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STATUTORY RULES OF NORTHERN IRELAND

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**2015 No. 354**

**MEDICINES**

**The Human Medicines (Amendment) (No.3) Regulations 2015**

<i>Made</i>	- - - -	<i>9th July 2015</i>
<i>Laid before Parliament</i>		<i>16th July 2015</i>
<i>Coming into operation</i>		<i>1st October 2015</i>

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.3) Regulations 2015 and shall come into force on 1st October 2015.

**Amendment of the Human Medicines Regulations 2012**

2. The Human Medicines Regulations 2012(3) are amended as follows.

**Amendment of regulation 8**

3.—(1) Regulation 8(4) (general interpretation) is amended as follows.

- (2) In paragraph (2), for “18(7) and (8)” substitute “18(4) and (5)”;
- (3) In paragraph (3), for “18(8)” substitute “18(5)”;
- (4) In paragraph (4), for “18(8)” substitute “18(5)”.

**Amendment of regulation 38**

4. In regulation 38 (imports from states other than EEA states), in paragraph (3)(b), for the words from “the principles” to the end substitute “good manufacturing practice for active substances”.

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(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 and 2593, 2014/490 and 1878 and 2015/323 and 903.

(4) Regulation 8 was amended by S.I.2013/1855 and 2593.

### **Amendment of regulation 39**

5. In regulation 39(5) (further requirements for manufacturer’s licence), in paragraph (8), for “44(4) to (6)” substitute “44(5) and (6)”.

### **Amendment of regulation 44**

6.—(1) Regulation 44(6) (requirements for wholesale dealers to deal only with specified persons) is amended as follows.

- (2) Omit paragraph (1).
- (3) In paragraph(2)—
  - (a) for “From 28th October 2013 the” substitute “The”;
  - (b) after sub-paragraph (b), insert “or”;
  - (c) in sub-paragraph (c), for “country A; or” (at the end of the sub-paragraph) substitute “country A.”;
  - (d) omit sub-paragraph (d).
- (4) In paragraph (3), omit “(1),”.
- (5) Omit paragraph (4).
- (6) In paragraph (5), for “From 28th October 2013, the” substitute “The”.

### **Amendment of regulation 233**

7.—(1) Regulation 233(7) (exemption for supply etc under a PGD by person conducting a retail pharmacy business) is amended as follows.

- (2) In paragraph (1)(a), after paragraph (ivc) insert—
 

“(ivd) Public Health England,  
(ive) Public Health Agency.”.
- (3) In paragraph (5), in sub-paragraph (a) for “to (ivc) (health bodies), on behalf of that body” substitute “to (ive) (health bodies), by or on behalf of the person specified in column 2 of Part 2 of Schedule 16 against the entry in column 1 for that body”.

### **Amendment of regulation 256E**

8. In regulation 256E(8) (removal of a person’s entry from the list), in paragraph (a), for “256I(1)(b)” substitute “256I(1)(c)”.

### **Amendment of regulation 346**

9.—(1) Regulation 346(9) (Secretary of State to carry out a review of certain provisions) is amended as follows.

- (2) In paragraph (2)—
  - (a) in sub-paragraph (c) after paragraph (xxviii)(10) insert—
 

“(xxviiiifa) 233(1)(a)(ivd) and (ive),”;and

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- (5) Regulation 39 was amended by [S.I.2013/1855](#).
  - (6) Regulation 44 was substituted by [S.I.2013/1855](#).
  - (7) Regulation 233 was amended by [S.I.2013/235](#).
  - (8) Regulation 256E was inserted by [S.I.2013/1855](#).
  - (9) Regulation 346 was substituted by [S.I.2013/1855](#).
  - (10) Paragraph (xxviii) was inserted by [S.I.2015/323](#).

(b) in sub-paragraph (d), for paragraph (iva)(g) substitute—

“(iva) 17, Part 1 item 12, Part 2 items 4a and 11, Part 4 items 11 and 12 and Part 5 items 7a and 18,”.

### **Amendment of Schedule 17**

**10.**—(1) Schedule 17 (exemption for sale, supply or administration by certain persons) is amended as follows.

(2) In Part 2(**11**) (exemption from the restriction on supply of prescription only medicines), after item 4 in the table add—

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“4a Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies-	4a A prescription only medicine for parental administration containing naloxone hydrochloride but no other substance that is classified as a product available on prescription only.	4a The supply shall be only in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency.”
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(a) an NHS body;

(b) a local authority;

(c) Public Health England; or

(d) Public Health Agency

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(3) In Part 5(**12**) (exemptions from the restrictions in regulation 220 and 221 for certain persons who supply certain medicinal products), after item 7 in the table add—

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“7a Persons employed or engaged in the provision of drug treatment services provided by, on the behalf of or under arrangements made by one of the following bodies-	7a A prescription only medicine for parental administration containing naloxone hydrochloride but no other substance that is classified as a product available on prescription only.	7a The supply shall be only in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency.”
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(a) an NHS body;

(b) a local authority;

(c) Public Health England; or

(d) Public Health Agency

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(11) Part 2 was amended by S.I.2014/1878.

(12) Part 5 was amended by S.I.2014/1878.

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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Signed by the authority of the Secretary of State.

9th July 2015

*Jane Ellison*  
Parliamentary Under-Secretary of State,  
Department of Health  
*Simon Hamilton*  
Minister,  
Department of Health, Social Services and  
Public Safety

9th July 2015

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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 7 amends regulation 233 of the 2012 Regulations to enable Public Health England and the Regional Agency for Public Health and Social Well-being in Northern Ireland to enter into arrangements with retail pharmacists to supply prescription only medicines under a patient group direction (PGD). A PGD is a written instruction for the supply or administration of medicines to patients in defined clinical situations without the need for a prescription.

Regulation 10 amends Schedule 17 to the 2012 Regulations to enable the prescription only medicine naloxone hydrochloride to be supplied by drug treatment services for the purpose of saving life in an emergency.

Regulation 9 amends the 2012 Regulations so that the new provisions relating to patient group directions and to drug treatment services are subject to review by the Secretary of State.

Additionally, regulations 3 to 6 and 8 make minor corrections, including updating cross-references and removing obsolete provisions in the 2012 Regulations.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, Victoria, London SW1W 9SZ and is published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).

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.1503/2015](#).