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STATUTORY INSTRUMENTS

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**2005 No. 2750**

**MEDICINES**

The Medicines (Traditional Herbal Medicinal  
Products for Human Use) Regulations 2005

*Made - - - - 6th October 2005*

*Laid before Parliament 7th October 2005*

*Coming into force*

*Except for the purposes  
of paragraphs 4(2)  
(a) and 8(a)(i) of  
Schedule 7*

*30th October 2005*

*For the purposes  
of paragraphs 4(2)  
(a) and 8(a)(i) of  
Schedule 7*

*20th November 2005*

THE MEDICINES (TRADITIONAL HERBAL MEDICINAL  
PRODUCTS FOR HUMAN USE) REGULATIONS 2005

1. Citation, commencement and extent
2. Interpretation
3. Responsibility for Member States' functions in relation to traditional herbal medicinal products
4. Traditional herbal registrations for traditional herbal medicinal products
5. Applications for the grant or renewal of a traditional herbal registration
6. Consideration, and grant or refusal, of an application for, or for renewal or variation of, a traditional herbal registration
7. Revocation, suspension or variation of a traditional herbal registration or the suspension of the use or marketing of traditional herbal medicinal products
8. Urgent safety restrictions
9. Obligations of holders of traditional herbal registrations, and offences by holders of traditional herbal registrations and other persons
10. Consequential and other amendments of the Act and other enactments
11. Application of enforcement provisions of the Act
12. Other Schedules to have effect

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

Signature

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SCHEDULE 1 — EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 4

1. Interpretation
2. Regulation 4(1) shall not apply to a traditional herbal medicinal...
3. The conditions mentioned in paragraph 2 are that—
4. (1) Subject to the following sub-paragraphs, regulation 4(1) shall not...
5. (1) Regulation 4(1) shall not apply to the placing on...
6. Any person who sells or supplies a traditional herbal medicinal...
7. A person required to maintain the records mentioned in paragraph...

SCHEDULE 2 — PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

PART 1 — INTERPRETATION AND APPLICATION

1. Interpretation
2. Scope and application of this Schedule
3. Subject to paragraphs 6 and 7, Part 3 applies to...
4. Subject to paragraphs 6 and 7, Part 4 applies where...
5. Subject to paragraphs 6 and 7, Part 5 applies where—...
6. This Schedule shall cease to apply if at any time...
7. This Schedule does not apply— (a) if an application relates...

PART 2 — PROCEDURES RELATING TO GRANT, RENEWAL, COMPULSORY VARIATION, REVOCATION OR SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

8. Requirement to consult the appropriate committee
9. Provisional opinion against traditional herbal registration
10. Licensing authority's decision after appropriate committee report
11. Licensing authority proposals in other cases
12. Right to be heard by a person appointed or to make further representations
13. Cases where suspension is to have immediate effect
14. If, after suspending a traditional herbal registration with immediate effect...

PART 3 — VARIATION OF TRADITIONAL HERBAL REGISTRATION ON APPLICATION OF HOLDER

15. Hearing before appropriate committee
16. Licensing authority decision
17. Right to be heard by a person appointed

PART 4 — REFERRAL TO THE COMMITTEE FOR HERBAL MEDICINAL PRODUCTS IN ACCORDANCE WITH ARTICLE 16C(4) OF THE 2001 DIRECTIVE

18. Hearing before appropriate committee
19. Licensing authority decision
20. Right to be heard by a person appointed

PART 5 — HEARING BEFORE PERSON APPOINTED

21. Hearing before person appointed

SCHEDULE 3 — OFFENCES, PENALTIES ETC

1. Offences
2. Any person who, in the course of a business carried...
3. Without prejudice to any other sanction which may be available...

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4. Any person who is the holder of a traditional herbal...
5. Where the use, supply or marketing of a traditional herbal...
6. Any person who is or, immediately before its revocation or...
7. Any holder of a traditional herbal registration who fails promptly...
8. Any holder of a traditional herbal registration who fails to...
9. Any holder of a traditional herbal registration who fails to...
10. Any person who is the holder of a traditional herbal...
11. Any holder of a traditional herbal registration who communicates to...
12. Any holder of a traditional herbal registration who fails to...
13. Any person responsible for placing on the market a traditional...
14. Any person responsible for placing a traditional herbal medicinal product...
15. Any person responsible for placing a traditional herbal medicinal product...
16. Any person who, while employed or engaged as an appropriately...
17. (1) Any person who in the course of an application...
18. Any holder of a traditional herbal registration who sells or...
19. Where, in relation to a traditional herbal medicinal product —...
20. Any person who fails to keep any record required under...
21. Any person who— (a) sells or supplies a traditional herbal...
22. Penalties
23. Miscellaneous
24. Where the holder of a traditional herbal registration is charged...
25. (1) A person does not commit an offence under paragraphs...

#### SCHEDULE 4 — MODIFICATIONS OF ENFORCEMENT PROVISIONS OF THE ACT

1. In section 107 (validity of decisions and proceedings relating thereto)—...
2. In section 108 (enforcement in England and Wales)—
3. In section 109 (enforcement in Scotland), for subsections (1) to...
4. For section 110 (enforcement in Northern Ireland) substitute— It shall...
5. In section 111 (rights of entry)— (a) in subsection (1)(a),...
6. In section 112 (power to inspect, take samples and seize...
7. In section 115 (analysis of samples in other cases)—
8. In section 116 (liability to forfeiture under Customs and Excise...
9. In section 118 (restrictions on disclosure of information), in subsection...
10. In section 119 (protection for officers of enforcement authorities)—
11. In section 121 (contravention due to default of other person)—...
12. In section 122 (warranty as defence)— (a) in subsection (1),...
13. In section 124 (offences by bodies corporate)—
14. In section 125 (prosecutions)— (a) in subsections (1) and (2),...
15. In section 127 (service of documents)— (a) for “any provision...
16. In Schedule 3 (sampling)— (a) in paragraph 1(1)(a), for the...

#### SCHEDULE 5 — LABELS

1. Interpretation
2. Introductory
3. Dispensed traditional herbal medicinal products
4. Traditional herbal medicinal products not on a general sale list
5. Exemptions

#### SCHEDULE 6 — TRANSITIONAL PROVISION

1. The provisions of these Regulations shall not apply until 30th...

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SCHEDULE 7 — CONSEQUENTIAL AMENDMENTS TO ORDERS AND REGULATIONS

1. In the Medicines (Retail Sale or Supply of Herbal Remedies)...
2. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980,...
3. (1) The Medicines (Pharmacy and General Sale-Exemption) Order 1980 is...
4. (1) The Medicines (Products Other Than Veterinary Drugs) (General Sale...
5. In the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994,...
6. In the Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order...
7. In the Medicines for Human Use (Kava-Kava) (Prohibition) Order 2002,...
8. In the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform...

Explanatory Note