
STATUTORY INSTRUMENTS

2005 No. 2754

MEDICINES

The Medicines (Advisory Bodies) (No. 2) Regulations 2005

Made - - - - 4th October 2005

Laid before Parliament 7th October 2005

Coming into force in accordance with regulation 1(2)

THE MEDICINES (ADVISORY BODIES) (NO. 2) REGULATIONS 2005

1. Citation, commencement and interpretation
 2. Amendments to the Act
 3. Amendments to the Marketing Authorization Regulations
 4. Amendments to the Clinical Trials Regulations
 5. Amendments to other enactments
 6. Transitional Provisions
- Signature

SCHEDULE 1 — AMENDMENTS TO THE ACT

1. Amendment of section 3 of the Act
2. Amendment of section 4 of the Act
3. Amendment of section 132 of the Act
4. Amendment of Schedule 1A to the Act

SCHEDULE 2 — AMENDMENTS TO THE MARKETING AUTHORIZATION REGULATIONS

1. (1) Schedule 2 to the Marketing Authorization Regulations (procedural provisions...

SCHEDULE 3 — AMENDMENTS TO THE CLINICAL TRIALS REGULATIONS

1. In regulation 2 (interpretation), in paragraph (1), for the definition...
2. In regulation 19 (authorization procedure for clinical trials involving medicinal...
3. In regulation 26 (reference to appropriate committee or the Medicines...
4. (1) Regulation 31 (suspension or termination of clinical trial) shall...

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5. For Schedule 5 (procedural provisions relating to the refusal or...
6. In Schedule 8 (procedural provisions relating to proposals to grant,...

SCHEDULE 4 — CONSEQUENTIAL AMENDMENTS TO OTHER ENACTMENTS

1. In the Medicines (Extension to Antimicrobial Substances) Order 1973, in...
2. In the Medicines (Labelling) Regulations 1976, in regulation 17 (general...
3. In the Medicines (Administration of Radioactive Substances) Regulations 1978—
4. In the Medicines (Exemption from Licences) (Importation) Order 1984, in...
5. In the Medicines (Fixing of Fees Relating to Medicinal Products...
6. In the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations...
7. (1) The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform...

SCHEDULE 5 — TRANSITIONAL PROVISIONS

PART 1 — TRANSITIONAL PROVISIONS IN RELATION TO THE GRANT, RENEWAL, REVOCATION, SUSPENSION OR VARIATION OF LICENCES UNDER THE MEDICINES ACT 1968

1. Licence applications or proposals where appropriate committee has given provisional opinion before 30th October 2005
2. (1) This sub-paragraph applies if, before 30th October 2005, the...
3. (1) This paragraph and paragraph (4) apply if the applicant...
4. (1) When the applicant or holder has submitted the representations...
5. (1) This paragraph applies if— (a) the appropriate committee do...
6. (1) The appropriate committee shall— (a) take into account such...
7. Licence applications or proposals where appropriate committee has given advice to the licensing authority before 30th October 2005
8. (1) This paragraph applies where the licensing authority has not,...
9. (1) This paragraph applies where, before 30th October 2005, the...
10. (1) This paragraph applies where— (a) the applicant or holder...
11. (1) The Commission shall— (a) take into account—
12. Right to be heard by person appointed in relation to licence applications or proposals made before 30th October 2005
13. (1) This paragraph applies where, before 30th October 2005—
14. (1) This paragraph applies where, before 30th October 2005—
15. (1) This paragraph applies where— (a) before 30th October 2005,...
16. (1) This paragraph applies where— (a) paragraph 8 or 9...
17. Other licensing authority proposals notified to applicant or holder before 30th October 2005
18. Licence applications or proposals where there was no requirement to refer to appropriate committee before 30th October 2005
19. Applicant has given notice of wish to appear before person appointed prior to 30th October
20. Notice of wish to appear before person appointed given under this Part
21. Written representations made before 30th October 2005 or under this Part
22. Emergency suspensions in force on 30th October 2005

PART 2 — TRANSITIONAL PROVISIONS APPLICABLE TO OTHER PROVISIONS UNDER THE ACT

1. (1) This paragraph applies where, before 30th October 2005—
2. (1) This paragraph applies where, before 30th October 2005—

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3. (1) This paragraph applies where, before 30th October 2005—
PART 3 — TRANSITIONAL PROVISIONS IN RELATION TO THE GRANT, RENEWAL, REVOCATION, SUSPENSION OR VARIATION OF MARKETING AUTHORIZATIONS UNDER THE MARKETING AUTHORIZATION REGULATIONS
 1. Applications for, or proposals in relation to, marketing authorizations, where appropriate committee has given provisional opinion before 30th October 2005
 2. (1) This sub-paragraph applies where, before 30th October 2005—
 3. (1) This paragraph applies if the applicant or holder—
 4. (1) When the applicant or holder has submitted the representations...
 5. (1) This paragraph applies if— (a) the appropriate committee do...
 6. (1) The appropriate committee shall— (a) take into account such...
 7. Marketing authorisation applications or proposals where appropriate committee has given advice to the licensing authority before 30th October 2005
 8. (1) This paragraph applies where the licensing authority have not,...
 9. (1) This paragraph applies where, before 30th October 2005, the...
 10. (1) This paragraph applies where— (a) the applicant or holder...
 11. (1) The Commission shall— (a) take into account—
 12. Right to be heard by person appointed in relation to marketing authorisation applications or proposals made before 30th October 2005
 13. (1) This paragraph applies where, before 30th October 2005—
 14. (1) This paragraph applies where— (a) before 30th October 2005,...
 15. (1) This paragraph applies where— (a) paragraph 8 or 9...
 16. Other licensing authority proposals notified to applicant or holder before 30th October 2005
 17. Marketing authorization applications or proposals where there was no requirement to refer to appropriate committee before 30th October 2005
 18. Applicant has given notice of wish to appear before person appointed prior to 30th October
 19. Notice of wish to appear before person appointed given under this Part
 20. Written representations made prior to 30th October or under this Part
 21. Procedure in cases of emergency
PART 4 — TRANSITIONAL PROVISIONS APPLICABLE TO THE CLINICAL TRIALS REGULATIONS
 1. Procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorizations and the suspension or termination of clinical trials
 2. (1) This paragraph applies where, before 30th October 2005—
 3. (1) This paragraph applies where, before 30th October 2005—
 4. Procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorizations
 5. If— (a) the applicant or holder made written representations to...
 6. Where before 30th October— (a) an applicant or holder gives...

Explanatory Note