STATUTORY RULES OF NORTHERN IRELAND

2018 No. 64

MEDICINES

The Human Medicines (Amendment) Regulations 2018

Made - - - -	*9th February 2018*
Laid before Parliament	*22nd February 2018*
Coming into operation	*1st April 2018*

The Secretary of State and the Department of Health in Northern Ireland(**1**) 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(**2**), having been designated for the purposes of section 2(2) of the Act in relation to medicinal products(**3**).

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) Regulations 2018 and shall come into force on 1st April 2018.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**4**) are amended as follows.

Amendment of regulation 8 (general interpretation)

3.—(1) Regulation 8(**5**) is amended as follows.

(2) In Paragraph (1)—

(a) after the definition of "the Paediatric Regulation" insert—

""paramedic independent prescriber" means a person—

(a) who is a registered paramedic; and

(**1**) The Department of Health, Social Services and Public Safety was renamed the Department of Health by s.1(5) of the Departments Act (Northern Ireland) 2016 c.5 (N.I.)

(**2**) 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).

(**3**) *See*S.I. 1972/1811 which designates the Secretary of State and any department of the Government of Northern Ireland for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products.

(**4**) S.I. 2012/1916

(**5**) Regulation 8 was amended by S.I. 2013/1855 and 2593, 2015/1503, 2016/186, 190 and 696 and 2017/715.

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber,";

(b) after the definition of "qualified person" insert—

""radiation emergency" has the meaning given by regulation 2(1) of the Radiation (Emergency Preparedness and Public Information) Regulations 2001(**6**);";

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

""registered paramedic" means a person who is registered in Part 8 of the Health and Care Professions Council register;";

(d) in the definition of "the relevant register", in paragraph (d)—

(i) after "an orthoptist" insert ", a paramedic";

(ii) in sub-paragraph (iii) omit "or"; and

(iii) after sub-paragraph (iv)—

", or

(v) paramedics;"; and

(e) in the definition of "supplementary prescriber", in paragraph (d) after "physiotherapist" insert ", paramedic".

Amendment of regulation 20 (mixing of medicines)

4.—(1) Regulation 20(**7**) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (cc), insert—

"(cd) a paramedic independent prescriber;"; and

(b) in sub-paragraph (d), after paragraph (vii) insert—

"(viii) paramedic independent prescriber; or".

Amendment of regulation 213 (interpretation of Part 12)

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

(2) In paragraph (1)—

(a) in the definition of "health prescription", after "therapeutic radiographer independent prescriber" insert ", paramedic independent prescriber";

(b) omit the definition of "registered paramedic"; and

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

"(fd) a paramedic independent prescriber;".

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

6. In regulation 214(**9**), after paragraph (5C), insert—

(**6**) S.I. 2001/1975
(**7**) Regulation 20 was amended by S.I. 2013/1855 and 2016/186.
(**8**) Regulation 213 was amended by S.I. 2013/235, 2014/490 and 1878, 2015/323, 2016/186 and 2017/715.
(**9**) Regulation 214 was amended by S.I. 2013/1855, 2014/490 and 2016/186.

"(5D) A paramedic 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; or

(d) Morphine.".

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

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

(2) In paragraph (3)(b)—

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

(b) after paragraph (x) insert—

", or

(xi) a paramedic independent prescriber.".

Amendment of regulation 228 (exemptions relating to prescriptions given by certain health professionals)

8.—(1) Regulation 228 is amended as follows.

(2) In paragraph (2)(d)—

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

(b) after paragraph (iii) insert—

"(iv) paramedics; or".

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

9. In regulation 229(**11**), in paragraph (2), after "therapeutic radiographer independent prescriber" insert ", paramedic independent prescriber".

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

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

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

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

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

11.—(1) Regulation 346(**13**) is amended as follows—

(**10**) Regulation 223 was amended by S.I. 2013/1855 and 2016/186.
(**11**) Regulation 229 was amended by S.I. 2013/235, 2015/323 and 2016/186.
(**12**) Regulation 248 was amended by S.I. 2016/186.
(**13**) 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, 2016/186 and 2017/715.