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STATUTORY RULES OF NORTHERN IRELAND

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**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<sup>(1)</sup> 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<sup>(2)</sup>, having been designated for the purposes of section 2(2) of the Act in relation to medicinal products<sup>(3)</sup>.

**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<sup>(4)</sup> are amended as follows.

**Amendment of regulation 8 (general interpretation)**

3.—(1) Regulation 8<sup>(5)</sup> 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

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(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;”;
- (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;”;
  - (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—

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(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—

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(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](#).

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- (2) In paragraph (2)—
  - (a) in sub-paragraph (c)—
    - (i) in paragraph (xxviiiiba), after “214(5C)” insert “and (5D)”; and
    - (ii) after paragraph (xxviiiiea) insert—  
“(xxviiiieb) 228(2)(d)(iv),”; and
  - (b) in sub-paragraph (d)—
    - (i) in paragraph (iva), after “and 18” insert to “to 20”; and
    - (ii) in paragraph (ivaa), for “(ix)” substitute “(x)”.

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

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

(2) In the table in Part 5(14) (exemptions from the restrictions in regulation 220 and 221 for certain persons who supply certain medicinal products), after item 18 in the table insert—

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|--|--|--|
| <p>“19 Persons supplying medicinal products under an off-site emergency plan prepared under the Radiation (Emergency Preparedness and Public Information) Regulations 2001</p> | <p>19 Pharmacy medicines which contain any of the following substances but no other active ingredient—</p> <p>(a) Potassium Iodide;</p> <p>(b) Potassium Iodate.</p> | <p>19 The supply shall be—</p> <p>(a) in accordance with the off-site emergency plan; and</p> <p>(b) only in the event that a radiation emergency has occurred or an event has occurred which could reasonably be expected to lead to a radiation emergency.</p>   |
| <p>20 A person or body listed in Part 1 or 2 of Schedule 1 to the Civil Contingencies Act 2004(15).</p>  | <p>20 Pharmacy medicines which contain any of the following substances but no other active ingredient—</p> <p>(a) Potassium Iodide;</p> <p>(b) Potassium Iodate.</p> | <p>20 The supply shall only be in response to the occurrence, or likely occurrence, of one of the following events—</p> <p>(a) an emergency within the meaning of section 1 of the Civil Contingencies Act 2004;</p> <p>(b) a radiological emergency within the meaning of regulation 24 of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009(16).”</p> |

(14) Part 5 was amended by S.I. 2014/1878 and 2015/1503.

(15) 2004 c.36. Parts 1 and 2 of Schedule 1 have been amended by other legislation.

(16) S.I. 2009/1348.

**Amendment of Schedule 23 (particulars in pharmacy records)**

13.—(1) Schedule 23(17) is amended as follows.

(2) In paragraph 1(a)—

(a) in paragraph (viii) omit “or”; and

(b) after paragraph (ix) insert—

“(x) a paramedic independent prescriber; or”.

Signed by the authority of the Secretary of State

8th February 2018

9th February 2018

*O’Shaughnessy*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care  
*Richard Pengelly*  
A senior officer of the Department of Health in  
Northern Ireland

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## 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 new definitions of radiation emergency and paramedic independent prescriber and to add paramedics to the list of health professionals who are included in the definition of a supplementary prescriber.

Regulations 4 to 10 and 13 are required to enable paramedic independent prescribers to mix, prescribe, sell or supply certain type of prescription only medicines.

Regulation 11 amends the 2012 Regulations to ensure that the new provisions are subject to review by the Secretary of State.

Regulation 12 amends Schedule 17 to the 2012 Regulations so that pharmacy medicines containing Potassium Iodide or Potassium Iodate can be supplied in the event of a radiation emergency by persons acting in accordance with an off-site emergency plan or by persons listed in Part 1 or 2 of Schedule 1 to the Civil Contingencies act 2004.

Amendments to the Human Medicines Regulations 2012 are subject to the requirements of the Statutory Rules (NI) Order 1979 and the corresponding SI in respect of this Statutory Rule is S.I. 199/2018.

An assessment of the impact of S.I. 199/2018 on the private and public sector has been prepared in relation to the amendments for paramedic independent prescribers. A copy of that impact assessment is published with the Explanatory Memorandum alongside the instrument on [www.legislation.co.uk](http://www.legislation.co.uk). Copies may also be obtained from the Department of Health and Social Care, 2E14 Quarry House, Leeds, LS2 7UE. A full impact assessment has not been produced for the amendments relating to Potassium Iodide and Potassium Iodate as no, or no significant, impact on the private, voluntary or public sectors is foreseen. However, an impact statement has been prepared and is available on request from the Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London, SW1H 0ET.