
STATUTORY INSTRUMENTS

2026 No. 000

MEDICINES

**The Human Medicines (Amendments Relating to Naloxone)
Regulations 2026**

Made - - - - - *2024*

Coming into force in accordance with regulation 1(2)

The Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland, make the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(h) and (n) and (2)(a), (c), (d) and (e) and 43(2) of the Medicines and Medical Devices Act 2021(a).

The Secretary of State and the Department of Health in Northern Ireland have carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 2(2) to (4) of that Act, the Secretary of State's and the Department of Health in Northern Ireland's overarching objective in making these Regulations is safeguarding public health, and the Secretary of State and the Department of Health in Northern Ireland have had regard to the matters specified in section 2(3) of that Act and consider that, where these Regulations may have an impact on the safety of human medicines, the benefits of making these Regulations outweigh the risks.

In accordance with section 47(3) and (6)(c) of that Act, a draft of these Regulations was laid before Parliament and the Northern Ireland Assembly and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendments Relating to Naloxone) Regulations 2026.

(2) These Regulations come into force on the 28th day after the day on which they are made.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(b) are amended in accordance with regulations 3 to 7.

(a) 2021 c. 3. The powers in section 2(1) of the Medicines and Medical Devices Act 2021, and in the provisions that relate to it, are exercisable by the “appropriate authority”. See section 2(6) of that Act, which contains the definition of “appropriate authority” that is relevant to the powers being exercised.

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

Amendment to regulation 8

3. In regulation 8 (general interpretation)(a), in paragraph (1), omit the definition of “local naloxone provider”.

Amendments to regulation 213

4. In regulation 213(interpretation)(b), in paragraph (1), at the appropriate places insert—

““appropriate national body” means—

- (a) in England, the Secretary of State;
- (b) in Scotland, the Scottish Ministers;
- (c) in Wales, the Welsh Ministers or Public Health Wales;
- (d) in Northern Ireland, the Public Health Agency or the Department of Health in Northern Ireland;”;

““daycentre for homeless people” means premises which are not a hostel for homeless people or a care home but—

- (a) in which there is provided for people experiencing homelessness or rough sleeping (or both), at specified hours on specified days, care, support or supervision (or a combination of these) with a view to assisting those people to be rehabilitated or resettled within the community; and
- (b) which—

(i) is operated other than on a commercial basis and in respect of which funds are provided wholly or in part by an appropriate national body or a local authority, or

(ii) is managed by a voluntary organisation or a registered charity, or is both;”;

““hostel for homeless people” means premises which are not a care home but—

- (a) in which there is provided, for people experiencing homelessness or rough sleeping (or both)—
 - (i) domestic accommodation, otherwise than as separate and self-contained premises, and either board or facilities for the preparation of food adequate to the needs of those people, or both, and
 - (ii) care, support or supervision (or a combination of these) with a view to assisting those people to be rehabilitated or resettled within the community; and
- (b) which—

(i) is managed or owned by a provider of social housing other than a local authority,

(ii) is operated other than on a commercial basis and in respect of which funds are provided wholly or in part by an appropriate national body or a local authority, or

(iii) is managed by a voluntary organisation or a registered charity, or is a combination of these;”;

““local naloxone provider” is to be construed in accordance with regulation 237D(3)(a); ”; and

““outreach service for homeless people” means a service provided for people experiencing homelessness or rough sleeping (or both), other than at a daycentre for

(a) The relevant amending instrument is....

(b) Relevant amendments have been made to regulation 213 by....

homeless people or at a hostel for homeless people (although a daycentre or hostel operator may also provide an outreach service), which—

- (a) is operated other than on a commercial basis and in respect of which funds are provided wholly or in part by an appropriate national body or a local authority, or
- (b) is managed by a voluntary organisation or a registered charity,

or is both, and which provides, by means of an outreach programme, care, support or supervision (or a combination of these) with a view to assisting those people to be rehabilitated or resettled within the community;”.

Substitution of 237A

5. For regulation 237A (appropriate suppliers of naloxone products) substitute—

“Supply of naloxone products – designated supplier model

237B.—(1) Regulations 214(1) and 220 do not apply to the supply of a naloxone product by an individual who is a designated supplier model appropriate supplier of naloxone products, if it is for an appropriate purpose.

(2) For the purposes of paragraph (1), the following are designated supplier model appropriate suppliers of naloxone products—

- (a) a person employed or engaged to provide drug treatment services that are provided by or on behalf of, or under arrangements with, one of the following—
 - (i) an NHS body,
 - (ii) a local authority,
 - (iii) the Secretary of State, or
 - (iv) the Public Health Agency;
- (b) a person employed or engaged to provide drug treatment services as part of the medical services of His Majesty’s forces;
- (c) a person employed or engaged to provide drug treatment services that are provided by or on behalf of, or under arrangements with, one of the bodies listed below, if the listed body is satisfied that the person has undergone appropriate training in the storage and supply of naloxone products—
 - (i) a police force in England, Wales or Scotland,
 - (ii) the Police Service of Northern Ireland,
 - (iii) a prison service,
 - (iv) a provider of probation services, or
 - (v) a provider of youth justice services;
- (d) a person employed or engaged to provide drug treatment services by a hostel for homeless people, a daycentre for homeless people or an outreach service for homeless people, if that hostel, daycentre or outreach service is satisfied that the person has undergone appropriate training in the storage and supply of naloxone products; or
- (e) a person who is one of the following—
 - (i) a pharmacist,
 - (ii) in England, Wales or Scotland, a registered pharmacy technician,
 - (iii) a registered nurse,
 - (iv) a registered midwife, or
 - (v) a registered paramedic,

if that person has undergone appropriate training in the storage and supply of naloxone products.

(3) For the purposes of this regulation, an individual provides drug treatment services if, whether or not the entity that employs or engages them would ordinarily be considered to be a provider of drug treatment services, the individual is required, as part of the arrangements under which they are employed or engaged by that entity, however rarely—

- (a) to supply a naloxone product to another person in circumstances where it may be needed by that other person, or by a person or a category of person for whom it was supplied to that other person, for the purpose of saving life in an emergency;
- (b) to administer a naloxone product to themselves (for example, in a case of accidental contamination at a place of work) or to supply or administer it to another person for the purposes of saving life in an emergency.

(4) For the purposes of this regulation and regulation 237C, and for the purposes of the definitions of expressions used in this regulation and regulation 237C, “local authority” —

- (a) in England, has the same meaning as in section 2B of the National Health Service Act 2006;
- (b) in Wales, means the council of a county or a county borough [or a community council];
- (c) in Scotland, means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994; and
- (d) in Northern Ireland, means the council of a county or a county borough, or a new town commission exercising the functions of the council of a county borough.

Appropriate suppliers of naloxone products – locked box model

237C.—(1) Regulations 214(1) and 220 do not apply to the supply of a naloxone product by a locked box model appropriate supplier of naloxone products, if it is for an appropriate purpose.

(2) For the purposes of paragraph (1), a person (ordinarily a corporate body) is a locked box model appropriate supplier of naloxone products if that person (“the locked box service provider”) provides drug treatment services remotely by supplying naloxone as part of a valid naloxone locked box supply service that is provided—

- (a) under arrangements that are part of the health service;
- (b) pursuant to arrangements with, or as part of a service that is funded in whole or in part by, an appropriate national body or a local authority.

(3) To be valid, a naloxone locked box supply service must have the following features—

- (a) boxes which contain naloxone products, which are ordinarily locked, have been fixed by the locked box service provider at locations which the locked box service provider determines are locations at which emergency supplies of naloxone products may be needed;
- (b) the locked box service provider is the person responsible for the stocking of the boxes with naloxone and accountable for—
 - (i) the state and maintenance of, and storage conditions inside, the boxes, and
 - (ii) the effectiveness of the locking mechanisms of the boxes and the arrangements for their release;
- (c) opening the boxes without force requires (apart from when the boxes are stocked by persons employed or engaged by the service provider)—
 - (i) remote release of their locking mechanisms by persons employed or engaged by the locked box service provider, or
 - (ii) the keying in, on a panel on the boxes, of a code to be supplied—
 - (aa) as part of approved automated opening procedures, or

- (bb) by persons employed or engaged either by the locked box service provider or as part of emergency services provided as part of the health service; and
- (d) the boxes only open (apart from when the boxes are stocked by persons employed or engaged by the service provider)—
 - (i) if it is by release of their locking mechanisms by persons employed or engaged by the locked box service provider remotely, following a discussion, via an audio or video link, with the persons seeking access to the naloxone products in the boxes, or
 - (ii) if it is by the keying in of a code—
 - (aa) as part of approved automated opening procedures, or
 - (bb) following discussions, via an audio or video link, between the persons seeking access to the naloxone products in the boxes and the persons employed or engaged either by the locked box service provider or as part of emergency services provided as part of the health service.

(4) For the purposes of paragraph (3)(c)(ii)(aa) and (d)(ii)(aa), approved automated opening procedures, means automated opening procedures approved for use by the locked box service provider by—

- (a) the body making the health service arrangements with the provider that are mentioned in paragraph (2)(a);
- (c) the appropriate national body or local authority—
 - (i) making the arrangements (which need not be remunerated arrangements) with the provider that are mentioned in paragraph (2)(b), or
 - (ii) providing the funding for the provider that is mentioned in paragraph (2)(b),

that allow a person seeking access to the box to receive, from either the locked box service provider or an emergency service that is part of the health service, via a messaging or internet service, a message containing a code that, if keyed in on a panel on the box, releases the box's locking mechanism (although the stocking of the box may be done by a person who already has the code).

(5) For the purposes of this regulation, a locked box model appropriate supplier of naloxone products supplies a naloxone product when—

- (a) following the keying in of the code mentioned in paragraph (3)(d)(ii) (whether the code is supplied by the locked box service provider or an emergency service that is part of the health service), the box is opened and the naloxone product is removed from the box, or
- (b) following the remote release a locking mechanism as mentioned in paragraph (3)(d)(i),

a locked box, stocked as mentioned in paragraph (3)(b), is opened and the naloxone product is removed from the box (the supply of the naloxone product is to the person removing the naloxone product from the box).

Supply of naloxone products – local network model

237D.—(1) Regulations 214(1) and 220 do not apply to the supply of a naloxone product by an individual who is a local network model appropriate supplier of naloxone products, if it is for an appropriate purpose.

(2) For the purposes of paragraph (1), a person is a local network model appropriate suppliers of naloxone product if that person is a person employed or engaged by a local naloxone provider, if that local naloxone provider is satisfied that the person has undergone appropriate training in the storage and supply of naloxone products.

(3) For the purposes of this regulation—

- (a) a local naloxone provider is an entity that has valid arrangements in place (“local naloxone arrangements”) with a naloxone supply network co-ordinator for the supply of naloxone products for an appropriate purpose; and
- (b) a naloxone supply network co-ordinator is an entity that has valid arrangements in place (“network creation arrangements”) with an appropriate national body as part of which the naloxone supply network co-ordinator creates and maintains a network of local naloxone providers that are willing to supply naloxone products for an appropriate purpose.

(4) For—

- (a) local naloxone arrangements to be valid, a naloxone supply network co-ordinator must ensure that any putative local naloxone arrangements that it has contain arrangements that ensure; and
- (b) network creation arrangements to be valid, the appropriate national body must ensure that any putative network creation arrangements that it has contain arrangements that ensure,

the outcomes listed in paragraph (6).

(5) Those outcomes are—

- (a) that only persons who are employed or engaged by the putative local naloxone provider and who have undergone appropriate training in the storage and supply of naloxone products are able to supply them under the putative local naloxone arrangements;
- (b) that any requirements that the appropriate national body has in respect of training in the storage and supply of naloxone products which are relevant to supply in accordance with this regulation are included in the putative local naloxone arrangements, and any such requirements are appropriate training for the purposes of paragraph (2) (but see regulation 237E);
- (c) that a record is kept by the putative local naloxone provider of all the persons employed or engaged by them who are able to supply naloxone products under the putative local naloxone arrangements, and of their relevant training;
- (d) that the putative local naloxone provider has a named individual responsible at all times for—
 - (i) the storage, any handling relating to storage and any handling relating to supply of naloxone products by or on behalf of the putative local naloxone provider under their putative local naloxone arrangements, and
 - (ii) the maintenance of appropriate records of those activities by the putative local naloxone provider;
- (e) that any requirements that the appropriate national body has in respect of storage and any handling relating to supply of naloxone products by local naloxone providers, which arise out of or relate to supply in accordance with this regulation, are included in the putative local naloxone arrangements; and
- (f) that any requirements that the appropriate national body has in respect of the processing of information by local naloxone providers, including in respect of—
 - (i) the records to be kept as part of local naloxone arrangements,
 - (ii) the information to be derived from those records, and
 - (iii) the provision of information to naloxone supply network co-ordinators, and the occasions on which and the frequency with which to do so,

which arise out of or relate to supply in accordance with this regulation, are included in the putative local naloxone arrangements.

(7) For network creation arrangements to be valid, the appropriate national body must also ensure that any putative network creation arrangements that it has contain arrangements that ensure the following outcomes—

- (a) that any requirements that the appropriate national body has in respect of the processing of information by naloxone supply network co-ordinators, including in respect of—
 - (i) the records to be kept as part of the network creation arrangements,
 - (ii) the information to be derived from those records, and
 - (iii) the provision of information to the appropriate national body, and the occasions on which and the frequency with which to do so,

which arise out of or relate to supply in accordance with this regulation, are included in the putative network creation arrangements; and
- (b) that any requirements that the appropriate national body has in respect of who may be a local naloxone provider, and how their status as such is recorded or advertised, are included in the putative network creation arrangements.

Appropriate suppliers of naloxone products - training

237E. In order for training in the storage and supply of naloxone products to be appropriate for the purposes of regulation 237B and 237D, its outcome must be that a person completing the training successfully (T) has the following competencies—

- (a) understanding of the legal framework for supply in accordance with this regulation which is sufficient for the purposes of ensuring that T is able to administer naloxone products lawfully and where appropriate to supply them to another person for that other person to administer them lawfully, having been trained to do so by T;
- (b) understanding of the safe storage and safe handling of naloxone products which is sufficient for the purposes of ensuring—
 - (i) that T is able to store and handle naloxone products safely and without compromising their efficacy, and
 - (ii) if T is to supply those products to another person for that other person to store and handle them, that the other person is able to store and handle them safely, and without compromising their efficacy, having been trained to do so by T; and
- (c) understanding of how and when to administer naloxone products which is sufficient for the purposes of ensuring—
 - (i) that T is able to do so safely, effectively and when appropriate, and
 - (ii) if T is to supply those products to another person for that other person to administer them, that the other person is able to administer them safely, effectively and when appropriate, having been trained to do so by T,

and if the appropriate national body for where a supply takes place has determined that that is the outcome of particular training for a particular (or any) category of person, then for where that supply takes place that determination is conclusive evidence, or in Scotland sufficient evidence, that the training is appropriate training for that category of person.

Appropriate purposes for the supply of naloxone products

237F.—(1) The following are appropriate purposes for the purposes of this regulation—

- (a) the naloxone product is needed by the person to whom or for whom it is supplied for the purpose of saving life in an emergency;
- (b) in the reasonable expectation of the appropriate supplier of naloxone, the supply of the naloxone product is to enable it to be kept at a place where the person supplied resides or which they frequent, in circumstances where that or another person may need it, at that place—

- (i) to administer it to themselves in an emergency for the purposes of saving their own life, or
- (ii) to administer it to another person, or to have it administered to them, for the purpose of saving life in an emergency; or
- (c) in the reasonable expectation of the appropriate supplier of naloxone, the supply of the naloxone product is to enable it to be carried about by the person to or for whom it is supplied, that person being a person who may need it—
 - (i) to administer it to themselves in an emergency for the purposes of saving their own life, or
 - (ii) to administer it to another person, or to have it administered to them, for the purpose of saving life in an emergency.

(2) For the avoidance of doubt, a person in possession of a naloxone product as a consequence of a supply pursuant to this regulation may administer it to another person for the purposes of saving their life in an emergency without breaching regulation 214, 220 or 238, even if that other person is not the person, or is not in the category of persons, to or for whom the naloxone was supplied.

(3) For the purposes of regulation this regulation and regulation 238, any use of a naloxone product that is indicated in a marketing authorisation for the product is to be treated as being for the purpose of saving life, even if the use is for, or partially for, diagnosis.

Information about supplies of naloxone

237G.—(1) Where an appropriate supplier of naloxone mentioned in paragraph 237B(2)(a) to (d) or 237D supplies a naloxone product—

- (a) that appropriate supplier of naloxone;
- (b) a provider of health care services that employs or engages the appropriate supplier of naloxone, if it is the entity that supplied the supplier with the naloxone product;
- (c) a body listed in regulation 237B (2)(a), (c) or (d), where that body provided or commissioned services as part of which a naloxone product was supplied pursuant to that regulation; or
- (d) locked box model appropriate supplier of naloxone products for the purposes of regulation 237C,

may provide an appropriate national body with any information about that supply, if that type of information, or information derived from that type of information, is information that a naloxone supply network co-ordinator would be required to supply to that body under network creation arrangements, it (or the information derived from it) being information included in requirements that the appropriate national body has as mentioned in paragraph (7)(a)(iii).

(2) For the purposes of section 8(c) of the Data Protection Act 2018 (lawfulness of processing: public interest etc)(a), provision of information in the circumstances described in paragraph (1) is to be considered necessary for the performance of a task carried out in the public interest.”.

Amendment to regulation 250

6. In regulation 250 (exceptions to regulation 249)(b), for paragraph (4B) substitute—

“(4B) A person may, in the course of a business consisting (wholly or partly) of manufacturing medicinal products, or of selling products by way of wholesale dealing, sell

(a) 2018 c. 12; amended by S.I. 2019/419.

(b) Amended by S.I. 2020/1125 (S.R. 2020/349).

or supply by way of wholesale dealing a naloxone product that is a prescription only medicine to—

- (a) a person who employs or engages individuals who are designated supplier model appropriate suppliers of naloxone products for the purposes of regulation 237B, but only if that person employs or engages those individuals (at least partly) as designated supplier model appropriate suppliers of naloxone products;
- (b) a locked box service provider for the purposes of regulation 237C; and
- (d) local naloxone providers.”.

Amendment of regulation 253

7. In regulation 253 (pharmacy records)(a), in paragraph (4), after sub-paragraph (a) insert—

“(aa) the sale or supply is of a naloxone product pursuant to regulation 237B (but regulation 237G applies to any record the person does keep of the sale or supply);”

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

Date Parliamentary Under-Secretary of State
Department of Health and Social Care

Sealed with the Official Seal of the Department of Health in Northern Ireland [date]

Name _____

A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 (“the 2012 Regulations”), which govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use.

A number of the amendments make provision about the supply of medicinal products containing naloxone or its salts, esters or stereoisomeric forms (“naloxone products”) which are prescription only medicines. Naloxone products are used in the diagnosis and treatment of cases of acute overdose or intoxication caused by natural or synthetic opioids.

A Regulatory Triage Assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be proportionate. These Regulations are 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.

(a) There are no relevant amendments to regulation 253.