STATUTORY RULES OF NORTHERN IRELAND

2014 No. 323

MEDICINES

The Human Medicines (Amendment) Regulations 2014

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(**1**), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**2**).

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(**3**) 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",

(**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, 2593.

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

""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(**4**);"

(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(**5**) or in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002(**6**) 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)(**7**)

(b) 217(3)(b);

(c) 219(1);

(d) 224(5);

(e) 225(4)(b);

(f) 240(5);

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

(**4**) 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).

(**5**) 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.

(**6**) 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.

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

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

Insertion of regulation 217A

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

"**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) 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,