
DRAFT STATUTORY INSTRUMENTS

2021 No. 0000

**EXITING THE EUROPEAN UNION
MEDICINES**

The Human Medicines (Amendment
etc.) (EU Exit) (No. 2) Regulations 2021

Made - - - - - ***

Coming into force ***

**THE HUMAN MEDICINES (AMENDMENT
ETC.) (EU EXIT) (NO. 2) REGULATIONS 2021**

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
4. Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

PART 2

Amendment of the Human Medicines Regulations 2012

5. Amendment of regulation 8 (general interpretation)
6. Amendment of regulation 43 (obligations of licence holder)
7. Amendment of regulation 45A (brokering in medicinal products)
8. Amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence)
9. Amendment of regulation 58 (consideration of application)
10. Amendment of regulation 60A (condition as to the submitting of samples and other information to the appropriate authority)
11. Amendment of regulation 60B (submitting of samples and other information: EU marketing authorisations)
12. Amendment of regulation 167 (supply to fulfil special patient needs)

Draft Legislation: This is a draft item of legislation and has not yet been made as a UK Statutory Instrument.

13. Amendment of regulation 182 (obligation on holder to operate pharmacovigilance system)
14. Amendment of regulation 188 (reporting obligations on holders)
15. Amendment of regulation 193 (harmonisation of PSUR frequency or date of submission)
16. Amendment of regulation 199 (submission of draft study protocols for required studies)
17. Amendment of regulation 200 (amendment to study protocols for required studies)
18. Amendment of regulation 201 (submission and evaluation of final study reports for required studies)
19. Amendment of regulation 202A (licensing authority power in relation to medicinal products subject to additional monitoring)
20. Amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation)
21. Amendment of Schedule 11 (advice and representations)
22. Amendment of Schedule 27 (package leaflets)
23. Amendment of Schedule 33A (transitional provisions)

PART 3

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

24. Amendment of regulation 19F (fee for testing of samples by the appropriate authority)
25. Amendment of regulation 27A (fee for renewals of a marketing authorisation)
26. Amendment of regulation 46 (fees for applications for certificates)
27. Amendment of Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates)
28. Amendment of Schedule 5 (fees for certificates of registration)

PART 4

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

29. Amendment of regulation 57 (functions in relation to good clinical practice)
Signature
Explanatory Note