STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

CHAPTER 3

Exemptions

Other exemptions

[F1Protocols relating to coronavirus and influenza vaccinations and immunisations

247A.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus (of any type) that meets the following conditions.

F2(2) . . . . . .

(3) Condition B is that the supply or administration is in accordance with the requirements of a protocol that is approved by the Secretary of State, the Scottish Ministers, the Welsh Ministers or the Minister of Health in Northern Ireland.

(4) Condition C is that the protocol specifies (amongst other matters)—

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

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

(c) requirements as to the recording of the name of a person who, on any particular occasion, administers a medicinal product under the protocol; and

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

(5) Condition D is that when the medicine is supplied, there is in force in relation to it—

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

(b) before 1st January 2021, a marketing authorisation; or

(c) on and after 1st January 2021, a UK marketing authorisation **[**F3(including in Northern Ireland if supply is in accordance with regulation 167A)**]** or, in Northern Ireland, an EU marketing authorisation.**]**

F4(6) . . . . . .

[F5(7) This regulation ceases to have effect on 1st April 2026.**]**

Textual Amendments

F1 Reg. 247A inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **14** and reg. 247A inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **14**

F2 Reg. 247A(2) omitted (E.W.S.) (31.3.2024) by virtue of The Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024 (S.I. 2024/344), regs. 1(2), **5(2)** and (N.I.) (31.3.2024) by virtue of The Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024 (S.R. 2024/68), regs. 1(2), **5(2)**

F3 Words in reg. 247A(5)(c) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **22**

F4 Reg. 247A(6) omitted (E.W.S.) (31.3.2024) by virtue of The Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024 (S.I. 2024/344), regs. 1(2), **5(3)** and (N.I.) (31,3,2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024 (S.R. 2024/68), regs. 1(2), **5(3)**

F5 Reg. 247A(7) inserted (E.W.S.) (31.3.2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024 (S.I. 2024/344), regs. 1(2), **5(4)** and (N.I.) (31.3.2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024 (S.R. 2024/68), regs. 1(2), **5(4)**

Status:
Point in time view as at 31/03/2024.

Changes to legislation:
The Human Medicines Regulations 2012, Section 247A is up to date with all changes known to be in force on or before 25 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.