STATUTORY INSTRUMENTS

1997 No. 322

MEDICINES

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997

Made - - - -	*12th February 1997*
Laid before Parliament	*18th February 1997*
Coming into force - -	*31st March 1997*

The Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to medicinal products, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

PART I

GENERAL

Title and commencement

1. These Regulations may be cited as the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 and shall come into force on 31st March 1997.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968(**3**);

"Article 24 authorisation" means an authorisation of the type specified in Article 24.1 of Directive 81/851;

"Article 8 documents" means the particulars and documents specified in Article 8 of the Homoeopathics Directive;

(**1**) S.I.1972/1811.
(**2**) 1972 c. 68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the Europen Economic Area Act 1993 (c. 51).
(**3**) 1968 c. 67.

"Article 8 dossier" means the Article 8 documents on which a registration relating to a product is based, and—

(a) where the registration relating to a product has been renewed in accordance with regulation 7, the expression shall mean the Article 8 documents as updated by the Article 15 dossier provided in connection with the renewal application, and

(b) where the documents have been altered in accordance with regulation 8, the expression shall mean the Article 8 documents as so altered;

"Article 15 dossier" means a dossier of the type specified in Article 15.1 of Directive 81/851;

"Article 11 ground" means a ground specified in—

(a) sub-paragraph 1 or 3 of the first paragraph, or

(b) the second paragraph,

of Article 11 of Directive 81/851;

"Article 25 particulars" means particulars which meet the requirements of sub-paragraphs (a) to (c) of Article 25 of Directive 81/851, and—

(a) where an Article 24 authorisation has been issued, it shall mean the Article 25 particulars on which such authorisation is based, and

(b) where, following the issue of an Article 24 authorisation, an Article 25 particular is changed in accordance with regulation 15, it shall mean the Article 25 particulars as so changed;

"the Board" means the Advisory Board on the Registration of Homoeopathic Products established by the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995(**4**);

"the Commission" means the Medicines Commission established by the Act;

"Directive 91/851" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**5**) as amended by Council Directives 90/676/EEC(**6**) and 93/40/EEC(**7**) as widened by the Homoeopathics Directive(**8**) and as adapted by the EEA Agreement;

"Directive 91/412" means Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**9**);

"EEA Agreement" means the Agreement on the European Economic Area(**10**) signed at Oporto on 2nd May 1993 as adjusted by the Protocol(**11**) signed at Brussels on 17th March 1993 and as amended by the Decision of the EEA Joint Committee No 7/94(**12**);

"EEA State" means a State which is a contracting party to the EEA Agreement other than the United Kingdom;

"the Homoeopathics Directive" means Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of the provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional

(**4**) S.I. 1995/309.
(**5**) OJ No. L317, 6.11.81, p. 1.
(**6**) OJ No. L373, 31.12.90, p. 15.
(**7**) OJ No. L214, 24.8.93, p. 31.
(**8**) OJ No. L297, 13.10.92, p. 12.
(**9**) OJ No. L228, 17.8.91, p. 70.
(**10**) OJ No. L1, 3.1.94, p. 3.
(**11**) OJ No. L1, 3.1.94, p. 572.
(**12**) OJ No. L160, 28.6.94, p. 1.

provisions on homeopathic veterinary medicinal products(**13**) as adapted by the EEA Agreement;

"homoeopathic veterinary medicinal product" has the meaning given by Article 1 of the Homoeopathics Directive;

"manufacture" includes the activities specified in the first paragraph of Article 24.2 of Directive 81/851 but does not include the activities specified in the second paragraph of that provision;

"the Ministers" means the Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England and the Secretaries of State for Wales and Scotland, the Department of Agriculture for Northern Ireland and the Department of Health and Social Services for Northern Ireland;

"notice" means notice in writing;

"product" means a product to which these Regulations apply by virtue of regulation 3(1);

"qualified person" means a person, other than a person in respect of whom a suspension notice served under regulation 27(4) is in force, who—

(a) fulfils the conditions laid down in Article 31 of Directive 81/851, or

(b) is eligible to act as a qualified person by virtue of Article 32 of that Directive;

"registered" means registered by the Ministers under these Regulations; and

"the relevant enforcement authority" means—

(a) in relation to England, the Minister of Agriculture, Fisheries and Food,

(b) in relation to Scotland and Wales, the Secretary of State, and

(c) in relation to Northern Ireland, the Department of Health and Social Services for Northern Ireland.

(2) The expressions listed in Part I of Schedule 1 have the same meaning as in the Homoepathics Directive, and any other expression which is used in these Regulations and the Homoeopathics Directive, other than an expression which is listed in Part II of Schedule 1, shall have, insofar as the context admits, the same meaning as in that Directive.

(3) The expressions listed in Part II of Schedule 1 have the same meaning as in Directive 81/851.

(4) Any reference in these Regulations to a provision of Directive 81/851 shall mean the specified provision of that Directive as such provision applies to a product by virtue of Article 3, 4 or 7.3 of the Homoeopathics Directive.

(5) Any function conferred on the Ministers under these Regulations may be performed by any one of those Ministers acting alone or by any two or more of them acting jointly.

(6) In these Regulations, unless the context otherwise requires—

(a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation of or the Schedule to these Regulations so numbered in these Regulations,

(b) any reference in a regulation or a Schedule to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which the reference occurs, and

(c) any reference in a paragraph to a numbered or lettered sub-paragraph is a reference to the sub-paragraph so numbered or lettered in the paragraph in which the reference occurs.

(**13**) OJ No. L297, 13.10.92, p. 12.

Homoeopathic veterinary medicinal products to which these Regulations apply

3.—(1) Subject to paragraph (2), these Regulations apply to homoeopathic veterinary medicinal products to which the provisions of the Homoeopathics Directive apply and which satisfy all of the conditions specified in Article 7.1 of that Directive.

(2) These Regulations do not apply to homoeopathic veterinary medicinal products that were marketed in the United Kingdom for the first time before 31st March 1997.

PART II

REGISTRATION OF PRODUCTS

Applications for registration

4.—(1) A person responsible for marketing, or intending to market a product, may apply to the Ministers to register the product.

(2) An application made under paragraph (1) shall be made in writing, in the English language, signed by or on behalf of the applicant, and shall contain the name and address of the applicant and be accompanied by the Article 8 documents relating to the product.

(3) The application may relate to a series of products derived from the same homoeopathic stock or stocks.

Examination of registration applications

5. Where an application is made under regulation 4, the Ministers shall examine it—

(a) in accordance with the criteria and rules of procedure relating to such applications specified in Articles 8 to 12 of Directive 81/851, with the exception, in the case of Article 11, of the proof of therapeutic effect, and

(b) taking account of the matters specified in Article 6.1 of the Homoeopathics Directive.

Registration of products

6.—(1) Subject to regulations 11 and 12, following the examination of an application to register a product pursuant to regulation 5, the Ministers shall register it in accordance with the provisions of Article 15 of Directive 81/851 unless, in their opinion, an Article 11 ground has been established in connection with that product or application.

(2) On registering a product the Ministers shall—

(a) give it a registration number,

(b) determine whether there is a need to exercise or further exercise the powers conferred by section 51, 57 or 58 of the Act concerning the conditions as to the sale or supply of the product, and

(c) publish details of the registration in accordance with the provisions in the second paragraph of Article 40 of Directive 81/851.

(3) Where the Ministers refuse to register a product, they shall notify the applicant in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Renewal of registrations

7.—(1) The registration of a product may be renewed on the application of the person responsible for marketing it.

(2) An application under paragraph (1) shall be made to the Ministers at least three months before the expiry of the registration relating to the product and shall be accompanied by an Article 15 dossier relating to it.

(3) Subject to regulations 11 and 12, following the examination of the application, the Ministers shall renew the registration unless, in their opinion, an Article 11 ground has been established in connection with the product.

(4) Where the Ministers refuse to renew a registration, they shall notify the applicant in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Alteration of Article 8 dossiers relating to registered products

8.—(1) An application for authorisation to make an alteration to an Article 8 dossier relating to a registered product may be made to the Ministers by the person responsible for marketing the product and shall be accompanied by full details of the proposed alteration.

(2) Where an application is made under paragraph (1), the Ministers shall authorise the proposed alteration unless, in their opinion, the making of the alteration would result in an Article 11 ground being established in connection with that product.

(3) Where the Ministers authorise a proposed alteration of an Article 8 dossier, they shall make any necessary amendments to the registration.

Suspension and revocation of registrations

9.—(1) Subject to paragraph (3) and regulations 11 and 12, the Ministers shall suspend or revoke the registration of a registered product if in their opinion a ground specified in sub-paragraph 1 or 3 of the first paragraph of Article 36 of Directive 81/851 has been established in connection with the product.

(2) Subject to paragraph (3), the Ministers may suspend or revoke the registration of a registered product if in their opinion a ground specified in the last paragraph of Article 36 of Directive 81/851 has been established in connection with the product.

(3) Where the Ministers suspend or revoke the registration of a registered product under paragraph (1) or (2), they shall notify the person responsible for marketing the product in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851 and shall comply with the publication requirements of the second paragraph thereof.

Prohibition and withdrawal notices

10.—(1) Subject to the paragraph (2) and to regulations 11 and 12, if in the opinion of the Ministers a ground specified in paragraph (a), (c) or (e) of Article 37.1 of Directive 81/851 has been established in connection with a product they shall serve a notice on the person responsible for marketing the product requiring that person to stop supplying the product and to withdraw it from the market.

(2) A notice served under paragraph (1) may relate to the registered product in general or to a specific batch of the product as specified in the notice.

Procedure where the Ministers propose to take certain action on grounds relating to safety or quality

11.—(1) Subject to paragraph (2), if the Ministers propose—

(a) to refuse a registration;

(b) to refuse to renew a registration;

(c) to suspend or revoke a registration; or

(d) to serve a notice under regulation 10(1) in respect of a product;

on a ground that concerns the safety or quality of the product in question, the provisions of Schedule 2 shall have effect.

(2) The provisions of paragraph (1) shall not apply where the Ministers propose to refuse to register a product, or to refuse to renew or to suspend or revoke its registration on the ground specified in sub-paragraph 3 of the first paragraph of Article 11 of Directive 81/851.

Procedure where the Ministers propose to take certain action on grounds other than grounds relating to safety or quality

12.—(1) Subject to paragraph (2), if the Ministers propose to act in a manner specified in sub-paragraphs (a), (b), (c) or (d) of regulation 11(1) on a ground that does not concern the safety or quality of the product, the provisions of Schedule 3 shall have effect.

(2) The provisions of paragraph (1) shall not apply where the Ministers propose to refuse to register a product, or to refuse to renew or to suspend or revoke its registration on the ground specified in sub-paragraph 3 of the first paragraph of Article 11 of Directive 81/851.

PART III

ARTICLE 24 AUTHORISATIONS

Applications for Article 24 authorisations

13.—(1) A person who—

(a) manufactures or intends to manufacture a registered product, or

(b) imports or intends to import such a product from a third country,

may apply to the Ministers for an Article 24 authorisation relating to the manufacture or import, as the case may be.

(2) An application made under paragraph (1) shall be in writing, in the English language, signed by or on behalf of the applicant, and shall contain the name and address of the applicant and be accompanied by Article 25 particulars.

Issue of Article 24 authorisations

14.—(1) Subject to regulation 17, following inquiry in accordance with Article 26.1 of Directive 81/851, the Ministers shall issue an applicant with an Article 24 authorisation in accordance with the provisions of Article 26.2 and 3 and Article 28.1 and 3 of that Directive unless they are not satisfied that the accuracy of the Article 25 particulars provided by the applicant has been established.

(2) Where the Ministers refuse to issue an Article 24 authorisation, they shall notify the applicant in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Change of Article 25 particulars

15.—(1) A request to change an Article 25 particular on which an Article 24 authorisation is based may be made to the Ministers by the holder of the authorisation.

(2) Where a request is made under paragraph (1), the Ministers shall authorise the change in the Article 25 particulars in accordance with the provisions of Article 28.2 and 3 of Directive

81/851 unless they are not satisfied that the authorisation holder will continue to meet the relevant requirements of Article 25 of Directive 81/851 if the change in the Article 25 particulars is made.

(3) Where, pursuant to paragraph (2), the Ministers authorise a change in the Article 25 particulars, they shall make any necessary amendments to the Article 24 authorisation in question.

Suspension and revocation of Article 24 authorisations

16.—(1) Subject to paragraph (3) and regulation 17, the Ministers shall suspend or revoke an Article 24 authorisation if they are not satisfied that the authorisation holder is complying with the Article 25 particulars on which the authorisation is based.

(2) Subject to paragraph (3), the Ministers may suspend or revoke an Article 24 authorisation—

(a) in relation to all registered products to which the authorisation relates, or

(b) in relation to one or some of such products,

if they are not satisfied that the holder of such authorisation has complied with the duties imposed on him by regulation 25.

(3) Where, pursuant to paragraph (1) or (2), the Ministers suspend or revoke an Article 24 authorisation they shall notify the authorisation holder in accordance with the provisions of the first paragraph of Article 40 of Directive 81/851.

Procedure where the Ministers propose to refuse Article 24 authorisations or to suspend or revoke such authorisations

17. If the Ministers propose to refuse to issue or to suspend or revoke an Article 24 authorisation the provisions of Schedule 4 shall have effect.

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.

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(**14**), 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(**15**) 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(**16**),

(b) the Landing of Carcasses and Animal Products Order (Northern Ireland) 1985(**17**),

(c) the Control of Pesticides Regulations 1986(**18**),

(d) the Control of Pesticides Regulations (Northern Ireland) 1987(**19**), and

(e) the Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996(**20**),

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.

Angela Browning
Parliamentary Secretary, Ministry of Agriculture, Fisheries and Food

11th February 1997

Lindsay
Parliamentary Under-Secretary of State, Scottish Office

12th February 1997

(**14**) 1968 c. 29.
(**15**) 1987 c. 43, to which there are amendments not relevant to these Regulations.
(**16**) S.I. 1980/14, to which there are amendments not relevant to these Regulations.
(**17**) S.R. 1985 No. 161.
(**18**) S.I. 1986/1510, to which there are amendments not relevant to these Regulations.
(**19**) S.R. 1987 No. 414.
(**20**) S.R. 1996 No. 81.

SCHEDULE 1 Regulation 2(2) and (3)

INTERPRETATION

PART I

Expressions having the same meaning as in the Homoeopathics Directive

market

person responsible for marketing

homoeopathic stock

PART II

Expressions having the same meaning as in Directive 81/851

batch

detailed record

import

manufacture

permanently and continuously at his disposal

register or equivalent document

sample

third countries

SCHEDULE 2 Regulation 11(1)

PROCEDURE WHERE THE MINISTERS PROPOSE TO TAKE CERTAIN ACTION ON GROUNDS RELATING TO SAFETY OR QUALITY

1. Subject to paragraph 8(1), where the Ministers propose to act in a manner specified in regulation 11(1) (in this Schedule called"the proposed regulation 11(1) action"), the Ministers shall not act in that manner except after consultation with the Board.

2. Where the Board is consulted pursuant to paragraph 1, the Board shall report to the Ministers their advice, and the reasons for their advice.

3. After the Board has reported to the Ministers pursuant to paragraph 2, the Ministers, taking account of that report, may—

(a) finally determine not to take the proposed regulation 11(1) action, or

(b) provisionally determine to take that action.

4. Where the Ministers provisionally determine to take the proposed regulation 11(1) action, they shall not act in that manner except after consultation with the Commission.

5.—(1) Where the Commission is consulted pursuant to paragraph 4, and they have reason to think that—

(a) on an Article 11 ground that concerns the safety or quality of the product, they may have to advise the Ministers that the registration of the product should be refused, or that it should not be registered unless the registration is made subject to certain specific obligations;

(b) on an Article 11 ground that concerns the safety or quality of the product, they may have to advise the Ministers that registration of the product should not be renewed, or that it should not be renewed unless the renewed registration is made subject to certain specific obligations;

(c) on a ground specified in Article 36 of Directive 81/851 that concerns the safety or quality of the product, they may have to advise the Ministers that the registration of the product ought to be suspended or revoked; or

(d) on a ground specified in Article 37.1 of Directive 81/851 that concerns the safety or quality of the product, they may have to advise the Ministers that a notice should be served under regulation 10(1),

the Commission, before giving that advice to the Ministers, shall serve a notice complying with the provisions of sub-paragraph (2) on the applicant, or the person responsible for marketing, as the case may be.

(2) Any notice served under sub-paragraph (1) shall—

(a) notify the person on whom it is served of the advice that the Commission is minded to give to the Ministers,

(b) state the reasons why the Commission is minded to give that advice, and

(c) specify that, on or before the response date specified in the notice, the person on whom the notice is served may make written representations to the Commission with respect to the advice or reasons.

6. Where the Commission is consulted pursuant to paragraph 4, the Commission shall report to the Ministers their findings and advice, and the reasons for their advice, and, in a case where a notice has been served under paragraph 5(1), they shall make that report after considering any written representation made to them on or before the response date specified in that notice.

7. After the Commission has reported to the Ministers pursuant to paragraph 6, the Ministers shall take that report into account in finally determining whether to take the proposed regulation 11(1) action.

8.—(1) The provisions of paragraph 1 shall not apply where the Ministers consider that it is necessary to take action of the type specified in regulation 11(1)(c) or (d) urgently in order to protect human or animal health or the environment.

(2) Where urgent action is taken by the Ministers, they shall—

(a) consult the Board within three months of taking the action, and

(b) comply with such of the provisions of this Schedule as are applicable in the circumstances to that action.

SCHEDULE 3

Regulation 12(1)

PROCEDURE WHERE THE MINISTERS PROPOSE TO TAKE CERTAIN ACTION ON GROUNDS OTHER THAN GROUNDS RELATING TO SAFETY OR QUALITY

1.—(1) Where the Ministers propose to act in a manner specified in regulation 12(1) (in this Schedule called "the proposed regulation 12(1) action"), the Ministers shall not take such action

unless, before doing so, they serve a notice complying with the requirements of sub-paragraph (2) on the applicant, or the person responsible for marketing the product, as the case may be.

(2) A notice served by the Ministers under sub-paragraph (1) shall—

(a) state what regulation 12(1) action the Ministers propose to take,

(b) state their reasons for proposing to take such action, and

(c) specify that, on or before the response date specified in such notice, the person on whom such notice is served make written representations to the Ministers with respect to the proposed action.

(2) Where a person on whom a notice is served makes written representations to the Ministers on or before the response date specified in the notice, the Ministers shall consider those representations before determining whether to take the proposed regulation 12(1) action.

SCHEDULE 4

Regulation 17

PROCEDURE WHERE THE MINISTERS PROPOSE TO REFUSE ARTICLE 24 AUTHORISATIONS OR TO SUSPEND OR REVOKE SUCH AUTHORISATIONS

1.—(1) Where the Ministers propose to act in a manner specified in regulation 17 (in this Schedule called "the proposed regulation 17 action"), the Ministers shall not take such action unless, before doing so, they serve a notice complying with the requirements of sub-paragraph (2) on the applicant or the authorisation holder, as the case may be.

(2) A notice served by the Ministers under sub-paragraph (1) shall—

(a) state what regulation 17 action the Ministers propose to take,

(b) state their reasons for proposing to take such action, and

(c) specify that, on or before the response date specified in such notice, the person on whom such notice is served may make written representations to the Ministers with respect to proposed action.

2. Where a person on whom such notice is served under paragraph 1(1) makes written representations to the Ministers on or before the response date specified in the notice, the Ministers shall consider those representations before determining whether to take the proposed regulation 17 action.

SCHEDULE 5

Regulation 34

APPLICATION OF VARIOUS SECTIONS OF THE ACT

sections 51 to 54 (provisions as to sale or supply of medicinal products)

sections 55 to 57 (exemptions from sections 52 and 53 of the Act)

sections 58 and 59 to 61 (additional provisions)

section 67 (offences)

sections 92 to 95 and 97 (promotion of sales of medicinal products)

section 107 (validity of decisions and proceedings relating thereto)

section 108 to 110 (enforcement)

section 111 (rights of entry)

section 112 (powers to inspect, take samples and seize goods and documents)

section 113 (application of sampling procedures)

section 114 (supplementary provisions as to rights of entry and related rights)

section 115 (analysis of samples in other cases)

section 119 (protection for officers of enforcement authorities)

section 121 (contravention due to default of other person)

section 122 (warranty as defence)

section 123 (offences in relation to warranties and certificates of analysis)

section 124 (offences by bodies corporate)

section 125 (prosecutions)

section 126 (presumptions)

section 127 (service of documents)

section 129 (order and regulations)

section 132 (general interpretation provisions)

section 133(2) (general provisions as to operation of the Act)

section 134(3), (4) and (5) (special provisions as to Northern Ireland)

Schedule 3 (sampling)

Schedule 4 (provisions relating to Northern Ireland)

SCHEDULE 6

Regulation 37

AMENDMENT

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**21**) shall be amended as follows—

(a) in regulation 2(1)—

(i) the word "and" following the definition of "ready-made veterinary medicinal product" shall be omitted, and the following definition shall be inserted after that definition—

> ""registered homoeopathic veterinary medicinal product" means a homoeopathic veterinary medicinal product registered under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, and", and

(ii) in the definition of "veterinary medicinal product", after the words "to which Article 2.1 of that Directive applies", the words "and shall include a homoeopathic veterinary medicinal product as defined in Article 1.1 of Council Directive 92/74/EEC" shall be inserted,

(b) in regulation 3, after the words "in respect of that product", the words "or the product is a registered homoeopathic veterinary medicinal product" shall be inserted, and

(c) in regulation 5(1)—

(i) for the words "or authorised veterinary medicinal product" the words ", authorised veterinary medicinal product or registered homoeopathic veterinary medicinal product" shall be substituted, and

(**21**) S.I. 1994/2987, amended by S.I. 1994/3142.

(ii) in sub-paragraph (a), after the words "in the same species", the words "or a registered homoeopathic veterinary medicinal product registered for administration to another animal species" shall be inserted.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which come into force on 31st March 1997, implement the provisions of Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products (OJNo. L297, 13.10.92, p. 12) insofar as they relate to homoeopathic veterinary medicinal products that satisfy all of the conditions specified in Article 7.1 of that Directive ("products").

The Regulations apply to products other than those that were marketed in the United Kingdom for the first time before 31st March 1997 (regulation 3).

The principal provisions of the Regulations—

(a) include provisions relating to applications for the registration of products to which the Regulations apply ("relevant products") (regulation 4), the renewal of such registrations (regulation 7), the alteration of dossiers on which registrations are based (regulation 8) , the suspension and revocation of registrations (regulation 9) and the service of prohibition and withdrawal notices relating to registered products (regulation 10);

(b) include provisions relating to applications for the grant of authorisations ("Article 24 authorisations") authorising the manufacture of registered products and the import of such products from third countries (regulation 13) and the suspension and revocation of such authorisations (regulation 16);

(c) prohibit the marketing of a relevant product on or after 1st September 1997 unless it is registered and complies with the dossier on which its registration is based (regulation 18);

(d) lay down requirements relating to the labelling of registered products and their package inserts (regulation 21);

(e) prohibit the manufacture of a relevant product, or the import of such a product from a third country, on or after 1st September 1997 unless the product is registered, an Article 24 authorisation has been obtained authorising its manufacture or import and its manufacture or import is in accordance with that authorisation (regulations 22 and 23);

(f) lay down requirements relating to the export of specified registered products to other EEA States (regulation 24);

(g) provide for the enforcement of the Regulations (regulation 31);

(h) make the contravention, or failure to comply with, provisions of specified regulations a criminal offence (regulation 32);

(i) apply specified provisions of the Medicines Act 1968 (c. 67) to relevant products (regulation 34); and

(j) disapply certain provisions of the Trade Descriptions Act 1968 (c. 29) and Part II of the Consumer Protection Act 1987 (c. 43) in relation to registered products (regulation 35).

A Compliance Cost Assessment has been prepared and a copy has been placed in the library of each House of Parliament. Copies can be obtained from the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3NB.