STATUTORY RULES OF NORTHERN IRELAND

2020 No. 350

MEDICINES

The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020

Made - - - - 17th December 2020

Laid before Parliament 18th December 2020
Coming into operation in accordance with regulation 1(2) and (3)

The Secretary of State and the Minister of Health in Northern Ireland make the following Regulations in exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972(**1**). They have been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**2**).

Citation and commencement

1.—(1) These Regulations may be cited as the Human Medicines (Coronavirus) (Further Amendments) Regulations 2020.

(2) Subject to paragraph (3), these Regulations come into force on the day after the day on which they are laid before Parliament.

(3) Regulations 2, 5(c), 6, 7, 8(a) and 9 to 14 come into force immediately after the coming into force of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019(**3**).

Revocation of provisions of the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

2. The following provisions of the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020(**4**) are revoked—

(**1**) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51) and section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7). Section 2(5) was amended by section 41(1) of, and Part 1 of Schedule 6 to, the Northern Ireland Constitution Act 1973 (c. 36). Section 2 has been repealed by section 1 of the European Union (Withdrawal) Act 2018 (c. 16) ("the 2018 Act") but, until IP completion day, it continues to have effect, by virtue of subsection (2) of section 1A of the 2018 Act (inserted by section 1 of the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act")), as provided by subsections (3) to (5) of that section. For these purposes, "IP completion day" has the meaning given in section 39 of the 2020 Act.

(**2**) S.I. 1972/1811.

(**3**) S.I. 2019/775; *see* regulation 1 of those Regulations.

(**4**) S.I. 2020/1125.

(a) regulation 7 (amendment of regulation 229);
(b) regulation 8 (amendment of regulation 230);
(c) regulation 9 (amendment of regulation 231);
(d) regulation 10 (amendment of regulation 233);
(e) regulation 11 (amendment of regulation 234);
(f) regulation 17 (amendment of regulation 279);
(g) regulation 25 (amendment of regulation 293); and
(h) regulation 27 (amendment of regulation 295).

Amendment of the Human Medicines Regulations 2012

3. The Human Medicines Regulations 2012(**5**) are amended as follows.

New regulation 3A

4. After regulation 3 (scope of these Regulations: special provisions), insert—

"**Preparation and assembly of medicinal products used for vaccination or immunisation against coronavirus or in the reformulation of such products**

3A.—(1) Regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) do not apply in circumstances where a medicinal product used for vaccination or immunisation against coronavirus is manufactured, prepared or assembled by or under the supervision of a doctor, a registered nurse or a pharmacist—

(a) who is acting in the course of his or her profession; and
(b) for the purposes of the supply or administration of the medicinal product to a patient under relevant arrangements.

(2) Regulation 46 does not apply in respect of a medicinal product—

(a) which is the result of the assembly of an authorised medicinal product;
(b) which is used for the reformulation of a medicinal product used for vaccination or immunisation against coronavirus; and
(c) the assembly of which (as mentioned in sub-paragraph (a)) is—
(i) in accordance with a manufacturer's licence, or
(ii) undertaken in circumstances where regulation 17(1) does not apply by virtue of regulation 3 (scope of these regulations: special provisions) or regulation 4 (special provisions for pharmacies etc.).

(3) Regulation 17(1) does not apply in circumstances where a medicinal product used for vaccination or immunisation against coronavirus is labelled by a holder of a wholesale dealer's licence to take account of a change to the shelf life of the product because of the thawing of the product.

(4) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products)—

(a) does not apply to a medicinal product that is the result of a process of manufacture, preparation or assembly in accordance with paragraph (1) or (2); and

(**5**) S.I. 2012/1916.

(b) is to be construed as permitting labelling in accordance with paragraph (3), in the case of a product which is otherwise labelled in accordance with that Part.

(5) For the purposes of this regulation—

"authorised" has the meaning given in regulation 3(15)(**6**); and

"relevant arrangements" has the meaning given in regulation 19(4C)(**7**) (exemptions from requirement for wholesale dealer's licence).

(6) This regulation ceases to have effect on 1st April 2022.".

Amendment of regulation 229

5. In regulation 229(**8**) (exemption for supply by national health service bodies and local authorities)—

(a) in paragraph (1), after "Regulations 214(1)" insert "and (2)";

(b) after paragraph (2), insert—

"(2A) In relation to a medicinal product that is for parenteral administration, condition A only applies if the person who has given the written directions is an appropriate practitioner in relation to that medicinal product.";

(c) in paragraph (3)(f), after "is supplied" insert ", either an authorisation by the licensing authority on a temporary basis under regulation 174 or"; and

(d) after paragraph (3), insert—

"(4) The following cease to have effect on 1st April 2022—

(a) in paragraph (1), "and (2)"; and

(b) paragraph (2A).".

Amendment of regulation 230

6. In regulation 230(**9**) (exemption for supply etc under a PGD to assist doctors or dentists), in paragraph (8), after "administered" insert ", either an authorisation by the licensing authority on a temporary basis under regulation 174 or".

Amendment of regulation 231

7. In regulation 231(**10**) (exemption for supply etc under a PGD by independent hospitals etc), in paragraph (8), after "is supplied" insert ", either an authorisation by the licensing authority on a temporary basis under regulation 174 or".

Amendment of regulation 233

8. In regulation 233(**11**) (exemption for supply etc under a PGD by person conducting a retail pharmacy business)—

(a) in paragraph (7), after "administered" insert ", either an authorisation by the licensing authority on a temporary basis under regulation 174 or"; and

(**6**) Regulation 3(15) is to be amended by S.I. 2019/775 as amended by S.I. 2020/1488.
(**7**) Paragraph (4C) was inserted by S.I. 2020/1125.
(**8**) Paragraph (1) of regulation 229 has been amended by S.I. 2013/235 and 2015/323. Paragraph (3)(f) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.
(**9**) Paragraph (8) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.
(**10**) Paragraph (8) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.
(**11**) Paragraph (7) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.

(b) after paragraph (7), insert—

"(8) Regulation 220 does not apply to the supply, or administration, of a prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus where paragraph (1)(a) and (b) applies and conditions A to F are met.

(9) Paragraph (8) ceases to have effect on 1st April 2022.".

Amendment of regulation 234

9. In regulation 234(**12**) (exemption from supply etc of products under a PGD to assist the police etc), in paragraph (9), after "is supplied" insert ", either an authorisation by the licensing authority on a temporary basis under regulation 174 or".

Amendment of regulation 277

10. In regulation 277(**13**) (interpretation), in paragraph (1), in the definition of "holder of a temporary authorisation", for "279(a) or (b) to (d)" substitute "281(1)(a) to (e)".

Amendment of regulation 279

11. In regulation 279(**14**) (products without a marketing authorisation etc)—

(a) in paragraph (1), after sub-paragraph (a) insert—

"(aa) an authorisation by the licensing authority on a temporary basis under regulation 174;"; and

(b) in paragraph (2), after sub-paragraph (a) insert—

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

Amendment of regulation 280

12. In regulation 280(**15**) (general principles), in paragraph (4), for "279(a) or (b) to (d)" substitute "281(1)(a) to (e)".

Amendment of regulation 293

13. In regulation 293(**16**) (prohibition of supply to the public for promotional purposes), in paragraph (1), after "The holder of" insert "either a temporary authorisation or".

Amendment of regulation 295

14. In regulation 295(**17**) (abbreviated advertisements), in paragraph (2)(d), after "the holder" at the first place where it occurs insert "of either the temporary authorisation or".

(**12**) Paragraph (9) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.
(**13**) The relevant amending instrument is S.I. 2020/1125.
(**14**) Regulation 279 is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.
(**15**) The relevant amending instrument is S.I. 2020/1125.
(**16**) Regulation 293(1) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.
(**17**) Regulation 295(2)(d) is to be substituted by S.I. 2019/775 as amended by S.I. 2020/1488.

Signed by the authority of the Secretary of State

Bethell
Parliamentary Under Secretary of State
17th December 2020 Department of Health and Social Care

Robin Swann
Minister of Health
17th December 2020 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.

Regulations 3 and 4 of the 2012 Regulations, read with section 10 of the Medicines Act 1968(**18**), contain exemptions from the requirements to hold a manufacturer's licence and a marketing authorisation that relate to final processing undertaken at the end of the medicines supply chain. Exemptions already exist that allow (amongst others) doctors, nurses and pharmacists to undertaken some final processing, subject to conditions. The new 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. Provision is also made to allow holders of wholesale dealer's licences who do not have manufacturer's licences to label coronavirus vaccines to take account of changes to the shelf life of the vaccines because of the thawing of the product. There is also a change in relation to the application of the packaging and package leaflet requirements of the 2012 Regulations to take account of these other changes. Regulation 3A of the 2012 Regulations ceases to have effect on 1st April 2022 (regulation 4).

Subject to various exceptions in Part 12 of the 2012 Regulations but by virtue of restrictions in that Part, 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). Prior to these Regulations, PGDs issued under regulation 229 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. These Regulations allow these PGDs also to set aside the second of these restrictions – the restriction relating to parenteral administration – until 1st April 2022 (regulation 5(a) and (d)). An additional amendment is made to ensure that this change cannot be construed as adding to the prescribing rights of appropriate practitioners who could not otherwise prescribe medicinal products for parenteral administration (regulation 5(b)).

Also, subject to various exceptions in Part 12 of the 2012 Regulations but by virtue of restrictions in that Part, 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. These Regulations allow, until 1st April 2022, the PGDs permitted for persons lawfully conducting a retail pharmacy business by regulation 233 of the 2012 Regulations to set aside these restrictions if the PGD is for a medicinal product used for vaccination or immunisation against coronavirus or influenza and the other conditions in regulation 233 are also made out (regulation 8(b)).

In response to certain types of public health threats, the licensing authority under the 2012 Regulations may temporarily authorise the sale or supply of medicinal products without marketing authorisations. The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

(**18**) 1968 c. 67.

made wide ranging provision in relation to such temporary authorisations, including adapting the provisions of the 2012 Regulations relating to PGDs and the advertising of medicinal products to accommodate them. These amendments were not taken into account, in error, when some of the same provisions were subject to further amendment as a consequence of changes made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 to the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019(**19**). These Regulations therefore make a number of consequential amendments to preserve the effect of the amendments made by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 in relation to PGDs and advertising of medicines that were not reflected in the changes made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 to the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (regulations 2, 5(c), 6, 7, 8(a) and 9 to 14).

Amendments to the Human Medicines Regulations 2012 are subject to the requirements of the Statutory Rules (NI) Order 1979 and the corresponding SI in respect of this Statutory Rule is S.I.1594/2020.

(**19**) S.I. 2019/775.