EXPLANATORY MEMORANDUM TO

THE MEDICINES (GONADOTROPHIN-RELEASING HORMONE ANALOGUES) (RESTRICTIONS ON PRIVATE SALES AND SUPPLIES) ORDER 2024

2024 No. 1319

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 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 This Order indefinitely restricts the sale or supply of gonadotrophin-releasing hormone analogues, with limited exceptions, under section 62 of the Medicines Act 1968 ("the Act"). It will commence on 1st January 2025 and will be subject to review in October 2027 in consultation with the Commission on Human Medicines (CHM). Subsequent reviews will be at four-yearly intervals. The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) (No. 2) Order 2024 (S.I. 2024/1110) ("the Existing Order") is due to expire at the end of 31st December 2024 and this Order is made to replace the Existing Order. 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 (referred to in this memorandum as puberty blockers), 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 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 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.

4.3 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.

4.4 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.

4.5 The Order does not prohibit importation of GnRH analogues.

Where does the legislation extend to, and apply?

4.6 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 incongruence/ dysphoria, 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

[1] Final Report – Cass Review - https://cass.independent-review.uk/home/publications/final-report/
[2] NHS England » Clinical policy: puberty suppressing hormones - https://www.england.nhs.uk/publication/clinical-policy-puberty-suppressing-hormones/

has implemented these recommendations. The Cass Review's conclusions have been accepted and endorsed by governments, regulators and clinical leaders in the UK.

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 previous 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 In order to give sufficient time for a consultation process to take place, and after careful consideration of the evidence, including the Cass Review and impact of the first emergency order, the Minister for Care and the Minister of Health for Northern Ireland made the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) Order 2024 (S.I. 2024/868) ("the Second Emergency Order"). The Second Emergency Order was 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 On the 6 November, the Secretary of State for Health and Social Care and the Minister for Health for NI made the Existing Order which commenced on the 27 November 2024 and expires at the end of 31 December 2024.

5.5 In order to determine a longer term solution, and in accordance with the Act, the Minister for Care and the Minister of Health for Northern Ireland issued a targeted consultation to those groups likely to be affected by an indefinite order from August 20th to October 8th 2024. Also, as required by the Act, Ministers sought independent expert advice from the Commission on Human Medicines (CHM).

5.6 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 incongruence/ dysphoria 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.

5.7 The government accepts the CHM position that the current prescribing and care pathway for puberty blockers for children and young people for the purposes of treating gender dysphoria or gender incongruence represents an unacceptable safety risk. The Order is therefore being renewed on an indefinite basis. Details of the recommendations, which include recommendations for reducing the risks, and the Government's response to them are set out in the consultation response that will be published on GOV.UK on 11th December 2024. A statutory review will be carried out and published by October 2027 to consider the progress made at that point, with subsequent reviews being carried out at four-yearly intervals.

5.8 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].

5.9 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 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.

5.10 Only legislation can achieve consistent action to ensure patient safety across all sources of prescriptions. The Order is being made 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 Second Emergency 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, and responds to the recommendations of CHM and the analysis of responses to a targeted consultation (see paragraph 7.2). In doing so, this Order ensures that there is no gap in legislative provision and restricts the sale or supply of gonadotrophin-releasing hormone analogues, with limited exceptions.

5.11 Breach of the Order is a criminal offence under the Act. 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.

5.12 Further information was published alongside the Second Emergency 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

[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

through Children and Young People mental health services or through the specialist gender pathway.

5.13 In support of this Order, NHS England will extend the offer of a prioritised mental health assessment to those children and young people not otherwise known to the NHS Children and Young People's Gender Service who had previously accessed medicines through EEA prescriptions and who have lost access as a result of the Orders made since June 2024. This will remain in place until 31 March 2025.

5.14 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?

5.15 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 for this purpose. 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 incongruence/ dysphoria, these expectations were not met, leading to variation in practice, and risks to patients' safety.

5.16 GnRH analogues are prescribed off-label (i.e. for purposes for which they are not licensed), and as found by the Cass review there is a lack of reliable evidence for prescribers to consider, when prescribing. 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 Act. 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 across the UK. The Existing Order is due to expire at the end of 31st December 2024 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 indefinite orders under section 62 of the Medicines Act 1968.

7.2 In accordance with the requirements of the legislation, the Secretary of State issued a targeted consultation 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 120 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. Following analysis of the consultation responses, and consideration of CHM's recommendations, it is the Government's view that the restrictions should remain in place indefinitely with a statutory review by 1st October 2027 with subsequent reviews four yearly thereafter.

7.3 The consultation was sent to 120 individuals and organisations and attracted 51 replies (42.5%). Respondents fell into one of three categories – supporters of an indefinite ban (18%), opponents (59%) and those who were neutral (23%).

7.4 CHM makes 8 recommendations, 3 relating to the order, which Ministers have accepted, and 5 on wider implementation, which have been partially accepted.

7.5 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, CHM, the General Medical Council and the General Pharmaceutical Council.

7.6 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 Second Emergency Order.

8. Applicable Guidance

8.1 Communications around the First Emergency Order and the Second Emergency Order are described in paragraphs 5.12. 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 requires that an Impact Assessment is published at the time the legislation is laid.

9.2 An 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.

9.3 The 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 incongruence/ 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 is indefinite. Monitoring and evaluation of impacts will also continue through engagement with the NHS, professional leaders and professional regulators, and monitoring of available prescribing data.

10.2 A statutory review clause is included in the Order. The review will take place by 1st October 2027 in consultation with CHM, with subsequent review four yearly thereafter.

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.

11.2 Section 62(1) permits Ministers to prohibit the sale or supply of medicinal products of any description where it appears necessary in the interests of safety. 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) (Restrictions on Private Sales And Supplies) 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").