EXPLANATORY MEMORANDUM TO

THE MEDICINES (GONADOTROPHIN-RELEASING HORMONE ANALOGUES) (EMERGENCY PROHIBITION) (EXTENSION) (NO. 2) ORDER 2024

2024 No. 1110

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 The Rt.Hon. Wes Streeting MP, Secretary of State for Health and Social Care 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 David Gosling 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 Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) Order 2024 ("the Existing Order") is due to expire at the end of 26th November 2024. This Order is made to replace the Existing Order, so that there is no break in legislative provision while Ministers consider whether an indefinite order should be made (see 7.2 and 11.2). It will commence on Wednesday 27th November 2024 and expires at the end of 31st December 2024.

4.2 The aim of this Order 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 but are not licensed for this purpose. 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 was not evidence based and should change. The desired

[1] Final Report – Cass Review https://cass.independent-review.uk/home/publications/final-report/

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.

4.3 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.

4.4 Sale or supply of GnRH analogues to a child or young person who is already on a course of prescribed medical treatment for gender incongruence/ dysphoria before 3rd June 2024, in Great Britain and before 27th August 2024, in Northern Ireland, will be able to continue where the prescription is from a UK registered prescriber.

4.5 The sale or supply of GnRH analogues under a prescription from an EEA or Switzerland registered prescriber issued on or after 3rd June 2024 in Great Britain and 27th August 2024 in Northern Ireland is banned in all circumstances for patients aged under 18. Those who were already on a course of treatment prescribed by an EEA or Switzerland registered prescriber before 3rd June 2024 in Great Britain and 27th August 2024 in Northern Ireland can legally switch to a UK based prescriber to continue their treatment. 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.

4.6 The Order does not prohibit importation of GnRH analogues.

Where does the legislation extend to, and apply?

4.7 The extent of the Order is the United Kingdom and the territorial application is the United Kingdom.

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 governments, regulators and clinical leaders in the UK.

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

5.2 Following the publication of the Cass Review, The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024 (S.I. 2024/727) ("the First Emergency Order") was made by the previous Secretary of State for Health and Social Care and Minister of Health for Northern Ireland. It was made alongside The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Amendment) Regulations 2024 (S.I. 2024/728) ("the Regulations"), which came into force on 26th June 2024 and do not have an expiry date. The Regulations restrict 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.

5.3 After careful consideration of the evidence, including the Cass Review, the Minister for Care and the Minister of Health for Northern Ireland made the Existing Order. The Existing Order is made in effectively the same terms as the First Emergency Order but was extended to Northern Ireland for the first time, following agreement from the First Minister and Deputy First Minister for the Minister of Health for Northern Ireland to sign it.

5.4 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. This government has committed to implementing the Cass Review and agrees with its 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.

5.5 The Order aligns 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 the Order (and the Regulations) are in the case of the under 18s 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].

5.6 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 on or after 3rd June 2024 in Great Britain and on or after the 27th August 2024 in Northern Ireland are no longer to be dispensed in the UK. Prescriptions of GnRH analogues from an EEA or Switzerland registered prescriber for patients over the age of 18 may be dispensed in the UK providing verification of age and identity 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.

[3] interim-service-spec-CYP-Gender-service-12-March-2024.docx (live.com) 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

5.7 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. Before the First Emergency Order was introduced, providers registered outside of the UK beyond the jurisdiction of UK regulators, were able to offer services that are not evidence based and treatment options that are not available through UK registered providers for safety reasons. The First Emergency Order closed these loopholes, and the Existing Order renewed the actions taken to prevent harm in Great Britain and extended them to Northern Ireland for the first time. This Order maintains the status quo, across the UK, while responses to a targeted consultation and the Commission on Human Medicines' ("CHM") advice are considered (see paragraph 7.2 and 11.2). In doing so, this Order ensures that there is no gap in legislative provision and prevents a scenario where these medicines are available for a short period of time, which could otherwise create a perverse incentive to begin taking them or to 'stockpile' the medication while decisions are made on whether to bring forward an indefinite order.

5.8 Breach of the Order is a criminal offence under the Medicines Act 1968. Following the introduction of the First Emergency Order, communications were published by the government and NHS England wrote to those on the waiting list for the NHS Children and Young People's Gender Service. These set out the new requirements to ensure all those affected have relevant information to ensure compliance.

5.9 Further information was published alongside the Existing Order. NHS England also wrote to all general practitioners in England, to provide guidance on how to support patients presenting to primary care across a range of scenarios. In the event a patient is under 18 years of age and is already being prescribed GnRH analogues from an EEA or Switzerland registered prescriber, the letter sets out that GPs can take continuation of the prescription of these medicines, if they consider that it is in the best interests of the patient, that relevant due diligence requirements have been met and that they feel competent to do so. In the event a prescription is discontinued, GPs should consider the individual's need for further professional support, including through Children and Young People mental health services or through the specialist gender pathway.

5.10 Alongside the Order, a study into the potential benefits and harms of puberty suppressing hormones as a treatment option for children and young people with gender incongruence is being developed through the National Research Collaboration Programme (NCRP), in place between NHS England and the National Institute for Health and Care Research (NIHR). The study team is now in place and are finalising their application for funding which will be assessed by an independent scientific review study ahead of the commencement of wider approvals, including ethics, and set up.

What was the previous policy, how is this different?

5.11 Prior to the introduction of the First Emergency Order (in Great Britain) and the Regulations (in England and the equivalent regulations in Wales), 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.

5.12 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, in conjunction with the Regulations, therefore, takes 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 for 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.

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 age, if the prescription is issued on or after 3rd June 2024 in Great Britain or 27th August 2024 in Northern Ireland. If the prescription was issued before that date, then the person must provide proof of age and identity. And if the person had already started a course of treatment at any point before 3rd June 2024 in Great Britain or 27th August 2024 in Northern Ireland, they may continue to be sold or supplied GnRH analogues. This would include having been issued with a prescription for a GnRH analogue in the six-month period before the relevant date, whether or not it had been dispensed.

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 aged 18 or over 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 3rd June 2024 in Great Britain or 27th August 2024 in Northern Ireland 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 Order.

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.

Why was this approach taken to change the law?

6.8 This is the only possible approach to make the necessary changes on an urgent basis across the UK. The Existing Order is due to expire at the end of 26th November and it is necessary, in the interests of patient safety, to continue to prohibit the sale and supply of GnRH analogues to patients under the age of 18 unless certain conditions are met.

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.

7.2 In accordance with the requirements of the legislation, the Secretary of State has issued a targeted consultation jointly with the Minister of Health for Northern Ireland on a proposal to make an indefinite order under section 62. It was open from 20th August 2024 and lasted for a duration of 7 weeks, closing on 8th October 2024. This targeted consultation sought the views of representatives from patient, academic, clinician, and prescriber organisations, in addition to the Devolved Administrations. As is required by the legislation, the Secretary of State and the Minister of Health for Northern Ireland have also consulted CHM for their independent expert view on the safety of these medicines. While the responses to the targeted consultation are being analysed, and while CHM's advice is considered, it is the Government's view that the restrictions should remain in place until 31st December 2024. By which time, next steps will be determined by the Secretary of State and the Minister of Health for Northern Ireland.

7.3 The government continues to engage with representative bodies and providers to understand the impact of the restrictions, including but not limited to: NHS England, the devolved administrations, Community Pharmacy England, the Commission on Human Medicines, the General Medical Council and the General Pharmaceutical Council. Where they have raised ways in which the implementation of the Order can continue to be improved, these are being considered on an ongoing basis.

7.4 The Secretary of State also met with LGBT+ representative groups to hear directly about the health and care issues that are most important to them. The restrictions were discussed, amongst a range of topics. Concerns were raised regarding access to these medicines for patients who were already prescribed a course of treatment prescribed by an EEA or Switzerland registered prescriber (before 3rd June 2024 in Great Britain), the impact the restrictions may have on mental health and wellbeing of children and young people with gender incongruence, as well as prescribers' understanding of the new rules. Further communications were issued following the introduction of the Existing Order.

8. Applicable Guidance

8.1 Communications around the First Emergency Order and the Existing Order are set out at 5.9 and 5.10. Further information will be publicly available before the commencement date of the Order.

8.2 Existing relevant guidance also includes: the General Medical Council's Good practice in prescribing and managing medicines and devices (available here: 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 on transgender care (available here: https://www.rcgp.org.uk/representing-you/policy-areas/transgender-care). General Pharmaceutical Council guidance on Gender identity services for children and young people: making compassionate, professional and ethical decisions (available here: https://assets.pharmacyregulation.org/files/2024-06/Gender-identity-services-for-children-and-young-people-making-compassionate-professional-and-ethical-

decisions-a.pdf). NHS England's clinical policy on puberty suppressing hormones (available here: https://www.england.nhs.uk/publication/clinical-policy-puberty-suppressing-hormones/). NHS Scotland's Service Update (available here: 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 Order and is published alongside the Explanatory Memorandum on the legislation.gov.uk website. A summary can be found at paragraphs 9.3 and 9.4. The Order is expected to have minimal impact on businesses. A full Impact Assessment will be prepared should an indefinite order be made, after the government has concluded its analysis of the consultation responses and considered CHM's advice.

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 or Health and Social Care Northern Ireland 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 Order maintains the status quo across the UK. 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 or Health and Social Care Northern Ireland provides alternative treatment where appropriate. Prescribers and dispensers will need to be familiar with the rules and provide appropriate advice to patients.

9.6 The Order 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 or Health and Social Care Northern Ireland care is expected.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The Order will expire at the end of 31st December 2024. Responses to a consultation on an indefinite order and CHM's advice are being carefully considered. Monitoring and evaluation of impacts will also continue to 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 at the end of 31st December 2024.

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. Section 62(4) of the Act provides that an order made in accordance with section 62(3) cannot have effect for longer than three months.

11.2 This Order is the third order to be made in accordance with section 62(3) and the second to extend to Northern Ireland in relation to GnRH analogues. The Secretary of State and the Minister of Health for Northern Ireland have deemed it necessary to make this Order to ensure that there is no gap in legislative provision, while the analysis of responses to the targeted consultation and consideration of CHM's independent expert advice is concluded. Article 1 of the Order provides that it will cease to have effect at the end of 31st December 2024, rather than the maximum three months permitted under section 62(4). The Secretary of State and the Minister of Health for Northern Ireland have assessed this to be the minimum amount of time required to ensure that all necessary work is concluded in advance of determining whether to make an indefinite order.

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.

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 Medicines (Gonadatrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) (No.2) 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").