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DRAFT STATUTORY INSTRUMENTS

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**2019 No. 0000**

**EXITING THE EUROPEAN UNION  
MEDICINES**

The Medicines for Human Use (Clinical Trials)  
(Amendment) (EU Exit) Regulations 2019

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

*Coming into force in accordance with regulation 1*

**THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS)  
(AMENDMENT) (EU EXIT) REGULATIONS 2019**

1. Citation and commencement
2. Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004
3. Amendment of regulation 2 (interpretation)
4. Insertion of regulation 2A (list of countries for the purpose of the definition of “marketing authorization”)
5. Amendment of regulation 3 (sponsor of a clinical trial)
6. Omission of regulation 4 (responsibility for functions under the Directive)
7. Amendment of regulation 13 (supply of investigational medicinal products for the purpose of clinical trials)
8. Amendment of regulation 15 (ethics committee opinion)
9. Amendment of regulation 20 (authorisation procedure for clinical trials involving medicinal products with special characteristics)
10. Amendment of regulation 21 (clinical trials conducted in third countries)
11. Insertion of regulation 27B (publication of information)
12. Amendment of regulation 31 (suspension or termination of clinical trial)
13. Amendment of regulation 31A (trial master file and archiving)
14. Amendment of regulation 33 (notification of suspected unexpected serious adverse reactions)
15. Amendment of regulation 34 (clinical trials conducted in third countries)
16. Amendment of regulation 35 (annual list of suspected serious adverse reactions and safety report)
17. Amendment of regulation 36 (requirement for authorisation to manufacture or import investigational medicinal products)
18. Amendment of regulation 43 (qualified persons)

19. Insertion of regulation 43A (approved country for import)
  20. Amendment of regulation 45 (suspension and revocation of manufacturing authorisation)
  21. Amendment of regulation 48 (infringement notices)
  22. Amendment of regulation 56 (transitional provisions)
  23. Insertion of regulation 57 (functions in relation to good clinical practice)
  24. Amendment of Schedule 3 (particulars and documents that must accompany an application for an ethics committee opinion, a request for authorisation, a notice of amendment and a notification of the conclusion of a trial)
  25. Amendment of Schedule 7 (standard provisions for manufacturing authorisations)
  26. Insertion of Schedule 13 (transitional provisions in relation to EU Exit)
- Signature  
Explanatory Note