STATUTORY RULES OF NORTHERN IRELAND

2015 No. 354

MEDICINES

The Human Medicines (Amendment) (No.3) Regulations 2015

Made - - - -	*9th July 2015*
Laid before Parliament	*16th July 2015*
Coming into operation	*1st October 2015*

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in the exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972(**1**), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**2**).

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) (No.3) Regulations 2015 and shall come into force on 1st October 2015.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**3**) are amended as follows.

Amendment of regulation 8

3.—(1) Regulation 8(**4**) (general interpretation) is amended as follows.

(2) In paragraph (2), for "18(7) and (8)" substitute "18(4) and (5)";

(3) In paragraph (3), for "18(8)" substitute "18(5)"; and

(4) In paragraph (4), for "18(8)" substitute "18(5)".

Amendment of regulation 38

4. In regulation 38 (imports from states other than EEA states), in paragraph (3)(b), for the words from "the principles" to the end substitute "good manufacturing practice for active substances".

(**1**) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7). Section 2(5) was amended by section 41(1) of and Part 1 of Schedule 6 to the Northern Ireland Constitution Act 1973 (c.36).
(**2**) See S.I.1972/1811 regarding the designation of Ministers.
(**3**) S.I.2012/1916 as amended by S.I.2013/235, 1855 and 2593, 2014/490 and 1878 and 2015/323 and 903.
(**4**) Regulation 8 was amended by S.I.2013/1855 and 2593.

Amendment of regulation 39

5. In regulation 39(**5**) (further requirements for manufacturer's licence), in paragraph (8), for "44(4) to (6)" substitute "44(5) and (6)".

Amendment of regulation 44

6.—(1) Regulation 44(**6**) (requirements for wholesale dealers to deal only with specified persons) is amended as follows.

(2) Omit paragraph (1).

(3) In paragraph(2)—

(a) for "From 28th October 2013 the" substitute "The";

(b) after sub-paragraph (b), insert "or";

(c) in sub-paragraph (c), for "country A; or" (at the end of the sub-paragraph) substitute "country A.";

(d) omit sub-paragraph (d).

(4) In paragraph (3), omit "(1),".

(5) Omit paragraph (4).

(6) In paragraph (5), for "From 28th October 2013, the" substitute "The".

Amendment of regulation 233

7.—(1) Regulation 233(**7**) (exemption for supply etc under a PGD by person conducting a retail pharmacy business) is amended as follows.

(2) In paragraph (1)(a), after paragraph (ivc) insert—

"(ivd) Public Health England,

(ive) Public Health Agency,".

(3) In paragraph (5), in sub-paragraph (a) for "to (ivc) (health bodies), on behalf of that body" substitute "to (ive) (health bodies), by or on behalf of the person specified in column 2 of Part 2 of Schedule 16 against the entry in column 1 for that body".

Amendment of regulation 256E

8. In regulation 256E(**8**) (removal of a person's entry from the list), in paragraph (a), for "256I(1)(b)" substitute "256I(1)(c)".

Amendment of regulation 346

9.—(1) Regulation 346(**9**) (Secretary of State to carry out a review of certain provisions) is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (c) after paragraph (xxviiif)(**10**) insert—

"(xxviiifa) 233(1)(a)(ivd) and (ive),";and

(**5**) Regulation 39 was amended by S.I.2013/1855.
(**6**) Regulation 44 was substituted by S.I.2013/1855.
(**7**) Regulation 233 was amended by S.I.2013/235.
(**8**) Regulation 256E was inserted by S.I.2013/1855.
(**9**) Regulation 346 was substituted by S.I.2013/1855.
(**10**) Paragraph (xxviiif) was inserted by S.I.2015/323.