DRAFT STATUTORY INSTRUMENTS

2020 No. 0000

EXITING THE EUROPEAN UNION MEDICINES

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020

Made - - - - ***

Coming into force in accordance with regulation 1

THE HUMAN MEDICINES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

1. Citation and commencement
2. Amendment of the Good Laboratory Practice Regulations 1999
3. Amendment of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019
4. Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019
5. Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Signature

SCHEDULES

SCHEDULE 1 — Amendment of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

1. Amendment of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019
2. In regulation 7 (amendment of regulation 13 (supply of investigational...
3. For regulation 17 (amendment of regulation 36 (requirement for authorisation...
4. For regulation 18 (amendment of regulation 43 (qualified persons)) substitute—...
5. In regulation 19 (insertion of regulation 43A (approved country for...
6. In regulation 20 (amendment of regulation 45 (suspension and revocation...
7. In regulation 23 (insertion of regulation 57 (functions in relation...

8. In regulation 24 (amendment of Schedule 3 (particulars and documents...
9. For regulation 25 (amendment of Schedule 7 (standard provisions for...
10. In regulation 26 (insertion of Schedule 13 (transitional provisions in...

SCHEDULE 2 — Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

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1. In regulation 4 (definitions in relation to advanced therapy medicinal...
2. In regulation 5 (amendment of regulation 3 (scope of Regulations:...
3. In regulation 6 (amendment of regulation 4 (special provision for...
4. In regulation 7 (amendment of regulation 5 (classification of medicinal...
5. For regulation 8 (amendment of Schedule 1 (further provisions for...
6. Omit regulation 9 (amendment of regulation 6 (the licensing authority...
7. In regulation 10 (amendment of regulation 8 (general interpretation))—

PART 2 — Amendment of Part 3 (amendment of Part 3 (manufacture and distribution of medicinal products and active substances))

8. In regulation 13 (new regulation B17 and C17 (good manufacturing...
9. In regulation 14 (amendment of regulation 17 (manufacturing of medicinal...
10. In regulation 15 (amendment of regulation 18 (wholesale dealing in...
11. In regulation 17 (amendment of regulation 19 (exemptions from requirement...
12. In regulation 18 (amendment of Schedule 3 (applications for licences...
13. After regulation 19 (amendment of regulation 23 (grant or refusal...
14. In regulation 20 (amendment of Schedule 4 (standard provisions of...
15. For regulation 21 (amendment of regulation 26 (general power to...
16. In regulation 24 (amendment of regulation 31 (certification of manufacturer's...
17. In regulation 27 (amendment of regulation 36 (conditions for manufacturer's...
18. In regulation 28 (amendment of regulation 37 (manufacturing and assembly))—...
19. In regulation 29 (amendment of regulation 38 (imports))—
20. In regulation 30 (amendment of regulation 39 (further requirements for...
21. In regulation 31 (amendment of regulation 42 (conditions for wholesale...
22. In regulation 32 (amendment of Schedule 7 (qualified persons))—
23. In regulation 33 (amendment of regulation 43 (obligations of licence...
24. For regulation 34 (omission of regulation 43A (requirement for wholesale...
25. In regulation 35 (amendment of regulation 44 (requirement for wholesale...
26. In regulation 36 (amendment of regulation 45 (requirement as to...
27. In regulation 37 (insertion of new regulations 45AA and 45AB...
28. In regulation 38 (amendment of regulation 45A (brokering in medicinal...
29. In regulation 40 (amendment of regulation 45E (criteria of broker's...
30. In regulation 41 (amendment of regulation 45F (provision of information)),...
31. In regulation 42 (amendment of regulation 45M (criteria for importation,...
32. In regulation 44 (amendment of regulation 45O (requirements for registration...

PART 3 — Amendment of Part 4 (amendment of Part 4 (requirement for authorisation))

33. In regulation 45 (amendment of regulation 46 (requirement for authorisation))—...
34. In regulation 46 (amendment of regulation 47 (breach of requirement)),...

PART 4 — Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

35. In regulation 47 (amendment of regulation 48 (application of Part...
36. In regulation 48 (amendment of regulation 49 (application for grant...
37. In regulation 49 (amendment of regulation 50 (accompanying material))—
38. In regulation 50 (amendment of Schedule 8 (material to accompany...
39. After regulation 51 (amendment of Schedule 8A (material to accompany...
40. In regulation 53 (new regulation 50A to 50J (applications in...
41. For regulation 56 (substitution of regulation 51 (applications relating to...
42. For regulation 57 (amendment of regulation 52 (applications relating to...
43. For regulation 58 (amendment of regulation 53 (applications relating to...
44. For regulation 60 (amendment of regulation 55 (applications relating to...
45. In regulation 62 (amendment of regulation 58 (consideration of application))—...
46. In regulation 63 (amendment of Schedule 11 (advice and representations)) —...
47. In regulation 64 (insertion of provisions concerning consideration of certain...
48. In regulation 65 (amendment of regulation 59 (conditions of UK...
49. For regulation 66 (amendment of regulation 60 (conditions of UK...
50. In regulation 67 (insertion of new regulations 60A (condition as...
51. In regulation 68 (amendment of regulation 61 (conditions of UK...
52. For regulation 69 (amendment of regulation 64 (duties of licensing...
53. In regulation 70 (obligation of licensing authority in case of...
54. In regulation 72 (validity of conditional marketing authorisation and variation...
55. In regulation 74 (amendment of regulation 66 (application for renewal...
56. After regulation 76 (renewal of conditional marketing authorisation) insert — Amendment...
57. In regulation 77 (amendment of regulation 68 (revocation, variation and...
58. In regulation 80(2) (amendment of regulation 71 (withdrawal of medicinal...
59. For regulation 81 (amendment of regulation 72 (sale etc of...
60. In regulation 82 (amendment of regulation 73 (obligation to notify...
61. For regulation 84 (amendment of regulation 76 (obligation in relation...
62. Omit regulation 85 (amendment of regulation 77 (record-keeping obligations)).
63. Omit regulation 86 (amendment of regulation 78 (obligation to ensure...
64. In regulation 87 (post authorisation requirements in relation to UK...
65. For regulation 88 (omission of regulation 79 (failure to provide...
66. In regulation 89 (amendment of regulation 80 (urgent safety restrictions)) —...
67. For regulation 90 (omission of regulations 81 to 94 (offences...
68. For regulation 91 (omission of regulation 94A (offences relating to...
69. For regulation 92 (amendment of regulation 95 (offences in connection...
70. Omit regulation 93 (amendment of regulation 96 (provision of misleading...
71. In regulation 94 (amendment of regulation 97 (breach of pharmacovigilance...
72. Omit regulation 95 (amendment of regulation 98 (general offence of...
73. Omit regulation 96 (amendment of regulation 99 (penalties)).
74. Omit regulation 97 (amendment of regulation 101 (defences)).
75. In regulation 98 (amendment of regulation 102 (regulation-making power to...

76. In regulation 99 (amendment of regulation 103 (application for certificate...
77. For regulation 100 (amendment of regulation 104 (consideration of application))...
78. In regulation 101 (amendment of regulation 108 (application for renewal...
79. After regulation 101 (amendment of regulation 108 (application for renewal...
    PART 5 — Amendment of Part 6 (amendment of Part 6 (certification of homoeopathic products))
80. In regulation 102 (amendment of regulation 110 (revocation, variation and...
81. For regulation 107 (amendment of regulation 116 (obligation in relation...
    PART 6 — Amendment of Part 7 (amendment of Part 7 (Traditional Herbal Registrations))
82. In regulation 110 (amendment of regulation 125 (traditional herbal medicinal...
83. In regulation 112 (insertion of new italic heading and regulation...
84. For regulation 113 (amendment of regulation 127 (application for grant...
85. For regulation 114 (amendment of regulation 128 (accompanying material)) substitute—...
86. For regulation 115(3)(a) (amendment of Schedule 12 (material to accompany...
87. In regulation 116 (amendment of regulation 130 (consideration of application))—...
88. In regulation 117 (Insertion of regulation 130A (procedure where less...
89. In regulation 118 (amendment of regulation 133 (application for renewal...
90. After regulation 118 amendment of regulation 133 (amendment of regulation...
91. In regulation 119 (amendment of regulation 135 (revocation, variation and...
92. In regulation 120(2) (amendment of regulation 136 (revocation by licensing...
93. In regulation 123 (amendment of regulation 140 (withdrawal of traditional...
94. In regulation 125 (amendment of regulation 142 (obligation to notify...
95. In regulation 126 (insertion of new regulation 143A (establishment of...
96. For regulation 127 (amendment of regulation 144 (obligation following new...
97. For regulation 129 (amendment of regulation 146 (obligation in relation...
98. In regulation 131 (amendment of regulation 149 (urgent safety restrictions))...
    PART 7 — Amendment of Part 8 (omission of Part 8 (Article 126a authorisations))
99. For regulation 132 (omission of Part 8), substitute— Amendment of...
    PART 8 — Amendment of Part 9 (amendment of Part 9 (borderline products))
100. In regulation 133 (amendment of regulation 159 (provisional determination)) for...
101. In regulation 134 (amendment of regulation 164 (effect of determination))...
    PART 9 — Amendment of Part 10 (amendment of Part 10 (exceptions to requirement for marketing authorisations etc))
102. Before regulation 135 (amendment of regulation 168 (use of non-prescription...
103. For regulation 135 (amendment of regulation 168 (use of non-prescription...
104. In regulation 136 (amendment of regulation 169 (mixing of general...

105. In regulation 137 (amendment of regulation 171 (exempt advanced therapy...
106. In regulation 138 (amendment of regulation 173 (exemption for certain...
PART 10 — Amendment of Part 11 (amendment of Part 11 (Pharmacovigilance))
107. In regulation 139 (amendment of regulation 177 (application of part...
108. After regulation 139 (amendment of regulation 177 (application of part...
109. In regulation 140 (amendment of regulation 180 (obligation on licensing...
110. For regulation 141 (omission of regulation 181 (delegation of obligations...
111. In regulation 142 (amendment of regulation 182 (obligation on holder...
112. In regulation 143 (amendment of regulation 184 (obligation on holder...
113. For regulation 145 (amendment of regulation 186 (reporting obligations on...
114. In regulation 147 (amendment of regulation 187 (recording obligations on...
115. In regulation 148 (amendment of regulation 188 (reporting obligations on...
116. In regulation 149 (amendment of regulation 189 (signal detection: licensing...
117. For regulation 150 (amendment of regulation 190 (signal detection: holder...
118. In regulation 151 (amendment of regulation 191 (obligation on holder...
119. In regulation 152 (amendment of regulation 192 (obligation to submit...
120. In regulation 153 (amendment of regulation 193 (harmonisation of PSUR...
121. In regulation 154 (omission of regulation 194 (responding to a...
122. In regulation 155 (amendment of regulation 195 (obligation on licensing...
123. Before regulation 156 insert— Amendment of regulation 196 (urgent action)...
124. In regulation 156 (substitution of regulation 196 (urgent action))—
125. In regulation 157 (omission of regulation 197 (EU urgent action...
126. In regulation 158 (amendment of regulation 198 (post-authorisation safety studies:...
127. In regulation 159 (amendment of regulation 199 (submission of draft...
128. In regulation 160 (amendment of regulation 200 (amendment to study...
129. In regulation 161 (amendment of regulation 201 (submission and evaluation...
130. For regulation 162 (omission of regulation 202 (follow up of...
131. For regulation 164(3) (amendment of regulation 203 (obligations on licensing...
132. In regulation 165 (omission of regulation 204 (obligation on licensing...
133. In regulation 166 (amendment of regulation 205 (obligations on holders...
134. In regulation 167 (insertion of regulation 205A (further obligations in...
135. In regulation 170 (amendment of regulation 206 (infringement notices)) for...
136. Omit regulations 172 (amendment regulation 208 (false and misleading information)),...
137. In regulation 175 (amendment of regulation 210A (offences in relation...
138. Omit regulation 176 (amendment of regulation 211 (persons liable)).
139. For regulation 177 (amendment of regulation 212 (transitional amendments)) substitute—...
140. In regulation 178 (amendment of Schedule 33 (transitional arrangements: pharmacovigilance))...
PART 11 — Amendment of Part 12 (amendment of Part 12 (dealings with medicinal products))
141. For regulation 187 (amendment of regulation 229 (exemption for supply...
142. For regulation 188 (amendment of regulation 230 (exemption for supply...

143. For regulation 189 (amendment of regulation 231 (exemption for supply...
144. For regulation 190 (amendment of regulation 232 (exemption for supply...
145. For regulation 191 (amendment of regulation 233 (exemption for supply...
146. For regulation 192 (amendment of regulation 234 (exemption for supply...
147. In regulation 193 (amendment of Schedule 17 (exemptions for sale,...
148. In regulation 194 (amendment of regulation 249 (restrictions on persons...
149. After regulation 194 (amendment of regulation 249 (restrictions on persons...
150. For regulation 196 (omission of regulation 255A to 255C (enforcement...
PART 12 — Amendment of Part 13 (omission of Part 12A (sale of medicines to the public at a distance))
151. For regulation 197 (omission of Part 12A) substitute— Amendment of...
PART 13 — Amendment of Part 14 (amendment of Part 13 (packaging and leaflets))
152. In regulation 198 (amendment of regulation 257 (packaging requirements: general))—...
153. For regulation 199 (omission of regulations 257A and 257B (packaging...
154. In regulation 200 (insertion of regulations 257C (packaging requirements: advanced...
155. In regulation 201 (amendment of Schedule 24 (packaging information requirements))—...
156. In regulation 202 (amendment of regulation 259 (packaging requirements: information...
157. In regulation 203 (amendment of regulation 260 (package leaflets))—
158. In regulation 204 (amendment of Schedule 27 (package leaflets))—
159. Omit regulation 205 (amendment of regulation 266 (language requirements etc))....
160. In regulation 206 (amendment of regulation 267 (submission of mock-ups...
161. In regulation 207 (amendment of regulation 268 (offence relating to...
162. After regulation 207 (amendment of regulation 268 (offence relating to...
163. In regulation 208 (amendment of regulation 269 (offences relating to...
164. After regulation 208 (amendment of regulation 269 (offences relating to...
165. In regulation 209 (amendment of regulation 270 (non-compliance with requirements...
166. After regulation 209 (amendment of regulation 270 (non-compliance with requirements...
PART 14 — Amendment of Part 15 (amendment of Part 14 (advertising))
167. For regulation 211 (amendment of regulation 279 (products without a...
168. In regulation 212 (amendment of regulation 280 (general principles))—
169. In regulation 213 (amendment of regulation 281 (duties of authorisation...
170. After regulation 213 (amendment of regulation 281 (duties of authorisation...
171. For regulation 214 (amendment of regulation 293 (prohibition of supply...
172. After regulation 214 (amendment of regulation 293 (prohibition of supply...
173. For regulation 215 (amendment of regulation 295 (abbreviated advertisements)) substitute—...
174. After regulation 215 (amendment of regulation 295 (abbreviated advertisements)) insert—...
175. For regulation 216 (amendment of Schedule 30 (particulars for advertisements...
176. In regulation 217 (amendment of regulation 299 (medical sales representatives)),...

177. After regulation 217 (amendment of regulation 299 (medical sales representatives))...
PART 15 — Amendment of Part 16 (amendment of Part 15 (British Pharmacopoeia))
178. In regulation 218 (amendment of regulation 321 (specified publications)), for...
PART 16 — Amendment of Part 17 (amendment of Part 16 (enforcement))
179. Omit regulation 219 (amendment of regulation 322 (validity of proceedings))....
180. In regulation 221 (amendment of regulation 327 (powers of inspection,...
181. In regulation 222 (amendment of regulation 331 (findings and reports...
182. In regulation 223 (insertion of regulation 331A (guidelines on inspections)),...
PART 17 — Amendment of Part 18 (amendment of Part 17 (miscellaneous and general))
183. Before regulation 224 (amendment of regulation 341 (decisions under the...
184. For regulation 224 (amendment of regulation 341 (decisions under the...
185. In regulation 225 (insertion of regulation 344A (modifications to deal...
186. For regulation 226 (amendment of regulation 345 (immunity from civil...
187. In regulation 227 (amendment of regulation 346 (Secretary of State...
PART 18 — Amendment of Schedule 1 (amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016)
188. In Schedule 1 (amendment of the Medicines (Products for Human...
189. In Schedule 2 (insertion of new Schedule 8B (modifications of...
PART 19 — Insertion of Schedule 2A (insertion of new Schedule 8C (material to accompany an application for a UK marketing authorisation under the unfettered access route))
190. After Schedule 2 (insertion of new Schedule 8B (modifications of...
PART 20 — Amendment of Schedule 4 (insertion of new Schedule 9A)
191. In Schedule 4 (insertion of new Schedule 9A), in the...
PART 21 — Amendment of Schedule 6 (insertion of new Schedule 12A (further provision as to the performance of pharmacovigilance activities))
192. In Schedule 6 (insertion of new Schedule 12A (further provision...
PART 22 — Amendment of Schedule 7 (insertion of new Schedule 33A (Transitional Provision))
193. In Schedule 7 (insertion of new Schedule 33A (Transitional Provision)),...
PART 23 — Amendment of Schedule 8 (consequential provision)
194. In Schedule 8 (consequential provision)— (a) in paragraph 4 (amendment...
PART 24 — Amendment of Schedule 9 (retained EU law: revocations)
195. In Schedule 9 (retained EU law: revocations), in paragraph 1,...

SCHEDULE 3 — Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
1. Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Explanatory Note