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.

DRAFT STATUTORY INSTRUMENTS

2024 No. 000

MEDICINES

The Human Medicines (Amendments Relating to Naloxone and Transfers of Functions) Regulations 2024

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(**1**).

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 and Transfers of Functions) Regulations 2024.

(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.

(**1**) 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.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**2**) are amended in accordance with regulations 3 to 13.

Amendments to regulation 8

3. In regulation 8 (general interpretation)(**3**), in paragraph (1), at the appropriate places insert—

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

""naloxone product" means a medicinal product that contains naloxone or a salt, ester or stereoisomeric form of naloxone;";

""provider of probation services"—

(a) in England and Wales, has the same meaning as in Part 1 of the Offender Management Act 2007 (new arrangements for the provision of probation services)(**4**); and

(b) 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 specified in section 38(4) of the Crime and Disorder Act 1998 (local provision of youth justice services)(**5**);

(b) in Scotland, a provider, other than a local authority, of the services in Scotland in respect of a child that most closely correspond to the services specified in section 38(4) of the Crime and Disorder Act 1998, and for these purposes "child" has the meaning given in section 199 of the Children's Hearings (Scotland) Act 2011 (meaning of "child")(**6**); and

(c) in Northern Ireland, a body or other person with which or whom the Department of Justice 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)(**7**);".

Amendments to regulation 213

4. In regulation 213 (interpretation of Part 12)(**8**), in paragraph (1)—

(a) in the definition of "health authority", in paragraph (d), for "the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009", substitute "the Department of Health in Northern Ireland"(**9**);

(b) omit the definition of "Public Health England"; and

(c) at the appropriate place insert—

""the United Kingdom Health Security Agency" means the executive agency of that name of the Department of Health and Social Care.".

(**2**) S.I. 2012/1916, as amended.
(**3**) Paragraph (1) has been amended by S.I. 2013/1855 and 2593, 2015/1503 (S.R. 2015/354), 2016/186 (S.R. 2016/407), 190 and 696, 2017/715 (S.R. 2017/241), 2018/199 (S.R. 2018/64), 2019/62 (S.R. 2019/10), 593 (as amended by S.I. 2020/1394), 703, 775 (as amended by S.I. 2020/1488) and 1094, 2020/1125 (S.R. 2020/349), 2021/1453 and 2022/352.
(**4**) 2007 c. 21. *See* section 3(6) of that Act.
(**5**) 1998 c. 37, as amended.
(**6**) 2011 asp 1.
(**7**) S.I. 1998/1504 (N.I. 9).
(**8**) Paragraph (1) has been amended by S.I. 2013/235, 2014/490 (S.R. 2014/323) and 1878 (S.R. 2014/324), 2015/323 (S.R. 2015/178), 2016/186 (S.R. 1016/407), 2017/715 (S.R. 2017/241), 2018/199 (S.R. 2018/64) and 378, 2019/775, 2022/634 and 2023/1071.
(**9**) *See* sections 1 and 2 of the Health and Social Care Act (Northern Ireland) 2022 (c.3).

Amendment to regulation 229

5. In regulation 229 (exemption for supply by national health service bodies and local authorities)(**10**), in paragraph (1), for sub-paragraph (db) substitute—

"(db) the United Kingdom Health Security Agency;".

Amendment to regulation 233

6. In regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)(**11**), in paragraph (1)(a), for paragraph (ivd) substitute—

"(ivd) the United Kingdom Health Security Agency,".

New regulation 237A

7. After regulation 237 (products consisting of or containing pseudoephedrine salts or ephedrine base or salts) insert—

"**Appropriate suppliers of naloxone products**

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

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

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

(c) a person employed or engaged by, or by an entity commissioned to provide drug treatment services by or on behalf of, 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 who is one of the following—

(i) a pharmacist,

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

(**10**) Paragraph (1) has been amended by S.I. 2013/235, 2015/323 (S.R. 2015/178), 2020/1594 (S.R. 2020/350) 2022/634 and 2023/1071.

(**11**) Paragraph (1) has been amended by S.I. 2013/235, 2015/1503 (S.R. 2015/354), 2022/634 and 2023/1071.

(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; 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 naloxone products.

(3) For the purposes of this regulation, 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.

(4) For the purposes of 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 naloxone products for an appropriate purpose.

(5) 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).

(6) 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)(e) (but see paragraph (8));

(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.

(8) In order for training in the storage and supply of naloxone products to be appropriate for the purposes of this regulation, 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.

(9) 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 a person resides or which they frequent, in circumstances 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 to have it administered to them, in accordance with regulation 238; 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, in accordance with regulation 238.

(10) Where, pursuant to this regulation, an appropriate supplier of naloxone mentioned in paragraph (2)(a) to (d) supplies a naloxone product—

(a) that appropriate supplier of naloxone;

(b) a provider of drug treatment services, medical services or other 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; or

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

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).

(11) For the purposes of section 8(c) of the Data Protection Act 2018 (lawfulness of processing: public interest etc)(**12**), provision of information in the circumstances described in paragraph (10) is to be considered necessary for the performance of a task carried out in the public interest.

(12) For the purposes of this regulation, the following are appropriate national bodies—

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

(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.

(13) For the purposes of 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.".

Amendment to regulation 250

8. In regulation 250 (exceptions to regulation 249)(**13**), after paragraph (4A) insert—

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

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

(b) the medical services of His Majesty's forces;

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

(d) local naloxone providers.".

Amendments to regulation 346

9. In regulation 346 (review)(**14**), in paragraph (2)(d)—

(a) in paragraph (ivza), for ""Public Health England"" substitute ""the United Kingdom Health Security Agency"";

(b) in paragraph (iva), omit "4a," and "7a and"; and

(c) in paragraph (ivb), for ""Public Health England"" substitute ""the United Kingdom Health Security Agency"".

Amendments to Schedule 16

10. In Schedule 16 (patient group directions)(**15**), in the table in Part 2 (persons on whose behalf a patient group direction must be signed)—

(a) in column 1 (class of person by whom product is supplied), at both places where it occurs, for "Public Health England" substitute "the United Kingdom Health Security Agency"; and

(b) in column 2 (person on whose behalf direction must be signed), at both places where it occurs, for "Public Health England" substitute "the United Kingdom Health Security Agency".

(**13**) Amended by S.I. 2020/1125 (S.R. 2020/349).
(**14**) The relevant amending instruments are S.I. 2015/323 (S.R. 2015/178) and 2020/1125 (S.R. 2020/349).
(**15**) Part 2 of Schedule 16 has been amended by S.I. 2013/235, 2015/323 (S.R. 2015/178), 2022/634 and 2023/1071.

Amendments to Schedule 17

11.—(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)(**16**), omit entry 4a in columns 1, 2 and 3.

(3) In the table in Part 5 (exemptions from the restrictions in regulations 220 and 221 for certain persons who supply certain medicinal products)(**17**), omit entry 7a in columns 1, 2 and 3.

Amendment to Schedule 19

12. In Schedule 19 (medicinal products for parenteral administration in an emergency), for "naloxone hydrochloride" substitute "naloxone products".

Amendments to Schedule 22

13. In Schedule 22 (classes of person for the purposes of regulation 249)(**18**), at both places where it occurs, for "Public Health England" substitute "the United Kingdom Health Security Agency".

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

Name
Parliamentary Under-Secretary of State
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

(**16**) Entry 4a was inserted by S.I. 2015/1503 (S.R. 2015/354) and has been amended by S.I. 2019/62 (S.R. 2019/10).
(**17**) Entry 7a was inserted by S.I. 2015/1503 (S.R. 2015/354) and has been amended by S.I. 2019/62 (S.R. 2019/10).
(**18**) The relevant amending instrument is S.I. 2015/323 (S.R. 2015/178).

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.

Prior to these Regulations, limited provision had previously been made to allow people working for drug treatment services to benefit, when supplying naloxone hydrochloride, 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 hydrochloride without being authorised prescribers. New exemptions introduced by these Regulations also allow people working for the police, prison services, probation services and youth justice services – as well as a list of registered health care professionals – to supply the broader range of naloxone products, provided those individuals have undergone appropriate training. A new exemption is also created for the medical services of His Majesty's forces.

A further new exemption is created for a new type of entity, referred to as local naloxone providers, whose workers will also benefit from the new exemptions. These local naloxone providers will be part of networks, run on behalf of central government and the devolved administrations by entities that agree to act as naloxone supply network co-ordinators. The local naloxone arrangements that are to govern the local supply are required to cover a list of issues that includes appropriate training, the storage and handling of naloxone products and record keeping. Specific provision has also been made for the transfer of information to specified national bodies.

Provision has also been made to allow specified national bodies to set national standards for training in the storage and supply of naloxone products nationally.

Supplies of naloxone by all the individuals coming within these exemptions will need to be for a specified purpose. Prior to these Regulations, under the exemption that was just for drug treatment services, the permitted purpose for supply 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 products, and to supply naloxone products to be carried about, for example by police officers, in case they are needed (regulations 3 and 7).

The earlier more limited exemption for drug treatment services has been subsumed into the new exemption, allowing for its revocation (regulations 9(b) and 11). The list of products that may be parenterally administered in an emergency has been updated so that it now refers to naloxone products rather than simply naloxone hydrochloride (regulation 12).

An adjustment has been made to the powers of medicines manufacturers and wholesalers to allow them to supply naloxone products to providers that are part of the new arrangements (regulation 8).

Public Health England (PHE), which has been dissolved, was an executive agency of the Department of Health and Social Care (DHSC) – and many of its functions have been transferred to the United Kingdom Health Security Agency (UKHSA), which is also an executive agency of DHSC. PHE's functions that were specified in the 2012 Regulations, and those of its chief executive, which relate predominantly to the supply of prescription only medicines under patient group directions, have

been transferred to the UKHSA and its chief executive (regulations 4(b) and (c), 5, 6, 9(a) and (c), 10 and 13).

Similarly, the functions of the Regional Health and Social Care Board in Northern Ireland which related to patient group directions have been transferred to the Department of Health in Northern Ireland. Regulation 4(a) of these Regulations amends a definition of "health authority" to make it clear that this transfer has taken place, although the transfer itself happened by virtue of a transitional provision in paragraph 1 of Part 2 of Schedule 4 to the Health and Social Care Act (Northern Ireland) 2022 (c. 3).

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.