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STATUTORY RULES OF NORTHERN IRELAND

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**2020 No. 349**

**The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020**

**Amendment of regulation 19**

**4.** In regulation 19(1) (exemptions from requirement for wholesale dealer’s licence), after paragraph (4) insert—

“(4A) Regulation 18 does not apply in connection with the distribution by way of wholesale dealing of a medicinal product to be used for vaccination or immunisation against coronavirus or influenza virus, where the person distributing the medicinal product—

- (a) was supplied with the medicinal product for the purposes of the administration of it under relevant arrangements;
- (b) is supplying the medicinal product for the purposes of the administration of it by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements; and
- (c) is authorised by the body making the arrangements to supply the medicinal product as mentioned in sub-paragraph (b) under the relevant arrangements.

(4B) Regulation 18 does not apply in connection with the distribution by way of wholesale dealing of a medicinal product to be supplied or administered in accordance with a protocol of the type mentioned in regulation 247, where the person distributing the medicinal product—

- (a) was supplied with the medicinal product for the purposes of the supply or administration of it to a patient under relevant arrangements;
- (b) is supplying the medicinal product for the purposes of the supply or administration of it to a patient by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements; and
- (c) is authorised by the body making the arrangements to supply the medicinal product as mentioned in sub-paragraph (b) under the relevant arrangements.

(4C) In this regulation, “relevant arrangements” means—

- (a) arrangements for the provision of services as part of—
  - (i) in England, the health service as defined by section 275(1) of the National Health Service Act 2006(2),
  - (ii) in Scotland, the health service as defined by section 108(1) of the National Health Service (Scotland) Act 1978(3),
  - (iii) in Wales, the health service as defined by section 206(1) of the National Health Service (Wales) Act 2006(4), and

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(1) Regulation 19 has been amended by [S.I. 2013/1855](#) and [2019/775](#).  
(2) [2006 c. 41](#). There are amendments to section 275(1), but none of them are relevant.  
(3) [1978 c. 29](#). There are amendments to section 108(1), but none of them are relevant.  
(4) [2006 c. 42](#). There are amendments to section 206(1), but none of them are relevant.

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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- (iv) in Northern Ireland, the system of health and social care promoted under section 2(1) of the Health and Social Care (Reform) Act (Northern Ireland) 2009~~(5)~~; or
  - (b) arrangements for the provision of services (otherwise than as mentioned in subparagraph (a)) as part of the medical services of Her Majesty's Forces.
- (4D) Paragraphs (4A) to (4C) cease to have effect on 1st April 2022.”.