STATUTORY INSTRUMENTS

2019 No. 775

EXITING THE EUROPEAN UNION MEDICINES

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

Made - - - - 1st April 2019

Coming into force in accordance with regulation 1

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

PART 1

General

PART 2

Amendment of Part 1 (General)

PART 3

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

PART 4

Amendment of Part 4 (requirement for authorisation)

PART 5

Amendment of Part 5 (marketing authorisations)

PART 6

Amendment of Part 6 (certification of homoeopathic products)

PART 7

Amendment of Part 7 (Traditional Herbal Registrations)

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. Amendment 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)
156ZA Amendment of regulation 196 (urgent action)
156. Insertion of new regulation 196A (major safety review by the licensing authority)
157. Amendment 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. Amendment 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. Amendment 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)

PART 13

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

PART 14

Amendment of Part 13 (packaging and leaflets)

PART 17

Amendment of Part 16 (enforcement)

PART 18

Amendment of Part 17 (miscellaneous and general)

PART 19

Transitional and consequential provision and revocations

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.