STATUTORY INSTRUMENTS

2024 No. 1319

MEDICINES

The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Restrictions on Private Sales and Supplies) Order 2024

Made - - - -at 10.06 a.m. on 11th December 2024

Laid before Parliament at 1.05 p.m. on 11th December 2024

Coming into force - - 1st January 2025

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.

In accordance with section 62(3) of that Act, the Ministers have consulted the Commission(**b**). In accordance with section 129(6) of that Act, the Ministers have also consulted such organisations as appear to them to be representative of interests likely to be substantially affected by the Order. In accordance with section 62(5) of that Act, the Ministers arranged that the consulted organisations that gave notice of their desire to be heard by the Commission were given an opportunity of appearing before and being heard by the Commission, and the Ministers also referred to the Commission the representations in writing of the consulted organisations.

Where the consulted organisations availed themselves of the opportunity of being heard, or after considering the representations of the consulted organisations, as the case may be, the Commission reported their findings and conclusions to the Ministers and the Ministers took that report into account in determining whether to make the Order. In accordance with section 129(7) of that Act(**c**), the Ministers also took the advice of the Commission into account before proceeding with their proposals.

Citation, commencement, extent and application

1.—(1) This Order may be cited as the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Restrictions on Private Sales and Supplies) Order 2024.

(2) This Order comes into force on 1st January 2025.

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

(**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 (N.I.)), section 1(5).

(**b**) *See* the definition of "the appropriate committee" in section 62(8) of that Act, inserted by S.I. 2012/1916, which is relevant to who is to be consulted.

(**c**) Section 129(7) has been amended by S.I. 2012/1916.

Interpretation

2.—(1) In this Order—

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

"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(**b**) (sale or supply of prescription only medicines);

"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);

"clinical trial" has the meaning given in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004(**c**) (interpretation);

"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(**d**) (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;

"licensing authority" has the meaning given in regulation 6(2) of the 2012 Regulations(**e**) (the licensing authority and the Ministers);

"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(**f**) (interpretation);

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

(c) in Wales, the health service as defined by section 206(1) of the National Health Service (Wales) Act 2006(**h**) (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(**i**) (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(**j**) (Parliamentary election rules – voting procedure and voter identification requirements);

"standard private prescription" means a private prescription which—

(**a**) S.I. 2012/1916, as amended.
(**b**) Regulation 214 has been amended by S.I. 2013/1855, 2014/490, 2016/186, 2018/199 and 2019/775.
(**c**) S.I. 2004/1031. There have been amendments to regulation 2(1) but none of them are relevant.
(**d**) 1971 c. 77.
(**e**) There have been amendments to regulation 6, but none are relevant. As a consequence of the renaming of the Department of Health, Social Services and Public Safety as the Department of Health by the Departments Act (Northern Ireland) 2016 (c. 5 (N.I.)), section 1(5), the powers of the Minister for Health, Social Services and Public Safety are now exercised by the Minister of Health.
(**f**) 2006 c. 41. There have been amendments to section 275(1), but none of them are relevant.
(**g**) 1978 c. 29. There have been amendments to section 108(1), but none of them are relevant.
(**h**) 2006 c. 42. There have been amendments to section 206(1), but none of them are relevant.
(**i**) 2009 c. 1 (N. I.).
(**j**) 1983 c. 2. Paragraph (1H) was inserted by the Elections Act 2022 (c. 37), Schedule 1, paragraph 18(4).

(a) is a prescription rather than a direction; and

(b) 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);

"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.

(2) For the purposes of this Order, treatment is treatment in respect of gender dysphoria, gender incongruence or a combination or both if it is, viewed objectively, treatment in respect of those conditions, as gender dysphoria and gender incongruence are ordinarily understood as part of medical practice in the United Kingdom.

Definition of "supply", which includes an exclusion from the scope of this Order of supplies for the purposes of an authorised clinical trial

3. In this Order, "supply" means supply in circumstances corresponding to retail sale (and "supplying" has a corresponding meaning), 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.

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

4. Subject to articles 5 to 8, the sale or supply of a GnRH analogue is prohibited.

Exception for all NHS prescriptions

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

Exception for private prescriptions: patients aged 18 or over

6.—(1) Article 4 does not apply to a sale or supply in pursuance of a private prescription where—

(a) Condition A is met; and

(b) if the prescription is a standard private prescription and the prescription was issued—

(i) by an approved UK prescriber, Condition B is met, or

(ii) by an authorised prescriber who is not an approved UK prescriber, Condition C is met.

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

(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

(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 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

(**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.

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 – treatment for a purpose other than puberty suppression in respect of gender dysphoria etc.

7.—(1) Article 4 does not apply to a sale or supply in pursuance of a private prescription, if 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, where—

(a) Condition A is met;

(b) if the prescription is a standard private prescription, Condition B is met; and

(c) if the prescription was issued—

(i) in England and Wales and Scotland, on or after 3rd June 2024, or

(ii) in Northern Ireland, on or after 27th August 2024,

Condition C is met.

(2) Condition A is that on the day the 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

(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 prescription was issued by an approved UK prescriber.

Exception for private prescriptions: patients aged under 18 – treatment for the purposes of puberty suppression in respect of gender dysphoria etc.

8.—(1) Article 4 does not apply to a sale or supply in pursuance of a private prescription, if the purpose for which the private prescription was issued is treatment for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both, where—

(a) Condition A is met;

(b) if the prescription is a standard private prescription, Condition B is met; and

(c) if the prescription was issued—

(i) in England and Wales and Scotland, on or after 3rd June 2024, or

(ii) in Northern Ireland, on or after 27th August 2024,

Condition C and condition D are met.

(2) Condition A is that on the day the 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

(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 prescription was issued by an approved UK prescriber.

(5) Condition D is that the sale or supply is to or for a person who, on any occasion, started a course of treatment with a GnRH analogue—

(a) in England and Wales and Scotland, before 3rd June 2024; or

(b) in Northern Ireland, before 27th August 2024.

(6) For the purposes of paragraph (5), a person is treated as having started a course of treatment with a GnRH analogue if—

(a) in England and Wales and Scotland, 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; or

(b) in Northern Ireland, 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.

Reviews

9.—(1) The Ministers must—

(a) carry out a review ("the first review") of this Order;

(b) as part of carrying out the first review, consult the Commission; and

(c) publish a report setting out the conclusions of the first review,

before the end of 1st October 2027.

(2) The report must, in particular—

(a) set out the objectives intended to be achieved by this Order;

(b) assess the extent to which those objectives are achieved;

(c) assess whether those objectives remain appropriate; and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(3) After the first review (if this Order, whether or not in an amended form, remains in force), the Ministers must carry out subsequent reviews of this Order at intervals not exceeding 4 years, and must—

(a) as part of each review consult the Commission; and

(b) publish a report of each review that both sets out the conclusions of the review and satisfies the requirements of paragraph (2).

Wes Streeting
Secretary of State
At 10.06 a.m. on 11th December 2024 Department of Health and Social Care

Mike Nesbitt
10th December 2024 Minister of Health

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 4). It is the fourth such Order – and is made in effectively the same terms as the temporary Order which preceded it, the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) (No. 2) Order 2024 (S.I. 2024/1110), which expires immediately before this Order comes into force.

Supplies of GnRH analogues as part of authorised clinical trials are excluded from the prohibition (article 3), as are orders for GnRH analogues in pursuance of NHS prescriptions or directions (article 5).

In the case of sales or supplies of GnRH analogues 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, but if the order for the GnRH analogue is in one of the standard formats for a prescription (as most have to be because of regulation 214(1) of the Human Medicines Regulations 2012 (S.I. 2012/1916)), there are prescription formalities in some cases, and age and identity checks in others. Age and identity checks will not be necessary where a patient's age is included in the prescription and an approved UK prescriber annotates the prescription with 'SLS' (article 6).

If the private prescription or direction is for a patient who is under 18, if the order is in one of the standard formats for a prescription there are again prescription formalities in some cases, and age and identity checks in others. In addition, only a limited range of authorised prescribers – a list of approved UK prescribers – will be able to have dispensed new prescriptions or directions that are issued after the start of the applicable restrictions. This list of approved prescribers does not include prescribers who are not United Kingdom registered.

Also, for patients under 18 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, subject to an exception. The exception is that a patient under 18 who is in this category but who 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, may continue to have GnRH analogues sold or supplied to or for them (articles 7 and 8).

Provision is also made for reviews on a four-year cycle, although the first review needs to be completed, with the publication of a report, by 1st October 2027 (article 9).

An impact assessment has been produced for this instrument and is available from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU. A copy of it is also published alongside this instrument on www.legislation.gov.uk.

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