STATUTORY RULES OF NORTHERN IRELAND

2014 No. 323

The Human Medicines (Amendment) Regulations 2014

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—

""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(1);"

- (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(2) or in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002(3) is designated as a product subject to special medical prescription."

⁽¹⁾ 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).

⁽²⁾ 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.

⁽³⁾ 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.

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