STATUTORY INSTRUMENTS

2015 No. 1503

MEDICINES

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

Made - - - -	*9th July 2015*
Laid before Parliament	*16th July 2015*
Coming into force - -	*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 [F1], having been designated for the purposes of section 2(2) of that Act in relation to medicinal products [F2].

F1 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).

F2 *See* S.I. 1972/1811 regarding the designation of Ministers.

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 [F3] are amended as follows.

F3 S.I. 2012/1916 as amended by S.I. 2013/235, 1855 and 2593, 2014/490 and 1878 and 2015/323 and 903.

Amendment of regulation 8

3.—(1) Regulation 8 [F4] (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) ".

F4 Regulation 8 was amended by S.I. 2013/1855 and 2593.

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 ".

Amendment of regulation 39

5. In regulation 39 [F5] (further requirements for manufacturer's licence), in paragraph (8), for "44(4) to (6)" substitute " 44(5) and (6) ".

F5 Regulation 39 was amended by S.I. 2013/1855.

Amendment of regulation 44

6.—(1) Regulation 44 [F6] (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 ".

F6 Regulation 44 was substituted by S.I. 2013/1855.

Amendment of regulation 233

7.—(1) Regulation 233 [F7] (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 ".

F7 Regulation 233 was amended by S.I. 2013/235

Amendment of regulation 256E

8. In regulation 256E [F8] (removal of a person's entry from the list), in paragraph (a), for "256I(1)(b)" substitute " 256I(1)(c) ".

F8 Regulation 256E was inserted by S.I. 2013/1855.

Amendment of regulation 346

9.—(1) Regulation 346 [F9] (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) [F10] insert—

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

(b) in sub-paragraph (d), for paragraph (iva) [F11] substitute—

"(iva) 17, Part 1 item 12, Part 2 items 4a and 11, Part 4 items 11 and 12 and Part 5 items 7a and 18,".

F9 Regulation 346 was substituted by S.I. 2013/1855.
F10 Paragraph (xxviiif) was inserted by S.I. 2015/323.
F11 Paragraph (iva) was substituted by S.I. 2014/1878.

Amendment of Schedule 17

10.—(1) Schedule 17 (exemption for sale, supply or administration by certain persons) is amended as follows.

(2) In Part 2 [F12] (exemption from the restriction on supply of prescription only medicines), after item 4 in the table add—

4a Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– (a) an NHS body; (b) a local authority; (c) Public Health England; or (d) Public Health Agency.	4a A prescription only medicine for parenteral administration containing naloxone hydrochloride but no other substance that is classified as a product available on prescription only.	4a The supply shall be only in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency.

(3) In Part 5 [F13] (exemptions from the restrictions in regulation 220 and 221 for certain persons who supply certain medicinal products), after item 7 in the table add—