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DRAFT STATUTORY INSTRUMENTS

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**2019 No. 0000**

**EXITING THE EUROPEAN UNION  
MEDICINES**

The Human Medicines (Amendment  
etc.) (EU Exit) Regulations 2019

*Made* - - - - - **\*\*\***

*Coming into force in accordance with regulation 1*

**THE HUMAN MEDICINES (AMENDMENT  
ETC.) (EU EXIT) REGULATIONS 2019**

PART 1

General

1. Citation and commencement
2. Amendment of the Human Medicines Regulations 2012
3. Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

PART 2

Amendment of Part 1 (General)

4. Definitions in relation to advanced therapy medicinal products
5. Amendment of regulation 3 (scope of Regulations: special provisions)
6. Amendment of regulation 4 (special provision for pharmacies etc)
7. Amendment of regulation 5 (classification of medicinal products)
8. Amendment of Schedule 1 (further provisions for classification of medicinal products)
9. Amendment of regulation 6 (the licensing authority and the Ministers)
10. Amendment of regulation 8 (general interpretation)
11. Insertion of Schedule 8B (modifications of Annex I to the 2001 Directive)
12. Insertion of Schedule 2A (modifications of Commission Directive 2003/94/EC)

### PART 3

#### Amendment of Part 3 (manufacture and distribution of medicinal products and active substances)

13. New regulation B17 and C17 (good manufacturing practice and good distribution practice)
14. Amendment of regulation 17 (manufacturing of medicinal products)
15. Amendment of regulation 18 (wholesale dealing in medicinal products)
16. Insertion of new regulation 18A (approved country for import)
17. Amendment of regulation 19 (exemptions from requirement for wholesale dealer's licence)
18. Amendment of Schedule 3 (applications for licences under Part 3)
19. Amendment of regulation 23 (grant or refusal of licence)
20. Amendment of Schedule 4 (standard provisions of licences under Part 3)
21. Amendment of regulation 26 (general power to suspend, revoke or vary licences)
22. Amendment of Schedule 5 (review upon oral representations)
23. Amendment of regulation 29 (variation of licence on the application of the holder)
24. Amendment of regulation 31 (certification of manufacturer's licence)
25. Amendment of regulation 33 (offence concerning data for advanced therapy medicinal products)
26. Amendment of Schedule 6 (manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products)
27. Amendment of regulation 36 (conditions for manufacturer's licence)
28. Amendment of regulation 37 (manufacturing and assembly)
29. Amendment of regulation 38 (imports)
30. Amendment of regulation 39 (further requirements for manufacturer's licence)
31. Amendment of regulation 42 (conditions for wholesale dealer's licence)
32. Amendment of Schedule 7 (qualified persons)
33. Amendment of regulation 43 (obligations of licence holder)
34. Omission of regulation 43A (requirement for wholesale dealer to decommission the unique identifier)
35. Amendment of regulation 44 (requirement for wholesale dealers to deal only with specified persons)
36. Amendment of regulation 45 (requirement as to responsible persons)
37. Insertion of new regulations 45AA and 45AB (responsible persons: import)
38. Amendment of regulation 45A (brokering in medicinal products)
39. Amendment of regulation 45D (grant or refusal of a broker's registration)
40. Amendment of regulation 45E (criteria of broker's registration)
41. Amendment of regulation 45F (provision of information)
42. Amendment of regulation 45M (criteria for importation, manufacture or distribution of an active substance)
43. Amendment of Schedule 7A (information to be provided for registration as an importer, manufacturer or distributor of active substances)
44. Amendment of regulation 45O (requirements for registration as an importer, manufacturer or distributor of an active substance)

### PART 4

#### Amendment of Part 4 (requirement for authorisation)

45. Amendment of regulation 46 (requirement for authorisation)

46. Amendment of regulation 47 (breach of requirement)

#### PART 5

#### Amendment of Part 5 (marketing authorisations)

47. Amendment of regulation 48 (application of Part 5)
48. Amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence)
49. Amendment of regulation 50 (accompanying material)
50. Amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation)
51. Amendment of Schedule 8A (material to accompany an application for a parallel import licence)
52. Amendment of Schedule 9 (undertakings by non-United Kingdom manufacturers)
53. New regulation 50A to 50J (applications in relation to particular medicinal products)
54. Insertion of new Schedule in relation to orphan provisions
55. Amendment of Schedule 10 (national homoeopathic products)
56. Substitution of regulation 51 (applications relating to generic medicinal products)
57. Amendment of regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc)
58. Amendment of regulation 53 (applications relating to similar biological medicinal products)
59. Amendment of regulation 54 (applications relating to products in well-established medicinal use)
60. Amendment of regulation 55 (applications relating to new combinations of active substances)
61. Amendment of regulation 56 (applications containing information supplied in relation to another product with consent)
62. Amendment of regulation 58 (consideration of application)
63. Amendment of Schedule 11 (advice and representations)
64. Insertion of provisions concerning consideration of certain applications for UK marketing authorisations
65. Amendment of regulation 59 (conditions of UK marketing authorisation or parallel import licence: general)
66. Amendment of regulation 60 (conditions of UK marketing authorisation: exceptional circumstances)
67. Insertion of new regulations 60A (condition as to the submitting of samples and other information to the appropriate authority)
68. Amendment of regulation 61 (conditions of UK marketing authorisation)
69. Amendment of regulation 64 (duties of licensing authority in connection with determination)
70. Obligation of licensing authority in case of change of classification
71. Amendment of regulation 65 (validity of UK marketing authorisation)
72. Validity of conditional marketing authorisation and variation of a UK marketing authorisation
73. Insertion of new Schedule 10A (variations to a UK marketing authorisation)
74. Amendment of regulation 66 (application for renewal of authorisation)
75. Amendment of regulation 66A (application for renewal of a parallel import licence)

76. Renewal of conditional marketing authorisation
77. Amendment of regulation 68 (revocation, variation and suspension of UK marketing authorisation or parallel import licence)
78. Amendment of regulation 69 (suspension of use etc of relevant medicinal product)
79. Omission of regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive)
80. Amendment of regulation 71 (withdrawal of medicinal product from the market)
81. Amendment of regulation 72 (sale etc of suspended medicinal product)
82. Amendment of regulation 73 (obligation to notify placing on the market etc)
83. Amendment of regulation 75 (obligation to provide information relating to safety etc)
84. Amendment of regulation 76 (obligation in relation to product information)
85. Amendment of regulation 77 (record-keeping obligations)
86. Amendment of regulation 78 (obligation to ensure appropriate and continued supplies)
87. Post authorisation requirements in relation to UK marketing authorisations with paediatric aspects and advanced therapy medicinal products
88. Omission of regulation 79 (failure to provide information on marketing authorisations to EMA)
89. Amendment of regulation 80 (urgent safety restrictions)
90. Omission of regulations 81 to 94 (offences relation to EU marketing authorisations)
91. Omission of regulation 94A (offences relating to Commission Regulation 2016/161)
92. Amendment of regulation 95 (offences in connection with application)
93. Amendment of regulation 96 (provision of misleading information)
94. Amendment of regulation 97 (breach of pharmacovigilance condition)
95. Amendment of regulation 98 (general offence of breach of Part 5)
96. Amendment of regulation 99 (penalties)
97. Amendment of regulation 101 (defences)

#### PART 6

##### Amendment of Part 6 (certification of homoeopathic products)

98. Amendment of regulation 102 (regulation-making power to amend regulation 102(4) to (6))
99. Amendment of regulation 103 (application for certificate of registration)
100. Amendment of regulation 104 (consideration of application)
101. Amendment of regulation 108 (application for renewal of certificate)
102. Amendment of regulation 110 (revocation, variation and suspension of certificate of registration)
103. Omission of regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive)
104. Amendment of regulation 112 (withdrawal of homoeopathic medicinal product from the market)
105. Amendment of regulation 113 (obligation to notify placing on the market etc)
106. Amendment of regulation 115 (obligation to provide information relating to safety etc)

107. Amendment of regulation 116 (obligation in relation to product information)

#### PART 7

##### Amendment of Part 7 (Traditional Herbal Registrations)

108. Amendment of italic heading above regulation 125 (traditional herbal medicinal products)
109. Insertion of regulation 124A (interpretation)
110. Amendment of regulation 125 (traditional herbal medicinal products)
111. Insertion of regulation 125A (list of approved countries for herbal medicinal products)
112. Insertion of new italic heading and regulation 126A (list of herbal substances, preparations and combinations for use in traditional herbal medicinal products)
113. Amendment of regulation 127 (application for grant of traditional herbal registration)
114. Amendment of regulation 128 (accompanying material)
115. Amendment of Schedule 12 (material to accompany an application for a traditional herbal registration)
116. Amendment of regulation 130 (consideration of application)
117. Insertion of regulation 130A (procedure where less than 15 years use of traditional herbal medicinal product)
118. Amendment of regulation 133 (application for renewal of registration)
119. Amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration)
120. Amendment of regulation 136 (revocation by licensing authority: further provisions)
121. Amendment of regulation 138 (suspension of use etc of traditional herbal medicinal product)
122. Omission of regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive)
123. Amendment of regulation 140 (withdrawal of traditional herbal medicinal product from the market)
124. Amendment of regulation 141 (sale etc of suspended traditional herbal medicinal product)
125. Amendment of regulation 142 (obligation to notify placing on the market etc)
126. Insertion of new regulation 143A (establishment of herbal monographs)
127. Amendment of regulation 144 (obligation following new herbal monograph)
128. Amendment of regulation 145 (obligation to provide information relating to safety etc)
129. Amendment of regulation 146 (obligation in relation to product information)
130. Insertion of regulation 148A (urgent safety restrictions)
131. Amendment of regulation 149 (urgent safety restrictions)

#### PART 8

##### Omission of Part 8 (Article 126a authorisations)

132. Omission of Part 8

## PART 9

### Amendment of Part 9 (borderline products)

- 133. Amendment of regulation 159 (provisional determination)
- 134. Amendment of regulation 164 (effect of determination)

## PART 10

### Amendment of Part 10 (exceptions to requirement for marketing authorisations etc)

- 135. Amendment of regulation 168 (use of non-prescription medicines in the course of a business)
- 136. Amendment of regulation 169 (mixing of general sale medicinal products)
- 137. Amendment of regulation 171 (exempt advanced therapy medicinal products)
- 138. Amendment of regulation 173 (exemption for certain radiopharmaceuticals)

## PART 11

### Amendment of Part 11 (Pharmacovigilance)

- 139. Amendment of regulation 177 (application of Part and interpretation)
- 140. Amendment of regulation 180 (obligation on licensing authority to audit pharmacovigilance system)
- 141. Omission of regulation 181 (delegation of obligations under Part 11)
- 142. Amendment of regulation 182 (obligation on holder to operate a pharmacovigilance system)
- 143. Amendment of regulation 184 (obligation on holder to audit pharmacovigilance system)
- 144. Amendment of regulation 185 (recording obligations on the licensing authority)
- 145. Amendment of regulation 186 (reporting obligations on the licensing authority)
- 146. Insertion of new regulation 187A (collaboration with the World Health Organisation)
- 147. Amendment of regulation 187 (recording obligations on holders)
- 148. Amendment of regulation 188 (reporting obligations on holders)
- 149. Amendment of regulation 189 (signal detection: licensing authority obligations)
- 150. Amendment of regulation 190 (signal detection: holder obligation)
- 151. Amendment of regulation 191 (obligation on holder to submit periodic safety update reports: general requirements)
- 152. Amendment of regulation 192 (obligation to submit periodic safety reports: derogation from general requirements)
- 153. Amendment of regulation 193 (harmonisation of PSUR frequency or date of submission)
- 154. Omission of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive)
- 155. Amendment of regulation 195 (obligation on licensing authority to assess PSURs)
- 156. Substitution of regulation 196 (urgent action)
- 157. Omission of regulation 197 (EU urgent action procedure)
- 158. Amendment of regulation 198 (post-authorisation safety studies: general provisions)

159. Amendment of regulation 199 (submission of draft study protocols for required studies)
160. Amendment of regulation 200 (amendment to study protocols for required studies)
161. Amendment of regulation 201 (submission and evaluation of final study reports for required studies)
162. Omission of regulation 202 (follow up of final study reports)
163. Insertion of new regulation 202A (medicinal products subject to additional monitoring)
164. Amendment of regulation 203 (obligations on licensing authority in relation to national medicines web-portal)
165. Omission of regulation 204 (obligation on licensing authority in relation to public announcements)
166. Amendment of regulation 205 (obligations on holders in relation to public announcements)
167. Insertion of regulation 205A (further obligations in respect of pharmacovigilance activities)
168. Insertion of new Schedule 12A (further provision as to performance of pharmacovigilance activities)
169. Insertion of regulation 205B (guidance in respect of good pharmacovigilance practice and post authorisation efficacy studies)
170. Amendment of regulation 206 (infringement notices)
171. Amendment of regulation 207 (offences)
172. Amendment of regulation 208 (false and misleading information)
173. Amendment of regulation 209 (penalties)
174. Omission of regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004)
175. Amendment of regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation)
176. Amendment of regulation 211 (persons liable)
177. Amendment of regulation 212 (transitional arrangements)
178. Amendment of Schedule 33 (transitional arrangements: pharmacovigilance)

## PART 12

### Amendment of Part 12 (dealings with medicinal products)

179. Amendment of regulation 213 (interpretation of Part 12)
180. Amendment of regulation 214 (sale or supply of prescription only medicines)
181. Amendment of regulation 216 (exceptions to regulation 215)
182. Amendment of regulation 217 (requirements for prescriptions: general)
183. Amendment of regulation 217A (requirements for prescriptions to be dispensed in an EEA State)
184. Amendment of regulation 218 (requirements for prescriptions: EEA health professionals)
185. Amendment of regulation 219 (electronic prescriptions)
186. Amendment of regulation 219A (electronic prescriptions: EEA health professionals)
187. Amendment of regulation 229 (exemption for supply by national health services bodies and local authorities)
188. Amendment of regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)

189. Amendment of regulation 231 (exemption for supply etc under a PGD by independent hospitals etc.)
190. Amendment of regulation 232 (exemption for supply etc under a PGD by dental practices and clinics: England and Wales)
191. Amendment of regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)
192. Amendment of regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)
193. Amendment of Schedule 17 (exemptions for sale, supply or administration by certain persons)
194. Amendment of regulation 249 (restrictions on persons to be supplied with medicinal products)
195. Amendment of regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products)
196. Omission of regulation 255A to 255C (enforcement and offences relating to Commission Regulation 2016/161)

#### PART 13

Omission of Part 12A (sale of medicines to the public at a distance)

197. Omission of Part 12A

#### PART 14

Amendment of Part 13 (packaging and leaflets)

198. Amendment of regulation 257 (packaging requirements: general)
199. Omission of regulations 257A and 257B (packaging requirements: medicinal products required to bear safety features and associated transitionals)
200. Insertion of regulations 257C (packaging requirements: advanced therapy medicinal products) and 257D and 257E (guidance and regulations in relation to packing, leaflets and labelling)
201. Amendment of Schedule 24 (packaging information requirements)
202. Amendment of regulation 259 (packaging requirements: information for blind and partially sighted patients)
203. Amendment of regulation 260 (package leaflets)
204. Amendment of Schedule 27 (package leaflets)
205. Amendment of regulation 266 (language requirements etc)
206. Amendment of regulation 267 (submission of mock-ups of packaging and leaflets to licensing authority)
207. Amendment of regulation 268 (offence relating to packaging and package leaflets)
208. Amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)
209. Amendment of regulation 270 (non-compliance with requirements of this Part)
210. Amendment of regulation 273 (child resistant containers for regulated medicinal products)

#### PART 15

Amendment of Part 14 (advertising)

211. Amendment of regulation 279 (products without a marketing authorisation)



- 212. Amendment of regulation 280 (general principles)
- 213. Amendment of regulation 281 (duties of authorisation holders and registration holders)
- 214. Amendment of regulation 293 (prohibition of supply to the public for promotional purposes)
- 215. Amendment of regulation 295 (abbreviated advertisements)
- 216. Amendment of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply)
- 217. Amendment of regulation 299 (medical sales representatives)

PART 16

Amendment of Part 15 (British Pharmacopoeia)

- 218. Amendment of regulation 321 (specified publications)

PART 17

Amendment of Part 16 (enforcement)

- 219. Amendment of regulation 322 (validity of proceedings)
- 220. Amendment of regulation 323 (enforcement in England, Wales and Scotland)
- 221. Amendment of regulation 327 (powers of inspection, sampling and seizure)
- 222. Amendment of regulation 331 (findings and reports of inspections)
- 223. Insertion of regulation 331A (guidelines on inspections)

PART 18

Amendment of Part 17 (miscellaneous and general)

- 224. Amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)
- 225. Insertion of regulation 344A (modifications to deal with serious shortages) and 344B (regulation making powers)
- 226. Amendment of regulation 345 (immunity from civil liability)
- 227. Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)

PART 19

Transitional and consequential provision and revocations

- 228. Transitional provision in relation to EU exit
- 229. Consequential amendments
- 230. Revocations of retained direct EU law  
Signature

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SCHEDULE 1 — Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

- 1. Amendment of regulation 19 (capital fees for applications for variations of authorisations)
- 2. Insertion of regulations 19A-19F (fees for plasma master files, vaccine antigen master files, post-authorisation safety studies, major safety reviews, periodic safety update reports and batch testing)

3. Amendment of regulation 23 (applications for multiple variations)
4. Insertion of regulation 27A (fee for renewals of a marketing authorisation)
5. Omission of Part 8 (Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the Assessment of Applications for the Renewal of Specified Marketing Authorisations)
6. Amendment of Schedule 1 (general interpretation provisions)
7. Amendment of Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates)
8. Amendment of Schedule 4 (periodic fees for licences)
9. Amendment of Schedule 7 (waiver, reduction or refund of capital fees)
10. Amendment of Schedule 8 (Adjustment, reduction or refund of periodic fees)
11. Savings

SCHEDULE 2 — Insertion of new Schedule 8B (modifications of Annex I to the 2001 Directive)

1. After Schedule 8A to the Human Medicines Regulations 2012, insert—...

SCHEDULE 3 — Insertion of new Schedule 2A (modifications of Commission Directive 2003/94/EC)

1. After Schedule 2 to the Human Medicines Regulations 2012, insert—...

SCHEDULE 4 — Insertion of new Schedule 9A

1. After Schedule 9, insert— SCHEDULE 9A Meaning of terms used...

SCHEDULE 5 — Insertion of new Schedule 10A (variations to a UK marketing authorisation)

1. After Schedule 10, insert— SCHEDULE 10A Variations to a UK marketing...

SCHEDULE 6 — Insertion of new Schedule 12A (further provision as to the performance of pharmacovigilance activities)

1. After Schedule 12 insert— SCHEDULE 12A Further provision as to the...

SCHEDULE 7 — Insertion of new Schedule 33A (transitional provision)

1. After Schedule 33 insert— SCHEDULE 33A Transitional provision in relation to...

SCHEDULE 8 — Consequential provision

PART 1 — Amendment of primary legislation

1. Amendment of the National Health Service Act 2006
2. Amendment of the Access to Medical Treatments (Innovation) Act 2016

PART 2 — Amendment of secondary legislation

3. Amendment of the Medicines (Bal Jivan Chamcho Prohibition) (No 2) Order 1977
4. Amendment of the Prescription Only Medicines (Human Use) Order 1997
5. Amendment of the Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001
6. Amendment of the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002
7. Amendment of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

8. Amendment of the Blood Safety and Quality Regulations 2005
9. Amendment of the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007
10. Amendment of the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008
11. Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
12. Amendment of the Genetically Modified Organisms (Contained Use) Regulations 2014
13. Amendment of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015
14. Amendment of the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015
15. Amendment of the Health Service Products (Provision and Disclosure of Information) Regulations 2018
16. Amendment of the Branded Health Service Medicines (Costs) Regulations 2018

SCHEDULE 9 — Retained EU law: revocations

1. Insofar as they apply to medicinal products for human use,...

Explanatory Note