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31st May 2024

Dear Patient, Parent, or Guardian

NHS England is sending this letter to everyone who is on the waiting list for the *NHS Children and Young People's Gender Service*, but this information will be of most interest to children and young people, and their parents or carers, who are taking Gonadotropin-releasing hormone analogues (GnRH analogues) for gender incongruence or gender dysphoria (commonly referred to as Puberty Blockers or Puberty Suppressing Hormones).

This letter provides urgent information on the implications of new Government policy.

The Government introduced emergency restrictions on 29 May 2024 on the use of a group of medicines called GnRH analogues when they are used to suppress puberty as part of treating gender incongruence or gender dysphoria in children and young people who are under 18 years of age. Some of these restrictions will take effect from 3 June 2024.

The Government's announcement is published here: https://www.gov.uk/government/news/new-restrictions-on-puberty-blockers

The new 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.

The individuals who will be most impacted are those who are currently receiving a prescription for GnRH analogues from a healthcare professional who is registered outside of the UK in the European Economic Area (EEA) or Switzerland, or who were intending to obtain such a prescription. It will also particularly impact on individuals who have not yet started on a course of treatment with GnRH analogues, depending on what the treatment is for.

If you need help

We understand that the Government's changes may cause worry and concern to some individuals and families. If it is impacting your mental health you may want to seek support. If you are under the care of an NHS mental health service, you should contact your team. If not, you can contact your GP practice. Further advice on getting mental health support is available at https://www.nhs.uk/mental-health/children-and-young-adults/mental-health-support/

If you need support because you are waiting to be seen by an *NHS Children and Young People's Gender Service*, support options can be found on the website for the <u>NHS Referral</u> Management Support Service for the Children and Young People's Service.

Need urgent support?

If you need urgent support you can contact <u>NHS 111</u> and choose the mental health option (option 2) <u>https://www.nhs.uk/nhs-services/mental-health-services/where-to-get-urgent-help-for-mental-health/</u>

Changes made by the Government

As a result of the new Government policy, from 3 June 2024 it will become a criminal offence for a pharmacist, doctor or any other individual in Great Britain to sell or supply these drugs to patients under the age of 18 **except in the following circumstances:**

- The child or young person is using an NHS prescription (for example, from the *NHS Children and Young People's Gender Service* or from an NHS GP).
- The child or young person is using a private prescription from a clinician registered in the United Kingdom that fulfils the following criteria:
 - If the prescription was dated prior to 3 June 2024, whether as a one off prescription or a repeat prescription, it can still be dispensed, whether the treatment is for gender incongruence/dysphoria or some other purpose. In practice, unless it is a repeat prescription, it will need to have been issued within the previous six months to still be valid; or
 - If the prescription is written on or after 3 June 2024, it can only be dispensed if it is written by a UK-registered doctor, nurse or pharmacist, whatever its purpose. It must be either for a purpose other than treatment for gender incongruence or, if it is for gender dysphoria/incongruence, the patient must have started treatment before 3 June 2024. In addition to those patients who have actually started treatment, patients are treated as having started treatment, whether or not they have actually taken a GnRH analogue, if they were prescribed with a GnRH analogue on or after 3 December 2023.

It will also be a criminal offence to possess these medicines, where the individual had reasonable cause to know that the medicine had been sold or supplied in breach of the ban.

<u>Additionally</u>, from 26 June 2024 NHS prescribers in GP practices in primary care will only be able to supply – or continue to supply - prescriptions for GnRH analogues in the following circumstances:

- The patient is aged <mark>18 years or ove</mark>r; or
- The patient is 17 years or under and has started treatment with these medicines (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 actually started to take the medicine); or

- The patient is 17 years or under and is being treated with GnRH analogues for gender incongruence or gender dysphoria by the NHS as part of a future clinical trial overseen by the National Institute for Health and Care Research; or
- The patient is 17 years or under and the purpose of the prescription is for a medical condition <u>other than</u> gender incongruence or gender dysphoria.

From 3rd June, private prescriptions of GnRH analogues from a prescriber registered in the European Economic Area (EEA) or Switzerland are banned from being supplied in Great Britain in all circumstances for patients aged under 18.

The impact of these changes

The individuals who will be most impacted by the Government policy are those under 18 years of age who are currently receiving a prescription for GnRH analogues for any reason from a healthcare professional who is registered outside of the United Kingdom in the European Economic Area (EEA) or Switzerland, or who intended to obtain such a prescription. Pharmacies in Great Britain will no longer be able to dispense new prescriptions for GnRH analogues from non-UK registered prescribers, including those in the EEA or Switzerland, for anyone aged 17 years or under. It will also particularly impact on those who have not started a course of treatment with GnRH analogues but might have started a private course of treatment with them for gender incongruence or gender dysphoria in the coming months.

Individuals who are already receiving NHS or private prescriptions from clinicians registered in the United Kingdom can continue to receive their prescriptions. However, such individuals and their families are strongly advised to meet with the prescribing clinician to fully understand the safety risks associated with GnRH analogues when prescribed for gender incongruence or gender dysphoria.

The appendix to this letter explains how the Government's changes may affect various individuals.

Buying GnRH analogues from un-regulated sources

No one should buy GnRH analogues (or any other medication) from unregulated sources such as the internet, friends or from street dealers.

From 3 June 2024 the consequences of the Government's changes will be that *possession* of GnRH analogues will become a criminal offence where the individual had reasonable cause to know that the medicine had been sold or supplied in breach of the Government's ban.

Where a child or young person is receiving GnRH analogues from unregulated sources or unregulated providers, GPs may conclude that safeguarding procedures should be explored.

Unregulated medicines can have potentially dangerous short and long term side effects; and even prescription drugs can be dangerous unless prescribed by, and managed by, an experienced and appropriately trained healthcare professional. Yours sincerely

Professor James Palmer

National Medical Director for Specialised Services

Sent by the NHS Arden and Greater East Midlands Commissioning Support Unit National Referral Support Service

https://www.ardengemcsu.nhs.uk/services/clinical-support/national-referral-support-service-for-the-nhs-gender-incongruence-service-for-children-and-young-people/

HOW DO THE CHANGES AFFECT ME?					
 I am under 18 years of age; and I am not yet under the care of the 	This is not possible either through the NHS or privately:				
I am not yet under the care of the NHS; and I want to start on GnRH analogues for gender incongruence or gender dysphoria	• The initiation of GnRH analogues is not possible in the NHS <i>Children and</i> <i>Young People's Gender Service</i> unless this is part of a future clinical study.				
	 GPs cannot initiate a new NHS prescription from 26 June 2024. 				
	• Private medical practitioners cannot initiate a new prescription from 3 June 2024 to patients who have not yet started treatment. Supply against such prescriptions will be unlawful.				
	• Pharmacies in Great Britain cannot dispense a new UK private prescription from 3 June or a new NHS prescription from 26 June 2024, unless the patient started treatment before the restrictions came into effect.				
	• Pharmacies in Great Britain cannot dispense any prescription for GnRH analogues from the European Economic Area (EEA) or Switzerland from 3 June 2024, unless the prescriber happens to be UK registered.				
 I am under 18 years of age; and I was referred to an NHS paediatric endocrinology team for assessment of suitability of GnRH analogues for gender incongruence or gender dysphoria on or before 31 March 2024 	You may be able to start on GnRH analogues if the new NHS team responsible for your care makes a recommendation for initiation of treatment following an assessment, and if the paediatric endocrinology team related to the <i>NHS Children and Young</i> <i>People's Gender Service</i> agrees to initiate prescribing directly.				
 I am under 18 years of age; and I am already being prescribed GnRH analogues through the NHS for gender incongruence or gender dysphoria 	You are able to continue to receive GnRH analogues. The NHS Children and Young People Gender Service and local prescribers (if they are already prescribing) can continue to prescribe; the prescription will have to be endorsed by the				

	prescriber to demonstrate that your situation meets the new requirements. However, you are strongly advised to meet with your clinician so that the risks of continuation / initiation are fully understood.
 I am under 18 years of age; and I am already being prescribed GnRH analogues by a private medical practitioner, using a UK prescription, for gender incongruence or gender dysphoria 	You are able to continue to receive GnRH analogues. The private medical practitioner can continue to prescribe; the prescription will have to be endorsed by the prescriber to demonstrate that your situation meets the new requirements. If the prescription was issued before 3 June 2024, you will need to provide proof of age when your medicines are dispensed if your prescription does not state your age/date of birth. However, you are strongly advised to
	nowever, you are strongly advised to meet with your clinician so that the risks of continuation / initiation are fully understood.
I am under 18 years of age; and I am already being prescribed GnRH analogues through a private prescription from a healthcare professional registered in the European Economic Area (EEA) or Switzerland	You will not be able to receive GnRH analogues from a pharmacy in Great Britain from 3 June 2024 for a prescription issued from that date. Pharmacies in Great Britain can no longer dispense new EEA / Swiss prescriptions for GnRH analogues from 3 June 2024. You will need to stop taking GnRH analogues, unless you are newly prescribed them by a UK-registered doctor, nurse or pharmacist. These medications can be safely stopped and you do not need to be weaned off. You are strongly advised to meet with your clinician who initiated treatment for further advice and support. If you require psychological support, ask your GP to refer you to your local NHS mental health service for children and young people.
	Contact <u>NHS 111</u> if you think that you are at immediate risk of psychological harm.

•	I am <mark>under 18 years of age; a</mark> nd		T <mark>he changes do not affect you,</mark> except that:	
•	I am already being prescribed GnRH analogues for a purpose <u>other than</u> gender incongruence or gender dysphoria	•	NHS prescriptions are unaffected, but from 26 June 2024 the prescription will have to be endorsed by the prescriber to demonstrate that your situation meets the new requirements.	
		•	If it is a private prescription, issued before 3 June 2024, will need to provide proof of age and identity when your medicines are dispensed.	
		•	If it is a new private prescription, the prescription will have to be endorsed by the prescriber to demonstrate that your situation meets the new requirements.	
		•	If you are being prescribed by a prescriber registered in the EEA or Switzerland but not in the UK, new prescriptions will not be valid. Any new prescription will have to be written by a UK registered doctor, nurse or pharmacist. Seek advice from your GP. They may be able to prescribe for you if this is within their clinical scope of practice or they may make a referral to a relevant specialist.	
•	I am aged 18 years or over	Th	e <mark>changes do not affect you.</mark>	
		•	If you are being prescribed by a UK private prescriber or a private prescriber registered in the EEA or Switzerland, you will need to provide documentary evidence of your age and identity such as your passport when your medicines are dispensed.	
		•	UK private prescribers will be able to endorse new prescriptions, issued on or after 3 June 2024, to save you the need to do this.	