STATUTORY INSTRUMENTS

2020 No. 1125

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

New regulation 247A

14. After regulation 247 (exemption for supply in the event or anticipation of pandemic disease) insert—

"**Protocols 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.

(2) Condition A is that the supply is made, or the medicinal product is administered, while a disease (which may be neither coronavirus disease nor influenza) is, or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially serious risk to human health.

(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 or, in Northern Ireland, an EU marketing authorisation.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol approved under this regulation has effect, the Secretary of State must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.".