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 (c. 3), for approval by resolution of each House of Parliament and the Northern Ireland Assembly.

DRAFT STATUTORY INSTRUMENTS

2026 No.

MEDICINES

The Human Medicines (Amendment) Regulations 2026

Made - - - -	***
Coming into force - -	*31st March 2026*

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)(a), (c), (d), (h), (j) and (n), 3(2)(a), (c) and (d) 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 overarching objective of the Secretary of State and the Department of Health in Northern Ireland in making these Regulations is safeguarding public health. 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 this 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 (Amendment) Regulations 2026.

(2) These Regulations come into force on 31st March 2026.

(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 15.

Amendment of regulation 3

3.—(1) Regulation 3 (scope of these Regulations: special provisions)(**3**) is amended as follows.

(2) In paragraph (2), after "paragraph (5A)", insert ", (5B)".

(3) After paragraph (5A), insert—

"(5B) This paragraph applies where a medicinal product is manufactured or assembled by a pharmacist—

(a) who is acting in the course of his or her profession; and

(b) where—

(i) the conditions in paragraphs (8) and (9) are met, and

(ii) treatment of the patient with the medicinal product is a treatment decision of the pharmacist.".

(4) In paragraph (11), after "paragraph (5)", insert ", (5B)".

(5) In paragraph (12), in sub-paragraph (b), for "or (5A)" substitute ", (5A) or (5B)".

Amendment of regulation 3A

4.—(1) Regulation 3A (preparation and assembly of medicinal products used for vaccination or immunisation against coronavirus or in the reformulation of such products)(**4**) is amended as follows.

(2) In the heading, for "vaccination or immunisation against coronavirus" substitute "vaccination against an infectious disease".

(3) Omit paragraphs (1) and (2).

(4) In paragraph (3), for "for vaccination or immunisation against coronavirus" substitute "under relevant arrangements for vaccination against an infectious disease".

(5) In paragraph (4), omit sub-paragraph (a).

(6) In paragraph (5), omit the definition of "authorised".

(7) Omit paragraph (6).

Amendment of regulation 8

5. In regulation 8 (general interpretation)(**5**), in paragraph (1), for the definition of "occupational health vaccinator" substitute—

""occupational health vaccinator" means a person who is employed or engaged by a person operating an occupational health scheme, who is an individual belonging to one of the classes of individuals specified in Part 4 of Schedule 16;".

(**2**) S.I. 2012/1916.
(**3**) Regulation 3 was amended by S.I. 2019/775, 2024/832 and 2025/758.
(**4**) Regulation 3A was inserted by S.I. 2020/1594 and S.R. 2020/350, and has been amended by S.I. 2024/344 and S.R. 2024/68.
(**5**) The relevant amending instruments are S.I. 2020/1125 and S.R. 2020/349.

Amendment of regulation 19

6.—(1) Regulation 19 (exemptions from requirement for wholesale dealer's licence)(**6**) is amended as follows.

(2) In paragraph (4A)—

(a) in the opening words—

(i) for "vaccination or immunisation against coronavirus or influenza virus" substitute "vaccination against an infectious disease", and

(ii) after "the person distributing the medicinal product", insert "(Person A)";

(b) in sub-paragraph (b)—

(i) after "relevant arrangements" insert "(Person B)", and

(ii) at the end, omit "and";

(c) at the end of sub-paragraph (c), insert "and"; and

(d) after sub-paragraph (c), insert—

"(d) conditions A and B in paragraphs (4E) and (4F) are met."

(3) Omit paragraph (4B).

(4) For paragraph (4D), substitute—

"(4E) Condition A is that supply between Person A and Person B is agreed with the body making the arrangements to supply the medicinal product and the distribution occurs in exceptional circumstances, which are such that Person A and Person B are satisfied, having made appropriate enquiries, that—

(a) there is an urgent public health need for a patient to have administered to them the medicinal product on a particular occasion that the distribution would facilitate;

(b) there is no other way that the patient could receive treatment with the medicinal product without undue delay; and

(c) there is no suitable alternative medicinal product that the patient could receive treatment with without undue delay.

(4F) Condition B is that the medicinal product remains in its manufacturer's original outer packaging, and is stored and transported, in accordance with the terms of its marketing authorisation.".

Amendment of regulation 213

7. In regulation 213 (interpretation), in paragraph (1), after the definition of "unit preparation", insert—

""vaccine group direction" means a written direction that relates to the supply and administration of a vaccine and that—

(a) is signed by any person who may be required to sign it in the circumstances specified for its use in regulation 235A; and

(b) relates to supply and to administration to eligible persons in accordance with regulation 235A (subject to any exclusions that may be specified in the vaccine group direction).".

(**6**) Paragraphs (4A), (4B) and (4D) were inserted by S.I. 2020/1125 and S.R. 2020/349 and paragraph (4D) has been amended by S.I. 2024/344 and S.R. 2024/68.

Amendment of regulation 233

8. In regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business)(**7**), in paragraph (8), for "vaccination or immunisation against coronavirus or influenza virus" substitute "vaccination against an infectious disease".

Insertion of new regulation 235A

9. After regulation 235 (exemption for sale, supply or administration by certain persons), insert—

"**Exemption for supply or administration of certain medicines used for vaccination**

235A.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product used for vaccination in accordance with conditions A to F by—

(a) a public health agency;

(b) a health authority or special health authority;

(c) an NHS Trust;

(d) an NHS Foundation Trust;

(e) a local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006); or

(f) a person under relevant arrangements.

(2) Condition A is that the medicinal product is used for vaccination—

(a) for the purpose of providing protection against an infectious disease; and

(b) as part of a vaccination programme that has been approved by the Secretary of State, the Scottish Ministers, the Welsh Ministers or the Minister of Health in Northern Ireland.

(3) Condition B is that the medicinal product is supplied for the purpose of being administered to a person in accordance with the requirements of a vaccine group direction which has been produced by a public health agency.

(4) Condition C is that the vaccine group direction—

(a) is signed by or on behalf of—

(i) in the case of supply or administration by a body listed in paragraph (1)(a) to (e), a senior manager of that body, or

(ii) in the case of supply or administration by a person as mentioned in paragraph (1)(f), a senior manager of the body that enters into the relevant arrangements with that person; and

(b) has effect at the time at which the medicinal product is administered.

(5) Condition D is that the individual who administers the medicinal product is either at the same location and under the supervision of an individual who, or is an individual who—

(a) has—

(i) assessed and determined that the person who is to receive the medicinal product is eligible for the treatment, and

(ii) obtained and recorded the informed consent of, or in respect of, the person who is to receive the medicinal product; and

(b) belongs to one of the classes of individuals specified in Part 4 of Schedule 16.

(**7**) The relevant amending instruments are S.I. 2020/1594 and S.R. 2020/350

(6) Condition E is that the vaccine group direction contains the particulars specified in Part 1 of Schedule 16, and specifies—

(a) the classes of persons permitted to administer medicinal products under the direction;

(b) the process by which a person of a specified class is designated, and by whom, as a person permitted to administer medicinal products under the direction; and

(c) requirements, where appropriate, for the supervision of a person who, on any particular occasion, administers a medicinal product under the direction.

(7) Condition F is that, when the medicinal product is administered, there is in force in relation to it—

(a) a UK marketing authorisation; or

(b) an authorisation by the licensing authority on a temporary basis under regulation 174.

(8) In this regulation—

"a public health agency" means—

(a) Public Health Scotland in respect of Scotland;

(b) Public Health Wales in respect of Wales;

(c) the UK Health Security Agency in respect of England;

(d) the Public Health Agency in respect of Northern Ireland;

"relevant arrangements" has the meaning given in regulation 19(4C) (exemptions from requirement for wholesale dealer's licence);

"senior manager" means a person who plays a significant role (irrespective of whether other individuals also do so) in—

(a) the making of decisions about how the whole or a substantial part of the activities of the body in question are to be managed or organised, or

(b) the actual managing or organising of the whole or a substantial part of those activities.".

Omission of regulation 247A

10. Omit regulation 247A (protocols relating to coronavirus and influenza vaccinations and immunisations)(**8**).

Amendment of regulation 250

11. In regulation 250 (exceptions to regulation 249)(**9**), in paragraph (4A)—

(a) for "regulation 247 or 247A" substitute "regulation 235A or 247"; and

(b) for "protocol of the types" substitute "direction or protocol of the type".

Amendment of regulation 346

12. In regulation 346 (review)(**10**), in paragraph (2)(c)(xxviiiga), for "regulation 247A" substitute "regulation 235A".

(**8**) Regulation 247A was inserted by S.I. 2020/1125 and S.R. 2020/349 and amended by S.I. 2021/1452, S.I. 2024/344, S.R. 2024/68 and S.I. 2024/832

(**9**) The relevant amending instruments are S.I. 2020/1125 and S.R. 2020/349.

(**10**) The relevant amending instruments are S.I. 2013/1855, S.I. 2020/1125 and S.R. 2020/349.

Amendment to Schedule 16

13. In Schedule 16 (patient group directions)—

(a) in the heading, after "directions" insert "and vaccine group directions"; and

(b) in the heading of Part 1, after "direction" insert "and a vaccine group direction".

Amendment to Schedule 17

14.—(1) Schedule 17 (exemption for sale, supply or administration by certain persons)(**11**) is amended as follows.

(2) In the table in Part 2 (exemption from the restriction on supply of prescription only medicines)—

(a) in entry 6a, in column 1, for "An NHS body or a local authority" substitute "Persons"; and

(b) in entry 6b, in column 2, omit "against coronavirus or influenza virus (of any type)".

(3) In the table in Part 3 (exemptions from the restriction on administration of prescription only medicines)—

(a) in entry 5a, in column 1, for "An NHS body or a local authority" substitute "Persons"; and

(b) in entry 5b, in column 2, omit "against coronavirus or influenza virus (of any type)".

(4) In the table in Part 5 (exemptions from the restrictions in regulations 220 and 221 for certain persons who supply certain medicinal products)—

(a) in entry 10a, in column 1, for "An NHS body or a local authority" substitute "Persons"; and

(b) in entry 10b, in column 2, omit "against coronavirus or influenza virus (of any type)".

Amendment to Schedule 26

15. In Schedule 26 (packaging requirements: special provisions)(**12**), in the heading of Part 1, for "nurses and midwives" substitute "nurses, midwives and pharmacists".

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

(**11**) Relevant amendments have been made to Schedule 17 by S.I. 2020/1125 and S.R. 2020/349.
(**12**) Relevant amendments have been made to Schedule 26 by S.I. 2025/758.

Sealed with the Official Seal of the Department of Health in Northern Ireland

[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.

Regulation 3 amends regulation 3 of the 2012 Regulations to enable pharmacists to prepare or assemble medicines for a patient without a manufacturer's licence. The existing arrangements for preparation or assembly by pharmacists in regulation 4 of the 2012 Regulations will continue to apply where someone other than the pharmacist takes the treatment decision to supply or administer the medicine. Regulation 15 amends Schedule 26 to the 2012 Regulations consequentially to specify the labelling requirements that would apply in this circumstance.

Regulation 4 amends regulation 3A of the 2012 Regulations, so that it is a permanent provision that extends to all vaccines against infectious diseases. However, regulation 3A of the 2012 Regulations is now limited only to assembly by holders of a wholesale dealer's licences to take account of changes to shelf life and no longer applies to acts of preparation and assembly undertaken by or under the supervision of a doctor, nurse or pharmacist.

Regulation 6 amends regulation 19 of the 2012 Regulations, so that it is a permanent provision that extends to all vaccines against infectious diseases. Regulation 19 of the 2012 Regulations provides for certain exemptions from the requirement to hold a wholesale dealer's licence, and paragraphs (4A) to (4F) of that regulation (which includes new paragraphs added by regulation 6) permit distribution of stocks of vaccinations between providers of vaccination services without the need for such a licence. Conditions are imposed to ensure the exceptional use of this exemption, which include that the situation must be such that there is an urgent public health need, there is no alternative medicine capable of meeting that need, and there is no alternative route for the patient to receive the product.

Subject to various exceptions in Part 12 of the 2012 Regulations, prescription only medicines and pharmacy medicines must be sold or supplied, by or under the supervision of a pharmacist, on premises that are a registered pharmacy. Regulation 233 of the 2012 Regulations provides that persons lawfully conducting a retail pharmacy business are exempted from this restriction if the supply or administration to the patient is in accordance with a patient group direction (amongst other conditions). Regulation 8 amends regulation 233 of the 2012 Regulations to extend the exemption to cover all vaccines against infectious diseases.

Regulation 9 introduces a new regulation 235A in the 2012 Regulations, which exempts the supply or administration of certain vaccines from the requirements relating to the supply of medicines under regulations 214, 220 and 221, where the administration to the patient is in accordance with a vaccine group direction produced by a public health agency (as defined in the regulation) and subject to other pre-conditions as outlined in the regulation. Regulation 7 introduces a new definition for a vaccine group direction. Regulation 13 makes consequential amendments to Schedule 16 to the 2012 Regulations.

Regulation 10 removes regulation 247A of the 2012 Regulations (as this is replaced by the above inserted regulation 235A of the 2012 Regulations). Regulations 11 and 12 make consequential amendments as a result of the removal of regulation 247A of the 2012 Regulations and the insertion of the new regulation 235A of the 2012 Regulations.

Regulation 14 amends Schedule 17 to the 2012 Regulations to enable occupational health vaccinators to administer any vaccine as part of an occupational health scheme (which is not restricted to a scheme operated by the NHS). Regulation 5 amends the definition of occupational health vaccinator to align with the classes of individuals specified in Part 4 of Schedule 16 to the 2012 Regulations.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen. A de minimis assessment is available from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU and is published with the explanatory memorandum alongside this instrument on www.legislation.gov.uk.