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

2022 No. 0000

MEDICINES

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022

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

The Secretary of State in relation to England and Wales and Scotland(**a**), and the Secretary of State and the Department of Health in Northern Ireland acting jointly in relation to Northern Ireland(**b**), in exercise of the powers conferred by sections 2(1)(**c**), 3(1)(a), (c), (d), (j), (n), (2)(a), (c) and (d) of the Medicines and Medical Devices Act 2021(**d**), and after having considered the matters in section 2(2) to (4) of that Act, make the following Regulations.

The Secretary of State and the Department of Health in Northern Ireland make these Regulations having 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 of the 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 (Coronavirus and Influenza) (Amendment) Regulations 2022.

(2) These Regulations come into force on 31st March 2022.

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

Amendments to the Human Medicines Regulations 2012

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

(**a**) Section 2(1) is exercisable by the "appropriate authority", and in relation to England and Wales and Scotland, this means the Secretary of State, as defined in section 2(6)(a) of the Medicines and Medical Devices Act 2021.
(**b**) Section 2(1) is exercisable by the "appropriate authority", and in relation to Northern Ireland, this can mean the Department of Health in Northern Ireland and the Secretary of State acting jointly, as defined in section 2(6)(b)(ii) of the Act.
(**c**) The "law relating to human medicines" is defined in section 9 of the Act.
(**d**) 2021 c. 3.
(**e**) S.I. 2012/1916, as amended.

Amendment to regulation 3A (preparation and assembly of medicinal products used for vaccination or immunisation against coronavirus or in the reformulation of such products)

3. In regulation 3A(6)(**a**), for "2022" substitute "2024".

Amendment to regulation 19 (exemptions from requirement for wholesale dealer's licence)

4. In regulation 19(4D)(**b**), for "2022" substitute "2024".

Amendment to regulation 229 (exemption for supply by national health service bodies and local authorities)

5. Omit regulation 229(4)(**c**).

Amendment to regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business)

6. Omit regulation 233(9)(**d**).

Amendment to regulation 235 (exemption for sale, supply or administration by certain persons)

7. Omit regulation 235(8)(**e**).

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

Name
Minister of State
Department of Health and Social Care

Address
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

(**a**) Regulation 3A, as inserted by S.I. 2020/1594.
(**b**) Regulation 19, amended by S.I. 2020/1125; there are other amending instruments but none is relevant.
(**c**) Regulation 229, amended by S.I. 2020/1594; there are other amending instruments but none is relevant.
(**d**) Regulation 233, amended by S.I. 2020/1594; there are other amending instruments but none is relevant
(**e**) Regulation 235, amended by S.I. 2020/1125.

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 human medicines for human use. The provisions in the 2012 Regulations to which the Note refers are presently due to cease to have effect on 1st April 2022.

Regulation 3 provides that regulation 3A (Preparation and assembly of medicinal products used for vaccination or immunisation against coronavirus or in the reformulation of such products) of the 2012 Regulations will cease to have effect on 1st April 2024. Regulation 3A of the 2012 Regulations ensures that all professionally justified acts of preparation and assembly of a coronavirus vaccine may be undertaken by or under the supervision of a doctor, nurse or pharmacist, at any location, without precipitating the need for a manufacturer's licence or marketing authorisation – provided those acts are done under NHS arrangements or arrangements as part of the medical services of Her Majesty's Forces. It also allows for authorised medicinal products used for the reformulation of coronavirus vaccines (for example, diluents) to be re-assembled at the end of the medicines supply chain without the resultant products needing marketing authorisations in order to be supplied.

Regulation 4 provides that regulation 19 (exemptions from requirement for wholesale dealer's licence) of the 2012 Regulations will cease to have effect on 1st April 2024. Amongst other things, regulation 19 provides that wholesale dealer's licences are not required when sharing stocks of coronavirus vaccinations between vaccination centres.

Subject to various exceptions in Part 12 of the 2012 Regulations, prescription only medicines may only be sold or supplied in accordance with a prescription of, or administered parenterally by, a health care professional who is classed as an appropriate practitioner. The 2012 Regulations already provide for either or both of these Part 12 restrictions to be set aside by instruments known as Patient Group Directions ("PGDs").

Previously, PGDs issued under regulation 229 (exemption for supply by national health service bodies and local authorities) of the 2012 Regulations by a number of listed NHS bodies, or bodies exercising public health functions, could only set aside the first of these two restrictions – the limitation relating to prescriptions. Regulation 229 was amended in December 2020 to allow these PGDs also to set aside the second of these restrictions – the restriction relating to parenteral administration – until 1st April 2022. The ability to administer parenterally, prescription only medicines supplied under a PGD made under regulation 229 is made permanent (regulation 5).

Also, 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 6 amends regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) to permanently provide that PGDs that permit persons lawfully conducting a retail pharmacy business to set aside these restrictions, can include the sale, supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza (subject to the other conditions in regulation 233 also being made out).

Another route to exceptions from the core Part 12 restrictions are a series of exceptions set out in Schedule 17, which are targeted at various practical situations and occupational health schemes. In addition to doctors and nurses who may administer prescription only medicines as part of occupational health schemes regulation 7 amends regulation 235 (exemption for sale, supply or administration by certain persons) to make permanent the other specified categories of registered health care professionals to administer coronavirus and influenza immunisations as part of the occupational health schemes of local authorities and specified NHS bodies.

The Explanatory Memorandum is published alongside these Regulations on www.legislation.gov.uk

A full impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from www.legislation.gov.uk. Copies may also be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU.

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£4.90

http://www.legislation.gov.uk/id/ukdsi/2022/9780348231885

ISBN 978-0-34-823188-5

9 780348 231885