Draft Regulations laid before Parliament and the Northern Ireland Assembly under section 47(3) and (6)(c) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament and the Northern Ireland Assembly.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2024 No. 000

MEDICINES

The Human Medicines (Amendments Relating to Naloxone) Regulations 2024

Made - - - -	*****
Coming into force	*2024*

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)(c) and (n) and (2) and 43 of the Medicines and Medical Devices Act 2021(**a**), after having considered the matters in section 2(2) to (4) of that Act.

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 47(3) and (6)(c) of that Act, a draft instrument 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 2024.

(2) These Regulations come into force on [date].

(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 of regulation 8

3.—(1) Regulation 8 (interpretation)(**a**) is amended as follows.

(2) In paragraph (1), at the appropriate places in the alphabetical order insert—

""local naloxone provider" is to be construed in accordance with regulation 237A(3);";

""pharmacy technician" means a person registered in Part 2 of the register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010 (establishment, maintenance of and access to the register)(**b**);";

""provider of probation services"—

(a) in England and Wales, has the same meaning as in Part 1 of the Offender Management Act 2007(**c**);

(b) in Scotland, means a local probation board, or a body that is providing probation services on behalf of, or under arrangements with, a local probation board; and

(c) in Northern Ireland, means the Probation Board for Northern Ireland.

""provider of youth justice services" means—

(a) in England and Wales, a provider, other than a local authority, of the services for the time being specified in section 38(4) of the Crime and Disorder Act 1998 (local provision of youth justice services)(**d**);

(b) in Scotland, a provider, other than a local authority, of services equivalent to the services for the time being specified in section 38(4) of the Crime and Disorder Act 1998; and

(c) in Northern Ireland, a body or other person with which or whom the Secretary of State has made arrangements for the provision of juvenile justice centres pursuant to Article 51(2) of the Criminal Justice (Children) (Northern Ireland) Order 1998 (juvenile justice centres)(**e**);".

New regulation 237A

4. After regulation 237 (products containing pseudoephedrine salts or ephedrine base or salts) insert—

"**Appropriate suppliers of naloxone**

237A.—(1) Regulations 214(1) and 220 do not apply to the supply of a medicinal product that contains naloxone hydrochloride by an individual who is an appropriate supplier of naloxone, if it is for an appropriate purpose.

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

(a) a person employed or engaged in the provision of drug treatment services provided by or on behalf of, or under arrangements with, one of the bodies listed below—

(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 in the provision of services as part of the medical services of His Majesty's forces;

(**a**) Amended by…
(**b**) S.I. 2010/231; article 19 has been amended by…
(**c**) 2007 c. 21. *See* section 3(6) of that Act.
(**d**) 1998 c. 37, as amended.
(**e**) S.I. 1998/1504 (N.I. 9).

(c) a person employed or engaged by, or by an entity commissioned to provide drug treatment services by on behalf of, one of the bodies listed below, if the listed body is satisfied that the person has undergone appropriate training in the supply of medicinal products that contain naloxone hydrochloride—

(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 a youth justice services;

(d) the following health care professionals—

(i) a pharmacist,

(ii) in England, Wales or Scotland, a pharmacy technician,

(iii) a registered nurse,

(iv) a registered midwife, or

(v) a registered paramedic

who have undergone appropriate training in the storage and supply of medicinal products that contain naloxone hydrochloride; and

(e) 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 medicinal products that contain naloxone hydrochloride.

(3) For the purposes of paragraph (2)(e), 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 products that contain naloxone hydrochloride for an appropriate purpose.

(4) In this regulation, 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 products that contain naloxone hydrochloride for an appropriate purpose.

(5) For the arrangements to be valid, the appropriate national body must ensure that the network creation arrangements that it has with a naloxone supply network co-ordinator contain arrangements that ensure, and a naloxone supply network co-ordinator must ensure that the local naloxone arrangements that it has with a local naloxone provider contain arrangements that ensure, the following outcomes—

(a) that only persons who are employed or engaged by the local naloxone provider and who have undergone appropriate training in the storage and supply medicinal products that contain naloxone hydrochloride are able to supply them under local naloxone arrangements;

(b) that any requirements that the appropriate national body has in respect of training in the storage and supply of medicinal products that contain naloxone hydrochloride which are relevant to supply in accordance with this regulation are included in the local naloxone arrangements, and any such requirements that are for inclusion in local naloxone arrangements are appropriate training for the purposes of paragraph (2)(e);

(c) that a record is kept by local naloxone providers of all the persons employed or engaged by them who are able to supply medicinal products that contain naloxone hydrochloride under their local naloxone arrangements, and of their relevant training;

(d) that the 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 distribution or supply of medicinal products that contain naloxone hydrochloride by or on behalf of the local naloxone provider under their local naloxone arrangements, and

(ii) the maintenance of appropriate records of those activities by the local naloxone provider;

(e) that any requirements that the appropriate national body has in respect of storage and handling of medicinal products that contain naloxone hydrochloride by local naloxone providers, which arise out of or relate to supply in accordance with this regulation, are included in their local naloxone arrangements; and

(f) that any requirements that the appropriate national body has in respect of the keeping or processing of information by local naloxone providers, including in respect of—

(i) the records that are 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 their local naloxone arrangements.

(6) For the purposes of paragraph (5)(b), the requirements that appropriate national body has may include training in the training that the persons supplying medicinal products that contain naloxone hydrochloride are to provide to the persons being supplied with those products.

(7) For the arrangements to be valid, the appropriate national body must ensure that the network creation arrangements that it has with a naloxone supply network co-ordinator contain arrangements to ensure the following outcomes—

(a) that any requirements that the appropriate national body has in respect of the keeping or processing of information by naloxone supply network co-ordinators, including in respect of—

(i) the records that are 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 bodies, 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 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 network creation arrangements.

(8) For the purposes of paragraph (2)(c) and (d), training is appropriate if, in the opinion of an appropriate national body for where the supply takes place, it is appropriate (although other training may, objectively, also be appropriate for the purposes of paragraph (2)(c) and (d)).

(9) For the purposes of paragraphs (4) to (7), the following are appropriate national bodies—

(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.

(10) The following are appropriate purposes for the purposes of this regulation—

(a) the medicinal product that contains naloxone hydrochloride is needed by the person to 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 medicinal product that contains naloxone hydrochloride is to enable it to be kept at a place where a person resides or which they frequent, in circumstance where that person may need, 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 have it administered to them, in accordance with regulation 238.

(c) in the reasonable expectation of the appropriate supplier of naloxone, the supply of the medicinal product that contains naloxone hydrochloride 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 have it administered to them, in accordance with regulation 238.

(11) Where, pursuant to this regulation, an appropriate supplier of naloxone mentioned in paragraph (2)(a) to (d) supplies a medicinal product that contains naloxone hydrochloride—

(a) that appropriate supplier of naloxone;

(b) a drug treatment services, medical services or other health care services provider employing or engaging the appropriate supplier of supplier, if it is the entity that supplied the supplier with the medicinal product that contains naloxone hydrochloride; or

(c) a body listed in paragraph (2)(a) or (c) that commissioned the drug treatment or other health care services as part of which the appropriate supplier of naloxone supplied the medicinal product that contains naloxone,

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 national supply 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).

(12) In circumstances where a person may provide information pursuant to paragraph (11), provision of information in those circumstances is to be considered necessary for the performance of a task carried out in the public interest.

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

Amendment of regulation 250

5.—(1) Regulation 250 (exceptions to regulation 249) is amended as follows.

(2) After paragraph (4A) insert—

"(4B) A person may, in the course of a business consisting (wholly or partly) of manufacturing medicinal products, or selling medicinal products by way of wholesale dealing, sell or supply by way of wholesale dealing a medicinal product that is a prescription only medicine that contains naloxone hydrochloride to—

(a) providers of drug treatment services that have arrangements as mentioned in regulation 237A(2)(a);

(b) the bodies mentioned in regulation 237A(2)(c); and

(c) local naloxone providers.".

Amendment of regulation 346

6.—(1) Regulation 346 (review) is amended as follows.

(2) In paragraph 2(c), before paragraph (xxviiiga) insert—

"(xxviiigza) 237A,".

Amendment of Schedule 17

7.—(1) Schedule 17 (exemption for sale, supply or administration by certain persons) is amended as follows.

(2) In the table in Part 2 (exemption from the restriction on the supply of prescription only medicines)(**a**), omit entry 4a in columns 1, 2 and 3.

(3) In the table in Part 5 (exemptions from the restriction in regulations 220 and 221 for certain persons who supply certain products)(**b**), omit entry 7a in columns 1, 2 and 3.

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

Name
Minister of State for Health
Department of Health and Social Care

Date

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.

The amendments make provision about the supply of medicinal products containing naloxone hydrochloride ("naloxone") which are prescription only medicines. Naloxone is used in the diagnosis and treatment of cases of acute overdose or intoxication caused by natural or synthetic opioids.

Limited provision had previously been made to allow people working for drug treatment services to benefit, when supplying naloxone, from an exemption from the ordinary restrictions in the 2012 Regulations on the supply of prescription only medicines. That exemption allowed people working for drug treatment services to supply naloxone without being authorised prescribers. New exemptions introduced by these Regulations also allow people working for the police, prison services and probation services to do so – as well as a list of registered health care professionals – provided those individuals have undergone appropriate training. A new exemption is also created for the medical services of His Majesty's forces.

These Regulations additionally create a new concept of entities whose workers will also benefit from the new exemptions, that of local naloxone provider. These local naloxone providers will be in networks, run on behalf central government and the devolved administrations by entities that

(**a**) The relevant amending instrument is S.I.….
(**b**) The relevant amending instrument is S.I.…

agree to act as naloxone supply network co-ordinators. The local naloxone arrangements that are to govern the local supply are required cover a list of issues that includes appropriate training, handling of naloxone and record keeping. Provision is made to allow the appropriate national bodies to set national standards for training in the supply of naloxone nationally. Specific provision has also been made for the transfer of information to national authorities.

Supplies of naloxone by all the individuals coming within the new exemption will need to be for a specified purpose. Previously, when a more limited exemption applied just to drug treatment services, the purpose restriction was limited to the actual saving of life in an emergency, but under the new arrangements, suppliers will be able to supply "take home" naloxone, and to supply naloxone to be carried about, for example by police officers, in case it is needed (regulation 3 and 4).

The earlier more limited exemption for drug treatment services have been subsumed into the new exemption, allowing for its repeal (regulation 7).

An adjustment is made to the powers of medicines manufacturers and wholesalers to allow them to supply into the new arrangements (regulation 5) and an amendment has been made to the review provision in the 2012 Regulations so that it includes the new naloxone exemption (regulation 6).

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.