STATUTORY INSTRUMENTS

1997 No. 322

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

PART V

MISCELLANEOUS AND SUPPLEMENTAL PROVISIONS

Confidentiality

28. Except in the performance of his duty, no person shall disclose any information in respect of any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of these Regulations, or any information obtained by him or furnished to him in pursuance of these Regulations.

Issue of certificates

29. Where requested to do so by—

(a) a manufacturer of a registered product who holds an Article 24 authorisation,

(b) the exporter of a product manufactured by such a manufacturer, or

(c) the authorities of a third country into which such a product is to be imported,

the Ministers shall certify that the manufacturer is in possession of an Article 24 authorisation.

Article 34 duties

30. It shall be the duty of the relevant enforcement authority to comply with Article 34 of Directive 81/851.

Enforcement

31. It shall be the duty of the relevant enforcement authority to enforce the provisions of these Regulations, and such duty shall be deemed to be a duty imposed by sections 108(1), 109(1) and 110(1) of the Act.

Offence and penalties

32.—(1) Any person who contravenes or fails to comply with any provision of regulation 18, 20 or 28 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Any person who contravenes or fails to comply with any provision of regulation 19, 21 to 26 or 27(6) shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(3) Where a Scottish partnership is guilty of an offence under these Regulations in respect of an act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner in the partnership, he, as well as the partnership, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Defence

33. Where a person responsible for marketing a registered product is charged with an offence under these Regulations in respect of anything which has been manufactured or assembled to his order by another person and which has been so manufactured or assembled as not to comply with his order, it shall be a defence for him to prove—

(a) that, in placing his order, a copy of the documents forming part of the Article 8 dossier relating to the manufacture and assembly of the product were available, or had been provided, to that other person and the person responsible for marketing the registered product had instructed that other person to manufacture or assemble the product in accordance with those documents or dossier, and

(b) that the person responsible for marketing the registered product did not know, and could not by the exercise of reasonable care have known, that those instructions had not been complied with.

Application of various sections of the Act

34.—(1) Only the provisions of the Act specified in Schedule 5, instruments made under those provisions and any other provision of the Act which relates to those provisions shall apply in relation to products to which these Regulations apply, and those provisions and instruments shall apply in relation to those products as if they were medicinal products to which the Act applies (whether or not they would otherwise be so).

(2) It shall be a duty of the Commission to consider any matter referred to them by the Ministers in accordance with the provisions of regulation 11(1) and Schedule 2, and to report their findings and advice in connection with any such matter, and their reasons for giving such advice, to the Ministers.

(3) It shall be a duty of the Board to consider any matter referred to them by the Ministers in accordance with the provisions of regulation 11(1) and Schedule 2, and to report their findings and advice in connection with any such matter, and their reasons for giving such advice, to the Ministers.

Partial disapplication of various enactments

35.—(1) Anything which, in accordance with the Trade Descriptions Act 1968(**1**), constitutes the application of a trade description to a registered product shall be deemed not to be a trade description if it is applied to such product in accordance with the requirements of regulation 21.

(2) The provisions of Part II of the Consumer Protection Act 1987(**2**) shall not apply to registered products.

Disapplication of various statutory instruments

36. The provisions of—

(a) the Importation of Animal Products and Poultry Products Order 1980(**3**),

(b) the Landing of Carcasses and Animal Products Order (Northern Ireland) 1985(**4**),

(**1**) 1968 c. 29.
(**2**) 1987 c. 43, to which there are amendments not relevant to these Regulations.
(**3**) S.I.1980/14, to which there are amendments not relevant to these Regulations.
(**4**) S.R. 1985 No. 161.

(c) the Control of Pesticides Regulations 1986(**5**),

(d) the Control of Pesticides Regulations (Northern Ireland) 1987(**6**), and

(e) the Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996(**7**),

shall not apply to registered products.

Amendment

37. The instrument specified in Schedule 6 shall have effect subject to the amendments specified in that Schedule.

(**5**) S.I. 1986/1510, to which there are amendments not relevant to these Regulations.
(**6**) S.R. 1987 No. 414.
(**7**) S.R. 1996 No. 81.