

Annex F – Table of origins

This document shows how the draft consolidated regulations relate to existing medicines legislation.

Note: 'MA 1968' = Medicines Act 1968

Part 1 (general)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|------------------------------|
| 2 [j002A] | S.I. 1994/3144 reg.1(2), (5) | 2001/83/EC Art.1(2) and 2(1) |
| 3 [j002B] | MA 1968 s.9, 11 and 12(1) | Art.(1) |
| 4 [j002C] | MA 1968 s.10 | |
| 5(1) [j500A] | MA 1968 s.51 and SI 1984/769 Art.2 | |
| 5(2) [j500A] | MA 1968 s. 58(1) and SI 1997/1830 Art.3 | |
| 5(3) [j500A] | MA 1968 s. 58(1) and SI 1997/1830 Art.3 | |
| 5(4) [j500A] | Drafting clarification to aid comprehension | |
| 5(5) [j500A] | Drafting clarification to aid comprehension | |
| 6 [j013] | MA 1968 s.6 | |
| 7 [j014] | | 2001/83/EC Art.86 |
| 8 [j002] | MA 1968 s.132 | 2001/83/EC Art.1 |

Part 2 (administration)

| <i>Regulation</i> | <i>Origin</i> | |
|--------------------|-----------------------------------|--|
| 9 [j003] | MA 1968 s.2A | |
| 10 [j004] | MA 1968 s.3 | |
| 11 [j013A] | MA 1968 s.4(4) and S.I. 1970/1256 | |
| 12 [j007] (1) | MA 1968 Sch.1A para. 1 | |
| 12 [j007] (2) –(4) | MA 1968 s.5(2) and (3) | |
| 13 [j008] | MA 1968 Sch.1A para. 2 | |
| 14 [j009] | MA 1968 Sch.1A para. 3 | |
| 15 [j011] | MA 1968 Sch.1A para. 5 | |
| 16 [j012] | MA 1968 s.5(1) | |

Part 3 (manufacturing and wholesale dealing)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|-----------------------------|--|
| 17 [j200] | MA 1968 s.8(2) to (2D) | |
| 18 [j201] | MA 1968 s.8(3) to (8) | |
| 19 [j226] | S.I. 1990/566, Art.2 | |
| 20 [j203](1) | S.I. 2009/3062, Art.2 | |
| 20 [j203](2) | S.I. 2009/3062, Art.1 | |
| 21 [j203A] | New regulation for drafting | |

| | | |
|------------|--|------------------------|
| | reasons, corresponding to reg. 162 [j127] | |
| 22 [j205] | MA 1968 s.18 | |
| 23 [j206] | MA 1968 s.19 (5) and (6) | |
| 24 [j207] | MA 1968 s.20 | |
| 25 [j213] | MA 1968 s.47 | |
| 26 [j209] | MA 1968 s.24 | |
| 27 [j210] | MA 1968 s.28(1), (2), (4), (5), (6) and (7). | |
| 28 [j211] | MA 1968 s.29 | |
| 29 [j211A] | MA 1968, Sch.2, paras 8-11 | |
| 30 [j212] | MA 1968 s.30 | |
| 31 [j228] | MA 1968 s.44(1) to (4) | |
| 32 [j228X] | MA 1968 s.50 | 2001/83/EC Art.77.4 |
| 33 [j232] | S.I. 2005/2789 reg.5 | |
| 34 [j232X] | S.I. 1994/3144 Sch.3 para 13C | |
| 35 [j229] | MA 1968 s.45(6) to (8) | |
| 36 [229A] | MA 1968 s.45(6) to (8) | |
| 37 [j218] | S.I. 1977/1038 reg.3 and SI 2005/2789 reg.12 | |
| 38 [j219] | S.I. 2005/2789 reg.2(1) and (2) | |
| 39 [j220] | S.I. 2005/2789 reg.3(a) to (c) | |
| 40 [j227] | S.I. 2005/2789 remainder of reg.2 | |
| 41 [j231] | | 2001/83/EC Art.8(3)(h) |
| 42 [j221] | S.I. 2005/2789 reg.4 | |
| 43 [j222] | S.I. 2005/2789 reg.8(1) and 12 | |
| 44 [j223] | S.I. 2005/2789 reg.8 | |
| 45 [j224] | S.I. 2005/2789 reg.9 | |
| 46 [j225] | S.I. 2005/2789 reg.10 | |

Part 4 (requirement for authorisation)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|---------------------|
| 47 [j005A] | 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) |
| 48 [j006A] | 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> | |
|-------------------|---|--|
| 49 [j101] | S.I. 1994/3144 reg.1(2) | |
| 50 [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) |
| 51 [j102A] | 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) |
| 52 [j105] | S.I. 1994/3144 reg.4(7) | 2001/83/EC Art.10(1) and (3) |
| 53 [j192] | | 2001/83/EC Art.10(1) and 11 |
| 54 [j105A] | | 2001/83/EC Art.10(2) |
| 55 [j105B] | | 2001/83/EC Art.10a |
| 56 [j191] | | 2001/83/EC Art.10(4) |
| 57 [j105B] | | |
| 58 [j105C] | | 2001/83/EC Art.10b and 12(2) |
| 59 [j116AA] | | 2001/83/EC Art.8(3) |
| 60 [j106] | S.I. 1994/3144 reg.5(1) | 2001/83/EC Art.17(1), 19(3) and 26 |
| 61 [j106A] | S.I. 1994/3144 reg.5(1) | 2001/83/EC Art.22 |
| 62 [j110] | S.I. 1994/3144 reg.5A; MA 1968 s.58A(2), (3) and (4) | 2001/83/EC Art.70(1), 71 and 72 |
| 63 [j190] | | 2001/83/EC Art.21 |
| 64 [j107] | S.I. 1994/3144 reg.5(6) and (7) | 2001/83/EC Art.24(1), (2) and (3) |
| 65 [j107A] | S.I. 1994/3144 regs.4(1), (2), (3), (8) and (9) and 5(1) and (2) | 2001/83/EC Art.24(2) |
| 66 [j109] | S.I. 1994/3144 reg.5(8); | 2001/83/EC Art.24(4) to (6) |
| 67 [j111] | S.I. 1994/3144 reg.6(1) and 6(7) | 2001/83/EC Art.107, 116 and 118(1) |
| 68[j112] | S.I. 1994/3144 reg.6(2), (3) and (4) | 2001/83/EC Art.117 |
| 69 [j193] | | 2001/83/EC Art.36 |
| 70 [j113] | 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) |
| 71[j116A] | S.I. 1994/3144 reg.7(1) | 2001/83/EC Art.23 |
| 72 [j116B] | S.I. 1994/3144 reg.7(1) | 2001/83/EC Art.23a |
| 73 [j116C] | S.I. 1994/3144 reg.7(1) | 2001/83/EC Art.23 |
| 74 [j117] | S.I. 1994/3144 reg.7(2) and (3) | |
| 75 [j172] | S.I. 1994/3144 Sch.3 para.6C | 2001/83/EC Art.81 |
| 76 [j169] | S.I. 1994/3144 Sch.3 para.6(a) | |
| 77 [j164] | S.I. 1994/3144 Sch.3 para.4 | |
| 78 [j166] | S.I. 1994/3144 Sch.3 | |

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|------------|---|--|
| | para.3A | |
| 79 [j170] | S.I. 1994/3144 Sch.3 para.6(b), (c) and (e) | |
| 80 [j170A] | S.I. 1994/3144 Sch.3 para.6(d) and (dd) | |
| 81 [j171] | S.I. 1994/3144 Sch.3 paras.6(cc), (d), (dd) and (f), 6A, 6AA and 6D | |
| 82 [j171X] | S.I. 1994/3144 Sch.3 para. 10B | |
| 83 [172X] | S.I. 1994/3144 Sch.3 para. 13C | |
| 84 [j181] | S.I. 1994/3144 Sch.3 para.6BA and 6BB | |
| 85 [j182] | S.I. 1994/3144 Sch.3 para.6G | |
| 86 [j183] | S.I. 1994/3144 Sch.3 para.13B(1) | |
| 87 [j185] | S.I. 1994/3144 Sch.3 para.13B(4) | |
| 88 [j186] | S.I. 1994/3144 Sch. 3 para.13B(7) | |
| 89 [j160] | S.I. 1994/3144 Sch.3 para.10A(1) | |
| 90 [j161] | S.I. 1994/3144 Sch.3 para.10A(2) | |
| 91 [j177] | S.I. 1994/3144 Sch.3 para.14 | |
| 92 [j177A] | S.I. 1994/3144 Sch.3 para.14 | |
| 93 [j178] | S.I. 1994/3144 Sch.3 para.15 | |
| 94 [j179] | S.I. 1994/3144 Sch.3 para.16 and 17 | |

Part 6 (certification of homoeopathic medicinal products)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|---|
| 95 [j300] | S.I. 1994/105 reg.2 | 2001/83/EC Art.13(1) and 14(1) |
| 96 [j302] | S.I. 1994/105 reg.4 | 2001/83/EC Art.15 |
| 97 [j303] | S.I. 1994/105 reg.5 | 2001/83/EC Art.1(28) and (28a), 17(1) and 26(1) and (2) |
| 98 [j310] | S.I. 1994/105 reg.5(1) | 2001/83/EC Art.22 |
| 99 [j305] | SI 1994/105 reg.6 | |
| 100 [j306] | S.I. 1994/105 reg.8(1) and (2); | 2001/83/EC Art.24(1), (2) and (3) |
| 101 [j307] | S.I. 1994/105 reg.8(2) and (5), reg.7A(1) | 2001/83/EC Art.24(2) |
| 102 [j308] | S.I. 1994/105 reg.8(2A) | 2001/83/EC Art.24(4) to (6) |

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|-------------|--|--------------------|
| 103[j309] | S.I. 1994/105 reg.9 | 2001/83/EC Art.116 |
| 104 [j328] | | 2001/83/EC Art.36 |
| 105 [j311] | S.I. 1994/105 reg.10 | 2001/83/EC Art.117 |
| 106 [j314] | S.I. 1994/105 reg.7A(1) | 2001/83/EC Art.23 |
| 107 [j316] | S.I. 1994/105 reg.7A(1) | 2001/83/EC Art.23a |
| 108 [j315] | S.I. 1994/105 reg.7A(1) | 2001/83/EC Art.23 |
| 109 [j312] | S.I. 1994/105 reg.7A(2) | |
| 110 [j322] | S.I. 1994/105 Sch.6 para.8 | |
| 111 [j319] | S.I. 1994/105 Sch.6 para.9(1) | |
| 112 [j320] | S.I. 1994/105 Sch.6 para.9(2) | |
| 113 [j326] | S.I. 1994/105 Sch.6 para.12 | |
| 114 [j326B] | S.I. 1994/105 Sch.6 para.12 | |
| 115 [j326A] | New regulation for consistency with reg.93 [j178] and reg.145 [j439] | |
| 116 [j327] | S.I. 1994/105 Sch.6 paras.13 and 14 | |

Part 7 (traditional herbal registrations)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--------------------------------------|--|
| 117 [j400] | S.I. 2005/2750 reg.2(2) | 2001/83/EC Art.16a(1) and (3) and 16c(3) |
| 118 [j400B] | S.I. 2005/2750 reg.2(2) | 2001/83/EC Art.16a(2) and 16d(1) |
| 119 [j402] | S.I. 2005/2750 reg.5(1) to (5); 9(1) | 2001/83/EC Art.16b |
| 120 [j405] | S.I. 2005/2750 reg.5(1) | 2001/83/EC Art.16c(1), 16f(2) and 19(3) |
| 121 [j416A] | | 2001/83/EC Art.8(3) |
| 122 [j406] | S.I. 2005/2750 reg.6(1) | 2001/83/EC Art.16e(1), 16d(2), 16f(2), 16h(3), 17(1) and 19(3) |
| 123 [j406A] | SI 2005/2750 reg.6(7) | |
| 124 [j408] | S.I. 2005/2750 reg.6(4) and (5) | 2001/83/EC Art.24(1), (2) and (3) |
| 125 [j409] | S.I. 2005/2750 reg.5 and 6(1) | 2001/83/EC Art.24(3) |
| 126 [j410] | S.I. 2005/2750 reg.6(6) | 2001/83/EC Art.24(4) to (6) |
| 127 [j412] | S.I. 2005/2750 reg.7(1) | 2001/83/EC Art.107, 116 and 118(1) |
| 128 [j412A] | S.I. 2005/2750 reg.7(1) | 2001/83/EC Art.16f(3) |
| 129 [j412B] | S.I. 2005/2750 reg.7(7) | |
| 130 [j413] | S.I. 2005/2750 reg.7(2) to (4) | 2001/83/EC Art.117 |
| 131 [j460] | | 2001/83/EC Art.36 |
| 132 [j414] | S.I. 2005/2750 reg.7(5) and (6) | |
| 133 [j417] | S.I. 2005/2750 reg.9(1) | 2001/83/EC Art.23 |

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| 134 [j450] | S.I. 2005/2750 reg.9(1) | 2001/83/EC Art.16h(3) |
| 135 [j419] | S.I. 2005/2750 reg.9(4) | 2001/83/EC Art.23a |
| 136 [j418] | S.I. 2005/2750 reg.9(1) | 2001/83/EC Art.23 |
| 137 [j419B] | S.I. 2005/2750 reg.9(3) | |
| 138 [j433] | S.I. 2005/2750 Sch.3 para.10 | |
| 139 [j426] | S.I. 2005/2750 Sch.3 para.5 | |
| 140 [j428] | S.I. 2005/2750 Sch.3 para.4 | |
| 141 [j423] | S.I. 2005/2750 Sch.3 para.17(1) | |
| 142 [j424] | S.I. 2005/2750 Sch.3 para.17(2) | |
| 143 [j438] | S.I. 2005/2750 Sch.3 para.7(c), 8 and 22 | |
| 144 [j438A] | S.I. 2005/2750 Sch.3 para.7(c), 8 and 22 | |
| 145 [j439] | S.I. 2005/2750 Sch.3 para.23 | |
| 146 [j440] | S.I. 2005/2750 Sch.3 para.24 and 25 | |

Part 8 (Article 126a authorisations)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|---------------------|
| 147 [j187] | S.I. 1994/3144 reg.5(5) | 2001/83/EC Art.126a |
| 148 [j188] | 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> | |
|-------------------|--|--|
| 149 [j150] | S.I. 1994/3144 reg.3A(1) | |
| 150 [j151] | S.I. 1994/3144 reg.3A(1) and (3) | |
| 151 [j152] | S.I. 1994/3144 reg.3A(5) | |
| 152 [j153] | S.I. 1994/3144 reg.3A(2), (3) and (5) | |
| 153 [j154] | S.I. 1994/3144 reg.3A(4) | |
| 154 [j155] | S.I. 1994/3144 reg.3A(6) | |
| 155 [j156] | S.I. 1994/3144 reg.3A(7) | |
| 156 [j168] | 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> | |
|-------------------|---|------------------|
| 157 [j122] | S.I. 1994/105 reg.2; S.I.1994/3144 Sch.1 paras.1 and 2; S.I. 2005/2750 Sch.1 paras.2 | 2001/83/EC Art.3 |

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| | and 3 | |
| 158 [j125] | 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 |
| 159 [j126] | 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 |
| 160 [j126X] | S.I 2010/1882 reg 2 | |
| 161 [j120AA] | Drafting clarification to aid comprehension | |
| 162 [j127] | S.I.1994/3144 Sch.1 para.5 | 2001/83/EC Art.3 |
| 163 [j121A] | | 2001/83/EC Art.5(2) |
| 164 [j429] | S.I. 2005/2750 Sch.3 paras.20 and 21 | |
| 165 [j429A] | 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)

The draft consolidated regulations do not, for now, contain Part 11. The MHRA is consulting on this part separately, as this area is subject to major change by Directive 2010/84/EU, which requires implementation by July 2012. When the regulations are laid before Parliament, they will include Part 11.

Part 12 (dealings with medicinal products)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|---|--|
| 166(1) [j500] | 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) | |
| 166(2) [j500] | SI 1980/1924 Art.1(2)(c) and SI 1997/1830 Art.1(7) | |
| 167 [j517] | MA 1968 s.58(2); S.I. 1997/1830 Arts.2 and 9 and SI 2008/1692 Art.2 | |
| 168 [j518] | S.I. 1997/1830 Art.3B | |
| 169 [j519] | S.I. 1997/1830 Art.3B and Art.3C | |
| 170 [j538] | S.I. 1997/1830 Art.15(1), (2) and (6) | |
| 171 [j541] | S.I. 2008/1692 Art.3 and 5 | |
| 172 [j539] | S.I. 1997/1830 Art.15(3), (4) and (7) and S.I. 2008/1692 Art.4 | |
| 173 [j501] | MA 1968 s.52(1) | |

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|-----------------------|---|--|
| 174 [j502] | MA1968 s.53 and S.I. 1980/1923 reg.4 and 8 | |
| 175 [j503] | MA 1968 s.52(3) and 54(1) and S.I. 1984/769 Art.3 | |
| 176 [j542] [and j504] | MA 1968 s.58(3) | |
| 177 [j526] | S.I. 1997/1830 Art.8(1), (2) and (5) and S.I. 2008/1692 Art.7 | |
| 178 [j527] | S.I. 1997/1830 Art.8(3), (4) and (5) and S.I. 2008/1692 Art.7 | |
| 179 [j527A] | S.I. 1997/1830 Art.8(6) and S.I. 2008/1692 Art.7 | |
| 180 [j530] | S.I. 1997/1830 Art.12 | |
| 181 [j536] | S.I. 1997/1830 Art.13A | |
| 182 [j531] [and j507] | S.I. 1997/1830 Art.12A | |
| 183 [j532] [and j508] | S.I. 1997/1830 Art.12B | |
| 184 [j509] [and j534] | S.I. 1997/1830 Art.12D | |
| 185 [j534A] | New provision for review proposal | |
| 186 [j533] | S.I. 1997/1830 Art.12C | |
| 187 [j510] [and j535] | S.I. 1997/1830 Art.12E | |
| 188 [j511] [and j529] | S.I. 1997/1830 Art.11 | |
| 189 [j521] | S.I. 1997/1830 Art.5A | |
| 190 [j522] | S.I. 1997/1830 Art.5B | |
| 191 [j523] | S.I. 1997/1830 Art.7 | |
| 192 [j524] | S.I. 1997/1830 Art.7A | |
| 193 [j525] | S.I. 1997/1830 Art.7B | |
| 194 [j505] | MA 1968 s.56 and S.I. 1977/2130 | |
| 195 [j512] | S.I. 1980/1924 art.6 | |
| 196 [j513] | S.I. 1980/1924 Art.6A | |
| 197 [j534] [and j506] | S.I. 1980/1924 Art.3 | |
| 198 [j537] | S.I. 1997/1830 Art.14 | |
| 199 [j540] | S.I. 1997/1830 Art 15(5) and S.I. 2008/1692 Art.6 | |
| 200 [j515] [and j535] | S.I. 1980/1924 Art.8 | |
| 201 [j516] | S.I. 1978/1421 | |
| 202 [j543] | S.I. 1980/1923 Art.5(1) | |
| 203 [j543] [j544] | S.I. 1980/1923 Art.5(2) | |
| 204 [j550] | MA 1968 s.65 | |
| 205 [j551] | MA 1968 s.65 | |
| 206 [j546A] | S.I. 1980/1923 Art.6 | |
| 207 [j560X] | S.I. 2010/1882, reg 4 | |
| 208 (1) [j547] | MA 1968 s.67(2) | |
| 208 (2) [j547] | MA 1968 s.67(1B) | |
| 208 (3) [j547] | MA 1968 s.67(1A) | |
| 208 (4) [j547] | MA 1968 s.67(3A) | |
| 208 (5) [j547] | MA 1968 s.67(4) | |
| 208 (6) [j547] | MA 1968 s.67(5) | |
| 208 (7) [j547] | MA 1968 s.67(5) | |
| 208 (8) [j547] | MA 1968 s.67(6) and S.I. 1980/1923 Art.9 | |

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|----------------|--|--|
| 208 (9) [j547] | MA 1968 s.67(6) and S.I. 1980/1923 Art.9 | |
| 209 [j548] | MA 1968 s.68 | |

Part 13 (packaging and leaflets)

| <i>Regulation</i> | <i>Origin</i> | |
|-----------------------|--|-------------------------------------|
| 210 [j600](1) | | 2001/83/EC Art.54, opening words |
| 210 [j600](2) and (4) | | 2001/83/EC Art.55(2), opening words |
| 210 [j600](3) and (5) | | 2001/83/EC Art.55(3), opening words |
| 210 [j600](6) | | 2001/83/EC Art.56 |
| 211 [j610] | S.I. 1994/3144, Sch.5 | |
| 212 [j601] | | 2001/83/EC Art.56a |
| 213 [j602](1) | | 2001/83/EC Art.58 |
| 213 [j602] (2) | | 2001/83/EC Art.59, opening words |
| 213 [j602](3) | | 2001/83/EC Art.59(3) |
| 214 [j604] | | 2001/83/EC Art.62 |
| 215 [j607] | | 2001/83/EC Art.66 |
| 216 [j608] | | 2001/83/EC Art.67 |
| 217 [j609] | | 2001/83/EC Art.69 opening words |
| 218 [j615] | | 2001/83/EC Art.16g(2) opening words |
| 219 [j603] | | 2001/83/EC Art.61 |
| 220 [j612] | 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 | |
| 221 [j613] | 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 | |
| 222 [j606] | | 2001/83/EC Art.64 |
| 223 [j614] | 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 | |
| 224 [j616] | S.I. 2003/2317, reg.1 | |
| 225 [j617] | S.I. 2003/2317, reg.2 | |
| 226 [j617] [and j618] | S.I. 2003/2317, reg.3 | |
| 227 [j619] | S.I. 2003/2317, reg.4 | |
| 228 [j620] | S.I. 2003/2317, reg.5 | |

Part 14 (advertising)

| <i>Regulation</i> | <i>Origin</i> |
|-------------------|---------------|
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| | | |
|-----------------------|---|---|
| 229 [j900] | MA 1968 s.92(4); S.I. 1994/1932 reg.2(1); S.I. 1994/1933 reg.2(1) | |
| 230 [j900A] | S.I. 1994/1932 reg.2(4); S.I. 1994/1933 reg.2(3) | |
| 231 [j901] | S.I. 1994/1932 reg.3 | 2001/83/EC Art.87(1) |
| 232 [j902] | S.I. 1994/1932 reg.3A | 2001/83/EC Art.87(2) and (3) |
| 233 [j903] | S.I. 1994/1932 reg.4 | 2001/83/EC Art.93(1) and 98 |
| 234 [j905] [and j904] | S.I. 1994/1932 reg.5 | |
| 235 [j905] | S.I. 1994/1932 reg.6 | |
| 236 [j906] | S.I. 1994/1932 reg.7 | 2001/83/EC Art.88(1)(a) |
| 237 [j907] | S.I. 1994/1932 reg.8 | 2001/83/EC Art.88(1)(b) |
| 238 [j908] | S.I. 1994/1932 reg.9(1)(a) and (i) and (2) | 2001/83/EC Art.90(a) and (i) |
| 239 [j909] | S.I. 1994/1932 reg.9(1)(b), (c), (d), (j) and (k) | 2001/83/EC Art.90(b), (c), (d), (j) and (k) |
| 240 [j910] | S.I. 1994/1932 reg.9(1)(g) and (h) | 2001/83/EC Art.90(g) and (h) |
| 241 [j911] | S.I. 1994/1932 reg.9(1)(f) | 2001/83/EC Art.90(f) |
| 242 [j912] | S.I. 1994/1932 reg.9(1)(e) | 2001/83/EC Art.90(e) |
| 243 [j913] | S.I. 1994/1932 reg.10 | 2001/83/EC Art.89 |
| 244 [j914] | S.I. 1994/1932 reg.11 | 2001/83/EC Arts.88(4) and 90(d) |
| 245 [j915] | S.I. 1994/1932 reg.12 | 2001/83/EC Art.88(6) |
| 246 [j917] | S.I. 1994/1932 regs.14 and 15 | 2001/83/EC Art.91(1) |
| 247 [j919] | S.I. 1994/1932 regs.2(1) and 16 | |
| 248 [j920] | S.I. 1994/1932 reg.17 | 2001/83/EC Art.91(2) |
| 249 [j921] | S.I. 1994/1932 reg.18 | 2001/83/EC Art.92 |
| 250 [j922] | S.I. 1994/1932 reg.19 and Sch.4 | 2001/83/EC Art.96 |
| 251 [j923] | S.I. 1994/1932 reg.20 | 2001/83/EC Art.93(2) and (3) |
| 252 [j924] | S.I. 1994/1932 reg.21 | 2001/83/EC Arts.94 and 95 |
| 253 [j925] | S.I. 1994/1932 reg.22 | 2001/83/EC Art.100 |
| 254 [j926] | S.I. 1994/1932 reg.22A | 2001/83/EC Art.16g(3) |
| 255 [j927] | S.I. 1994/1932 reg.23 | 2001/83/EC Art.99 |
| 256 [j931] | S.I. 1994/1933 Sch. paras.1 and 2 | 2001/83/EC Art.97(1) |
| 257 [j932] | S.I. 1994/1933 Sch. para.3 | 2001/83/EC Art.97(1) |
| 258 [j933] | S.I. 1994/1933 Sch. paras.4 and 5 | 2001/83/EC Art.97(1) |
| 259 [j934] | S.I. 1994/1933 Sch. para.6; | 2001/83/EC Art.97(1) |
| 260 [j935] | S.I. 1994/1933 Sch. paras.7 and 8 | 2001/83/EC Art.97(1) |
| 261 [j936] | S.I. 1994/1933 reg.4(1) and (2) | 2001/83/EC Art.97(1) |
| 262 [j937] | S.I. 1994/1933 reg.5 | 2001/83/EC Art.97(5) |
| 263 [j938] | S.I. 1994/1933 regs.2(1) and (4), 3(1), 6 and 7(2), | 2001/83/EC Art.97(1), (2) and (3) |

| | | |
|------------|---|-----------------------------------|
| | (3), (6) and (7) | |
| 264 [j939] | S.I. 1994/1933 reg.7(4) and (5) | 2001/83/EC Art.97(1), (2) and (3) |
| 265 [j940] | S.I. 1994/1933 reg.8 | 2001/83/EC Art.97(4) |
| 266 [j941] | S.I. 1994/1933 regs.2(1), 9(1) and 11 | 2001/83/EC Art.97(2), (3) and (4) |
| 267 [j942] | S.I. 1994/1933 regs.4(3), 7(1) and 9(2) | 2001/83/EC Art.97 (2) |
| 268 [j943] | S.I. 1994/1933 reg.3(3) | |

Part 15 (British Pharmacopoeia)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--------------------------|--|
| 269 [j800] | MA 1968, s.99 | |
| 270 [j801] | MA 1968, s.100 | |
| 271 [j802] | MA 1968, s.101 | |
| 272 [j803](1) | MA 1968, s.102(2) | |
| 272 [j803](2) | MA 1968, s.102 (4) | |
| 272 [j803](3) | MA 1968, s.102(5) | |
| 273 [j804] | MA 1968 s.103(1) and (2) | |

Part 16 (enforcement)

| <i>Regulation</i> | <i>Origin</i> | |
|-----------------------|---|--|
| 274 [j700] | MA 1968 s.107 | |
| 275 [j701](1) to (4) | MA 1968 s.108(1) to (3) | |
| 275 [j701](5) and (7) | MA 1968 s.108(6); S.I. 1980/1923 reg.2(3) | |
| 275 [j701](6) and (7) | S.I. 1980/1923 reg. 2(1) and (2) | |
| 275 [j701](8) | MA 1968 s.108(2) and (6) | |
| 275 [j701] (9) | MA 1968 s.108(9) | |
| 275 [j701](10) | MA 1968 s.108(12) | |
| 276 [j722] | Same provisions as reg.275 [j701] but applicable to Wales | |
| 277 [j711] | MA 1968 s.109 | |
| 278 [j703] | MA 1968 s.110 | |
| 279 [j704] | MA 1968 s.111(1) to (4) | |
| 280 [j705] | MA 1968 s.111(5) to (7) | |
| 281 [j706] | MA 1968 s.112(1) to (5) | |
| 282 [j707] | MA 1968 s.112(6) to (9) | |
| 283 [j708] | MA 1968 s.113 | |
| 284 [j710] | MA 1968 s.115 | |
| 285 [j713] | MA 1968 s.118 | |
| 286 [j714] | MA 1968 s.119 | |
| 287 [j709] | MA 1968 s.114 | |

Part 17 (miscellaneous and general)

| <i>Regulation</i> | <i>Origin</i> | |
|-------------------|--|--------------------|
| 288 [j715] | MA 1968 s.121 | |
| 289 [j716] | MA 1968 s.122 | |
| 290 [j717] | MA 1968 s.123 | |
| 291 [j718] | MA 1968 s.124 | |
| 292 [j719] | MA 1968 s.125 | |
| 293 [j720] | MA 1968 s.126 | |
| 294 [j900B] | 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 |
| 295 [j118] | S.I. 1994/3144 reg.7(5); S.I. 2005/2750 reg.9(7) | |
| 296 [j721] | MA 1968 s.127 | |
| 297 [j723] | MA 1968 s.128(4) | |
| 298 [j121] | S.I. 1994/3144 reg.3B | |
| 299 [j990X] | New provision for review proposal | |
| 300 [j992] | Introduces schedule 32 [j992s] | |
| 301 [j990] | Introduces schedule 33 [j990s] | |
| 302 [j991] | Introduces schedule 34 [j991s] | |

The schedules

Schedule 1 [j500As] (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 [j001s] (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 [j003s] (application for licence)

| <i>Paragraph</i> | <i>Origin</i> |
|------------------|-------------------------|
| 1(1) | S.I. 1971/974 reg.3(1) |
| 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 [j004s] (standard provisions)

| <i>Paragraph</i> | <i>Origin</i> |
|------------------|--|
| 2-14 | S.I. 2005/2789 Sch.1 |
| 16-23 | S.I. 2005/2789 Sch.2 |
| 24-27 | S.I. 2010/1882 Sch.2 |
| 28-31 | S.I. 2005/2789 Sch.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 [j211s] (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 [j218s] (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 [j005s] (qualified persons)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|---------------|-------------------|
| 1-8 | | 2001/83/EC Art.49 |
| 9-11 | | 2001/83/EC Art.50 |
| 12-15 | | 2001/83/EC Art.51 |

Schedule 8 [j102As] (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 [j102Bs] (undertakings by non-EEA manufacturers)

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

Schedule 10 [j102s] (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 [j106As] (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 [j405s] 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 [j517s] (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 [j518s] (prescription etc by supplementary prescribers)

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

Schedule 15 [j502s] (requirements for specific products subject to general sale)

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

Schedule 16 [j507s] (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 [j511s] [j529s] (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 [j527s] (substances that may not be sold or supplied by a pharmacist without a prescription in reliance on regulation 223 [j527])

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

Schedule 19 [j523s] (medicinal products for parenteral administration in an emergency)

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

Schedule 20 [j505s] (herbal medicinal products specified for the purposes of regulation 194 [j505])

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

Schedule 21 [j512s] (medicinal products at high dilutions)

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

Schedule 22 [j543s] (classes of person for the purposes of regulation 202 [j543])

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

Schedule 23 [j546As] (particulars in pharmacy records)

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

Schedule 24 [j600s] (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 [j610s] (specific requirements for particular types of medicine)

| | | |
|------------------|-----------------------|--|
| <i>Paragraph</i> | <i>Origin</i> | |
| 1-13 | S.I. 1994/3144 Sch. 5 | |

Schedule 26 [j002Cs] (packaging requirements: special provisions for pharmacies etc.)

| | | |
|------------------|-----------------------|--|
| <i>Paragraph</i> | <i>Origin</i> | |
| 1-6 | S.I. 1994/3144 Sch. 5 | |

Schedule 27 [j602s] (package leaflets)

| | | |
|------------------|---------------|--|
| <i>Paragraph</i> | <i>Origin</i> | |
| 1-14 | | Directive 2001/83/EC Art.59(1) and (2) |

Schedule 28 [j609s] (Labelling requirements for registrable homoeopathic medicinal products)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|------------------------------------|-----------------------------|
| 1-12 | | Directive 2001/83 Art.69(1) |
| 13-26 | For conformity with sch.24 [j600s] | |

Schedule 29 [j611s] (labelling of traditional herbal medicinal products)

| <i>Paragraph</i> | <i>Origin</i> | |
|------------------|-----------------------|---------------------------------|
| 1-2 | | Directive 2001/83/EC Art.16g(2) |
| 3-10 | S.I. 2005/2750 Sch. 5 | |

Schedule 30 [j917s] (particulars for advertisements to qualified persons)

| <i>Schedule</i> | <i>Origin</i> | |
|-----------------|----------------------|----------------------|
| | S.I. 1994/1932 Sch.2 | 2001/83/EC Art.91(1) |

Schedule 31 [j707s] (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 [j990s] (Amendments to existing law)

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