STATUTORY INSTRUMENTS

2016 No. 186

MEDICINES

The Human Medicines (Amendment) Regulations 2016

Made - - - -	*16th February 2016*
Laid before Parliament	*23rd February 2016*
Coming into force - -	*1st April 2016*

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) Regulations 2016 and shall come into force on 1st April 2016.

Amendment of the Human Medicines Regulations 2012

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

Amendment of regulation 8 (general interpretation)

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

(2) In paragraph (1)—

(a) after the definition of "suspected" insert—

> ""therapeutic radiographer independent prescriber" means a person—
>
> (a) who is a registered radiographer; and
>
> (b) against whose name is recorded in the relevant register—
>
> (i) an entitlement to use the title "therapeutic radiographer"; and

(**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, 903 and 1503.

(**4**) Regulation 8 was amended by S.I. 2013/1855 and 2593.

(ii) an annotation signifying that the person is qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber;";

(b) after the definition of "radiopharmaceutical" insert—

""registered dietitian" means a person registered in Part 4 of the Health and Care Professions Council register;";

(c) after the definition of "registered pharmacy" insert—

""registered physiotherapist" means a person registered in Part 9 of the Health and Care Professions Council register;

"registered podiatrist" means a person registered in Part 2 of the Health and Care Professions Council register;

"registered radiographer" means a person registered in Part 11 of the Health and Care Professions Council register;";

(d) in the definition of "supplementary prescriber"—

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

(ii) after paragraph (e) insert—

"or

(f) a registered dietitian;".

Amendment of regulation 18 (wholesale dealing in medicinal products)

4. In regulation 18(**5**), in paragraph (6) omit sub-paragraph (a).

Amendment of regulation 20 (mixing of medicines)

5.—(1) Regulation 20(**6**) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (cb) insert—

"(cc) a therapeutic radiographer independent prescriber;"; and

(b) in sub-paragraph (d)—

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

(ii) after paragraph (vi) insert—

"(vii) therapeutic radiographer independent prescriber; or".

Amendment of regulation 43 (obligations of licence holder)

6.—(1) Regulation 43(**7**) is amended as follows.

(2) In paragraph (6)—

(a) in sub-paragraph (b) omit "or"; and

(b) after sub-paragraph (c) insert—

"or

(d) the wholesale distribution of medicinal products to a person in a third country.".

(**5**) Regulation 18 was substituted by S.I. 2013/1855.
(**6**) Regulation 20 was amended by S.I. 2013/1855.
(**7**) Regulation 43 was amended by S.I. 2013/1855.

Amendment of regulation 44 (requirement for wholesale dealers to deal only with specified persons)

7. In regulation 44(**8**), in paragraph (6) omit "(4)(c),".

Amendment of regulation 213 (interpretation of Part 12)

8.—(1) Regulation 213(**9**) is amended as follows.

(2) In paragraph (1)—

(a) in the definition of "health prescription", for "pharmacist — independent prescriber" substitute "pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber";

(b) omit the definition of "registered dietitian";

(c) omit the definition of "registered physiotherapist";

(d) omit the definition of "registered podiatrist";

(e) omit the definition of "registered radiographer"; and

(f) in the definition of "relevant prescriber", after paragraph (f) insert—

"(fa) a physiotherapist independent prescriber;

(fb) a podiatrist independent prescriber;

(fc) a therapeutic radiographer independent prescriber;".

Amendment of regulation 214 (sale or supply of prescription only medicines)

9. In regulation 214(**10**), after paragraph (5B) insert—

"(5C) A therapeutic radiographer independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a product subject to special medical prescription other than—

(a) Codeine;

(b) Fentanyl;

(c) Midazolam;

(d) Morphine;

(e) Oxycodone;

(f) Temazepam; or

(g) Tramadol."

Amendment of regulation 223 (exemptions for doctors and dentists etc)

10.—(1) Regulation 223(**11**) is amended as follows.

(2) In paragraph (3)(b)—

(a) in paragraph (viii) omit "or"; and

(b) after paragraph (ix) insert—

"or

(**8**) Regulation 44 was substituted by S.I.2013/1855 and amended by S.I. 2015/1503.
(**9**) Regulation 213 was amended by and S.I. 2013/235, 2014/490 and 1878 and 2015/323.
(**10**) Regulation 214 was amended by S.I. 2013/1855 and 2014/490.
(**11**) Regulation 223 was amended by S.I. 2013/1855.

(x) a therapeutic radiographer independent prescriber.".

Amendment of regulation 229 (exemption for supply by national health service bodies and local authorities)

11. In regulation 229(**12**), in paragraph (2), after "optometrist independent prescriber" insert ", physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber".

Amendment of regulation 248 (exemption for certain collection and delivery arrangements)

12.—(1) Regulation 248 is amended as follows.

(2) In paragraph (1)(a), after "pharmacist independent prescriber" insert ", physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber".

(3) In paragraph (2)(a), after "pharmacist independent prescriber" insert ", physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber".

Amendment of regulation 256A (interpretation of Part 12A)

13. In regulation 256A(**13**)—

(a) the existing text becomes paragraph (1); and

(b) after that paragraph insert—

"(2) In this Part, references to selling a medicinal product at a distance to the public by means of information society services, however expressed, include supplying and offering to sell or supply a medicinal product at a distance to the public by means of information society services (and related expressions are to be interpreted accordingly).".

Amendment of regulation 256B (person who may sell medicinal products by information society services)

14. In regulation 256B(**14**), in paragraph (8)(b), for "the notification from that person" substitute "that person's entry on the list".

Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)

15.—(1) Regulation 346(**15**) is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (c)—

(i) in paragraph (i) for "18(6)(a)" substitute "18(6)";

(ii) in paragraph (iv) after "(6)(a)" insert "and (d)";

(iii) after paragraph (xxviiib) insert—

"(xxviiiba) 214(5C),";

(**12**) Regulation 229 was amended by S.I. 2013/235 and 2015/323.
(**13**) Regulation 256A was inserted by S.I. 2013/1855.
(**14**) Regulation 256B was inserted by S.I. 2013/1855.
(**15**) Regulation 346 was substituted by S.I. 2013/1855 and then amended by S.I. 2013/2593, 2014/490 and 1878 and 2015/323, 903 and 1503.