible to explain the defendant's reasoning and I should disregard them. See *R v Westminster City Council, ex parte Ermakov* [1996] 2 All ER 302.

99. Notwithstanding this point, the claimants make the following submissions:

(a) The defendant's starting point was wrong. To apply the medical model to associate regulation fails to recognise that doctors and associates belong to fundamentally different professions. As such, the approach taken by the defendant from the outset was misconceived as a matter of principle. Associates present what Mr de la Mare characterises as a "systemic risk" to patient safety because the limited nature of their training and expertise means that an associate will be unable to recognise their own limits of competence. The requirement in GMP that the associate adheres to a standard which requires the associate to work within the limits of their competence is therefore meaningless. It is equally difficult for the doctor bearing the responsibility of supervising the associate to know what tasks the associate is capable of performing.

(b) Having adopted the wrong starting point, the defendant then compounded the error by taking the approach that it could only deviate from the starting point in the face of 'compelling evidence'. Mr de la Mare submits that the origin of what he labels the "compelling evidence test" is not clear. It is not derived from the 2024 Order and it does not appear in any of the contemporaneous documents. Wherever it came from, it is the wrong test.

(c) Even if the compelling evidence test were lawful (which he does not accept), Mr de la Mare submits that there is no evidence that the test was ever applied by the defendant. Had it been applied, the only rational response to the serious concerns raised by the defendant's own COI survey, by surveys undertaken by third parties (including the BMA), by coroners and by doctors would have been for the defendant to issue a scope of practice for associates or, at least, adopt and endorse a scope of practice published by another professional body.

(d) Mr de la Mare's oral submissions included a detailed analysis of the COI survey and subsequent surveys which, he says, provide more than compelling evidence that patient safety was and continues to be put at risk by the defendant's continuing failure to devise safe ceilings of practice for associates. The responses to the COI survey demonstrated comprehensive concerns over patient safety

arising from associates working outside their competence and a lack of understanding by the public of the role of associate. Neither the associates themselves nor their wider healthcare team are able to identify the limits of their competence, which is essential to ensuring safe delegation and supervision. Those concerns were then echoed in the BMA survey and the survey undertaken by DAUK. The results of the surveys all tally. Further, the later RCGP survey demonstrated that a large majority of respondents had concerns over patient safety and for over 60% of respondents PAs were the first point of contact of undiagnosed/undifferentiated patients. The PFD reports were highly relevant. Mr de la Mare submitted that "any regulator would look at them and say that the documents should be seen, and consideration given to whether the current course is justifiable". In short, there was, he submits, a large amount of relevant material which the defendant should have grappled with. Had the defendant done so, whatever its starting position, it should have changed course and introduced limits on practice. Not to do so was irrational.

(e) The responses to the COI Survey demonstrate that doctors have repeatedly experienced issues in safely delegating to, and determining safe supervision levels for, associates because they cannot easily determine their competence. These concerns, of which the defendant was aware and which were closely linked to the absence of a scope of practice, posed serious risks to patient safety.

(f) The defendant's reliance upon the role of the Trust employing the associate in determining safe limits of practice was misplaced and irrational. It fails to recognise that the employers are "part of the problem and not the cure". Trusts are financially and otherwise motivated (eg to reduce waiting lists) to push the boundaries of what associates can do. The fact that Trusts are subject to clinical governance controls themselves and overseen in various ways by other bodies is irrelevant. This oversight existed before regulation and is not designed to, and does not, deal with associate-specific issues. Ms Richards adds that the reliance upon locally determined limits on practice will inevitably (and indeed already has) led to variability and lack of clarity as between different NHS Trusts. Further, the defendant's approach to regulation ignores the reality of NHS working patterns which may mean that doctors may frequently need to delegate to an associate they have never worked with before (and therefore do not have any understanding of their skills, training or competence) under significant time pressure.

(g) Even if the defendant is correct to say that it is not best-placed to set limits for associates (which again, the claimants do not accept) in the circumstances it was incumbent upon it to 'come off the fence' where the Royal Colleges or other bodies had published scopes of practice and endorse them either in their entirety or those specific parts which it agreed with. The failure to do so is irrational.

(h) The defendant's current regulatory model relies upon quality assured pre-qualification associate training, the power to bring fitness to practise proceedings against associates, and the forthcoming revalidation system. This is insufficient to address the systemic risks posed by associates. This is because (i) the regulation of pre-qualification training does not address those associates who are already working in the system; (ii) fitness to practise proceedings are by definition ex post facto responses to harm which has already occurred, and they are not useful in

addressing systemic issues as opposed to individual failings; and (iii) the adequacy of the fitness to practise and revalidation systems are undermined by the lack of a national scope of practise.

(i) Finally, Mr de la Mare submitted that in reaching its judgement upon how to exercise its powers under the 2024 Order rationally, the defendant was required to consider and assess the potential risks to patient safety and take rational precautions to avoid those risks. In so doing, it should have erred on the side of caution, in particular by not relying upon uncertainty about the risk eventuating. This, he says, accords with the "precautionary principle" see (*R (TransActual CIC) v SSHSC [2025] PTSR* and *R (Plan B Earth) v Secretary of State for Transport [2020] EWCA Civ 214 at para 258 – 261).*

(j) The BMA echoes the claimants' submissions. Ms Richards KC additionally challenged the most recent guidance from the defendant on supervision (the Supervision Practice Advice of April 2025) which requires doctors to '*establish what care [associates] can undertake.*' This, submits Ms Richards, begs the question of how doctors are supposed to do so in the absence of any national scope of practice or guidance endorsed by the defendant.

(k) She submits that the current supervision requirements impose unrealistic demands upon individual supervising doctors who are left to work out how to approach supervision and delegation. Furthermore, far from assisting doctors, it makes matters worse by in some instances being internally inconsistent and presenting a contradictory message. As an example, she cites how the document refers readers to various non-statutory guides including various interim scopes of practice published by the RCA and the RCGP as well as advice published by the College of Medical Associate Professionals, the *MAPS Employer Guidelines General Practice 2024*. That guidance explicitly disavows the BMA and RCGP's Scope of Practice, but also sets out (in an example job description for PAs) various tasks such as providing the first point of contact with undifferentiated patients, 'baby checks', minor surgeries, and holding telephone conferences with patients. All of these tasks, however, fall outside the RCGP's 2024 scope of practice. This begs the question – what is a named supervising doctor, who has now been saddled with the obligation to work out what associates can or cannot do when delegating tasks to them, to do when presented with this contradictory information? She submits that it must be that it is both perverse and unfair to doctors to place the burden of navigating through this uncertainty upon their shoulders.

Defendant's submissions

100. Mr Dunlop raises a preliminary objection to the scope of the claim in Ground 1. He contends that Ground 1 of the claim as pleaded is limited to an outcome rationality challenge to an ongoing state of affairs. He draws my attention to the pleaded case, which concerns the defendant's 'ongoing failures' to impose the safe and lawful practice measures; and that this was reflected not only in the claimants' SFG, but also the claim form and the relief sought (a declaration that the defendant is failing to fulfil its duties and lawfully exercise its powers). These are outcome rationality arguments. During the course of the claimants' oral submissions, the arguments have been reframed to include process rationality arguments (e.g., that the defendant had adopted the wrong

starting point; or that it had failed to reconsider its approach in the light of emerging evidence which allegedly establishes that associates pose a systemic risk to patient safety). This, Mr Dunlop submits, is impermissible. Had a process rationality complaint been pleaded, the defendant may have filed evidence directed to the particular aspects of the alleged flawed process, may have reconsidered one or more issues in a new formal decision or may have raised a defence under s. 31(3D) of the Senior Courts Act 1981. Mr Dunlop does not go so far as to submit that, when considering the rationality of the outcome, I should disregard the process by which the decision was reached. He accepts that the process may affect the margin of discretion available to the defendant. But he submits that the sole question for the court remains whether the outcome falls outside the range of reasonable responses. The case is about the defendant's failure to set nationally applicable hard limits on what associates can (or cannot) do, whatever their experience, even under supervision.

101. The defendant denies that the current regulatory regime is "hollow" and rejects the complaint that it has done nothing meaningful to address the risks posed by associates. The defendant highlighted the requirements for registration (to become mandatory by December 2026), revalidation (albeit that this system is still currently being developed), and the fitness to practise process. In short:

    (a) The defendant has set standardised learning outcomes and educational standards which will assist associates with understanding the limits of their competence.

    (b) Associates who are already practising in the system (and therefore not subject to these new training standards) are required to meet the training standards in order to be registered; and those who fail to provide adequate evidence or simply fail to meet those standards will not be able to work as associates after December 2026.

    (c) The forthcoming revalidation system will involve a five-yearly formal process, but it is anticipated that there will be annual appraisals at the employer level. Those are expected to consider whether the associate has been acting within the scope of their practice (and whether there have been any adverse clinical incidents). The information from the annual appraisals will be highly relevant to the five-year formal revalidation. As before, a failure to meet the relevant standards will mean that an associate will not be revalidated and therefore cannot continue practising.

    (d) Where there are serious concerns which arise during the annual or formal appraisals which cannot be dealt with locally, it is expected that these will lead to fitness to practise proceedings being brought against the associate. As with doctors, there will be a range of sanctions which can be imposed for a breach of professional standards, ranging from imposing conditions on practice to suspension up to removal from the register.

102. The defendant accepts that the principal purpose of the 2024 Order is to protect the public, just as with the regulation of doctors the overarching function of regulation is patient safety. The defendant also accepts that its own COI survey raised serious concerns from a range of respondents about associates working beyond their competence; inadequate supervision of associates; associates failing to explain who they are to patients and patients themselves not knowing and understanding who

associates are. The defendant accepts that those concerns were echoed in surveys conducted by others and in the coronial reports and that those concerns needed to be addressed. The question which arises in this claim is not whether there are concerns over safe associate practice but how those concerns are best addressed, whether they require the introduction of limits on practice and by whom they should be addressed. The claimants' case is that those concerns can only, rationally, be addressed by the imposition of (further) limits on associates' practice and that those (further) limits must be imposed by the defendant. For a number of reasons, including those set out in Professor Melville's evidence, the defendant takes a different view.

103. Mr Dunlop submits that, logically, the case breaks down into two questions. First, whether it would be of net benefit to public protection for limits to be set on associates' practice. Second, if so, is it irrational for the defendant not to set such limits.

104. Concerning the first question, Mr Dunlop accepts that there is scope for disagreement about whether national limits on associates' practice further patient safety and that it is a topic upon which reasonable people may disagree. The claimants have presented the court with one side of the argument but, he argues, there is another side. There are "pros and cons" to the imposition of limits on the practice of associates. Mr Dunlop submits that I must be careful not to enter the debate and seek to resolve it. This would not only be an impermissible exercise of the court's function but is a role the court is not equipped to fulfil. The court's role in this application is limited to answering the question of whether the defendant's approach is rational and therefore lawful.

105. An important downside to the imposition of limits on associates' practice is that it might unduly restrict the contribution which associates can make to the NHS both now and in the future. Mr Dunlop submits that there is abundant evidence of a looming healthcare workforce gap over the next ten or so years. In this context associates will make an important contribution. The DHSC's consultation document (which accompanied a draft of the 2024 Order) set out that "*strengthening the future NHS workforce remains one of the government's priorities*." It continued: "*..associates are already a valued and integral part of the multi-disciplinary healthcare team but have the potential to make an even greater contribution.. The GMC is best placed to regulate the AAs and PAs as they form part of the medical team and are trained to the medical model. Regulation also paves the way for broadening their scope of practice by, for example requesting ionising radiation where local governance allows and, in the future, the possibility of being able to prescribe.*" Mr Dunlop drew my attention to correspondence from the Academy of Medical Royal Colleges (the umbrella body for all Royal Colleges) to the BMA dated 6 March 2024 which suggested that broad profession-wide limits of practice were inappropriate. The author pointed to the dangers of broad profession wide limits commenting that the issue of scope of practice is "a complex issue which is both location and specialty specific."

106. Mr Dunlop submitted that the best account of the pros and cons of imposing limits on associates' practice is provided by the Professional Standards Authority's ("the PSA") submissions to the Leng Review dated March 2025. The PSA oversees all healthcare regulators. The Leng Review was set up by the government in autumn 2024. It is an independent review of the physician associate and anaesthesia associate professions by Professor Gillian Leng for the purpose of agreeing recommendations for the future. It will consider the safety of the roles and their contribution to multidisciplinary

healthcare teams. It is described as an "*end to end*" review of associates' practice covering; selection and recruitment; training; day to day work; scope of practice; oversight; supervision; professional regulation.

107. The PSA's position on the topic of limits on practice is neutral. The object of the paper submitted to Professor Leng was to set out considerations in relation to scopes of practice of health and care professionals. It remarked that the issue of limits on practice had been central to debates about the safety of the physician associate and anaesthesia associate roles.

108. The PSA paper sets the question of limits on practice in context. The authors note that scopes of practice have not been a significant feature of professional regulation within the UK to date and that in the UK, the GDC is the only regulator to have defined scopes of practice for the roles which it regulates. The PSA has not, to date, taken a formal position in relation to the role of scopes of practice within professional regulation but it has been supportive of the GDC's proposals to build greater flexibility into their scopes of practice for the dental team. It noted that scopes of practice have been relevant to debates about the regulation of advanced nursing practice and that for "*several years now, people have been raising concerns about nurses and other professions working at an advanced level, undertaking tasks which, they argue, go beyond the scope of practice and training of registrants*."

109. The PSA highlights the scale of the workforce change which will be needed to deliver healthcare in the future with increasingly challenging economic and social circumstances, with an aging population with increasingly complex needs. This will require the development of new roles, and the evolution of existing roles. It is in the context of this potential work force gap that the PSA considered some of the unintended consequences, or potentially significant downsides, of defined scopes of practice. The PSA noted that the unintended consequences of defined scopes of practice was likely to be one of the central questions for Professor Leng.

110. The unintended consequences may include:

    (a) hindering workforce flexibility and preventing adaptation to fast-paced changes in healthcare delivery which came into sharp focus during the pandemic;

    (b) where scopes of practice are defined, a '*calcifying effect*' upon the boundaries between different medical professions, in which scopes of practice may be used as a mechanism to enforce '*occupational closure*' where any attempt to shift tasks or limits can trigger professional boundary disputes;

    (c) indemnifiers who have a stake in the scope of practice debate may use them to determine the boundaries of indemnity cover;

    (d) even where scopes of practice are not intended to be defined tightly this can be how they are interpreted by professionals – an indicative list of tasks can become an exhaustive list in the eyes of the professionals as was the case in the GDC;

(e) the PSA noted that *'[w]hile it may be necessary for scopes of practice to be set, it may not be necessary for this to be done by the professional regulator ... Royal Colleges and professional bodies can also play a part here*';

(f) The PSA concluded that optimising flexibility in the workforce is going to be a matter of increasing importance and "*so we need to think carefully about how we balance this with safety and accountability*."

111. Mr Dunlop argues that the submission of the PSA to the Leng Review illustrates that the question of limits on practice is a complex issue which engages policy and political issues. The complexity and the nature of the issues engaged is further demonstrated by the fact of the Leng Review itself. Mr Dunlop agrees with the claimants that the Leng Review is of limited relevance to the claim, in the sense that Professor Leng's conclusions, one way or another, will not have a direct bearing on the lawfulness of the decision making of the defendant. He submits however that the fact that the review is considering scope of practice and all aspects of associates' working illustrates why it would be inappropriate for this court to rule on the topic. Importantly, the fact of the review underlines the inherently political and policy-based nature of the issues raised in the claim. Mr Dunlop therefore submits that it would be inappropriate for the court to resolve them even if there were not a review currently underway. Mr Dunlop submitted that it was not for me to "wade in" and rule on the rights and wrongs of the imposition of scopes of practice. The task of regulation had been entrusted by government to the defendant, and not to the court or the claimants and that it is not "for judges to weigh utilitarian calculations of social, economic or political preference." I should guard against the danger of judges "*wrongly though unconsciously substituting their own views for the views of the decision-maker who alone is charged and authorised by Parliament to exercise a discretion*" see *R v Secretary of State for Trade and Industry ex p Lonrho Plc* [1989] 1 WLR 525) at 535. A *Wednesbur*y challenge should not be used as "cover" for the court to impose what it considers as ideal solutions.

112. The question of whether to impose detailed profession-wide limits on the practice of PAs and AAs is a complex multi factorial policy question which is not appropriate for a court to determine in a claim for judicial review. It does not matter whether or not the defendant considered each (or any) of the factors informing the debate when determining not to impose limits on associates' practice. The fact is there is a debate and it is one which engages policy and politics. This means that the outcome rationality ground must inevitably fail. The court cannot rule on whether the premise of the claimants' criticisms is correct.

113. Mr Dunlop says that even if I were to find against him on the first question, the claimants have still failed to show that it was irrational for the defendant not to have set those limits. There are five main reasons for this submission:

(a) First, the court should take into account the defendant's own experience of regulating doctors. It was reasonable for the defendant to take this experience into account. Its understanding drawn from that experience was (and continues to be) that the imposition of high level principles can be an effective means of regulation.

(b) Second, the defendant refers to the consistent advice it received from other regulators not to set detailed limits on associates' tasks. These arose out of separate meetings on 7 October 2019 with the Nursing and Midwifery Council and the GDC. The latter advised the defendant to '*avoid defining role or scope of practice as that inhibits growth of the profession and the role*.'

(c) Third, the defendant lacks expertise in specific fields of clinical management. The Royal Colleges and individual employers are best placed to devise appropriate scopes of practice. As the Academy of Royal Colleges said in its letter to the BMA on 6 March 2024 (in response to the BMA's scope of practice) '*it would be inappropriate for the BMA to set out the scope of practice for [Associates] … it is clear that [curricula and professional practice]* ***falls firmly within our area of responsibility***' (emphasis added). Outside of this litigation both the First Claimant and the BMA have made statements that align with the defendant's argument that it is not best placed to set limits of practice. Mr Dunlop draws my attention to the First Claimant's website entry on 30 January 2024 that the defendant "*does not have the knowledge to define the standards of practice in each of the many different branches of medicine*." In its submission to the Leng Review, the BMA recommended that there should be nationally agreed scopes of practice, not drafted by the defendant, but "*led by medical royal colleges, specialist medical organisations and the BMA with input from associate representatives and patient organisation*s."

(d) Fourth, the DHSC's commentary on a draft of the 2024 Order (addressed to the defendant), and its response to its 2023 consultation, indicated that it expected the defendant to set standards of the kind it set for doctors under s. 35 MA 1983 – which would not include limits on practice but instead comply with the general requirement that they must 'recognise and work within their competence'.

(e) Fifth, the 2024 Order does not require the defendant to impose limits on the clinical tasks which associates may undertake. Had Parliament considered this necessary, it would have included an express duty on the defendant to do so. Moreover, the wording of Art. 3 of the 2024 Order mirrors that of s. 35 MA 1983. It follows that even ignoring what the DHSC had to say, Parliament itself expected the defendant to set high-level standards for associates in the same way it did for doctors.

Ground 1(c): the Supervision and Delegation issue

114. Mr Dunlop submits that the claimants' main residual complaint about the defendant's published supervision guidance is that it lacks granularity. Lack of granularity or detail is not, he submits, a ground for an irrationality challenge. Moreover, the April 2025 Supervision Practice Advice is a complete answer to any criticism.

Ground 1: Discussion/Conclusion

(a) The scope of Ground 1: process and outcome rationality

115. Irrationality as a ground of judicial review encompasses two aspects: *R (Law Society) v Lord Chancellor* [2018] EWHC 2094 (Admin).

(a) The first is concerned with whether the decision under review is capable of being justified or whether in the classic Wednesbury formulation it is "so unreasonable that no reasonable authority could ever have come to it": see *Associated Picture Houses Ltd v Wednesbury Corp* [1948] 1 KB 223, 233-4. Another, simpler formulation of the test is whether the decision is outside the range of reasonable decisions open to the decision-maker: see e.g. *Boddington v British Transport Police* [1998] UKHL 13; [1999] 2 AC 143, 175.

(b) The second aspect of irrationality/unreasonableness is concerned with the process by which the decision was reached. As explained by Chamberlain J in *R (on the application of KP) v Secretary of State for Foreign Commonwealth and Development Affairs* [2025] EWHC 370 (Admin), process rationality includes the requirement that the decision maker must have regard to all mandatorily relevant considerations and no irrelevant ones; and that the process of reasoning should contain no logical error or critical gap.

116. Mr Dunlop drew my attention to the recent decision of *R (Bibi) v Secretary of State for the Home Department* [2025] EWCA Civ 622 (which cited *Talpada v Secretary of State for the Home Department* [2018] EWCA Civ 841). In *Bibi,* the ground of appeal which the appellant obtained permission to advance was not pleaded. It had been raised informally at the time of the oral renewal of the application for permission to proceed with the claim for judicial review but no application was ever made to amend the grounds for judicial review to include it. Notwithstanding these circumstances, permission to appeal was sought (and obtained) on the basis that the lower court had not addressed the issue. These procedural errors were then compounded by service of a (substitute) skeleton argument which recast the ground of appeal in terms for which permission had never been sought and which were conceptually different from and much wider that the ground for which permission was given. *Bibi* and *Talpada* emphasise the need for procedural rigour in public law proceedings and warn against the tendency of grounds of challenge to 'evolve' during the course of those proceedings. This warning is echoed in Chapter 2 of the Administrative Court Guide. This, Mr Dunlop asserts, is precisely what has happened here. The claim has evolved between the original pleadings and the claimants' oral submissions. There has been no application to amend the claim. He submits that process rationality has not been pleaded and the claimants should not now be permitted to advance their case on that basis.

117. I am satisfied that the pleadings sufficiently raise the issue of procedural irrationality and that that aspect of the irrationality challenge is before the court, alongside the question of outcome rationality. I reach this conclusion for the following reasons:

(a) Many of the claimants' submissions both in writing (in the pleaded claim) and oral submissions are not tied to any particular legal issue. The initial focus of the SFG was upon the defence advanced in pre-action correspondence that the defendant did not have the power under the 2024 Order to impose limits on practice. For both of these reasons, understanding the current claim, as expressed in the SFG at least, is more difficult. However, the claimants' case, namely, that the defendant's exercise of its regulatory powers in the 2024 Order was irrational and hollow given its adoption of the "medical model" of regulation and in the face of the emerging evidence from different sources of the risks posed by associates

is sufficiently pleaded. The SFG sets out the complaint of inadequate regulatory response within the context of a factual matrix which refers to the perception by doctors and others of the risks posed by associates; the circumstances of the deaths of Emily Chesterton and Susan Pollitt; the role of the Royal Colleges and the role of employing Trusts. The defendant could not have been in doubt that the challenge it faced in this judicial review was to the outcome of its reasoning process but also that the challenge extended to how it had arrived at that conclusion given its approach to regulation generally and the body of evidence of patient safety risk. No doubt this is the reason for the statements from Professor Melville which set out, chronologically, the defendant's preparation for associate regulation, the work of the MAPS programme and its extensive consultation processes. How the end point (or current state of affairs) was reached and the underlying reasoning are covered in over 150 paragraphs in Professor Melville's first statement and then amplified (and re-emphasised) in 120 odd paragraphs in his second witness statement.

(b) There is an element of artificiality to the argument that process irrationality is not in issue in this case. Any rationality challenge logically involves some engagement with the process by which it was arrived at, as explained by Saini J in this Court in *R (Wells) v Parole Board* [2019] EWHC 2710 (Admin). He described an alternative formulation of the approach to a rationality challenge in this way:

> 32. A more nuanced approach in modern public law is to test the decision-maker's ultimate conclusion against the evidence before it and to ask whether the conclusion can (with due deference and with regard to the Panel's expertise) be safely justified on the basis of that evidence, particularly in a context where anxious scrutiny needs to be applied.
>
> 33. I emphasise that this approach is simply another way of applying Lord Greene MR's famous dictum in *Wednesbury* (at 230: "no reasonable body could have come to [the decision]") but it is preferable in my view to approach the test in more practical and structured terms on the following lines: does the conclusion follow from the evidence or is there an unexplained evidential gap or leap in reasoning which fails to justify the conclusion?

In this claim, the claimants' submissions do not differentiate between process and outcome. This is not just a pleading issue but a function of the fact that process and outcome are here so closely threaded together. The defendant undertook extensive preparatory work over a period of four years in connection with its forthcoming regulatory role of associates. During that preparation, as set out by Professor Melville, it confronted serious concerns regarding associates working outside their limits of competence; working with inadequate supervision and confusion over roles. Professor Melville's statement explains how the defendant responded to those concerns. The end point and the process are in this case impossible to separate.

(c) I agree with Mr Dunlop that *Bibi* is binding upon me and that procedural rigour is essential. But this is not a case (such as *Bibi*) in which a wholly new ground of

challenge is advanced in the absence of an application to amend or in which the case at hearing bears no relationship with the pleaded case. As stated in *R v Secretary of State for the Home Department ex p. Oladehinde* [1990] 1 AC 254 at 280E, per Lord Donaldson MR, "*it would be a mistake to approach the judicial review jurisdiction as if it consisted of a series of entirely separate boxes into which judges dipped as occasion demanded"*. Here the ground of challenge, namely irrationality, is clearly set out in the SFG. Nor do I find that the fact that this is a challenge to an ongoing situation or, as alleged, a continuing failure to implement a safe system of regulation must therefore mean, as Mr Dunlop suggests, that the challenge can only be to outcome and not process. I see no reason why an ongoing situation which is said to be irrational may not be due to ongoing procedural defects or failures which are, in turn, said to be irrational

(d) In any event, given the evidence before the court from Professor Melville, there is no unfairness to the defendant in the case being litigated on the basis of both a process and outcome rationality challenge. Although Mr Dunlop submits that he is disadvantaged in dealing with a process challenge in that he would have served further evidence dealing with specific aspects of the decision, he did not set out what that evidence would have covered. Nor is it clear to me, given Professor Melville's comprehensive statements, what further areas could be covered in supplemental witness evidence

118. I am therefore against the defendant on this preliminary pleading point. I find that this claim includes issues of both process and outcome irrationality.

(b) Ground 1(a) and Ground 1(c): process irrationality

119. I address the process and outcome irrationality arguments separately but, as I have already observed, neither the claimants nor the BMA differentiated between the two aspects of the rationality challenge either in their written or oral submissions. There is considerable overlap and what follows on process applies to the outcome rationality challenge also.

120. I start by recording that I do not accept that the contents of Professor Melville's statements amount to an exercise in which he seeks, retrospectively, to rationalise the approach taken by the defendant. Although in the letter of response the defendant took the point that the 2024 Order did not confer a power on the defendant to impose limits, this letter was written on 16 August 2024. As Mr Dunlop has observed, the process of evolution of GMP and the other advice and guidance started four years' earlier in 2019 at around the time that the defendant was selected to be the regulator. Whatever the position may have been in 2024 after the defendant had had sight of the draft Order could have had no bearing on its approach some years earlier.

121. Nor am I persuaded by the claimants' further point that there can have been, in reality, no active consideration of the issue of the imposition of limits because there is no contemporaneous documentation from the defendant confirming or recording the debate. Professor Melville explains that the decision-making was iterative in the sense that there was no particular date upon which a decision was made not to impose limits on associates' practice. In his second statement he says that it is not unusual for the defendant not to record formally a decision not to do something and that everyone in

the organisation thought that the imposition of scope of practice was inappropriate. He added that the defendant had a very large number of matters to consider when deciding how to regulate associates and that formal records and consultation tend to relate to actions which the defendant was minded to take and not to actions which no decision maker thought appropriate. I accept his evidence.

122. In respect of the process challenge, as I understand the claimants' case, they make two main points. First that the defendant adopted a flawed starting point. Second that the defendant failed to take into account the extensive evidence of patient safety risk due to associates working beyond their competence.

123. I reject the submission that the defendant's starting point was irrational. The decision to apply the medical model to associate regulation:

    (a) reflected the defendant's extensive experience as a regulator;

    (b) was supported by the defendant's review of the practice of other healthcare regulators;

    (c) was consistent with the concerns expressed by the GDC which had adopted limits on practice but was due to consult on that approach given concerns over its implementation by registrants; and

    (d) was consistent with the views expressed by the DHSC when it determined that the defendant was the appropriate regulator.

124. The defendant took into account the findings from its own COI survey. It accepts that those findings demonstrated significant concerns over patient safety due to associates working beyond their scope of practice, concerns over the supervision of associates and delegation of tasks to members of the healthcare team. The defendant considered that those concerns would be addressed by regulation. This response was not irrational. The registration process would include quality assurance of all courses leading to qualification and for those who are already associates the registration process would include evidence that the associate possessed the specified competencies. The defendant was satisfied that by 2026 (although it anticipated the majority of currently working associates to have sought registration within 6 months) all associate registrants would have demonstrated their ability to comply with professional standards and recognise the limits of their competence. The regulation process will include a process of revalidation and appraisal. I agree that other surveys (BMA, DAUK) revealed the same concerns, albeit that those surveys may have been of lesser quality (due for example to bias and anonymity of respondents) and importantly Mr Dunlop does not dispute that much of what is recorded by the claimants in annex 2 of the skeleton argument "evidence of problems with AAs and PAs" from practitioners, Royal Colleges and patients is germane. However, I accept his further submission that, having identified those serious concerns through its own COI survey, the defendant was not obliged either to seek out further evidence of the same points of concern and review or to reconsider its position on limits of practice in the light of other material to the same effect.

125. Mr de la Mare appeared to suggest (in his response) that the evidence of risk was qualitatively different by 2024 compared with earlier in the process leading up to regulation. I do not accept this. By 2024 there had been more surveys but they revealed the same concerns which had been raised earlier. There was evidence of patient safety issues from a different source, in the coronial reports which were generated between 2023 and 2025. Such reports contain material of great importance. But following Ms Chesterton's death, there was no PFD report (to any person or agency) and no doctor was referred to the fitness to practise processes of the defendant. There was a scope of practice document which if followed ought to have prevented the associate from seeing Emily Chesterton on (at least) the second occasion. The report concerning the death of Mr Peters was not addressed to the defendant, but the information provided by the Trust concerning that death did not appear to raise patient safety concerns about PAs (albeit that document has been reviewed by Professor Melville in the context of this claim).

126. There were two PFD reports (Susan Pollitt 31 July 2024) and Pamela Marking (24 February 2025) addressed to the defendant, amongst others. Professor Melville's response to each was to emphasise that the concerns would be addressed by the introduction of regulation. This response was not irrational. At the time of the deaths, associates worked in regulated healthcare settings and had to be supervised, but there were no profession-specific mandatory standards for their pre-qualification training or education or conduct, nor any professional accountability to any statutory body.

127. In addition to his complaint about the starting point (which I reject), Mr de la Mare submits that the defendant took another wrong course by applying a "compelling evidence" test. In my judgment, however, Professor Melville was not intending to set out a legal test which the defendant was then applying to the question of limits. All that he was saying was that the medical model had been a successful model of regulation and there would therefore need to be good reasons to do something different. That was a rational conclusion. The defendant was not entrenched in its view, as Mr de la Mare suggests. Rather, it raised questions relevant to the limits issue in its own COI survey and considered the concerns raised. The question of limits appears to have been raised on at least two occasions in meetings of the EAG without objection.

128. As Professor Melville states, the defendant's approach to the imposition of limits on associates' practice was informed by its understanding of the role of employers and local clinical governance arrangements in ensuring that associates practised safely. Scopes of practice or limits on practice were best identified and implemented locally, taking into account the individual competence and experience of the associate. The level of supervision was best determined locally on an individual basis. This is how supervision generally within the NHS workforce is undertaken. Guidance had been issued by other bodies on the role of associates and the need to have clinical governance arrangements in place. In March 2024, NHSE published guidance for medical directors which emphasised the need for Trusts to have policies and systems in place to ensure that associates were supported, supervised and integrated into the multidisciplinary team. Clinical governance is the responsibility of NHS employers and the various oversight bodies.

129. I find no failure by the defendant to take into account material evidence or mandatory relevant consideration. I find no logical error or critical gap in the defendant's

reasoning. The defendant's approach was I find coherent and not irrational. I therefore reject the claimants' submission based on process irrationality.

(c) Outcome Irrationality

130. The question for me here is whether the defendant's decision not to impose limits of practice for the purpose of patient safety was one which was within the range of reasonable decisions open to it. This raises two further questions: first, whether patient safety requires the imposition of limits on associates' practice and second, if so, whether the defendant is the body which must introduce such limits.

131. I accept that there are patient safety advantages to the introduction of fixed limits on the practice of associates. Those patient safety advantages have been set out in detail by the claimants and are self-evident: the imposition of a general prohibition on associates undertaking certain tasks or performing certain functions means that all risks associated with that activity are eradicated. But I also accept that there are downsides to imposing such limits in practice.

132. Professor Melville referred to various downsides in his evidence. He noted that the creation of hard and fast rules for all associates might restrict associates from undertaking work that they had the competence and experience to perform safely. This in turn may have a detrimental impact upon patient safety overall because a potentially valuable resource is not being utilised. He noted that the defendant's engagement with other regulators suggested that it would be preferable "*to avoid defining roles or scopes of practice because that would inhibit growth of the profession and the role*." This view underpinned the GDC's desire to move away from a prescriptive rules-based approach to standards. Professor Melville referred to the possibility of such ceilings on practice fettering the development of the individual associate.

133. The submission of the PSA to the Leng Review reveals perhaps a fuller range of policy issues. It also places those issues in their relevant economic and social context. The associate profession is expected to make an important contribution to the healthcare workforce over coming years. NHS England has set out in its NHS Long Term Workforce Plan that the number of people aged over 85 years is estimated to grow by 55% by 2037 and that without "concerted and immediate action" the NHS will face a workforce gap of more than 260,000 – 360,000 staff by 2036/37. The impetus from the government is to increase the scope of associates' practice to include tasks currently prohibited (for example, prescribing), the object being that they are able, under supervision, to perform tasks which will free up doctors for the more complex work. Whilst I agree that this may on the one hand suggest the need, perhaps the strong need, for appropriately defined limits on practice, the authors of the PSA submission point out a range of other countervailing considerations. I also agree that the fact of the Leng Review, an "end to end" review of safe working practices of associates, confirms the existence of a genuine debate engaging a range of stakeholders and policy issues, economic and social.

134. I am satisfied therefore that there exists a genuine debate about whether the imposition of national limits on the practice of associates is overall in the interests of patient safety. The GDC's experience is particularly relevant. As the only regulator to have imposed a "pared down" version of a scope of practice on its registrants, it is now actively

reviewing that decision in favour of a less prescriptive approach which would "enable dental professionals to use professional judgment to make decisions in the interests of their patients." Its experience has been that the scope of practice was limiting and restricting a professional's practice which could impact patient care. Further, the fact that the balance sheet is not loaded on one side only is spelt out by the fact of the Leng Review, the submission of the PSA to that Review and the defendant's own findings.

135. The existence of this debate is fatal to ground 1(a) of this claim. It is not for me to enter the debate and resolve it one way or the other. That is not this court's role: my only role is to determine whether the defendant's decision not to impose a ceiling on practice is irrational. Further, this court is simply not equipped to weigh complex social, political and economic issues and then express a concluded view on the pros and cons of limits of practice. This may be a matter for Professor Leng in her wide-ranging inquiry but it is not a matter for me.

136. Mr de la Mare seeks to address this issue by arguing that the defendant itself did not undertake the sort of "meaningful polycentric balancing" to which the defendant refers. By "meaningful polycentric balancing", I understand him to be referring to the weighing of the various pros and cons of the imposition on limits. But this misses the point. The fact that the defendant did not engage with the detail of the social, economic and political issues connected to the looming work-force gap is not relevant. There is robust evidence before me that the debate exists and has yet to be resolved. If there is evidence of a range of opinion, particularly one involving economic and policy issues, then the court is not equipped to judge the issue, irrespective of whether those points featured in the defendant's approach. I agree with Mr Dunlop that the fact that political and policy decisions may not have influenced the decision maker does not matter, although in this case, whilst perhaps not expressed in exactly the same way, the defendant's thinking was influenced by the need not to fetter the development of competent associates or to restrict their potentially valuable role as members of the healthcare workforce which might impact negatively on patient safety.

137. I am satisfied that the defendant's decision not to impose national limits on associates' practice was rational for another reason. Even if the imposition of national limits of practice were the only rational outcome to the debate which I refer to above, then I am satisfied that it was not irrational for the defendant not to impose those limits for the following reasons:

    (a) Outside this litigation, no one (including the First Claimant and the BMA) has suggested that the defendant is best placed to define such limits. The Chair of the Royal Academy (the umbrella body of the Royal Colleges) wrote to the BMA on 6 March 2024 (in response to the production by the BMA of a scope of practice) to say that it had been "inappropriate" for the BMA to draft the scope of practice and that "the issue fell firmly within our area of responsibility." The Chair informed that BMA that work on the project had been underway for many months "within the Academy and among the colleges and faculties." There was no suggestion from that organisation that the defendant was best placed to draft national limits of practice. On the contrary, the issue fell firmly within the remit of the Royal Colleges.

(b) The defendant itself does not accept that it has the expertise to define tasks and functions which are off limits to associates in primary care, medical and anaesthetic practice. Nor does the defendant consider it appropriate to simply "endorse" a scope of practice drafted by one of the Royal Colleges (see above at para. 89(b).

(c) The defendant does not assert that there is no role for limits on practice. On the contrary, as I understand Professor Melville's evidence, individual limits are, or may be, appropriate and developed in discussion between the named supervisor and the associate and taking into account the experience of the associate. In this context:

(i) The defendant has promulgated Supervision Practice Advice (April 2025) which sets out, amongst other things, the role of the named supervisor. Part of that role is to determine the competence of the associate and with that the level of supervision required. It sets out how a doctor, other than a named supervisor, can find out the range of tasks and the extent of the competence of the associate.

(ii) The defendant has taken into account local clinical governance arrangements on the basis that patient safety is not the remit solely of the regulator. In its December 2024 guidance the defendant sets out that "*effective clinical governance systems are vital to make sure that PAs and AAs are properly and safely deployed. Organisations that employ PAs and AAs should make sure their governance arrangements take into account that these professionals are trained and will be registered on the basis that they will always work under supervision."*

138. For these reasons I dismiss ground 1(a). I am satisfied that the defendant's exercise of its role as regulator of associates was coherent and rational. I am against the claimants on both the process and outcome challenge. I make two further points:

(a) First, the precautionary principle referred to by Mr de la Mare adds nothing to the ordinary application of the *Wednesbury* test: see *Plan B Earth v Secretary of State for Transport* [2020] EWCA Civ 214 at [73-75].

(b) Second, even if I am wrong on the question of whether the process adopted by the defendant was irrational and that the defendant either failed to take into account a mandatory consideration or there was a logical gap in the defendant's reasoning, I am quite satisfied that, but for any such defect of reasoning, the outcome for the claimant would have been highly likely to be the same. That being so, I would have been obliged to refuse relief under s. 31(2A) of the Senior Courts Act 1981.

139. I also dismiss ground 1(c). It seems to me that grounds 1(a) and 1(c) go hand in hand given the claimants' case that, absent defined limits of practice, delegation of tasks and supervision of associates cannot be safely undertaken.

140. I add however that to the extent that there was ever a free-standing challenge to the defendant's failure to set standards and produce guidance on safe supervision of

associates by doctors, any such challenge has been completely answered by the promulgation of the April 2025 "Supervision Practice Advice." There was no objection to my reading this document (and others which post-dated the issue of the claim) and taking it (and others) into account. Its development and imminent publication was heralded by Professor Melville in his first statement. It was not, I find, a response to the claim (as at one stage suggested by Mr de la Mare) given its genesis some months before the claim was issued and a disclosure application seeking underlying documents was not pursued. In any event, such challenges to this publication as maintained by Mr de la Mare and Ms Richards at the hearing are, as Mr Dunlop characterises them, challenges to its "granularity" or detail only. A lack of detail in a guidance document does not make it unlawful or irrational. I dismiss this ground also.

Ground 1(b): Informed Consent

Submissions

141. Ms Patel KC, for the claimants on this ground, advanced an argument on two bases: do either (i) the statutory objectives of patient safety and public confidence (the primary submission), or (ii) the law on informed consent as set out in *Montgomery v Lanarkshire Health Board* [2015] AC 1430 (the secondary submission) require patients to be made aware that they are being treated by associates instead of doctors?

142. Ms Patel cited the various surveys and coroners' investigations and PFD reports (as well as the evidence of Mrs Chesterton and Mr Pollitt) as evidence that knowledge of an associate's role – and specifically the fact that they are not a doctor – is material to the statutory objectives of patient safety and public confidence. She submits that the evidence shows that patients and the wider public lack an understanding of the differences between associates and doctors, in circumstances where they expect to be seen by the latter. That is a problem which goes to public confidence.

143. These issues are also relevant to the validity of the patient's consent to being treated. As Ms Patel submits, without valid consent, any treatment of the patient may amount to battery. In *Montgomery*, the Supreme Court held that doctors are under a duty to take reasonable care to ensure that patients are aware of any 'material' risks involved in recommended treatment. The judgment reflected a shift from the paternalistic relationship between medical professionals and patients to one which respects patient autonomy. Doctors must apply the test of materiality, as explained by Lord Reed and Lord Kerr in the judgment of the Court:

> 87. … The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

144. Ms Patel accepts that *Montgomery* concerns doctors and not associates. She accepts also that the case concerned material risks of the treatment proposed rather than the risks associated with the treatment provider. She submits however that the case is authority for the proposition that the fact that an associate is not medically qualified is a material factor to the patient's consent to receiving treatment from the associate. The

fact that associates are not medically qualified and far more lightly trained than doctors may have an important bearing on, say, the patient's decision to seek a second opinion or choice of follow-up care.

145. Ms Patel argues that a rational exercise of the powers conferred under the 2024 Order required the defendant to ensure patients are made aware that they are being treated by associates in certain contexts, in order to satisfy the statutory objectives and comply with the law on informed consent. This is something which has been recognised by other bodies, yet the defendant has failed to do the same.

146. One way of ensuring this would be to require associates to introduce their title and explain their role in all circumstances, but Ms Patel accepts that something less than this would be lawful. She accepts that it is not always material to know that the person treating you is not a doctor. Treatment by an associate is not necessarily more risky than treatment by a doctor. It depends upon the nature of the treatment and the context. In the SFG, the claimants submit that the key is whether in a particular context the patient would reasonably expect the practitioner in question to be a doctor. This is context specific, considering factors such as the setting and task to be undertaken. The patient may not have a reasonable expectation that minor matters such as those routinely performed by nurses would be performed by a doctor. But when an associate undertakes a task that the patient would reasonably expect to be ordinarily performed by a doctor especially where the setting contributes to the impression then informed consent does require a clear statement that the associate is not medically qualified.

147. The defendant's standards and guidance are deficient and have not, it is submitted, satisfied the threshold. The current standards and guidance either approve or direct associates to act in a way which is unlawful in certain contexts (being contrary to the law on informed consent for the reasons set out above). In particular, the guidance is said to fall within the three categories of unlawful policy set out at *R(A) v Secretary of State for the Home Department* [2021] UKSC 37 in that it (i) includes a positive statement of the law which is wrong and would induce an associate to breach their legal duty in some way; (ii) omits to explain the correct legal position in circumstances where the Defendant is under a legal duty to provide accurate advice about the law; and (iii) even if the defendant was under no such duty, the defendant has nevertheless failed to give a full account of the legal position because of that omission.

148. For the BMA, Ms Richards echoes the submissions of the claimants and adds two further points of her own.

149. First, she highlights the discrepancy between the defendant's approach to the issue of informed consent as between on the one hand (i) doctors and associates; and on the other (ii) doctors and medical students. In both circumstances, there is said to be a "type" difference between doctors and the other group. Unlike associates, however (and as set out in its guidance for medical students in *Achieving good medical practice: guidance for medical students*), the defendant recognises that it is both necessary for a medical student to inform a patient that they are a medical student and not a doctor and that this knowledge is explicitly linked to the issue of informed consent. The discrepancy is particularly illogical where there is ample evidence that patients and the wider public do not know or understand how an associate differs from a doctor; whereas

they would much more easily recognise that a medical student is not a fully-trained doctor.

150. Second, the interim GMP (drafted in anticipation of a delay in the 2024 Order coming into effect) itself noted the link between providing patients with information about an associate's '*role and responsibilities in the [medical care] team*', and informed consent. That is the reason why the BMA's own scope of practice requires associates to make clear that they are not doctors to patients. In contrast, the existing provision in GMP does not in fact require associates to do anything of this sort. It provides that:

> "You must always be honest about your experience, qualifications, and current role. You should introduce yourselves to patients and explain your role in their care."

As GMP itself makes clear however, the words '*You must*' are used for '*for a legal or ethical duty you're expected to meet (or be able to justify why you didn't)"* whereas *"You should"* is used for *"duties or principles that either: may not apply to you or the situation you're currently in, or you may not be able to comply with because of factors outside your control*'. In the upshot, taken at its highest GMP could be said to only require an associate to state their title – which patients will not correctly understand – but not to require associates to convey the critical fact that they are not a doctor.

151. Mr Dunlop submits that the standard set in GMP is that associates should explain their role. The guidance, in particular the guidance set out in the December 2024 document "PAs and AAs in Practice" explains how that standard is to be achieved. There will be some contexts in which explaining one's role means setting it out in full and saying you are not a doctor; and there will be others where this is not necessary. In these circumstances, it is not therefore appropriate to be prescriptive of precisely what associates should tell a patient. He argues that nobody applying the defendant's advice appropriately would end up in a situation where they would simply state '*I am a PA/AA*' in circumstances which warranted a fuller explanation.

152. As to the claimants' secondary submission on the ingredients of informed consent, Mr Dunlop observes that the claimants are asking the court to extend the legal principle in *Montgomery* to apply in an entirely different context where the risk to the patient arises not from the treatment, but rather the person treating them. There is no authority to support such a proposition. It amounts to a significant and novel development of the common law. He submits that it is not appropriate for the court to do this, particularly not in the abstract and not in a very sensitive area of law which could have serious criminal consequences for medical practitioners.

153. Turning to *R(A)*, Mr Dunlop submits that none of the three categories of unlawful guidance set out at para. 147 apply here. In relation to category (i), the claimants have not pointed out any specific example of guidance which the defendant had produced which was wrong, and which would induce an associate following it to act unlawfully in some way. The claimants' argument is not that GMP or the guidance and advice are wrong, but rather that they do not go far enough. As to category (ii), neither Art. 3 of the 2024 Order nor the common law required the defendant to produce guidance or advice on informed consent, and in any event the advice which is offered is accurate.

Finally, as to category (iii), the guidance issued by the defendant does not purport to be a full account of the legal position on informed consent. Instead, it says quite simply that medical professionals should give patients the information they want to make a decision.

Ground 1(b): Discussion/Conclusion

154. I start by setting out what I understand to be the residual issue between the parties on the claimants' first (and primary) argument, which focusses upon standards of professional conduct (rather than informed consent).

155. Both parties are in agreement that patient safety and public confidence in the profession do not require an associate to inform a patient that he or she is not medically qualified in all circumstances. The claimants' case is that associates must inform patients that they are not medically qualified if undertaking a task which a patient might reasonably expect a doctor to perform. To this extent there is, or can be, no complaint by the claimants that the existing standard (set out in GMP) "*You must always be honest about your experience, qualifications, and current role. You should introduce yourselves to patients and explain your role in their care*" is not apt. The complaint is that the defendant has not gone far enough and it should set out in (either in GMP or in guidance) that an associate must inform the patient that he or she is not medically qualified if, broadly, they are performing a task or function that the patient might expect a doctor to perform.

156. Mr Dunlop draws my attention to the advice on Introductions in "PAs and AAs in practice" (February 2025). The document provides advice on the requirement that associates must introduce themselves to patients and explain their role in their care. It provides examples of how associates can or should introduce themselves. It advises (a) using and explaining their title in full before using any abbreviations (b) taking time to explain their role during clinical interactions (c) remembering that role titles may not always be immediately clear to others and could sometimes be misunderstood if not clearly explained and (d) offering patients and staff the opportunity to ask for more information about their role and taking sufficient time to explain.

157. I asked Mr Dunlop why the section did not spell out that an introduction might require the associate to state clearly that they were not medically qualified in certain circumstances. His response was that the February 2025 advice "amounts to the same thing" and that an associate following this advice will "in many contexts" be required to say that they are not doctors. Although he made no concession on the point, I did not understand Mr Dunlop to be disagreeing that those contexts would include the situation in which a patient might reasonably expect a doctor to be the one performing the task or function.

158. As I understand the position, therefore, the defendant's case is that the current advice, if followed by the associate, will require him or her to say that they are not medically qualified if they are engaged in a task or function that a patient might reasonably expect a doctor to perform. The claimants require this to be spelled out. This is the difference between the parties.

159. The question for the court is whether the defendant's guidance is irrational. My view is that the current state of affairs is not. The advice set out in GMP and associated guidance properly understood is to the same effect as that contended for by the claimants. I accept that the February 2025 advice could be clearer but, as Mr Dunlop has submitted, there will always be alternative ways of expressing the advice and it not the role of the court to get drawn into a detailed review of the drafting of the guidance and/or to make suggestions on how it might be improved. As the Supreme Court has made clear in *R(A)* a challenge to guidance will only succeed if the guidance falls into one of the three categories set out in paragraph 46. The defendant's guidance does not fall into any one of those categories.

160. I move on then to Ms Patel's further argument under ground 1(b) by which, by her proposed extension of the principles in *Montgomery*, she submits that an associate who fails to inform a patient that he or she is not an associate will have failed to inform the patient of a material risk or factor and have failed to obtain informed consent.

161. I can deal with this point shortly. I have no hesitation in declining the invitation to extend the scope of the law on informed consent as suggested by Ms Patel. The contention that the qualifications of the person offering the advice or performing the task is a "material risk" is a novel and very significant extension of the principle in *Montgomery*. If Ms Patel's submission were accepted, then as she acknowledges, a failure by an associate to tell the patient that he or she is not medically qualified may result in the associate being subject to criminal sanction.

162. I have a number of difficulties with Ms Patel's proposition. First, there is no authority for the proposition advanced and I have no doubt that if any such authority existed either in this jurisdiction or elsewhere it would have been unearthed. Second, any such argument should be considered in the context of an individual set of facts, either agreed or as found at trial, rather than in the abstract. Third, the proposition for which Ms Patel contends has far more wide ranging implications for healthcare professionals generally than she appears to acknowledge. If, as she submits, the qualifications of an associate are a material risk factor to any treatment undertaken then it may be argued that any medically qualified professional who has failed to disclose that they have never undertaken the proposed procedure before, or not for a long time, or that there are others who are more experienced has failed to disclose a material fact or risk and have failed to obtain informed consent and may therefore be guilty of a criminal act. Further, Ms Patel appears to suggest that the principle in *Montgomery* extends beyond the duty of a doctor to advise a patient upon the material risks of a treatment or procedure but to advice on other topics, for example diagnosis (as in the case of Ms Chesterton) and that (presumably) such advice is vitiated by the associate's failure to inform the patient of their qualifications. Such an extension is novel to say the least. It is axiomatic that the common law develops incrementally and by analogy and in the context of a particular set of facts. It is not developed in giant leaps by reference to theoretical situations.

163. For all of these reasons I am against Ms Patel in her submissions on ground 1(b).

Ground 2: *Tameside* duty of inquiry

164. Mr de la Mare submits that the enactment of the 2024 Order gave rise to a question which the defendant had to answer concerning the use of its discretionary regulatory

powers (since the 2024 Order did not prescribe the approach it had to take). In his skeleton argument he poses the question thus: "*What regulatory approach was the Defendant going to adopt to address the various risks posed by Associates in order to safeguard public safety (and would this include the safe and lawful practice measures)?*". In the course of his oral submissions, Mr de la Mare ventured that the words within the brackets could be deleted (in response to the defendant's written submissions), but that did not alter the fundamental submission which was this. The core question was one of risks to patient safety, and how those ought to have been managed. It was therefore incumbent upon the defendant to make appropriate inquiries into those matters. However, as a result of its irrational starting point it had sidelined this issue and focused solely upon the question of regulatory approach divorced from risk. It follows that the defendant's approach was *Tameside* deficient for having failed to inquire into the topic of what was in fact happening on the ground.

165. In their written submissions, the claimants list specific examples of the defendant's unreasonable approach to its inquiries:

(a) Failing to make adequate focused inquiries into the serious problems and harm to which the existing system had given rise and, on the contrary, assuming that the longstanding nature of the problems supported essentially continuing the status quo. Rather than explore the differences between associates and doctors, and investigating the particular patient risks posed thereby, the defendant started from the premise that they could be regulated just like doctors, such that nothing further needed to be done.

(b) Failing to investigate the risks posed by the absence of any or any consistent employer approach to associates' scope of practice (e.g. how is safe delegation possible when little is known about the skills of a particular associate and there is no training path against which to benchmark them?). Instead of considering the risks posed by the absence of such a scope of practice, the defendant decided that fixing limits was not for it and so did not consider the systemic risks posed by its absence or whether there was anything it could do to mitigate or control such risks.

(c) Failing to gather adequate evidence about the risks posed by the different approaches being taken by NHS Trusts and other employers in order: (i) to understand whether, how and why they were creating a problem of associates acting beyond competence (as the PFD Reports indicated); and (ii) to inform any conclusion as to whether such employers could be trusted, absent further regulation from the defendant, to empower delegating and supervising doctors to set safe limits on associate practice. Indeed, the defendant did not simply fail to make inquiries but seemingly ignored evidence that could easily have been obtained about employers pushing the boundaries of safe practice, such as was obtained by the claimants.

(d) Even after receipt of the PFDs (the two PFD reports and one record of inquest which existed at the time and raised serious concerns), failing to gather and consider further information on serious harm, including deaths, caused by the lack of safeguards. This failure to investigate is said to be particularly striking in the context of informed consent. For instance, the defendant did not research into

whether or not patients were confused or had any expectation in certain clinical contexts that they were being treated by a doctor.

(e) Viewing its COI survey results as supportive of its approach, when the defendant should have raised a red flag as to the need to consider taking a different approach, in particular by considering introducing the safe and lawful practise measures; and subsequently claiming to have addressed relevant concerns when in reality they were ignored or dismissed.

(f) Dismissing concerns raised in workshops, other meetings and responses to consultations, rather than further investigating them, where they did not suit the defendant's settled approach, and/or claiming to have addressed the problems raised when in fact they had not

166. Mr Dunlop submits that the core of the claimants' complaint on this ground is that the defendant's inquiry has not been of a sufficient intensity. Yet as *R (Khatun) v Newham LBC* [2004] EWCA Civ 55, [35] (Laws LJ) shows, the manner and intensity of inquiry into a relevant factor to be undertaken are matters for the decision-maker and not this court to decide, subject only to *Wednesbury* reasonableness. Moreover, the question framed by the claimants is one of their own creation arising in these proceedings – there is nothing in the terms of the 2024 Order which requires the defendant to answer it, and it is in any event based on the faulty assumption that the public would be safer if the defendant implemented the safe and lawful practise measures. Even accounting for Mr de la Mare's deletion of the wording in the brackets, their formulation of the question is based solely on the aspect of risk but does not account for the other side of the coin of public protection, which is that in the future associates may be required to provide further healthcare assistance in new and developing ways (as articulated in the PSA's submissions to the Leng Review).

167. The correct question which the defendant needed to answer under the 2024 Order was, quite simply, '*What regulatory approach should be adopted to best protect the public?*'. In determining the standards which should apply to associates, the defendant took various steps as set out above by Professor Melville in his evidence. It has never been suggested that the various consultations were in any way deficient, nor have they been challenged on that basis. It follows that these extensive inquiries satisfy the requirements of the defendant's *Tameside* duty.

168. The list of failings spelled out by the claimants above represents a misunderstanding of what *Tameside* requires. It is not required to conduct the sort of end-to-end review which Professor Leng is undertaking; there was no obligation upon the defendant to commission further evidence in light of the steps which it had already taken above. In any event, the defendant was well aware of the differences between doctors and associates, since these were inherently interlinked with matters which the defendant regulated such as education, training and different types of registration. Moreover, it had explored a wide range of concerns through its initial research and subsequent engagement, and it did substantively respond to the two PFD reports which had been addressed to it. Nor was it for the defendant to undertake detailed investigations into alleged failings by employers since those were for NHS England, the CQC and other regulators to resolve. To the extent that concerns were raised which were appropriate for the defendant to consider and deal with, that had been done; and it had also noted

those concerns which were more appropriately dealt with by others. There was therefore no merit in Ground 2.

Ground 2 Discussion:

169. In exercising a discretionary power, a decision-maker has a duty to take reasonable steps to acquaint itself with the relevant information needed to enable it to answer the question which it has to answer: *R (Campaign Against Arms Trade) v Secretary of State for International Trade* [2019] 1 WLR 5765, [2019] EWCA Civ 1020, [58] (citing *Tameside Metropolitan Borough Council* [1977] AC 1014, 1065). The *Tameside* duty of inquiry is a distinct ground of rationality which requires the decision-maker to have made sufficient factual enquiries as to factors relevant to the problem(s) which it seeks to address by exercising its powers. The test to be applied was set out by the Divisional Court in *R (Plantagenet Alliance) v Secretary of State for Justice* [2014] EWHC 1662 (Admin), [139] as: "*Could a rational decision-maker, in this statutory context, take this decision without considering these particular facts or factors?*"

170. The relevant principles in relation to the *Tameside* duty of inquiry were summarised by the Divisional Court in *Plantagenet Alliance* (later cited with approval by the Court of Appeal in *Balajigari v SSHD* [2019] EWCA Civ 673). As the Divisional Court explained:

> "1. The obligation upon the decision-maker is only to take such steps to inform himself as are reasonable.
>
> 2. Subject to a *Wednesbury* challenge, it is for the public body, and not the court to decide upon the manner and intensity of inquiry to be undertaken (*R(Khatun) v Newham LBC* [2005] QB 37 at paragraph [35], per Laws LJ).
>
> 3. The court should not intervene merely because it considers that further inquiries would have been sensible or desirable. It should intervene only if no reasonable authority could have been satisfied on the basis of the inquiries made that it possessed the information necessary for its decision (per Neill LJ in *R (Bayani) v. Kensington and Chelsea Royal LBC* (1990) 22 HLR 406).
>
> 4. The court should establish what material was before the authority and should only strike down a decision by the authority not to make further inquiries if no reasonable council possessed of that material could suppose that the inquiries they had made were sufficient (per Schiemann J in *R (Costello) v Nottingham City Council* (1989) 21 HLR 301; cited with approval by Laws LJ in (*R(Khatun) v Newham LBC* (*supra*) at paragraph [35]).
>
> 5. The principle that the decision-maker must call his own attention to considerations relevant to his decision, a duty which in practice may require him to consult outside bodies with a particular knowledge or involvement in the case, does not spring from a duty of procedural fairness to the applicant, but from the Secretary of State's duty so to inform himself as to arrive at a rational

> conclusion (per Laws LJ in (*R (London Borough of Southwark) v Secretary of State for Education* (*supra*) at page 323D).
>
> 6. The wider the discretion conferred on the Secretary of State, the more important it must be that he has all relevant material to enable him properly to exercise it (*R (Venables) v Secretary of State for the Home Department* [1998] AC 407 at 466G)."

The Divisional Court also explained that '*the Tameside information must be of such importance, or centrality, that its absence renders the decision irrational*' (**[139]**).

171. I find that, when considering the regulatory approach to be implemented when exercising its powers under the 2024 Order, the defendant needed to bear in mind the overarching objective in the MA 1983 (as well as the subsidiary statutory objectives in both of those enactments). It is common ground between the parties that the objective of protecting, promoting and maintaining public safety, health and well-being included considering the risks which are or were posed by associates. I agree with Mr Dunlop, however, that that was only one part of the inquiry, and the defendant would also have been required under the overarching objective of protection of the public to consider the bigger picture of evolving healthcare provision in the UK, and in particular how best to accommodate the development of the associate roles.

172. I turn to consider the information which was available to the defendant when deciding upon its regulatory approach. Preparatory work began as early as October 2019 and continued on into 2024 (and work is still ongoing on the revalidation system). During that period, as explained by Professor Melville in his witness statements, the defendant undertook extensive work including literature reviews, engaging with other stakeholders and healthcare regulators, holding meetings with its EAG and Advisory Forum, the COI survey, discussions with focus groups, and two public consultations on the amended GMP and the guidance for PAs respectively. The defendant accordingly had before it the following information (although I do not suggest this to be an exhaustive list):

    (a) The defendant's experience regulating doctors using the existing regulatory model;

    (b) Information from other regulators including the NMC and GDC suggesting it was appropriate not to set limits or scope of practice on associates' work so as not to inhibit the growth of the profession and the role; and

    (c) Feedback from the COI survey which reflected significant concerns that associates were acting outside of their limits; were lacking in supervision and that there was confusion over their role.

173. The defendant was aware of the risks which the claimants argue it should have looked into. Thus the claimants' submission, properly understood, is that the defendant ought to have gone further in assessing issues arising at the local/employer level. It may very well have been desirable for it to do so – but the question of the matter and intensity of

the inquiry to be undertaken was a matter for the defendant to decide, subject only to the threshold of *Wednesbury* unreasonableness.

174. Stepping back, the question which this court must ask itself is whether a reasonable decision-maker in the defendant's position, with the information that it had available to it, could have decided upon adopting the regulatory approach that it did. I have little hesitation in answering that question in the affirmative. The defendant embarked on an extensive research program to inform the development of its professional standards and guidance to be applied to associates. That what was required of it under the 2024 Order. I do not consider that the failure to inquire further about the situation 'on the ground' comes anywhere close to rendering its chosen regulatory approach irrational.

Conclusion

175. I dismiss this claim on all grounds.

176. I add by way of postscript that the Leng Review was published on 16 July 2025 and forwarded to me by the defendant. The report does not propose a national scope of practice for associates, nor does it recommend that the defendant produces any further or different guidance on supervision or consent. The report recommends a defined national initial job description for PAs in primary and secondary care and for AAs when they first qualify and opportunities for further training through a national "credentialing programme" approved by new faculties for associates and supported by host Royal Colleges. The review recommends that PAs should not see undifferentiated patients except within clearly defined clinical protocols. The report does not however say that the defendant should enshrine this restriction in its regulatory framework.

177. I received short submissions as to its relevance from the parties on 24 and 25 July. In summary only:

    (a) The defendant submits that the report is fatal to the claimants' outcome irrationality grounds. The scope of the inquiry was wide-ranging and the evidence considered far more extensive than that which I have seen. The report did not conclude that there should be a national scope of practice for associates, save that they should not see undifferentiated patients. There is no suggestion that the defendant should have, or should going forward, incorporate this restriction into its rules. The procedural challenges are now academic.

    (b) The claimants submit that I should put the conclusions of the report to one side. The report is by a different person and for a different function. It cannot affect the legality or not of the defendant's actions. It does not address the core question raised by this claim which is whether the defendant has acted unlawfully in its regulation of associates. At most it goes to relief.

    (c) Ms Richards submits that the Leng review and its conclusions do not affect the claim one way or another. She also submits that because the Leng review is undertaken by someone other than the public body whose actions are under challenge and which post dates the matters under challenge, the conclusions of the review cannot render an unlawful decision or action lawful. She points out

that the review is a "mixed bag" and that there are a number of comments and findings which are consistent with submissions made by the BMA before me.

178. I agree with Mr de la Mare and Ms Richards. The contents of the report are not relevant to the issues which I must decide. It was a report prepared by a different person for a different purpose. It is not directed to ascertaining the lawfulness or otherwise of the defendant's regulation of associates. The evidence before the review was more extensive than that before me. In these circumstances I have had no regard to the report in reaching the conclusions which I have set out in this judgment.

179. I thank all counsel and their legal teams involved in this case. I have received a great deal of assistance from them. Each team presented their client's case skill and care.