E: medicines.policy@gov.scot



Dear Colleague,

UK Government restrictions on the use of Puberty Suppressing Hormones (Puberty Blockers); additional information for prescribers and pharmacists/dispensing doctors

Overview

On 29 May 2024, the UK Government introduced emergency restrictions on the use of **gonadotrophin releasing hormone (GnRH) analogues** when prescribed to suppress puberty as part of treating gender incongruence and/or gender dysphoria in children and young people who are under 18 years of age.

The First Emergency Order commenced on 3 June and expired at the end of 2 September. Two further orders were laid with the Second Emergency Order commencing in Northern Ireland on 27 August and in Great Britain on 3 September – it expired across the UK at the end of 26 November. The Third Emergency Order came into force from 27 November 2024 in the UK and expired on 31 December 2024.

Following a targeted consultation and advice from the Commission on Human Medicines (CHM), the UK Government laid <u>legislation</u> on 11 December 2024, which came into effect on 01 January 2025, that put in place an indefinite ban. In line with the CHM recommendations, there will be a review of the Order, in consultation with the CHM recommendations, this is expected to start in April 2027, with a report to be published by the end of October 2027. The UK Government's announcement is published here: <u>Ban on puberty blockers to be made indefinite on experts' advice - GOV.UK.</u>

The arrangements apply to medicines that consist of or contain buserelin, gonadorelin, goserelin, leuprorelin acetate, nafarelin, or triptorelin. This includes, but is not limited to, medicines sold under the brand names: Decapeptyl[®], Gonapeptyl Depot[®], Salvacyl[®], Prostap[®], Staladex[®], Zoladex[®], Synarel[®].

From the Chief Medical Officer for Scotland Professor Sir Gregor Smith

The Chief
Pharmaceutical Officer
Professor Alison Strath

22 May 2025

SGHD/CMO(2025)9

Addresses

For action
Medical Directors
Directors of Pharmacy
Directors of Nursing
Directors of Public Health
Heads of Psychology

Please cascade to:
All General Practices
All community pharmacies
Any healthcare professionals
involved in providing Gender
Identity services

Further Enquiries to:

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Background

The introduction of these restrictions by the UK Government is in response to the <u>Cass Review</u> which was commissioned by NHS England to make recommendations on how to improve NHS gender identity services it commissions 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, and that is safe, holistic and effective.

The Cass Review highlighted that the evidence base for prescribing GnRH analogues to suppress puberty is poor and the risk of short- or long-term harm is uncertain. Amongst its recommendations the review concluded that the UK Government should consider statutory solutions that would prevent inappropriate overseas prescribing of puberty suppressing hormones to children and young people. In addition, Dr Cass highlighted a focus purely on puberty suppressing hormones and beliefs in their efficacy has meant that other treatment options, including alternative medicines, have not been studied or developed to support children and young people experiencing gender dysphoria.

On 5 July 2024, the Chief Medical Officer issued a report on the implications of the Cass review for Scotland, which supported the findings of the Cass review. The full report can be viewed here: Cass Review – implications for Scotland: findings report - gov.scot.

Prior to this, on 18 April 2024 NHS Greater Glasgow and Clyde (GGC) and NHS Lothian issued a joint statement highlighting that both Health Boards would pause any new prescribing of GnRH analogues via their Paediatric Endocrinology teams to children and young people under 18 years of age for the purpose of suppressing puberty as a treatment for gender dysphoria. It is important to emphasise that this was a decision made by the Health Boards, on clinical advice.

Children and young people who were already receiving these medicines for this purpose were not affected by the pause. All children and young people directly affected by this change in NHS prescribing were notified prior to the announcement. As a result of this position and the recent UK Government legislation, the only route to access puberty blockers for gender incongruence and/or gender dysphoria for children and young people under 18 years of age will be via clinical research within the NHS currently being established, unless treatment was started before 3 June 2024, in which case their treatment can continue.

NHS Research Study

In August 2024, following a period of engagement by Scottish Government officials and senior medical officers, the Scottish Government's Chief Scientist Office (Health) wrote to their UK Department of Health and Social Care (DHSC) counterpart to confirm that representatives from Scottish Government, NHS GGC and the University of Glasgow (as academic partner) were available to join the NHS England/National Institute for Health and Care Research (NIHR) long-term research study on puberty suppressing hormones, as a treatment option for gender incongruence/dysphoria.

This study was first announced by NHS England in summer 2022 and has now become a four nations research study into this treatment. It is currently expected to go-live i.e. recruit children and young people, in spring 2025. More details of the study will be shared as they become available.







Summary of the restriction changes

The restrictions mean it is a **criminal offence** for a doctor, pharmacist or any other individual to sell or supply a GnRH analogue to a child or young person under the age of 18 years other than in the specific circumstances described in this letter.

The restrictions affect private prescriptions for GnRH analogues authorised by non-UK registered and UK registered prescribers although the way in which they are affected differs depending on whether the prescriber is registered in the UK.

The most significant impact is on children and young people who were under the age of 18 years and were receiving a private prescription for a GnRH analogue for any reason from a prescriber who was in the European Economic Area (EEA) or Switzerland, but who was not UK registered. Community pharmacies are no longer able to dispense new private prescriptions, dated on or after 3 June 2024 for GnRH analogues from the EEA or Switzerland for anyone under 18 years of age.

Many other children and young people who began their treatment before the restrictions came into effect on 3 June 2024 were able to continue to receive their prescriptions. However, they and their families, are strongly advised to discuss with their prescriber the safety risks associated with GnRH analogues when prescribed for gender incongruence or gender dysphoria. Further information for children, young people, their families and carers can be found on NHS Inform.

Further information on the specific primary care prescribing scenarios can be found in the **annex** to this letter.

If a child or young person is unable to access further prescriptions from their usual provider, then they are being advised to speak to the GP in the first instance. GPs and members of their team should assess whether referral to the NHS gender identity clinic or for mental health support is appropriate.

The continuation of puberty supressing hormones can be considered where the GP feels competent to do so where confirmation that treatment has been underway in the six-month period before 3 June 2024.

Whilst puberty supressing hormones can be stopped without tailoring off or the need for any endocrine monitoring, individuals may benefit from psychological and potentially psychiatric support in view of the incidence of mental health presentations in some of these children and young people.

Private prescriptions by non-UK registered prescribers

From 3 June 2024, it has no longer been possible to sell or supply GnRH analogues to any child or young person under 18 years of age if the private prescription was dated on or after 3 June 2024, and the prescriber was registered in an EEA country or Switzerland but not the UK.

GnRH analogues could continue to be sold or supplied to any young person aged 18 years or over where the prescriber is registered in an EEA country or Switzerland but only where the person who is selling or supplying the medicine is able to verify the age and identity of the young person by seeing their UK birth certificate or a current national identity document.







Private prescriptions by UK registered prescribers

It continues to be possible to sell or supply GnRH analogues against private prescriptions by UK registered prescribers for any child or young person under 18 years of age provided that the prescription:

- is annotated "SLS" by the prescriber and includes the patient's age, or if the prescription was issued before 3 June 2024, the person who sells or supplies the medicine can verify the age of the patient by seeing their UK birth certificate or a current national identity document
- was issued for a purpose other than the treatment of gender incongruence or gender dysphoria; or the prescription is for the treatment of gender incongruence and/or gender dysphoria and the child or young person started treatment before 3 June 2024 and has had a prescription for a GnRH analogue in the six months prior to the ban coming into force (whether or not the prescription has been dispensed or the GnRH taken by the child or young person)

NHS prescriptions

It continues to be possible to sell or supply GnRH analogues on an NHS prescription under certain circumstances. For primary care, New Directions from the Scottish Ministers (published on 2 September 2024 and which took effect from 17 September 2024) set out further restrictions on the prescribing of GnRH analogues by General Practitioners (GPs) in the provision of General Medical Services. A similar restriction has been introduced in England and Wales. These Directions mean that GPs in Scotland are only able to supply prescriptions for GnRH analogues:

- if a young person is aged 18 years or over
- or the child or young person is under 18 years old, and the purpose of the prescription is for a medical condition other than gender incongruence or gender dysphoria
- or the child or young person is under 18 years old and has previously started treatment with these medicines, and for these purposes they will be treated as having started treatment if they have been issued with a prescription for these medicines since 3 December 2023, even if they have not yet started taking the medicines. The NHS prescription should be endorsed SLS by the prescriber
- or if the child or young person is under 18 years old and is being treated with a GnRH
 analogue as part of a clinical trial related to treatment for the purpose of puberty
 suppression in respect of gender dysphoria, gender incongruence or a combination
 of both.

These changes will also be reflected in the Drug Tariff and eventually also in GP prescribing and pharmacy dispensing IT systems, although this will take a little longer to implement. The advice of the Royal College of General Practitioners is that GPs should not routinely prescribe GnRH analogues for children and young people for the treatment of gender incongruence and/or gender dysphoria.

Whilst services need to meet holistic needs of children and young people, prescribing of GnRH analogues should only take place in the context of an individualised care plan overseen by a specialist gender identity service.

The General Pharmaceutical Council has published a resource for pharmacy professionals to support them in providing information, support and services to children and young people with gender incongruence and/or gender dysphoria; 'Gender identity services for children and young people: making compassionate, professional and ethical decisions' is available at:







Gender identity services for children and young people: making compassionate, professional and ethical decisions (pharmacyregulation.org)

Emergency supplies by pharmacies

Another effect of the emergency restriction is that an emergency supply of a GnRH analogue made under Regulations 224 (Emergency sale etc by pharmacist: prescriber unable to provide prescription) and 225 (Emergency sale etc by pharmacist: at patient's request) of the Human Medicines Regulations 2012, is no longer permitted.

Buying GnRH analogues from unregulated sources

Healthcare professionals should advise children, young people and their families not to buy GnRH analogues (or any other medicines) from unregulated sources such as the internet, friends or street dealers.

Possession of GnRH analogues is now a criminal offence where the individual had reasonable cause to know that the medicine had been sold or supplied in breach of the UK Government ban.

Where a child or young person is receiving GnRH analogues from unregulated sources or providers, a healthcare professional may conclude that safeguarding procedures may need to be explored.

Guidance on working with unregulated providers

This guidance also advises General Practitioners against entering into voluntary arrangements with unregulated providers in relation to hormone medication to children and young people aged under 18 years in response to gender incongruence / gender dysphoria.

A GP **should** refuse to support the private prescribing or supply of GnRH analogues.

A GP **should** refuse to support an unregulated provider in the prescribing or supply of alternative medication that may be used to suppress pubertal development.

A GP **should** refuse to support an unregulated provider in the prescribing of exogenous hormones.

A GP **should** always be prepared to refer a child or young person for an appropriate non-routine investigation under an NHS contract where there is a concern that the child or young person may come to harm as an outcome of a medication from unregulated sources. In all cases, safeguarding measures should be considered where the administration of a medicine from an unregulated source presents an immediate safety risk.

The hormone interventions referred to are:

- GnRH analogues and other medication that may be used to suppress pubertal development
- exogenous hormones (testosterone / oestrogen) used for the purpose of masculinisation or feminisation

This advice covers any unregulated provider operating in the field of gender dysphoria/gender incongruence for children and young people, including online providers. GPs are specifically cautioned against a voluntary arrangement with two unregulated providers who have published statements that oppose the restrictions that have been put in







place around the supply of GnRH analogues to children and young people under 18 years of age:

- GenderGP
- Anne Transgender Healthcare Ltd

Support for children and young people affected by this change

Some children and young people may be concerned or distressed by these changes. If they are already under Child and Adolescent Mental Health Services (CAMHS) or other mental health service they can contact their team for advice. If they are not, they may wish to contact their GP practice for advice.

Additional resources include:

- <u>Childline</u> provides a free, private and confidential service online and on the phone where you can talk about anything. They can be contacted on 0800 1111
- LGBT Youth Scotland can provide confidential advice and support, including one to one support and peer support, for those who are exploring their gender identity: <u>Get</u> Support - LGBT Youth Scotland
- Breathing Space offers free and confidential advice for people experiencing low mood, depression or anxiety, whatever the cause. They can be contacted on 0800 83 85 87, 6pm to 2am Monday to Thursday; and 6pm Friday through the weekend to 6am Monday. Calls to Breathing Space are free from landlines and from mobile networks. You can also access www.breathingspace.scot which provides a wide range of information and advice about coping with low mood, depression and anxiety
- <u>Samaritans</u> on 116 123 provide confidential non-judgemental emotional support, for people who are experiencing feelings of distress or despair, 24 hours a day
- <u>LGBT Health and Wellbeing</u> offer individual support and provide information. Their staff offer support in accessing healthcare as well as providing mental health support.

We hope this information provides a useful update.

Yours sincerely,

Gregor Smith Alison Strath

Professor Sir Gregor Smith Professor Alison Strath FRPharmS

Chief Medical Officer for Scotland Chief Pharmaceutical Officer







Annex PRESCRIBING SCENARIOS FOR PRESCRIBERS AND DISPENSERS

GnRH analogues as puberty suppressing hormones			
Patient group	Advice	Prescriber	Dispenser
Under 18 years and not previously prescribed a GnRH analogue for gender incongruence or gender dysphoria.	No under 18-year-old should be started on a GnRH analogue to supress puberty for gender incongruence or gender dysphoria either through the NHS or privately. The request should be declined but a referral to the NHS gender identity clinic or for mental health support as appropriate.	The initiation of a GnRH analogue is not possible for a child or young person under 18 years for gender incongruence or gender dysphoria including from a Gender Identity Clinic unless: 1) it is part of the future NIHR research study; or 2) the child or young person was referred to an NHS paediatric endocrinology team for assessment for their suitability for a GnRH analogue for gender incongruence or gender dysphoria on or before 31 March 2024. A UK registered private prescriber cannot initiate a new prescription from 3 June 2024 to a child or young person who has not yet started treatment in the six months prior to 3 June 2024.	Community pharmacies cannot dispense a new prescription for initiation of treatment issued by any prescriber, unless the child or young person under 18 years started treatment before the restrictions came into effect on 3 June 2024. This includes all prescriptions issued in the UK (NHS or private) and the European Economic Area (EEA) or Switzerland for a child or young person under 18 years.
Under 18 years and already being prescribed a GnRH analogue via the NHS for gender	Prescribing can continue with reference to the new Directions which set out further prescribing restrictions for GPs in the	If as part of a shared decision- making conversation on the risks a decision is made to continue treatment an NHS prescriber can continue to prescribe a GnRH	NHS prescriptions for continuation of existing treatment for a child or young person under 18 years are





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incongruence and/or gender dysphoria.	provision of General Medical Services. UK NHS prescribers are advised to ensure a child or young person under 18 years fully understands the risks of continuing to take a GnRH analogue for puberty suppression at the next available opportunity. These medicines can be stopped and do not need to be reduced gradually.	analogue for a child or young person under 18 years for puberty suppression. A GP10 prescription in primary care must be annotated SLS by the prescriber to satisfy the regulations.	not covered by the legislation. A GP10 prescription for continuation of existing treatment must be annotated SLS by the prescriber to be dispensed.
Under 18 years and already being prescribed a GnRH analogue by a UK-registered private prescriber in Great Britain for gender incongruence and/or gender dysphoria.	Prescribing can continue however UK registered private prescribers are advised to ensure a child or young person under 18 years fully understands the risks of continuing to take a GnRH analogue for puberty suppression at the next available opportunity. These medicines can be stopped and do not need to	If as part of a shared decision-making conversation on the risks a decision is made to continue treatment a UK registered private prescriber can continue to prescribe a GnRH analogue for a child or young person under 18 years for puberty suppression. New UK private prescriptions must be annotated SLS by the prescriber and include a person's age, if issued after 3 June 2024.	UK private prescriptions for continuation of existing treatment for a child or young person under 18 years must be annotated SLS by the prescriber and include a person's age to be dispensed. Prescriptions issued in the six months prior to 3 June 2024, can only be dispensed if proof of age and identity is
	stopped and do not need to be reduced gradually.	issued after 3 Julie 2024.	if proof of age and identity is produced.
Under 18 years and already being prescribed a GnRH analogue via a prescription from the	A child or young person under 18 years is advised to discuss with their prescriber the risks of continuing to take a GnRH analogue for	If a child or young person wants to continue treatment an NHS or private prescriber can continue to prescribe a GnRH analogue for a child or young person under 18	Prescriptions from EEA or Switzerland can no longer be dispensed to a child or young person under 18 years unless they were issued





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for gender incongruence and/or gender dysphoria.	puberty suppression at the next available opportunity. If they are already under Child and Adolescent Mental Health Services (CAMHS) or other mental health service they can contact their team for advice. If they are not, they may wish to contact their GP practice for advice. These medicines can be stopped and do not need to be reduced gradually.	years for puberty suppression following a shared decision-making conversation about the risks. NHS prescribers including GPs, are not obliged to do so and should only prescribe within their competence and scope of practice. An NHS or UK private prescription must be annotated SLS by the prescriber and include the person's age, if issued after 3 June 2024.	before 3 June 2024 and are still valid, and the dispenser has proof of age and identity.
18 years or older and being prescribed a GnRH analogue but has not started on gender affirming hormones.	Prescribing can continue however prescribers are advised to ensure a young person aged 18 years or older fully understands the risks of continuing to take a GnRH analogue for puberty suppression at the next available opportunity. These medicines can be stopped and do not need to be reduced gradually.	If as part of a shared decision-making conversation on the risks a decision is made to continue treatment prescribers can continue to prescribe a GnRH analogue for a young person aged 18 years or over for puberty suppression. An NHS or UK private prescription must be annotated SLS by the prescriber and should include their age.	An NHS or UK private prescription for continuation of existing treatment for a young person aged 18 years or older annotated SLS by the prescriber can be dispensed. If a private prescription is not annotated SLS and does not include their age then a young person may instead provide proof of age and identity. Prescriptions from the EEA or Switzerland can be dispensed if a young person is able to provide proof of



			age and identity. The prescription does not need to be annotated SLS.
GnRH analogues for conditions other than gender incongruence or gender dysphoria			
Under 18 years and already being prescribed a GnRH analogue for a licensed indication or for other reasons.	A child or young person receiving an NHS prescription or a private prescription from a UK registered private prescriber can continue to a receive a prescription for a GnRH analogue.	A GP or UK registered private prescriber can prescribe NHS or private prescriptions. An NHS or UK private prescription must be annotated SLS by the prescriber to confirm the prescription is for the treatment of a condition other than gender incongruence or gender dysphoria.	Both NHS and private prescriptions annotated SLS by the prescriber can be dispensed. Private prescriptions must include the patient's age. Private prescriptions issued by a UK registered prescriber which include the patient's age and which are annotated SLS may be dispensed. Prescriptions from the EEA or Switzerland for a GnRH analogue cannot be dispensed to a child or young person under 18 years.
Over 18 years and already being prescribed a GnRH analogue for a licensed indication or for other reasons.	A young person over 18 years can continue to receive a prescription for a GnRH analogue.	A GP or UK registered private prescriber can prescribe NHS or private prescriptions. An NHS or UK private prescription must be annotated SLS by the prescriber to confirm the prescription is for the treatment of a	Both NHS and private prescriptions annotated SLS by the prescriber can be dispensed. A prescription from a UK registered private prescriber which doesn't include the young person's age will







condition other than gender incongruence or gender dysphoria.	require the young person to provide proof of age and identity.
	Prescriptions from the EEA or Switzerland can be dispensed if the young person is able to provide proof of age and identity. The prescription does not need to be annotated SLS

