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 6

Amendment of Part 6 (certification of homoeopathic products)

PART 7

Amendment of Part 7 (Traditional Herbal Registrations)

PART 8

Omission of Part 8 (Article 126a authorisations)

PART 9

Amendment of Part 9 (borderline products)

PART 10

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

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)

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