STATUTORY RULES OF NORTHERN IRELAND

2016 No. 407

MEDICINES

The Human Medicines (Amendment) Regulations 2016

Made - - - -	*16th February 2016*
Laid before Parliament	*23rd February 2016*
Coming into operation -	*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(**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 2016 and shall come into force on 1st April 2016.

Amendment of the Human Medicines Regulations 2012

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

Amendment of regulation 8 (general interpretation)

3.—(1) Regulation 8(**d**) 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

(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;";

(**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 and 2593, 2014/490 and 1878 and 2015/323, 903 and 1503.

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

(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(**a**) in paragraph (6) omit sub-paragraph (a).

Amendment of regulation 20 (mixing of medicines)

5.—(1) Regulation 20(**b**) 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(**c**) 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.".

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

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

Amendment of regulation 213 (interpretation of Part 12)

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

(**a**) Regulation 18 was substituted by S.I. 2013/1855.
(**b**) Regulation 20 was amended by S.I. 2013/1855.
(**c**) Regulation 43 was amended by S.I. 2013/1855.
(**d**) Regulation 44 was substituted by S.I.2013/1855 and amended by S.I. 2015/1503.
(**e**) Regulation 213 was amended by and S.I. 2013/235, 2014/490 and 1878 and 2015/323.

(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(**a**), 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(**b**) is amended as follows.

(2) In paragraph (3)(b)—

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

(b) after paragraph (ix) insert—

"or

(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(**c**), 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.

(**a**) Regulation 214 was amended by S.I. 2013/1855 and 2014/490.
(**b**) Regulation 223 was amended by S.I. 2013/1855.
(**c**) Regulation 229 was amended by S.I. 2013/235 and 2015/323.

(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(**a**)—

(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(**b**), 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(**c**) 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),";

(iv) after paragraph (xxviiie) insert—

"(xxviiiea) 223(3)(b),";

(v) in paragraph (xxviiif) after "and (dc)" insert "and (2)";

(vi) after paragraph (xxviiig) insert—

"(xxviiih) 248(1)(a) and (2)(a),";

(b) in sub-paragraph (d)—

(i) for paragraph (iva) substitute—

"(iva) 17, Part 1 items 12 and 13, Part 2 items 4a, 11 and 12, Part 4 items 11 to 13 and Part 5 items 7a and 18,

(ivaa) 23, paragraph 1(a)(vii) to (ix), and".

(**a**) Regulation 256A was inserted by S.I. 2013/1855.
(**b**) Regulation 256B was inserted by S.I. 2013/1855.
(**c**) 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.

Amendment of Schedule 17 (exemption for sale, supply or administration by certain persons)

16.—(1) Schedule 17 is amended as follows.

(2) In the table in Part 1(**a**) (exemption from restrictions on sale and supply of prescription only medicines), after item 12 in the table insert—

"13 Registered orthoptists.	13 The following prescription only medicines- (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol, (i) Fusidic acid.	13 The sale or supply shall be only in the course of their professional practice."

(3) In the table in Part 2(**b**) (exemption from the restriction on supply of prescription only medicines), after item 11 in the table insert—

"12 Registered midwives.	12 Prescription only medicines for parenteral administration that contain- (a) Diamorphine, (b) Morphine, (c) Pethidine hydrochloride.	12 The supply shall be only in the course of their professional practice."

(4) In the table in Part 4(**c**) (exemption for certain persons who sell or supply certain medicinal products), after item 12 in the table insert—

"13 Registered orthoptists	13 All medicinal products on a general sale list, all pharmacy medicines and the following prescription only medicines- (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol, (i) Fusidic acid.	13 The sale or supply shall be only in the course of their professional practice."

(**a**) Part 1 was amended by S.I. 2014/1878.
(**b**) Part 2 was amended by S.I. 2014/1878 and 2015/1503.
(**c**) Part 4 was amended by S.I. 2013/2593.

Amendment of Schedule 23 (particulars in pharmacy records)

17. In Schedule 23, for paragraphs 1(a)(v) and (vi) substitute—

"(v) an optometrist independent prescriber,

(vi) a pharmacist independent prescriber,

(vii) a podiatrist independent prescriber,

(viii) a physiotherapist independent prescriber, or

(ix) a therapeutic radiographer independent prescriber, or".

Signed by the authority of the Secretary of State

George Freeman
Parliamentary Under Secretary of State
Department of Health

8th February 2016

Simon Hamilton
Minister for Health, Social Services and Public Safety

16th February 2016

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations").

Regulation 3 updates the general interpretation provisions in the 2012 Regulations to insert a new definition of therapeutic radiographer independent prescribers and to add registered dietitians to the list of health professionals who are included in the definition of a supplementary prescriber.

Regulations 5, 8-12 and 17 are required to enable therapeutic radiographer independent prescribers to mix, prescribe, sell or supply certain types of prescription only medicines.

Regulations 4, 6, 7, 13 and 14 make minor drafting amendments to the 2012 Regulations to increase the clarity of certain provisions.

Regulation 15 amends the 2012 Regulations to ensure that the new provisions relating to therapeutic radiographer independent prescribers, orthoptists and midwives are subject to review by the Secretary of State.

Regulation 16 amends Schedule 17 to the 2012 Regulations to enable general sale, pharmacy and certain prescription only medicines to be supplied by registered orthoptists and to enable the prescription only medicines diamorphine, morphine and pethidine hydrochloride to be supplied by registered midwives.

An assessment of the impact of these Regulations on the private and public sector has been made. A copy of this impact assessment is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk. Copies may also be obtained from the Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ.

Amendments to the Human Medicines Regulations 2012 are subject to the requirements of the Statutory Rules (NI) Order 1979 and the corresponding Statutory Instrument in respect of this Statutory Rule is S.I.2016 No.186.

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