STATUTORY INSTRUMENTS

1997 No. 322

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

PART IV

CONTROLS

Restrictions on the marketing of products

18. No person shall market a product on or after 1st September 1997 unless the product is registered and complies with the Article 8 dossier relating to it.

Duties on persons responsible for marketing registered products

19. The person responsible for marketing a registered product shall comply with the applicable requirements of Articles 14, 35 and 42.2 of Directive 81/851 in connection with such product.

Prohibition on supply and withdrawal from the market

20. A person on whom a notice is served under regulation 10(1) in relation to the supply of a product or its withdrawal from the market, or of particular batches, shall comply with the terms of the notice.

Labelling and package inserts

21. No person shall market a registered product unless the labelling and any package insert complies with the applicable requirements specified in Articles 2.2 and 7.2 of the Homoeopathics Directive.

Restrictions on the manufacture of products

22. No person shall manufacture a product on or after 1st September 1997 unless it is registered and he holds an Article 24 authorisation relating to its manufacture, and the manufacture is in accordance with the authorisation.

Restrictions on imports of products from third countries

23. No person shall import a product from a third country on or after 1st September 1997 unless it is registered and he holds an Article 24 authorisation relating to its import, and the import is in accordance with the authorisation.

Restrictions on exports of certain products to EEA States

24. If a product has been imported into the United Kingdom from a third country and is destined for an EEA State, no person shall export it to an EEA State on or after 1st September 1997 unless

it is accompanied by a copy of the Article 24 authorisation relating to the import of the product into the United Kingdom.

Duties on holders of Article 24 authorisations

25. The holder of an Article 24 authorisation shall—

(a) comply with the applicable provisions of Article 27(a) to (e) of Directive 81/851;

(b) comply with the applicable principles and guidelines of good manufacturing practice set out in Articles 4 to 14 of Directive 91/412 as interpreted in accordance with the second paragraph of Article 3 of that Directive;

(c) keep a detailed record, in accordance with the provisions of Article 27(g) of Directive 81/851, in respect of a registered product or sample of such product supplied by him;

(d) make such record available to the relevant enforcement authority for inspection for a period of three years from and including the date on which such record is made;

(e) have permanently and continuously at his disposal the services of at least one qualified person (who may be himself if he fulfils the conditions laid down in Article 31 of Directive 81/851) who is responsible in particular for carrying out the duties specified in Article 30 of Directive 81/851; and

(f) furnish the relevant enforcement authority, upon request, with proof that he has carried out the applicable control tests specified in Article 35 of Directive 81/851.

Duties on qualified persons

26.—(1) A qualified person shall carry out the duties specified in Article 30 of Directive 81/851.

(2) Where the qualified person certifies a batch of a registered product in a register or equivalent document in accordance with Article 30.2 of Directive 81/851, he shall keep the register or equivalent document at the disposal of the relevant enforcement authority for a period of five years from and including the date on which the certification is made.

Suspension of persons acting as qualified persons

27.—(1) Where it appears to the Ministers that a person acting as a qualified person—

(a) does not satisfy the requirements of Article 31 or 32 of Directive 81/851, or

(b) has failed to comply with regulation 26,

the Ministers shall serve a notice complying with the provisions of paragraph (2) on that person (in this regulation called"the notified person").

(2) A notice served under paragraph (1) shall—

(a) notify the person on whom it is served that the Ministers propose to serve a suspension notice on him directing him not to act as a qualified person,

(b) state the reasons why the Ministers are proposing to serve such a notice, and

(c) specify that, on or before the response date specified in the notice, the notified person may make written representations to the Ministers in connection with such proposed notice or reasons.

(3) Where the Ministers decide not to serve a suspension notice on a notified person they shall notify him of their decision.

(4) Where the Ministers decide to serve a suspension notice on a notified person, they shall serve a notice on him directing him not to act as a qualified person.

(5) A suspension notice served on a notified person under paragraph (4) may be revoked at any time by the Ministers serving a notice on the notified person notifying him that he may resume acting as a qualified person.

(6) During the period in which a suspension notice is in force in relation to a notified person—

(a) that person shall not act as a qualified person, and

(b) no other person shall permit that person to act for him as a qualified person.