
STATUTORY RULES OF NORTHERN IRELAND

2014 No. 323

The Human Medicines (Amendment) Regulations 2014

Amendment of regulation 346

9.—(1) Regulation 346(1) (review provisions) is amended as follows.

(2) In paragraph (2)—

(a) In sub-paragraph (c) after paragraph “(xxviiiia)” insert—

“(xxviiiib) 213(3),

(xxviiiic) xxviiiic)217A,

(xxviiiid) xxviiiid)218(2)(b) and (c), (3) and (5),

(xxviiiie) xxviiiie)219(4)(b)(ii).”;

(b) In sub-paragraph (d) for paragraph “(iv)” substitute—

“(iv) 12 paragraph 21,

(iva) iva)17, Part 4 items 11 and 12(2), and”

(3) For paragraph (4) substitute—

“(4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how—

(a) the 2001 Directive;

(b) Directive 2010/84/EU of the European Parliament and of the Council of 15 October 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.(3);

(c) Article 11 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare(4);

(d) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products(5); and

(e) Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State(6),

are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).”

(4) In paragraph (5)(a) for “(xxix)” substitute “(xxxii)”.

(1) Regulation 346 was substituted by S.I. 2013/1855 and paragraph (2) was subsequently amended by S.I. 2013/2593.

(2) These provisions were inserted by S.I. 2013/2593.

(3) OJ No L 348, 31.12.2010, p74.

(4) OJ No L 88, 4.4.2011, p45.

(5) OJ No L 174, 1.7.2011, p74.

(6) OJ No L 356, 22.12.2012, p68.

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