STATUTORY INSTRUMENTS

1994 No. 3144

MEDICINES

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

Made - - - -	*8th December 1994*
Laid before Parliament	*9th December 1994*
Coming into force	*1st January 1995*

THE MEDICINES FOR HUMAN USE (MARKETING AUTHORISATIONS ETC.) REGULATIONS 1994

1. Citation, commencement and interpretation
2. Responsibility for Member States' functions under the Regulations and Directives
3. Marketing authorizations for relevant medicinal products
4. Applications for the grant, renewal or variation of a United Kingdom marketing authorization
5. Consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization.
6. Revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products.
7. Obligations of holders of marketing authorizations, and offences by holders of marketing authorizations and other persons
8. Control of retail sale of supply of relevant medicinal products
9. Consequential and other amendments of the Act and the Medicines Act 1971
10. Application of enforcement provisions of the Act
11. Other Schedules to have effect

Signature

SCHEDULE 1 — EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 3

1. Regulation 3(1) shall not apply to a relevant medicinal product...
2. The conditions mentioned in paragraph 1 are that—

3. (1) Subject to the following sub-paragraphs, regulation 3(1) shall not...
4. (1) Regulation 3(1) shall not apply to the placing on...
5. (1) Regulations 3(1) shall not apply to a radiopharmaceutical for...
6. Any person who sells or supplies a relevant medicinal product...
7. A person required to maintain the records mentioned in paragraph...

SCHEDULE 2 — PROCEDURAL PROVISIONS RELATING TO THE GRANT, REVOCATION AND SUSPENSION OF UNITED KINGDOM MARKETING AUTHORIZATIONS

1. Interpretation
2. ***Scope and application of the procedural provisions***
3. This Schedule shall cease to apply if at any time...
4. This Schedule does not apply— (a) if the licensing authority...
5. ***Requirement to consult the appropriate committee or the Medicines Commission***
6. ***Provisional opinion against authorization***
7. ***Licensing Authority's decision***
8. Confirmation or alteration of the decision after taking into account the advice of the Medicines Commission
9. ***Person appointed to hear representations***
10. Any notification given under paragraph 9— (a) in a case...
11. ***Right to be heard by a person appointed or to make further representations***
12. (1) Where the applicant or holder gives notice under paragraph...
13. ***Cases where suspension is to have immediate effect***
14. If after suspending an authorization with immediate effect by virtue...

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...
4. Where the use, supply or marketing of a relevant medicinal...
5. Any person who is or, immediately before its revocation or...
6. Any holder of a marketing authorization who fails promptly to—...
7. Any person responsible for placing on the market a relevant...
8. Any person responsible for placing a relevant medicinal product on...
9. Any person responsible for placing a relevant medicinal product on...
10. Any person who, while employed or engaged as an appropriately...
11. Any holder of a marketing authorization who sells or supplies...
12. Where, in relation to a relevant medicinal product—
13. Any person who fails to keep any record required under...
14. ***Penalties***
15. ***Miscellaneous***
16. Where the holder of a marketing authorization is charged with...

SCHEDULE 4 — MODIFICATIONS OF ENFORCEMENT PROVISIONS OF THE ACT

1. In section 107 of the Act (validity of decisions and...
2. In section 108 of the Act (enforcement in England and...
3. In section 109 of the Act (enforcement in Scotland), in...
4. In section 110 of the Act (enforcement in Northern Ireland),...
5. In section 111 of the Act (rights of entry)—
6. In section 112 of the Act (power to inspect, take...

7. In section 118 of the Act (restrictions on disclosure of...
8. In section 119 of the Act (protection for officers of...
9. In section 121 of the Act (contravention due to default...
10. In section 122 of the Act (warranty as a defence)—...
11. In section 124 of the Act (offences by bodies corporate),...
12. In section 125 of the Act (prosecutions)—
13. In section 127 of the Act (service of documents), the...
14. In Schedule 3 to the Act (sampling), in paragraph 1(1),...

SCHEDULE 5 — LABELS

1. ***Interpretation***
2. ***Introductory***
3. ***Dispensed relevant medicinal products***
4. ***Delivery and storage***
5. ***Relevant medicinal products on a general sale list***
6. ***Relevant medicinal products not on a general sale list***
7. ***Prescription only relevant medicinal products***
8. ***Exemptions***

SCHEDULE 6 — TRANSITIONAL PROVISIONS

1. If on 1st January 1995 there is in force in...
2. Accordingly any right conferred or obligation imposed by these Regulations...
3. (1) Subject to sub-paragraph (2), any application for a product...
4. The provisions of the Medicines (Labelling) Regulations 1976 and of...
5. Until 31st March 1995 the Medicines (Products for Human Use—Fees)...

SCHEDULE 7 — CONSEQUENTIAL AMENDMENTS TO REGULATIONS

1. In the Medicines (Exemption from Licences) (Wholesale Dealing in Confectionery)...
2. In the Medicines (Child Safety) Regulations 1975 in sub-paragraph (d)...
3. In the Medicines (Labelling) Regulations 1976— (a) for the heading...
4. In the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977...
5. In the Medicines (Leaflets) Regulations 1977 (a) for the heading...
6. In the medicines (Fluted Bottles) Regulations 1978, in paragraph (g)...
7. In the Importation of Animal Products and Poultry Products Order...
8. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980,...
9. In the Medicines (Pharmacy and General Sale) Exemption Order 1980—...
10. In the Health and Safety (Dangerous Pathogens) Regulations 1981, in...
11. In the Food Labelling Regulations 1984, in Column 2 of...
12. In the Natural Mineral Waters Regulations 1985, in sub-paragraph (c)...
13. In the Merchant Shipping (Medical Stores) Regulations 1986, in sub-paragraph...
14. In the Trade Descriptions (Places of Production) (Marking) Order 1988,...
15. In the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990—...
16. In the Children's Homes Regulations 1991, in paragraph (1) of...
17. In the Medicines (Applications for Grant of Product Licences-Products for...
18. In the Specified Animal Pathogens Order 1993, in sub-paragraph (a)...
19. In the Drinking Water in Containers Regulations 1994, in paragraph...

20. In the Medicines (Advertising) Regulations 1994— (a) in paragraph (1)...
21. In the General Product Safety Regulations 1994, in regulation 11(c)(ii) (aa),...
22. In the Medicines (Restrictions on the Administration of Veterinary Medicinal...

Explanatory Note