STATUTORY RULES OF NORTHERN IRELAND

# 2014 No. 323

# MEDICINES

## The Human Medicines (Amendment) Regulations 2014

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| *Made - - - -* | *4th March 2014* |
| *Laid before Parliament* | *10th March 2014* |
| *Coming into operation -* | *31st March 2014* |

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, commencement and interpretation**

**1.**—(1) These Regulations may be cited as the Human Medicines (Amendment) Regulations 2014.

(2) These Regulations come into force on 31st March 2014.

**Amendment of the Human Medicines Regulations 2012**

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

**Amendment of regulation 165**

**3.** In regulation 165 (determination in other cases) after "medicinal product" insert "in relation to these Regulations".

**Amendment of regulation 213**

**4.** In regulation 213 (interpretation provisions for dealings with medicinal products)—

(a) in paragraph (1)—

(i) omit the definition of "controlled drug",

(ii) after the definition of "the dental care professionals register" insert—

(**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.

""Council Directive 2005/36/EC" means Council Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications(**a**);"

(iii) For the definition of "EEA health professional" substitute—

""EEA health professional" means—

(a) a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist as those professionals are defined within the meaning of Council Directive 2005/36/EC;

(b) a professional exercising activities in the health care sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC; or

(c) a person of equivalent professional status to a health care professional within the meaning of regulation 8;";

(iv) omit the definition of "EEA prescription";

(v) after the definition of "prison service" insert—

""product subject to special medical prescription" means a prescription only medicine that has been designated as subject to special medical prescription in accordance with paragraph (3);"; and

(b) after paragraph (2) insert—

"(3) In this Part any substance or product for the time being specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations 2001(**b**) or in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002(**c**) is designated as a product subject to special medical prescription."

**Amendment of regulations 214, 217, 219, 224, 225, 240, 242 and 253**

**5.**—(1) In the provisions listed in paragraph (2) for the words "controlled drug" substitute "product subject to special medical prescription".

(2) The listed provisions are—

(a) 214(5)(a), (5A), (5B) and (6)(**d**)

(b) 217(3)(b);

(c) 219(1);

(d) 224(5);

(e) 225(4)(b);

(f) 240(5);

(g) 242(1)(a) and (3)(a);

(h) 253(5)(b)(ii).

**Insertion of regulation 217A**

**6.** After regulation 217 (general requirements for prescriptions) insert—

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(**a**) OJ No L 255, 30.9.2005, p22, as last amended by Council Directive 2013/25/EU of 13 May 2013 adapting certain directives in the field of right of establishment and freedom to provide services, by reason of the accession of the Republic of Croatia (OJ No L 158, 10.6.2013, p368).

(**b**) S.I. 2001/3998. Schedule 1 has been amended by S.I. 2005/1653, 2009/3136, 2010/1144, 1799, 2011/448, 2012/1311, 2013/176, 625. Schedule 2 has been amended by S.I. 2003/1432, 2009/3136, 2011/448. Schedule 3 has been amended by S.I. 2007/2154, 2011/1311.

(**c**) S.R. (N.I.) 2002 No. 1. Schedule 1 has been amended by S.R. 2005 No. 360, S.R. 2009 No. 390, S.R. 2010 No. 148 and 247, S.R. 2011 No. 153, S.R. 2012 No. 213, S.R. 2013 No. 78. Schedule 2 has been amended by S.R. 2003 No.314, S.R. 2009 No. 390, S.R. 2011 No. 153. Schedule 3 has been amended by S.R. 2007 No. 348, S.R. 2012 No. 213.

(**d**) Paragraphs (5A) and (5B) were inserted by S.I. 2013/1855.

"**Requirements for prescriptions to be dispensed in an EEA state other than the UK**

**217A.**—(1) In this regulation—

"B" means a person who is an appropriate practitioner for the purposes of regulation 214(3) to (5B);

"P" means a person who is the patient of B.

(2) The information specified in paragraph (3) is to be included in any prescription where—

(a) P requests a prescription that is to be dispensed in an EEA state other than UK; and

(b) B determines that such a prescription is appropriate.

(3) The specified information is—

(a) the patient's—

(i) surname,

(ii) first names written out in full, and

(iii) date of birth;

(b) the issue date of the prescription;

(c) B's—

(i) surname,

(ii) first names written out in full,

(iii) professional qualification,

(iv) direct contact details including—

(aa) email address,

(bb) telephone or fax number with the appropriate international prefix,

(v) work address,

(vi) confirmation that B works as a health professional in the UK, and

(vii) electronic signature or a signature written in ink;

(d) details about the prescribed product, including where applicable the—

(i) common name of the product as defined by Article 1 of the 2001 Directive,

(ii) brand name if—

(aa) the prescribed product is a biological medicinal product, or

(bb) B deems it medically necessary for that product to be dispensed and B's reasons justifying the use of the branded product,

(iii) pharmaceutical formulation (tablet, solution etc.),

(iv) quantity,

(v) strength of the medicinal product as defined in Article 1 of the 2001 Directive, and

(vi) dosage regimen.

(4) A prescription under this regulation may only be issued by B in relation to those products that B is authorised to prescribe under regulation 214(3) to (5B)."

**Amendment of regulation 218**

**7.**—(1) Regulation 218 (requirements for prescriptions: EEA health professionals) is amended as follows.

(2) For paragraph (2) substitute—

"(2) Condition A is that—

(a) the prescription is issued in an EEA State other than the United Kingdom or Switzerland; and

(b) the prescribing EEA health professional is legally entitled to issue a prescription of that kind in the EEA State in which the prescription is issued."

(3) For paragraph (3) substitute—

"(3) Condition B is that the prescription is signed in ink by the prescribing EEA health professional."

(4) For paragraph (5) substitute—

"(5) Condition D is that the prescription contains—

(a) the patient's—

(i) surname,

(ii) first names written out in full, and

(iii) date of birth;

(b) the issue date of the prescription;

(c) the prescribing EEA health professional's—

(i) surname,

(ii) first names written out in full,

(iii) professional qualifications,

(iv) direct contact details including—

(aa) email address, and

(bb) telephone or fax number with the appropriate international prefix,

(v) work address, and

(vi) name of the relevant member State in which that EEA health professional works; and

(d) details about the prescribed product, including where applicable the—

(i) common name of the product,

(ii) brand name if—

(aa) the prescribed product is a biological medicinal product, or

(bb) the prescribing EEA health professional deems it medically necessary for that product to be dispensed and the EEA health professional's reasons justifying the use of the branded product,

(iii) pharmaceutical formulation (tablet, solution, etc.),

(iv) quantity,

(v) strength of the medicinal product as defined in Article 1 of the 2001 Directive, and

(vi) dosage regimen."

**Amendment of regulation 219**

**8.** In regulation 219 (electronic prescriptions) for paragraph (4)(b) substitute

"(b) signed with—

(i) an advanced electronic signature in the case of a prescription falling within paragraph (2), or

(ii) an electronic signature in the case of a prescription falling within paragraph (3); and".

**Amendment of regulation 346**

**9.**—(1) Regulation 346(**a**) (review provisions) is amended as follows.

(2) In paragraph (2)—

(a) In sub-paragraph (c) after paragraph "(xxviiia)" insert—

"(xxviiib) 213(3),

(xxviiic) 217A,

(xxviiid) 218(2)(b) and (c), (3) and (5),

(xxviiie) 219(4)(b)(ii),"; and

(b) In sub-paragraph (d) for paragraph "(iv)" substitute—

"(iv) 12 paragraph 21,

(iva) 17, Part 4 items 11 and 12(**b**), and"

(3) For paragraph (4) substitute—

"(4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how—

(a) the 2001 Directive;

(b) Directive 2010/84/EU of the European Parliament and of the Council of 15 October 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.(**c**);

(c) Article 11 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare(**d**);

(d) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products(**e**); and

(e) Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State(**f**),

are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2)."

(4) In paragraph (5)(a) for "(xxix)" substitute "(xxxii)".

**Amendment of Schedule 1**

**10.** In paragraph 1(b) of Part 1 of Schedule 1 (further provisions for classification of medicinal products certain medicinal products to be available only on prescription), after "controlled drug" insert "as defined in section 2(1)(a) of the Misuse of Drugs Act 1971(**g**)".

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(**a**) Regulation 346 was substituted by S.I. 2013/1855 and paragraph (2) was subsequently amended by S.I. 2013/2593.
(**b**) These provisions were inserted by S.I. 2013/2593.
(**c**) OJ No L 348, 31.12.2010, p74.
(**d**) OJ No L 88, 4.4.2011, p45.
(**e**) OJ No L 174, 1.7.2011, p74.
(**f**) OJ No L 356, 22.12.2012, p68.
(**g**) 1971 c.38: section 2(1) was amended by the Police Reform and Social Responsibility Act 2011 (c.13), Schedule 17 para 2(a) and (b).

**Amendment of Schedule 17**

**11.** In Part 3 of Schedule 17 (exemption from the restriction on administration of prescription only medicines), after item 9 in the table add—

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| "10. Persons ("P") who are members of Her Majesty's armed forces. | 10. All prescription only medicines. | 10. The administration shall be—<br>(a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and<br>(b) where P is satisfied that it is not practicable for another person who is legally entitled to administer a prescription only medicine to do so; and<br>(c) only in so far as is necessary—<br>(i) for the treatment of a sick or injured person in an emergency, or<br>(ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not administered." |

Signed by the authority of the Secretary of State.

*Earl Howe*
Parliamentary Under-Secretary of State,
Department of Health

26th February 2014

*Edwin Poots*
Minister for Health, Social Services and Public Safety

4th March 2014

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations") in order to implement—

— Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare ("the cross-border Directive");

— Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another member State ("Directive 2012/52/EU").

These Regulations correct two provisions that were not properly consolidated in the 2012 Regulations because of an error and they also clarify a provision that was reported by the House of Lords and the House of Commons Joint Committee on Statutory Instruments (JCSI).

Further to the reports of the JCSI on regulation 165 of the 2012 Regulations (Ninth Report of Session 2012-13 and Eleventh Report of Session 2013-14) and the response given by the Department of Health in reply, regulation 3 clarifies the wording of this regulation to make it clearer that the provision does not preclude the licensing authority from determining that a product is a medicinal product under other provisions in those Regulations.

These Regulations introduce new provisions into the 2012 Regulations in order to implement Article 11 of the cross-border Directive on the recognition of prescriptions issued in another member State. In particular—

— regulation 4(a) substitutes a definition of "EEA health professional" that accords with provisions in Article 3 of the cross-border Directive. It also inserts a definition of "product subject to special medical prescription";

— regulation 4(b) designates certain controlled drugs as products subject to a special medical prescription so that such products do not need to be dispensed under a prescription issued by an EEA member State;

— regulation 5 substitutes certain references to "controlled drugs" with references to "product subject to special medical prescription".

These Regulations also insert a new provision into and amend two existing provisions of the 2012 Regulations in order to implement the requirements for prescriptions to contain certain information in accordance with the Annex to Directive 2012/52/EU. In particular—

— regulation 6 inserts a new provision that requires prescriptions issued in the UK for dispensing in another EEA State to contain certain information;

— regulation 7 amends existing provisions for incoming EEA prescriptions so that they accord with the new requirements;

— regulation 8 amends the requirements for incoming electronic EEA prescriptions.

Regulation 9 amends the 2012 Regulations to ensure that the new provisions on incoming and outgoing EEA prescriptions are subject to a review by the Secretary of State.

Regulation 10 amends the definition of controlled drugs to clarify that this relates to the definition of controlled drugs in the Misuse of Drugs Act 1971.

Regulation 11 inserts a provision that should have been consolidated in the 2012 Regulations whereby members of Her Majesty's armed forces are able to administer prescription only medicines in some emergency circumstances.

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.

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. 2014/490.

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Printed in the UK by The Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty's Stationery Office being the Government Printer for Northern Ireland and the Officer appointed to print Acts of the Northern Ireland Assembly.

ISBN 978-0-337-99633-7


£6.00

N6469 03/2015 456469T 19585