

SCHEDULES

SCHEDULE 34

Amendments to existing law

PART 6

Northern Ireland statutory rules

Control of Pesticides Regulations (Northern Ireland) 1987

102. For regulation 3(2)(b)(i) of the Control of Pesticides Regulations (Northern Ireland) 1987(1) substitute—

“(i) the Human Medicines Regulations 2012;”.

Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995

103. In rule 4 of the Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995(2)—

- (a) omit the definition “the 1997 Order”;
- (b) in the definitions “nurse independent prescriber” and “pharmacist independent prescriber” for “article 1(2) of the 1997 Order” substitute “regulation 8(1) of the Human Medicines Regulations 2012”; and
- (c) in the definition “prescription only medicine” for “article 1(2) of the 1997 Order” substitute “regulation 5(3) of the Human Medicines Regulations 2012”.

Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996

104. In the Schedule to the Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996(3) for “Medicines Act 1968” substitute “Human Medicines Regulations 2012”.

Pharmaceutical Services Regulations (Northern Ireland) 1997

105. In Part 2 of Schedule 2 to the Pharmaceutical Services Regulations (Northern Ireland) 1997(4), in paragraph 2(12) for the words from “Articles” to the end of the paragraph substitute regulation 224 of the Human Medicines Regulations 2012”.

(1) S.R. (NI) 1987 No 414, as amended by S.R. (NI) 1997 No 469.

(2) S.R. (NI) 1995 No 8, as amended by S.R. (NI) 2009 No 429. There are other amendments, but none is relevant.

(3) S.R. (NI) 1996 No 81.

(4) S.R. (NI) 1997 No 381, as amended by S.R. (NI) 1999 No 405. There are other amendments, but none is relevant.

Status: This is the original version (as it was originally made).

Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998

106. In Schedule 1, Chapter 4, Section 4.8, Part C of the Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998⁽⁵⁾, for the words from “means” to the end of the Part substitute “has the meaning given in regulation 2 of the Human Medicines Regulations 2012”.

Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998

107. The Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998⁽⁶⁾ are amended as follows—

- (a) in regulation 10(1)(a) for “section 8 of the Medicines Act 1968” substitute “regulation 17 of the Human Medicines Regulations 2012”; and
- (b) in regulation 11(1) for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

Importation of Animal Pathogens Order (Northern Ireland) 1999

108. In article 5(a) of the Importation of Animal Pathogens Order (Northern Ireland) 1999⁽⁷⁾ for “the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

Biocidal Products Regulations (Northern Ireland) 2001

109. In Schedule 2 to the Biocidal Products Regulations (Northern Ireland) 2001⁽⁸⁾—

- (a) omit entry (f); and
- (b) for entry (i) substitute—
 - “(i) the Human Medicines Regulations 2012;”.

Misuse of Drugs Regulations (Northern Ireland) 2002

110.—(1) The Misuse of Drugs Regulations (Northern Ireland) 2002⁽⁹⁾ are amended as follows.

(2) In regulation 2(2)—

- (a) in the definitions “clinical management plan”, “nurse independent prescriber”, “patient group direction”, “registered chiropodist”, “registered midwife”, “registered nurse”, “registered occupational therapist”, “registered optometrist”, “registered orthoptist”, “registered orthotist and prosthetist”, “registered paramedic”, “registered physiotherapist”, “registered radiographer” and “supplementary prescriber”, for “the Prescription Only Medicines (Human Use) Order 1997” substitute “the Human Medicines Regulations 2012”; and
- (b) in the definition “medicinal product” for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”

⁽⁵⁾ S.R. (NI) 1998 No 28.

⁽⁶⁾ S.R. (NI) 1998 No 45, as amended by S.R. (NI) 2011 No 124.

⁽⁷⁾ S.R. (NI) 1999 No 433.

⁽⁸⁾ S.R. (NI) 2001 No 422.

⁽⁹⁾ S.R. (NI) 2002 No 1, as amended by S.R. (NI) 2003 No 324, S.R. (NI) 2003 No 420, S.R. (NI) 2005 No 119, S.R. (NI) 2005 No 564, S.R. (NI) 2006 No 214, S.R. (NI) 2006 No 264, and S.R. (NI) 2007 No 348.

(3) In regulation 6A(1)(e) for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

(4) In regulation 8(2)—

- (a) in sub-paragraph (h) after the first occurrence of “the Medicines Act 1968” insert “or of Schedule 31 to the Human Medicines Regulations 2012”; and
- (b) in sub-paragraph (j) after “the Medicines Act 1968” insert “or of regulation 324 of the Human Medicines Regulations 2012”.

(5) In regulation 9(2)—

- (a) in sub-paragraph (f) after “the Medicines Act 1968” insert “or of Schedule 31 to the Human Medicines Regulations 2012”; and
- (b) in sub-paragraph (h) after “the Medicines Act 1968” insert “or of regulation 324 of the Human Medicines Regulations 2012”.

(6) In regulation 11(1) for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

(7) In regulation 17—

- (a) after “the Medicines Act 1968” insert “or of the Human Medicines Regulations 2012”; and
- (b) after “that Act” insert “or of those Regulations”.

(8) In regulation 18 for paragraph (3) substitute—

“(3) In this regulation, “clinical trial” has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004.”.

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003

111. In regulation 5(2)(c) of the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003(**10**) for “section 58 of the Medicines Act 1968” substitute “regulation 214 of the Human Medicines Regulations 2012”.

Waste Management Licensing Regulations (Northern Ireland) 2003

112. In paragraph 2 of Schedule 1 to the Waste Management Licensing Regulations (Northern Ireland) 2003(**11**), in the definition “hazardous waste” for the words following ““medicinal product” means” to the end of the definition substitute “a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012”.

Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004

113.—(1) The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004(**12**) are amended as follows.

(2) In regulation 2—

- (a) in the definition “licensing authority” for “section 6(3) of the Medicines Act 1968” substitute “regulation 6 of the Human Medicines Regulations 2012”;
- (b) omit the definition “the POM Order” and

(10) S.R. (NI) 2003 No 34.

(11) S.R. (NI) 2003 No 493.

(12) S.R. (NI) 2004 No 140, as amended by S.R. (NI) 2005 No 368.

Status: This is the original version (as it was originally made).

- (c) in the definition “prescription only medicine” for the words from “referred” to the end of the definition substitute “within the meaning of regulation 5(3) of the Human Medicines Regulations 2012”.
- (3) In regulation 47(2) for the words from “Part 3” to the end of the regulation substitute “Part 12 of the Human Medicines Regulations 2012”.
- (4) In Schedule 5—
 - (a) in paragraph 11A(1) in the definition “Patient Group Direction” for “the Prescription Only Medicines (Human Use) Order 1997” substitute “the Human Medicines Regulations 2012”; and
 - (b) in paragraph 41(2)(a)—
 - (i) for “article 3B(3) of the POM Order” substitute “regulation 215 of the Human Medicines Regulations 2012”; and
 - (ii) for “that Order” substitute “those Regulations”.

Nursing Homes Regulations (Northern Ireland) 2005

114. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005(**13**) for “section 58 of the Medicines Act 1968” substitute “regulation 214 or 215 of the Human Medicines Regulations 2012”.

Residential Care Homes Regulations (Northern Ireland) 2005

115. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005(**14**) for “section 58 of the Medicines Act 1968” substitute “regulation 214 or 215 of the Human Medicines Regulations 2012”.

Children’s Homes Regulations (Northern Ireland) 2005

116. In regulation 20(4)(b) of the Children’s Homes Regulations (Northern Ireland) 2005(**15**), for “section 58 of the Medicines Act 1968” substitute “regulations 214 or 215 of the Human Medicines Regulations 2012”.

Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006

117. In regulation 3(1) of the Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006(**16**) in the definition “Pharmacist” for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007

118. In regulation 71(3)(a) of the Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007(**17**), for “section 8(2) of the Medicines Act 1968” substitute “regulation 17 of the Human Medicines Regulations 2012”.

(13) S.R. (NI) 2005 No 160.

(14) S.R. (NI) 2005 No 161.

(15) S.R. (NI) 2005 No 176.

(16) S.R. (NI) 2006 No 478.

(17) S.R. (NI) 2007 No 68.

Day Care Setting Regulations (Northern Ireland) 2007

119. In regulation 13(6)(b) of the Day Care Setting Regulations (Northern Ireland) 2007(**18**) for “section 58 of the Medicines Act 1968” substitute “regulations [214](#) or [215](#) of the Human Medicines Regulations 2012”.

Residential Family Centres Regulations (Northern Ireland) 2007

120. In regulation 13(4)(b) of the Residential Family Centres Regulations (Northern Ireland) 2007(**19**) for “section 58 of the Medicines Act 1968” substitute “regulations [214](#) or [215](#) of the Human Medicines Regulations 2012”.

Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007

121. In regulation 3(1)(a) of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007(**20**) for “the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

Specified Animal Pathogens Order (Northern Ireland) 2008

122. In article 5(2)(b) of the Specified Animal Pathogens Order (Northern Ireland) 2008(**21**) for “the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994” substitute “the Human Medicines Regulations 2012”.

Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

123. In regulation 2(2) of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009(**22**), in the definition “retail pharmacy business” for “section 132 of the Medicines Act 1968” substitute “regulation [8\(1\)](#) of the Human Medicines Regulations 2012”.

Private Water Supplies Regulations (Northern Ireland) 2009

124. In regulation 4(b) of the Private Water Supplies Regulations (Northern Ireland) 2009(**23**) for “the Medicines Act 1968” substitute “the Human Medicines Regulations 2012”.

(18) S.R. (NI) 2007 No 234.

(19) S.R. (NI) 2007 No 236.

(20) S.R. (NI) 2007 No 420.

(21) S.R. (NI) 2008 No 336.

(22) S.R. (NI) 2009 No 225.

(23) S.R. (NI) 2009 No 413.