STATUTORY INSTRUMENTS

2015 No. 903

MEDICINES

The Human Medicines (Amendment) (No. 2) Regulations 2015

Made - - - -	*24th March 2015*
Laid before Parliament	*27th March 2015*
Coming into force - -	*1st July 2015*

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 and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) (No. 2) Regulations 2015 and shall come into force on 1st July 2015.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**3**) are amended in accordance with regulations 3 to 8.

Amendment of regulation 218

3. In regulation 218(**4**) (requirements for prescriptions: EEA health professionals), in paragraph (8), for the words "219 (electronic prescriptions)" substitute "219A (electronic prescriptions: EEA health professionals)".

Amendment of regulation 219

4.—(1) Regulation 219(**5**) (electronic prescriptions) is amended as follows.

(**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**) S.I. 1972/1811.
(**3**) S.I. 2012/1916 as amended by S.I. 2013/235, 1855 and 2593, 2014/490 and 1878 and 2015/323.
(**4**) Regulation 218 was amended by S.I. 2014/490 and 2014/1878.
(**5**) Regulation 219 was amended by S.I. 2014/490.

(2) In paragraph (1), for the words "product subject to special medical prescription" substitute "substance or product for the time being specified in Schedule 1 to the Misuse of Drugs Regulations 2001(**6**) or in Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002(**7**)".

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) for the words "paragraphs (2)(b) and (3)(b)" substitute "paragraph (2)(b)";

(b) for sub-paragraphs (b) and (c) substitute—

"(b) signed with an advanced electronic signature; and

(c) sent to the person by whom it is dispensed—

(i) as an electronic communication (whether or not through one or more intermediaries), and

(ii) via the electronic prescription service, if it is for a substance or product for the time being specified in Schedule 2 or 3 to the Misuse of Drugs Regulations 2001(**8**) or in Schedule 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002(**9**).".

(5) For paragraph (5) substitute—

"(5) In this regulation—

"advanced electronic signature" means an electronic signature that is—

(a) uniquely linked to the person giving the prescription;

(b) capable of identifying that person;

(c) created using means which that person can maintain under that person's sole control; and

(d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"electronic prescription service" means the service of that name which is managed by the Health and Social Care Information Centre established under section 252 of the Health and Social Care Act 2012(**10**) (the Health and Social Care Information Centre).".

Insertion of regulation 219A

5. After regulation 219 (electronic prescriptions) insert—

"**Electronic Prescriptions: EEA health professionals**

219A.—(1) This regulation applies to a prescription that is not a health prescription for a product subject to special medical prescription.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an EEA health professional if—

(**6**) S.I. 2001/3998. Schedule 1 was amended by S.I. 2005/1653, 2009/3136, 2010/1144 and 1799, 2011/448, 2012/1311, 2013/176 and 625, 2014/1275, 1377 and 3277 and 2015/231.

(**7**) S.R. (N.I.) 2002 No. 1. Schedule 1 was 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, S.R. 2014 No. 21, 158 and 261 and S.R. 2015 No. 53.

(**8**) Schedule 2 was amended by S.I. 2003/1432, 2009/3136, 2011/448 and 2014/1275 and 3277. Schedule 3 was amended by S.I. 2007/2154, 2012/1311 and 2014/1275.

(**9**) Schedule 2 was amended by S.R. 2003 No. 314, S.R. 2009 No. 390, S.R. 2011 No. 153, S.R. 2014 No. 158 and S.R. 2015 No. 53. Schedule 3 was amended by S.R. 2007 No. 348, S.R. 2012 No. 213 and S.R. 2014 No. 158.

(**10**) 2012 c. 7.

(a) conditions B and C in regulation 218 are not met; but

(b) the conditions in paragraph (3) of this regulation and conditions A and D to F in regulation 218 are met.

(3) The conditions mentioned in paragraph (2)(b) are that the prescription is—

(a) created in electronic form;

(b) signed with an electronic signature; and

(c) sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries).".

Amendment of regulation 246

6. In regulation 246 (exemption where requirements for prescriptions not met), in sub-paragraph (a), for the words "or 219" substitute ", 219 or 219A".

Amendment of regulation 269

7. In regulation 269 (offences relating to packaging and package leaflets: other persons), in paragraph (1), after the words "in the course of a business" insert "carried on by that person,".

Amendment of regulation 346

8. In regulation 346(**11**) (Secretary of State to carry out a review of certain provisions), in paragraph (2), for paragraph (xxviiie)(**12**) substitute—

"(xxviiie) 219 and 219A,".

Signed by the authority of the Secretary of State.

Earl Howe
Parliamentary Under-Secretary of State
Department of Health
24th March 2015

Jim Wells
Minister for Health, Social Services and Public Safety
24th March 2015

(**11**) Regulation 346 was substituted by S.I. 2013/1855 and then amended by S.I. 2013/2593, 2014/490 and 1878 and 2015/323.
(**12**) Paragraph (xxviiie) was inserted by S.I. 2014/490.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012, which sets out the requirements in respect of the manufacture, distribution, sale and supply (amongst other things) of medicines for human use in the United Kingdom.

Regulation 4 amends regulation 219 of the 2012 Regulations in order to allow appropriate practitioners other than EEA health professionals to use electronic prescriptions for a product specified in Schedule 2 or 3 to the Misuse of Drugs Regulations 2001 or in Schedule 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002, provided these are sent via the Electronic Prescription Service.

Regulations 3, 5 and 6 are required to preserve the current arrangements for electronic prescriptions given by an EEA health professional.

Regulation 7 corrects an error in regulation 269 of the 2012 Regulations by adding in words that were included in the equivalent provision of the Medicines Act 1968 (c. 67), which the 2012 Regulations replaced.

Regulation 8 amends regulation 346 of the 2012 Regulations to ensure that the new provisions relating to electronic prescriptions are subject to review by the Secretary of State.

A full impact assessment has not been produced for this instrument as no adverse impact on private, public or voluntary sectors is foreseen.