



The Human Medicines Regulations 2012 (SI 2012/1916) – table of origins

This document shows how the Human Medicines Regulations 2012 consolidate UK medicines legislation. It is intended as a reference material to help users and has no legal effect.

Note: 'MA 1968' = Medicines Act 1968

MHRA, August 2012

Key:

Part 1 (general)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|------------------------------|
| 1 | | |
| 2 | S.I. 1994/3144 reg.1(2), (5) | 2001/83/EC Art.1(2) and 2(1) |
| 3 | MA 1968 s.9, 11 and 12(1) | Art.(1) |
| 4 | MA 1968 s.10 | |
| 5(1) | MA 1968 s.51 and SI 1984/769 Art.2 | |
| 5(2) | MA 1968 s. 58(1) and SI 1997/1830 Art.3 | |
| 5(3) | MA 1968 s. 58(1) and SI 1997/1830 Art.3 | |
| 5(4) | Drafting clarification to aid comprehension | |
| 5(5) | Drafting clarification to aid comprehension | |
| 6 | MA 1968 s.6 | |
| 7 | Reg 1(2) 2010/1882 | 2001/83/EC Art.86 |
| 8 | MA 1968 s.132 | 2001/83/EC Art.1 |

Part 2 (administration)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|-----------------------------------|--|
| 9 | MA 1968 s.2A | |
| 10 | MA 1968 s.3 | |
| 11 | MA 1968 s.4(4) and S.I. 1970/1256 | |
| 12 (1) | MA 1968 Sch.1A para. 1 | |

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|-------------|------------------------|--|
| 12 (2) –(4) | MA 1968 s.5(2) and (3) | |
| 13 | MA 1968 Sch.1A para. 2 | |
| 14 | MA 1968 Sch.1A para. 3 | |
| 15 | MA 1968 Sch.1A para. 5 | |
| 16 | MA 1968 s.5(1) | |

Part 3 (manufacturing and wholesale dealing)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|------------------------|
| 17 | MA 1968 s.8(2) to (2D) | |
| 18 | MA 1968 s.8(3) to (8) | |
| 19 | S.I. 1990/566, Art.2 | |
| 20(1) | S.I. 2009/3062, Art.2 | |
| 20 (2) | S.I. 2009/3062, Art.1 | |
| 21 | MA 1968 s.18 | |
| 22 | MA 1968 s.19 (5) and (6) | |
| 23 | MA 1968 s.20 | |
| 24 | MA 1968 s.47 | |
| 25 | MA 1968 s.24 | |
| 26 | MA 1968 s.28(1), (2), (4), (5), (6) and (7). | |
| 27 | MA 1968 s.29 | |
| 28 | MA 1968, Sch.2, paras 8-11 | |
| 29 | MA 1968 s.30 | |
| 30 | MA 1968 s.44(1) to (4) | |
| 31 | MA 1968 s.50 | 2001/83/EC Art.77.4 |
| 32 | S.I. 2005/2789 reg.5 | |
| 33 | S.I. 1994/3144 Sch.3 para 13C | |
| 34 | MA 1968 s.45(6) to (8) | |
| 35 | MA 1968 s.45(6) to (8) and 2010/1882 reg.5 | |
| 36 | SI 2005/2789 reg.12 <u>S.I. 2010/1882 regulation 3(1) and Schedule 1</u> | |
| 37 | S.I. 2005/2789 reg.2(1) and (2) <u>Schedule 1 S.I. 2010/1882</u> | |
| 38 | S.I. 2005/2789 reg.3(a) to (c) | |
| 39 | S.I. 2005/2789 remainder of reg.2 <u>Schedule 1 S.I. 2010/1882</u> | |
| 40 | | 2001/83/EC Art.8(3)(h) |
| 41 | S.I. 2005/2789 reg.4 | |
| 42 | S.I. 2005/2789 reg.8(1) and 12 | |
| 43 | S.I. 2005/2789 reg.8 <u>Schedule 3 S.I. 2010/1882</u> | |
| 44 | S.I. 2005/2789 reg.9 | |

| | | |
|----|---|--|
| | paragraph 15 of schedule 6 <u>S.I. 2010/1882</u> | |
| 45 | S.I. 2005/2789 reg.10[paras (a) to (d) sched 3 <u>S.I.</u> 2010/1882] | |

Part 4 (requirement for authorisation)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|---------------------|
| 46 | S.I. 1994/105 reg.3 and Sch.6 para.2; S.I. 1994/3144 reg.3, Sch.1 para.5A and Sch.3 para.2; S.I. 2005/2750 reg.4 and Sch.3 para.2 | 2001/83/EC Art.6(1) |
| 47 | S.I. 1994/105 Sch.6 para.1 and 2; S.I. 1994/3144 Sch.3 paras.1 and 2; S.I. 2005/2750 Sch.3 para.1 and 2 | 2001/83/EC Art.6(1) |

Part 5 (UK marketing authorisations)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|--|
| 48 | S.I. 1994/3144 reg.1(2) | 2001/83/EC Art.10(2) |
| 49 [j102] | S.I. 1994/3144 reg.4(1), (1A), (2), (3), (5), (8) and (9); reg.7(1) | 2001/83/EC Art.8(1) and (2) |
| 50 | S.I. 1994/3144 reg.4(1) and (1A); and MA 1968 s.19 (3)(b) | 2001/83/EC Art.8(3), 9 and 19(3) |
| 51 | S.I. 1994/3144 reg.4(7) | 2001/83/EC Art.10(1),(3), (5), (6) and 11 |
| 52 | | 2001/83/EC Art.10a |
| 53 | | 2001/83/EC Art.10(4) |
| 54 | | 2001/83/EC Art.10a |
| 55 | | 2001/83/EC Art.10b and 12(2) |
| 56 | | |
| 57 | | 2001/83/EC Art.8(3) |
| 58 | S.I. 1994/3144 reg.5(1) | 2001/83/EC Art.17(1), 19(3) and 26 |
| 59 | | |
| 60 | S.I. 1994/3144 reg.5(1) | 2001/83/EC Art.22 |
| 61 | | |
| 62 | S.I. 1994/3144 reg.5A; MA 1968 s.58A(2), (3) and (4) | 2001/83/EC Art.70(1), 71 and 72 |
| 63 | | |
| 64 | | 2001/83/EC Art.21 |
| 65 | S.I. 1994/3144 reg.5(6) and (7) | 2001/83/EC Art.24(1), (2) and (3) |
| 66 | S.I. 1994/3144 regs.4(1), | 2001/83/EC Art.24(2) |

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| | (2), (3), (8) and (9) and 5(1) and (2) | |
| 67 | S.I. 1994/3144 reg.5(8); | 2001/83/EC Art.24(4) to (6) |
| 68 | S.I. 1994/3144 reg.6(1) and 6(7) | 2001/83/EC Art.107, 116 and 118(1) |
| 69 | S.I. 1994/3144 reg.6(2), (3) and (4) | 2001/83/EC Art.117 |
| 70 | | 2001/83/EC Art.36 |
| 71 | S.I. 1994/3144 reg.6(5) and (6) | 2001/83/EC Art.34(3), 36(2) and 117; Regulation 726/2004 Art.20(4) |
| 72 | <i>S.I. 1994/3144 Sch.3 para.4</i> | |
| 73 | S.I. 1994/3144 reg.7(1) | 2001/83/EC Art.23a |
| 74 | S.I. 1994/3144 reg.7(1) | 2001/83/EC Art.23 |
| 75 | S.I. 1994/3144 reg.7(1) | 2001/83/EC Art.23 |
| 76 | | |
| 77 | S.I. 1994/3144 reg.7(2) and (3) | |
| 78 | S.I. 1994/3144 Sch.3 para.6C | 2001/83/EC Art.81 |
| 79 | | |
| 80 | S.I. 1994/3144 Sch.3 para.3A | |
| 81 | S.I. 1994/3144 Sch.3 para.6(a) | |
| 82 | S.I. 1994/3144 Sch.3 para.6(d) and (dd) | |
| 83 | S.I. 1994/3144 Sch.3 para.6(b), (c) and (e) | |
| 84 | S.I. 1994/3144 Sch.3 paras.6(cc), (d), (dd) and (f), 6A, 6AA and 6D | |
| 85 | | |
| 86 | | |
| 87 | S.I. 1994/3144 Sch.3 para. 10B Includes S.I. 2010/1882 regulation 8 and Schedule 5 paragraph 3(2) and (5)] | |
| 88 | S.I. 1994/3144 Sch.3 para. 13C S.I. 2010/1882 regulation 8 and Schedule 5 paragraph 3(4) | |
| 89 | S.I. 1994/3144 Sch.3 para.6BA and 6BB | |
| 90 | S.I. 1994/3144 Sch.3 para.6G | |
| 91 | S.I. 1994/3144 Sch.3 para.13B(1) | |
| 92 | S.I. 1994/3144 Sch.3 para.13B(4) | |
| 93 | S.I. 1994/3144 Sch. 3 para.13B(7) | |

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| 94 | | |
| 95 [j160] | S.I. 1994/3144 Sch.3 para.10A(1) | |
| 96 [j161] | S.I. 1994/3144 Sch.3 para.10A(2) | |
| 97 | | |
| 98 | S.I. 1994/3144 Sch.3 para.14 | |
| 99 | S.I. 1994/3144 Sch.3 para.14 | |
| 100 | S.I. 1994/3144 Sch.3 para.15 S.I. 2010/1882 regulation 8 and Schedule 5 paragraph 3(2) and (5) | |
| 101 | S.I. 1994/3144 Sch.3 para.16 and 17 | |

Part 6 (certification of homoeopathic medicinal products)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|---|
| 102 | S.I. 1994/105 reg.2 | 2001/83/EC Art.13(1) and 14(1) |
| 103 | S.I. 1994/105 reg.4 | 2001/83/EC Art.15 |
| 104 | S.I. 1994/105 reg.5 | 2001/83/EC Art.1(28) and (28a), 17(1) and 26(1) and (2) |
| 105 | S.I. 1994/105 reg.5(1) | 2001/83/EC Art.22 |
| 106 | SI 1994/105 reg.6 | |
| 107 | S.I. 1994/105 reg.8(1) and (2); | 2001/83/EC Art.24(1), (2) and (3) |
| 108 | S.I. 1994/105 reg.8(2) and (5), reg.7A(1) | 2001/83/EC Art.24(2) |
| 109 | S.I. 1994/105 reg.8(2A) | 2001/83/EC Art.24(4) to (6) |
| 110 | S.I. 1994/105 reg.9 | 2001/83/EC Art.116 |
| 111 | | 2001/83/EC Art.36 |
| 112 | S.I. 1994/105 reg.10 | 2001/83/EC Art.117 |
| 113 | S.I. 1994/105 reg.7A(1) | 2001/83/EC Art.23a |
| 114 | S.I. 1994/105 reg.7A(1) | 2001/83/EC Art.23 |
| 115 | S.I. 1994/105 reg.7A(1) | 2001/83/EC Art.23 |
| 116 | | |
| 117 | S.I. 1994/105 reg.7A(2) | |
| 118 | S.I. 1994/105 Sch.6 para.8 | |
| 119 | S.I. 1994/105 Sch.6 para.9(1) | |
| 120 | S.I. 1994/105 Sch.6 para.9(2) | |
| 121 | S.I. 1994/105 Sch.6 para.12 | |
| 122 | S.I. 1994/105 Sch.6 para.12 | |
| 123 | New regulation for consistency with reg.93 | |

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| | [j178] and reg.145 [j439] | |
| 124 | S.I. 1994/105 Sch.6 paras.13 and 14 | |

Part 7 (traditional herbal registrations)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|--|
| 125 | S.I. 2005/2750 reg.2(2) | 2001/83/EC Art.16a(1) and (3) and 16c(3) |
| 126 | S.I. 2005/2750 reg.2(2) | 2001/83/EC Art.16a(2) and 16d(1) |
| 127 | S.I. 2005/2750 reg.5(1) to (5); 9(1) | 2001/83/EC Art.16b |
| 128 | S.I. 2005/2750 reg.5(1) | 2001/83/EC Art.16c(1), 16f(2) and 19(3) |
| 129 | | 2001/83/EC Art.8(3) |
| 130 | S.I. 2005/2750 reg.6(1) | 2001/83/EC Art.16e(1), 16d(2), 16f(2), 16h(3), 17(1) and 19(3) |
| 131 | SI 2005/2750 reg.6(7) | |
| 132 | S.I. 2005/2750 reg.6(4) and (5) | 2001/83/EC Art.24(1), (2) and (3) |
| 133 | S.I. 2005/2750 reg.5 and 6(1) | 2001/83/EC Art.24(3) |
| 134 | S.I. 2005/2750 reg.6(6) | 2001/83/EC Art.24(4) to (6) |
| 135 | S.I. 2005/2750 reg.7(1) | 2001/83/EC Art.107, 116 and 118(1) |
| 136 | S.I. 2005/2750 reg.7(1) | 2001/83/EC Art.16f(3) |
| 137 | S.I. 2005/2750 reg.7(7) | |
| 138 | S.I. 2005/2750 reg.7(2) to (4) | 2001/83/EC Art.117 |
| 139 | | 2001/83/EC Art.36 |
| 140 | S.I. 2005/2750 reg.7(5) and (6) | |
| 141 | S.I. 2005/2750 Sch.3 para.5 | |
| 142 | S.I. 2005/2750 reg.9(4) | 2001/83/EC Art.23a |
| 143 | S.I. 2005/2750 reg.9(1) | 2001/83/EC Art.23 |
| 144 | S.I. 2005/2750 reg.9(1) | 2001/83/EC Art.16h(3) |
| 145 | S.I. 2005/2750 reg.9(1) | 2001/83/EC Art.23 |
| 146 | | |
| 147 | S.I. 2005/2750 reg.9(3) | |
| 148 | S.I. 2005/2750 Sch.3 para.10 | |
| 149 | S.I. 2005/2750 Sch.3 para.4 | |
| 150 | S.I. 2005/2750 Sch.3 para.17(1) | |
| 151 | S.I. 2005/2750 Sch.3 para.17(2) | |
| 152 | S.I. 2005/2750 Sch.3 para.7(c), 8 and 22 | |
| 153 | S.I. 2005/2750 Sch.3 | |

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| | para.7(c), 8 and 22 | |
| 154 | S.I. 2005/2750 Sch.3 para.23 | |
| 155 | S.I. 2005/2750 Sch.3 para.24 and 25 | |

Part 8 (Article 126a authorisations)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|---------------------|
| 156 | S.I. 1994/3144 reg.5(5) | 2001/83/EC Art.126a |
| 157 | | |
| 158 | S.I. 1994/3144 regs.5A and 6(7A) and Sch.3 para.18 and 19 | |

Part 9 (borderline products)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|--|
| 159 | S.I. 1994/3144 reg.3A(1) | |
| 160 | S.I. 1994/3144 reg.3A(1) and (3) | |
| 161 | S.I. 1994/3144 reg.3A(5) | |
| 162 | S.I. 1994/3144 reg.3A(2), (3) and (5) | |
| 163 | S.I. 1994/3144 reg.3A(4) | |
| 164 | S.I. 1994/3144 reg.3A(6) | |
| 165 | S.I. 1994/3144 reg.3A(7) | |
| 166 | S.I. 1994/3144 Sch.3 paras.1A and 14 | |

Part 10 (exceptions to requirement for marketing authorisation etc)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|------------------|
| 167 | S.I. 1994/105 reg.2; S.I.1994/3144 Sch.1 paras.1 and 2; S.I. 2005/2750 Sch.1 paras.2 and 3 | 2001/83/EC Art.3 |
| 168 | S.I. 1994/105 reg.2; S.I.1994/3144 Sch.1 para.4; S.I. 2005/2750 Sch.1 para.5 | 2001/83/EC Art.3 |
| 169 | ? | ? |
| 170 | S.I. 1994/105 reg.2; S.I.1994/3144 Sch.1 paras.6 and 7; S.I. 2005/2750 Sch,1 paras.6 and 7 | 2001/83/EC Art.3 |
| 171 | (a) S.I 2010/1882 reg 2 10 and para (r) sched 3 | |
| 172 | Drafting clarification to aid | |

| | | |
|-----|---|---------------------|
| | comprehension | |
| 173 | S.I.1994/3144 Sch.1 para.5 | 2001/83/EC Art.3 |
| 174 | | 2001/83/EC Art.5(2) |
| 175 | S.I. 2005/2750 Sch.3 paras.20 and 21 | |
| 176 | S.I. 1994/3144 Sch.3 paras.13, 13A, 14, 15(2) and 17; S.I. 2005/2750 Sch.3 paras.22, 23(2) and 25 | |

Part 11 (pharmacovigilance)

| | | |
|------------|--|---|
| 177 [j442] | | |
| 178 [j451] | | 2001/83/EC Art.102 |
| 179 [j452] | | 2001/83/EC Art.101 |
| 180 [j453] | | 2001/83/EC Art.101(2), 2 nd sentence |
| 181 [j454] | | 2001/83/EC Art.103 |
| 182 [j455] | | 2001/83/EC Art.104 (except 104(2), 2 nd para) |
| 183 [j456] | | 2001/83/EC Art.104a |
| 184 | | 2001/83/EC Art.104(2) , 2 nd para |
| 185 | | 2001/83/EC Art.107a |
| 186 [j457] | | 2001/83/EC Art.107a |
| 187 [j444] | | 2001/83/EC Art.107(1) and (2) |
| 188 [j445] | | 2001/83/EC Art.107(3) to (5) |
| 189 [j460] | | 2001/83/EC Art.107h |
| 190 [j461] | | 2001/83/EC Art.107h(3), 2 nd para |
| 191 [j446] | | 2001/83/EC Art.107b |
| 192 [j462] | | 2001/83/EC Art.107b(3) |
| 193 [j463] | | 2001/83/EC Art.107c(4), 3 rd para, last line; 107c(6), 2 nd para, last line and 107c(6), 1 st para |
| 194 [j464] | | 2001/83/EC Art.107g |
| 195 [j465] | | 2001/83/EC Art.107d and 107f |
| 196 [j466] | | 2001/83/EC Art.107i |
| 197 [j467] | | 2001/83/EC Art.107j and 107k |
| 198 [j468] | | 2001/83/EC Art.107m |
| 199 [j469] | | 2001/83/EC Art.107m(8) and 107n |
| 200 [j470] | | 2001/83/EC Art.107o |
| 201 [j471] | | 2001/83/EC Art.107p |
| 202 | | 2001/83/EC Art.107q(2) |
| 203 [j473] | | 2001/83/EC Art.106 |
| 204 [j474] | | 2001/83/EC Art.106a(2) |
| 205 [j475] | | 2001/83/EC Art.106a(1) |

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| 206 [j476] | | 2001/83/EC Art.102(f) |
| 207 [j477] | | 2001/83/EC Art.102(f) |
| 208 [j478] | | 2001/83/EC Art.102(f) |
| 209 [j438X] | | 2001/83/EC Art.102(f) |
| 210 [j479] | | Regulation (EC) No. 726/2004 (as amended, in particular, by Regulation (EU) No. 1235/2010) |
| 211 [j439X] | | 2001/83/EC Art.102(f) |
| 212 [j480] | | Directive 2010/84/EU Art. 2 |

Part 12 (dealings with medicinal products)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|--|
| 213(1) | MA 1968 s.132(1); S.I. 1984/769 Art.1(2); S.I. 1980/1924 Art.1(2); S.I. 1997/1830 Art.1(2) and S.I. 2008/1692 Arts.1(2) and 3(3) | |
| 213(2) | SI 1980/1924 Art.1(2)(c) and SI 1997/1830 Art.1(7) | |
| 214 | MA 1968 s.58(2); S.I. 1997/1830 Arts.2 and 9 and SI 2008/1692 Art.2 | |
| 215 | S.I. 1997/1830 Art.3B | |
| 216 | S.I. 1997/1830 Art.3B and Art.3C | |
| 217 | S.I. 1997/1830 Art.15(1), (2) and (6) | |
| 218 | S.I. 2008/1692 Art.3 and 5 | |
| 219 | S.I. 1997/1830 Art.15(3), (4) and (7) and S.I. 2008/1692 Art.4 | |
| 220 | MA 1968 s.52(1) | |
| 221 | MA1968 s.53 and S.I. 1980/1923 reg.4 and 8 | |
| 222 | MA 1968 s.52(3) and 54(1) and S.I. 1984/769 Art.3 | |
| 223 | MA 1968 s.58(3) | |
| 224 | S.I. 1997/1830 Art.8(1), (2) and (5) and S.I. 2008/1692 Art.7 | |
| 225 | S.I. 1997/1830 Art.8(3), (4) and (5) and S.I. 2008/1692 Art.7 | |
| 226 | S.I. 1997/1830 Art.8(6) and S.I. 2008/1692 Art.7 | |
| 227 | S.I. 1997/1830 Art.12 | |
| 228 | S.I. 1997/1830 Art.13A | |
| 229 | S.I. 1997/1830 Art.12A | |
| 230 | S.I. 1997/1830 Art.12B | |

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| 231 | S.I. 1997/1830 Art.12D | |
| 232 | New provision for review proposal | |
| 233 | S.I. 1997/1830 Art.12C | |
| 234 | S.I. 1997/1830 Art.12E | |
| 235 | S.I. 1997/1830 Art.11 | |
| 236 | S.I. 1997/1830 Art.5A | |
| 237 | S.I. 1997/1830 Art.5B | |
| 238 | S.I. 1997/1830 Art.7 | |
| 239 | S.I. 1997/1830 Art.7A | |
| 240 | S.I. 1997/1830 Art.7B | |
| 241 | MA 1968 s.56 and S.I. 1977/2130 | |
| 242 | S.I. 1980/1924 art.6 | |
| 243 | S.I. 1980/1924 Art.6A | |
| 244 | S.I. 1980/1924 Art.3 | |
| 245 | S.I. 1997/1830 Art.14 | |
| 246 | S.I. 1997/1830 Art 15(5) and S.I. 2008/1692 Art.6 | |
| 247 | S.I. 1980/1924 Art.8 | |
| 248 | S.I. 1978/1421 | |
| 249 | S.I. 1980/1923 Art.5(1) | |
| 250 | S.I. 1980/1923 Art.5(2) | |
| 251 | MA 1968 s.65 | |
| 252 | MA 1968 s.65 | |
| 253 | S.I. 1980/1923 Art.6 | |
| 254 | S.I. 2010/1882, reg 4 | |
| 255 (1) | MA 1968 s.67(2) | |
| 255 (2) | MA 1968 s.67(1B) | |
| 255 (3) | MA 1968 s.67(1A) | |
| 255 (4) | MA 1968 s.67(3A) | |
| 255 (5) | MA 1968 s.67(4) | |
| 255 (6) | MA 1968 s.67(5) | |
| 255 (7) | MA 1968 s.67(5) | |
| 255 (8) | MA 1968 s.67(6) and S.I. 1980/1923 Art.9 | |
| 255 (9) | MA 1968 s.67(6) and S.I. 1980/1923 Art.9 | |
| 256 | MA 1968 s.68 | |

Part 13 (packaging and leaflets)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|-----------------------|-------------------------------------|
| 257 (1) | | 2001/83/EC Art.54, opening words |
| 257 (2) and (4) | | 2001/83/EC Art.55(2), opening words |
| 257 (3) and (5) | | 2001/83/EC Art.55(3), opening words |
| 257 (6) | | 2001/83/EC Art.56 |
| 258 | S.I. 1994/3144, Sch.5 | |

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|---------|--|-------------------------------------|
| 259 | | 2001/83/EC Art.56a |
| 260 (1) | | 2001/83/EC Art.58 |
| 260 (2) | | 2001/83/EC Art.59, opening words |
| 260 (3) | | 2001/83/EC Art.59(3) |
| 260 (4) | ? | ? |
| 260 (5) | ? | ? |
| 261 | | 2001/83/EC Art.62 |
| 262 | | 2001/83/EC Art.66 |
| 263 | | 2001/83/EC Art.67 |
| 264 | | 2001/83/EC Art.69 opening words |
| 265 | | 2001/83/EC Art.16g(2) opening words |
| 266 | ? | ? |
| 267 | | 2001/83/EC Art.61 |
| 268 | S.I. 1994/3144, Sch.3, para. 11, S.I. 2005/2750, Sch.3, para. 18 and S.I.1994/105, Sch. 6, para.10 | |
| 269 | S.I. 1994/3144, Sch.3, para 12, S.I. 2005/2750, Sch.3, para 19 and S.I. 1994/105, Sch.6, para.11 | |
| 270 | | 2001/83/EC Art.64 |
| 271 | S.I. 1994/3144 , Sch.3, para.14, S.I. 2005/2750, Schedule 3, para.22 and S.I. 1994/105, Sch.6, para.12 | |
| 272 | S.I. 2003/2317, reg.1 | |
| 273 | S.I. 2003/2317, reg.2 | |
| 274 | S.I. 2003/2317, reg.3 | |
| 275 | S.I. 2003/2317, reg.4 | |
| 276 | S.I. 2003/2317, reg.5 | |

Part 14 (advertising) VRMM

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|------------------------------|
| 277 | MA 1968 s.92(4); S.I. 1994/1932 reg.2(1); S.I. 1994/1933 reg.2(1) | |
| 278 | S.I. 1994/1932 reg.2(4); S.I. 1994/1933 reg.2(3) | |
| 279 | S.I. 1994/1932 reg.3 | 2001/83/EC Art.87(1) |
| 280 | S.I. 1994/1932 reg.3A | 2001/83/EC Art.87(2) and (3) |
| 281 | S.I. 1994/1932 reg.4 | 2001/83/EC Art.93(1) and 98 |
| 282 | S.I. 1994/1932 reg.5 | |
| 283 | S.I. 1994/1932 reg.6 | |
| 284 | S.I. 1994/1932 reg.7 | 2001/83/EC Art.88(1)(a) |

| | | |
|-----|--|---|
| 285 | S.I. 1994/1932 reg.8 | 2001/83/EC Art.88(1)(b) |
| 286 | S.I. 1994/1932 reg.9(1)(a) and (i) and (2) | 2001/83/EC Art.90(a) and (i) |
| 287 | S.I. 1994/1932 reg.9(1)(b), (c), (d), (j) and (k) | 2001/83/EC Art.90(b), (c), (d), (j) and (k) |
| 288 | S.I. 1994/1932 reg.9(1)(g) and (h) | 2001/83/EC Art.90(g) and (h) |
| 289 | S.I. 1994/1932 reg.9(1)(f) | 2001/83/EC Art.90(f) |
| 290 | S.I. 1994/1932 reg.9(1)(e) | 2001/83/EC Art.90(e) |
| 291 | S.I. 1994/1932 reg.10 | 2001/83/EC Art.89 |
| 292 | S.I. 1994/1932 reg.11 | 2001/83/EC Arts.88(4) and 90(d) |
| 293 | S.I. 1994/1932 reg.12 | 2001/83/EC Art.88(6) |
| 294 | S.I. 1994/1932 regs.14 and 15 | 2001/83/EC Art.91(1) |
| 295 | S.I. 1994/1932 regs.2(1) and 16 | |
| 296 | S.I. 1994/1932 reg.17 | 2001/83/EC Art.91(2) |
| 297 | S.I. 1994/1932 reg.18 | 2001/83/EC Art.92 |
| 298 | S.I. 1994/1932 reg.19 and Sch.4 | 2001/83/EC Art.96 |
| 299 | S.I. 1994/1932 reg.20 | 2001/83/EC Art.93(2) and (3) |
| 300 | S.I. 1994/1932 reg.21 | 2001/83/EC Arts.94 and 95 |
| 301 | S.I. 1994/1932 reg.22 | 2001/83/EC Art.100 |
| 302 | S.I. 1994/1932 reg.22A | 2001/83/EC Art.16g(3) |
| 303 | S.I. 1994/1932 reg.23 | 2001/83/EC Art.99 |
| 304 | S.I. 1994/1933 Sch. paras.1 and 2 | 2001/83/EC Art.97(1) |
| 305 | S.I. 1994/1933 Sch. para.3 | 2001/83/EC Art.97(1) |
| 306 | S.I. 1994/1933 Sch. paras.4 and 5 | 2001/83/EC Art.97(1) |
| 307 | S.I. 1994/1933 Sch. para.6; | 2001/83/EC Art.97(1) |
| 308 | S.I. 1994/1933 Sch. paras.7 and 8 | 2001/83/EC Art.97(1) |
| 309 | S.I. 1994/1933 reg.4(1) and (2) | 2001/83/EC Art.97(1) |
| 310 | S.I. 1994/1933 reg.5 | 2001/83/EC Art.97(5) |
| 311 | S.I. 1994/1933 regs.2(1) and (4), 3(1), 6 and 7(2), (3), (6) and (7) | 2001/83/EC Art.97(1), (2) and (3) |
| 312 | S.I. 1994/1933 reg.7(4) and (5) | 2001/83/EC Art.97(1), (2) and (3) |
| 313 | S.I. 1994/1933 reg.8 | 2001/83/EC Art.97(4) |
| 314 | S.I. 1994/1933 regs.2(1), 9(1) and 11 | 2001/83/EC Art.97(2), (3) and (4) |
| 315 | S.I. 1994/1933 regs.4(3), 7(1) and 9(2) | 2001/83/EC Art.97 (2) |
| 316 | S.I. 1994/1933 reg.3(3) | |

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--------------------------|--|
| 317 | MA 1968, s.99 | |
| 318 | MA 1968, s.100 | |
| 319 | MA 1968, s.101 | |
| 320 (1) | MA 1968, s.102(2) | |
| 320 (2) | MA 1968, s.102 (4) | |
| 320 (3) | MA 1968, s.102(5) | |
| 321 | MA 1968 s.103(1) and (2) | |

Part 16 (enforcement)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|--|
| 322 | MA 1968 s.107 | |
| 323 (1) to (4) | MA 1968 s.108(1) to (3) and s.109 | |
| 323 (5) and (7) | MA 1968 s.108(6) to (7); S.I. 1980/1923 reg.2(3) | |
| 323 (6) and (7) | MA 1968 s.108 (8) S.I. 1980/1923 reg. 2(1) and (2) | |
| 323 (8) | MA 1968 s.108(2) and (6) | |
| 323 (9) | MA 1968 s.108(9) | |
| 323 (10) | MA 1968 s.108(12) | |
| 324 | MA 1968 s.110 | |
| 325 | MA 1968 s.111(1) to (4) | |
| 326 | MA 1968 s.111(5) to (7) | |
| 327 | MA 1968 s.112(1) to (5) | |
| 328 | MA 1968 s.112(6) to (9) | |
| 329 | MA 1968 s.113 | |
| 330 | MA 1968 s.115 | |
| 331 | | |
| 332 | MA 1968 s.118 | |
| 333 | MA 1968 s.119 | |
| 334 | MA 1968 s.114 | |

Part 17 (miscellaneous and general)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|--------------------|
| 335 | MA 1968 s.121 | |
| 336 | MA 1968 s.122 | |
| 337 | MA 1968 s.123 | |
| 338 | MA 1968 s.124 | |
| 339 | MA 1968 s.125 | |
| 340 | MA 1968 s.126 | |
| 341 | S.I. 1994/105 reg.5(1); S.I. 1994/3144 reg.5(1); S.I. 2005/2750 reg.6(1) | 2001/83/EC Art.125 |
| 342 | S.I. 1994/3144 reg.7(5); S.I. 2005/2750 reg.9(7) | |

| | | |
|-----|-----------------------------------|--|
| 343 | MA 1968 s.127 | |
| 344 | MA 1968 s.128(4) | |
| 345 | S.I. 1994/3144 reg.3B | |
| 346 | New provision for review proposal | |
| 347 | Introduces schedule 32 | |
| 348 | Introduces schedule 33 | |
| 349 | Introduces schedule 34 | |

The schedules

Schedule 1 (further provisions for classification of medicinal products)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-------------------------|--|
| 1 | S.I. 1997/1830 art.3 | |
| 2 | S.I. 1997/1830 art.1(2) | |

Schedule 2 (Supplementary provision relating to advisory bodies and expert advisory groups)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-----------------------------------|--|
| 1 | MA 1968 Sch.1A para.7 | |
| 2 | MA 1968 Sch.1A para.8 | |
| 3 | MA 1968 Sch.1A para.9 | |
| 4 | S.I. 2005/2788 reg.2 | |
| 5 | S.I. 2005/2788 reg.4 | |
| 6 | S.I. 2005/2788 reg.6 | |
| 7 | S.I. 2005/2788 reg.5 | |
| 8 | MA 1968 Sch.1A para.10 | |
| 9 | MA 1968 Sch.1A para.11 | |
| 10 | New provision for review proposal | |
| 11 | New provision for review proposal | |
| 12 | MA 1968 Sch.1A para.12 | |

Schedule 3 (application for licence)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|---|--|
| 1(1) | S.I. 1971/974 reg.3(1) SI 2010/1882 regulation 7(3) | |
| 1(2) and (3) | S.I. 1971/974 Sch.1 | |
| 2(1) | S.I. 1971/974 reg.3(1A) | |
| 2(2) and (3) | S.I. 1971/974 Sch.1A | |
| 3(1) | S.I. 1971/974 reg.3(2) | |
| 3(2) and (3) | S.I. 1971/974 Sch.2 | |
| 4 | S.I. 1971/974 reg.4 | |

Schedule 4 (standard provisions)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|---------------|--|
|------------------|---------------|--|

| | | |
|-------|--|--|
| 2-14 | S.I. 2005/2789 Sch.1 S.I. 2010/1882 regulation 3(2) and Schedule 2 | |
| 16-23 | S.I. 2005/2789 Sch.2 | |
| 24-27 | S.I 2010/1882 Sch.2 S.I. 2010/1882 regulation 3(2) and Schedule 2 | |
| 28-31 | S.I. 2005/2789 Sch.4 S.I. 2010/1882 regulation 3(4) and Schedule 4 | |
| 32-42 | SI 2005/2789, reg.11 and para.3 | |
| 43-44 | S.I 2010/1882 reg.3(4) and sch.4 sub-para (d) | |

Schedule 5 (review upon oral representations)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|--|--|
| | S.I. 2005/2789 Sch.1 | |
| 1 | MA 1968 Sch. 2 para.6; S.I. 1994/105 Sch.5 para.3; S.I. 1994/3144 Sch.2 para.4; S.I. 2005/2750 Sch.2 para.5 | |
| 2 | MA 1968 Sch. 2 para. 7; S.I. 1994/105 Sch.5 para.12(1) and (2); S.I. 1994/3144 Sch.2 para.17(1) and (2); S.I. 2005/2750 Sch.2 para.21(1) and (2) | |
| 3 | MA 1968 Sch. 2 para. 8; S.I. 1994/105 Sch.5 para.12(3) to (6); S.I. 1994/3144 Sch.2 para.17(3) to (6); S.I. 2005/2750 Sch.2 para.21(3) to (6) | |
| 4 | MA 1968 Sch. 2 para. 10; S.I. 1994/105 Sch.5 para.12(7) and (8); S.I. 1994/3144 Sch.2 para.17(7) and (8); S.I. 2005/2750 Sch.2 para.21(7) and (8) | |
| 5 | MA 1968 Sch. 2 para. 11; S.I. 1994/105 Sch.5 para.12(9) and (10); S.I. 1994/3144 Sch.2 para.17(9) and (10); S.I. 2005/2750 Sch.2 para.21(9) and (10) | |

Schedule 6 (manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products)

| <i>Paragraph</i> | <i>Origin</i> |
|------------------|---------------|
|------------------|---------------|

| | | |
|------|--|---|
| 1-20 | SI 2010/1882, reg. 3(1) and (3) and sub-paras (b)(iii) and (h) to (r) of Sch.1; and sub-paras (i) to (k) and (n) to (q) of Sch.3 | 2001/83/EC Art.3.7 (as amended by Regulation 1394/2007) |
|------|--|---|

Schedule 7 (qualified persons)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-----------------------|-------------------|
| 1-8 | Reg 4 of SI 2005/2789 | 2001/83/EC Art.49 |
| 9-11 | Reg 4 of SI 2005/2789 | 2001/83/EC Art.50 |
| 12-15 | Reg 4 of SI 2005/2789 | 2001/83/EC Art.51 |

Schedule 8 (material to accompany an application for a UK marketing authorisation)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|---------------|--|
| Part 1 | | 2001/83/EC Art.1(20), 8(3) and 12(1) and (3) |
| Part 2 | | 2001/83/EC Art.11 |

Schedule 9 (undertakings by non-EEA manufacturers)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|----------------|--|
| 1-12 | S.I. 1977/1038 | |

Schedule 10 (national homoeopathic products)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-------------------------------------|----------------------|
| 1 | S.I. 1994 /3144 reg.4(1B) and (1C); | 2001/83/EC Art.16(2) |
| 2 | S.I. 1994/3144 Sch.1A paras.1 and 2 | |
| 3 | S.I. 1994/3144 Sch.1A para.3 | |
| 4 | S.I. 1994/3144 Sch.1A para.4 | |
| 5 | S.I. 1994/3144 Sch.1A para.5 to 7 | |

Schedule 11 (advice and representations)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|--|--|
| 1 | S.I. 1994/105 Sch.5 para.2; S.I. 1994/3144 Sch.2 para.2; S.I. 2005/2750 Sch.2 para.2 | |
| 2 | S.I. 1994/105 Sch.5 para.5; S.I. 1994/3144 reg.1(2) and Sch.2 para.7; S.I. 2005/2750 reg.1(2) and Sch.2 para.8 | |
| 3 | S.I. 1994/3144 Sch.2 para.7 | |

| | | |
|----|--|--|
| 4 | S.I. 1994/105 Sch.5 paras.10 and 11; S.I. 1994/3144 Sch.2 paras.12 and 13; S.I. 2005/2750 Sch.2 paras.13 and 14 | |
| 5 | S.I. 1994/105 Sch.5 para.6(1); S.I. 1994/3144 Sch.2 para.8(1); S.I. 2005/2750 Sch.2 para.9(1) | |
| 6 | S.I. 1994/105 Sch.5 paras.1 and 6(2) and (3); S.I. 1994/3144 Sch.2 paras.1 and 8(2) and (3); S.I. 2005/2750 Sch.2 paras.1 and 9(2) and (3) | |
| 7 | S.I. 1994/105 Sch.5 para.6(4) to (6) and (8); S.I. 1994/3144 Sch.2 para.8(4) to (6) and (8); S.I. 2005/2750 Sch.2 para.9(4) to (6) and (8) | |
| 8 | S.I. 1994/105 Sch.5 para.6(4) to (8); S.I. 1994/3144 Sch.2 para.8(4) to (8); S.I. 2005/2750 Sch.2 para.9(4) to (8) | |
| 9 | Drafting clarification to aid comprehension | |
| 10 | S.I. 1994/105 Sch.5 para.7; S.I. 1994/3144 Sch.2 para.9; S.I. 2005/2750 Sch.2 para.10 | |
| 11 | S.I. 1994/105 Sch.5 para.9(1); S.I. 1994/3144 Sch.2 para.11(1); S.I. 2005/2750 Sch.2 para.12(1) | |
| 12 | S.I. 1994/105 Sch.5 para.8; S.I. 1994/3144 Sch.2 para.10; S.I. 2005/2750 Sch.2 para.11 | |
| 13 | S.I. 1994/105 Sch.5 para.9(2) and (3); S.I. 1994/3144 Sch.2 para.11(2) and (3); S.I. 2005/2750 Sch.2 para.12(2) and (3) | |
| 14 | S.I. 1994/3144 Sch.2 paras.1 and 3; S.I. 2005/2750 Sch.2 para.3 | |
| 15 | S.I. 2005/2750 Sch.2 para.1 | |
| 16 | S.I. 2005/2750 Sch.2 para.1 | |
| 17 | S.I. 1994/3144 Sch.2 para.3; S.I. 2005/2750 Sch.2 para.3 | |
| 18 | S.I. 1994/3144 Sch.2 paras.1 and 14(1), (2) and | |

| | | |
|----|---|--|
| | (3); S.I. 2005/2750 Sch.2 paras.1 and 15(1), (2) and (3) | |
| 19 | S.I. 1994/3144 Sch.2 para.14(4) to (6) and (8); S.I. 2005/2750 Sch.2 para.15(4) to (6) and (8) | |
| 20 | S.I. 1994/3144 Sch.2 para.14(4) to (8); S.I. 2005/2750 Sch.2 para.15(4) to (8) | |
| 21 | Drafting clarification to aid comprehension | |
| 22 | S.I. 1994/3144 Sch.2 para.15; S.I. 2005/2750 Sch.2 para.16 | |
| 23 | S.I. 1994/3144 Sch.2 para.16; S.I. 2005/2750 Sch.2 para.17 | |
| 24 | S.I. 2005/2750 Sch.2 para.4 | |
| 25 | S.I. 2005/2750 Sch.2 paras.1 and 18(1) to (3) | |
| 26 | S.I. 2005/2750 Sch.2 para.18(4) to (6) and (8) | |
| 27 | S.I. 2005/2750 Sch.2 para.18(4) to (8) | |
| 28 | Drafting clarification to aid comprehension | |
| 29 | S.I. 2005/2750 Sch.2 para.19 | |
| 30 | S.I. 2005/2750 Sch.2 para.20 | |
| 31 | S.I. 1994/3144 Sch.2 para.2(a)(i) | |
| 32 | S.I. 1994/105 Sch.5 para.2(a); S.I. 1994/3144 Sch.2 para.2(a)(ii); S.I. 2005/2750 Sch.2 para.2(a) | |
| 33 | S.I. 1994/3144 Sch.2 para.5; S.I. 2005/2750 Sch.2 para.6 | |
| 34 | S.I. 1994/105 Sch.5 para.4; S.I. 1994/3144 Sch.2 para.6(a) | |
| 35 | S.I. 2005/2750 Sch.2 para.7(a) | |
| 36 | S.I. 1994/3144 Sch.2 para.6(b) | |
| 37 | Drafting clarification to aid comprehension | |
| 38 | S.I. 2005/2750 Sch.2 para.7(b) | |
| 39 | S.I. 2005/2750 Sch.2 para.7(c) | |

Schedule 12 Part 2 (application for traditional herbal registration)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|-------------------------|---------------------------------------|
| Part 1 | S.I. 2005/2750 reg.5(1) | 2001/83/EC Art.1(20), 8(3) and 16c(1) |
| Part 2 | S.I. 2005/2750 reg.5(1) | 2001/83/EC Art.8(3), 11 and 16c(1) |

Schedule 13 (medicinal products for which community practitioner nurse prescribers are appropriate practitioners)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|--|
| | S.I. 1997/1830 Sch.3 | |

Schedule 14 (prescription etc by supplementary prescribers)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|-----------------------|--|
| | S.I. 1997/1830 Sch.3B | |

Schedule 15 (requirements for specific products subject to general sale)

| <i>Paragraphs</i> | <i>Origin</i> | |
|-------------------|----------------------|--|
| 1-2 | S.I. 1980/1923 reg.8 | |

Schedule 16 (patient group directions)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|---|--|
| Parts 1 to 4 | S.I. 1980/1924 Sch.3 and S.I. 1997/1830 Sch.7 | |

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

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|--|
| Parts 1-5 | S.I. 1997/1830 Sch.5 | |

Schedule 18 (substances that may not be sold or supplied by a pharmacist without a prescription in reliance on regulation 223)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|--|
| | S.I. 1997/1830 Sch.4 | |

Schedule 19 (medicinal products for parenteral administration in an emergency)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|--|
| | S.I. 1997/1830 Art.7 | |

Schedule 20 (herbal medicinal products specified for the purposes of regulation 194)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|---------------------|--|
| Parts 1 and 2 | S.I. 1977/2130 Sch. | |

Schedule 21 (medicinal products at high dilutions)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|--|
| Parts 1-4 | S.I. 1980/1924 Sch.2 | |

Schedule 22 (classes of person for the purposes of regulation 202)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|--|
| | S.I. 1980/1923 Sch.1 | |

Schedule 23 (particulars in pharmacy records)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|----------------------|--|
| 1-6 | S.I. 1980/1923 Sch.2 | |

Schedule 24 (packaging information)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|---------------|----------------------|
| Part 1 | | 2001/83/EC Art.54 |
| Part 2 | | 2001/83/EC Art.55(2) |
| Part 3 | | 2001/83/EC Art.55(3) |

Schedule 25 (specific requirements for particular types of medicine)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-----------------------|--|
| 1-18 | S.I. 1994/3144 Sch. 5 | |

Schedule 26 (packaging requirements: special provisions for pharmacies etc.)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-----------------------|--|
| Parts 1-2 | S.I. 1994/3144 Sch. 5 | |

Schedule 27 (package leaflets)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|---------------|--|
| 1-15 | | Directive 2001/83/EC Art.59(1) and (2) |

Schedule 28 (Labelling requirements for registrable homoeopathic medicinal products)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|------------------------------------|-----------------------------|
| 1-12 | | Directive 2001/83 Art.69(1) |
| 13-24 | For conformity with sch.24 [j600s] | |

Schedule 29 (labelling of traditional herbal medicinal products)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-----------------------|---------------------------------|
| 1-2 | | Directive 2001/83/EC Art.16g(2) |
| 3-4 | S.I. 2005/2750 Sch. 5 | |

Schedule 30 (particulars for advertisements to qualified persons)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|---------------|--|
| | | |

| | | |
|-----|----------------------|----------------------|
| 1-9 | S.I. 1994/1932 Sch.2 | 2001/83/EC Art.91(1) |
|-----|----------------------|----------------------|

Schedule 31 (sampling)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|----------------------------|--|
| 1 -26 | MA 1968 Sch 3 para.1 to 26 | |
| 27 | MA 1968 Sch.3 para 28 | |

Note: Schedules 32 to 34 are not included here, because they generally have a technical function. This is with the exception of the following:

Schedule 33 (Amendments to existing law)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|---------------------|--|
| 3 | S.I. 2005/765 reg.2 | |