

Neutral Citation Number: [2025] EWHC 2015 (Admin)

Case No: AC-2024-LON-001142

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: Thursday 31 July 2025

Before :

MRS JUSTICE EADY DBE

- -

Between :

THE KING **on the application of: (1) SUSAN EVANS and (2) XX**	**Claimants**
- and -	
CARE QUALITY COMMISSION	**Defendant**
(1) GENDER PLUS HEALTHCARE LIMITED **(2) SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** **(3) NATIONAL HEALTH SERVICE COMMISSIONING BOARD** **(4) YY** **(5) ZZ**	**Interested Parties**

- - - - - - - - - - - - - - - - - - - -
- -

Tom Cross KC and Oliver Jackson (instructed by **Sinclairslaw**) for the **Claimants**
Jamie Burton KC (instructed by **CQC Legal Services**) for the **Defendant**
Peter Mant KC (instructed by **Rook Irwin Sweeney LLP**) for the **First Interested Party**

Hearing dates: 24 and 25 June 2025

- -

Approved Judgment

This judgment was handed down by the Judge remotely by circulation to the parties' representatives by email and release to The National Archives. The date and time for hand down is deemed to be 2pm on 31 July 2025.

Introduction 1
Preliminary issue 3
The decisions under challenge and the issues for determination 8
The factual background 10
The parties 10
The context 14
The chronology relevant to the decisions under challenge and the current proceedings 30
The registration decision 35
The assessment decision 41
IP1 patient data 50
Advocacy 51
O v P 57
The statutory framework 60
The CQC's statutory objectives 60
Regulated activity 62
Registration of persons who carry on regulated activity 64
Reviews and performance *assessments* 69
Fundamental standards 70
Statutory guidance *for registered* persons 71
Relevant legal principles 73
The applicable standard of review 73
Process rationality 78
Outcome rationality 81
The Padfield principle 83
The parties' arguments 84
The claimants' position 84
The position of the CQC 88
IP1's position 92
Analysis and conclusions 95
Preliminary observations 95
(1) Process irrationality 100
(2) Outcome irrationality 118
(3) The Padfield challenge 134
Disposal 136

Mrs Justice Eady DBE:

Introduction

1. This claim relates to decisions taken by the Care Quality Commission ("CQC") regarding the registration and assessment of Gender Plus Healthcare Limited (a private gender dysphoria clinic), which is the first interested party in these proceedings ("IP1"). The case brought by the two claimants ("C1" and "C2") is concerned with treatment provided by IP1 to 16 and 17 year olds involving the prescription of hormones, referred to either as "*cross-sex hormones*" or "*gender-affirming hormones*"; for the purposes of this judgment, I have referred to this as "*the hormone treatment*".

2. The hormone treatment in issue involves the prescription of masculinising or feminising hormones (oestrogen; testosterone), introducing irreversible changes to the patient's body. There are strongly held views about this treatment and an expert panel is due to report to the Secretary of State for Health and Social Care on its use for those under 18. At present, however, the treatment provided by IP1 to 16 and 17 year olds is permitted by law, and the issue I am required to determine is not whether that is correct, but whether specific decisions made by the CQC are irrational and/or unlawful.

Preliminary issue

3. The way in which this claim has been put has changed over the course of the proceedings. This was in part envisaged at the permission stage: in his order of 8 November 2024, Foxton J allowed that the claimants might seek to rely on amended grounds so as to be able to include reference to potentially relevant events that had occurred since the commencement of the proceedings. An amended statement of facts and grounds of claim was duly filed and served in January 2025, with detailed grounds

of defence (for the CQC) and detailed grounds for contesting the claim (for IP1) being filed and served in February 2025.

4. In both the original and the amended claims, the grounds identified by the claimants were threefold: ground 1, regarding the CQC's decision to register IP1in January 2024, where reference was made to both the provision of puberty blockers ("PBs") and to the hormone treatment, with a clear focus on the safety of the provision of these treatments; ground 2, regarding what was said to be the CQC's failure to consider exercising its power to impose a condition on IP1, so as to be satisfied that the treatment could be provided in a safe way; ground 3, relating to the assessment decision of December 2024, contending there was insufficient evidence to support a conclusion as to the safety and efficacy of the hormone treatment. In the skeleton argument for the hearing, and in the claimants' oral submissions, however, not only has there been a clarification and re-ordering of the grounds of challenge (see below, where, in identifying the issues for determination, I have sought to reflect the claimants' case as it was put before me), there has been a clear shift in focus, from the safety of the treatments provided by IP1 (albeit the claimants make clear this remains the relevant context for their challenge) to five particular issues relating to how IP1 operates, which are relied on as demonstrating that the decisions made by the CQC (or, in relation to the failure to impose a condition, the CQC's omission) are irrational (as to process and/or outcome) and unlawful.

5. For the CQC it is complained that this represents a change to the claimants' case that ought properly to be the subject of a formal (re-)amendment. For the claimants it is said that this is simply drawing out particular aspects of the claim that were (certainly since the earlier, permitted, amendment) already present; in any event, however, the

claimants have made a formal application to re-amend their claim to expressly incorporate the points identified in their skeleton argument.

6. I do not consider it would be right to characterise the change in the way the claimants' case is put as simply a shift in emphasis. The earlier iterations of the claim clearly focused on the particular treatments it was considered IP1 prescribed. The case as now advanced relies on five particular operational features of IP1 as demonstrating the irrationality (process/outcome) and/or unlawfulness of the impugned decisions. While some aspects of those five matters might be discernible from the amended statement of facts and grounds, as the case is now advanced, it could not be said that the earlier pleadings set out each ground of challenge with sufficient detail of each alleged breach of law/legal principle to enable the essential issues to be identified. As such, I agree with the CQC that a formal application to amend was required.

7. Turning then to the question whether that application should be allowed, neither the CQC nor IP1 sought to suggest that the proposed re-amended claim would give rise to any insurmountable prejudice or that this should lead to an adjournment of the hearing. Equally, although the claimants also made a late application to adduce further evidence, it was not argued that this must lead to a postponement so as to enable the CQC or IP1 to further investigate matters/have time to obtain evidence in rebuttal. Seeking to do justice to all sides, and in accordance with the overriding objective, I therefore allow the claimants' applications to re-amend the statement of facts and grounds, and to adduce further evidence, also allowing applications by the CQC and IP1 to rely on the evidence they have submitted in response.

The decisions under challenge and the issues for determination

8. The claimants' amended case essentially challenges three decisions by the CQC: (1) a decision of 9 January 2024, to register IP1 as a provider of a regulated activity, namely treatment for a disease, disorder or injury ("TDDI") by a healthcare professional ("the registration decision"); (2) a decision of 3 December 2024, to rate IP1 as "outstanding" overall, and "good" for safety following an assessment, and thus continue its registration ("the assessment decision"); and (3) what is characterised as a failure to impose a condition on IP1's registration "*akin to the requirement for a second opinion from independent and impartial persons which is required in equivalent circumstances for safety reasons on the NHS*" ("the condition decision").

9. The claimants put their case under three heads: (1) process irrationality; (2) outcome irrationality; (3) breach of the *Padfield* principle (*Padfield v Minister of Agriculture and Fisheries* [1968] AC 997). By the claimants' re-amended grounds, this case is advanced in reliance on the following five points:

9.1 referrals of 16-17 year olds for the hormone treatment on the NHS may only be made by entities regulated by the CQC, which is not the position with IP1, where referrals are made by Kelly Psychology Ltd ("Kelly Psychology"), which is not regulated by the CQC;

9.2 new referrals of 16-17 year olds to the NHS gender service are only permitted by NHS paediatric services or NHS mental health services for children and young people, which is not the position with Kelly Psychology or IP1;

9.3 within the NHS, there is institutional separation between the entities that make the referral and those that administer the hormones, which is not present in relation to referrals by Kelly Psychology to IP1;

9.4 the NHS national multi-disciplinary team ("MDT"), which is required to approve the hormone treatment for any child on the NHS, has different features from the MDT which decides whether IP1 should accept a child for such treatment;

9.5 individuals who staff or run IP1 and Kelly Psychology have made public statements relevant to the question of registration/continued registration and/or demonstrate that they advocate for the hormone treatment.

The claimants contend that (1) the failure to reasonably enquire into, and/or take into account, these matters give rise to process irrationality; alternatively, (2) having regard to these matters, the CQC's decisions were irrational in outcome; alternatively, (3) that the CQC's decisions frustrate the policy and objects of the relevant legislative regime.

The factual background

The parties

10. C1 is a mental health nurse and psychotherapist who previously worked in the now closed NHS Gender Identity Development Service ("GIDS") at the Tavistock and Portman NHS Foundation Trust ("the Tavistock" and "Tavistock GIDS"). C2 is the mother of IP4, a transgender child.

11. The CQC was established on 1 April 2009 by the Health and Social Care Act 2008 ("HSCA"); it is the independent statutory regulator of healthcare, adult social care and primary care services in England.

12. IP1 is a private healthcare service and is the subject of this claim. IP1 was incorporated in May 2023 and uses the trading name Gender Plus Hormone Clinic ("GPHC"). Dr Aidan Kelly, a consultant clinical psychologist registered in the UK with the Health and

Care Professions Council, is the founder owner of IP1 and has been its clinical director since its registration by the CQC on 9 January 2024. Dr Kelly is also the founder owner, and clinical director, of Kelly Psychology, which uses the trading name "Gender Plus" and which operates as a private provider of non-medical psychology, assessment, and mental health services. Following an assessment by Kelly Psychology, a patient aged 16 or over may be referred to IP1 for the hormone treatment.

13. IP4 is the child of C2 and is a natal female who has identified as male since December 2020. IP4 has lived with IP5, C2's ex-husband, since October 2021, and has intermittent contact with C2. There have been family court proceedings concerning IP4's wish to seek hormone treatment from IP1 (see *O v P* [2024] EWHC 1077 (Fam) and [2024] EWCA Civ 1577); neither IP4 nor IP5 have played an active part in the current proceedings. As for IP2 and IP3, both have remained neutral and have not sought to actively participate in these proceedings.

The context

14. There is a wider context to the challenges pursued in this case, which relates to the treatment of children aged 16-17 who experience gender dysphoria or gender incongruence. This is an area of controversy, which raises moral and ethical issues as well as questions as to the correct approach to treatment from a clinical medical perspective. It is also a matter that has been the subject of both litigation and policy review, and the legal and regulatory landscape, which has already undergone significant changes in recent years, continues to evolve. Certain aspects of this background are relevant to the challenges in the present proceedings, and it is therefore helpful to first set out some of the key events that form the context to these claims.

15. Part of the relevant background relates to the particular controversy which arose in relation to Tavistock GIDS. The service provided by Tavistock GIDS was explained by the Court of Appeal in the case of *Bell v The Tavistock and Portman NHS Foundation Trust* [2021] EWCA Civ 1363, as follows:

> "5. ... Patients with gender dysphoria are referred to Tavistock from all over the country for assessment. There is usually a wait of between 22 and 24 months before they can be seen for a series of assessment appointments. If, following assessment, Tavistock is satisfied that it is medically appropriate to do so, the patient is referred to the paediatric endocrinologists at either University College London Hospitals NHS Foundation Trust ("UCH") or Leeds Teaching Hospitals NHS Trust ("Leeds") (together the "Trusts"). A referral takes place only if Tavistock assesses that the child would benefit from treatment and is capable of giving consent to puberty blockers (the first step in any such treatment). Referral requires the consent of the child and of the parents. ... The puberty blocking drug treatment at issue in this case is gonadotropin-releasing hormone agonists. They suppress the physical developments that would otherwise occur during puberty. The next step in treatment, for which UCH and Leeds obtain further informed consent from child and parents, is to prescribe cross-sex hormones and then, in adulthood, consideration of surgery."

16. As the Court of Appeal went on to observe, the Divisional Court in *Bell* (see [2020] EWHC 3274 (Admin)) had found no illegality in the policy or practice of Tavistock GIDS or the Trusts, and had further rejected a claim that the information provided was inadequate for informed consent, albeit expressing concern about the ability of children to understand and weigh that information. That concern had led the Divisional Court to give guidance, recommending that the sanction of the court should be sought before prescribing puberty blocking drugs ("PBs") to those under 18; the Court of Appeal held it had been inappropriate for the Divisional Court to have given that guidance.

17. Around the time of the proceedings before the Divisional Court in *Bell*, in the autumn/winter of 2020, the CQC was carrying out a review of Tavistock GIDS. In its inspection report of January 2021, the CQC went on to rate Tavistock GIDS as inadequate overall.

18. Following the Divisional Court's decision in *Bell*, and before that case reached the Court of Appeal, new referrals for PBs were suspended and a requirement put in place that children who were already receiving that treatment would be reviewed, with a view to seeking judicial sanction. That requirement was changed following the decision of the High Court in March 2021, in *AB v CD* [2021] EWHC 741 (Fam), which accepted the possibility of parental consent to such treatment, albeit expressing the concern that "*the taking of strong, and perhaps fixed, positions as to the appropriateness of use of PBs*" might mean it was difficult for a parent to be given a truly independent second opinion, which the court considered must be "*a matter for the various regulatory bodies, NHS England and the [CQC] to address when imposing standards and good practice* ..." (see paragraphs [122]-[124]). Acknowledging those concerns, an external panel – the Multi Professional Review Group ("MPRG") – was established, to ensure that procedures for assessment and for informed consent had been properly followed. That did not change following the decision of the Court of Appeal in *Bell*.

19. Meanwhile, and prior to the hearing before the Divisional Court in *Bell*, in September 2020, NHS England commissioned Dr Hilary Cass to chair an independent review and make recommendations on how to improve services for children and young people experiencing gender identity or gender incongruence issues ("the Cass Review").

20. In February 2022, the Cass Review published its interim report, which highlighted the inconclusive evidence base as to the appropriate management of children and young people with gender incongruence and dysphoria, the lack of agreement as to the appropriate treatment options, and how the different experiences and positions of the professionals involved might determine their clinical approach. It further made specific observations regarding the service provided by Tavistock GIDS.

21. The final report of the Cass Review was subsequently published on 10 April 2024; it has received widespread publicity, with strongly held views being expressed on both sides of the debate, often expressed through the prism of a pre-existing perspective on the issues addressed without seeking to engage with the full findings and recommendations of the final report. For these proceedings, I have read the Cass Review final report in full, referring in this judgment to particular parts of the report summary, and to specific recommendations, to convey relevant, albeit selective, parts of the conclusions.

22. In the final report, the Cass Review noted the very different conclusions drawn by clinicians working in gender clinics about the best way to support young people with gender-related distress, recording:

> "There remains diversity of opinion as to how best to treat these children and young people. The evidence is weak and clinicians have told us they are unable to determine with any certainty which children and young people will go on to have an enduring trans identity." (Cass Review final report, summary [13])

And further observing that this was an area of "*remarkably weak evidence*", in which:

> "results of studies are exaggerated or misrepresented by people on all sides of the debate", and where there were "serious questions about the reliability of current [international] guidelines" (Cass Review final report, foreword)

Concluding that:

> "current understanding of the long-term health impacts of hormone interventions is limited and needs to be better understood" (Cass Review final report, summary [13])

23. Given the particular issues raised in this litigation, it is also relevant to note the following observations at [97]-[101] of the summary to the Cass Review final report:

> "97. … consent is more than just capacity and competence. It requires clinicians to ensure that the proposed intervention is clinically indicated as they have a duty to offer appropriate treatment. It also requires the patient to be provided with appropriate and sufficient information about the risks, benefits and expected outcomes of the treatment.
> 98. Assessing whether a hormone pathway is indicated is challenging. A formal diagnosis of gender dysphoria is frequently cited as a prerequisite for accessing hormone treatment. However, it is not reliably predictive of whether that young person will have longstanding gender incongruence in the future, or whether medical intervention will be the best option for them.
> 99. In addition, the poor evidence base makes it difficult to provide adequate information on which a young person and their family can make an informed choice.
> ...
> 101. Although young people often express a sense of urgency in their wish to access medical treatments, based on personal experience some young adults have suggested that taking time to explore options is preferable. The option to provide masculinising/feminising hormones from the age of 16 is available, but the Review would recommend an extremely cautious clinical approach and a strong clinical rationale for providing hormones before the age of 18. This would keep options open during this important developmental window, allowing time for management of any co-occurring conditions, building of resilience, and fertility preservation, if required."

These provide context for the Cass Review recommendations, as follows:

> "Recommendation 8
> NHS England should review the policy on masculinising/feminising hormones. The option to provide masculinising/feminising hormones from age 16 is available, but the Review would recommend extreme caution. There should be a clear clinical rationale for providing hormones at this stage rather than waiting until an individual reaches 18."

> "Recommendation 9
> Every case considered for medical treatment should be discussed at a national Multi Disciplinary Team (MDT) hosted by the National Provider Collaborative replacing the Multi Professional Review Group (MPRG)."

24. The impact of the Cass Review has been significant; as the Master of the Rolls recorded in *O v P*,

> "18. ... (i) the Cass Interim Review in 2022 led to the closure of the Tavistock clinic that had been in issue in *Bell v. Tavistock*; (ii) on 12

> March 2024, NHS England published a clinical policy concluding that there was not enough evidence to support the safety or clinical effectiveness of puberty blockers to make the treatment routinely available (outside a research protocol); (iii) ... NHS Scotland had announced ... that persons under 18 would not be prescribed cross-sex hormones; (iv) on 21 March 2023 *[this must in fact be a typographical error; the relevant date is 21 March 2024]*, NHS England published a clinical commissioning policy laying down stringent eligibility and readiness requirements to be met before cross-sex hormones could be administered to those over 16; (v) on 9 April 2024, NHS England wrote to all NHS gender dysphoria clinics asking them to defer offering first appointments to those under 18 "as an immediate response to Dr Cass's advice that 'extreme caution' should be exercised before making a recommendation for [cross-sex hormones] in [children]"; (vi) on 10 April 2024, the Cass Review was published; and (vii) on 11 December 2024 ... the government announced that the temporary embargo on the use of puberty blockers would be made indefinite (subject to a review in 2027)."

25. I pause at this stage to note that although the claimants were initially concerned that IP1 would be providing PB treatment, given the decisions made in 2024, that would not be lawful, and it is not something that IP1 provides. In the event, the way in which the case has been advanced before me has focused solely on IP1's provision of the hormone treatment, which – while still the subject of considerable debate – is lawful.

26. Expanding (so far as relevant) on some of the references made in *O v P*:

26.1 On 21 March 2024, NHS England published its clinical commission policy, "*Prescribing of Gender Affirming Hormones (masculinising or feminising hormones) as part of the Children and Young People's Gender Service*" ("the 21 March 2024 policy"), which made clear:

> "Gender Affirming Hormones (masculinising or feminising hormones) (GAH) are available as a routine commissioning treatment option for young people with continuing gender incongruence/gender dysmorphia from around their 16th birthday subject to individuals meeting the eligibility and readiness criteria ..."

but requiring that:

> "Patients must meet ALL of the eligibility and readiness criteria listed ..."

which included the following:

> "The individual has been assessed by the appropriate specialist multi-disciplinary team over a period of time* and fulfils the criteria for a diagnosis of Gender Incongruence ... .
> *The duration of the assessment to be determined by the clinical team as relative to the needs of the individual."

> "Reason for this criterion
> To ensure that the individual is highly likely to be continue to identify in the experienced gender, meaning that GAH therapy is an appropriate treatment in the long term."

and

> "The [Children and Young person] Gender Service National MDT, that includes clinicians not directly involved in the formulation of the individual's care plan, agrees on the suitability of the individual receiving GAH based on the consideration of these eligibility and readiness criteria."

> "Reason for this criterion
> To ensure that the individual understands that there is limited clinical evidence on the effects and harms of prescribing GAH treatment below their 16th *[sic]* birthday; and also that GAH treatment is a significant decision with long term indications."

further providing that:

> "Patients meeting ANY of the below exclusion criteria are not eligible for treatment:
> ...
> If the individual is having a significant psychotic episode or has another significant mental health disorder that is not adequately controlled as this may reduce their ability to manage the emotional issues that may arise from the changes in hormone levels from the hormone treatments and may impact on their capacity to consent; ..."

26.2 The decommissioning of Tavistock GIDS had been announced on 28 July 2022; the clinic closed on 31 March 2024.

26.3 On 2 April 2024, the NHS launched its new children gender service. In a letter from Evelina London (part of the Guy's and St Thomas' NHS Foundation Trust) to the claimants' solicitor, produced shortly before the hearing, it is explained that there are now three regional gender services in England that can make referrals to the NHS national MDT, which are separate from the endocrinology services that would, if a case was approved by the national MDT, then administer the hormone treatment. The national MDT has an independent chair (Dr Camilla Kingdon) and although it includes endocrinology representation, that does not come from any endocrinology service that would provide the hormone treatment.

26.4 This description of the new NHS gender service is, however, not agreed. Dr Kelly says that in fact endocrinologists at NHS Trusts that would provide the hormone treatment are members of the national MDT. It is also pointed out that Dr Kingdon is employed at two of the Trusts that provide the children and young people's gender service in London, albeit she does not work in that service in either Trust.

26.5 On 9 April 2024, NHS England wrote to all adult gender dysphoria clinics, advising that:

> "We will ... define the role of gender affirming hormones through the development of a new evidence based national clinical policy which will cover all people over the age of 18 ... details on the procedure to be followed in its development will follow."

but requesting, in the meantime:

> "[given the Cass review's advice at recommendation 8 ("extreme caution"), that you should] defer offering first appointments to patients until their 18th birthday ...".

26.6 The evidence before me suggests that, since April 2024, there have been no prescriptions for hormone treatment for new 16-17 year old patients in the NHS in England, because the national MDT has not approved the treatment, having not identified any patient for whom it would be appropriate. I also understand that there have been no new prescriptions for the hormone treatment for this age group in Scotland, because the only NHS specialist gender service for under-18s in that country has stopped making such prescriptions.

27. In May 2024, the Secretary of State for Health and Social Care commissioned Dr Penny Dash to conduct a review into the CQC ("the Dash review"). The Dash review published an interim report on 26 July 2024, with its final report being published on 15 October 2024. The Dash review reached the conclusion that there were "*significant failings in the internal workings of CQC*", identifying (relevantly) a "*loss of credibility within the health and care sectors due to the loss of sector expertise*", and finding that:

> "the current model of generalist inspectors and a lack of expertise at senior levels of CQC, combined with a loss of relationships across CQC and providers, is impacting the credibility of CQC, resulting in a lost opportunity to improve health and social care services." (Dash review final report conclusions, particularly conclusion 4)

28. On 7 August 2024, NHS England published its "*Consultation report for the service specification: referral pathway for children and young people's gender service*", stating that (from 1 September 2024) new referrals to the NHS gender service could only be made by NHS paediatric services or NHS mental health services for children and young people. That was seen to be consistent with the Cass Review, which had highlighted the absence of a structured approach for identifying clinical risk within Tavistock GIDS, with the objective for this change stated to be:

> "... to increase the quality of the referral information that accompanies the child or young person into the gender service (thereby reducing the

> risk of unnecessary delay at the assessment stage) and to ensure that the health needs of children and young people are identified and addressed at the point of referral and while they remain on the waiting list for the gender service."

29. More recently, on 28 April 2025, at the request of the Secretary of State for Health and Social Care, the NHS established a working group to examine the hormone treatment for children. It was initially envisaged that the working group would deliver detailed advice within eight weeks, but this has been delayed. In the meantime, I understand that an agreement on the definition of "*extreme caution*" (Cass Review recommendation 8) is still under discussion within the NHS children gender service.

The chronology relevant to the decisions under challenge and the current proceedings

30. On 26 May 2023, IP1 was incorporated and, on 28 July 2023, it applied to the CQC for registration as a provider of the regulated activity of TDDI. Dr Kelly was identified as the "*Nominated Individual*" and there was an accompanying application for registration of Mr Carruthers as "*Registered Manager*. IP1's application was assigned to registration inspector Amy Robson on 13 September 2023 (see further below); its registration was approved on 9 January 2024, subject to the agreed condition that it would not deliver TDDI to those under the age of 16.

31. I pause in the narrative to note that, as explained by Dr Kelly, although Kelly Psychology made a modest profit last year, IP1 operates at a loss. It pays its staff broadly in line with the NHS and charges a flat fee for its services, and the team includes a research lead and two research assistants, who generate no income. It is Dr Kelly's evidence that IP1 would remain viable if it stopped treating 16 and 17 year olds (a relatively small percentage of its patients).

32. Returning to the chronology: on 26 January 2024, the claimants sent a pre-action letter; in February 2024, the CQC and IP1 responded; these proceedings were issued on 5 April 2024 (then focusing on the decision of 9 January 2024 to register IP1).

33. In September 2024, the CQC commenced an assessment of IP1, with Jessica Huntley as the lead assessor (see further below). On 4 December 2024, the CQC's inspection report for IP1 was published, rating it as "outstanding" overall.

34. On 17 January 2025, the claimants served their amended statement of facts and grounds, which incorporated challenges to the CQC's December assessment and to its continuing decision not to place any further condition on IP1's registration. In February 2025, detailed grounds of defence and detailed grounds for contesting the claim were served by the CQC and IP1.

The registration decision

35. Amy Robson was the CQC's registration inspector who carried out the registration assessment for IP1. They have a PhD and a level 5 in health and social care management, and previously worked as a manager for a health and social care service.

36. Amy Robson has explained that, at around the same time as IP1's application for registration, it was identified that there was a need for the CQC to have a standard operating procedure for the registration of private providers of gender identity services, including specialist endocrinology interventions. Amy Robson was involved in this process, bringing together others with appropriate expertise to assist; regard was had to the Cass Review interim report, and it was recognised that those assessing providers of gender identity services would need to be familiar with this and other relevant guidance; more specifically, the limited evidence available as to the outcomes of the hormone

treatment was expressly acknowledged, meaning there would be a need to ensure that providers had robust consent processes in place.

37. In assessing IP1, Amy Robson led a team that also comprised a regional medicines manager, a national professional adviser for primary medical services and integrated care who had oversight for on-line provision, and a senior specialist in mental health who had been involved in the inspection of Tavistock GIDS and had experience of mental health services. The assessment framework used identified five key questions relating to the provider and the services to be provided: are they safe; are they effective; are they caring; are they responsive to people's needs; are they well led? In completing the assessment, specific regard was had to a number of guidance documents, including the Cass Review interim report, relevant NHS guidance, and the inspection history of Tavistock GIDS. The paperwork obtained from IP1 was fully assessed, and additional information and clarification obtained; the process included meetings with Dr Kelly and Mr Carruthers, and a separate fit person interview with Mr Carruthers. A (59-page) research and planning evidence record was produced, dated 11 December 2023, which included Amy Robson's analysis of evidence collected during the assessment and their recommendation to grant registration.

38. In her evidence in these proceedings, Amy Robson has confirmed their awareness at the time of undertaking this assessment of the sensitivity around the hormone treatment, and that they had specifically considered the content of Cass Review interim report and the NHS position at that time. She has explained that the assessment team considered the evidence provided by IP1 against the criteria for endocrine treatment in the NHS commissioning policy then in place, concluding that it was broadly aligned; specifically, the evidence demonstrated there would be: (a) assessment by a MDT over

a period of time, which would include a medical practitioner with specialist expertise in gender incongruence in children and adolescents; (b) continued psychological support through engagement with the MDT; (c) no hormone treatment before age 16; (d) discussion about the impact on fertility; (e) parental involvement in decision-making; (f) robust processes for seeking consent; and (g) involvement of a consultant endocrinologist in the service provision.

39. A management review meeting was held on 14 December 2023 to consider the recommendation to grant registration, at which it was determined that a condition should be imposed that would prevent the provision of TDDI to those under 16. Further oversight was provided by the CQC's director of national operations, chief inspector of adult social care and integrated care, and the senior government engagement officer, before registration was confirmed on 9 January 2024.

40. Subsequent to the registration decision relating to IP1, in or around April 2024 the regulatory leadership within CQC (which is distinct from its operational activities) established a CQC Cass oversight group, headed up by Janet Kirton de Ortega, a deputy director for primary and community care. The purpose of this group was to provide oversight of CQC activities relating to the regulation of gender identity services, and it then took forward the standard operating procedure for the registration of such services.

The assessment decision

41. After IP1's registration, it fell within the (geographic) responsibility of Amanda Lyndon, CQC's deputy director of operations within the Midlands. Ms Lyndon had extensive experience carrying out inspections for CQC and had previously been a registered nurse, working within both the NHS and private sector. The CQC tries to

inspect new providers within a year of registration, and it was determined that IP1 should be inspected after nine months.

42. As the relevant deputy director, Ms Lyndon had oversight of the assessment process, but Ms Huntley was the lead assessor, working in a team with CQC's national professional advisor, medicines manager, senior specialist, the registration manager, and with support from an expert by experience representative from CQC's LGBT network. The inspection assessment was undertaken using the same five key questions as for the registration assessment.

43. In the current proceedings, the claimants' concerns have focused on the issue of patient safety. As such, it is helpful to consider the inspection assessment with reference to the question: is the service safe? This was addressed by reference to the quality statements that are then set out (and further elaborated upon) under each question within the assessment framework, directed to: learning culture; safe systems, pathways and transitions; safeguarding; involving people to manage risks; safe environments; safe and effective staffing; infection prevention and control; and medicines optimisation. Also relevant, under the question: is the service effective?, the quality statements include "*delivering evidence-based care and treatment*", which means that "*people receive care, treatment and support that is evidence-based and in line with good practice standards*".

44. Ms Huntley has explained that, in approaching this assessment, she made sure to read the Cass Review final report, and the most up-to-date NHS commissioning policies and service specifications, along with other guidance and information; she also read the information that CQC held about IP1 at that time. In addition to following CQC's

standard procedures (which included reviewing all IP1's policies and procedures), the assessment team also directly observed patient consultations, which enabled them to:

> "... witness how consent was obtained in practice; including seeing and understanding how the risks (including known unknown risks) are explained to service users. It would also allow us to observe if fertility preservation was being discussed in a meaningful manner and allow us to see if the consultation was holistic and person-centred. Many of these were key elements that the Cass Report raised as important, as well as being areas of concern for people who have strong views about this service type." (Ms Huntley's witness statement at [15])

45. Ms Huntley's statement provides a full account of the investigation assessment and the inquiries undertaken. In summary, Ms Huntley (assisted by others in the assessment team) observed three patient consultations, attended a MDT meeting (which involved an independent child psychiatrist (Dr Adams) who attended when a patient was under 18) during which patients for referral to IP1 were discussed, and spoke with two patients and their families, as well as to Dr Kelly, Mr Carruthers, and to IP1's administrator. In addition, questionnaires were completed by three health professionals selected at random from Kelly Psychology, and by 15 patients and their families, some of which were followed up with telephone calls to discuss the results (in fact the report records that the team spoke with 21 patients and their families). A random selection of individual patient records was reviewed by both Ms Huntley and the CQC's medicines manager, who also spoke to the independent pharmacist dispensing IP1 prescriptions, and Ms Huntley spoke directly with a visiting mental health nurse who attended all initial face-to-face appointments to ensure patients had any mental health support they needed, and was able to satisfy herself that there was liaison with patients' GPs. A further interview with Dr Kelly and Mr Carruthers was separately conducted by Dr Tim Ballard, focusing on the clinical aspects of the service, during which the Cass Review's findings were discussed, and details provided of IP1's process of auditing patient

outcomes and of sharing of information with GPs, with a view to entering shared care arrangements.

46. Given the focus on the role of IP1's MDT, and whether this could rationally be considered to be broadly aligned with the NHS national MDT, it is helpful to set out Ms Huntley's evidence on this point in more detail.

47. Ms Huntley has confirmed her familiarity with the 21 March 2024 policy, and the requirement that the suitability of the individual receiving the hormone treatment must be agreed by the national MDT. She has explained how she was able to satisfy herself as to the extensive process of psychological assessment that all patients have to undergo before being referred for consideration by IP1, with no referral being made unless the individual has a confirmed diagnosis of gender dysphoria *and* the clinician considers this to be the best course of action. Aware that the IP1 MDT was unlikely to be identical to the NHS MDT, Ms Huntley explains how she was assured by the IP1's requirement that there would then be a MDT for every patient referred (including those over 18), which would include IP1's nurse consultant, clinicians from Kelly Psychology, and an independent paediatric psychiatrist (for under 18s), and that all decisions must be reached by consensus. Given: the requirement for MDT agreement to the acceptance of any referral; the involvement (in the case of under 18s) of an independent psychiatrist, not concerned with the patient's care planning; and having regard to the open and detailed discussions she had herself witnessed at the MDT, Ms Huntley's judgement was that IP1's practice was sufficiently aligned with the NHS.

48. Ms Huntley also details how she (and the other members of the assessment team) satisfied themselves that all the other eligibility and readiness criteria in the 21 March

2024 policy were being properly considered, with IP1's operating procedure expressly stating that the referral criteria would be in line with that policy.

49. After the assessment was complete, Ms Huntley collated the evidence, analysed it, and produced a draft assessment report which was then considered and approved by senior and other colleagues, and was reviewed by Ms Kirton de Ortega, as head of the CQC's Cass oversight group. The assessment report was published on 4 December 2024, rating IP1 as "outstanding" overall, as it had achieved "outstanding" ratings for four of the key questions (well-led; responsive; effective; caring); for safe, the service was rated "good" (i.e. performing well and meeting expectations).

IP1 patient data

50. For the purposes of these proceedings, in early December 2024, responding to a request for further information from the claimants, IP1 provided patient data for the period 1 July 2023 and 30 June 2024 (this date range being dictated by the fact that it would take around six months for a patient to complete an assessment with Kelly Psychology). This showed that, of 123 patients aged 16-17 who had presented to Kelly Psychology, 88 had been recommended by Kelly Psychology's MDT for the hormone treatment, 69 had then been presented at IP1's MDT, and 66 had been accepted, three patients having been advised to undergo further assessment and/or treatment before subsequently returning and being accepted for the hormone treatment at IP1 at a later date.

Advocacy

51. One of the matters relied on in support of this claim relates to statements made by/attributed to Dr Kelly, Mr Carruthers, and others who work for IP1 and/or Kelly Psychology.

52. Thus, reference is made to comments attributed to Dr Kelly, in articles in The Guardian and Attitude magazine in April 2024 (shortly after publication of the Cass Review final report), in which it was stated that he "*disputed many of Cass's findin*gs", pointing to evidence from Germany to claim that *"puberty blockers were safe and effective"*, that he was *"very, very worried"* about the NHS's ability to deliver a suitable gender service based on the findings of the Cass Review and that the service was *"going backwards instead of forwards*, arguing that the NHS was *"out of step with the rest of the world"*, and he felt "*we need to be very careful that [the NHS approach] doesn't become conversion therapy in disguise*". On 19 July 2024, Dr Kelly wrote an opinion piece for The Guardian, criticising the Government's ban on PBs, claiming that the Secretary of State for Health and Social Care was *"clearly misinformed about the treatment"*, and calling the ban *"misguided, cruel"*. On 12 April 2025, Dr Kelly wrote a letter to the Times in which he criticised the NHS for *"prioritizing a non-medical pathway at all costs"*, for conducting *"an effective lobotomy on trans healthcare services"*, and for pursuing a psycho-social approach that *"have zero evidence to support their effectiveness"*, again arguing that the NHS approach was akin to *"conversion therapy"*.

53. Otherwise, reliance has been placed on a report of 27 October 2024, when an organisation called ReportOUT welcomed Mr Carruthers as a new patron, citing (amongst other qualities) his "*activism in transgender healthcare*". And reference has been made to a social media post in 2019, by Dr Sophie Quinney, an endocrinologist and IP1's medical lead and resource, responding to an academic article in the British Journal of General Practice, in which she said: "*Deeply concerning to find utter tripe with clear poisonous undertones published ... on gender incongruence. ...*".

54. For his part, Dr Kelly has not denied the various citations attributed to him but has also referred to the substantial body of peer reviewed academic articles he (and Mr Carruthers) has authored over the years relevant to these issues, and his participation in various academic conferences, which he relies on as evidence of a thoughtful and nuanced approach, consistent with his professional obligations and the requirements of academic research.

55. For the CQC, Ms Rawlings, director for network operations South, has observed that it would be unusual for the CQC to trawl through the media for articles written by or about individuals concerned with a registration or assessment. She notes, however, that, as the Cass Review recognised, there are a wide range of views around clinical practice in this area and those involved in IP1 would be entitled to hold, and express, particular views, provided they were complying with the law and regulatory framework.

56. Both Dr Kelly and Mr Carruthers had formerly worked at Tavistock GIDS and, as Amy Robson has confirmed, at the time of the assessment for registration purposes, regard was had to the CQC's records relating to inspections at that service, and there were no adverse reports relating to either Dr Kelly or Mr Carruthers (although that was not particularly remarkable, as neither of them had held a post at Tavistock GIDS that would have been the subject of CQC regulation). As for the inspection assessment, Ms Huntley responded to the suggestion that Mr Carruthers is an "activist", stating:

> "My notes of my interview with Paul Carruthers show that he was aware of the [21 March 2024 policy] and the criteria within that policy and that the service was working in a way that was aligned to these criteria. ... I considered his answers to be detailed, transparent and informative. He was aware of and responsive to the contents of the CASS report. ... whilst I found [Mr Carruthers] to be passionate about the work of [IP1], I did not form the impression that this undermined his commitment to patient safety or compromised his professional judgment." (Ms Huntley's witness statement at paragraph [48])

O v P

57. As I have previously referenced, C2 and IP4 and IP5 have also been involved in family law proceedings relating to the potential provision of the hormone treatment by IP1 to IP4. The main issue in those proceedings concerned the court's power to override consent given or withheld by a child over 16 on best interests grounds (see *O v P* [2024] EWCA Civ 1577 at [3]), but the judgments of both Judd J in the High Court, and the Master of the Rolls in the Court of Appeal, touch on some points of relevance to the current litigation.

58. In her first instance decision of 8 May 2024, Judd J concluded that the proceedings should be dismissed as there was no realistic basis upon which the court would override IP4's consent to treatment by a regulated clinician in this jurisdiction, observing:

> "60. The controversy over treatment of young people (whether privately or through the NHS) for gender-related distress or dysphoria is a matter of public interest, but it is something which should fall to be considered by medical and associated professions and their regulators, or if need be, the government. Although Gender Plus is a private provider the hormone clinic requires continued registration. Those who treat [IP4] could be liable in negligence if they do not provide a proper standard of care or fail to abide by guidelines without good reason. Ms Phillimore [then counsel for C2] submits that safeguards to date have not been sufficient for many young people, but once again, such issues are a matter for regulation and professional standards rather than a judge sitting in the Family or High Court."

59. The Court of Appeal disagreed with the conclusion reached at first instance. In giving the lead judgment of the court (with which both Sir Andrew McFarlane P, and King LJ agreed), the Master of the Rolls explained the decision, as follows:

> "38. ... The judge did not, I think, place enough weight on the rapidly changing regulatory environment and the situation of private providers like Gender Plus in the light of the recommendations made by the Cass Review.
> 39. The parents agreed before the judge that it was appropriate for [IP4] to undergo a 6-month assessment by Gender Plus. But it was clear, as

> the judge acknowledged, that Gender Plus could not comply with recommendation 9 of the Cass Review as to the need for the case to be discussed by a national multi-disciplinary team of the kind envisaged. It is impossible now to predict the outcome of Gender Plus's assessment (we were told it is in progress, if not complete), nor the consequences that might or might not occur as a result of a potential non-compliance by the private provider with the good practice suggested by Dr Cass. ... In those circumstances, I think that the judge ought to have accorded significantly more weight to the possibility of genuine future disagreement, the rapidly changing regulatory environment and the fact that the services provided by private hormone clinics seem already to be in a somewhat different position from the same services provided by the NHS."

The statutory framework

The CQC's statutory objectives

60. The CQC was established on 1 April 2009 by the Health and Social Care Act 2008 ("HSCA"); its functions include registration functions under Chapter 2 HSCA and review and investigation functions under Chapter 3. Pursuant to section 3 HSCA, "*in performing its functions*", CQC's main objective is to "*protect and promote the health, safety and welfare of people who use health and social care services*"; it is to perform its functions for the general purpose of encouraging (a) the improvement of health and social care services, (b) the provision of health and social care services in a way that focuses on the needs and experiences of people who use those services, and (c) the efficient and effective use of resources in the provision of health and social care services (see section 3(2) HSCA).

61. Further, by section 4 HSCA, in "*performing its functions*" the CQC must have regard, among other things, to: "*the need to protect and promote the rights of people who use health and social care services (including, in particular, the rights of children*" (section 4(1)(d)); "*the need to ensure that action by the [CQC] in relation to health and social*

care services is proportionate to the risks against which it would afford safeguards and is targeted only where it is needed" (section 4(1)(e)); "*best practice among persons performing functions comparable to those of [CQC]*" (section 4(1)(g)); and "*... such aspects of government policy as the Secretary of State may direct*." (section 4 (2)).

Regulated activity

62. All providers of regulated healthcare activities in the United Kingdom must be registered with the CQC and it is an offence to carry on a regulated activity without being registered (section 10(1) HSCA). Section 8(1) HSCA defines "*regulated activity*" as activity of a prescribed kind; the provision of treatment for a disease, disorder or injury ("TDDI") by a healthcare professional is a prescribed regulated activity (section 8 HCSA 2008, read with paragraph 4(1) of Schedule 1 to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations")).

63. By section 20(1) HSCA, the Secretary of State must, by regulations, impose requirements that s/he considers necessary to secure that services provided in the carrying on of regulated activities cause no avoidable harm to the persons for whom the services are provided. By section 20(2), the Secretary of State may by regulations impose any other requirements in relation to regulated activities that the Secretary of State thinks fit, including in particular provision with a view to (a) securing that any service provided in the carrying on of a regulated activity is of appropriate quality, and (b) securing the health, safety and welfare of persons for whom any such service is provided. The relevant regulations made under section 20 include the 2014 Regulations and the Care Quality Commission (Registration) Regulations 2009.

Registration of persons who carry on regulated activity

64. A person (whether an individual or a service provider) who provides a regulated activity in England must apply to register with the CQC (section 11(1) HSCA).

65. By section 12(2), where CQC is satisfied that the requirements of regulations made under section 20, and the requirements of any other enactment which appears to CQC to be relevant, "*are being and will continue to be complied with (so far as applicable) in relation to the carrying on of the regulated activity it must grant the application; otherwise it must refuse it* ."

66. The application may be granted either unconditionally or subject to such conditions as the CQC thinks fit (section 12(3)); it may at any time (a) vary or remove any condition for the time being in force in relation to a person's registration as a service provider, or (b) impose any additional condition (section 12(5)), and it may also suspend a registration at any time (section 18(1)). The CQC has the power to impose, remove or vary a condition, or suspend a registration urgently, on written notice, if it "*has reasonable cause to believe that unless it acts… any person will or may be exposed to the risk of harm*" (section 31(1)).

67. The Care Quality Commission (Registration) Regulations 2009 require any service provider that is an organisation to have a "*registered manager*" as a condition of a service provider's registration; a registered manager is a person who is in day-to-day charge of delivering a service provider's regulated activity (in a particular location). A registered manager must apply to CQC to be registered for a regulated activity in the same way as a provider. Regulation 7 of the 2014 Regulations sets out the additional statutory requirements that registered managers must satisfy to be assessed as fit to manage the regulated activity; these include being of good character and having the necessary qualifications, skills, competence and experience to manage the regulated

activity (assessed as specific to the sector, intended service user group and specifications of the proposed service).

68. Regulation 6 of the 2014 Regulations requires providers who are not partnerships to notify the CQC of a "*nominated individual*" who must be a director or manager of the providers responsible for *"supervising the management of the carrying on of the regulated activity*".

Reviews and performance assessments

69. The CQC must conduct reviews of the carrying on of the regulated activities by the service providers, assess the performance of the service providers following each such review, and publish a report of its assessment (section 46(1) HSCA). The assessment of the performance of a registered service provider is to be by reference to whatever indicators of quality the CQC devises (section 46(3)).

Fundamental standards

70. Part 4 of the 2014 Regulations (regulations 8 – 20) sets out the fundamental standards of safety and quality that a registered person must comply with (regulation 8). The claimants' case is focused on regulation 12, which provides:

> "(1) Care and treatment must be provided in a safe way for service users. (2) Without limiting paragraph (1) the things which a registered person must do to comply with that paragraph include— (a) assessing the risks to the health and safety of service users of receiving the care or treatment; (b) doing all that is reasonably practicable to mitigate any such risks; (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely; … (g) the proper and safe management of medicines; ... (i) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users."

Statutory guidance for registered persons

71. Regulation 21 of the 2014 Regulations states that for the purposes of compliance with the 2014 Regulations, the registered person must have regard to guidance issued by the CQC under section 23 of HSCA. The CQC has issued such guidance entitled *"Guidance for providers on meeting the regulations."* ("the Guidance").

72. The Guidance states in relation to regulation 12(1):

> "The intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Providers must assess the risks to people's health and safety during any care or treatment and make sure that staff have the qualifications, competence, skills and experience to keep people safe….. CQC understands that there may be inherent risks in carrying out care and treatment, and we will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment.
> Providers should consult nationally recognised guidance about delivering safe care and treatment and implement this as appropriate."

Relevant legal principles

The applicable standard of review

73. The standard of review applicable to a judicial review case varies "*depending on the importance of the interests affected by it or, to put the point another way, the gravity of its potential consequences*"; per Chamberlain J at paragraph [76] of *R (KP) v Secretary of State for Foreign, Commonwealth and Development Affairs* [2025] EWHC 370 (Admin). As Lord Reed explained in *R (King) v Secretary of State for Justice* [2015] UKSC 54, [2016] AC 384, at paragraph [126]:

> "126. … the test of unreasonableness has to be applied with sensitivity to the context, including the nature of any interests engaged and the gravity of any adverse effects on those interests".

74. Where a heightened standard of review exists, that has implications for the way the court evaluates both complaints of process and outcome irrationality; as Chamberlain J went on to explain in *KP*:

> "77. ... In the former case [of process irrationality], the court will subject the decision to "more rigorous examination, to ensure that it is in no way flawed" (*Bugdaycay,* 531 [*Bugdaycay v SSHD* [1987] AC 514]). In this connection, the court will expect the decision-maker "to show by their reasoning that every factor which might tell in favour of an applicant has been properly taken into account" (*YH (Iraq),* [24] [*YH (Iraq) v SSHD* [2010] EWCA Civ 116]). Where the complaint is of outcome irrationality, more will be required by way of justification (*ex p. Smith,* 554 [*R v MoD ex p Smith* [1996] QB 517]); ...."

75. In the present case, the claimants contend that the court's approach must be to apply a heightened standard of review given that the decision-making in question concerns the provision of permanent and irreversible medical treatment to extremely vulnerable children. They seek to draw analogies with the approach in *R (Rogers) v Swindon NHS Primary Care NHS Trust* [2006] EWCA Civ 392, where a decision to refuse funding for medical treatment was subjected to "*rigorous scrutiny*" (see per Clarke MR at paragraph [56]), and with that in *R (Hillingdon London Borough Council) v Lord Chancellor* [2008] EWHC 2683 (Admin) per Dyson LJ at paragraph 67 ("... *because the interests of vulnerable children are potentially at stake, the court should consider the issue of irrationality with anxious scrutiny*"). For the CQC, it is observed that *Rogers* concerned "*a life-or-death decision for the appellant*", in which it was argued Article 2 ECHR applied, and that the *Hillingdon* case could be seen as a case in which the human rights of children were at risk (see per Bennet J at paragraph [101]). Acknowledging, however, that the decisions in issue in the present proceedings could indirectly impact vulnerable children, the CQC contends that, even allowing for a heightened standard of review, in this context due respect would still need to be

afforded to the expert regulator; as was observed in *R (Seabrooke Manor Ltd) v CQC* [2024] EWHC 2203 at paragraph [10]:

> "… the court will always be cautious in overturning the good faith assessment and evaluative conclusions of an expert regulator. … particularly … where, as here, the regulator is operating in an area where public safety is of primary concern."

76. The point being made on behalf of the CQC is that, even where the test is one of anxious scrutiny, because a heightened standard of review is required, in considering a complaint of outcome irrationality, the importance of a claimant's interests is not the only relevant factor for the court to assess; as Chamberlain J observed in *KP*:

> "78. ... The nature and importance of the public interests on the other side of the balance may also be important ..."

As was emphasised in *R (Hoareau) v Secretary of State for Foreign and Commonwealth Affairs* [2020] EWCA Civ 1010, a recognition that a case concerns an important right (or otherwise gives rise to a need for anxious scrutiny):

> "155. ... does not answer the question about the extent to which a court, in the absence of any applicable statutory duties or statutory limitations on the decisionmaker, will recognise that the evaluative judgement involved is a matter for the decision-maker".

77. That said, it is for the court to assess how broad the range of rational decisions is in the circumstances of any given case; as Lord Sumption made clear in *Pham v Secretary of State for the Home Department* [2015] UKSC 19, [2015] 1 WLR 1591:

> "107. …That must necessarily depend on the significance of the right interfered with, the degree of interference involved, and notably the extent to which, even on a statutory appeal, the court is competent to reassess the balance which the decision-maker was called on to make given the subject-matter. ... In some cases, the range of rational decisions is so narrow as to determine the outcome."

Process rationality

78. The present claim includes a process rationality challenge. That requires *inter alia* that a decision-maker "*must have regard to all mandatorily relevant considerations"*; see *R (Law Society) v Lord Chancellor* [2018] EWHC 2094 (Admin), [2019] 1 WLR 1649 at paragraph [98]. A mandatory relevant consideration is one that is *"so obviously material to a decision … that anything short of direct consideration of them"* would be unlawful (although weight is a matter for the public authority); see *R (Friends of the Earth) v Heathrow Airport Ltd* [2020] UKSC 52 at paragraphs [117]-[121].

79. Further, the decision-maker cannot have "*failed to grapple with the relevant evidence*"; see *R (Kerman) v Charity Commission* [2025] EWHC 1223 (Admin) at paragraph [59]. And the process of reasoning "*should contain no logical error or critical gap*"; *KP* at paragraph [56] (and see *R (Wells) v Parole Board* [2019] EWHC 2710 (Admin), where Saini J said the question for the court was whether the conclusion reached followed from the evidence, or "*is there an unexplained evidential gap or leap in reasoning which fails to justify the conclusion*?").

80. In the context of a process irrationality challenge, applying a heightened standard of review means that the court will subject the decision to *"more rigorous examination, to ensure that it is in no way flawed"*; see *Bugdaycay v Secretary of State for the Home Department* [1987] AC 514, HL, per Lord Bridge at p 531. The court will look to see if the reasoning of the decision-maker demonstrates *"that every factor which might tell in favour of* [the claimant] *has been properly taken into account"*; *R (YH (Iraq)) v Secretary of State for the Home Department* [2010] EWCA Civ 116, [2010] 4 All ER 448, per Carnwath LJ at paragraph [24], and see *KP* at paragraph [77].

Outcome rationality

81. The present claim also includes a rationality challenge as to outcome. This gives rise to the question whether – even if the process of reasoning leading to the challenged decision is not materially flawed – the outcome is "*so unreasonable that no reasonable authority could ever have come to it*" (*Associated Wednesbury Picture Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223, 233-4), or, as the test is often put in more recent cases, is outside the "*range of reasonable decisions open to the decision-maker*" in those circumstances (*Boddington v BTP* [1999] 2 AC 143, at p 175).

82. Ordinary judicial review principles allow a court "*to determine whether [the regulator's] conclusions are adequately supported by evidence, that the facts have been properly found, that all material factual considerations have been taken into account, and that material facts have not been omitted*"; *Unichem v Office for Fair Trading* [2005] CAT 8, [2005] 2 All ER 400 at paragraph [174], and, therefore, to inquire whether there was adequate material to support the decision reached; see per Carnwath LJ at paragraph [93] *IBA Healthcare Ltd v Office of Fair Trading* [2004] EWCA Civ 142.

The Padfield principle

83. The claimants' alternative way of putting their case is in reliance on the principle that a public body must not use its powers to frustrate the purpose of the law it is implementing; see *Padfield v Minister of Agriculture, Fisheries and Food* [1968] AC 997 (and see *R (Saadat) v The Rent Service* [2001] EWCA Civ 1559, per Sedley LJ at paragraph [13], in relation to secondary legislation).

The parties' arguments

The claimants' position

84. It is the claimants' case that the CQC cannot rationally (whether considered as a matter of process or outcome) have concluded that the process by which the hormone treatment is provided by IP1 is safe, which is what is required by regulation 12(1) of the 2014 Regulations; further/alternatively (albeit conceding in oral argument that this added little to the case on rationality), it is contended that the decisions reached by the CQC breach the *Padfield* principle, in that they frustrate, or run counter to, the policy and objects of HSCA and/or the 2014 Regulations (in particular, regulation 12).

85. In arguing that the higher standard of review applies to the irrationality challenge in this case, the claimants point out that that the hormone treatment is often sought by vulnerable and emotionally distressed individuals (here, children aged 16-17, with rates of autism spectrum disorder, anxiety, depression, eating disorders and other mental health needs "*much greater ... than age matched peers*"; the Cass Review final report [5.26]-[5.27]), and can have significant, irreversible, long-term physical and psychological consequences. It is, moreover, the claimants' case that the claimed expertise of the CQC should not carry particularly strong weight with the court: this was a generalist regulator and the relevant assessments were carried out by individuals without relevant expertise (as compared, for example, to the Cass Review).

86. The claimants say that the statutory framework must be read with its primary purpose in mind, namely, to protect and promote the health, safety and welfare of people who use healthcare services. Within this context, they submit that regulation 12(1) of the 2014 Regulations requires the CQC itself to be satisfied (in accordance with public law principles) that the process by which the hormone treatment is provided must be safe. As the CQC recognised, relevant to that obligation were the standards applied within the NHS; in reaching its decisions, however, the CQC then failed to consider/take into

account a number of aspects of the position within the NHS that were obviously material to its assessment of safety, alternatively (to the extent these were taken into account) meant that its conclusions were outside the reasonable range open to it (a point made good by the contrast in the numbers accepted for hormone treatment by IP1 and the position in the NHS).

87. Specifically: (1) while referrals of 16-17 year olds for the hormone treatment on the NHS may only be made by entities regulated by the CQC, that was not the position with IP1, where referrals are made by Kelly Psychology; (2) new referrals of 16-17 year olds to the NHS gender service are only permitted by NHS paediatric services or NHS mental health services for children and young people, which is not the position with Kelly Psychology or IP1; (3) within the NHS, there is institutional separation between the entities that make the referral and those that administer the hormones, which is not present in relation to referrals by Kelly Psychology to IP1; and (4) the NHS national MDT, which is required to approve the hormone treatment for any child on the NHS, has different features from the MDT which decides whether IP1 should accept a child for such treatment. The claimants further contend, (5) that an additional risk to safety arose from the strong positions advocated by Dr Kelly and others associated with IP1 and Kelly Psychology.

The position of the CQC

88. While not entirely accepting the claimants' position as to the standard of review required in this case, the CQC's position was that this was unlikely to be determinative; allowing for the fact that vulnerable children could be impacted by the decisions in question, it was submitted that the court was nevertheless required to afford due respect to the assessment and evaluation it had carried out as the expert regulator. As for the

Padfield challenge, as had been acknowledged in oral argument, this added nothing to the claimants' case on rationality.

89. As for the first decision under challenge, registration had required a binary decision in January 2024, at a time pre-dating the 21 March 2024 policy, the new NHS gender service, the Cass Review final report, and the guidance regarding NHS new patient referrals from 1 September 2024; little of the way in which the claimants' case was now put had relevance to the registration decision. The assessment decision in December 2024 involved a rating evaluation; it was the claimants' case that this should have led to a withdrawal of registration/the attachment of further conditions, but that would have been inconsistent with the overall outstanding assessment.

90. Turning to the substance of the case now pursued by the claimants, it was important to bear in mind the CQC's role: it did not regulate the prescription of drugs/the treatment provided; it did not (and could not) audit each individual decision. The only question for the CQC was whether the provider was complying with the requirements of the 2014 Regulations (and the patient referral data relied on by the claimants could not answer that question). Further, the legislation did not drive the conclusion that this must replicate NHS processes, albeit the CQC had made clear that it looks to private providers to seek to emulate standards in the NHS, and, in its decisions regarding IP1, it had had regard to NHS standards and policies, finding that IP1 was adequately aligned to these.

91. For the CQC it was submitted that it was significant that the claimants had not taken issue with the detailed evidence provided as to the assessments undertaken leading to the CQC's registration or assessment decisions. As for the distinctions drawn by the claimants between the NHS and IP1 (such as IP1's inability to access the NHS national

MDT), these arose from/related to structural aspects of the NHS, which could not be determinative of the registration or assessment decisions the CQC was required to undertake. Having been unable to challenge the substantive findings made by the CQC as to IP1's alignment with the 21 March 2024 policy within the NHS, the claimants' position had been that NHS policy had moved on, and they emphasised the Cass Review recommendation of "extreme caution". However, no new public policy had been published at the time of CQC's assessment decision and there was no agreement on what "extreme caution" required; it was not irrational for the CQC to have regard to that which was the public statement of the NHS position. As for any public advocacy for particular treatment by Dr Kelly or others, that was not necessarily wrong (it was unsurprising that private providers might advocate for the service they provided); the relevant question for the CQC was not how the views of those involved in IP1 might be perceived by others but whether they were demonstrating compliance with regulation 12.

IP1's position

92. For IP1, it was emphasised that the process of assessment by Kelly Psychology is rigorous and closely aligned to that current within the NHS, with a MDT structure common across NHS child and adolescent mental health services, including a mechanism for peer review and quality control; although the NHS MDT also includes a paediatrician, that would be required as the NHS gender services include much younger children (within the NHS, those age 16 and over would be referred to adult services). As for the relationship between Kelly Psychology and IP1, the degree of integration (whilst still maintaining independence) was both transparent and consistent with the Cass Review final report (paragraph 18.3); the criticism made by the claimants

suggested a potential conflict of interest but that would be inconsistent with professional obligations and IP1 was run at a loss. Accepting that IP1, as a private provider, would not have input from a range of providers, it nevertheless ensured there was input from a range of professionals from different disciplines, including a wholly independent member of IP1's MDT.

93. Commenting on the statistical data regarding patient referrals, it was notable that around one third of those assessed by Kelly Psychology had not been recommended for treatment; the fact that most of those recommended had then been accepted by IP1 reflected the rigorous assessment process. Given differences in patient profiles (NHS will see a far broader pool, with no minimum age), and NHS waiting lists, it was not possible to make a meaningful comparison of IP1 and NHS figures.

94. As for the views expressed by Dr Kelly/others, to the extent these related to PBs, that had no relevance to the service IP1 was offering; more generally, the selected quotes had to be seen in context, and there had been no expression of disagreement with the requirement for caution and care when prescribing the hormone treatment.

Analysis and conclusions

Preliminary observations

95. Before turning to consider the particular issues raised by the claimants, it is first necessary to identify how the grounds of claim have evolved. Ground 1 (as pleaded) was put as a *Padfield* challenge; that has now been treated as the third ground of claim, effectively as another label for the claimants' irrationality arguments. Ground 2, the rationality challenge, has been divided into two parts, the first addressing process irrationality, the second outcome irrationality. Ground 3, which related to what is said

to be the CQC's unlawful failure to impose a condition, has been subsumed into the other grounds. More specifically, however, by their re-amended case, the claimants have identified five particular considerations on which they rely as demonstrating the irrationality of the CQC's decision-making, both as to process and outcome. Under separate sub-headings - *(1) Process irrationality* and *(2) Outcome irrationality* - I have therefore considered each of the five matters identified by the claimants individually, before then standing back to consider the cumulative impact of these criticisms; I have then sought to address *(3) The Padfield challenge*.

96. In approaching the irrationality challenges at (1) and (2) and in considering the relevant standard of review, I am mindful of the context. As made clear by the Cass Review's findings, and the evidence submitted on behalf of the claimants, those seeking to access the TDDI services in issue are often particularly vulnerable children. Although clinicians working in this area can have very different views as to the advisability of the hormone treatment, it has not been suggested to me that this is other than a life-changing course, and an extremely serious step for an adolescent, age 16-17, to take.

97. When assessing decisions taken in this context, I am willing to accept that a heightened standard of review is required.

98. That does not mean, however, that I should not exercise caution when urged to reach a conclusion that is contrary to the assessments and evaluative judgements of the CQC in this context. For the claimants it is suggested that, given the general regulatory nature of the CQC's role, and the lack of particular sector expertise on the part of those carrying out the assessments (a point of criticism in the Dash review, and something the claimants say is true of the decision-making in issue), less deference is required than might otherwise be expected. I am, however, not persuaded that is the correct inference

to draw, still less that it would be appropriate to do so in this case. The CQC's expertise relates to its particular statutory functions. Whether or not its inspectors have a relevant sector specialism, their regulatory experience within health and social care, having particular regard to public safety, provides meaningful expertise when assessing a provider's ability to comply with the requirements of the 2014 Regulations. When approaching the decisions under challenge in these proceedings, I do not disregard the expertise that those carrying out the assessments brought to their task.

99. Regardless of the degree of deference to be afforded to the CQC, the claimants have argued that only one outcome was rationally open to the CQC and/or would further the legislative requirements, namely that IP1's registration ought to have been refused (in January 2024), alternatively withdrawn (in December 2024), alternatively that a condition was to be imposed such as to require IP1 to achieve procedural equivalence with the NHS (an on-going failure). I have not understood the claimants' case in this regard to be put as high as to assert that, given that this was a private sector provider, operating outside the NHS, the impugned decisions would necessarily be irrational for that reason; but, to the extent that was the implication of the claimants' argument, I would reject it: there is nothing in the legislative regime that would suggest this was Parliament's intent, nor can it be inferred from the requirements of HSCA or the relevant secondary legislation. As for "*procedural equivalence*" with the NHS, the difference between the parties in this regard is one of degree. The CQC has stated that it looks to private providers to seek to emulate NHS standards, and, for its part, IP1 has said it has sought to ensure there is close alignment between the processes of the NHS and those it operates in partnership with Kelly Psychology. That there might not be a precise alignment was acknowledged by the Court of Appeal in *O v P* (see [39]), leading it to conclude that there might still be a requirement for the court to exercise its

supervisory role in this context. The question posed by this case is as to whether any differences in process – even if in part arising from structural differences inherent in a private, rather than NHS, service – place the decisions reached by the CQC outside the range of reasonable responses open to it in these circumstances.

(1) Process irrationality

100. Under this ground, the claimants say that, although the CQC had acknowledged that the NHS position relating to safeguards for the hormone treatment was a relevant consideration, it had then omitted to take into account a number of obviously material factors, which were either apparent from the material before it or into which it ought reasonably to have enquired but did not. Applying a heightened standard of review to the process adopted by the CQC, I have separately considered each of the factors thus identified, before standing back to assess the process as a whole.

101. **Referrals to IP1 by non-CQC regulated entity**. The first matter relied on by the claimants is the fact that, within the NHS, only CQC regulated entities can refer 16 and 17 year olds for the hormone treatment whereas referrals to IP1 are made by Kelly Psychology, which is not CQC-regulated. The claimants complain that there was no reference to this point in the registration decision, and, to the extent referenced at the assessment stage, there was a failure to have regard to how this reduced safeguards for patients; as a referral is not a neutral act but a positive recommendation for treatment, the claimants say this was an obviously relevant distinction giving rise to an enhanced risk to patient safety.

102. In considering this point, it is necessary to be clear that the objection relates specifically to the fact that Kelly Psychology is not regulated by the CQC; the conduct of every psychologist employed by Kelly Psychology is regulated by the Health and Care

Professions Council, and the conduct of every psychotherapist by the UK Council for Psychotherapy. As for the fact that Kelly Psychology does not fall within the remit of the CQC, it is apparent that those involved in the registration and assessment decisions (and, therefore, in determining whether or not to impose additional conditions on IP1's registration) were clearly aware of this (indeed, this was a point referenced by Ms Huntley in her statement in these proceedings before it had been highlighted as a materially relevant consideration by the claimants). Given the CQC's understanding of the entities that would, and would not, fall under its ambit of responsibility, I would not readily infer that a failure to expressly reference this feature (a not uncommon distinction between the NHS and private sector, which will exist in many CQC registration and assessment decisions) demonstrates that it was not taken into account.

103. Moreover, looking for an acknowledgement of the materiality of this point as if this was some form of tick-box exercise fails to engage with the substance of the CQC's decision-making process (both at the registration and the assessment stage), as revealed by the evidence in this case. Engaging with that evidence shows that the process adopted by the CQC expressly took account of *how* patients arrive at IP1 (speaking to both patients and Kelly Psychology staff, as well as reviewing the relevant documentation). Ultimately, the question for the CQC was whether IP1 could demonstrate compliance with the requirements of the 2014 Regulations; the process it adopted in answering that question demonstrated a clear appreciation of the context, which included the fact that referrals came from an entity that the CQC did not itself regulate. This objection is not made out on the facts.

104. **Referrals to IP1 from an entity that provides only non-medical psychological treatment**. In this respect, the claimants rely on the fact that within the NHS referrals

of 16 and 17 year olds for the hormone treatment are only permitted from entities that provide specialist secondary medical care, whereas such patients can be referred to IP1 by Kelly Psychology without having been seen by a medical professional. The claimants say this is a material consideration as it means that wider, specialist medical knowledge and expertise can be brought to bear on NHS referral decisions in circumstances where there may be co-morbidities, such as autism, anxiety, depression, eating disorders, or other mental health needs (rates of which, as the Cass Review recognised, are much greater in this cohort of vulnerable children than their peers).

105. The distinction identified in this regard does not directly arise from the NHS referral process for the hormone treatment but from the requirement that the prior referrals to its children and young persons gender services may only be made by NHS paediatric services or NHS mental health services for children and young people. This was the point made in the NHS England announcement of 7 August 2024; it is a requirement that came into effect as from 1 September 2024, albeit that the lengthy waiting list for such services in the NHS means that existing patients will have continued to be seen absent such a referral from a specialist service. In any event, it is not in dispute that the same restriction on referrals to Kelly Psychology (the direct comparison relevant to this point) does not exist. Again, however, it is apparent from the evidence that this was something of which the relevant decision-takers within the CQC were well aware.

106. Although the NHS referral pathway announced on 7 August 2024 was not in force at the time of the registration decision, it was one of the documents to which Ms Huntley expressly had regard when carrying out the subsequent assessment of IP1; it was also a matter which Ms Kirton de Ortega had in mind when she reviewed that assessment. In this regard, the CQC's evidence makes clear that, having had regard to the structure of

the service provided by the NHS (but also being aware of the different environment in which the NHS operates), the support provided to patients was a specific point of concern addressed through the assessment. Relevantly, although Kelly Psychology was not the subject of the CQC assessment, evidence was obtained about the process at that stage, which would include consideration of any potential referral by Kelly Psychology's own MDT, subject to the patient meeting inclusion/exclusion criteria mirroring those of the NHS 21 March 2024 policy, with other (psycho-social) treatment options also being available, and with mental health and other support. Then following the process through, and considering cases that had been referred to IP1, regard was had to the mental health and other support available to patients at that stage, with a mental health nurse (who attended every initial face to face appointment) being one of those interviewed by Ms Huntley. Further consideration was given as to how IP1 continued to engage with others involved in the care of an individual patient, which was found to include information sharing with GPs, with a view to entering into shared care plans. The evidence thus demonstrates a detailed engagement with this point when holistically assessing the process of referrals to IP1; again, the objection raised by the claimants in this regard, is not made out on the facts.

107. **IP1 is inextricably intertwined with Kelly Psychology; both entities operate "for profit", and there is a risk that decision-making will be influenced by considerations of mutual benefit**. In this regard, the claimants rely on the fact that IP1 and Kelly Psychology were both founded, and are both owned and operated, by Dr Kelly; that the two entities have the same registered address and are portrayed as an integrated service, with one booking process; and that some staff are employed by both organisations and their employees are often involved in joint presentations. The

claimants say this inevitably gives rise to a risk of a conflict of interest, which will not exist in the NHS where there is no such interconnectedness.

108. Considering this issue under the heading of process irrationality, it is again apparent that the points being made were very much in the minds of those undertaking the relevant assessments. The CQC regulates thousands of private organisations operating in the health and social care sectors; it does not impose conditions in respect of the business models operated by such private businesses, nor does it seek to control the commercial arrangements they enter into. That does not mean, however, that the CQC does not have regard to the potential conflicts of interest that might arise when (as will generally be the case in the "for profit" independent sector) independent providers of TDDI services stand to benefit from any positive prescribing decisions they make. Even putting to one side the fact that individual clinicians will be bound by their own professional obligations and regulation, the CQC has explained that it will specifically have regard to the transparency of the processes operated by private sector providers, including clear prescribing criteria, and to evidence of adherence to those processes and to fundamental standards generally. In the present case, the evidence shows there was a clear focus on governance and on the safety of processes operated by IP1. The links between IP1 and Kelly Psychology were transparent at all stages, and made clear in the documents reviewed by the CQC. Equally, the integrated nature of the service was apparent from the documentation considered both at the registration stage and in the later assessment of IP1. The evidence demonstrates that due account was given to this feature, and, adopting the more rigorous examination required, I am satisfied that there is no gap in the CQC's reasoning in this regard; this objection also fails.

109. **There are clear differences between IP1's MDT and the NHS national MDT**. This issue was the primary focus of the claimants' argument at the hearing, with the point being made that, while the CQC had reasoned that IP1's MDT was "*sufficiently aligned*" with the NHS in this regard, the only basis for that conclusion was the presence of a single child psychiatrist, Dr Adams, who was not part of the referring team of clinicians. That, the claimants contend, revealed a failure to make reasonable enquiries into the NHS position and/or omitted to take into account a number of clear differences between the NHS national MDT and that of IP1. Specifically, the claimants say the NHS national MDT chair does not stand to benefit from any decision to approve treatment, whereas the chair of IP1's MDT is paid by IP1 and cannot be said to be fully independent; all members of the IP1 MDT are employed and/or paid by either IP1 or Kelly Psychology, whereas there is no one on the NHS national MDT who works in a service providing the hormone treatment; moreover, IP1 MDT decisions are made by consensus and Dr Adams is but one individual, with all others being employees of Kelly Psychology or IP1, so it was unrealistic to consider she could provide a meaningful check; yet further, Dr Adams represents only one discipline, whereas the national NHS MDT is comprised of members from multiple specialisms and there is also a multi-disciplinary holistic assessment by the NHS gender service prior to any referral (consistent with the new model proposed by the Cass Review).

110. During the course of oral submissions, it was apparent that there was a disagreement between the parties as to whether, by considering IP1's processes by reference to the NHS 21 March 2024 policy, the CQC had (at least in reaching its assessment decision) properly had regard to the way in which the NHS service was now structured. In this respect, the claimants placed particular reliance on the content of the letter from Evelina London, explaining how relevant services within the NHS currently operate. This was,

however, obtained only shortly before the hearing and it was apparent that the claimants' interpretation of that letter – and, therefore, description of how NHS services operate – was not agreed. This is not a dispute that I can resolve at this stage, but, in any event, I am satisfied it is unnecessary to do so. The CQC was concerned with whether IP1 could demonstrate compliance with the requirements of the 2014 Regulations; as such, while it saw NHS standards as highly relevant, it did not (and could not) treat those as determinative of questions of compliance by a private sector provider. It has not been suggested that the 21 March 2024 policy had been superseded by a later public statement of policy, or that there was clear NHS guidance as to what was meant by "*extreme caution*" (as per recommendation 8 of the Cass Review), to which the CQC ought, but failed, to have regard when reaching its assessment decision, (it plainly could not have done so when reaching the registration decision made in January 2024). In any event, the real issue must be whether proper regard was had to the reasons underlying the structures adopted in the NHS following the Cass Review; that is, does the evidence as to the assessment carried out by the CQC demonstrate that, as a matter of substance and not merely of form, account was taken of the risks that NHS safeguards were designed to address?

111. In approaching this question, it is again apparent that many of the points identified by the claimants are inherent in the fact that IP1 is a private provider that does not have access to the structures operated by the NHS. Inevitably, IP1's MDT is principally comprised of those who are employed by it, or by Kelly Psychology, and the one person who does not fall into these categories (Dr Adams) is paid by IP1 on a contract basis. Equally inevitably, IP1 does not have access to the NHS national MDT, nor would it be able to precisely replicate that entity. These are matters that were, however, obvious to Ms Huntley and her colleagues: the CQC regulates both NHS and private sector

providers and is aware of the structural differences that exist between a national, non-profit making, publicly funded, general health service, and a small, specialist, independent provider which is privately financed; I would not infer that a failure to expressly set out these points means they were not taken into account.

112. What is, moreover, clearly apparent from the CQC's evidence is the detailed scrutiny that was undertaken in order to be able to assess IP1's compliance with the regulatory requirements. Having carefully reviewed the evidence of Ms Huntley and her fellow assessors, it is apparent that this was an assessment that drilled down to the detail of the service provided by IP1, with patient safety foremost in mind. I have already summarised the work undertaken by those carrying out the assessment and am clear that careful regard was had both to the eligibility and readiness criteria set out within the 21 March 2024 policy, and to the reasons for those criteria. Thus, in considering the NHS requirement for the national MDT to include "*clinicians not directly involved in the formulation of the individual's care plan*", Ms Huntley took into account that this was to "*ensure that the individual understands that there is limited clinical evidence on the effects and harms of [the hormone treatment] ... which is a significant decision with long term indications*." (see Ms Huntley's statement at paragraph 35). In then assessing IP1 against that standard, Ms Huntley not only looked at the structure that it had put in place, but sat in on MDT discussions and formed an independent view as to the role played by Dr Adams as a member of that body who had no involvement in the patient's care and who stood neither to lose or gain as a result of any decision reached on the referral. Other than the structural differences inherent in the comparison between the NHS and a small private provider, the evidence does not support the criticisms made under this point of challenge and the objection again fails.

113. **IP1 and Kelly Psychology advocate for the hormone treatment.** In this regard, the claimants rely on various comments made by/attributed to Dr Kelly and (to a lesser extent) others connected to IP1 and/or Kelly Psychology. The CQC accepts that it did not have these various citations in mind when reaching its registration and assessment decisions (indeed, the comments in question post-dated the registration decision), although it did undertake a check with earlier records relating to Tavistock GIDS (where both Dr Kelly and Mr Carruthers had previously worked), which revealed no issues relating to any of the individuals involved with IP1.

114. In approaching this point, I bear in mind the concerns expressed by the Cass Review as to the polarised views held by many clinicians as to the appropriate treatment of children presenting with gender incongruence and dysmorphia, and as to how this can impact upon clinical decision-making. This provides relevant context to the claimants' contention as to how the strong views attributed to Dr Kelly might be potentially material to the decisions the CQC had to take (although, for completeness, I should say that I am unable to see that the citations relied on in relation to Mr Carruthers (a description by a third party which is insufficiently precise to have any real meaning) or Dr Quinney (a one-off social media comment dating back to 2019) assist the claimants' argument in this respect). Had the CQC tracked down these various statements, however, it seems likely that Dr Kelly would also have directed it to the various academic articles and conference papers, which he says make clear that his views are more nuanced than newspaper comments might suggest.

115. Given that the CQC was required to reach its own conclusion as to IP1's compliance with the requirements of the 2014 Regulations, it seems to me that, in respect of the decisions in issue, it legitimately limited its research to that which might be available

from past records (specifically, past reviews of Tavistock GIDS), whilst forming its own view as to the suitability of those involved in IP1's provision of the regulated service, as derived from the very full assessments undertaken, which included interviews with each of the relevant individuals. In the circumstances, I do not find the claimants have demonstrated that the "advocacy" evidence relied on is such as to have been so obviously material to the CQC's decisions that its failure to find and take this into account reveals an irrationality in its process or reasoning. On the contrary, I am satisfied the steps taken by the CQC were rationally focused on scrutinising the actual process by which IP1 provided the service in issue. I duly reject this objection.

116. **Process irrationality: an overview.** Having considered each of the factors identified by the claimants individually, I have then sought to stand back to consider the approach adopted by the CQC, and its process of reasoning, taken overall. Acknowledging that the standards applied in the NHS are relevant to the assessments the CQC undertakes of the private sector provision of TDDI services by healthcare professionals, the question is whether it properly had regard to the particular, and changing, approach adopted by the NHS at the relevant time. Although many of the criticisms now relied on by the claimants are of little relevance to the registration decision – which was taken at a time prior to the key changes in NHS policy relied on - by the time of the assessment decision there had been a very real change in how the NHS approached the treatment of under 18s presenting with issues of gender incongruence and dysmorphia. It is the claimants' case that the assessment undertaken by the CQC, subjected to the required standard of anxious scrutiny, fails to demonstrate a rational engagement with the considerations identified by the Cass Review, which form the basis for the policy that now underpins NHS services; it is their contention that this reveals a critical gap in the

CQC's approach to the discharge of its primary objective, to promote the health and safety of those who use health services.

117. Having duly carried out a rigorous examination of the relevant decision-making processes in this case, however, I have reached the conclusion that the claims made are focused on issues of form rather than substance. Most of the criticisms the claimants have identified relate to the structural differences inherent in the private provision of an independent, specialised, TDDI service as compared to the way in which a similar service will (and can) be provided by a national, publicly funded, entity of the size and scale of the NHS. Simply identifying those differences says little as to the rationality of the process adopted by the CQC in reaching the decisions in issue in these proceedings. That requires engagement with the detail of the evidence as to the actual assessments carried out, something that is largely absent from the claimants' case. Having regard to that evidence, however, I am satisfied that this reveals a full and proper consideration of all relevant considerations, not simply ticking the boxes, but undertaking a thorough appraisal of each aspect of the service provided by IP1. The assessment process replicated each of the questions identified under regulation 12 of the 2014 Regulations. In then assessing IP1 in the light of those questions, the CQC undertook a detailed consideration of the documentary records, alongside interviews with patients and with those involved in the provision of the service at each stage (including employees of Kelly Psychology, notwithstanding it was itself not subject to CQC regulation); interviews were also undertaken with Dr Kelly and Mr Carruthers, and assessors sat in on patient consultations and on IP1 MDT decision-making discussions. Little issue has been taken with any of this evidence, but it is the answer to this ground of challenge: the decision-takers within the CQC had proper regard both to the relevant regulatory requirements and to each of the points of concern identified

by the claimants; a detailed process of assessment was undertaken that fully engaged with those (and other relevant) concerns, considered through the prism of the requirements of the 2014 Regulations. The challenge on the basis of process irrationality duly fails.

(2) Outcome irrationality

118. Regardless of the rationality of the process adopted by the CQC, the claimants further contend that its conclusion that IP1's registration should be continued, absent further condition, was not one that was rationally open to it. Having regard to the five matters identified, it is the claimants' case that, applying the appropriate level of heightened scrutiny, the range of rational decisions was so narrow as to determine the outcome (per *Pham* at [107]): either the CQC had to impose a condition which rationally ensured patient safety, or, if that were not possible, it was bound to decide not to continue the registration; it could not reasonably treat the continuation of the registration as sufficient to ensure patient safety. In support of this case, the claimants point to the patient data, showing that, for the period 1 July 2023 to 30 June 2024, all 69 referrals of 16-17 year olds from Kelly Psychology had been accepted by IP1 (albeit three patients had had to undergo a period of further assessment or treatment); in contrast, since at least April 2024, no new referrals have been made for hormone treatment for anyone within this age range within the NHS in England (or Scotland).

119. Before returning to the specific points relied on, I should first address the question of the patient data figures referenced in the claimants' argument. As Ms Huntley has observed in her evidence, the difficulty with these figures is that they are not comparing like with like. The NHS data refers to referrals of new patients post April 2024, which provides no information regarding the position of those already on the waiting list.

Even focusing on the absence of referrals of such new patients, however, it has to be born in mind that those being considered by the national NHS MDT will include children below the 16-17 age group relevant to the hormone treatment provided by IP1, and there are likely to be other differences between the two groups of patients which might explain different referral rates. In any event, given both NHS waiting lists and the time required for assessment before cases are referred for consideration by the national MDT, it may well be that few cases have reached that stage in the process. As for IP1, as the claimants have themselves pointed out, Kelly Psychology and IP1 operate an integrated service; if the assessments undertaken by Kelly Psychology are carried out with due rigour, applying the appropriate degree of caution in making referral decisions for the hormone treatment, it might not be particularly surprising if there was then a high acceptance rate of those referrals by IP1.

120. Allowing that there could come a time when a long-term and striking disparity in referral numbers might make this a relevant consideration for the CQC, that is not provided by the current evidence. Even if such data was to be considered relevant, however, it is hard to see how this could be determinative. As Ms Huntley has pointed out, it is not the CQC's role to review each and every treatment decision: whether or not an appropriate clinical decision has been made to treat an individual patient with the hormone treatment must be a matter for specialist knowledge, exercising a clinical expertise and judgment outside the remit of the CQC and falling, instead, within the purview of the individual clinician's professional body.

121. **Referrals to IP1 by non-CQC regulated entity**. Although a relevant consideration (and seen as such by the CQC), the evidence shows that this is not an unusual feature for the CQC: regulated providers (including those who offer TDDI services for

vulnerable children) will often work with unregulated entities and may accept patient self-referrals. Neither the HSCA nor the 2014 Regulations prohibit such arrangements and, allowing for the particular context of the decision under challenge in these proceedings, I cannot see that this feature meant that the CQC was bound to refuse IP1's registration. Indeed, at the registration stage, section 12(2) HSCA requires the CQC to make a binary determination: if satisfied that the provider is complying with the requirements of the relevant regulations, and will continue to do so, it must grant an application for registration; if not, it must refuse it. That requires an assessment of compliance/the likelihood of continued compliance; the answer will not be provided simply by reference to the fact that a CQC-regulated provider might accept referrals from an entity falling outside the CQC's remit. As for the subsequent assessment decision, while that involved a rating exercise, the CQC evaluated IP1 against standards that were clearly tied to the requirements of the 2014 Regulations; having assessed IP1 as "outstanding" in the majority of categories, it cannot be said to be irrational for it to have continued the registration without imposing further conditions.

122. At each stage, the substantive question for the CQC was whether the provision of the regulated activity complied with the relevant regulations. In answering that question, it was entitled to take into account the safeguards provided by the professional regulatory standards to which the individuals within both IP1 and Kelly Psychology were bound. Beyond that, however, the CQC had regard to how patients arrived at the service provided by IP1, with the integrated nature of the relationship between IP1 and Kelly Psychology affording the CQC visibility over the quality of the latter's referrals and its treatment of patients. As for the CQC's assessment of IP1, having found demonstrable compliance with the fundamental standards, it was entitled to see that as mitigating any risks arising from the fact that IP1 was accepting referrals from an entity

that fell outside the CQC's remit. The detailed findings made by the CQC in these respects have not been challenged; these attest to the high standards of care provided to patients throughout the integrated service operated by Kelly Psychology and IP1. On the evidence, I cannot see that the relevant decisions reveal any irrationality as to outcome in this regard.

123. **Referrals to IP1 from an entity that provides only non-medical psychological treatment**. The comparison being made in this regard concerns referrals to the NHS gender service, not to subsequent providers of the hormone treatment. Given that it was concerned solely with the regulation of IP1, it is unclear as to how it is suggested that the CQC ought to have approached this factor when reaching its conclusions on registration or in its subsequent assessment. In any event, it is apparent that the assessment process led by Ms Huntley had regard to the explanation for this requirement (as identified in the NHS consultation report of 7 August 2024) and was satisfied that the service provided, viewed as a whole (including the assessment stage at Kelly Psychology), demonstrated a holistic approach to treatment planning, with referrals back to the patient's GP, and with specific training for staff to support patients with additional needs. Taking into account this difference between IP1 and the NHS service, but having regard to the detailed findings made on the CQC's assessment (which have not been the subject of specific challenge in these proceedings), I am unable to conclude that the conclusion reached was outside the range of rational responses open to the CQC. Moreover, having found that, measured against the requirements of the 2014 Regulations, IP1 was to be rated "outstanding" overall, I cannot see that the CQC can be said to have reached an irrational conclusion in not imposing any further condition on IP1.

124. **IP1 is inextricably intertwined with Kelly Psychology; both entities operate "for profit", and there is a risk that decision-making will be influenced by considerations of mutual benefit**. As I have already observed, the potential for conflicts of interest will be a relatively common feature in the independent sector that the CQC regulates. When considering this under the heading of outcome irrationality, a direct comparison with the NHS is inapt: there is no intrinsic reason why the private sector should be forced to mirror the public sector in terms of working structures and relationships (even if that was a reasonably practicable option); the issue for the CQC must be whether it is satisfied as to the provider's compliance with the requirements of the relevant regulations.

125. The claimants' case in relation to this point affords no weight to the professional obligations owed by individual practitioners at IP1 and Kelly Psychology, although such professional regulation will provide a significant and important safeguard in the provision of regulated TDDI services. The CQC's registration and assessment decisions did not, however, rest solely on that point; those decisions were based on the detailed evaluations carried out in each instance and, although alive to the structure of IP1's business, and its links with Kelly Psychology, the CQC found no evidence of improper decision-making or anything else that could give rise to a legitimate concern relevant to patient safety or well-being. The claimants' case does not engage with the findings made by the CQC at either the registration or the subsequent assessment stages, but those findings demonstrate why there was no irrationality in the decisions reached, and why it was not irrational for the CQC to consider IP1's registration should not be subject to further conditions.

126. **There are clear differences between IP1's MDT and the NHS national MDT**. In this regard, the claimants contend that the CQC's finding that IP1's MDT was "sufficiently aligned" with the NHS national MDT was outside the range of reasonable conclusions open to it, objecting that the only basis for that conclusion was the presence of Dr Adams, who was not truly independent and who could not provide the same breadth of specialist input available within the NHS.

127. I do not accept that the claimants' case provides a fair characterisation of the CQC's reasoning in this regard. Although the presence of Dr Adams in all referral decisions relating to 16 and 17 year olds was certainly an important factor, it is also apparent that Ms Huntley and her colleagues had regard to other features of IP1's referral decisions that were also relevant to the conclusion reached. Thus, regard was had to the prior process of assessment, over some six months, by Kelly Psychology; it was also considered relevant that IP1's MDT – which was (as the name suggests) itself multi-disciplinary – would involve psychologists from Kelly Psychology who were not themselves involved in the care of the patient under discussion; in relation to Dr Adams, accepting that she would be paid a fee by IP1, it was nevertheless apparent that she would have no continuing interest in whether or not a referral was agreed; at the same time, conscious of the majority presence of representatives of IP1 and Kelly Psychology, the fact that consensus agreement was required was seen to ensure that Dr Adams' independent viewpoint could not be outvoted; and, significantly, Ms Huntley had herself sat in on IP1's MDT discussions and formed her own view as to the safeguards it provided.

128. Returning then to the comparison with the NHS national MDT, accepting that IP1 could neither access the NHS structure, nor precisely replicate it, I have gone back to consider

the stated purpose for requiring referral decisions to be taken by the national MDT; that is, to ensure the patient understands the limited clinical evidence as to the effects and harms of the hormone treatment at ages 16-17, and that such treatment involves a significant decision with long-term indications. Accepting the way in which it has been decided that this purpose is to be achieved within the NHS, I do not consider that this requires that referrals for hormone treatment for 16 and 17 year olds can only be determined by the NHS national MDT, or a precise replica. That would effectively mean there could be no private provision of the hormone treatment for this age group, which is not a limitation that has (yet) been imposed (accepting that this is an area where there may well be further regulation). Allowing, therefore, that there was a range of responses open to the CQC in assessing IP1's decision-making structures, the real question is whether its conclusion was compatible with the cautionary approach that underpins the NHS model to which IP1's process was being compared.

129. Again, the detailed evidence provided explains the decision reached; in particular, Ms Huntley's statement sets out what she witnessed when sitting in on IP1's MDT discussions and why this supported the conclusion arrived at on the assessment. It is apparent that Ms Huntley had in mind the purpose of the NHS MDT, and was focused on whether the structure put in place by IP1, even if not the same, was sufficiently aligned as to be able to meet that purpose. Relevantly, further detailed consideration was given to other aspects of the consent process, with the assessment report again setting out the various features that weighed with Ms Huntley (and her colleagues) in this regard. Accepting that IP1 could neither access the NHS national MDT nor precisely replicate it, but keeping in mind the purpose of the NHS model, I cannot say that the CQC's finding of sufficient alignment was outside the reasonable range of conclusions open to it.

130. **IP1 and Kelly Psychology advocate for the hormone treatment.** For the reasons I have already identified, this is a point that I consider can only sensibly relate to the statements made by/attributed to Dr Kelly. It is, however, not part of the claimants' case that Dr Kelly could not be a nominated individual, and it must be allowed that he is entitled to hold and express views about the provision of gender services. The substantive question for the CQC was as to whether those involved in the provision of regulated activities through IP1 were able to demonstrate compliance with the regulatory requirements; it determined this question through its investigation of the professionalism demonstrated by those involved in the management of IP1, which included Dr Kelly and which extended back to consideration of whether there were any recorded concerns relating to his previous work at Tavistock GIDS.

131. The CQC's findings at both registration and assessment stages are set out in the relevant reports. No issue has been taken with those findings, which explain why the CQC found the professionalism of IP1, and its senior leadership team, to be commensurate with a well-run service. Even viewing the statements relied on by the claimants alongside the patient referral data, I cannot see that would suggest that the conclusions reached by the CQC were other than within a reasonable range. As I have already observed, to the extent that regard was to be had to comments by/attributed to Dr Kelly in various newspapers, it would be necessary to consider these in the light of other statements he had made, including in academic journals or conference papers. As for the patient data, I have already referenced the problems that arise in seeking to compare these figures with NHS referrals. Even if just considering patient referrals to IP1, regard would also need to be given to the fact that a significant number of those assessed by Kelly Psychology are not referred for the hormone treatment. Yet further limiting consideration to patients referred to IP1, a high rate of acceptance would be entirely

compatible with the assessment process having been undertaken with due rigour, exercising the degree of caution recommended by the Cass Review. Certainly, the evidence available in this regard does not provide a basis for concluding that the CQC did other than reach decisions that were within the reasonable range.

132. **Outcome irrationality: an overview**. Having considered each of the five factors individually, I have again sought to stand back to consider the outcome irrationality challenge take as a whole. Thus, undertaking the anxious scrutiny required, I have taken into account the conclusions reached by the Cass Review and the recommendations in the final report, understanding that these have informed changes to NHS policies that have, in turn, been accepted as providing relevant comparisons for the CQC's assessments of IP1. For the claimants it is contended that this is a case where there ought properly to have been only one answer (per *Pham*), such that IP1's registration, or continued registration, ought to have been refused or subjected to the imposition of a condition akin to the requirement for a second opinion from independent and impartial persons required in equivalent circumstances within the NHS. In advancing that argument, the claimants have at times come close to suggesting that the provider of the regulated TDDI activities in this context would have to operate as part of the NHS. Acknowledging that this might be a matter for the on-going policy debate in this area (and I am mindful of the fact that an expert working group is due to report on the use of the hormone treatment for children), I am unable to see that this is a requirement that can be read into the legislative and regulatory regime currently in place.

133. Thus accepting (as I do) that the range of rational decisions open to the CQC allowed for the possibility of it approving the registration/continued registration of IP1 as a

private provider of the hormone treatment, I would, however, agree that the extent of the range is necessarily informed by the findings of the Cass Review and the NHS response to those findings. In this respect there is a degree of common ground: the CQC accepts that the standards set by the NHS will be relevant to the assessments it makes in regulating the healthcare sector, and IP1 has made clear that it has looked to NHS policies in establishing its own structures and procedures. Where, however, IP1 was unable to precisely replicate the NHS process, I consider it was open to the CQC to look to the objectives that the NHS was seeking to achieve and to use those as the relevant standard against which to assess IP1; thus the range was set by reference to the substance that underpinned the NHS structures, not merely the choices made as to the form that those structures should take. Applying that approach (as I am satisfied the CQC did) the decisions reached fall within the rational range, and the CQC was entitled to conclude that no further conditions were required.

(3) The Padfield challenge

134. This is not a point that was developed in submissions, the claimants effectively accepting that the *Padfield* principle takes matters no further in this case.

135. For completeness, however, for the reasons I have already provided. I am unable to see that the matters relied on by the claimants would demonstrate that the CQC's decisions amount to a frustration of the law (the HSCA or the 2014 Regulations) it was bound to implement.

Disposal

136. For the reasons explained in the body of this judgment, I duly dismiss the claimants' claim.