STATUTORY INSTRUMENTS

2015 No. 323

MEDICINES

The Human Medicines (Amendment) Regulations 2015

Made - - - -	*17th February 2015*
Laid before Parliament	*25th February 2015*
Coming into force - -	*1st April 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(**a**), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**b**).

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) Regulations 2015 and shall come into force on 1st April 2015.

Amendment of the Human Medicines Regulations 2012

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

Amendment of regulation 213

3.—(1) Regulation 213 (interpretation for the purposes of Part 12) is amended as follows.

(2) In paragraph (1)—

(a) after the definition of "local authority"(**d**) insert—

""Maritime and Coastguard Agency" means the executive agency of that name of the Department for Transport;" and;

(b) after the definition of "product subject to special medical prescription"(**e**) insert—

""Public Health Agency" means the Regional Agency for Public Health and Social Well-being established by section 12 of the Health and Social Care (Reform) Act (Northern Ireland) 2009(**f**);

"Public Health England" means the executive agency of that name of the Department of Health;".

(**a**) 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).
(**b**) *See* S.I. 1972/1811 regarding the designation of Ministers.
(**c**) S.I. 2012/1916 as amended by S.I. 2013/235, 1855, 2593, 2014/490 and 1878.
(**d**) The definition of "local authority" was inserted by S.I. 2013/235.
(**e**) The definition of "product subject to special medical prescription" was inserted by S.I. 2014/490.
(**f**) 2009 c.1 (N.I.).

Amendment of regulation 229

4.—(1) Regulation 229(**a**) (exemption for supply by national health service bodies and local authorities) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (da) omit "or";

(b) after sub-paragraph (da) insert—

"(db) Public Health England;

(dc) Public Health Agency; or"; and

(c) in sub-paragraph (f) for "(da)" substitute "(dc)".

Amendment of regulation 234

5.—(1) Regulation 234 (exemption for supply etc of products under a PGD to assist the police etc) is amended as follows.

(2) In paragraph (2), for sub-paragraphs (c) and (d) substitute—

"(c) a prison service;

(d) Her Majesty's Forces; or

(e) a contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency.".

Amendment of regulation 346

6.—(1) Regulation 346(**b**) (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 (xxviiie)(**c**) insert—

"(xxviiif) 229(1)(db) and (dc),

(xxviiig) 234(2)(e),", and

(b) in sub-paragraph (d)—

(i) after paragraph (iv)(**d**) insert—

"(ivza) 16, Part 2 entries relating to "Public Health England" and "Public Health Agency" and Part 3 entries relating to "search and rescue operations",";

(ii) in paragraph (iva)(**e**) omit "and"; and

(iii) after paragraph (iva) insert—

"(ivb) 22, entries relating to "Public Health England", "Public Health Agency" and "search and rescue operations", and".

Amendment of Schedule 16

7.—(1) Schedule 16 (patient group directions) is amended as follows.

(2) In the table in Part 2(**f**) (persons on whose behalf a patient group direction must be signed)—

(a) after the row relating to Local Authority add—

(**a**) Regulation 229 was amended by S.I. 2013/235.
(**b**) Regulation 346 was substituted by S.I. 2013/1855.
(**c**) Paragraph (xxviiie) was inserted by S.I. 2014/490.
(**d**) Paragraph (iv) was substituted by S.I. 2014/490.
(**e**) Paragraph (iva) was inserted by S.I.2014/490.
(**f**) Part 2 was amended by S.I. 2013/235.

"Public Health England	The Chief Executive of Public Health England
Public Health Agency	The Public Health Agency"

(b) in the last row, in column 1—

(i) in paragraph (dc) omit "or"; and

(ii) after paragraph (dc) insert—

"(dd) Public Health England;

(de) Public Health Agency; or"; and

(c) in the last row, in column 2—

(i) in paragraph (cc) omit "or"; and

(ii) after paragraph (cc) insert—

"(cd) Chief Executive of Public Health England,

(ce) Public Health Agency, or".

(3) In the table in Part 3 (persons by whom or on whose behalf a patient group direction used as described in regulation 234 must be signed), after the row relating to Her Majesty's Forces add—

"Contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency	Medical Director of the contractor carrying out search and rescue operations on behalf of the Maritime and Coastguard Agency".

Amendment of Schedule 22

8.—(1) Schedule 22(**a**) (classes of persons who may be supplied with medicinal products for the purposes of regulation 249) is amended as follows.

(2) Before the first occurrence of "The Common Services Agency" insert—

"Public Health England.

Public Health Agency.".

(3) For "(bc) a local authority; or" substitute—

"(bc) a local authority;

(bd) Public Health England;

(be) Public Health Agency; or".

(4) After "(c) a prison service;" omit "or".

(5) For "(d) Her Majesty's Forces" substitute—

"(d) Her Majesty's Forces; or

(e) a contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency.".

Signed by authority of the Secretary of State.

George Freeman
Parliamentary Under-Secretary of State
Department of Health

2nd February 2015

Jim Wells
Minister for Health, Social Services and Public Safety

17th February 2015

(**a**) Schedule 22 was amended by S.I. 2013/235.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012.

Regulations 3, 5, 7 and 8 are required to enable contractors carrying out search and rescue operations on behalf of the Maritime and Coastguard Agency to supply prescription only medicines under a patient group direction.

Regulations 3, 4, 7 and 8 are required to enable Public Health England and the Regional Agency for Public Health and Social Well-being in Northern Ireland to supply prescription only medicines under a patient group direction.

Regulation 6 amends the 2012 Regulations so that the new provisions relating to search and rescue operators, patient group directions and exemption from rules governing supply of medicines by national health service bodies are subject to review by the Secretary of State.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on private, public or voluntary sectors is foreseen.

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