STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 17

Miscellaneous and general

Immunity from civil liability

Immunity from civil liability

345.—(1) This regulation applies where the licensing authority makes a recommendation or requirement to which paragraph (2) applies in response to the suspected or confirmed spread of—

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which may cause harm to human beings.

(2) This paragraph applies to a recommendation or requirement—

(a) for the use of a medicinal product without an authorisation; or

(b) for the use of a medicinal product with an authorisation, but for a therapeutic indication that is not permitted under the authorisation.

(3) None of the following are to be subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement—

(a) any holder of an authorisation for the product;

[F1(aa) if there is no holder of an authorisation for the product but the sale or supply of the product is authorised by the licensing authority on a temporary basis under regulation 174, the person responsible for placing the product on the market in the United Kingdom;**]**

(b) any manufacturer of the product;

(c) any officer, servant, employee or agent of a person within **[**F2sub-paragraph (a), (aa) or (b);**]**

(d) any health care professional**[**F3; or**]**

[F4(e) any person, not being a health care professional, who administers the product in accordance with a protocol of the type mentioned in regulation 247A.**]**

(4) This regulation does not apply in relation to liability under section 2 (liability for defective products) of the Consumer Protection Act 1987M1 or article 5 of the Consumer Protection (Northern Ireland) Order 1987M2.

(5) In this regulation "authorisation" means a **[**F5UK marketing authorisation, EU marketing authorisation**]**, certificate of registration, traditional herbal registration or Article 126a authorisation.

Textual Amendments

F1 Reg. 345(3)(aa) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(a)** and reg. 345(3)(aa) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(a)**

F2 Words in reg. 345(3)(c) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(b)** and words in reg. 345(3)(c) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(b)**

F3 Word in reg. 345(3)(d) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(c)** and word in reg. 345(3)(d) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(c)**

F4 Reg. 345(3)(e) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(d)** and inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(d)**

F5 Words in reg. 345(5) substituted (31.12.2020) by S.I. 2019/775, **reg. 226** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 186**)

Marginal Citations

M1 1987 c.43. Section 2(4) was repealed in relation to England and Wales by S.I. 2000/2771 article 2(1) and (3) and in relation to Scotland by S.S.I. 2001/265 article 2(1) and (3).

M2 S.I. 1987/2049 (N.I. 20), as amended by 2001 c.13 (NI).

[F6Obligation on licensing authority to maintain list of medicinal products to which derogations have applied

345A.—(1) The licensing authority must publish a list of medicinal products to which the derogations described in Articles 5a, 8(2a) and (2b), 18a, 20 (second paragraph), 40(1a) and (3a), 48(3) and 104(3) of the 2001 Directive have applied.

(2) The licensing authority must update the list referred to in paragraph (1) at least every six months.**]**

Textual Amendments

F6 Reg. 345A inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **5**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Immunity from civil liability.