STATUTORY RULES OF NORTHERN IRELAND

# 2020 No. 350

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

**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

(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)(**1**); and

(**1**) Regulation 3(15) is to be amended by S.I. 2019/775 as amended by S.I. 2020/1488.

"relevant arrangements" has the meaning given in regulation 19(4C)(**2**) (exemptions from requirement for wholesale dealer's licence).

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

(**2**) Paragraph (4C) was inserted by S.I. 2020/1125.