STATUTORY INSTRUMENTS

1994 No. 3142

MEDICINES

The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994

Made - - - -	*5th December 1994*
Laid before Parliament	*9th December 1994*
Coming into force - -	*1st January 1995*

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:

Title, commencement and interpretation

1.—(1) These Regulations, which implement parts of:

Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**3**);

Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products(**4**);

Council Directive 90/676/EEC amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**5**);

Council Directive 90/677/EEC extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products(**6**);

Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**7**);

(**1**) S.I. 1972/1811.
(**2**) 1972 c. 68.
(**3**) OJ No. L317, 6.11.81, p.1.
(**4**) OJ No. L317, 6.11.81, p.16 as amended by Council Directive 87/20/EEC (OJ No. L15, 17.1.87, p.34) and Commission Directive 92/18/EEC (OJ No. L97, 10.4.92, p.1).
(**5**) OJ No. L373, 31.12.90, p.15.
(**6**) OJ No. L373, 31.12.90, p.26.
(**7**) OJ No. L228, 17.8.91, p.70.

Commission Directive 92/18/EEC modifying the Annex to Council Directive 81/852/EEC(**8**);

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(**9**);

Council Regulation 2309/93/EEC laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(**10**); and

Council Directive 93/40/EEC amending Directives 81/851/EEC and 81/852/ EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**11**);

may be cited as the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 and shall come into force on 1st January 1995.

(2) These Regulations shall apply in respect of products to which Council Directive 81/851/EEC applies by virtue of article 2 of that directive, including products intended for the uses set out in article 3 of that directive, but do not apply to products specified in article 1.3 or 1.4 of Council Directive 90/677/EEC.

(3) These Regulations shall apply to homeopathic veterinary medicinal products other than those specified in article 7 of Council Directive 92/74/EEC.

(4) In these Regulations, unless the context otherwise requires, any expressions used have the meaning they bear in Council Directives 81/851/EEC and 90/677/EEC and Council Regulation 2309/93/EEC;

"the appropriate committee" has the meaning assigned by section 4(6) of the Medicines Act 1968(**12**);

"the commission" means the Medicines Commission established by the Medicines Act 1968;

"marketing authorisation" means an authorisation to place on the market a veterinary medicinal product to which these Regulations apply;

"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.

(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) Any reference in these Regulations to a directive is to that directive as amended.

Circumstances in which these Regulations do not apply

2.—(1) These Regulations shall not apply to the placing on the market of veterinary medicinal products prepared extemporaneously in the circumstances described in article 4.4(c) of Council Directive 81/851/EEC.

(2) These Regulations shall not apply to the placing on the market of veterinary medicinal products under sections 32 to 39 of the Medicines Act 1968.

(**8**) OJ No. L97, 10.4.92, p.1.
(**9**) OJ No. L297, 13.10.92, p.12.
(**10**) OJ No. L214, 24.8.93, p.1.
(**11**) OJ No. L214, 24.8.93, p.31.
(**12**) 1968 c. 67.

(3) These Regulations shall not apply to any product which by virtue of regulation 19(1) below continues to have a product licence under section 7 of the Medicines Act 1968 so long as that licence remains in force.

Placing veterinary medicinal products on the market

3. No person shall place on the market, or have in his possession for the purposes of placing on the market, any veterinary medicinal product unless a marketing authorisation (or, in the circumstances described in article 4.1, third paragraph of Council Directive 81/ 851/EEC, an allowance within the terms of that paragraph) has been granted—

(a) by the Ministers, or

(b) in accordance with Council Regulation 2309/93/EEC,

and it is placed on the market in accordance with such authorisation or allowance.

Form and manner of application

4.—(1) Every application for a marketing authorisation by the Ministers shall be made to them in accordance with this regulation.

(2) The application shall be in writing, in the English language and signed by the applicant.

(3) The applicant shall supply four copies of each application, and shall supply a further twenty-two copies if the Ministers so direct.

(4) The application shall be—

(a) as specified in articles 5, 5a, 6 and 7 of Council Directive 81/851/EEC (or, in the case of an application for authorisation of a product already authorised in another member State, may be in accordance with article 17 of that directive) and in accordance with the Introduction to the Annex to Council Directive 81/ 852/EEC, or

(b) in the circumstances described in article 15.2 of Council Directive 81/851/EEC, shall be accompanied by all relevant data available to the applicant.

(5) If the application is in respect of a product which is not an immunological product the application shall in addition be in accordance with the requirements of Schedule 1 to these Regulations.

(6) If the application is in respect of an immunological product, the application shall in addition be in accordance with the provisions of article 2 of Council Directive 90/677/ EEC and the requirements of Schedule 2 to these Regulations.

(7) In the case of a product which the applicant intends to import from outside the European Economic Area, the application shall in addition be in accordance with article 25 of Council Directive 81/851/EEC.

(8) An applicant shall not be required, by virtue of paragraph 10 of article 5 of Council Directive 81/851/EEC, to provide the results of toxicological and pharmacological tests and clinical trials if he can demonstrate that he is entitled to the benefit of any of sub-paragraphs (a)(i) to (iii) thereof.

(9) The preceding paragraph shall not apply where the applicant claims the benefit of article 5.10(a)(iii) of Council Directive 81/851/EEC, unless the product authorised within the European Community to which the applicant refers has been so authorised for a period of not less than ten years before the making of the application.

Grant of an authorisation

5. The Ministers shall consider an application for, and where appropriate grant, a marketing authorisation for a veterinary medicinal product—

(a) in accordance with articles 4.2, 5b, 8 to 11, 15, 36.3, 40, 41, 42.1 and 43 of Council Directive 81/851/EEC, and, as appropriate, in accordance with article 12 of that directive and Title I, Part 4, Chapter II. 1, sixth paragraph of the Annex to Council Directive 81/852/EEC, or

(b) in the case of a product already authorised in another member State, in accordance with article 4.1, second paragraph, or articles 4.2, 8, 8a, 40 and 41 and Chapter IV of Council Directive 81/851/EEC,

and in both cases, where appropriate, in accordance with article 4 of Council Directive 90/677/EEC.

Duties on persons responsible for placing products on the market

6.—(1) After a marketing authorisation has been issued, the person responsible for placing a veterinary medicinal product on the market shall comply with:

(a) articles 5.2.13, 14, 15, 42.2, 42c, 42d and 43 to 48 of Council Directive 81/851/ EEC;

(b) the third paragraph of the introduction to the Annex to Council Directive 81/ 852/EEC and, if appropriate, the final paragraph of Title I, Part 4, Chapter II.1 and the final paragraph of Title I, Part 4, Chapter III, 2.1 of Council Directive 81/852/EEC;

(c) if appropriate, articles 2 and 3 of Council Directive 90/677/EEC;

(d) any direction given by the Ministers in accordance with article 37 of Council Directive 81/851/EEC; and

(e) the requirement in article 35 of Council Directive 81/851/EEC to provide the data specified in that article.

(2) In addition to the requirements in the provisions referred to in the preceding paragraph relating to information to be provided on labels and package inserts, the holder of a marketing authorisation shall ensure that labels and package inserts—

(a) include the words “store out of reach of children”;

(b) include the following initials in a box within which there is no other written material:

(i) in the case of a product categorised under the Medicines Act 1968 as a medicinal product on prescription only (that is, a prescription only medicine), the capital letters “POM”;

(ii) in the case of a product categorised under that Act as a Pharmacy and Merchants' List product, the capital letters “PML”;

(iii) in the case of a product categorised under that Act as a medicinal product on a general sale list, the capital letters “GSL”;

(iv) in any other case the capital letter “P”;

(c) do not include any reference to the Medicines Act 1968, the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, any committee established under section 4 of the Medicines Act 1968, the Medicines Commission or the Committee for Veterinary Medicinal Products;

(d) do not refer to any other product except in accordance with the marketing authorisation; and

(e) do not falsely describe the product, or mislead as to its nature, quality, uses or effects.

Products manufactured outside the European Economic Area

7.—(1) Where a product to which a marketing authorisation relates is to be imported from outside the European Economic Area, the holder of that authorisation shall comply with article 27(c) of Council Directive 81/851/EEC and shall obtain an undertaking, given by the manufacturer of the product, that the manufacturer will comply with the provisions of this regulation.

(2) The manufacturer shall comply with any conditions attached to the authorisation.

(3) The manufacturer shall comply with the provisions of paragraphs (a), (b) (d) and (e) of article 27 of Council Directive 81/851/EEC.

(4) In accordance with article 35 of Council Directive 81/851/EEC, the manufacturer shall give to the Ministers on request the data specified in that article.

(5) Subject to the following paragraph, the manufactuerer shall comply with the principles and guidelines of good manufacturing practice as set out in articles 4 to 14 of Commission Directive 91/412/EEC, and such principles and guidelines shall be interpreted in accordance with article 3, second paragraph of that directive.

(6) In order to comply with the provisions of article 12 of Commission Directive 91/412/EEC, the manufacturer shall ensure that the terms of the contract require that the contractor complies with the requirements of article 12.3 and 12.4 of that directive.

Duties on an importer who holds a marketing authorisation

8.—(1) Where the holder of a marketing authorisation imports the products to which the authorisation relates from outside the European Economic Area, he shall comply with the provisions of this regulation.

(2) He shall have permanently and continuously at his disposal the services of at least one Qualified Person, who satisfies the requirements as to qualifications and experience set out in article 31 of Council Directive 81/851/EEC, or who is permitted to act as a Qualified Person by virtue of the provisions of article 32 of that directive.

(3) He may himself undertake the duties of the Qualified Person if he satisfies the provisions of article 31 or 32 of that directive.

(4) The Qualified Person shall be responsible in particular for carrying out the duties specified in article 30.1(a) and 30.1(b) of that directive, and article 30.2 of that directive.

(5) Where, after the holder of the marketing authorisation and the person acting as Qualified Person have been given the opportunity to make written or oral representations, the Ministers have served written notice on the holder of the marketing authorisation stating that the person acting as Qualified Person does not satisfy the requirements of article 31 or 32 of Council Directive 81/851/EEC, or that the person has failed to carry out the duties required by this regulation, which notice has not been withdrawn, the holder of the marketing authorisation shall not permit that person to act as a Qualified Person for him.

Variations of authorisations

9. The Ministers may, on the application of the holder of a marketing authorisation, vary the conditions relating to the authorisation in accordance with any proposals contained in the application, if they are satisfied that the variation will not adversely affect the safety, quality or efficacy of a product of any description to which the authorisation relates.

Renewals of authorisations

10.—(1) Every application for renewal of a marketing authorisation by the Ministers shall be made to them in accordance with this regulation.

(2) The application shall be in accordance with article 15 of Council Directive 81/851/ EEC, and shall be submitted not earlier than five months before the expiry date of the existing authorisation.

(3) The application shall include any information required under articles 5, 5a, 6 and 7 of Council Directive 81/851/EEC and the relevant parts of the Annex to Council Directive 81/852/EEC which has not previously been submitted to the Ministers.

(4) Where an application for the renewal of a marketing authorisation has been made under this regulation, the marketing authorisation shall remain in force pending the decision of the Ministers.

Suspension and revocation

11. The Ministers may suspend or revoke a marketing authorisation in accordance with articles 36, 37, 38.2, 41, 42h and 49 of Council Directive 81/851/EEC, and shall do so in accordance with article 40 of that directive.

Refusal, etc., of a marketing authorisation on grounds relating to safety, quality or efficacy

12.—(1) If, in the circumstances where there will be no right of appeal under article 21.4 of Council Directive 81/851/EEC, the Ministers propose—

(a) acting in accordance with regulation 5(a) above to refuse to grant a marketing authorisation on any grounds relating to safety, quality or efficacy, or

(b) acting in accordance with regulation 11 above to suspend or revoke an authorisation on those grounds,

they shall consult the appropriate committee or, if for the time being there is no such committee, with the commission in accordance with Schedule 3, and shall take account of their advice in coming to a decision; but this paragraph shall not apply if the Ministers are acting in accordance with article 11.3 or 36.3 of Council Directive 81/851/EEC.

(2) Such consultation shall take place before Ministers act except that when, in relation to paragraph (1)(b) above, Ministers consider urgent action necessary to protect human or animal health or the environment, it shall take place within three months of their acting.

(3) If the Ministers propose to determine the issue in a way which differs from the advice of the commission (or, where there has been no hearing before and no representations have been made or referred to the commission, the appropriate committee) they shall notify the applicant or authorisation holder accordingly, and, before determining the issue, shall afford him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the Ministers, or of making representations in writing to the Ministers with respect to that proposal.

(4) Any notification given to the applicant or authorisation holder under the preceding paragraph shall state the advice of the commission or of the appropriate committee and the reasons stated by the commission or the committee for giving that advice, the proposals of the Ministers and the reasons for them.

(5) Where the applicant or authorisation holder avails himself of the opportunity of appearing before, and being heard by, a person appointed for the purpose—

(a) the person so appointed shall not, except with the consent of the applicant or authorisation holder, be an officer or servant of any of the Ministers;

(b) if the applicant or authorisation holder so requests, the hearing shall be in public; and

(c) if the applicant or authorisation holder so requests, the Ministers shall furnish to him a copy of the report of the person so appointed.

Refusal, etc., of a marketing authorisation on other grounds

13.—(1) If, in the circumstances where there is no right of appeal under article 21.4 of Council Directive 81/851/EEC, the Ministers propose—

(a) acting in accordance with regulation 5(a) above to refuse to grant a marketing authorisation on any grounds not relating to safety, quality or efficacy, or

(b) acting in accordance with regulation 11 above to suspend or revoke an authorisation on grounds not relating to safety, quality or efficacy,

then before doing so they shall serve notice on the applicant or authorisation holder stating their proposals and the reasons for them and specifying a time within which he may apply to a person appointed by the Ministers under this regulation; except that this paragraph shall not apply if the Ministers are acting in accordance with article 11.3 or 36.3 of Council Directive 81/851/EEC.

(2) If, within the time allowed after the service of a notice under this regulation, the applicant or authorisation holder gives notice to the Ministers of his desire to be heard by the appointed person, or makes representations in writing to the Ministers with respect to their proposals, then, before determining the issue, the Ministers shall afford to him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the Ministers, or shall take those representations into account.

(3) When a person is appointed under this regulation, the provisions of regulation 12(5) above have effect.

Confidentiality

14. Except in the performance of his duty, no person shall disclose—

(a) 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

(b) any information obtained by him or furnished to him in pursuance of these Regulations.

Fees

15. The provisions of the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1994(**13**) shall apply to marketing authorisations granted by the Ministers as they apply to product licences granted under the Medicines Act 1968(**14**); and for the purposes of those Regulations, any notification to the Ministers of information which requires authorisation in accordance with the first paragraph of article 14.1 or article 14.4 of Council Directive 81/851/EEC shall be treated as an application for the variation of the authorisation.

Offences and penalties

16.—(1) Any person contravening any provision of regulation 3, 6, 7, 8, or 14 of these Regulations shall be guilty of an offence and liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(2) Where a Scottish partnership is guilty of an offence under these Regulations in respect of any 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.

(**13**) S.I. 1994/1554.
(**14**) 1968 c. 67.

Defence

17. Where the holder of a marketing authorisation 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 has been so manufactured or assembled as not to comply with the provisions of that authorisation, it shall be a defence for him to prove—

(a) that he had communicated the provisions relating to the authorisation to that other person, and

(b) that he did not know, and could not by the exercise of reasonable care have known, that those provisions had not been complied with.

Application of the Medicines Act 1968, the Trade Descriptions Act 1968 and the Consumer Protection Act 1987 to marketing authorisations

18.—(1) Section 7 of the Medicines Act 1968 (which requires, inter alia, the products to which these Regulations apply to be the subject of product licences) shall not apply to the placing on the market of a veterinary medicinal product to which these Regulations apply except for those products which are to retain product licences by virtue of the provisions of regulation 19(1) below.

(2) The following provisions of the Medicines Act 1968 and instruments made under those provisions shall apply in relation to marketing authorisations as they apply in relation to product licences granted under that Act:

section 23 (special provisions as to effect of manufacturer's licence);

section 40 (medicated animal feeding stuffs);

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

sections 55 to 57 (exemptions from sections 52 and 53);

sections 58 to 63 (additional provisions);

sections 67 and 68 (offences and provision for disqualification);

sections 85 and 86 (labelling and marking);

sections 92 to 97 (promotion of sales of medicinal products);

sections 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);

section 115 (analysis of samples);

section 119 (protection of officers of enforcement authorities);

section 121 (contravention due to default of another person);

section 122 (warranty as defence);

section 123 (offences in relation to warranties);

section 124 (offences by bodies corporate);

section 125 (prosecutions);

section 126 (presumptions);

section 127 (service of documents);

section 132 (interpretation);

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

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

(3) In sections 3 and 4 of the Medicines Act 1968, which relate to the commission and committees, any function of the commission or a committee relating to product licences shall apply to marketing authorisations in the same way as they apply to licences.

(4) In sections 32 to 39 of the Medicines Act 1968, which relate to animal tests, a marketing authorisation granted under these Regulations shall be sufficient for any requirement in those sections that any person must be in possession of a product licence.

(5) The provisions of the Trade Descriptions Act 1968(**15**) shall apply to the application of a trade description to goods subject to a marketing authorisation in the same way as, by virtue of section 2(5)(b) of that Act, they apply to the application of a trade description to goods subject to any provision made under Part V of the Medicines Act 1968.

(6) The provisions of the Consumer Protection Act 1987(**16**) shall apply to a product for which a marketing authorisation has been granted in the same way as they apply to a licensed medicinal product as defined in section 19 of that Act.

(7) It shall be the duty of—

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

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

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

to enforce the provisions of these Regulations, and such duty shall be deemed to be a duty imposed by sections 108 to 110 of the Medicines Act 1968 as appropriate.

Transitional Provisions

19.—(1) On 1st January 1995 all existing product licences granted for veterinary medicinal products under the Medicines Act 1968, other than product licences for immunological veterinary medicinal products (except for those granted in response to an application made on or after 1st April 1993, including any application made under the Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993(**17**)) will be deemed to be marketing authorisations granted under these Regulations and shall be subject to the same terms and conditions, except that whenever any report of a suspected adverse reaction is required to be submitted to the Ministers within a period of less than fifteen days, that period shall be extended to fifteen days.

(2) The expiry dates of such marketing authorisations shall be the same date as the date on which the product licence would have expired.

(3) This Regulation shall apply to any licences which on 1st January 1995 continue in force pending renewal under the provisions of section 24(6) of the Medicines Act 1968.

(4) Any product licence which becomes a marketing authorisation by virtue of the operation of this regulation shall be subject to the following additional conditions—

(a) the labels of containers or packages of a veterinary medicinal product categorised under the Medicines Act 1968 as a medicinal product on a general sale list, if they are large enough, or the package insert if they are not, shall bear the words "If signs of disease persist or appear consult your veterinary surgeon or veterinary practitioner"; and

(**15**) 1968 c. 29; the relevant amendment to section 2(5) is in the Medicines Act 1968, Schedule 5, paragraph 16.
(**16**) 1987 c. 43.
(**17**) S.I. 1993/2399.

(b) the labels of containers or packages of a veterinary medicinal product not categorised under that Act as a medicinal product on the general sale list, if they are large enough, or the package insert if they are not, shall, if the product is embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only, bear the words "For external use only".

(5) In the case of a container placed on the market on or after 1st January 1995 but on or before 31st December 1996 and not labelled in conformity with these Regulations, it shall be a defence in any proceedings for a defendant to prove that the container as labelled was in conformity with the relevant legislation current before the coming into force of these Regulations; and the provisions of this paragraph shall apply to package inserts in the same way as it applies to labels.

(6) The requirement for the holder of a marketing authorisation to be established within the European Economic Community shall not apply to the holder of a product licence deemed to be a marketing authorisation under these Regulations until the authorisation is due to be renewed.

Revocations

20. The instruments listed in Schedule 4 to these Regulations are hereby revoked.

Amendments

21. The instruments listed in Schedule 5 to these Regulations are hereby amended in accordance with that Schedule.

Angela Browining
Parliamentary Secretary, Ministry of Agriculture,
2nd December 1994 Fisheries and Food

Signed by authority of the Secretary of State for Health.

Tom Sackville
Parliamentary Under Secretary of State,
5th December 1994 Department of Health

SCHEDULE 1

Regulation 4(5)

REQUIREMENTS IN RESPECT OF PRODUCTS OTHER THAN IMMUNOLOGICAL PRODUCTS

1. The applicant shall comply with all the requirements set out in Parts 1 and 4 of Title I of the Annex to Council Directive 81/852/EEC.

2.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 2 of Title I of the Annex to Council Directive 81/852/EEC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process, and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by them relating to any such modification,

and shall submit the data and confirmation received to the Ministers.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

3. The applicant shall comply with the requirements set out in Part 3 of Title I of the Annex to Council Directive 81/852/EEC, and shall supply a copy of any certificate issued by a laboratory which carried out any such test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in the second paragraph of Part 3.

SCHEDULE 2

Regulation 4(6)

REQUIREMENTS IN RESPECT OF IMMUNOLOGICAL PRODUCTS

1. The applicant shall comply with the requirements set out in Part 5, 7, 8 and 9 of Title II of the Annex to Council Directive 81/852/EEC and shall supply a copy of any certificate issued by a laboratory which carried out a safety test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in paragraph 3 of Section A of Part 7 of that Title.

2.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 6. Title II of the Annex to Council Directive 81/852/EEC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process or specifications, and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by the authority relating to any such modification,

and shall submit the data and confirmations received to the Ministers.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

SCHEDULE 3

Regulation 12

PROCEDURE ON REFERENCE TO APPROPRIATE COMMITTEE OR COMMISSION

1. Where the appropriate committee or the commission consulted under regulation 12 have reason to think that—

(a) they may be unable to advise the Ministers to grant an authorisation,

(b) they may be unable to advise the Ministers to grant it unless it contains provisions otherwise than in accordance with the application, or

(c) they may advise the Ministers to suspend or revoke an authorisation,

the committee or commission shall notify the applicant or authorisation holder accordingly, and, before giving their advice to the Ministers, shall afford to him an opportunity of appearing before and being heard by them, or of making representations in writing to them with respect to those grounds.

2. Whether the applicant or authorisation holder has been heard or has made representations under this Schedule or not, if the appropriate committee or the commission advise the Ministers that the authorisation ought to be refused, suspended or revoked, or ought, if granted, to contain provisions specified in their advice, the Ministers shall provisionally determine the issue taking account of that advice and shall notify the applicant or authorisation holder of such determination and of the advice taken into account, and including in the notification a time within which he can appeal against such determination.

3. If, within the time allowed in the notification of a provisional determination, in a case where the applicant or authorisation holder has not been heard by, or made representations to, the commission under this Schedule, he gives notice to the Ministers of his desire to be heard with respect to the provisional determination or advice given to the Ministers, or makes representations in writing to the Ministers with respect to that provisional determination or advice, then—

(a) if the applicant or authorisation holder has given notice of his desire to be heard, the Ministers shall arrange for him to have an opportunity of appearing before, and being heard by, the commission, or

(b) if he has made representations in writing, the Ministers shall refer those representations to the commission,

after which the commission shall report to the Ministers their findings and advice and the reasons for their advice.

SCHEDULE 4

Regulation 20

REVOCATIONS

Title of instrument	Reference
The Medicines (Leaflets for Veterinary Drugs) Regulations 1983	S.I.1983/1727

Title of instrument	Reference
The Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993	S.I. 1993/2398
The Medicines (Veterinary Medicinal Products) (Applications for Product Licences) (Amendment) Regulations 1994	S.I. 1994/2157

SCHEDULE 5

Regulation 21

AMENDMENTS

1. Article 3 of the Sheep Scab Order (Northern Ireland) 1970(**18**), shall be amended as follows:

(a) in the definition of "approved sheep dip" after the words "product licence" there shall be inserted the words "or marketing authorisation";

(b) after the definition of "fat sheep" there shall be inserted the following—

> ""marketing authorisation" means a marketing authorisation valid in Northern Ireland to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;".

2. In the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971(**19**), there shall be inserted after article 3 the following article—

"**Marketing authorisations**

4. The restriction imposed by regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to veterinary medicinal products which have been imported in the circumstances set out in article 3 of this Order, subject to the conditions of that article and accordingly in the case of marketing authorisations references in that article to the "licensing authority" shall be construed as references to "the Ministers" as defined in the 1994 Regulations."

3. The Medicines (Data Sheet) Regulations 1972(**20**), shall be amended as follows—

(a) in regulation 1 after the definition of "mark" there shall be inserted the following—

> ""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in regulation 2 after the words "product licence" and "product licences", in each place where they occur, there shall be inserted the words "or marketing authorisation" and "or market authorisations" respectively;

(c) in sub-paragraph (c) of regulation 2(5) after the words "the licensing authority" there shall be inserted the words "or, in the case of a marketing authorisation, the Ministers as defined in the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994,";

(**18**) S.R. 1970/240; relevant amending instruments are S.R. 1978/247 and S.R. 1981/311.
(**19**) S.I. 1971/1326 to which there are amendments not relevant to these Regulations.
(**20**) S.I. 1972/2076 to which there are amendments not relevant to these Regulations.

(d) in regulation 4 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(e) in Schedule 3 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation".

4. In the Medicines (Labelling) Regulations 1976(**21**) after regulation 3 there shall be inserted the following regulation—

"**3A.** Other than regulations 9 and 13 below, these Regulations shall not apply in relation to any product placed on the market in accordance with the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994.".

5. In the Medicines (Prohibition of Importation and Possession of Veterinary Drugs) Order (Northern Ireland) 1977(**22**) in article 3(2) after the words "product licence" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

6. The Medicines (Fluted Bottles) Regulations 1978(**23**) shall be amended as follows—

(a) in regulation 1(2) after the definition of "external use" there shall be inserted the following—

""marketing authorisation"means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(b) in regulation 3(g) after the words "a product licence," there shall be inserted the words "marketing authorisation," and after the words "any such licence" there shall be inserted the words "or authorisation".

7. In the Importation of Animal Products and Poultry Products Order 1980(**24**), in the Schedule, after the words "Medicines Act 1968" there shall be inserted the words "or the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994".

8. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**25**), in regulation 5(1) in sub-paragraph (a) after the words "holder of a product licence" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

9. The Medicines (Pharmacy and General Sale — Exemption) Order 1980(**26**) shall be amended as follows—

(a) in article 5(3) after the words "product licence granted under Part II of the Act" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(b) in Schedule I, Part I at point 11 after the words "product licences" in column 1 and after the words "licences" in column 2 there shall be inserted the words "or marketing authorisations to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

10. In the Health and Safety (Dangerous Pathogens) Regulations 1981(**27**), in regulation 2(1) after the words "any substance in respect of which there is in force a" there shall be inserted the

(**21**) S.I. 1976/1726 to which there are amendments not relevant to these Regulations.
(**22**) S.R. 1977/359 as amended by S.R. 1981/182.
(**23**) S.I. 1978/40.
(**24**) S.I. 1980/14 as amended by S.I. 1994/2920.
(**25**) S.I. 1980/1923 to which there are amendments not relevant to these Regulations.
(**26**) S.I. 1980/1924 to which there are amendments not relevant to these Regulations.
(**27**) S.I. 1981/1011.

words "marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply or".

11. The Warble Fly (Scotland) Order 1982(**28**) shall be amended as follows—

(a) in article 2 in the definition of "product" after the words "granted under the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(b) in the Schedule in paragraph 1 of Form A after the words "product licensed" there shall be inserted the words "or authorised".

12. The Warble Fly (England and Wales) Order 1982(**29**), shall be amended as follows—

(a) in article 2 in the definition of "dressing" after the words "granted under the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(b) in the Schedule in paragraph (a) of Form A after the words "by using a dressing licensed" there shall be inserted the words "or authorised".

13. In the Natural Mineral Waters Regulations 1985(**30**) in paragraph (c) of regulation 3 after the words "the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations apply".

14. In the Warble Fly (England and Wales) (Infected Areas) Order 1985(**31**), in article 2 in the definition of "product" after the words "granted under the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

15. The Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986(**32**) shall be amended as follows—

(a) there shall be inserted after article 3 the following article—

"**Exemption from marketing authorisations for certain imported veterinary drugs**

3A. Subject to the conditions in article 4 below, the restriction imposed by regulation 3 of the Marketing Authorisations for Veterinary Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to the importation of a veterinary medicinal drug (not being an immunological veterinary drug) or to the sale or supply of any such imported veterinary drug.";

(b) in article 4(1) for the words "Article 3" there shall be substituted the words "Article 3 or by Article 3A";

(c) in article 4(1) in sub-paragraph (a) after the words "section 7(2) of the Act" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(d) in article 4(1) in sub-paragraphs (b) and (c) after the word "licence", in each place where it occurs, there shall be inserted the words "or marketing authorisation".

(**28**) S.I. 1982/207.
(**29**) S.I. 1982/234 to which there are amendments not relevant to these Regulations.
(**30**) S.I. 1985/71.
(**31**) S.I. 1985/1542.
(**32**) S.I. 1986/228.

16. In the Control of Pesticides Regulations 1986(**33**) in Regulation 3(2)(b) after the words "under that enactment is exercised" there shall be inserted the words "or substances controlled by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994";

17. The Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988(**34**) shall be amended as follows—

(a) in regulation 2—

(i) after the definition of "international non-proprietry name" and before the definition of "medicated feeding stuff" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(ii) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation";

(b) in regulation 9(6)—

(i) after the words "any licence or certificate granted or issued under the Act" there shall be inserted the words "or to any marketing authorisation"; and

(ii) for the words "or such regulations, orders, licence or certificate" there shall be substituted the words "or such regulations, orders, licence, certificate or marketing authorisation";

(c) Schedule 2 shall be amended as follows—

(i) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(ii) in paragraph 2 after the words "the licensing authority" there shall be inserted the words "or, in the case of a marketing authorisation, the Ministers as defined in the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994," and

(d) Schedule 3 shall be amended as follows—

(i) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(ii) after the word "licence", in each place where it occurs, there shall be inserted the words "or marketing authorisation".

18. In the Trade Descriptions (Places of Production) (Marking) Order 1988(**35**) in article 1(2)(d) after the words "Medicines Act 1968" there shall be inserted the words "or to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994".

19. In the Medicines (Exemptions from Licences) (Intermediate Medicated Feeding Stuffs) Order 1989(**36**) there shall be inserted after article 2 the following article—

"**Marketing authorisations**

3.—(1) The restriction imposed by regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to anything done in relation to an intermediate mediciated feeding

(**33**) S.I. 1986/1510.
(**34**) S.I. 1988/1009.
(**35**) S.I. 1988/1771.
(**36**) S.I. 1989/2325 to which there are amendments not relevant to these Regulations.

stuff in the circumstances set out in article 2 of this Order, subject to the conditions in that article.

(2) For the purposes of paragraph (1) above the reference in article 2 of this Order to a product licence shall be construed as a reference to a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply.".

20. The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990(**37**) shall be amended as follows—

(a) in article 1(2) after the definition of "intermediate feed" and before the definition of "medicinal product" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(b) in article 2(1) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation".

21. The Medicines (Veterinary Drugs) (Prescription Only) Order 1991(**38**) shall be amended as follows—

(a) in article 1(2) after the definition of "intermediate feed" and before the definition of "the Misuse of Drugs Regulations" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in article 3(1) in sub-paragraph (d)(iii) after the words "product licence" there shall be inserted the words "or marketing authorisation";

(c) in article 4(1) after the words "product licence" there shall be inserted the words "or marketing authorisation";

(d) in Schedule 1 after the words "Product Licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(e) in Schedule 3 in Part I at point 10, after the words "product licences" in column 1 and after the word "licences" in column 2 there shall be inserted the words "or marketing authorisations".

22. In the Children's Homes Regulations 1991(**39**) in regulation 2(1) in the definition of "medicinal product" after the words "the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

23. In the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991(**40**), regulation 2 shall be amended as follows—

(a) in the definition of "unlicensed substance" in sub-paragraph (a)(i) after the words "product licence" there shall be inserted the words "or marketing authorisation";

(b) after the definition of "unlicensed substance" and before the definition of "veterinary medicinal product" there shall be inserted the following—

""veterinary medicinal marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(**37**) S.I. 1990/566.
(**38**) S.I. 1991/1392, as amended by S.I. 1991/2568.
(**39**) S.I. 1991/1506.
(**40**) S.I. 1991/2843 as amended by S.I. 1993/990.

(c) in the definition of "withdrawal period" after the words "current veterinary medicinal product licence" there shall be inserted the words "or marketing authorisation".

24. The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992(**41**) shall be amended as follows—

(a) in article 2(1) in the definition of "a specially authorised person" for (b) there shall be substituted the following—

"(b) a person specially authorised by the product licence or by the marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply in respect of that drug to sell the drug under the alternative product name specified in the licence or marketing authorisation;";

(b) in article 2(1) in the definition of "veterinary drug" after the words "in respect of which a product licence" there shall be inserted the words "or a marketing authorisation";

(c) in article 3 after the words "holder of the product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation";

(d) in article 6(1) after the words "holder of a product licence" there shall be inserted the words "or marketing authorisation";

(e) in article 9 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation";

(f) in article 11(1) after the words "product licence" there shall be inserted the words "or marketing authorisation"; and

(g) in Schedules 1, 2, 3 and 4 for the words "product licence no.", in each place where they occur, there shall be substituted the words "product licence/marketing authorisation no.".

25. In the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1992(**42**) article 2(2) shall be amended as follows—

(a) in the definition of "unlicensed substance" after the words "product licence" there shall be inserted the words "or marketing authorisation";

(b) after the definition of "unlicensed substance" and before the definition of "veterinary medicinal product" there shall be inserted the following—

""veterinary medicinal marketing authorisation" means a marketing authorisation valid in Northern Ireland to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(c) in the definition of "withdrawal period" after the words "product licence" there shall be inserted the words "or marketing authorisation".

26. The Medicines (Medicated Feeding Stuffs) (No. 2) Regulations 1992(**43**) shall be amended as follows—

(a) in regulation 2(1)—

(i) after the definition of "licensed medicinal product" and before the definition of "medicinal product" the following definition shall be inserted:

""marketing authorisation" means an authorisation to place on the market a veterinary medicinal product to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(ii) in the definition of "withdrawal period" after the words "current product licenced" there shall be inserted the words "or marketing authorisation";

(**41**) S.I. 1992/33, as amended by S.I. 1992/3081 and S.I. 1994/599.
(**42**) S.R. 1992/39.
(**43**) S.I. 1992/1520, as amended by S.I. 1994/1531.

(b) in regulation 4—

(i) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(ii) in paragraph (4) after the words "no effective licensed medicinal product" there shall be inserted the words "or medicinal product for which a marketing authorisation has been granted";

(c) in regulation 6 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(d) in Schedule 2—

(i) in section I(1) for the words "product licence number(s)" there shall be substituted the words "product licence/marketing authorisation number(s)"; and

(ii) in section IV(2) for the words "unlicensed combination of medicinal products" there shall be substituted the words "unlicensed or unauthorised combination of medicinal products".

27. In the Specified Animal Pathogens Order 1993(**44**) in article 5(2) for sub-paragraphs (a) and (b) there shall be substituted the following—

"(a) a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply, or

(b) a product licence has been granted in accordance with the provisions of section 7(2) of the Medicines Act 1968, or

(c) an animal test certificate has been issued in accordance with the provisions of section 32 of that Act.".

28. In the Aujeszky's Disease Scheme Order (Northern Ireland) 1994(**45**) the Schedule shall be amended as follows—

(a) in paragraph 2(1) after the definition of "holding number" and before the definition of "Officially Aujeszky's Disease free holding" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation valid in Northern Ireland to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in paragraph 2(1) in the definition of "vaccine" after the words "valid product licence" there shall be inserted the words "or marketing authorisation"; and

(c) in paragraph 8(1) after the words "product licence" there shall be inserted the words "or marketing authorisation".

29. In the General Product Safety Regulations 1994(**46**) in regulation 11(c)(ii)(aa) after the words "licensed in accordance with the provisions of the 1968 Act" there shall be inserted the words "or authorised in accordance with the provisions of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994".

30. The Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994(**47**) shall be amended as follows—

(a) in regulation 2(1) after the definition of "Directive 91/412/EEC" and before the definition of "veterinary medicinal product" there shall be inserted the following—

(**44**) S.I. 1993/3250.
(**45**) S.R. 1994/199.
(**46**) S.I. 1994/2328.
(**47**) S.I. 1994/2852.

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(b) in regulation 6 for the words "product licence" there shall be substituted the words "marketing authorisation".

31. In the Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994(**48**) for article 3(1) there shall be substituted the following—

"**Exemption from marketing authorisations for certain veterinary medicinal products**

3.—(1) Subject to the conditions in paragraph (2) below, the restrictions imposed by regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to the importation of a ready-made veterinary medicinal product from another member State, or to its subsequent sale or supply.".

32. The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**49**) shall be amended as follows—

(a) in regulation 2(1)—

(i) after the definition of "the Act" and before the definition of "homeopathic medicinal product" there shall be inserted the following—

""authorised veterinary medicinal product" means a veterinary medicinal product which has been granted a marketing authorisation;"; and

(ii) after the definition of "homeopathic medicinal product" and before the definition of "ready-made veterinary medicinal product" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in regulation 3 after the words "product licence has been granted under the Act" there shall be inserted the words "or marketing authorisation has been granted"; and

(c) in reguation 5—

(i) in paragraph (1) after the words "licensed veterinary medicinal product" there shall be inserted the words "or authorised veterinary medicinal product";

(ii) in sub-paragraph (a) of paragraph (1) and in sub-paragraph (a) of paragraph (2) after the word "licensed", in each place where it occurs, there shall be substituted the word "authorised"; and

(iii) in sub-paragraph (b) of paragraph (1) for the word "licensed" there shall be inserted the words "or authorised".

(**48**) S.I. 1994/2986.
(**49**) S.I. 1994/2987.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Council Directive 93/40/EEC, which is the latest in a series of amendments to Council Directive 81/851/EEC. They provide for veterinary medicinal products to be placed on the market subject to marketing authorisations rather than the previous system of product licences. These authorisations may be granted either by the Ministers or, in accordance with Council Regulation 2309/93/EEC, by the European Agency for the Evaluation of Medicinal Products (regulation 3).

They provide for the form and manner of an application, and the terms on which the Ministers may grant an authorisation (regulations 4 and 5 and Schedules 1 and 2).

They place duties on persons responsible for placing products on the market (regulation 6), on person where a product is manufactured outside the EEA (regulation 7) and on an importer who holds a marketing authorisation (regulation 8).

There are provisions for the variation, renewal, suspension and refusal of an authorisation (regulations 9 to 13 and Schedule 3), provisions as to confidentiality (regulation 14) and fees (regulation 15).

Breach of the regulations is an offence under regulation 16, with a defence in regulation 17.

Provisions of the Medicines Act 1968, under which the system was previously enforced, and provisions of the Trade Descriptions Act 1968 and the Consumer Protection Act 1987, are applied to marketing authorisations in the same way as they previously applied to product licences (regulation 19). Regulation 20 contains transitional provisions.

Schedule 4 revokes the Medicines (Leaflets for Veterinary Drugs) Regulations 1983, S.I. 1983/1727, the Medicines (Veterinary Medicinal Products) (Applications for Product Licences Regulations) 1993, S.I. 1993/2398 and the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) (Amendment) Regulations 1994, S.I. 1994/2157.

Schedule 5 makes amendments to statutory instruments consequential on changing from product licences to marketing authorisations.

A Compliance Cost Assessment has been prepared and placed in the library of each House of Parliament.