Neutral Citation Number: [2024] EWHC 1936 (Admin)

Case No: AC-2024-LON-002062

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

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 29 July 2024

Before :

MRS JUSTICE LANG DBE

- -

Between :

THE KING	**Claimants**
on the application of	
(1) TRANSACTUAL CIC **(2) YY (BY HER LITIGATION FRIEND ZZ)** **- and -** **(1) SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** **(2) MINISTER OF HEALTH FOR NORTHERN IRELAND**	**Defendants**

- -
- -

Jason Coppel KC, David Lock KC, Rob Harland, Charles Bishop and Christian Davies
(instructed by **Russell-Cooke LLP**) for the **Claimants**
Julian Milford KC, Natasha Barnes and Darragh Coffey
(instructed by the **Government Legal Department**) for the **Defendants**

Hearing date: 12 July 2024

- -

Approved Judgment

This judgment was handed down remotely at 11 am on 29 July 2024 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

.....

Mrs Justice Lang :

1. The Claimants challenge the lawfulness of secondary legislation which limits the prescription, sale or supply of Gonadotrophin-Releasing Hormone Analogues ("puberty blockers") for the purposes of puberty suppression to children and young people under 18 who are experiencing gender dysphoria and gender incongruence. The claim was ordered to be heard as an expedited rolled-up hearing by Garnham J. on 19 June 2024.

2. The secondary legislation under challenge is as follows:

   i) The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024/727 ("the Order"), made pursuant to section 62(1) of the Medicines Act 1968 ("MA 1968").

      a) This is a temporary Order, made by the First and Second Defendants, on 29 May 2024. It took effect on 3 June 2024 and expires on 2 September 2024. The Order applies to England, Wales and Scotland.

      b) The Second Defendant was required, under the terms of section 62 MA 1968, to make the Order jointly with the First Defendant, even though the Order does not extend to Northern Ireland (see paragraphs 131 to 132 below).

   ii) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2024 (SI 2024/728), made by the First Defendant, with effect from 26 June 2024 ("the Regulations"). The Regulations only apply to England.

3. The First Claimant ("C1") is a Community Interest Company which seeks to improve life for transgender people in the UK, with a particular focus on healthcare.

4. The Second Claimant ("C2") is aged 15. She is a transgender female who was in the process of acquiring her first prescription for puberty blockers from an overseas provider when the Order was made. As a result of the Order, pharmacists in England, Scotland and Wales can no longer dispense puberty blockers on a prescription issued by a prescriber in the European Economic Area ("EEA") or Switzerland.

5. The Claimants' grounds of challenge may be summarised as follows:

Ground 1

6. The First Defendant acted unlawfully in utilising the emergency procedure[1] under section 62(3) MA 1968, without following the standard procedure of consultation, and advice from the Commission on Human Medicines ("CHM"), when the conditions for doing so were not met. She was not rationally entitled to conclude, on the evidence, that

[1] The term "emergencies" was used by Sedley LJ in *R (National Association of Health Stores) v Department of Health* [2005] EWCA Civ 154, at [12], when describing the exception in section 62(3) MA 1968.

it was essential to take immediate action to prohibit the sale or supply of puberty blockers to children in order to avoid a serious danger to health.

Ground 2

7. In the alternative, even if the First Defendant was entitled to utilise the emergency procedure, the First Defendant carried out a partial, unfair and unlawful consultation, in failing to consult C1, or any similar organisation which represented the interests of patients potentially affected by the Order and the Regulations, but consulting a number of other individuals and bodies.

Ground 3

8. The First Defendant acted in breach of Article 8 ECHR by failing to consult or involve C2, or organisations who would represent her interests, prior to taking a decision which had substantial implications for her medical treatment.

9. The Claimants do not allege that it would have been unlawful for the Defendants to make the Order if the First Defendant had complied with the consultation requirements for which the Claimants contend. The Claimants do not invite the Court to decide that puberty blockers are safe or should be available. The focus of the claim is on the procedure adopted by the First Defendant.

10. The Defendants' response may be summarised as follows:

Ground 1

11. The First Defendant was entitled to conclude that the test in section 62(3) MA 1968 was met. Vulnerable children were being placed on medical pathways which had substantial, albeit unquantified, risks and no or very limited clear benefits. The Independent Review of Gender Identity Services for Children and Young People, chaired by Dr Hilary Cass ("the Cass Review") recommended that puberty blockers should only be prescribed under a research protocol. However, the First Defendant had no way of enforcing this recommendation on overseas prescribers, who were prescribing in ways that were both unethical and unsafe. Her conclusion that an emergency order was required was a complex assessment, involving the application of clinical judgment, with which the Court should be slow to intervene.

Ground 2

12. There is an exemption from the consultation requirements in section 62(5) MA 1968 when the emergency procedure is followed: see section 62(6) and 129(6) MA 1968. In those circumstances, a duty to consult cannot be implied.

13. The First Defendant did not undertake a voluntary "consultation". Having made the "in-principle decision" to enact the Order, she performed a limited stakeholder exercise aimed at refining and ensuring the smooth implementation of the Order. Even if (contrary to the First Defendant's case) this was a "consultation" in the legal sense of

the word, there was no obligation to consult C1 and the failure to do so was neither irrational nor unfair.

14. Further, consultation would not have led to a substantially different outcome. Therefore permission to apply for judicial review, or alternatively relief, should be refused pursuant to section 31(2A) or (3D) of the Senior Courts Act 1981.

Ground 3

15. Article 8 ECHR is engaged but the limitations on the supply of puberty blockers do not breach any substantive or procedural rights under Article 8. Under domestic law, there was no obligation to consult before legislating in a way that affected Article 8 rights.

16. In response to a request from the Court, the First Defendant indicated that the Government supports implementation of the Cass Review, and subject to the outcome of these proceedings, is minded to renew the emergency banning order which is due to expire on 2 September 2024, with a view to converting it into a permanent ban, subject to appropriate consultation.

Factual and legal background

Regulatory framework

17. The introduction to the National Institute for Health and Care Excellence ("NICE") evidence review on puberty blockers, dated October 2020, provides an overview of gender dysphoria and puberty blockers, as follows:

> "Gender dysphoria in children, also known as gender identity disorder or gender incongruence of childhood (World Health Organisation 2020), refers to discomfort or distress that is caused by a discrepancy between a person's gender identity (how they see themselves regarding their gender) and that person's sex assigned at birth and the associated gender role, and/or primary and secondary sex characteristics (Diagnostic and Statistical Manual of Mental Disorders 2013).
>
> GnRH analogues suppress puberty by delaying the development of secondary sexual characteristics. The intention is to alleviate the distress associated with the development of secondary sex characteristics, thereby providing a time for on-going discussion and exploration of gender identity before deciding whether to take less reversible steps. In England, the GnRH analogue triptorelin (a synthetic decapeptide analogue of natural GnRH, which has marketing authorisations for the treatment of prostate cancer, endometriosis and precocious puberty [onset before 8 years in girls and 10 years in boys]) is used for this purpose. The use of triptorelin for children and adolescents with gender dysphoria is off-label."

18. GnRH analogues have manufacturing and marketing authorisations issued either by the European Medicines Agency ("EMA") on a Europe wide basis, or by the Medicines and Healthcare Products Regulatory Agency ("MHRA") for UK purposes. The terms of an authorisation limit the therapeutic purposes for which a medicinal product can be marketed. Puberty blockers are not licensed by the MHRA for the purpose of puberty suppression, and so they can only be prescribed off-label for that purpose. Doctors are entitled to prescribe a drug off-label for any patient where the doctor reaches the conclusion that the medicine has sufficient therapeutic benefit for that patient, even if that is outside the terms of the Summary of Product Characteristics annexed to the relevant Marketing Authorisation, and the patient gives consent to the treatment[2]. General guidance on off-label prescribing is given in General Medical Council ("GMC") professional standards and MHRA guidance.

19. Whether a medicine is available for supply by an NHS clinician depends upon there having been a recommendation for its use by NICE, and whether the relevant NHS Commissioner has decided that such treatment should be available. The relevant NHS commissioner for gender identity development services for children and adolescents is NHS England: see paragraph 56 of Schedule 4 to the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the NHS Commissioning Regulations 2012").

20. An NHS commissioner is entitled to have a policy which does not usually fund a particular medical treatment, but each NHS commissioner is obliged to have "arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention": see regulation 34(2)(b) of the NHS Commissioning Regulations 2012.

21. Puberty blockers are classified in the UK as "prescription only medicines". Prescriptions for medicines are valid for dispensing by authorised clinicians in the UK. Pursuant to regulation 214(6) of the Human Medicines Regulations 2012, a UK based pharmacist can lawfully dispense a medicine based on a prescription written by prescribers located in the EEA and Switzerland. Each such prescriber is subject to professional regulation in the state in which they practice and is described in regulations 214(6) as "approved country health professionals". The Department of Health and Social Care ("DHSC") published guidance for pharmacists on dispensing EEA/Swiss prescriptions in 2021.

22. Where a clinician has issued a prescription which is presented to a pharmacist for dispensing, pharmacists have their own legal and professional obligations which must be discharged before the medicine is supplied to the patient (whether the prescription was written in the UK or not). It is the duty of the dispensing professional to check that a prescription is valid and clinically appropriate. Any concerns about the appropriateness of the medication should be raised with the prescriber. See the guidance issued by the General Pharmaceutical Council ("GPhC"), in particular, on "Gender identity; pharmaceutical care for children and young people" (January 2023).

---

[2] The legal framework was considered in *R (Bayer plc) v NHS Darlington Clinical Commissioning Group* [2020] PTSR 1153.

Case law

23. Until April 2024, the only clinical service commissioned by NHS England to provide medical support for trans children was the Gender Identity Development Service ("GIDS") run by the Tavistock and Portman NHS Foundation Trust ("the Tavistock").

24. In *R (Bell) v The Tavistock and Portman NHS Foundation Trust & Ors* [2020] EWHC 3274 (Admin), the Divisional Court (Dame Victoria Sharp P., Lewis LJ and Lieven J.) heard a challenge to the Tavistock's practice as to the prescription of puberty blockers to children and young people under 18. There was no finding of illegality in the policy or practice at the Tavistock. The Court granted declaratory relief specifying, and limiting, the circumstances in which a patient under 18 would have capacity to give informed consent to treatment of gender dysphoria with puberty blockers: see [151] – [153].

25. After the judgment was handed down, NHS England issued a new service specification stating, *inter alia*, that under 16s must not be referred to paediatric endocrinology clinics for puberty blockers unless a court order was obtained stating that this is in the 'best interests' of the child.

26. In *AB v CD* [2021] EWHC 741 (Fam), Lieven J. held, at [68] – [70], that, as a matter of law, the parents of a child patient could consent to puberty blockers on their child's behalf, without the need for a "best interests" application to the court (save where they were insisting upon that medication, contrary to the wishes of the child). She rejected the suggestion that puberty blockers were in a special category of medical intervention which always required the sanction of the court, despite the controversial nature of the treatment, at [115] - [128].

27. In *R (Bell) v The Tavistock and Portman NHS Foundation Trust & Ors* [2021] EWCA Civ 1363, the Court of Appeal held, per Lord Burnett CJ, at [85] – [94], that the declarations made by the Divisional Court were inappropriate as the court should not have given generalised guidance on consent and the need for applications to the court. The House of Lords ruling in *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112 applied: it was for doctors and not judges to decide on the capacity of a person under 16 to consent to medical treatment. Applications to court would only be needed in difficult or disputed cases.

The Cass Review and steps taken by NHS England

28. The Cass Review was commissioned by NHS England in 2020 to make recommendations on how to improve NHS gender identity services, and ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria receive a high standard of care that meets their needs, is safe, holistic and effective.

29. Among other topics, the Terms of Reference included:

> "[the] use of gonadotropin-releasing hormone analogues and gender affirming drugs, supported by a review of the available evidence by the National Institute for Health and Care

> Excellence; any treatment recommendations will include a description of treatment objectives, expected benefits and expected outcomes, and potential risks, harms and effects to the individual;".

30. The Cass Review was set up because there had been a significant increase in the number of referrals to GIDS from under 250 in 2011/12 to over 5,000 in 2021/22. This had occurred at a time when the service had moved from a psychosocial and psychotherapeutic model to one that also prescribed medical interventions by way of hormone drugs. This medicalised approach was based on the 'Dutch Protocol,' which involved the use of puberty suppressing medications (see page 68 of the Final Report of the Cass Review).

31. To help to inform the Cass Review, NICE conducted an Evidence Review into the use of puberty blockers for children and adolescents with gender dysphoria in October 2020. The review concluded that the existing evidence at that time concerning the impact of treatment with these medications on gender dysphoria, mental health and quality of life was of very low quality.

32. The Cass Review undertook significant consultation, engagement and research to inform its work. This is described in Chapter 1 of the Cass Review ("Methodology"). The Cass Review prioritised consultation with two groups of stakeholders. The first was people with relevant lived experience (direct or as a parent/carer) and organisations working with LGBTQ+[3] children and young people generally. The second was clinicians and other relevant professionals with responsibility for providing care and support to children and young people within specialist gender services and beyond. In total, the Cass Review met with over 1,000 individuals in a range of different formats. This included:

    i) Weekly listening sessions to hear directly from people with primary or secondary lived experience relevant to the Cass Review.

    ii) Commissioning six support and advocacy organisations to facilitate 18 focus groups to better understand the thoughts and ideas of young people and adults (aged 14-30) with lived experience.

    iii) Regular meetings with support and advocacy organisations for which support of gender-questioning young people is their primary function or a significant element of their work. Separate meetings were held with each organisation to encourage open and frank conversations.

    iv) Commissioning the University of York to deliver an independent research programme aimed at providing the Cass Review with the best available collation of published evidence relating to epidemiology, clinical management, models of care and outcomes, and to understand the experiences and perspectives of service users, their families and clinicians.

[3] Acronym for Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual and the + stands for all other identities.

v) Consulting with a very wide range of clinicians and academics. A Clinical Expert Group was established to consider the strength of the evidence and findings from the Cass Review's research programme. Roundtable discussions also took place in a range of associated topics to explore specific questions in greater depth.

vi) Meetings with international clinicians and policy makers.

33. This work was underpinned by more detailed data and an enhanced evidence base, delivered through the Cass Review's academic research programme that included six systematic reviews, qualitative and quantitative studies and an online international survey. An overview of the research programme commissioned by the Cass Review is set out in the Final Report of the Cass Review at Table 1.

34. An Interim Report was published in February 2022. Among other matters, it identified the following concerns:

> "**Service capacity and delivery**
>
> 1.9. A rapid change in epidemiology and an increase in referrals means that the number of children seeking help from the NHS is now outstripping the capacity of the single national specialist service, the Gender Identity Development Service (GIDS) at The Tavistock and Portman NHS Foundation Trust.
>
> 1.10. The mix of young people presenting to the service is more complex than seen previously, with many being neurodiverse and/or having a wide range of psychosocial and mental health needs. The largest group currently comprises birth-registered females first presenting in adolescence with gender-related distress.
>
> 1.11. Until very recently, any local professional, including non-health professionals, could refer to GIDS, which has meant that the quality and appropriateness of referrals lacks consistency, and local service provision has remained patchy and scarce.
>
> 1.12. The staff working within the specialist service demonstrate a high level of commitment to the population they serve. However, the waiting list pressure and lack of consensus development on the clinical approach, combined with criticism of the service, have all resulted in rapid turnover of staff and inadequate capacity to deal with the increasing workload. Capacity constraints cannot be addressed through financial investment alone; there are some complex workforce (recruitment; retention; and training) and cultural issues to address.
>
> 1.13. Our initial work has indicated that many professionals working at primary and secondary level feel that they have the transferable skills and the commitment to offer more robust

support to this group of children and young people, but are nervous about doing so, partly because of the lack of formal clinical guidance, and partly due to the broader societal context.

1.14. Primary and secondary care staff have told us that they feel under pressure to adopt an unquestioning affirmative approach and that this is at odds with the standard process of clinical assessment and diagnosis that they have been trained to undertake in all other clinical encounters.

1.15. Children and young people are waiting lengthy periods to access GIDS, during which time some may be at considerable risk. By the time they are seen, their distress may have worsened, and their mental health may have deteriorated.

1.16. Another significant issue raised with us is one of diagnostic overshadowing – many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues that would normally be managed by local services can sometimes be overlooked.

1.17. The current move to adult services at age 17-18 may fall at a critical time in the young person's gender management. In contrast, young people with neurodiversity often remain under children's services until age 19 and some other clinical services continue to mid-20s. Further consideration will be needed regarding the age of transfer to adult services.

Service standards

1.18. The Multi-Professional Review Group (MPRG), set up by NHS England to ensure that procedures for assessment and for informed consent have been properly followed, has stated that the following areas require consideration:

- From the point of entry to GIDS there appears to be predominantly an affirmative, non-exploratory approach, often driven by child and parent expectations and the extent of social transition that has developed due to the delay in service provision.

- From documentation provided to the MPRG, there does not appear to be a standardised approach to assessment or progression through the process, which leads to potential gaps in necessary evidence and a lack of clarity.

- There is limited evidence of mental health or neurodevelopmental assessments being routinely documented, or of a discipline of formal diagnostic or psychological formulation.

> • Of 44 submissions received by the MPRG, 31% were not initially assured due to lack of safeguarding information. And in a number of cases there were specific safeguarding concerns. There do not appear to be consistent processes in place to work with other agencies to identify children and young people and families who may be vulnerable, at risk and require safeguarding."

35. The Interim Report advised that the single specialist provider (the Tavistock) was neither safe nor viable in view of the increasing number of referrals and concerns about the quality of the service. It recommended the establishment of regional hubs to provide support to referrers and professionals, and some limited provision for direct contact with children and young people and their families.

36. The Interim Report also found that the lack of routine and consistent data collection meant that it was not possible to accurately track the outcomes and pathways children and young people took through the service. The Interim Report advised that standardised data collection was required in order to audit service standards and inform understanding of the epidemiology, assessment and treatment of this group. To that end, the Interim Report recommended that children and young people put on hormone treatment should be formally followed up into adult services, ideally as part of an agreed research protocol, to improve outcome data.

37. In July 2022 Dr Cass wrote to NHS England sharing the outcome of her discussions with the Royal Colleges and support and advocacy groups and expanding upon the advice in the Interim Report. Dr Cass recommended that young people being considered for hormone treatment be enrolled into a formal research programme. She said:

> "Given the particular uncertainties regarding long-term outcomes of medical intervention, and the broader knowledge gaps in this area, there is an imperative to build research capacity into the national network. This research capacity is needed to provide ongoing appraisal of new literature and rapid translation into clinical practice, to continue to identify areas of practice where further research is needed, and to develop a research portfolio that will inform policy on assessment, support and clinical care of children with gender dysphoria, from presentation through to appropriate social, psychological and medical management.
>
> As already highlighted in my interim report, the most significant knowledge gaps are in relation to treatment with puberty blockers, and the lack of clarity about whether the rationale for prescription is as an initial part of a transition pathway or as a 'pause' to allow more time for decision making. For those who will go on to have a stable binary trans identity, the ability to pass in later life is paramount, and many will decide that the trade-offs of medical treatment are a price that is fully justified by the ability to live confidently and comfortably in their identified gender. The widely understood challenge is in determining when a point of certainty about gender identity is

reached in an adolescent who is in a state of developmental maturation, identity development and flux.

It is the latter option regarding a 'pause' for decision making about which we have the least information. The rationale for use of puberty blockers at Tanner Stage 2 of development was based on data that demonstrated that children, particularly birth-registered boys who had early gender incongruence, were unlikely to desist once they reached early puberty; this rationale does not necessarily apply to later-presenting young people, including the predominant referral group of birth-registered girls. We do not fully understand the role of adolescent sex hormones in driving the development of both sexuality and gender identity through the early teen years, so by extension we cannot be sure about the impact of stopping these hormone surges on psychosexual and gender maturation. We therefore have no way of knowing whether, rather than buying time to make a decision, puberty blockers may disrupt that decision-making process.

A further concern is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by puberty blockers, which could have significant impact on the ability to make complex risk-laden decisions, as well as possible longer-term neuropsychological consequences. To date, there has been very limited research on the short-, medium- or longer-term impact of puberty-blockers on neurocognitive development.

In light of these critically important unanswered questions, I would suggest that consideration is given to the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for hormone treatment into a formal research programme with adequate follow up into adulthood, with a more immediate focus on the questions regarding puberty blockers. The appropriate research questions and protocols will need to be developed with input from a panel of academics, clinicians, service users and ethicists.

Without an established research strategy and infrastructure, the outstanding questions will remain unanswered and the evidence gap will continue to be filled with polarised opinion and conjecture, which does little to help the children and young people, and their families and carers, who need support and information on which to make decisions."

38. The Cass Review Final Report was published on 10 April 2024, and included 32 recommendations across several areas including assessment, diagnosis, psychological assessments, medical pathways, and service model.

39. Chapter 14 set out the 'Rationale for the use of puberty blockers for gender dysphoria', as follows:

> "14.4 As set out in Chapter 2, the practice of pausing puberty at Tanner Stage 2 was initiated in the Netherlands, and subsequently adopted in the UK and internationally. The idea was based on a theory from Dr Peggy Cohen-Kettenis whose initial clinical experience was in adult care. Her rationale was that pausing puberty early would help young people to 'pass' better in adulthood and 'extend the diagnostic period' by buying time to think. The use of puberty blockers for this purpose was initially reported in a single case study (Cohen-Kettenis & van Goozen, 1998) and then in the original Dutch cohort (de Vries, 2011b).
>
> 14.5 It may appear surprising that the novel use of a drug for this purpose did not require a more rigorous drug trial. This is because of the way drugs are licensed and can be used off-label (see Explanatory box 5).
>
> 14.6 GnRH hormones (referred to as puberty blockers in the treatment of young people) are licensed for patients with precocious puberty (that is, young children who enter puberty too early), as well as for the treatment of some cancers in adults and some gynaecological issues in adults. They have undergone extensive testing for use in precocious puberty (a very different indication from use in gender dysphoria) and have met strict safety requirements to be approved for this condition.
>
> 14.7 The situation for the use of puberty blockers in gender dysphoria is different. Although some endocrinologists have suggested that it is possible to extrapolate or generalise safety information from the use of puberty blockers in young children with precocious puberty to use in gender dysphoria, there are problems in this argument. In the former case, puberty blockers are blocking hormones that are abnormally high for, say, a 7-year-old, whereas in the latter they are blocking the normal rise in hormones that should be occurring into teenage years, and which is essential for psychosexual and other developmental processes.
>
> 14.8 This approach to the use of puberty blockers in gender dysphoria has been an ongoing source of controversy both nationally and internationally.
>
> 14.9 The lack of consensus across the clinical community was highlighted by a 2015 study (Vrouenraets et al., 2015), which

> approached multi-professional treatment teams worldwide to determine their views on use of puberty blockers. They identified seven themes on which there were widely disparate views:
>
> • the (non-) availability of an explanatory model for gender dysphoria
>
> • the nature of gender dysphoria (normal variation, social construct or [mental] illness)
>
> • the role of physiological puberty in developing gender identity
>
> • the role of comorbidity
>
> • possible physical or psychological effects of refraining from) early medical interventions
>
> • child competence and decision-making authority
>
> • the role of social context in how gender dysphoria is perceived.
>
> 14.10 The professionals who participated in the study were often conflicted because they recognised the distress of young people and felt the urge to treat them, but at the same time, most had doubts because of the lack of information on long-term physical and psychological outcomes. For several participants, a reason to use puberty suppression was the fear of increased suicidality in untreated adolescents with gender dysphoria.
>
> 14.11 The authors of the study concluded that as long as debate remains on these seven themes and only limited long-term data are available, there will be no consensus on treatment. Eight years later, the position is unchanged and many of the same considerations apply to the use of masculinising/feminising hormones in young people."

40. The benefits and risks of puberty blockers were considered in Chapter 14.

41. The Cass Review's findings were set out in the Summary as follows:

> "**Medical pathways**
>
> 80. The original rationale for use of puberty blockers was that this would buy 'time to think' by delaying onset of puberty and also improve the ability to 'pass' in later life. Subsequently it was suggested that they may also improve body image and psychological wellbeing.
>
> 81. The systematic review undertaken by the University of York found multiple studies demonstrating that puberty blockers exert their intended effect in suppressing puberty, and also that bone density is compromised during puberty suppression.

82. However, no changes in gender dysphoria or body satisfaction were demonstrated. There was insufficient/inconsistent evidence about the effects of puberty suppression on psychological or psychosocial wellbeing, cognitive development, cardio-metabolic risk or fertility.

83. Moreover, given that the vast majority of young people started on puberty blockers proceed from puberty blockers to masculinising/feminising hormones, there is no evidence that puberty blockers buy time to think, and some concern that they may change the trajectory of psychosexual and gender identity development.

84. The Review's letter to NHS England (July 2023)[4] advised that because puberty blockers only have clearly defined benefits in quite narrow circumstances, and because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, they should only be offered under a research protocol. This has been taken forward by NHS England and National Institute for Health and Care Research (NIHR).

85. The University of York also carried out a systematic review of outcomes of masculinising/feminising hormones. Overall, the authors concluded that "There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow-up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health. There is suggestive evidence from mainly pre-post studies that hormone treatment may improve psychological health, although robust research with long-term follow-up is needed".

86. It has been suggested that hormone treatment reduces the elevated risk of death by suicide in this population, but the evidence found did not support this conclusion.

87. The percentage of people treated with hormones who subsequently detransition remains unknown due to the lack of long-term follow-up studies, although there is suggestion that numbers are increasing.

88. A problem, that has become increasingly apparent as the Review has progressed is that research on psychosocial interventions and longer-term outcomes for those who do not access endocrine pathways is as weak as research on endocrine treatment. This leaves a major gap in our knowledge about how

[4] The date on the letter is July 2022 not July 2023

> best to support and help the growing population of young people with gender-related distress in the context of complex presentations."

42. The Final Report made 32 recommendations, including as follows:

    i) Clinicians should apply the assessment framework developed by the Review's Clinical Expert Group to ensure children and young people referred to NHS gender services receive a holistic assessment of their needs to inform an individualised care plan. This should include screening for neurodevelopmental conditions, including autism spectrum disorder, and a mental health assessment. The framework should be kept under review and evolve to reflect emerging evidence (Recommendation 2).

    ii) The evidence base underpinning medical and non-medical interventions in this clinical area must be improved, and a full programme of research should be established. This should look at the characteristics, interventions and outcomes of every young person presenting to the NHS gender services. The puberty blocker trial should be part of a programme of research which also evaluates outcomes of psychosocial interventions and masculinising/feminising hormones. Consent should routinely be sought for all children and young people for enrolment in a research study with follow-up into adulthood (Recommendation 6).

    iii) 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) (Recommendation 9).

    iv) The DHSC should work with the GPhC to define the dispensing responsibilities of pharmacists of private prescriptions and consider other statutory solutions that would prevent inappropriate overseas prescribing (Recommendation 27).

EEA & Swiss prescribers

43. Recommendation 27 arose out of the Final Report's consideration of the concerns associated with overseas providers. Paragraph 19.39 states:

> "The Review understands and shares the concerns about the use of unregulated medications and of providers that are not regulated within the UK. Any clinician who ascertains that a young person is being given drugs from an unregulated source should make the young person and their family aware of the risks of such treatment."

44. EEA prescribers, who are not based in the UK, are not subject to the authority of UK regulators. They must comply with the standards required to practise in their country of registration, but there may be differences in standards between the UK and other countries. In the past when attempts have been made by the Care Quality Commission ("CQC") and the GMC to report unsafe EEA prescribers to the relevant regulator, the

report was met with a lack of engagement and resistance (see Ministerial Submission 7 December 2023).

45. In her witness statement, Ms Sacks, Director of Medicines in the Department of Health and Social Care, gave an account of the work done in this area, at GS/41 – 48:

> "41. In this context, policy officials have been working with regulators and other stakeholders since 2021 to better understand the risks, and the opportunities, for addressing specific concerns raised with the Department about online prescribing. In particular, this work had highlighted a key risk in the continued recognition of prescriptions originating from EEA or Swiss registered prescribers.
>
> 42. These issues were discussed at the first of what would become a series of meetings on the topic of online and overseas prescribing, on 25 May 2022. These meetings did not focus solely or mainly on the prescribing of puberty blockers but on overseas and online prescriptions generally – an issue of much wider application. They were initiated after a number of concerns relating to online and overseas prescribing came together, including patients getting access to medicines without sufficient clinical oversight and coming to harm as a result. This meeting took place between DHSC officials and representatives of NHS England, the GMC, the GPhC, the British Medical Association ("BMA") and the RCGP [Exhibit GS1/014], [DB/680-684].
>
> 43. Here it was noted that there was growing concern about online private prescribing, and the dispensing of these prescriptions. The meeting was provided with a document entitled 'Evidence Table – as at May 2021' compiled by DHSC, which identified a number of incidents or events that gave rise to these concerns. This included reference to a number of coronial Reports to Prevent Future Deaths which raised concerns about online prescribing mechanisms [Exhibit GS1/015], [DB/685-688]. The references to the 'Welsh Gender Clinic" on the second page of that document relate to the clinicians who went on to set up what is now known as GenderGP. The GPhC also provided a briefing paper on the regulation of online pharmacy services [Exhibit GS1/016], [DB/689-692].
>
> 44. The meeting heard that there had been:
>
> "…a number of UK based companies deliberately attempting to evade the regulatory framework. Regulatory action has resulted in fines, GMC hearings against a provider, and GPhC action. There are concerns that new models are continuing to be operated to evade scrutiny – for example acting as an introducer to, and agent for, properly registered pharmacies that supply medicines."

The note of this meeting records the various concerns and issues that were raised by the attendees from their perspectives. Of particular note are:

a. the views of Claire Bryce Smith of the GPhC, who told the meeting that:

…the GPhC had inspected 394 online pharmacies since April 2019 which didn't meet the standards in quite the same way as bricks and mortar pharmacies. 85% of all pharmacies inspected by the regulator meet its standards but this percentage goes down to 71% for online pharmacies, with some failing as many as nine of the GPhC's standards. GPhC has served 55 legal enforcement notices on these online pharmacies linked to their provision of online pharmacy services. Most pharmacies comply with improvement notices but some pharmacies have actually been shut down. Inspections found that GPhC standards were not being met and their guidance on providing pharmacy services at a distance was not being followed. This meant the dispensing pharmacies did not adequately safeguard vulnerable people who may be trying to obtain medicines which are not clinically appropriate for them. This puts patients at risk of serious harm or death…

b. The views of Martin Marshall of the RCGP, who "felt that gender drugs and HRT are the biggest current issues" and that overseas pharmacies and prescribing operations often shut down and reopened the same business in another name making this a difficult area to police.

c. The contributions from Cathy Finnegan of the GMC, who expressed that the GMC case examiners were most concerned about prescribing from abroad. She expressed concerns about the limited patient information that was available to online prescribers and the risks that this created, stating:

> "…some of the online systems being used are complex and professionals working in them don't understand their full functionality. They don't see other parts of the pathway, like accessing checks and balances where patients repeatedly ordering/ ordering too early, or the requirement to ask additional questions. These safeguards are absent. Not all of the people involved are seeing all the information. Whether prescribing or supplying, you still need to decide whether it's appropriate and prescribers can't make an informed decision.

Over subsequent examination of this topic, this question of information sharing has emerged as a key concern for all the regulators. Undertaking prescribing activity without full knowledge of the patient's medical history is dangerous.

> 46. The reports from coroners and other reports of poor practice that were discussed at this meeting were a very real concern. However, the challenge was that there is no data to determine the volume of use of EEA prescriptions. In 2023 it was, therefore, suggested that a consultation mechanism could be used to gather evidence before finalising the proposals (See §10 of Ministerial Submission of 7 December 2023 [Exhibit GS1/013], [DB/675-679] (see:[DB/677])).
>
> 47. In November 2023 the SoSH held a meeting with representatives of NHS England including the National Director for Specialised Services, John Stewart, to discuss children's gender identity services. The note of this meeting is produced as [Exhibit GS1/17], [DB/693-697]. Discussing the setting up of a new holistic service specification for children's gender services in the light of the interim report of the Cass Review and Dr Cass' recommendations of July 2022, Mr Stewart set out the overall objectives which were "dismantling the legacy of the Tavistock and removing any inappropriate influence of campaign groups on clinical practice." At this meeting NHS England raised with the SoSH the importance of DHSC closing off a route of private prescription of puberty suppressing medication to children and adolescents in the UK through reciprocal agreements.
>
> 48. It was following this meeting that in December 2023 the workstreams in DHSC on the issue of online and overseas private prescriptions and on the outcome of the Cass review were brought together. The SoSH sought advice from officials about ending EEA prescriptions. A Ministerial Submission of 7 December 2023 was provided in response [Exhibit GS1/013], [DB/675-679]. This set out the background to the issue and summarised the concerns and issues that had emerged, and the initial steps that had been taken arising out of engagement with the stakeholders. It was in this context that the SoSH asked that the work around online and overseas private prescriptions be refined to focus solely on the medicines relevant to gender dysphoria that the Cass review had highlighted as a concern."

46. GenderGP is an online provider of gender healthcare services established in 2015. It is registered in Singapore. As the DHSC understands it, GenderGP uses a prescriber who is a Spanish national who is registered in Romania. GenderGP provides prescriptions for puberty blockers to patients in the UK. Ms Sacks describes (GS/65) the concerns raised in 2022 by the National Pharmacy Association about a sample prescription issued by GenderGP where the electronic signature was simply a QR Code linking to a statement saying "this confirms that the prescription QR Code scanned today on [date] is authentic". It gave no further details about the prescription. The statement occurred each time the QR Code was scanned and so could be accessed from multiple pharmacy sites.

47. Following the publication of the Final Report of the Cass Review, GenderGP and some other prescribers criticised the Report, claiming it was biased and inaccurate. GenderGP

provided advice to patients on how to continue to receive medicines from outside the UK and circumvent the controls that had been introduced in the UK.

48. On 11 May 2024 The Times ran an exposé about GenderGP, alleging that it was using an AI-generated "knowledge base" rather than staff to respond to queries; the use of highly inexperienced staff; and the use of algorithms to recommend treatment plans. It reported that prescriptions were issued by a doctor who had never met the patient. According to Ms Sacks, this added to the DHSC's concern that the treatment model adopted by GenderGP was contrary to the Cass Review recommendations, which are for a holistic, multifaceted model of care.

49. In an interview with The Times that was published on 28 June 2024, Dr Helen Webberley, a founder and director of GenderGP, confirmed that the company now uses AI algorithms in place of the healthcare advisers who had previously been employed, stating it is "run like self-service now" with no phone or email service. She claimed that GenderGP had facilitated treatment for thousands of children, from different countries. She also claimed that since the UK Government's ban on EEA prescriptions, parents were travelling abroad to get puberty blockers for their children.

50. Dr Webberley agreed with the World Professional Association of Transgender Healthcare that the Cass Review had "selective and inconsistent use of evidence", and claimed that the Cass Review had put children at risk.

51. Dr Webberley also criticised the expert evidence given to the Court in *Re J (Transgender: Puberty Blocker and Hormone Replacement Therapy)* [2024] EWHC 922 (Fam) to the effect that GenderGP's prescribed high dosage of testosterone to *J* was abnormal and negligent. In his judgment, at [58], the President of the Family Division urged "any other court faced with a case involving GenderGP to proceed with extreme caution before exercising any power to approve or endorse treatment that that clinic may prescribe".

52. In contrast, the evidence adduced on behalf of the Claimants from users of GenderGP's services is very favourable: see the second witness statements of Lui Asquith, ZZ and Chay Brown.

NHS England: response to Cass Review

53. Following the Interim Report, NHS England took steps to increase capacity and manage the closure of the GIDS service at the Tavistock. It established two new nationally networked services to be led by specialist children's hospitals. New services based in the North West (a partnership between Alder Hey Children's and Royal Manchester Children's Hospital) and London (a partnership between Great Ormond Street Hospital, Evelina London and South London & Maudsley NHS Foundation Trust) opened on 1 April 2024. It is said that up to six more regional centres based within children's hospitals are to be established by NHS England by 2026.

54. Between 3 August and 1 November 2023, NHS England conducted a consultation on a revised approach to treatment by the NHS of gender dysphoria with puberty blockers. The "policy proposition" consulted on was that "puberty suppressing hormones are not recommended to be available as a routine commissioning option for the treatment of

children and adolescents who have gender incongruence or dysphoria". 4,040 responses were received, including 906 from patients, 869 from parents and 397 from trans adults.

55. On 12 March 2024, NHS England announced a new policy, namely, that the NHS in England will not routinely prescribe Puberty Suppressing Hormones ("PSH") to children and young people with gender dysphoria, from 1 April 2024, save that "a patient's clinician can make an application under NHS England's Individual Funding Request process". It stated that there was "not enough evidence to support the safety or clinical effectiveness of PSH to make the treatment routinely available at this time".

56. On 10 April NHS England wrote to Dr Cass setting out its response to the Final Report. It summarised the steps which had already been taken in response to the Interim Report and advice in 2022, and set out proposals for a full implementation plan. This will include a service specification that defines access into the children and young people's gender services.

57. On 11 April 2024, the Chief Executive Officer of NHS England wrote to the First Defendant summarising its proposals to implement the recommendations of the Cass Review. She expressed concerns about private prescribing, as follows:

> "9. Concerns about private prescribing of Puberty Suppressing Hormones and Gender Affirming Hormones are shared widely, including by GPs, pharmacists and organisations representing primary care. The NHS National Medical Director for Specialised Services met with you on 23 November to raise his concerns, and to ask for your support in moving forward with potential solutions to close this loophole which also poses a risk to safety. These issues had also been raised on several occasions with DHSC officials and ultimately require Ministerial action, such as legislation to curtail private prescriptions issued from within the EEA. Alternatively, or at the same time, changes could be made to part XVIIIB of the national Drug Tariff with Ministerial approval. It would be helpful to understand your intentions and likely timeframe in this regard, particularly in view of social media posts made in the past 24 hours by on-line providers who are not regulated in the UK and who have stated their intention to continue to issue prescriptions to children in this country contrary to NHS policy and contrary to the Cass Review."

Royal College of GPs: response to the Cass Review

58. The Royal College of GPs ("RCGP") published an updated position statement on 26 April 2024, which set out the role and expectations of GPs in relation to transgender care, in the light of the Cass Review. It stated:

> "The RCGP recognises that some GPs have particular expertise, or an extended role, in the area of transgender care and supports them to act in their patient's best interests, within the limits of

> their competence. For the majority of GPs, without this expertise or extended role, the RCGP considers that the role of the GP does not include the following:
>
> - Prescribing bridging prescriptions for those on the waiting list for a GIC.
>
> - Prescribing puberty blockers for a patient aged under 18, even on a shared care basis, given the concerns about the evidence base in this area as well as the specialist expertise required to monitor dosage and side effects. The Cass review notes that 'the Review has already advised that because puberty blockers only have clearly defined benefits in quite narrow circumstances, and because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, they should only be offered under a research protocol. This has been taken forward by NHS England (NHSE) and the National Institute for Health and Care Research (NIHR)' and that 'if an individual were to have taken puberty blockers outside the study, their eligibility may be affected'. This precludes GPs from ever prescribing puberty blockers, excepting any GPs working on clinical trials in this area.
>
> ….."

GPhC: response to the Cass Review

59. In January 2023, in response to the Interim Report from the Cass Review, the GPhC published guidance to dispensing pharmacists providing pharmacy services to children and young people experiencing gender distress. It stated:

> "It is not enough for a prescription to be legally valid; that is just one consideration alongside others, including judgement as to whether a prescription is clinically appropriate. In some cases, prescriptions may have been issued by overseas gender clinics and prescribers who are not under the jurisdiction of UK regulators, which creates additional risk. We expect pharmacies to have taken active steps to assure themselves that all prescribers, including those from overseas, comply with relevant UK regulatory and professional guidance.
>
> Reasonable precautions should be taken by pharmacies to assure themselves that the prescriber has sufficient specialist expertise to assess and diagnose gender dysphoria, and to recommend prescriptions for the person concerned..."

60. Ms Sacks observed in her witness statement (GS/29) that it was unusual for the GPhC to publish resources specific to a particular group of patients in this way, and that they did so reflected the challenging situations dispensing pharmacists were reporting, and

the particularly complex needs of a vulnerable patient group. She also considered (GS/31) that it was often not practicable for pharmacists to speak to prescribers in EEA countries to determine why a particular medicine has been prescribed or whether it is appropriate. The dispensing professional is not necessarily qualified to (and their role within the system does not require them to) second-guess the clinical judgement of the prescriber.

The decision-making process

61. The Ministerial Submission of 7 December 2023 introduced the ongoing work on gender dysphoria in the DHSC to the First Defendant and offered to provide further advice regarding setting up a public consultation. The focus at that stage was around ending recognition of all EEA prescriptions.

62. A follow-up Ministerial Submission was provided on 26 February 2024 which set out advice on how dispensing of EEA prescriptions for treatment of gender dysphoria could be restricted. There was also reference to the wider concerns about EEA prescriptions. This was followed by a Ministerial Submission on 26 March 2024 which considered four different options for restricting the dispensing of EEA prescriptions.

63. On 4 April 2024, the First Defendant clarified with officials that she wanted to focus only on banning the dispensing of overseas prescriptions for puberty blockers and gender affirming (cross-sex) hormones for under 18s.

64. Following the publication of the Cass Review on 10 April 2024, a Ministerial Submission was provided on 12 April, which addressed the possibility of amending the Human Medicines Regulations 2012 to provide for a list of medicines that could not be dispensed to children in the UK. That change would require formal public consultation and the amended regulations would be subject to the affirmative procedure.

65. According to Ms Sacks, at a meeting on 13 April 2024, the First Defendant indicated that these proposals were insufficient. In her view, the evidence in the Cass Review Final Report, which precipitated the change in NHS England's policy, was sufficiently concerning to require an urgent change to the regulations to prevent private and overseas prescriptions to children and young people in the UK.

66. The First Defendant then instructed officials that, in the light of her concerns, speed was of the essence. She no longer wanted to carve out an exemption for the Republic of Ireland and Spain and she was sceptical about a very lengthy consultation.

67. On 15 April 2024, the First Defendant delivered an Oral Statement to the House of Commons on the Cass Review in which she said:

> "It was morally and medically reprehensible that some online providers not registered in the UK have stated their intention to continue to issue prescriptions to children in this country. I am looking closely at what can be done to curtail any loopholes in prescribing practices, including legislative options."

68. Officials spent time considering the possible options. At a meeting with the First Defendant, on 19 April 2024, the option of using a prohibition order under section 62 MA 1968 in relation to puberty blockers for patients under 18 was discussed. The First Defendant was advised on the statutory test for either a standard or an emergency order under section 62 MA 1968 which would be a more stringent legal ban than the NHS England policy, with a commensurate criminal offence. The Permanent Secretary noted that this route was rarely used and banning orders usually focus on the substance, rather than the treatment it is used for. One of the difficulties was that they were "trying to target the intervention at those who might deliberately attempt to circumvent the existing rules and consensus which makes it more complex". Advice was given on the role of the CHM whose members provide expert advice but usually on the basis of a product's safety and so it was possible that they might see a decision such as this as outside their remit.

69. Officials advised on the consultation requirements and timings under section 62 MA 1968, and considered the justification for an emergency order. The meeting note states:

> "PS said that one justification for acting quickly would be that we are trying to clamp down on rogue actors who are deliberately trying to act on loopholes. LP noted that there needed to be something new which justifies action now: SoS said this was the Cass report (with JY adding that NHSE's acceptance of the report was also new). [JB] also stated that the Royal College of GPs might put out a policy statement next week. SoS also said that there were already individual stories in the media of certain clinicians trying to circumvent the report's findings. PS summarise (*sic*) that the report justified the ban, while the risk of rogue actors justifies the immediacy – with SoS noting that the difficulty in reversing these treatments was a key point."

70. The meeting considered the position of patients already on puberty blockers:

> "GS said that the 'open caseload' of those already on these drugs needed to be managed carefully. SoS stated that there would need to be exceptions – e.g. for those using the drugs for precocious puberty or the menopause – and there would also need to be an element of clinical judgement allowed for those already on these drugs where it might not be safe to stop them instantly. PS emphasised that we would need to have a very low tolerance for safety risk, to avoid any harm even if the overall numbers were fairly small. SoS agreed with this."

71. At the request of the First Defendant, a Ministerial Submission was provided on 25 April 2024 which advised on the advantages and disadvantages of a standard and/or emergency order under section 62 MA 1968, and proposed next steps. The 'pros' of an emergency order were that it would "provide a near immediate stop to inappropriate prescribing of gender dysphoria medicines to children, would provide cover whilst longer-term restrictions were put in place". It could be laid in about a month, subject to the necessary Parliamentary and legal procedures. The 'cons' of an emergency order were largely redacted, in reliance on legal advice privilege, but included advice that

"Given the speed of implementation there is greater risk of disrupting existing treatment and appropriate use".

72. Annex B set out the challenges with policy and delivery, including the following points:

    i) It would take approximately 5 to 6 months to introduce a permanent prohibition order.

    ii) Officials did not know the extent to which puberty blockers were used for clinically appropriate uses, and did not have a complete list of the sources of prescriptions (e.g. GPs, specialists, NHS/private/overseas). They were seeking advice, but evidence could also be explored during the consultation.

    iii) "The Order risks disrupting current courses of treatment, and this is a concern for national clinical leaders. More work is needed to understand the non-controversial uses for these medicines in children so risks of disrupting their treatment can be managed. For those currently being prescribed these medicines for gender dysphoria, there will be safety/health concerns associated with discontinuing treatment for a particularly vulnerable patient cohort."

    iv) A permanent order requires consultation with the CHM and organisations representative of the interests likely to be substantially affected by the Order.

73. DHSC officials liaised with the Chair of the CHM over the telephone on 19 April 2024 and a written brief followed. The discussions largely focused on the procedures to be followed.

74. On 30 April 2024, officials met with the First Defendant to discuss progress and further work required. The starting point for this discussion was that the case was made for use of the emergency order as an interim measure to tackle the risk posed by rogue actors, and the meeting was focused on whether it would work in practice, noting that clinical advice was still awaited from NHS England. The position of the devolved administrations was discussed.

75. On 3 May 2024, DHSC officials met with representatives of the CQC, GPhC, GMC, RCGP and NHS England.

76. On 3 May 2024, NHS England provided DHSC officials with a 'Briefing paper on restricting access to medicines for the purpose of puberty suppression due to gender incongruence/gender dysphoria'. It advised on the medicines that might need to be included, their licensing indications and other legitimate uses. Access to the medicines was currently obtained from NHS commissioned gender services, NHS primary care services and private practitioners. The regulation of private practitioners was described as follows:

> "Private practitioners. The prescription of unlicensed or off-label medications is subject to individual professional regulation by the General Medical Council and other relevant professional regulators. Practitioners should usually prescribe licenced medications in accordance with the terms of their licence but on the basis of an assessment of the individual patient the

> practitioner may conclude for medical reasons that it is necessary to prescribe a medicine to meet the specific needs of a patient. The GMC guidance states that the practitioner must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy. In addition, the practitioner must take responsibility for prescribing and overseeing the patient's care including monitoring and follow up treatment. ”

77. The Briefing paper considered the implications of a prescribing ban. It considered that there was “a strong argument that practitioners should not be initiating prescribing off-label GnRH analogues for the purposes of puberty suppression … because of the recent published systematic reviews both in the UK and other nation states”. However, potential unintended consequences might include:

> “For other CYP who have accessed GnRH analogues for the purposes of puberty suppression for gender dysphoria through NHS or non-NHS prescribing, stopping these medicines can be achieved without significant impact on endocrinology homeostasis but the emotional impact for a group of young individuals known to have a high risk of self-harm and suicide on acute treatment withdrawal must be mitigated. With the recent initiation of the CYP gender services in the North West and London there is capacity only to manage the current transferred workload from the Tavistock GIDS service and no capacity to provide any additional support as a consequence of legislation. In principle those accessing PSH from private providers will need to secure additional psychosocial support from those private providers who initiated treatment. Adequate notice of the change in legislation would be important to give the CYP and their parents time to access appropriate support either within the private sector or securing referrals to local CYP mental health services if significant mental health instability is likely to ensue. In turn we know the current constraints of the CYP mental health services across many parts of the country. Harms that might occur in this young patient cohort may be attributed to a change in legislation whether or not they are directly related to that change.”

78. On 7 May 2024, officials held a roundtable meeting bringing together regulators (CQC, GPhC, MHRA) with trade representative bodies (Community Pharmacy England, National Pharmacy Association) and professional bodies (RCGP, Royal Pharmaceutical Society, Academy of Medical Royal Colleges) to discuss the options on prescribing and dispensing in response to the Cass Review.

79. On 9 May 2024, officials met with the First Defendant and discussed the clinical advice received concerning the risk of a ban for vulnerable children and young people who were either already using puberty blockers or seeking to use them. There were no physical health risks in coming off puberty blockers but these children and young people would need psychological support. In terms of next steps, the First Defendant said she wanted to move quickly.

80. Further advice was provided to the First Defendant in a Ministerial Submission dated 13 May 2024. Different options were set out. It was recommended that, for EEA prescriptions, the ban should extend to all prescriptions for puberty blockers, irrespective of clinical indication or age, because of the difficulty pharmacists had in verifying the identity of the prescriber and the reason for the prescription.

81. On 22 May 2024, the Prime Minister called a general election to be held on 4 July 2024. Parliament would be dissolved on 30 May 2024.

82. On 23 May 2024, the First Defendant delivered an Oral Statement to the House of Commons stating that it was her intention to make a banning order. As part of that Oral Statement she said:

> "I have also made it my priority to protect our children, who have been questioning their identity in ever increasing numbers. The Cass review laid bare the damaging effect that social media and degrading pornography have had on young people's sense of self. It also set out clearly the need for extreme caution in medical interventions. Today, I want to set out my clear intention to introduce a banning order on puberty blockers, with limited exceptions, under section 62 of the Medicines Act 1968. This is an extraordinary use of that power, but it is the right use of that power because we must protect our children and young people from this risk to their safety.[5]"

83. There was cross-party support for this approach as the then Shadow Secretary of State for Health and Social Care (Mr Wes Streeting) said in response to the Statement:

> "I also welcome what she said about the justifiably cautious and responsible approach she is taking in relation to puberty blockers in the light of the Cass report."

84. Following a meeting on 23 May 2024 between the First Defendant and officials, a Ministerial Submission was provided on 24 May 2024. It is heavily redacted. It set out the options for making an order under Section 62 MA 1968, with regulations made in parallel to amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 to restrict prescribing/supplying of gender dysphoria medicines to children. The Submission recommended that if the First Defendant considered it necessary to proceed with the measures before dissolution, a temporary emergency Section 62 MA 1968 prohibition order be prepared that:

a) Bans sale or supply of puberty blocker medicines against new prescriptions for under 18s which would start a child on a medical pathway for gender incongruence/dysphoria from the UK independent sector;

---

[5] Hansard, HC Deb 23 May 2024, vol. 750 col. 1045.

b) Bans sale or supply against all prescriptions for puberty blocker medicines from EEA and Swiss prescribers (EEA);

c) Provides exceptions for sale or supply against NHS prescriptions, and by way of wholesale dealing; and

d) Is mirrored by changes to the Prescription of Drugs Regulations limiting NHS primary care prescribing of these medicines for gender dysphoria/incongruence to existing patients in under 18s.

85. As Parliament was due to be dissolved on 30 May 2024 for the election, and these were both negative resolution instruments, they would need to be made (i.e. signed) and laid in Parliament by 29 May 2024.

86. At paragraph 13b of the Submission, it was recommended that an exception be made for NHS provision of these medications. The primary reason for this was that the NHS had established a clinical policy in line with the Cass Review. Prescribing could be more effectively restricted in primary care by amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004.

87. In regard to EEA prescriptions, paragraph 15 of the Submission advised that, because of the difficulty in verifying EEA prescriptions, the only practical option was that the order be extended to all prescriptions for puberty blockers, irrespective of clinical indication, age, or whether it was a new patient or a patient already on a course of puberty suppressant treatment. There was a risk of disruption to treatment for patients receiving these drugs for wider uses but the risk could not be quantified in the absence of data on prescription volumes. Gender dysphoria patients were likely to be on NHS waiting lists or otherwise already known to the NHS.

88. In the light of the concerns about impacting legitimate use, it was later ascertained that it was practical for pharmacists to check for proof of age and therefore the restriction was limited to patients aged under 18 only.

89. Ms Sacks commented, at GS/115, that the risks associated with verification of EEA prescriptions, coupled with the knowledge of prescribing activity in direct conflict with the Cass Review, meant that continued recognition of any prescriptions for puberty blockers for children and young people was considered to have too great a risk of being exploited. It thus would undermine the intention to protect more patients from accessing inappropriate care. It was therefore recommended that all EEA prescriptions for puberty blockers for patients under 18 should no longer be recognised. It would, however, remain legally possible for these patients to continue to be prescribed puberty blockers by a UK registered prescriber.

90. Paragraph 16 of the Submission advised on private prescriptions as follows:

> "You indicated that you wanted the ban to apply to all UK private prescriptions for puberty blockers for gender incongruence/gender dysphoria in children, with NHS services taking on any children currently fully established on puberty blockers and supporting them to stop taking these medicines.

> Clinical advice from NHS England (see annex A) is that this is an extremely vulnerable group, liable to self-harm without intensive psycho-social support. The number of children in this group is unknown. There is insufficient capacity within the new specialist NHS services to be able to offer a guaranteed pathway for these additional children at a point when private prescriptions become unlawful. Clinical advice is that it would cause a larger patient safety issue to force them to stop treatment without adequate support in place, than it would to allow them to continue in the short-term. On patient safety grounds and in order to secure continuity of care, we therefore recommend that the banning order continue to allow UK private providers to prescribe to children who are already established on a medical pathway…"

91. At paragraph 24, the Submission warned of the risk that implementation of changes at such short notice would run the risk of confusion on the part of prescribers and pharmacists. As the Order makes it a criminal offence to dispense, pharmacists may refuse to do so, to the detriment of patients.

92. Ms Sacks explained, at GS/116, that it was initially recommended that the commencement of both measures be deferred for four weeks. There were various reasons for this. One main reason was that by this time DHSC was aware that up to 80,000 NHS patients used puberty blockers for reasons not related to gender dysphoria, and their treatment needed to be protected. The mechanism for operationalising the restrictions to NHS prescribing was through established processes linked to the electronic prescribing systems used by GPs, and dispensing systems used by pharmacists. There are a variety of different prescribing and dispensing systems, but in principle the need for consideration of the restrictions would be flagged at the point of prescribing, and similarly pharmacists would be prompted to check for an endorsement at the point of dispensing. The NHS Business Services Authority advised it would take around 4 weeks for systems to update. If the restrictions were brought into force before the systems had been updated (or most of them had), then it would be likely that prescriptions would have to be manually endorsed. In the time available this would not be well understood and there would be a high risk of failure, with patients inconvenienced and the potential risk to patient safety if there was a break in their treatment.

93. However, Ms Sacks explained, at GS/119, that officials subsequently revised their view on the timing of the Order. In the light of GenderGP's intention to continue prescribing, officials believed that, if there was a delay between the announcement of the order and the date it came into effect, patients would rush to "beat the ban" and try to initiate treatment, knowing they would be allowed to continue once treatment had begun. The Further Advice to the First Defendant, dated 26 May 2024, also identified a risk that UK-based private GPs might attempt to attract new patients, or accelerate the commencement of treatment of new patients, before the ban came into force. The final sentence of this redacted note states:

> "In previous meetings, the SoS has indicated that in light of the Cass report she did not wish to consult specialist orgs claiming

> to represent those with GD and their families/carers. Can you confirm that this steer remains?"

94. Ms Sacks explained, at GS/125, that officials wanted to make sure that, within the limited time available, they had spoken with the national bodies whose expertise would enable them to make the Order as effective as could be, and mitigate the risks.

95. Discussions took place with NHS England on 26 May 2024 and the Chief Pharmaceutical Officers on 27 May 2024 which considered the likely impact on patients and developing a support strategy.

96. On 28 May 2024, officials met the GPhC and GMC to discuss the prohibition order and how best to communicate the changes to their respective sectors. On the same day, a meeting with the British Medical Association ("BMA") took place where the importance of monitoring the ban was raised, as they were concerned about the impact on vulnerable children. A meeting with Community Pharmacy England ("CPE") discussed how the ban could be made operational. They also wanted to ensure the rules were clear for prescribers and pharmacists and agreed to help disseminate information to pharmacists.

97. On 29 May 2024, a meeting was held with NHS England to confirm the approach on communications. NHS England agreed to communicate with the NHS and patients on the waiting list. DHSC agreed to provide information to professional bodies, regulators, and patient groups. There was a meeting with the Academy of Medical Royal Colleges to clarify the scope of the banning order. A meeting with RCGP was also held on 29 May 2024, with concerns raised about the unintended consequences of the ban and the impact on those accessing puberty blockers via EEA routes who would no longer be able to do so. They also stressed the importance of monitoring and evaluating the Order. On 30 May 2024, a meeting with key pharmacy representatives was convened and the Regulations were discussed.

98. On 28 May 2024, the First Defendant was provided with an updated summary risk assessment. This assessment highlighted the risks to patients and professionals from proceeding with the prescribing restrictions and action underway to mitigate those risks.

99. Further to the draft Interim Equality Impact Assessment that was provided to the First Defendant on 24 May 2024, a Limited Impact Assessment was published on 29 May 2024. It summarised the problems that needed to be addressed, the rationale for government intervention, the policy objectives and the expected effects. It outlined the supporting evidence base and presented a qualitative assessment of costs and benefits. It identified risks and associated mitigation and explained the arrangements for monitoring and evaluation.

100. The Order and the Regulations were made on 29 May 2024.

101. On 30 May 2024, NHS England issued guidance headed "New Government restrictions on use of Puberty Suppressing Hormones (Puberty Blockers); Information for prescribers and pharmacists/dispensing doctors". The guidance for a patient under 18 who is already being prescribed puberty blockers on an EEA/Swiss prescription is as follows:

> "Patients under 18 are strongly advised to meet with their clinician to fully understand the risks of continuing taking GnRH analogues for puberty suppression.
>
> If the patient wants to continue an NHS or private prescriber can continue to prescribe following a shared decision-making conversation about the risks with the patient. Prescription must be marked SLS."

102. On 31 May 2024, NHS England wrote to all those on the waiting list for NHS gender services informing them of the legislation and the policy changes.

Claimants' evidence

C1: Chay Brown

103. Chay Brown, who is C1's Director of Operations and Director for Healthcare, made a witness statement dated 17 June 2024. C1 has a particular focus on healthcare for transgender people. For example, it convenes the Trans Health Forum and coordinates the Trans Healthcare Coalition and it sits on the steering committee of The National LGBT+ Partnership. It has published guidance resources for transgender people and healthcare professionals.

104. In the light of its work, C1 considered that it was well-placed to be consulted as an organisation representative of transgender people in the UK and the leading voice on transgender healthcare. Therefore it wrote to the First Defendant on 24 May 2024, asking to be consulted about the proposed ban, but it did not receive a reply. C1 could have provided the First Defendant with relevant information and data. It also has channels of communication with young transgender people and their parents who distrust the NHS because of their experience on the waiting list for specialist care and are more likely to communicate openly with C1.

105. There have been unacceptably long waits for specialist NHS gender services for a number of years. The new regional centres only started accepting patients who had been under the care of GIDS in April 2024. There is no indication as to when new patients will be seen.

106. The Cass Review recommended that in future puberty blockers should only be accessed through a clinical research programme. However, the clinical research programme is not yet in place.

107. For young people in England and Wales, the route to care is via a national referral support service hosted by the NHS Arden and Greater East Midlands (GEM) Commissioning Support Unit (CSU). The final referral specification has not yet been published, but it seems likely that referral will need to be made by secondary care providers in Children and Young People's Mental Health Services ("CYPMHS") and paediatric services.

108. A Freedom of Information Act response from NHS England has confirmed that, as at 30 April 2024, there were 5,676 children and young people on the waiting list for gender services, most of whom had been waiting between 2 and 5 years.

109. There are very limited options for access to private gender care clinics, for those who can afford it. Chay Brown states at paragraph 20 of his witness statement that GenderPlus, which is CQC regulated, offers post-assessment referrals and prescriptions for puberty blockers for young people aged 16 and over. However, Lui Asquith states in their second witness statement, at paragraph 42, that GenderPlus does not offer puberty blockers to any of its patients. Harley Street Gender Clinic offers support and guidance for adolescents but does not prescribe hormone therapy to people under 18. YourGP accepts referrals for people aged 17 and over, but does not prescribe to people under 18.

110. Because of the difficulties in obtaining treatment in the UK, parents and patients have resorted to using EEA/Swiss registered services. Some have taken the risk of using entirely unregulated services, accessed online.

111. In C1's experience, the new legislation has been difficult for parents, patients and their advisers to understand and apply. The letter from NHS England to patients, dated 31 May 2024, explained that pharmacies in Great Britain could no longer dispense new EEA/Swiss prescriptions for puberty blockers, and they could only be supplied by a UK registered doctor. Patients were strongly advised to meet with their clinician.

112. The letter did not explain how patients with EEA/Swiss prescriptions could continue to receive puberty blockers. It did not say that puberty blockers will be prescribed through the NHS to EEA patients, and in practice this is unlikely to happen because NHS policy is that they cannot be routinely prescribed but only as part of a clinical research programme (which has not started) or under an exceptional request for funding. The long waiting list effectively prevents new patients from being considered for treatment.

113. The letter of 31 May 2024 advised patients that puberty blockers "can be safely stopped and you do not need to be weaned off". Chay Brown criticises this advice for failing to recognise the possible significant mental health effects of stopping upon a trans person, summarised in CB/32.

114. The witness statement includes case studies which vividly describe the difficulties caused by the cessation of puberty blockers, or the inability to commence puberty blockers.

115. Although the letter refers to support services, they are not trans-specific and are not equipped to deal with the complexities of the cessation of puberty blockers. Furthermore, provision of mental health support is poor for all young people in the UK with more than a quarter of a million children and young people on a waiting list for CYPMHS.

116. NHS Specialised Commissioning has provided for funding for NHS Child and Adolescent Mental Health Services ("CAMHS") to offer an assessment appointment to young people who have been transferred from GIDS to the new regional centres.

117. In his second witness statement, dated 7 July 2024, Chay Brown confirmed that the vast majority of GPs are not prescribing further puberty blockers to those who already have a prescription. He is only aware of one GP who has done so. In one instance, the patient's father was told by the GP that it was illegal to do so, and this was confirmed by the Chief Pharmaceutical Officer of the local Integrated Care Board, despite advice to the contrary from the DHSC. Case studies are included in the witness statement which refer to the difficulties in obtaining puberty blockers from GPs, praise the quality of the service from GenderGP, and endorse the benefit of puberty blockers.

118. Chay Brown submits that if C1 had been consulted it could have shared this information with the First Defendant. It could also have ascertained the number of UK patients receiving puberty blockers through GenderGP.

C2: ZZ

119. ZZ is the mother of YY who is aged 15. ZZ's first witness statement, dated 17 June 2024, describes YY's struggle with gender dysphoria as a child and as a teenager. YY was referred to GIDS by CAMHS in January 2023 but she remained on the waiting list and was never seen. She became highly distressed and self-harmed as her body changed with the onset of puberty and she planned to take her own life in May 2024. YY has attended regular appointments at CAMHS, but they are not gender specialists. She is currently being assessed for autism.

120. The family researched the options for YY and came to realise that she could not access treatment in time from the NHS or a UK private practice. The only option was for her to go to GenderGP. YY had two information gathering sessions and one clinician information session that have helped her to ascertain what she wants and how sure she is about her transition. ZZ considers that YY has a competent and mature understanding of the effects of puberty blockers. YY's parents believe that the benefits of puberty blockers outweigh the disadvantages.

121. YY decided to defer puberty blockers until she turned 15 in July 2024, so that she could remain on them until she has surgery when she is 18. After the legislation was introduced, but before it took effect, the family had a further information session with GenderGP and were advised that she would need a "capacity to consent session" before she could be prescribed puberty blockers. It was not possible to complete this stage of the process before the ban took effect. Since the ban, YY's mental health has rapidly deteriorated, and her parents fear she may try to take her own life.

122. In her second witness statement, dated 7 July 2024, ZZ responded to the criticisms of GenderGP, stating its clinicians took considerable care to ensure that treatment with puberty blockers was clinically appropriate for YY; that the family understood the implications of the treatment; and that YY gave informed consent.

123. ZZ provided an update on YY's circumstances. She recently sat her mock exams and has taken a music exam. However, she is distressed, self-harming and has suicidal ideation. ZZ considers she is an active suicide risk.

Lui Asquith

124. Lui Asquith is the Claimants' solicitor. Lui Asquith has exhibited to their second witness statement reports from Coroners following inquests into the deaths of trans children. Lui Asquith states that, in each case, there was an identified lack of adequate support from the NHS gender services or mental health services.

125. In both their first and second witness statements Lui Asquith has referred to case studies of transgender young people. Some were on a course of puberty blockers from an EEA prescriber; others were planning to commence a course of puberty blockers. They could not get treatment in time in the UK because the NHS waiting list was so long. Those who went to GenderGP gave positive accounts of the treatment received. Once treated with puberty blockers, there was a significant improvement in their previous poor mental health. They ceased to self-harm and/or experience suicidal ideation.

126. The ban on puberty blockers has had severely detrimental effects on patients, some of whom say that they have lost the will to live. The Good Law Project, which supports this litigation, has provided details of four young people who have made a suicide attempt following the ban on puberty blockers.

127. Lui Asquith's research among parents and patients, and the charity Mermaids, indicates that GPs are not willing to prescribe puberty blockers to patients who were on a course of treatment with GenderGP or other EEA providers. Only one GP has been identified who is willing to do so (the same GP who is referred to by Chay Brown).

Dr Vickie Pasterski

128. Dr Vickie Pasterski is a Gender Specialist with more than 25 years' experience. She is the director of the Harley Street Gender Clinic. She made witness statements on 17 June 2024 and 7 July 2024. She explains that, prior to the recent legislation, GenderGP was the only private prescriber available to UK patients under the age of 18. Since 3 June 2024, there has been an increase in the number of families contacting her clinic looking for mental health support and guidance, because of a rapid deterioration in mental health among children who are going to be forced into a puberty that is at odds with their gender identity at school and among friends.

Legislation

Medicines Act 1968

129. The Order was made pursuant to section 62 MA 1968.

130. Section 62 provides, so far as is material:

> "(1) Subject to the following provisions of this section, the Ministers, where it appears to them to be necessary to do so in the interests of safety, may by order—

(a) prohibit the sale or supply, or the importation, of medicinal products of any description, or falling within any class, specified in the order, or (in such manner as may appear to them to be sufficient to identify the products in question) designate particular medicinal products and prohibit the sale or supply, or the importation, of those particular products.

(2) A prohibition imposed by order under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the order.

(3) Before making an order under this section the Ministers, unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health, shall consult the appropriate committee.

(4) Where an order is made under this section without prior consultation with the appropriate committee in accordance with subsection (3) of this section, the prohibition imposed by the order shall not have effect after the end of such period, not exceeding three months from the date on which it comes into operation, as may be specified in the order, but without prejudice to the making of any further order in accordance with the provisions of this section (including this subsection).

(5) If any organisation consulted in pursuant of section 129(6) of this Act with respect to a proposal to make an order under this section have given notice to the Ministers of their desire to be heard under this subsection, or have made representations in writing to the Ministers with respect to that proposal, then before making the order –

(a) if the organisation have given notice of their desire to be heard, the Ministers shall arrange for them to have an opportunity of appearing before, and being heard by, the appropriate committee, or

(b) if they have made representations in writing, the Ministers shall refer those representations to the appropriate committee,

and, where the organisation have availed themselves of the opportunity of being heard, or after considering the representations, as the case may be, the appropriate committee shall report their findings and conclusions to the Ministers and the Ministers shall take that report into account in determining whether to make the order.

(6) Subsection (5) of this section shall not have effect where in the opinion of the Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

> (7) …
>
> (8) In this section, "appropriate committee" means whichever the Ministers consider appropriate of –
>
> (a) the Commission; or
>
> (b) An expert committee appointed by the Ministers, or by one of them acting alone."

131. The First Defendant was required to make the Order jointly with the Second Defendant under section 62 MA 1968. The term "Ministers" in subsection 62(1) MA 1968 refers to the Secretary of State and the Northern Ireland Minister of Health. Section 1 MA 1968 provides that in this Act, 'the Ministers' has the meaning given by regulation 6(6)-(8) of the 2012 Regulations. Section 132(1)(b) defines the 2012 Regulations as the Human Medicines Regulations 2012. Regulation 6(6) of the Human Medicines Regulations 2012 refers to the Secretary of State and the Minister of Health, Social Services and Public Safety (now known as the Northern Ireland Minister of Health).

132. The regulation of medicines is devolved to Northern Ireland. As explained by Ms Sacks, at GS/128 – 133, there was insufficient time for the Second Defendant to discharge the obligations required to make a similar order for Northern Ireland (see the letter from the Second Defendant dated 29 May 2024). Therefore the Order applies to Great Britain only (i.e. England, Scotland and Wales). However, the approval of the Second Defendant was still required for the Order under the provisions of section 62 MA 1968. On the basis of the information and recommendations from the First Defendant, the Second Defendant was "satisfied on the evidence that it is essential to make the Order with immediate effect to avoid serious danger to health" (letter of 29 May 2024). The Second Defendant duly co-signed the Order.

133. The "Commission", referred to in section 62(8) MA 1968, means the CHM. It is an independent body of experts, established under section 2 MA 1968. It provides expert advice to ministers on the safety, quality and efficacy of medicines, and promotes the collection and investigation of information relating to adverse reactions for human medicines.

134. Section 62(3) MA 1968 sets out a statutory consultation process which requires the Ministers to consult the CHM before making an Order. By subsection (5), organisations who are consulted can appear before the CHM and/or make written representations to it. The CHM then reports its findings and conclusions to the Ministers, and the Ministers are required to take that report into account when determining whether or not to make the order (section 62(5) MA 1968; section 129(7) MA 1968).

135. Further duties on the Ministers to consult "such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order" (except in urgent cases) are described in section 129(6) MA 1968 which provides:

> "Before making any regulations under this Act and before making any order under this Act (except an order made in accordance with any provision of this Act under which, in case of urgency, an order can be made with immediate effect) the

> Ministers proposing to make the regulations or order shall consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order."

136. Section 62(3) MA 1968 permits the statutory consultation and CHM advisory report to be bypassed where, in the opinion of the Ministers, "it is essential to make the order with immediate effect to avoid serious danger to health" (see subsection (6)). In those emergency cases, the order expires after 3 months from the date on which it is made, but a further order can be made (subsection (4)).

137. By section 129(3) MA 1968, any statutory instrument made under section 62 is subject to the negative resolution procedure.

138. In *R (National Association of Health Stores) v Department of Health* [2005] EWCA Civ 154, which concerned a ban on the sale of kava-kava, Sedley LJ described, at [12], the standard procedure under section 62 MA 1968, including the duty to consult, as "subject to an exception for emergencies".

139. The power under section 62 MA 1968 has seldom been relied upon. According to research carried out by the Claimants, in the last 56 years, it has been used on 11 occasions, most recently in 2008. It has not been used to prohibit the use of a medicinal product which has an EMA or MHRA marketing authorisation. The Claimants suggest, and I agree, that the likely reason for this is that the processes for obtaining a marketing authorisation create a high level of assurance that the product is safe and clinically effective for the specified uses (though puberty blockers are prescribed off-label, as explained above).

140. Ministers have rarely exercised the power to impose emergency restrictions under section 62 MA 1968. The Claimants have only identified two such orders. First, a prohibition on Bal Jivan Chamcho, an ayurvedic baby tonic which the Chief Medical Officer had warned contained lead (SI 1976/186). Second, restrictions on the sale, supply and importation of products containing Aristolochia, an ingredient used in Chinese herbal medicine which causes rapidly progressive kidney failure (SI 1999/2109). This was subject to several exemptions, including where the product had a marketing authorisation.

141. By section 67(2)-(3) MA 1968, breach of an order made under section 62 MA 1968 is a criminal offence, punishable on indictment by up to two years imprisonment and an unlimited fine. This would apply to a doctor who prescribes, or a pharmacist who dispenses, a product in contravention of an order. An offence is also committed by a person who possesses medicine which they know or have reasonable cause to suspect has been sold or supplied in contravention of an order.

The Order

142. The Order was made and laid before Parliament on 29 May 2024. It came into force on 3 June 2024. It ceases to have effect at the end of 2 September 2024. It applies in England, Wales and Scotland, but not in Northern Ireland.

143. The preamble to the Order states that the Ministers, acting jointly, make the Order in exercise of the powers conferred by sections 62 and 129(5) MA 1968, "it appearing to them to be necessary to do so in the interests of safety, and their being of the opinion that it is essential to make the Order with immediate effect to avoid serious danger to health". The preamble also records that the appropriate committee has not considered the proposal to make the Order.

144. Article 3 of the Order prohibits the sale or supply of puberty blockers subject to exceptions.

145. Article 4 provides an exception for a sale or supply pursuant to an NHS prescription.

146. Article 5 provides an exception for a sale or supply, pursuant to a private prescription by a UK or overseas prescriber, to a person who is 18 or over. The prescription must either be annotated with 'SLS' and the person's age, or they must provide proof of age and identity at the point of sale / supply. "SLS" is an acronym for "Selected List Scheme". It refers to the fact that some drugs are restricted to prescribing in certain circumstances under Part XVIIIA of the Drug Tariff.

147. Article 6 deals with the sale or supply of puberty blockers, pursuant to a private prescription, to a person under 18. It provides as follows:

> "**Exception for private prescriptions: patients aged under 18**
>
> 6(1) Article 3 does not apply to a sale or supply in pursuance of a private prescription, if—
>
> (a) Condition A is met;
>
> (b) if the private prescription is a prescription, rather than a direction, which is or purports to be in accordance with the requirements of regulation 217, 218, 219 or 219A of the 2012 Regulations (which relate to requirements for paper and electronic prescriptions), Condition B is met;
>
> (c) if the private prescription was issued on or after 3rd June 2024, Condition C is met; and
>
> (d) unless the sale or supply is to or for a person who, on any occasion, started a course of treatment with a GnRH analogue before 3rd June 2024, Condition D is met.
>
> (2) Condition A is that on the day the private prescription was issued, the patient in respect of whom it was issued was aged under 18.
>
> (3) Condition B is that—
>
> (a) the prescription has included within it the patient's age and is annotated by the prescriber with "SLS"; or

> (b) if the prescription was issued before 3rd June 2024, the person to whom the GnRH analogue is to be sold or supplied produces to the person selling or supplying the GnRH analogue a specified document, a UK birth certificate or a current national identity document that verifies, to the reasonable satisfaction of the person selling or supplying the GnRH analogue, the age and identity of the person to or for whom the GnRH analogue is to be sold or supplied.
>
> (4) Condition C is that the private prescription was issued by an approved UK prescriber.
>
> (5) Condition D is that the purpose for which the private prescription was issued is a purpose other than treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.
>
> (6) For the purposes of paragraph (1)(d), a person is treated as having started a course of treatment with a GnRH analogue if, in the six month period before 3rd June 2024, that person was issued with a NHS or private prescription for a GnRH analogue, whether or not the prescription has been dispensed or the prescribed GnRH analogue has been taken by that person before 3rd June 2024.
>
> (7) For the purposes of paragraph (5), treatment is treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination or both if it is, viewed objectively, treatment for that purpose, as gender dysphoria and gender incongruence are ordinarily understood as part of medical practice in Great Britain."

148. The effect of the Order on the prescribing of puberty blockers to people under 18, for the purposes of puberty suppression in those experiencing gender dysphoria/incongruence, may be summarised as follows.

i) The Order provides a total ban on the sale or supply of puberty blockers pursuant to an overseas prescription issued on or after 3 June 2024.

ii) The Order does not ban the sale or supply of puberty blockers pursuant to a private UK prescription, but it does restrict the circumstances in which such sale or supply can take place. Those restrictions seek to align the position for UK private prescribers with that of the NHS, as set out in regulation 2(2)(b) of the Regulations and in NHSE's Clinical Policy.

iii) Where a person has not yet commenced a course of treatment, then puberty blockers can only be supplied as part of an authorised clinical trial (whether it be a trial run by NHSE or a private trial).[6] The only exception to this is that

[6] For NHS prescriptions, see the definition of patients to whom a puberty blocker may be supplied in regulation 2(2)(b) of the Regulations. For private prescriptions, see the definition of 'supply' in Article 2 of the Order. The licensing authority referred to is the MHRA.

NHS primary care bodies can prescribe on an individual basis outside the General Medical Services Contract.[7]

iv) The Order does not prohibit the sale or supply of puberty blockers pursuant to either a private or NHS prescription issued on or after 3 June 2024 where the person "started a course of treatment" before 3 June 2024. This is the case regardless of whether the puberty blockers were previously prescribed by a NHS, UK private or EEA prescriber. However, private prescriptions issued to such patients on or after 3 June 2024 must be issued by an "approved UK prescriber", as defined in Article 2 (see Article 6(4)).

v) A person is deemed to have started a course of treatment where they were issued with a prescription for puberty blockers between 3 December 2023 and 3 June 2024 (see Article 6(6)). This is the case regardless of whether that prescription had been dispensed or the patient has actually commenced the treatment.

vi) All prescriptions issued after 3 June 2024 must include the patient's age and be annotated with "SLS".

The Regulations

149. The Regulations were made and laid before Parliament on 29 May 2024. They came into force on 26 June 2024. They only apply to England.

150. The Regulations were made pursuant to section 88 of the National Health Service Act 2006 which permits the First Defendant to give directions, set out in regulations, to people providing services under a general medical services contract (usually GPs).

151. Regulation 2 inserts provisions into the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 that restrict NHS Primary Care prescribing of puberty blockers to patients under the age of 18 unless:

i) Either the treatment is part of a National Institute for Health and Care Research clinical trial;

ii) Or they started a course of treatment with puberty blockers before 26 June 2024.

152. A patient is deemed to have started a course of treatment where they were issued with a prescription for puberty blockers between 3 December 2023 and 26 June 2024, whether or not the prescription has been dispensed or the patient has commenced the treatment.

[7] See Reg.34(2)(b) of the NHS Commissioning Regulations 2012 which requires each NHS commissioner to have "arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention"

Ground 1

Claimants' submissions

153. The Claimants submitted that the First Defendant acted unlawfully in utilising the emergency procedure under section 62(3) MA 1968, without following the standard procedure of consultation and advice, when the conditions for doing so were not met. She was not rationally entitled to conclude, on the evidence, that it was essential to take immediate action to prohibit the sale or supply of puberty blockers to children in order to avoid a serious danger to health.

154. The First Defendant's rationale for the Order, as set out in the Explanatory Memorandum ("EM") and the Limited Impact Assessment, was based on the conclusions in the Cass Review. However, the Cass Review did not conclude that puberty blockers cause a serious danger to health, still less one that required immediate action. Its position was that not enough was known about the longer-term impacts of puberty blockers for children and young people to know whether they are safe or not. Therefore the First Defendant should have commissioned bespoke clinical advice to address the question whether there was "a serious danger to health", but she did not do so. Instead she informed her officials that she wished to ban puberty blockers and instructed them to develop the arguments that would support her decision (Ministerial Submission of 25 April 2024).

155. The legal principles governing availability of medicines in the NHS are different from those which govern private medicine. Where a medicine is not available under the NHS, it does not subvert NHS policy for the medicine to be obtained in the private sector and it is a draconian measure to prohibit it.

156. The exceptions to the prohibition on puberty blockers in article 2 of the Order fatally undermine the case for puberty blockers causing a serious danger to health. If there truly was evidence to support that proposition, it is inconceivable that the Order would permit the continued sale or supply of puberty blockers to patients under 18 who had already been prescribed them, or permit their provision on the NHS. Furthermore, although the Second Defendant signed the Order for England, Scotland and Wales, puberty blockers are still available in Northern Ireland without restriction.

157. The safety concerns referred to in the EM do not come close to satisfying the "serious danger to health" criterion or require immediate action. The Cass Review did not recommend that all overseas prescribing be prohibited. Rather, Recommendation 27 recommended that "inappropriate overseas prescribing" be prevented. The Cass Review expressed concern about patients accessing unregulated medications from unregulated sources, but NHS England's clinical advice and the Equality Impact Assessment referred to the risk that prohibition would serve to increase use of unregulated sources.

158. The rationale for the Order prohibiting all EEA/Swiss prescribing that dispensing pharmacists cannot easily verify the purpose for which a prescription has been written ignores the professional duties of pharmacists not to dispense medication unless they satisfy themselves that it is clinically appropriate and safe for the patient.

159. There was no evidence to support the concern that a full consultation would have encouraged young people to accelerate commencement of their treatment in order to obtain prescriptions before the restrictions took effect. The assertion was inherently implausible. The exemption for existing users might not have been included in the final Order. Alternatively, the risk could have been guarded against by excluding from any exemption patients who commenced treatment during the consultation period.

160. Prohibiting all EEA/Swiss prescribing presented potentially severe consequences for the mental health of those affected, given the difficulties in finding a UK prescriber, and the risks consequent upon treatment interruption.

161. In breach of her *Tameside* duty, the First Defendant deliberately chose not to seek the views of organisations representing patients who would be affected by the emergency ban (Ministerial Submission 26 May 2024). The First Defendant pressed ahead with the legislation in the face of advice from her officials that there had been insufficient time to consult with expert bodies and other stakeholders.

162. Whilst the precautionary principle may be relevant to whether a prohibition order is "necessary" within section 62(1), the criteria in section 62(3) require there to be a "serious danger to health", not merely the possibility of such danger. Therefore the precautionary principle was not applicable. The Court of Appeal in the *Health Stores* case decided that a "high-grade scientific assessment" is necessary before that principle can be invoked [67], because "the decision-making process must be as well-informed as science permits" [69]. There was no such assessment before the First Defendant in this case. Nor was there any weighing of the harm that a prohibition would bring as against the possible risks that it might avert.

Defendants' submissions

163. The First Defendant was entitled to conclude that the test in section 62(3) MA 1968 was met on the basis of the evidence, conclusions and recommendations in the Cass Review Final Report, combined with the evidence of private prescribing. Vulnerable children were being placed on medical pathways which had substantial, albeit unquantified, risks and no or very limited clear benefits. The Cass Review recommended that puberty blockers should only be prescribed under a research protocol. However, the First Defendant had no way of enforcing this recommendation on overseas prescribers, who were prescribing in ways that were both unethical and unsafe. Her conclusion that an emergency order was required was a complex assessment, involving the application of clinical judgment, with which the Court should be slow to intervene.

164. When making an assessment of danger within section 62(3) MA 1968, it is appropriate and indeed necessary to adopt a precautionary approach if the scientific evidence indicates that there is a real albeit unquantified risk. The protection of human health justifies it.

165. The Cass Review did not conclude in terms that puberty blockers caused a serious danger to health as that was not the question it was asked to address. However, its findings about the substantial risks associated with the use of puberty blockers, together

with evidence about the conditions under which they were being prescribed, entitled the First Defendant to hold that the statutory test was met.

166. The exceptions to the prohibition in the Order did not undermine it. The exceptions for young people already on a course of treatment with puberty blockers simply showed that the First Defendant thought carefully about how best to ameliorate any unintended consequences and recognised that the balance of risk and benefit for young people who were already on a course of treatment was different from the balance for young people who had not yet been prescribed puberty blockers.

167. Medicines and healthcare in Northern Ireland are devolved matters, and it was not possible to make an emergency order covering Northern Ireland for the reasons explained by Ms Sacks at GS/131-133.

168. The effect of the Order and Regulations is, in general terms, to align NHS and private practice. The problem with permitting overseas prescribing is the absence of any regulatory control by the UK, in circumstances where the main EEA prescriber, GenderGP, has engaged in practices which the First Defendant considers to be unsafe and intends to continue to prescribe puberty blockers without regard to the conclusions and recommendations in the Cass Review.

169. Despite the legal and professional obligations on pharmacists, the evidence of Ms Sacks (GS/103–105) demonstrates that in practice there were considerable difficulties for UK pharmacists in verifying the identity of EEA prescribers, and expecting them to be able to verify the reasons for a prescription for puberty blockers was simply not credible.

170. As to the timing of the legislation, it would have been inappropriate to act on the basis of the Interim Report alone. Once the Final Report was published, the matter was addressed with urgency. The statutory question to be asked was not whether, in principle, the Order could have been made days or weeks earlier. On that, there was a difficult balance to be struck between pressing ahead quickly, and giving sufficient thought to the detail of the Order. The question was whether, on 29 May 2024 when she made the Order, the First Defendant reasonably considered it was essential to make it with immediate effect. And when addressing that issue, it was also necessary to consider what the alternative would have been: in this case, a 5 to 6 month process involving the CHM, during which EEA bodies would have continued prescribing, putting children and young people at risk of serious danger to health. In those circumstances, the First Defendant's conclusion that it was essential to make the order immediately was one she was entitled to reach.

Conclusions

The criteria in section 62 MA 1968

171. Under section 62 MA 1968, the Defendants were required to form a series of judgments when deciding whether to restrict the sale or supply of puberty blockers:

i) First, whether "it appears to them to be necessary to do so in the interests of safety";

ii) Second, whether "in their opinion it is essential to make the order with immediate effect to avoid serious danger to health", thus dispensing with consultation.

172. By subsection 62(2) MA 1968, an order could impose a total prohibition or a prohibition subject to exceptions.

173. The starting point in interpreting the statutory terms used is to ascertain the ordinary and natural meaning of the words, read in their statutory context. The statutory context here is safeguarding human health where a low tolerance of risk is appropriate.

174. The word "necessary" is a high threshold, going beyond what is merely useful or desirable. The word "essential" is an even higher threshold than "necessary", defined in the dictionary as "absolutely necessary",[8] also meaning something that is fundamental or indispensable.

175. The Divisional Court in *R (Liberty) v Secretary of State for the Home Department* [2024] EWHC 1181 (Admin) set out the ordinary meaning and dictionary synonyms of the word "serious" at [50]:

> ""Serious" in ordinary parlance connotes something towards the top end of the scale. Dictionary synonyms of the adjective are consistent with this and include: severe, grave, big, and major"

176. I do not consider that the statutory definition of a "serious adverse reaction" in regulation 8 of the Human Medicines Regulations 2012 is of any relevance here as it specifically relates to the requirement, imposed on licence-holders to report instances where licensed drugs have had a particularly adverse effect on an individual patient.

Assessment of risk

177. In assessing whether or not restrictions on the supply of puberty blockers were necessary in the interest of safety, and whether they present a serious danger to health, the Defendants were entitled, and indeed required, to consider and assess the potential adverse risks. Where medicines have been licensed, such risks are quantified and balanced against the benefits, and a decision taken that the benefits outweigh the risk: see *Wilkes v Deputy International Ltd* [2018] QB 627, at [7], [13]-[14], per Hickinbottom J. As the Cass Review explained, puberty blockers are prescribed off-label and not licensed for treating gender dysphoria in children and young people.

178. In *Health Stores* (paragraph 138 above), which concerned a ban on the sale of kava-kava, the Court of Appeal found that the precautionary principle applied to the assessment under section 62 MA 1968. Sedley LJ said, at [67]:

> "67. The EU has a clear interest under the Treaty in national restrictions on the sale and movement of goods. The ECJ accordingly requires member states to limit marketing bans, which are the most drastic form of measure, to cases where "the real risk alleged for public health appears sufficiently established

[8] Oxford English Dictionary

> on the basis of the latest scientific data available at the adoption" of the measure in question: *Commission v Denmark* [2003] ECR I-9693, §48. In *Alpharma v Commission* [2002] ECR II-3495 the Court made it clear that high-grade scientific assessment of risks was "an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures". Subject to these procedural protections, the precautionary principle not only permits but requires states to put public health and safety before economic interests where specific risks are established."

179. In *Alpharma Inc v Council of the EU* T-70/99 [2002] ECR II-3495, the ECJ also held:

> "152….as the Court of Justice and the Court of First Instance have held, where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (the BSE judgment .., the NFU judgment … and the judgment at first instance in *Bergaderm and Goupil v Commission ….*
>
> 153. It follows that, as a result of the precautionary principles, as enshrined in Article 130r(2) of the Treaty, the Community institutions were entitled to take a preventive measure regarding the use of bacitracin zinc as an additive in feedingstuffs, even though, owing to existing scientific uncertainty, the reality and the seriousness of the risks to human health associated with that use were not yet fully apparent.
>
> 154 *A fortiori*, the Community institutions were not required, for the purpose of taking preventative action, to wait for the adverse effects of the use of the product as a growth promoter to materialise..."
>
> 155. Thus, in a situation in which the precautionary principle is applied, which by definition coincides with a situation where there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality (see … *Mondiet* …and *Spain v Council …*)."

See also *Lumsdon v Legal Services Board* [2016] AC 697, at [57], [58].

180. The Defendants were entitled to rely upon the precautionary principle when making their judgments under section 62(1) and (3) MA 1968. The First Defendant expressly stated at the meeting of 19 April 2024, that the level of risk she was prepared to tolerate, in the context of protecting the health of vulnerable children, was low. In my view, the guidance in *Alpharma*, set out above, accords with a rational and balanced approach to the assessment of risk in this context, where there remains scientific uncertainty.

Contrary to the Claimants' submission, the precautionary principle does not undermine or negate section 62(3) MA 1968. It will be a matter for the judgment of the Ministers to decide whether section 62(3) MA 1968 is satisfied in a case where there is scientific uncertainty.

The scope of the Court's review

181. The Defendants' conclusions on the statutory criteria are subject to review on rationality grounds. Here, the context calls for "anxious scrutiny" given that the ECtHR has held that issues of gender identity are likely to engage Article 8 ECHR. See *Kennedy v Charity Commission* [2014] UKSC 20 [2015] AC 455, at [245] per Lord Carnwath; *Pham v Secretary of State for the Home Department* [2015] UKSC 19 [2015] 1 WLR 1591, at [114] – [115], per Lord Reed.

182. The criteria which the Defendants have to apply under section 62 MA 1968 are inherently imprecise and call for a judgment on which different decision-makers, each acting rationally, might legitimately differ (see *R v Monopolies and Mergers Commission ex parte South Yorkshire Transport Ltd* [1993] 1 WLR 23, at 32G-H, per Lord Mustill).

183. I accept that the Court should exercise restraint before second-guessing the Defendants' judgment on whether the test in section 62(3) MA 1968 was met. Parliament has entrusted the Ministers to exercise this significant power, in the exercise of their discretionary judgment. It required a complex and multi-factored predictive assessment, involving the application of clinical judgment and the weighing of competing risks and dangers.

184. I accept the Defendants submission that a margin of appreciation is appropriate for a responsible decision-maker who "is required, under the urgent pressure of events, to take decisions which call for the evaluation of scientific evidence and advice as to public health risks, and which have serious implications for the…general public": *R v Secretary of State for Health ex p Eastside Cheese Company* [1999] 3 CMLR 123, at [50], per Lord Bingham.

The Explanatory Memorandum and the Limited Impact Assessment

185. The EM provided with the Order when it was laid before Parliament explained the reasons for making the Order as follows:

> "**Policy Context**
>
> **What is being done and why?**
>
> 5.1 The Cass Review found that there is not a reliable evidence base upon which to make clinical decisions about the use of GnRH analogues to treat gender dysphoria/incongruence, or for children and their families to make informed choices.
>
> The Cass Review concluded that because of the limited evidence, and potential risks to patient safety, these medicines

should only be offered for this purpose under a research protocol, and/or with the agreement of the national multi-disciplinary team. The NHS has implemented these recommendations. The Cass Review's conclusions have been accepted and endorsed by the UK governments, UK regulators and clinical leaders.

5.2 It is the government's view that the same principles to ensuring the safety of children and young people should be taken regardless of the clinician or setting responsible for their care. The government agrees with the Cass Review conclusions that for this group of children and young people safety can be best assured under the supervision of a national multi-disciplinary team and with new initiations onto a medical pathway for gender dysphoria/incongruence done under the governance of a clinical trial. The government is aware that not all prescribing of these medicines is being done in accordance with this position, and is of the view that this presents a risk to patient safety. The Order is therefore focused on the immediate actions required to prevent harm.

5.3 The Regulations and the Order align with the NHS's clinical policy, providing clarity and removing ambiguity for all parties – patients and their families, prescribers, employers/ commissioners and regulators. Where a patient is under the care of a UK-regulated prescriber, to ensure patient safety use of these medicines should be consistent regardless of the setting in which the prescriber is operating. The only excepted prescribers from these regulations are in NHS secondary or tertiary care, where the detailed approach to managing patients with gender dysphoria is set out in the interim service specification[3].

5.4 In the case of prescriptions issued in the EEA and Switzerland, dispensing pharmacists in the UK cannot easily verify the purpose for which a prescription has been written. For this reason all prescriptions of GnRH analogues from an EEA or Switzerland registered prescriber for patients under the age of 18 dated after 3rd June 2024 will no longer be dispensed in the UK. Prescriptions of GnRH analogues from an EEA or Switzerland registered prescriber for patients over the age of 18 will be dispensed in the UK providing verification of age can be shown to the dispensing pharmacist. This provision is included because it is not mandatory for prescriptions from EEA prescribers to include the age/date of birth of patients over the age of 12.

5.5 Only legislation can achieve consistent action to ensure patient safety across all sources of prescriptions. The Order is being made on an emergency basis to respond to the serious safety risks for vulnerable children and young people without delay. At present providers registered outside of the UK, beyond the jurisdiction of UK regulators, are able to continue to offer services that are not evidence based and treatment options that

> are not available through UK registered providers for safety reasons. The emergency order enables these loopholes to be closed immediately. It is necessarily a temporary measure, enabling further work to be done to determine the appropriate legislative approach for the future.
>
> 5.6 Breach of the Order is a criminal offence under the Medicines Act 1968. Communications and guidance will be issued to set out clearly the new requirements to ensure all those affected have relevant information to ensure compliance with the Order.
>
> **What was the previous policy, how is this different?**
>
> 5.7 The previous policy was that there were no legal restrictions which solely related to prescribing of GnRH analogues. Prescribers were expected to prescribe these medicines in accordance with the medicine's marketing authorisation and best available clinical evidence. In the case of gender dysphoria/gender incongruence, these expectations were not met, leading to variation in practice, and risks to patients' safety.
>
> 5.8 GnRH analogues are prescribed off-label (i.e. for purposes for which they are not licensed) to treat gender dysphoria and gender incongruence in children, and there is a lack of reliable evidence for prescribers to use, with variation in prescribing practice. The Order and the Regulations therefore take necessary steps to ensure consistent access to and prescribing of GnRH analogues."

186. After setting out the relevant legal provisions, the EM concluded:

> "**Why was this approach taken to change the law?**"
>
> "6.12 This is the only possible approach to make the necessary changes on an urgent basis. It is necessary in the interests of safety to prohibit the sale and supply of GnRH analogues to patients under the age of 18 in the case of both private and NHS prescriptions, unless certain conditions are met, and the Order taken with the Regulations achieves this aim.
>
> 6.13 The approach of amending the 2004 Regulations in order to restrict NHS prescribing was taken, rather than using the Order, because this is a legal approach that is familiar to NHS practitioners. There are structures in place to respond to changes to the 2004 Regulations and to ensure that those changes are communicated to practitioners as quickly as possible, and embedded in digital systems for prescribing and dispensing."

187. A Limited Impact Assessment was published on 29 May 2024. It assessed the policy benefits as follows:

> "The Order and the Regulations will deliver:
>
> • Reductions in clinical risk for all children currently using EEA prescriptions to obtain puberty blockers in the UK, and those who would otherwise seek to do so via this route;
>
> • Reductions in clinical risk for new patients seeking to use UK private prescribing to obtain puberty blockers for gender dysphoria specifically;
>
> • Reductions in clinical risk for new patients seeking to use NHS prescribing to obtain puberty blockers for gender dysphoria specifically; and
>
> • Improved consistency of treatment."

188. It summarised the risks as follows:

> "• A risk to physical or mental health where patients' treatment is changed or disrupted;
>
> • A risk to mental health where patients are unable to get treatment that they were expecting, or which they believed might be beneficial despite limited evidence;
>
> • A potential increase in demand for NHS care, if people stop using alternative providers;
>
> • A potential risk of confusion and uncertainty given that the Order is temporary, albeit with a more permanent solution likely to follow; and
>
> • A potential risk of patients seeking unsafe treatment and/or the creation of "black market" demand.
>
> These risks will be mitigated in part by the policy design (e.g. allowing existing patients to continue their treatment) and in part through provision of support through the NHS and the voluntary sector and guidance provided to patients and their families, prescribers and pharmacists."

The Cass Review

189. I do not accept the Claimants' submission that the First Defendant should have commissioned bespoke clinical advice and/or a high-grade scientific assessment based on the latest scientific data[9] because the Cass Report did not provide a sufficient evidential basis upon which the First Defendant could conclude that puberty blockers caused a serious danger to health that required immediate action.

[9] *Health Stores*, per Sedley LJ at [67].

190. As I have described at paragraphs 28 to 33 above, the Cass Review conducted an intensive review of existing research and commissioned further research, over a number of years. In Chapter 1, headed 'Methodology', the Review described the approach taken, at paragraph 1.1, stating that the Review "has to be grounded in a thorough examination of the most robust existing evidence. To support this, we commissioned systematic reviews on a range of issues from epidemiology through to treatment approaches, and international models of current practice". At paragraph 1.11, the Review explains that the Review "has sought to better understand the existing evidence, as well as fill some of the gaps through qualitative and quantitative research".

191. The University of York was commissioned to deliver an independent research programme, whose aim was "to provide the Review with the best available collation of published evidence relevant to epidemiology, clinical management, models of care and outcomes, and to understand the experiences and perspectives of service users, their families and clinicians" (paragraph 1.12). Evidence of international guidelines and clinical practice in international healthcare systems was appraised. Table 1 in Chapter 1 sets out an overview of the academic research programme commissioned by the Cass Review.

192. The Cass Review also received a high level of clinical input in a variety of forms (paragraph 1.52) and a Clinical Expert Group was established to consider the strength of the evidence and assist the Cass Review in achieving clinical consensus where evidence was not available or limited (paragraph 1.53).

193. Ms Sacks explained, at (GS/16):

> "Given the rigorous evidential reviews and research upon which the Cass Review's final report was based, and particularly in light of the low quality of the existing evidence in this area prior to the Cass Review, the recommendations contained in the final report were considered by the Department to constitute the most appropriate and sufficiently evidence-based clinical guidance upon which to base policy decisions in this area."

194. In my view, the First Defendant was entitled to conclude that the Cass Review was the best and most up-to-date scientific evidence available, and further research on the effects and safety of puberty blockers for children and young people was not required.

195. I refer to the Interim Report, dated February 2022, and Dr Cass's letter of 22 July 2022, which I summarise at paragraphs 33 to 37 above. Key passages in the Final Report are at paragraphs 39 to 42 above. The benefits and risks of puberty blockers were considered in Chapter 14 of the Final Report. The conclusion was that any benefits of puberty blockers were (save in one "very narrow" respect) unproven or non-existent.

196. Puberty blockers were first used with the intention of pausing development to allow patients to "buy time to think" and lead to better cosmetic outcomes. But the evidence was that puberty blockers were not "buying time to think" (paragraph 14.25); and neither of the two studies looking at gender dysphoria and body satisfaction reported any change before and after puberty suppression (paragraph 14.26).

197. There was insufficient and/or inconsistent evidence about the effects of puberty suppression on psychological or psychosocial health (paragraphs 14.27 – 14.29). Blocking hormonal surges might dampen distress in the short-term, but that might not be an appropriate response to pubertal discomfort: paragraph 14.51.

198. It was unclear how helpful puberty blockers were in improving "passing" in adult life. They did not seem to lead to substantially reduced height in transgender females or increased height in transgender males: paragraphs 14.30-14.32.

199. There was "a very narrow indication for the use of puberty blockers" for transgender females, to stop irreversible pubertal changes such as a lower voice and facial hair; but that needed balancing against adequacy of penile growth for vaginoplasty. Any other benefits remained unproven: paragraphs 14.57-14.58.

200. The Final Report also "set out the very complex events that take place in the adolescent brain during puberty. Neuroscientists believe that these changes are driven by a combination of chronological age and sex hormones. Blocking the release of these sex hormones could have a range of unintended and as yet unidentified consequences": paragraph 14.35. Such risks included that:

    i) "There is no way of knowing whether the normal trajectory of the sexual and gender identity may be permanently altered [by the use of puberty blockers]" (paragraph 14.37).

    ii) "A further concern…is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by the use of puberty blockers, which could have a significant impact on the young person's ability to make complex risk-laden decisions, as well has having possible longer-term neuropsychological consequences." (paragraph 14.38). There was very limited research on this: paragraphs 14.39-14.40.

    iii) Puberty suppression started too early in birth-registered males could make subsequent vaginoplasty more difficult (paragraph 14.41).

    iv) Multiple studies had found that bone density is compromised during puberty suppression and height gain may lag behind that seen in other adolescents. Much more longer-term follow-up was required to determine whether there was full recovery in adulthood (paragraph 14.43).

    v) The same was true of other short-term physical effects of puberty suppression, with little knowledge about whether it leads to any long-term effects, such as on metabolic health and weight (paragraph 14.44).

201. A known side effect of puberty blockers was to reduce psychological functioning (paragraph 14.52).

202. The Final Report considered the strongly-held belief that gender-affirming treatment reduces suicide risk. It noted widespread fear in parents and clinicians that delayed

access to medical treatment might lead to suicidal thoughts and behaviours (paragraph 15.43). It observed nevertheless that suicide risk in the cohort of children and young people with gender dysphoria remained comparable to other young people with a similar range of mental health and psychosocial challenges, and the evidence did not support the conclusion that gender-affirming treatment reduced suicide risk: paragraphs 15.36-15.43.

203. The Interim Report was critical of the service provided by GIDS, and it led to the closure of the Tavistock, as it was no longer safe or viable, to be replaced by a different service model. In her Foreword, Dr Cass observed that:

> "Some practitioners abandoned normal clinic approaches to holistic assessment, which has meant that this group of young people have been exceptionalised compared to other young people with similarly complex presentations. They deserve very much better."

204. The Final Report concluded that "the adoption of a treatment with uncertain benefits without further scrutiny is a significant departure from established practice" (paragraph 23).

205. Paragraph 84 of the Final Report confirmed the Cass Review's earlier conclusion that, because puberty blockers only had clearly defined benefits in quite narrow circumstances, and because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, they should only be offered under a research protocol. The Final Report also recommended that every patient considered for treatment should be discussed at a national multi-disciplinary team.

206. The Cass Review's proposal to restrict access to puberty blockers was adopted by NHS England on 12 March 2024. Its revised policy states that the NHS in England will not routinely prescribe puberty blockers because there is not enough evidence to support their safety or clinical effectiveness to make the treatment routinely available (subject to any applications for individual funding).

207. The research protocol has not yet been established. However, it will, in all likelihood, mean that access is only available under tightly controlled circumstances to a limited number of patients who meet the research specification.

208. The RCGP published an updated position statement dated 26 April 2024 advising GPs that they should not prescribe puberty blockers to children and young people, unless they have particular expertise or an extended role in the area of transgender care, on the basis of the findings in the Cass Review.

209. The GPhC, in response to the Interim Report from the Cass Review, issued guidance to pharmacists dispensing prescriptions for puberty blockers to children and young people, dated January 2023.

210. In my judgment, the Cass Review's findings about the very substantial risks and very narrow benefits associated with the use of puberty blockers, and the recommendation that in future the NHS prescribing of puberty blockers to children and young people should only take place in a clinical trial, and not routinely, amounted to powerful

scientific evidence in support of restrictions on the supply of puberty blockers on the grounds that they were potentially harmful. Although the Cass Review did not state in terms that puberty blockers cause "a serious danger to health", that was not the question that the Cass Review was asked to consider. That was a matter for the Defendants to determine on all the evidence before them. It would have been premature to do so before the Final Report had been published.

The decision

211. The fact that the Cass Review's findings and recommendations had been acted upon by NHS England, the RCGP and the GPhC gave them considerable further weight. On 11 April 2024, the Chief Executive Officer of NHS England wrote to the First Defendant informing her of the concerns about the private prescribing of puberty blockers which were widely-shared, including by GPs, pharmacists, and organisations representing primary care. She considered that these required Ministerial action such as legislation to curtail private prescriptions from within the EEA.

212. I refer to the concerns in the DHSC about EEA/Swiss prescribers at paragraphs 43 to 51 above. They pre-dated the Final Report and were widely held among professional bodies. The Cass Review stated at paragraph 19.39 that it "understands and shares the concerns about the use of unregulated medications and of providers that are not regulated within the UK". In Recommendation 27 it advised the DHSC to "consider other statutory solutions that would prevent inappropriate overseas prescribing". NHS England urged further legislative action "to close this loophole which also poses a risk to patient safety", in its letter dated 11 April 2024.

213. Critical reports about the practice of GenderGP, the main EEA prescriber for UK children and young people aged under 16, escalated in 2024. Then following the publication of the Cass Review, GenderGP issued a series of social media reports, describing it as "an unethical and unscientific document", and made clear their intention to continue to issue prescriptions.

214. Following the publication of the Final Report on 10 April 2024, the First Defendant was of the opinion that the evidence was sufficiently concerning to require an urgent change to the law, to avoid serious danger to health by preventing private and overseas prescriptions being issued to children and young people in the UK, which would evade the restrictions recommended by the Cass Review and implemented by NHS England. The Claimants submit that there was no justification for seeking to align private prescribing practice with NHS practice. However, section 62 MA 1968 is not confined to NHS prescribing and it was reasonable to impose restrictions on private prescribing as well.

215. On 15 April 2024, the First Defendant delivered an Oral Statement in the House of Commons stating that she was "looking closely at what can be done to curtail any loopholes in prescribing practices, including legislative options".

216. The decision-making process is summarised at paragraphs 61 to 100 above. DHSC officials provided the First Defendant with full and detailed advice, in Ministerial Submissions and meetings, which identified the options, the risks and possible unintended consequences. She was advised of the criteria which applied under section

62(1) and (3) MA 1968. On my reading of the material, I consider that the First Defendant was both proactive and responsive in her approach to the complex issues that had to be determined.

217. Medicines and healthcare in Northern Ireland are devolved matters, and it was not possible to make an emergency order covering Northern Ireland for the reasons explained by Ms Sacks at GS/131-133.

218. In regard to timing, the First Defendant reasonably considered that it was essential to make the Order as soon as possible to protect children and young people from irresponsible prescribing of puberty blockers by EEA providers, such as GenderGP, contrary to the recommendations of the Cass Review. The standard procedure, under which the CHM would conduct a consultation procedure and then provide advice, was estimated to take between 5 and 6 months. In my view, it was rational for the First Defendant to decide that it was essential to adopt the emergency procedure to avoid serious danger to the health of children and young people who would otherwise be prescribed puberty blockers during that 5 to 6 month period. Under the emergency procedure, there is no requirement to hold a consultation procedure.

219. DHSC officials believed that, if there was a delay between the announcement of the Order and the date it came into effect, patients would rush to "beat the ban" and try to initiate treatment, knowing that they would be allowed to continue once treatment had begun. In my view, it was reasonable for the First Defendant to accept this advice. It would be an obvious reaction by supporters of puberty blockers to the news of an impending ban.

220. On 23 May 2024, the First Defendant delivered an Oral Statement to the House of Commons stating:

> "I have also made it my priority to protect our children, who have been questioning their identity in ever increasing numbers. The Cass review laid bare the damaging effect that social media and degrading pornography have had on young people's sense of self. It also set out clearly the need for extreme caution in medical interventions. Today, I want to set out my clear intention to introduce a banning order on puberty blockers, with limited exceptions, under section 62 of the Medicines Act 1968. This is an extraordinary use of that power, but it is the right use of that power because we must protect our children and young people from this risk to their safety.[10]"

221. There was cross-party support for this approach as the then Shadow Secretary of State for Health and Social Care (Mr Wes Streeting) said in response to the Statement:

---

[10] Hansard, HC Deb 23 May 2024, vol. 750 col. 1045.

> "I also welcome what she said about the justifiably cautious and responsible approach she is taking in relation to puberty blockers in the light of the Cass report."

222. The First Defendant was briefed about the mental health risks for children and young people if their current treatment with puberty blockers was abruptly terminated (e.g. meeting 9 May 2024, Ministerial Submission 24 May 2024, risk assessment 28 May 2024). The First Defendant agreed that an exception to the ban for this cohort should be inserted into the Order. DHSC officials were also concerned that patients who had used an EEA prescriber might have difficulty in finding a UK prescriber for future prescriptions, if needed. Ms Sacks advised in the risk assessment of 28 May 2024:

> "We are endeavouring to mitigate this risk by: ensuring prescribing routes remain open for existing users, planning for wide communications to the health system and patients about the support available to this group of patients, and asking the NHS to signpost to and prepare mental health and crisis support services …."

223. In my view, it was reasonable for the First Defendant to conclude that the terms of the Order in regard to this cohort met the requirements of section 62(1) and (3) MA 1968. An exception to the ban had been granted, but it was essential to prevent continued prescribing by EEA prescribers to avoid serious danger to health as they would not comply with the recommendations of the Cass Review adopted by NHS England and the UK professional bodies. As Ms Sacks explains in her witness statement at GS/103 – 104 and GS/115, there was clear evidence that, in practice, pharmacists were not able to verify the identity of EEA prescribers and the reasons for the prescription.

224. Contrary to the Claimants' submissions, this exception did not undermine the case for the Order. It demonstrated that the First Defendant had given careful thought to the balance of risks and benefits for young people who were already on a course of treatment, where there might be mental health issues associated with stopping a course of treatment, and concluded that it was different to the balance for young people who had not already been prescribed puberty blockers.

225. In my view, it was appropriate and reasonable for the First Defendant to decide, on the advice of her officials, that the future care of this cohort should be undertaken by UK registered GPs and mental health services for young people. Clearly, each patient would need an individualised assessment to determine the best way forward.

226. The Claimants criticised the First Defendant for not undertaking further investigations and consultation prior to making the Order, to ascertain the availability of medical support for this cohort. In my view, further investigations and consultation at this stage would have been unlikely to have made any difference. It would not have been possible to ascertain the responses of GPs to individual requests for prescriptions in advance of the Order being made. NHS England and DHSC officials were already aware of the difficulties and warned the First Defendant of them. The First Defendant made a lawful judgment as to the scope of the exception for this cohort, taking into account the advice about potential difficulties.

227. I recognise that the Claimants' evidence does show that this cohort has had difficulties in obtaining access to UK registered GPs and mental health services since the Order was made. In my view, this is essentially an issue about achieving a successful implementation of the new scheme, not the lawfulness of the Order. NHS England and the DHSC should consider how implementation can be improved as soon as possible, and in any event, before the next Order is made. This may require additional resources to be made available to this cohort. I note the commitments which Ms Sacks set out, at GS/154:

> "154. Given the emergency nature of the Order and the short timeframe in which these measures were necessarily implemented, the production, development and refinement of guidance and other measures to mitigate any negative impacts of the Legislation will necessarily be an iterative process. It will be informed by continuing monitoring and evaluation of the impacts of the order through continued engagement with the NHS, professional leaders and professional regulators, and monitoring of available prescribing data."

228. In conclusion, applying the heightened test of anxious scrutiny, I am satisfied that the decision to make the emergency Order on 29 May 2024, was a rational one, for the reasons set out above. Parliament has entrusted the Ministers to exercise the powers in section 62 MA 1968, in the exercise of their discretionary judgment. This decision required a complex and multi-factored predictive assessment, involving the application of clinical judgment and the weighing of competing risks and dangers, with which the Court should be slow to interfere.

229. For these reasons, Ground 1 does not succeed.

Ground 2

230. Under Ground 2, the Claimants submitted that, even if the First Defendant was entitled to utilise the emergency procedure under section 62(3) MA 1968, she ought to have undertaken a prior consultation with C1 or any similar organisation which represented the interests of patients potentially affected by the Order and the Regulations. Instead, she undertook a partial, unfair and unlawful consultation, consulting a number of other individuals and bodies but not C1 or other similar organisations.

231. The Claimants submitted that the position was directly comparable to that in *R (Article 39) v Secretary of State for Education* [2020] EWCA Civ 1577, at [85], where the Court of Appeal held that it had been conspicuously unfair not to have consulted bodies representing the rights and interests of vulnerable children in the care system on proposed legislation which would have a substantial impact on them. However, in that case no "in-principle" decision had been taken at the relevant time, and there was no statutory exemption from consultation.

232. It was common ground that, if the First Defendant voluntarily undertook a consultation, it would trigger the obligation to do so properly. In *R v North and East Devon Health Authority ex parte Coughlan* [2001] QB 213, Lord Woolf MR held, at [108]:

> "108 It is common ground that, whether or not consultation of interested parties and the public is a legal requirement, if it is embarked upon it must be carried out properly. To be proper, consultation must be undertaken at a time when proposals are still at a formative stage; it must include sufficient reasons for particular proposals to allow those consulted to give intelligent consideration and an intelligent response; adequate time must be given for this purpose; and the product of consultation must be conscientiously taken into account when the ultimate decision is taken: *R v Brent London Borough Council, Ex p Gunning* (1985) 84 LGR 168."

233. However, I accept the First Defendant's submission that there was no consultation prior to the legislation being made. In early May 2024, the DHSC had discussions with stakeholders (CQC, GPhC, GMC, RCGP and NHS England) about the response to the Cass Review and implementation of its recommendations (see the witness statement of Ms Sacks at GS/95-98). This was part of the normal exchange of views between the First Defendant and regulators and NHS bodies. It could not be characterised as a consultation.

234. Following the announcement of the general election, the First Defendant made the "in-principle" decision to enact the Order on 22 or 23 May 2024, and she announced it in Parliament on 23 May 2024. From that date, her thinking was no longer at a formative stage, and so a *Gunning* compliant consultation would not have been possible.

235. After her decision, she conducted a truncated engagement exercise with stakeholders aimed at refining and ensuring the smooth implementation of the Order. The exercise was described as "consultation" at the time and in the EM, but the label used was not determinative, and did not entail legal consequences. See *R (Eveleigh) v Secretary of State for Work and Pensions* [2023] 1 WLR 3599 at [81], per Elizabeth Laing LJ).

236. The undertaking of limited voluntary engagement after an "in principle" decision has been taken does not attract the application of the *Gunning* criteria, because such engagement cannot amount to a lawful consultation. See *R (Association of Personal Injury Lawyers) v Secretary of State for Justice* [2013] EWHC 1358 (Admin), at [37], [44] – [46] per Elias LJ; *R (FDA) v Minister for the Cabinet Office* [2018] EWHC 2746 (Admin), at [103], per Simler J..

237. The position was confirmed in the subsequent exchange of correspondence between the BMA and the Permanent Secretary at the DHSC. On 21 June 2024, the BMA wrote to complain about the inaccurate reference in paragraph 7.2 of the EM to consultation with the BMA, along with other organisations. The letter stated:

> "On 24 May 2024, the BMA's general practitioner committee chair and a member of staff were contacted via email by DHSC civil servants with a request to meet on 28 May 2024 for an "urgent discussion" following the [First Defendant] informing the House of Commons of her intention to introduce a "banning order on puberty blockers" the previous day.

> At this meeting the DHSC civil servants provided details of the process of how the banning order was intended to be introduced and its scope. BMA members of staff raised a small number of questions for clarification. No views were formally sought, or provided, from the BMA. To describe this meeting as a "consultation" is, we believe, wholly inappropriate and misleading. I repeat my request to you to correct the record where this has been stated."

238. A reply dated 9 July 2024, sent by the Government Legal Department on behalf of the Permanent Secretary stated as follows:

> "…. Organisations such as yours were spoken with about the SoS's intentions to understand the implications of restrictions on, for example, vulnerable children. Officials were not seeking the BMA or other organisations' views on the rationale for the introduction of the legislation – as the Secretary of State already had a clear view on their appropriateness – but, given the BMA's expertise, officials sought to understand any risks from its introduction and how they could be mitigated.
>
> We accept that this was not a formal consultation exercise, but a matter of informally seeking views of stakeholders. It did not occur while the Secretary of State's thinking was at a "formative stage", and it did not involve provision of the sort of information, or time for response, which would be expected in a formal consultation exercise. Furthermore, as stated in paragraph 5.18 of our response to the pre-action letter from Russell Cooke, with regard to the engagement with BMA and others on the emergency prohibition order: 'Nothing in that process fell to be treated as amounting to "consultation".'
>
> On that basis, the Department accepts that it would have been preferable not use the word "consultation", rather than simply to state that this was a process of informal engagement.
>
> Subject to confirmation by new Ministers, a revised EM will be published in due course alongside SI 2024/727 and 728. In the meantime, we are of course happy for you to refer publicly to this clarification, if you are minded to."

239. Furthermore, I accept the First Defendant's submission that there is an exemption from the consultation requirements in section 62(5) MA 1968 when the emergency procedure is followed: see section 62(6) and 129(6) MA 1968. In those circumstances, a common law duty to consult cannot be implied. In my view, this is a complete answer to this ground of challenge, and so I do not go on to consider the submissions made in the alternative.

240. For these reasons, Ground 2 does not succeed.

Ground 3

241. Under Ground 3, C2 submitted that the First Defendant acted in breach of Article 8 ECHR by failing to consult or involve C2, or organisations who would represent her interests, prior to making the Order and the Regulations which had substantial implications for her medical treatment by potentially preventing her from being prescribed puberty blockers.

242. C2 stated that her claim was limited to her procedural rights. She did not claim that the legislation amounted to a breach of her substantive Article 8 rights. However, she submitted that the effect of the legislation was to interfere with her Article 8(1) rights because it restricted the prescribing of puberty blockers. The First Defendant will only have acted lawfully in making the legislation if the interference complies with the requirements of Article 8(2) ECHR, and in particular the First Defendant must show that her decision was "necessary in a democratic society".

243. In response, the First Defendant accepted that Article 8(1) ECHR was engaged but contended that the limitations on the supply of puberty blockers did not breach any substantive or procedural rights under Article 8. Under domestic law, there was no obligation to consult before legislating in a way that affected Article 8 rights.

244. ECtHR case law recognises that issues of gender identity are likely to engage Article 8 ECHR. Most recently, in *WW v Poland* (Application no. 31842/20), which concerned a prisoner who was refused hormone replacement therapy associated with gender reassignment whilst in prison, the ECtHR held:

> "82. The Court reiterates that the concept of "private life" is a broad term not susceptible to exhaustive definition. It includes not only a person's physical and psychological integrity but can sometimes also embrace aspects of an individual's physical and social identity. Elements such as gender identity or identification, names, sexual orientation and sexual life fall within the personal sphere protected by Article 8 of the Convention (see, in particular, Van Kück, cited above, § 69 and Schlumpf v. Switzerland, no. 29002/06, § 77, 8 January 2009, and the references cited therein)."

245. The Article 8 right to respect for private life, in particular as it safeguards the autonomy of individuals, has been recognised in the context of medical treatment, such as prohibition of abortion (*A, B, C v Ireland* [2011] 53 EHRR 13, at [214]) and failure to warn a patient of the risk of a vaginal delivery and the option of delivery by caesarean section (*Mongomery v Lankarkshire Health Board* [2015] AC 1430, at [80]).

246. C2 relied on two authorities concerning procedural rights under Article 8. In *R (B) v The Combined Court at Stafford* [2006] EWHC 1645 (Admin), the Divisional Court held that the Article 8 rights of a 14 year old prosecution witness had been infringed by the Court's failure to comply with procedural fairness by not notifying her, or giving her an opportunity to make representations, before ordering disclosure of her medical records to the defence. May LJ said, at [23]:

> "… although Article 8 contains no explicit procedural requirements, the court will have regard to the decision making process to determine whether it has been conducted in a manner that, in all the circumstances, is fair and affords due respect to the interests protected by Article 8. The process must be such as to secure that the views of those whose rights are in issue are made known and duly taken account of. What has to be determined is whether, having regard to the particular circumstances of the case and notably the serious nature of the decisions to be taken, the person whose rights are in issue has been involved in the decision making process, seen as a whole, to a degree sufficient to provide them with the requisite protection of their interests. If they have not, there will be a failure to respect their family life and privacy and the interference resulting from the decision will not be capable of being regarded as "necessary" within the meaning of Article 8."

247. C2 also referred to *Verein KlimaSeniorinnen Schweiz v Switzerland* (2024) 79 EHRR 1, at [553]-[554], concerning the State's failure to take steps to address climate change, where the ECtHR held that "[p]rocedures must be available through which the views of the public, and in particular the interests of those affected or at risk of being affected by the relevant regulations and measures or the absence thereof, can be taken into account in the decision-making process". C2 submitted that this case demonstrated that procedural rights were not limited to individuals and applied in the case of legislation.

248. However, as the First Defendant rightly submitted, the ECtHR has never found that a State has breached Article 8 by refusing to authorise a particular type of medical treatment, even at an individual level, still less as a matter of general policy. It has repeatedly held that matters of healthcare policy fall within the State's margin of appreciation, and the type of complex ethical or resourcing issues entailed in such policy decisions are not ones which should be second-guessed by the Court. See *Hristozov v Bulgaria* (app. 47039/11, 13 November 2012) at [105] – [122] (challenge to the refusal to allow the use of an experimental anti-cancer drug); *Shelley v United Kingdom* (app. 23800/06, 4 January 2008) at pp. 10-12; *Sentges v Hungary* (app. 27677/02) at pp. 6-7.

249. In *R (Condliff) v North Staffordshire PCT* [2011] EWCA Civ 910, [2011] HRLR 38, the claimant's challenge to a refusal of NHS funding for gastric by-pass surgery was refused under Article 8. Toulson LJ held:

> "36. Private and family life are very broad concepts. There is no doubt that Mr Condliff's state of health is having a seriously adverse effect on his private and family life in the most basic ways, which without bariatric surgery will continue and is likely to become worse. However, harsh as this must seem to Mr Condliff, I do not see that the application of the IFR policy involves a lack of respect for Mr Condliff's private and family life. The policy of allocating scarce medical resources on a basis of the comparative assessment of clinical needs is intentionally non-discriminatory. The statutory function of the PCT is to use the limited resources provided to it for the purposes of the

provision of healthcare, i.e. services in connection with the prevention, diagnosis and treatment of illness. To perform that function by allocating those resources strictly according to the PCT's assessment of medical need, i.e. an assessment based on clinical factors, is to do no more than to apply the resources for the purpose for which they are provided without giving preferential treatment to one patient over another on non-medical grounds.

…

41. Although the Strasbourg Court has recognised that in principle article 8 may be relied on to impose a positive obligation on a state to take measures to provide support for an individual, including medical support, there is no reported case in which the court has upheld such a claim by an individual complaining of the state's non-provision of medical treatment. Attempts have been made, but they have been unsuccessful. I would adopt the summary given by Lord Brown in *R (McDonald) v Royal Borough of Kensington and Chelsea* [2011] UKSC 33. In that case the Supreme Court rejected a claim that the defendant local authority was in breach of article 8 by failing to provide the claimant with the level of care which she felt was necessary for the maintenance of her basic human dignity.

42. Lord Brown said:

> "15. Article 8 is too well known to require citation again here. There is no dispute that in principle it can impose a positive obligation on a state to take measures to provide support and no dispute either that the provision of home-based community care falls within the scope of the article provided the applicant can establish both (i) "a direct and immediate link between the measures sought by an applicant and the latter's private life" – *Botta v Italy* (1998) 26 EHRR 241, paras 34 and 35 – and (ii) "a special link between the situation complained of and the particular needs of [the applicant's] private life": *Sentges v The Netherlands* (2003) 7 CCLR 400, 405.
>
> 16. Even assuming that these links do exist, however, the clear and consistent jurisprudence of the Strasbourg Court establishes "the wide margin of appreciation enjoyed by states" in striking "the fair balance … between the competing interests of the individual and of the community as a whole" and "in determining the steps to be taken to ensure compliance with the Convention", and indeed that "this margin of appreciation is even wider when … the issues involve an assessment of the priorities in the context of the allocation of limited state resources" – *Sentges*, at p 405, *Pentiacova v Moldova* (Application No 14462/03

> (unreported) 4 January 2005, p 13) and *Molka v Poland* (Application No 56550/00 (unreported) 11 April 2006, p 17). Really one only has to consider the basic facts of those three cases to recognise the hopelessness of the article 8 argument in the present case. *Sentges* (considered by Rix LJ at para 64 of his judgment) concerned a sufferer from muscular dystrophy complaining of a refusal to supply him with a robotic arm. Without it he depended on others for every single act and so was unable to develop and establish relationships with others; with it, his "severely curtailed level of self determination would be increased": 7 CCLR 400, 404. The applicants in *Pentiacova* suffered from renal failure and complained of insufficient funding for their haemodialysis treatment. The applicant in *Molka* was confined to a wheelchair and, for want of positive assistance, was unable to vote in local elections. The complaints in all three cases were unanimously held to be manifestly ill-founded and thus inadmissible.""

250. Applying these principles to this case, I consider it very unlikely that the Order and Regulations would be found to be in breach of C2's substantive Article 8 rights, if that submission were to be pursued.

251. C2's submission, if upheld, would mean that the Government would have to undertake a public consultation exercise whenever it proposed to legislate in a way which potentially affected the Article 8 rights of individuals. I accept the First Defendant's submission that this would impose a far-reaching and uncertain obligation and I reject C2's submission for the following reasons.

252. First, section 62 MA 1968 read with section 129(6) MA 1968, expressly provides for consultation of organisations that are representative of interests likely to be substantially affected. Parliament clearly excluded consultation of individuals.

253. Second, there is an exemption from the consultation requirement in section 62(5) MA 1968 when the emergency procedure is followed: see section 62(6) and 129(6) MA 1968.

254. Third, in *R (Bapio) v Secretary of State for the Home Department* [2007] EWCA Civ 1139, where the Court of Appeal rejected a claim that the Home Secretary should have consulted those potentially affected before amending the Immigration Rules, Maurice Kay LJ held (Rimer LJ agreeing):

> "58….. as a matter of principle, I consider that where Parliament has conferred a rule-making power on a Minister of the Crown, without including an express duty to consult, but subject to a Parliamentary control mechanism such as the negative resolution procedure, it is not generally for the courts to superimpose additional procedural safeguards."

255. The *Bapio* principle applies equally where Parliament has made provision for a limited duty to consult in certain circumstances only. It is not for the Courts to impose an additional duty to consult.

256. For these reasons, Ground 3 does not succeed.

Final conclusion

257. Permission to apply for judicial review is granted on Grounds 1 to 3. The claim for judicial review is dismissed on Grounds 1 to 3.