EXPLANATORY MEMORANDUM TO

THE MEDICINES (GONADOTROPHIN-RELEASING HORMONE ANALOGUES) (EMERGENCY PROHIBITION) (ENGLAND, WALES AND SCOTLAND) ORDER

2024 No. 727

AND

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC.) (AMENDMENT) REGULATIONS 2024

2024 No. 728

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Victoria Atkins, Secretary of State at the Department of Health and Social Care, confirms that this Explanatory Memorandum meets the required standard.

2.2 Kathryn Glover and Helen Lovell, Deputy Directors for medicines regulation and prescribing at the Department of Health and Social Care confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Noor Salik at the Department of Health and Social Care, e-mail: prescribingpolicy@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The aim of these two pieces of legislation is to reduce and remove risks to patient safety through ensuring that a consistent approach to prescribing of gonadatrophin-releasing hormone (GnRH) analogues is taken by all prescribers. These medicines are hormones that are licensed to treat conditions in children including precocious puberty or certain growth disorders, and in adults prostate and breast cancers as well as other disorders. These medicines can also have the effect of suppressing puberty as a treatment for gender dysphoria or gender incongruence. The independent review of gender identity services for children and young people ("Cass Review[1]"), found that the use of these medicines in the context of gender dysphoria or gender incongruence

[1] https://cass.independent-review.uk/home/publications/final-report/

was not evidence based and should change. The desired approach was set out in the Cass Review, namely that prescribing of GnRH analogues for the treatment of gender dysphoria or gender incongruence in children and young people under the age of 18 should only be done with the agreement of the national multi-disciplinary team and/ or under a research protocol. In practice this will usually mean prescribing done in, or under the supervision of, NHS specialised services. NHS England[2] and the NHS in Scotland have paused new prescribing of GnRH analogues for the treatment of gender dysphoria or gender incongruence in children and young people under the age of 18.

4.2 The Medicines (Gonadatrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024 ("the Order") seeks to achieve this aim through (1) prohibiting the sale or supply of specified medicines against prescriptions from a UK private prescriber which would start a child or young person under the age of 18 on a medical pathway for gender incongruence/ dysphoria; (2) prohibiting sale or supply against prescriptions from a EEA or Switzerland-registered prescriber for specified medicines to a child or young person under the age of 18; (3) making exceptions for sale or supply against NHS prescriptions. The Order will expire on 2 September 2024.

4.3 Sale or supply of GnRH analogues to a child or young person who is already on a medical pathway for gender incongruence/ dysphoria at the time the Order comes into force will be able to continue, where the prescription is from a UK registered prescriber.

4.4 Prescriptions of GnRH analogues from an EEA or Switzerland registered prescriber which post-date the Order coming into force are banned in all circumstances for patients aged under 18. For patients aged 18 or over, a prescription from an EEA or Switzerland registered prescriber will be dispensed in the UK providing verification of age and identity can be shown to the dispensing pharmacist.

4.5 The Order does not prohibit importation of GnRH analogues. The Order will come into force on Monday 3 June.

4.6 The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2024 ("the Regulations") seek to achieve this aim through restricting NHS primary care prescribing of specified medicines where this would start a child or young person under the age of 18 on a medical pathway for gender incongruence/ dysphoria. A child or young person who is already on a medical pathway for gender incongruence/ dysphoria at the time the Regulations come into force, or who is being treated as part of a National Institute for Health Research (NIHR) clinical trial, will be able to continue to be prescribed GnRH analogues. The Regulations will come into force on 26th June 2024.

Where does the legislation extend to, and apply?

4.7 The extent of the Order is the United Kingdom and the territorial application is England, Wales and Scotland.

4.8 The extent of the Regulations is England and Wales. They apply in relation to England only.

[2] https://www.england.nhs.uk/publication/clinical-policy-puberty-suppressing-hormones/

5. 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

[3] https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.england.nhs.uk%2Fwp-content%2Fuploads%2F2023%2F04%2Finterim-service-spec-CYP-Gender-service-12-March-2024.docx&wdOrigin=BROWSELINK

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.

6. Legislative and Legal Context

How has the law changed?

6.1 Section 62 of the Medicines Act 1968 enables the Secretary of State and the Minister of Health in Northern Ireland to prohibit the sale, supply or importation of medicinal products, either totally or subject to exceptions. The Order is made under section 62, and prohibits the sale or supply of GnRH analogues, subject to exceptions.

6.2 The first exception is a sale or supply under an NHS prescription. NHS prescribing is dealt with in the Regulations.

6.3 Secondly, in the case of private prescriptions issued by UK prescribers, a sale or supply to a person who is 18 or over is excepted, provided that the prescription is annotated with "SLS" and the person's age, or they provide proof of age and identity at the point of sale or supply.

6.4 Thirdly, also in the case of private UK prescriptions, a sale or supply to a person under the age of 18 is excepted if it is for a purpose other than treatment for puberty suppression related to gender dysphoria or gender incongruence, provided that the prescription meets the conditions of the Order and is annotated with "SLS" and the person's date of birth (if the prescription is issued after the Order comes into force). If the prescription was issued before the Order comes into force, then the person must provide proof of age and identity. And if the person had been issued with a prescription for a GnRH analogue in the six month period before the Order came into force, then they have already started a course of treatment and may continue to be sold or supplied GnRH analogues.

6.5 Fourthly, in the case of private prescriptions issued by prescribers in the EEA and Switzerland, a sale or supply to a person who is over the age of 18 is excepted, provided that the person provides proof of age and identity at the point of sale or supply. EEA and Swiss prescriptions issued before the date of the Order to a person under the age of 18 are also excepted if proof of age and identity is provided at the point of sale or supply.

6.6 Breach of the Order is a criminal offence under the Medicines Act 1968. This also applies to possession, where the individual had reasonable cause to know that the medicine had been sold or supplied in breach of the ban.

6.7 A person guilty of breaching the Order is liable on summary conviction to a fine of up to £400, or on conviction on indictment to a fine and/or to imprisonment for a term of up to two years. In addition, breaching the Order would provide the relevant regulator with evidence for a fitness to practice investigation.

6.8 The Order comes into force five days after it is made. This is because it is the opinion of the Ministers that it is essential to make the Order with immediate effect to avoid serious danger to health. The reasons for this are set out above at paragraph 5.5. The Order will expire on 2 September 2004.

6.9 The Regulations are made under section 88 of the National Health Act 2006. They amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 ("the 2004 Regulations"). Regulation 3 of the 2004 Regulations provides that specified products can only be ordered for a patient under a general medical services contract in certain circumstances. The patient must be of a description in Schedule 2 to the 2004 Regulations, and the intended purpose must also be set out in that Schedule.

6.10 The Regulations amend Schedule 2 to the 2004 Regulations so that GnRH analogues may be prescribed for any purpose to a patient who is aged 18 or over. In the case of a patient who is under the age of 18, the products may only be supplied for a purpose other than the treatment of puberty suppression related to gender dysphoria and gender incongruence. However, if a patient who is under the age of 18 has been issued with a prescription for a GnRH analogue for that purpose in the six month period prior to the date on which the Regulations come into force, then they may continue to be issued with prescriptions for that purpose. The same applies to patients under the age of 18 who are being treated as part of an NIHR clinical trial.

6.11 The Regulations come into force four weeks after they are made.

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.

7. Consultation

Summary of consultation outcome and methodology

7.1 There are consultation requirements applicable to the making of orders under section 62 of the Medicines Act 1968, but when making an emergency order under section 62(3) of the Medicines Act 1968, no prior consultation is required. There is no statutory consultation requirement when making regulations under section 88 of the National Health Service Act 2006.

7.2 The following parties have been consulted: NHS England, the devolved administrations, the British Medical Association, Community Pharmacy England, the chair of the Commission on Human Medicines, the General Medical Council and the General Pharmaceutical Council. Given the time constraints this has been done through meetings rather than through the production of consultation documents. Should further legislative action be required, further consultation will be undertaken.

7.3 All parties endorsed the conclusions of the Cass Report. All parties expressed concern about variation in prescribing practice in respect of treatment of gender dysphoria and gender incongruence. Concerns around risks of disrupting treatment of patients prescribed these medicines for other purposes, or who were already on a medical pathway for gender dysphoria/incongruence were raised. Operational considerations for dispensing pharmacists were also raised. These concerns have been reflected in the drafting of this legislation, and the legislation will be accompanied by communications to patients and their families, prescribers and pharmacists to mitigate these risks.

8. Applicable Guidance

8.1 Information for patients and their families, prescribers and pharmacists will be publicly available before the commencement dates of this legislation.

8.2 Existing relevant guidance includes: the General Medical Council's https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices. Royal College of GPs position statement https://www.rcgp.org.uk/representing-you/policy-areas/transgender-care. General Pharmaceutical Council guidance https://assets.pharmacyregulation.org/files/2024-05/gender-identity-services-for-children-and-young-people-making-compassionate-professional-and-ethical-decisions-may-2024.pdf. NHS England's clinical policy: https://www.england.nhs.uk/wp-content/uploads/2024/03/clinical-commissioning-policy-gender-affirming-hormones-v2.pdf. NHS Scotland https://www.nhsggc.scot/service-update/.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 The Better Regulation Framework allows, where legislation is required to address an emergency situation such as essential public safety reforms, for insufficient time being available for a full assessment at the time the legislation is laid.

9.2 A Limited Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website. A full Impact Assessment has not been prepared for this instrument because the Order has a temporary duration of three months, while the NHS regulations reform relates to the maintenance of existing regulatory standards. Both are expected to have minimal impact on businesses. A full Impact Assessment will be prepared should the Order be made permanent.

9.3 The Limited Impact Assessment presents a qualitative assessment of costs and benefits. The main benefit is an improvement in patient safety for under 18s starting a medical pathway for gender incongruence/dysphoria, as UK prescribing of puberty blockers for gender dysphoria, and all puberty blocker prescribing originating in the

EEA, are reduced. The reform also delivers improved consistency of treatment for such patients.

9.4 The expected costs include time spent on familiarisation with the new rules, monitoring and enforcement. Potential risks include increased demand for alternative NHS care, disruption to patients should treatment be delayed or changed, and (notwithstanding the weak evidence base) a loss of any health benefits that might have arisen from puberty blocker use.

Impact on businesses, charities and voluntary bodies

9.5 The impact on business, charities or voluntary bodies is expected to be minimal, given the relatively low number of patients affected and on the assumption that the NHS provides alternative treatment where appropriate. Prescribers and dispensers will need to be familiar with the new rules and provide appropriate advice to patients.

9.6 The legislation does impact small and micro businesses - mainly pharmacies and surgeries involved with patient care.

9.7 The impact on the public sector is expected to be minimal, given the relatively low number of patients affected, but some increased demand for NHS care is expected.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The Order has a duration of 3 months. After that, it may be that another order is made a further temporary period, or a permanent order may be made, or there may be no further legislative action. Monitoring and evaluation of impacts of the Order and Regulations will be done through continued engagement with the NHS, professional leaders and professional regulators, and monitoring of available prescribing data.

10.2 A statutory review clause is not included in the Order because it will cease to have effect after three months. A statutory review clause is not included in the Regulations because they will have a minimal regulatory impact on business.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 The Order is made under section 62 of the Medicines Act 1968. Ministers are of the opinion that it is essential to make the order with immediate effect to avoid serious danger to health. The rationale for this has been set out above. That rationale is also the basis for the breach of the 21-day rule with regard to the commencement of the Order.

11.2 Section 62(4) of the Act provides that an order made in accordance with section 62(3) cannot hae effect for longer than three months, and article 1 of the Order provides that it will cease to have effect after three months.

11.3 Section 62(1) permits Ministers to prohibit the sale or supply of medicinal products of any description. That prohibition may be total, or subject to specified exceptions. The Order does not impose an outright ban on the sale or supply of GnRH analogues. Instead, it creates exceptions in relation to specified categories of patients, and in relation to specified purposes, and makes sale or supply subject to conditions. This might be considered an unusual use of the power in section 62.

12. European Convention on Human Rights

12.1 The Secretary of State for Health and Social Care has made the following statement regarding Human Rights:

"In my view the provisions of the NHS (GMS Contract Regulations)(Prescription of Drugs etc.)(Amendment) Regulations 2024 and the Medicines (Gonadatrophin-Releasing Hormone Analogues)(Emergency Prohibition)(England, Wales and Scotland) Order 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").