STATUTORY INSTRUMENTS

2017 No. 715

MEDICINES

The Human Medicines (Amendment) Regulations 2017

Made - - - -	*29th June 2017*
Laid before Parliament	*5th July 2017*
Coming into force - -	*1st October 2017*

The Secretary of State and the Department of Health in Northern Ireland(**1**) make the following Regulations. They do so in exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972(**2**), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(**3**).

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment) Regulations 2017 and shall come into force on 1st October 2017.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**4**) are amended as follows.

Amendment of regulation 8 (general interpretation)

3.—(1) Regulation 8(**5**) is amended as follows.

(2) In paragraph (1)—

(a) in the appropriate place, insert—

""external use" in relation to a medicinal product—

(**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 has been previously amended by S.I. 2013/1855 and 2593, 2015/354 and 2016/186, 190 and 696.

(a) means its use by application to the skin, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal in circumstances where local action only is necessary and systemic absorption is unlikely to occur; but

(b) does not include its use by means of a throat spray, nasal spray, nasal inhalation or teething preparation or by means of throat pastilles, throat lozenges, throat tablets or nasal drops;"; and

(b) in the definition of "the relevant register", in paragraph (d)—

(i) after " a physiotherapist" insert ", an orthoptist";

(ii) in sub-paragraph (ii) omit "or"; and

(iii) after sub-paragraph (iii) insert—

", or

(iv) orthoptists;".

Amendment of regulation 45B (application for brokering registration)

4. In regulation 45B(**6**), in paragraph (1), after "unless paragraphs" insert "(2)".

Amendment of regulation 167 (supply to fulfil special patient needs)

5.—(1) Regulation 167 is amended as follows.

(2) In paragraph (7)—

(a) in sub-paragraph (b), at the end, for the full stop substitute a comma; and

(b) after sub-paragraph (b) insert (as full out words)—

"and it is imported by the holder of a wholesale dealer's licence in relation to the product in question.".

Amendment of regulation 213 (interpretation of Part 12)

6. In regulation 213(**7**), in paragraph (1), omit the definition of "external use".

Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)

7. In regulation 346(**8**), in paragraph (2)(d)(iva), after "Part 2 items 4a, 11 and 12," insert "Part 3 item 11,".

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

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

(2) In the table in Part 1(**9**) (exemption from restrictions on sale and supply of prescription only medicines)—

(a) in item 12—

(i) for the words in column 2 substitute—

(**6**) Regulation 45B was inserted by S.I. 2013/1855.
(**7**) Regulation 213 was amended by and S.I. 2013/235, 2014/490 and 1878, 2015/323 and 2016/186.
(**8**) 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 and 2016/186.
(**9**) Part 1 was amended by S.I. 2014/1878 and 2016/186.