STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 10

Exceptions to requirement for marketing authorisation etc

Exceptions

[F1Conditions of temporary authorisations under regulation 174

174A.—(1) Where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis under regulation 174, the licensing authority may attach conditions to that authorisation, those being conditions to which the following are subject—

(a) its recommendation or requirement as to the use of that product for the purposes of regulation 345; and

(b) its authorisation of the sale or supply of that product.

(2) The sale or supply of that medicinal product is not authorised by the licensing authority for the purposes of regulation 174 if—

(a) the sale or supply is for the purpose of any use other than the recommended or required use, as mentioned in paragraph (1)(a); or

(b) a condition attached in accordance with paragraph (1) to the authorisation of the sale or supply is breached.

(3) The use of that medicinal product is not in accordance with a recommendation or requirement of the licensing authority for the purposes of regulation 345 if—

(a) a condition attached in accordance with paragraph (1) to the authorisation of its sale or supply is breached; and

(b) any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person with relevant expertise in the subject matter of the breach would regard the breach as sufficiently serious to justify the licensing authority setting aside the recommendation or requirement.

(4) Notwithstanding paragraph (3), the persons mentioned in regulation 345(3) are not subject to any civil liability resulting from a use of that medicinal product that was (but for the operation of that paragraph) in accordance with the recommendation or requirement of the licensing authority, if those persons were not wholly or partly responsible for the breach in question.

(5) As soon as is reasonably practical after the end of one year beginning on the day on which the first conditions are attached in accordance with paragraph (1), 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 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.**]**

Textual Amendments

F1 Reg. 174A inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **6** and reg. 174A inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **6**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 174A.