Case No: AC-2024-LON-002062

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

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**

The Judgment and Press Summary are embargoed until 11 am on Monday, 29 July 2024 when the Approved Judgment will be handed down

PRESS SUMMARY

1. The Administrative Court has dismissed the Claimants' challenge to the lawfulness of secondary legislation which limits the prescription and 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 secondary legislation

2. The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024/727 ("the Order") is a temporary order, made by the First and Second Defendants, with effect from 3 June 2024, using emergency powers. It expires on 2 September 2024. It only applies to England, Wales and Scotland (not Northern Ireland).

3. In summary, the effect of the Order is 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, in the Regulations referred to in paragraph 4 below, and in NHS England'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). The only exception to this is that NHS primary care bodies can prescribe on an individual basis outside the General Medical Services Contract.

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".

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

5. In summary, the effect of the Regulations is to 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.

6. 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.

The Court's conclusions on the grounds of challenge

Ground 1

7. The First Defendant was entitled to conclude, under section 62 of the Medical Act 1968 ("MA 1968"), that it was "necessary to make the Order in the interests of safety" (subsection (1)), and that it was "essential to make the order with immediate effect to avoid serious danger to health" (subsection (3)).

8. The findings of the Cass Review about the very substantial risks and very narrow benefits associated with the use of puberty blockers, and its recommendation that in future they should be prescribed in a clinical trial, and not routinely prescribed, amounted to powerful scientific evidence in support of restrictions on the supply of puberty blockers on the grounds that they were potentially harmful. The fact that the Cass Review's findings and recommendations had been acted upon by NHS England, the Royal College of GPs and the General Pharmacy Council gave them considerable further weight.

9. 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, contrary to the recommendations of the Cass Review, NHS England policy, and the guidance from professional bodies. The standard consultation procedure under MA 1968 takes 5 to 6 months. 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.

10. The First Defendant concluded that children and young people who were already being prescribed puberty blockers should be exempt from the Order and the Regulations, because of the adverse psychological impact of treatment withdrawal. She made an appropriate and reasonable decision that the future care of this cohort should be undertaken by UK registered GPs and mental health services for young people, not by overseas providers who were not regulated by the UK and who had indicated that they

would not comply with the recommendations of the Cass Review and the UK professional bodies.

11. However, in the light of the Claimants' evidence, the Judge found that more needed to be done to assist this cohort to access UK registered health services and NHS England and the Department for Health and Social Care should consider how this could be achieved 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.

Ground 2:

12. Under section 62 Medical Act 1968, there is an exemption from the consultation requirements when the emergency procedure is followed, as it was in this case. In those circumstances, a duty to consult could not be implied. On the evidence, the First Defendant did not undertake a voluntary "consultation".

Ground 3:

13. The absence of a consultation did not breach the Second Claimant's procedural rights under Article 8 of the European Convention on Human Rights.