STATUTORY INSTRUMENTS

2024 No. 868

MEDICINES

The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) Order 2024

Made - - - -	*21st August 2024*
Laid before Parliament	*22nd August 2024*
Coming into force in accordance with article 1(3)	

The Secretary of State for Health and Social Care and the Minister of Health, acting jointly, make the following Order in exercise of the powers conferred by sections 62 and 129(5) of the Medicines Act 1968(**a**), it appearing to them to be necessary to do so in the interests of safety, and their being of the opinion that it is essential to make the Order with immediate effect to avoid serious danger to health.

The appropriate committee have not considered the proposal to make the Order.

Citation, commencement, extent, application and expiry

1.—(1) This Order may be cited as the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) Order 2024.

(2) This Order extends and applies to England and Wales, Scotland and Northern Ireland.

(3) This Order comes into force—

(a) in so far as it applies to Northern Ireland, on 27th August 2024; and

(b) in so far as it applies to England and Wales and Scotland, on 3rd September 2024.

(4) This Order ceases to have effect at the end of 26th November 2024.

Interpretation

2. In this Order—

"2012 Regulations" means the Human Medicines Regulations 2012(**b**);

"approved UK prescriber" means an authorised prescriber who is an appropriate practitioner in relation to any prescription only medicine by virtue of regulation 214(3)(a), (c), (d) or (e) of the 2012 Regulations(**c**) (sale or supply of prescription only medicines);

(**a**) 1968 c. 67. Section 62 has been amended by S.I. 2005/1094, 2006/2407 and 2012/1916. Section 129(5) has been amended by the Health Act 2006 (c. 28), section 32. *See* regulation 6(6) and (7) of the Human Medicines Regulations 2012 (S.I. 2012/1916), read with sections 1 and 132(1) of the Medicines Act 1968 (both as substituted by S.I. 2012/1916), for the definition of "the Ministers" which is relevant to the powers being exercised. The Department of Health, Social Services and Public Safety was renamed the Department of Health by the Departments Act (Northern Ireland) 2016 (c. 5), section 1(5).

(**b**) S.I. 2012/1916, as amended.

(**c**) Regulation 214 has been amended by S.I. 2013/1855, 2014/490, 2016/186, 2018/199 and 2019/775.

"authorised prescriber" means any person who is an appropriate practitioner for the purposes of regulation 214 of the 2012 Regulations (subject to any limits on their prescribing rights included in that regulation);

"current national identity document" means a document that is a current national identity document for the purposes of the rules under section 3(2) of the Immigration Act 1971(**a**) (general provisions for regulation and control);

"gonadotrophin-releasing hormone analogue" or "GnRH analogue" means a medicinal product that consists of or contains buserelin, gonadorelin, goserelin, leuprorelin acetate, nafarelin or triptorelin;

"NHS prescription" means an order for a medicinal product which is in the form of a prescription or direction and which is issued by an authorised prescriber as part of arrangements for the provision of services as part of—

(a) in England, the health service as defined by section 275(1) of the National Health Service Act 2006(**b**) (interpretation);

(b) in Scotland, the health service as defined by section 108(1) of the National Health Service (Scotland) Act 1978(**c**) (interpretation and construction);

(c) in Wales, the health service as defined by section 206(1) of the National Health Service (Wales) Act 2006(**d**) (interpretation);

(d) in Northern Ireland, the system of health and social care promoted under section 2(1) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(**e**) (Department's general duty);

"private prescription" means an order for a medicinal product which is in the form of a prescription or direction which is not a NHS prescription (whether or not it would otherwise be considered a private prescription);

"sale" means sale by retail (and "selling" has a corresponding meaning);

"specified document" has the meaning given in rule 37(1H) of the election rules in Schedule 1 to the Representation of the People Act 1983(**f**) (Parliamentary election rules – questions to be put to voters);

"supply" means supply in circumstances corresponding to retail sale (which includes supply by way of administration but does not include supply for the purposes of a clinical trial that has been authorised by the licensing authority);

"UK birth certificate" means a certified copy of a United Kingdom birth register entry or a valid certificate of birth compiled from such an entry.

Prohibition on the sale or supply of medicinal products consisting of or containing gonadotrophin-releasing hormone analogues

3. Subject to articles 4 to 6, the sale or supply of a GnRH analogue is prohibited.

Exception for NHS prescriptions

4. Article 3 does not apply to a sale or supply in pursuance of a NHS prescription.

Exception for private prescriptions: patients aged 18 or over

5.—(1) Article 3 does not apply to a sale or supply in pursuance of a private prescription, if—

(**a**) 1971 c. 77.
(**b**) 2006 c. 41. There are amendments to section 275(1), but none of them are relevant.
(**c**) 1978 c. 29. There are amendments to section 108(1), but none of them are relevant.
(**d**) 2006 c. 42. There are amendments to section 206(1), but none of them are relevant.
(**e**) 2009 c. 1 (N. I.).
(**f**) 1983 c. 2. Paragraph (1H) was inserted by the Elections Act 2022 (c. 37), Schedule 1, paragraph 18(4).

(a) Condition A is met; and

(b) if the private prescription is a prescription, rather than a direction, which is or purports to be in accordance with the requirements of regulation 217, 218, 219 or 219A of the 2012 Regulations(**a**) (which relate to requirements for paper and electronic prescriptions), either Condition B or Condition C is met.

(2) Condition A is that on the day the private prescription was issued, the patient in respect of whom it was issued was aged 18 or over.

(3) Condition B, which applies if the prescription was issued by an approved UK prescriber, is that—

(a) the prescription has included within it the patient's age and is annotated by the prescriber with "SLS"; or

(b) the person to whom the GnRH analogue is to be sold or supplied produces to the person selling or supplying the GnRH analogue a specified document, a UK birth certificate or a current national identity document that verifies, to the reasonable satisfaction of the person selling or supplying the GnRH analogue, the age and identity of the person to or for whom the GnRH analogue is to be sold or supplied.

(4) Condition C, which applies if the prescription was issued by an authorised prescriber who is not an approved UK prescriber, is that the person to whom the GnRH analogue is to be sold or supplied produces to the person selling or supplying the GnRH analogue a specified document, a UK birth certificate or current national identity document that verifies, to the reasonable satisfaction of the person selling or supplying the GnRH analogue, the age and identity of the person to or for whom the GnRH analogue is to be sold or supplied.

Exception for private prescriptions: patients aged under 18

6.—(1) Article 3 does not apply to a sale or supply in pursuance of a private prescription, if—

(a) Condition A is met;

(b) if the private prescription is a prescription, rather than a direction, which is or purports to be in accordance with the requirements of regulation 217, 218, 219 or 219A of the 2012 Regulations(**b**) (which relate to requirements for paper and electronic prescriptions), Condition B is met;

(c) in England and Wales and Scotland, if the private prescription was issued on or after 3rd June 2024, Condition C is met;

(d) in Northern Ireland, if the private prescription was issued on or after 27th August 2024, Condition C is met;

(e) in England and Wales and Scotland, unless the sale or supply is to or for a person who, on any occasion, started a course of treatment with a GnRH analogue before 3rd June 2024, Condition D is met; and

(f) in Northern Ireland, unless the sale or supply is to or for a person who, on any occasion, started a course of treatment with a GnRH analogue before 27th August 2024, Condition D is met.

(2) Condition A is that on the day the private prescription was issued, the patient in respect of whom it was issued was aged under 18.

(3) Condition B is that—

(a) the prescription has included within it the patient's age and is annotated by the prescriber with "SLS"; or

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(**a**) Regulation 217 has been amended by S.I. 2014/490 and 2019/775. Regulation 218 has been amended by S.I. 2014/490 and 1878, 2015/903 and 2019/775. Regulation 219 has been amended by S.I. 2015/903, 2016/696, 2019/775 and 2023/98. Regulation 219A was inserted by S.I. 2015/903 and amended by S.I. 2019/775.

(**b**) Regulation 217 has been amended by S.I. 2014/490 and 2019/775. Regulation 218 has been amended by S.I. 2014/490 and 1878, 2015/903 and 2019/775. Regulation 219 has been amended by S.I. 2015/903, 2016/696, 2019/775 and 2023/98. Regulation 219A was inserted by S.I. 2015/903 and amended by S.I. 2019/775.

(b) in—

(i) England and Wales and Scotland, if the prescription was issued before 3rd June 2024, or

(ii) Northern Ireland, if the prescription was issued before 27th August 2024,

the person to whom the GnRH analogue is to be sold or supplied produces to the person selling or supplying the GnRH analogue a specified document, a UK birth certificate or a current national identity document that verifies, to the reasonable satisfaction of the person selling or supplying the GnRH analogue, the age and identity of the person to or for whom the GnRH analogue is to be sold or supplied.

(4) Condition C is that the private prescription was issued by an approved UK prescriber.

(5) Condition D is that the purpose for which the private prescription was issued is a purpose other than treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.

(6) For the purposes of paragraph (1)(e), a person is treated as having started a course of treatment with a GnRH analogue if, in the six month period before 3rd June 2024, that person was issued with a NHS prescription or a private prescription for a GnRH analogue, whether or not the prescription has been dispensed or the prescribed GnRH analogue has been taken by that person before 3rd June 2024 or since.

(7) For the purposes of paragraph (1)(f), a person is treated as having started a course of treatment with a GnRH analogue if, in the six month period before 27th August 2024, that person was issued with a NHS prescription or a private prescription for a GnRH analogue, whether or not the prescription has been dispensed or the prescribed GnRH analogue has been taken by that person before 27th August 2024 or since.

(8) For the purposes of paragraph (5), treatment is treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination or both if it is, viewed objectively, treatment for that purpose, as gender dysphoria and gender incongruence are ordinarily understood as part of medical practice in the United Kingdom.

Signed by authority of the Secretary of State for Health and Social Care

Stephen Kinnock
Minister of State
Department of Health and Social Care

21st August 2024

Mike Nesbitt
Minister of Health

21st August 2024

EXPLANATORY NOTE

(This note is not part of the Order)

This Order prohibits, subject to exceptions, the retail sale, and the supply in circumstances corresponding to retail sale, of medicinal products that consist of or contain a list of gonadotrophin-releasing hormone ("GnRH") analogues (article 3). It is the second such Order – and, as it applies in Great Britian, it is made in effectively the same terms as the previous Order, the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024 (S.I. 2024/727), which expires immediately before this Order comes into force as it applies in England and Wales and Scotland. As this Order applies in Northern Ireland, it comes into force earlier – and there are adaptations to take account of the fact that the previous Order did not apply in Northern Ireland.

Orders for GnRH analogues in pursuance of NHS prescriptions or directions are excluded from the prohibition (article 4).

In the case of orders in pursuance of private prescriptions or directions, different conditions apply depending on the age of the patients. If the patient is 18 or over, GnRH analogues can continue to be sold or supplied for any purposes, subject to prescription formalities in some cases, and age and identity checks in others. Identity checks will not be necessary where a patient's age is included in a prescription and an approved UK prescriber annotates the prescription with 'SLS' (article 5).

If the private prescription or direction is for a child who is under 18 when the prescription or direction is issued, in addition to prescription formalities or potential identity checks, only a limited range of authorised prescribers – a list of approved UK prescribers – will be able to have new prescriptions issued since the start of the applicable restrictions dispensed, a list which does not include prescribers who are not United Kingdom registered. Also, the prescription or direction must be for a purpose other than treatment for the purpose of puberty suppression in respect of either or a combination of gender dysphoria and gender incongruence. However, if a child under 18 started a course of treatment with a GnRH analogue before 3rd June 2024, as the Order applies in England and Wales and Scotland, or before 27th August 2024, as the Order applies in Northern Ireland, GnRH analogues may continue to be sold or supplied to or for them, if the other conditions for private prescribing for such children are met (article 6).

An assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be undertaken. This Order is not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.

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