SCHEDULE 1 Regulation 4(3)

MARKETING AUTHORISATIONS

CONTENTS

PART 1

Application for a marketing authorisation

Application for a marketing authorisation

1. An application under these Regulations for a marketing authorisation for a veterinary medicinal product shall be made to the Secretary of State.

Information with the application

2.—(1) An application must include all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the product.

(2) In particular, the applicant must provide all the data required in Annex I to Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**1**), generated in accordance with that Annex.

(3) The application shall contain the following information—

(a) the name of the person who will hold the marketing authorisation, that person's address and, if different, the name and address of all the manufacturers involved in each stage of the manufacture, and the sites where the manufacture will take place;

(b) the name of the veterinary medicinal product, which may be either—

(i) an invented name provided that this is not liable to be confused with the common name of the product or the international non-proprietary name (INN) recommended by the World Health Organization; or

(ii) a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;

(**1**) OJ No. L 311, 28.11.2001, p. 1 as amended by Directive 2004/28/EC of the European Parliament and of the Council (OJ No. L 136, 30.4.2004, p. 58).

(c) the qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its INN recommended by the World Health Organization, where an INN exists, or its chemical name;

(d) a description of the method of manufacture;

(e) all therapeutic indications, contra-indications and adverse reactions;

(f) the dosage for each species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;

(g) any proposed precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals or disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human or animal health or to plants, together with the reasons;

(h) in the case of medicinal products intended for food-producing species, the proposed withdrawal period necessary to ensure that the maximum residue limits specified in Council Regulation (EEC) No. 2377/90 (laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin(**2**)) are not exceeded;

(i) a description of the testing methods to be used during manufacture;

(j) the results of—

(i) pharmaceutical (physico-chemical, biological or microbiological) tests;

(ii) safety tests and residue tests;

(iii) pre-clinical and clinical trials;

(iv) tests assessing the potential risks to the environment from the product;

(k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;

(l) a summary of the product characteristics, mock-ups of all proposed packaging and the proposed package leaflet, if any;

(m) a document showing that the manufacturer is authorised in his own country to produce veterinary medicinal products;

(n) copies (which must be updated if there are any changes while the application is being considered) of—

(i) any marketing authorisation obtained in another member State or in a third country for the relevant veterinary medicinal product, and a list of any other member States in which an application for authorisation of the product has been submitted;

(ii) if the product is already authorised outside the United Kingdom, the summary of product characteristics for each authorisation;

(iii) any decision to refuse authorisation, whether in the Community or a third country and the reasons for that decision;

(o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance (referred to in these Regulations as a qualified person (pharmacovigilance)) and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country;

(p) if the veterinary medicinal product is intended for food-producing species and contains one or more pharmacologically active substances not yet included for the species in question

(**2**) OJ No. L 224, 18.8.1990, p. 1 as last amended by Commission Regulation (EC) No. 869/2005 (OJ No. L 145, 9.6.2005, p. 19).

in Annex I, II or III to Council Regulation (EEC) No. 2377/90, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with paragraph 5.

(4) All documents relating to the results of tests or trials must be accompanied by a detailed and critical expert report that has been drafted and signed by a person with the requisite technical or professional qualifications and that has a brief curriculum vitae of the person signing the report attached to it.

(5) In the case of immunological products, the applicant must submit a description of the methods used to establish that the manufacturing process will consistently produce a veterinary medicinal product that is in accordance with the marketing authorisation.

Summary of product characteristics

3. The summary of product characteristics required under the preceding paragraph shall include the following information, set out in the same format—

Summary of product characteristics	
1	Name of the veterinary medicinal product, including its strength and pharmaceutical form.
2	The name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons.
3	Pharmaceutical form.
4	Clinical particulars—
4.1	target species;
4.2	indications for use, specifying the target species;
4.3	contra-indications;
4.4	special warnings for each target species;
4.5	special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals;
4.6	adverse reactions (frequency and seriousness);
4.7	use during pregnancy, lactation or lay;
4.8	interaction with other medicinal products and other forms of interaction;
4.9	amounts to be administered and administration route;
4.10	overdose (symptoms, emergency procedures, antidotes) if necessary;
4.11	withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero.

Summary of product characteristics	
5	Pharmacological properties—
5.1	pharmacodynamic properties;
5.2	pharmacokinetic particulars.
6	Pharmaceutical particulars—
6.1	list of excipients;
6.2	major incompatibilities;
6.3	shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time;
6.4	special precautions for storage;
6.5	nature and contents of immediate packaging;
6.6	special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate.
7	Marketing authorisation holder.
8	Marketing authorisation number.
9	Date of the first authorisation or date of renewal of the authorisation.
10	Date of any revision of the text.
11	Any other information required by the Secretary of State.

Supply of a copy of the summary of product characteristics

4. A holder of a marketing authorisation must supply a copy of the summary of product characteristics to any person on demand.

Time limits for applications for products for use in food-producing animals

5. In the case of a veterinary medicinal product for food-producing animals (including food-producing horses), a marketing authorisation may not be applied for until at least six months after a valid application has been made for the establishment of a maximum residue limit in accordance with Council Regulation (EEC) No. 2377/90.

PART 2

Derogations from some of the requirements in Part 1

Scope

6. This Part provides for applications for marketing authorisations in which not all the information required in Part 1 is required, but for the avoidance of doubt any applicant may apply for a marketing authorisation using Part 1 if he wishes to do so.

Bibliographic application

7.—(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the active substance of the veterinary medicinal product has been in an authorised veterinary medicinal product for that species in the Community for at least ten years, and the applicant provides appropriate scientific literature to demonstrate this.

(2) He may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically equivalent product for a period of three years from the grant of the authorisation for the additional species.

Application for a product using a new combination of active substances

8. If an application is for a veterinary medicinal product containing active substances already used in an authorised veterinary medicinal product but not previously used in that combination in a veterinary medicinal product, he need not provide the safety and efficacy data for the individual active substances.

Application using existing data

9. If the Secretary of State has granted a marketing authorisation, the holder may permit him to use data submitted in support of that marketing authorisation when assessing an application for another marketing authorisation.

Application for a pharmacologically equivalent medicinal product

10.—(1) An applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if he can demonstrate that the veterinary medicinal product is pharmacologically equivalent to a veterinary medicinal product already authorised in the Community.

(2) For the purposes of this paragraph a product is pharmacologically equivalent to an existing product if—

(a) it has the same qualitative and quantitative composition in active substances;

(b) it has the same pharmaceutical form; and

(c) bioequivalence has been demonstrated by means of appropriate bioavailability studies.

(3) For the purposes of this paragraph—

(a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

(b) if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

(4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.

(5) Bioavailability studies are not required if the bioequivalence guidelines produced by the Agency exempt the product.

(6) In the case of a reference product authorised in another member State but not in the United Kingdom, the Secretary of State must be satisfied that the risk-benefit balance of the original product is appropriate for the product to be placed on the market in the United Kingdom, and if the data provided under Article 13, third paragraph of Directive 2001/82/EC by the member State in which the product is authorised are insufficient for him to be satisfied of this, he may notify the applicant and require the applicant to provide further data.

Time limits for marketing authorisations granted under the procedure for a pharmacologically equivalent product

11.—(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a pharmacologically equivalent product.

(2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.

(3) The product shall not be placed on the market until ten years (or, in the case of medicinal products for fish or bees where the application for a marketing authorisation was submitted after 30th October 2005, thirteen years) have elapsed from the initial authorisation of the reference product.

(4) Time limits in this paragraph shall be calculated from the first grant of the marketing authorisation for the reference product.

Extension of time limits

12.—(1) This paragraph applies in relation to veterinary medicinal products that—

(a) are intended for administration to food-producing species, and

(b) contain a new active substance that was not authorised in the Community by 30th April 2004.

(2) If a person submits an application for a marketing authorisation for a product on or after 30th October 2005, and within 5 years of the original marketing authorisation being granted, the marketing authorisation is extended to include additional food-producing species, the ten-year period provided for in paragraph 11 shall be extended by one year for each additional food-producing species added to the marketing authorisation.

(3) The total period shall not exceed 13 years.

(4) The extension applies only if the marketing authorisation holder originally applied for determination of the maximum residue limits for the active substance.

Parallel imports

13.—(1) The Secretary of State may grant a marketing authorisation in relation to a veterinary medicinal product authorised in another member State and imported into the United Kingdom from that member State in accordance with this paragraph without the data required in Part 1 if the applicant can demonstrate compliance with this paragraph.

(2) If the product is for a food-producing species it must be identical to a product authorised in the United Kingdom.

(3) Other products must be therapeutically the same as a product authorised in the United Kingdom unless the importer can justify any differences.

(4) The member State from which it is imported must have authorised the product in accordance with Directive 2001/82/EC.

(5) The applicant must be established within the Community.

(6) The applicant must hold (or have a contract with the holder of) a wholesale dealer's authorisation in the United Kingdom appropriate to the type of product to be imported.

(7) If re-labelling is to take place in the United Kingdom the applicant must also be (or have a contract with) the holder of a suitable manufacturing authorisation in the United Kingdom.

Specific batch control scheme

14.—(1) Where a veterinary medicinal product (other than a biological veterinary medicinal product) has been granted a marketing authorisation or an animal test certificate, and any starting material (active substance, excipient or packaging) or any batch of the product does not fully meet the requirements of the authorisation or animal test certificate, the holder may apply to the Secretary of State to place one or more batches on the market notwithstanding this.

(2) The Secretary of State may authorise the placing on the market if he is satisfied that the safety, quality and efficacy of the product are not compromised, and that in all the circumstances of the case the product should be placed on the market.

(3) This paragraph does not apply in relation to a product recognised in more than one member State.

(4) In this paragraph a biological veterinary medicinal product is a veterinary medicinal product, the active substance of which is a biological substance; and a biological substance is a substance that is produced by or extracted from a biological source and for which a combination of physico-chemical-biological testing and the production process and its control is needed for its characterisation and the determination of its quality.

Similar immunological products

15. Where an immunological veterinary medicinal product is pharmacologically equivalent to a reference product other than differences in raw materials or in the manufacturing process, the results of the appropriate pre-clinical tests or clinical trials must be provided, but the applicant need not provide the results of safety tests or residue tests.

Marketing in exceptional circumstances

16. Where the health situation so requires, the Secretary of State may authorise the placing on the market of a veterinary medicinal product that has been authorised by another member State or, if there is no such authorised product, authorised in a third country.

PART 3

Grant of a marketing authorisation

Time limits

17. The Secretary of State shall ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of the application.

Place of establishment of applicant

18. Only an applicant established in a member State may be granted a marketing authorisation.

Procedure

19. The Secretary of State may require the applicant to provide additional information or to generate additional data, including laboratory testing, or may require the applicant to provide samples of any medicinal product, its starting materials and intermediate products or other constituent materials so that he can test them in a laboratory.

Products authorised in another member State

20. Where the Secretary of State is informed or discovers that another member State has authorised a veterinary medicinal product that is the subject of an application for authorisation by the Secretary of State, he shall reject the application unless it was submitted in accordance with the mutual recognition procedure or the decentralised procedure in Part 6.

Assessment reports

21. The Secretary of State shall produce an assessment of the dossier, consisting of an evaluation of the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned, and any additional related information.

Grant of a marketing authorisation

22. When granting a marketing authorisation, the Secretary of State shall inform the applicant of the summary of product characteristics that he has approved, and the distribution category of the product.

Marketing authorisations for food-producing species

23.—(1) The Secretary of State shall not grant a marketing authorisation for a veterinary medicinal product for food-producing species unless all its pharmacologically active substances appear in Annex I, II or III to Council Regulation (EEC) No. 2377/90.

(2) This shall not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared as not intended for slaughter for human consumption in accordance with—

(a) the Horse Passports (England) Regulations 2004(**3**);

(b) the Horse Passports Regulations (Northern Ireland) 2004(**4**);

(**3**) S.I.2004/1397.
(**4**) S.R. (NI) 2004 No. 497.

(c) the Horse Passports (Scotland) Regulations 2005(**5**);

(d) the Horse Passports (Wales) Regulations 2005(**6**),

but the product must not include an active substance that appears in Annex IV to Council Regulation (EEC) No. 2377/90 and must not be intended for the treatment of a condition for which a veterinary medicinal product is already authorised for horses.

(3) In this paragraph "horse" includes any member of the equidae family.

Refusal of a marketing authorisation

24.—(1) The Secretary of State shall refuse to grant a marketing authorisation if the application does not comply with these Regulations.

(2) In addition, he shall refuse to grant it if—

(a) the data submitted with the application are inadequate;

(b) the risk-benefit balance of the veterinary medicinal product is unfavourable;

(c) the product has insufficient therapeutic effect;

(d) the withdrawal period proposed by the applicant is not long enough to ensure that Council Regulation (EEC) No. 2377/90 is complied with, or is insufficiently substantiated;

(e) the veterinary medicinal product is for a prohibited use;

(f) the way that the product will be used will have an unnecessarily undesirable effect on the environment.

(3) The Secretary of State may refuse a marketing authorisation—

(a) if there is Community legislation pending that is incompatible with the requested authorisation; or

(b) if he requests additional data and those data are not provided within such time limit as he may stipulate.

Publication following the grant of a marketing authorisation

25.—(1) When he grants a marketing authorisation the Secretary of State shall publish—

(a) the notice granting the marketing authorisation;

(b) the summary of the product characteristics;

(c) an assessment report which shall be the assessment report he has already prepared but with any commercially confidential or personal information deleted.

(2) He shall update the assessment report whenever new information that is of importance and relates to the quality, safety or efficacy of the veterinary medicinal product becomes available.

(3) He shall send a copy of the assessment report, and any update, to the holder of the marketing authorisation before he publishes it to enable the holder to make representations to him concerning any confidential or personal information that may be in it, and may specify a date by which representations must be made.

Provisional marketing authorisation

26.—(1) In exceptional circumstances, the Secretary of State may grant a provisional marketing authorisation subject to a requirement for the applicant to provide further data.

(**5**) S.S.I. 2005/223.
(**6**) S.I. 2005/231 (W. 21).

(2) The Secretary of State shall reassess the authorisation annually.

Provisions of samples and expertise

27.—(1) The Secretary of State may require a marketing authorisation holder to provide, at any time and at any stage of the manufacturing process, samples of starting materials or the veterinary medicinal product for testing.

(2) At the request of the Secretary of State, the marketing authorisation holder must provide his technical expertise to facilitate any analysis of the product.

(3) It is an offence to fail to comply with this paragraph or a requirement under it.

Supply of information

28.—(1) A marketing authorisation holder must immediately inform the Secretary of State if he receives any new information that might adversely affect the risk-benefit balance of the veterinary medicinal product.

(2) He must immediately inform the Secretary of State of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is authorised.

(3) The Secretary of State may at any time require the marketing authorisation holder to provide data relating to the risk-benefit balance.

(4) It is an offence to fail to comply with this paragraph or a requirement under it.

Duties on the holder of a marketing authorisation relating to an immunological product

29.—(1) The holder of a marketing authorisation for an immunological product must submit to the Secretary of State the results of all tests carried out on each batch of the product at least fifteen days before he places the product on the market.

(2) It is an offence to fail to comply with this paragraph.

Control tests

30.—(1) The holder of a marketing authorisation must give to the Secretary of State on demand evidence that he has carried out all control tests required under the marketing authorisation, and the results of those tests.

(2) It is an offence to fail to comply with this paragraph.

Placing on the market

31.—(1) When a holder of a marketing authorisation first places the veterinary medicinal product on the market in the United Kingdom he must notify the Secretary of State that he has done so, and the date on which it was placed on the market.

(2) If he removes the veterinary medicinal product from the market in the United Kingdom, he must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before he does so.

(3) Upon request by the Secretary of State, the marketing authorisation holder must provide him with—

(a) all data relating to the volume of sales of the veterinary medicinal product by him, and

(b) any data in his possession relating to the number of prescriptions written for the product and the total volume supplied under those prescriptions.

(4) It is an offence to fail to comply with this paragraph.

Duration and validity of a marketing authorisation

32.—(1) A marketing authorisation is initially valid for five years.

(2) The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.

(3) An application for renewal must be made at least six months, and not more than nine months, before the marketing authorisation ceases to be valid.

(4) When he applies for the renewal of the marketing authorisation the applicant must enclose a list of all documents concerning the product that he has submitted to the Secretary of State since the marketing authorisation was granted.

(5) The Secretary of State may require the applicant to provide a copy of any of the listed documents at any time.

(6) Once renewed, the marketing authorisation is valid indefinitely unless, within five years of the renewal, the Secretary of State notifies the holder, on justified grounds relating to pharmacovigilance, that the authorisation will cease to be valid five years from the first renewal unless the holder applies for a further renewal.

(7) The further renewal is not time-limited.

(8) Any marketing authorisation granted under these Regulations that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in the United Kingdom ceases to be valid.

(9) When a veterinary medicinal product authorised under these Regulations and previously placed on the market in the United Kingdom is not present on the market in the United Kingdom for a period of three consecutive years, its marketing authorisation ceases to be valid.

(10) The Secretary of State may, on human or animal health grounds, grant exemptions from sub-paragraphs (8) and (9).

PART 4

Variations of marketing authorisations on the application of the holder

Variation of a marketing authorisation for a mutually recognised veterinary medicinal product

33. Where a veterinary medicinal product is authorised in more than one member State, the Secretary of State is the competent authority for the purposes of Commission Regulation (EC) No. 1084/2003 (concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a member State)(**7**).

Variation of a marketing authorisation not authorised in another member State

34.—(1) Where a veterinary medicinal product is not authorised in another member State, an application to vary it shall be made by the holder to the Secretary of State.

(2) Paragraph 24 of this Schedule (refusal of a marketing authorisation) applies to an application for a variation in the same way as it applies to an application for a marketing authorisation.

(3) In granting a variation of a veterinary medicinal product the Secretary of State shall (unless there are exceptional circumstances necessary to protect human or animal health or the

(**7**) OJ No. L 159, 27.6.2003, p. 1.

environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

Administrative variations

35.—(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an "administrative variation").

(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, he shall notify the marketing authorisation holder, require him to submit an application for a variation enabling data to be assessed and revoke the administrative variation.

Changes after a marketing authorisation has been issued

36. After a marketing authorisation has been issued, the holder must take account of scientific and technical progress in manufacturing and control methods, and apply to the Secretary of State for any variation in the marketing authorisation that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

Compulsory variation

37.—(1) If the Secretary of State decides, in order to protect human or animal heath or the environment, that a variation to a marketing authorisation is necessary, he shall notify the marketing authorisation holder in writing of the required variation, together with his reasons.

(2) In the notification he may specify a time limit within which the marketing authorisation holder must apply for the variation.

(3) If the marketing authorisation holder fails to apply within that time limit the Secretary of State may suspend or revoke the marketing authorisation.

PART 5

Suspension, etc. of a marketing authorisation

Suspension, etc. of a marketing authorisation

38.—(1) The Secretary of State may suspend, vary or revoke a marketing authorisation at any time if he is satisfied that—

(a) this is necessary for the protection of animal or public health or the environment;

(b) the terms of the marketing authorisation have not been complied with;

(c) the veterinary medicinal product has insufficient therapeutic effect.

(2) He must suspend, vary or revoke a marketing authorisation if he is satisfied that—

(a) the risk-benefit balance is unfavourable;

(b) the withdrawal period does not ensure that residues in foodstuffs obtained from the treated animal comply with Council Regulation (EEC) No. 2377/90;

(c) information given in the application documents is incorrect;

(d) any control tests required have not been carried out;

(e) changes have been made to the manufacturing process without the authority of the Secretary of State;

(f) any information required to be supplied to the Secretary of State has not been communicated to him.

(3) He may also suspend, vary or revoke a marketing authorisation if he is satisfied that a marketing authorisation holder has failed to make an application for a variation to take account of scientific and technical progress in manufacturing and control methods to enable a veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(4) When he suspends, varies or revokes a marketing authorisation, the Secretary of State may additionally prohibit the supply of a veterinary medicinal product, and if necessary require the marketing authorisation holder to recall the product; and failure to comply with a requirement or prohibition under this sub-paragraph is an offence.

(5) He shall publicise a revocation in such manner as he sees fit.

Suspension, etc. of a marketing authorisation of a product authorised in more than one member State

39.—(1) In the case of a veterinary medicinal product that is authorised in more than one member State, where the Secretary of State considers that a variation, suspension or revocation is necessary for the protection of human or animal health or the environment, he shall immediately refer the matter to the Agency, and shall comply with a decision of the Commission within 30 days of the decision.

(2) Where the Secretary of State considers that immediate suspension is necessary to protect human or animal health or the environment, he may suspend the marketing and the use of the veterinary medicinal product concerned in the United Kingdom pending a decision of the Agency, and in this case he shall inform the Commission and the other member States no later than the following working day of the reasons for his action.

Prohibiting the supply of veterinary medicinal products

40.—(1) In addition to his powers to suspend a marketing authorisation, if he is satisfied that a product has not been manufactured in accordance with the marketing authorisation the Secretary of State may prohibit the supply of a veterinary medicinal product, and if necessary require the marketing authorisation holder to recall it, and failure to comply with a requirement or prohibition under this sub-paragraph is an offence.

(2) He may confine the prohibition on supply and the requirement for recall to specific production batches.

(3) In the case of an immunological veterinary medicinal product manufactured outside the United Kingdom, if a batch has had all the tests that were originally carried out by the manufacturer repeated by the competent authority of another member State, the Secretary of State may not prohibit the release of that batch if all the results have been submitted to him and the results demonstrate that the product is within the terms of the authorisation.

PART 6

Mutual recognition and multiple applications

Application for a marketing authorisation where one already exists in another member State

41.—(1) If a veterinary medicinal product has already received a marketing authorisation in another member State at the time of application, and the holder of the marketing authorisation applies for a marketing authorisation in the United Kingdom, the following procedure ("the mutual recognition procedure") applies.

(2) The applicant must submit to the Secretary of State a dossier identical to the one submitted to the competent authority of the member State in which the veterinary medicinal product has been authorised ("the reference member State").

(3) If there is a marketing authorisation current in more than one member State the applicant must identify which member State is acting as the reference member State.

(4) If the applicant is applying in more than one member State he must supply the Secretary of State with a list of all the States in which he is applying.

(5) The Secretary of State shall obtain an assessment report from the reference member State and, if the application is made under paragraph 7 (bibliographic applications) or paragraph 10 (applications for pharmacologically equivalent products), ask for the report to include an explanation of any extension of the protection period generated under paragraph 11 or 12.

(6) Within 90 days after receipt of the assessment report, the Secretary of State must, subject to the following provisions, either—

(a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or

(b) notify the reference member State that he will not approve them, and provide the reference member State with a detailed statement of the reasons.

(7) He may only refuse an application on the grounds of serious risk to human or animal health or the environment.

(8) If he approves the assessment report, the summary of product characteristics, the labelling and the package leaflet he shall ensure that he is in a position to decide whether or not to grant a marketing authorisation within 30 days of approving them.

(9) If the Secretary of State is notified by the reference member State that—

(a) not all member States concerned have within 90 days approved the assessment report, summary of product characteristics, labelling or package leaflet; and

(b) the reference member State has sent a detailed statement of the reasons to the other member States involved in the application, the applicant and the coordination group for action in accordance with Article 33(3) of Directive 2001/82/EC,

the Secretary of State shall within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(10) The Secretary of State may grant the marketing authorisation even though not all member States have agreed to grant it, but shall revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.

Application in another member State

42.—(1) When the Secretary of State has granted a marketing authorisation for a veterinary medicinal product and he is notified by the marketing authorisation holder that he has applied to have

that veterinary medicinal product authorised in another member State, he shall prepare an assessment report for the product within 90 days of the notification and send it to the member State or States concerned.

(2) If the other member State (or, if there is more than one, all of them) agrees with the assessment report, the summary of product characteristics, the labelling and the package leaflet he need take no further action.

(3) If not all the other member States concerned so agree within a further 90 days he shall send a detailed statement setting out why they have disagreed to the other member States, the applicant and the coordination group for action in accordance with Article 33(3) of Directive 2001/82/EC.

(4) The Secretary of State shall within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

Application for a marketing authorisation in multiple member States where a marketing authorisation does not exist in any member State

43.—(1) If an applicant wishes to apply for a marketing authorisation in more than one member State, and a marketing authorisation does not exist in any member State for the product ("the decentralised procedure"), he must—

(a) apply simultaneously in all the relevant member States;

(b) submit a dossier to the Secretary of State that is identical to the dossier being submitted to all the other member States;

(c) include a list of all member States in which he has applied; and

(d) nominate one of them to act as the reference member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet for consideration by the other member States ("the concerned member States").

(2) If the United Kingdom is the reference member State, the Secretary of State shall prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet within 120 days of the receipt of a valid application and shall send them to the other concerned member States and to the applicant.

(3) If the United Kingdom is not the reference member State, within 90 days after receipt of the assessment report and drafts of the summary of product characteristics, labelling and package leaflet from the reference member State, the Secretary of State shall, subject to the following provisions, either—

(a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or

(b) notify the reference member State that he will not approve it, and provide the reference member State with a detailed statement of the reasons.

(4) He shall only refuse an application on the grounds of serious risk to human or animal health or the environment.

(5) If all the member States involved agree the assessment report, the summary of product characteristics, the labelling and the package leaflet within 90 days, the Secretary of State shall ensure that he is in a position to decide whether or not to grant a marketing authorisation within 30 days.

(6) If, within 90 days, not all the member States have agreed the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human or animal health or to the environment, the Secretary of State (if the United Kingdom is the reference member State) shall send a detailed statement of the reasons to the other member States involved in the application, the applicant, and the coordination group to act in accordance with Article 33(3) of Directive 2001/82/EC.

(7) If reference has been made to the coordination group by any member State, the Secretary of State shall within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(8) If the Secretary of State wishes to do so, he may grant the marketing authorisation even though not all member States have agreed to grant it, but shall revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.

PART 7

Labelling and package leaflets

Approval by the Secretary of State

44. When the Secretary of State issues the marketing authorisation he shall approve all containers, packaging, labels and package leaflets.

Reference to being authorised

45. A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words "UK authorised veterinary medicinal product" or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in the United Kingdom.

Language

46.—(1) All labels and package leaflets must be in English, but may contain other languages provided that the information given is identical in all the languages.

(2) This requirement does not apply in the case of a product imported by a veterinary surgeon and administered by or under the supervision of that same veterinary surgeon.

Labelling with all the information on the immediate packaging

47.—(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters—

(a) the name, strength and pharmaceutical form of the veterinary medicinal product;

(b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription";

(g) the contents by weight, volume or number of dose units;

(h) the marketing authorisation number;

(i) the name and address of the marketing authorisation holder or, if there is a distributor authorised in the marketing authorisation, that distributor;

(j) a suitably labelled space to record discard date (if relevant);

(k) the target species;

(l) the distribution category;

(m) the words "Keep out of reach of children";

(n) storage instructions;

(o) the in-use shelf-life (if appropriate);

(p) for food-producing species, the withdrawal period for each species or animal product concerned;

(q) any warning specified in the marketing authorisation;

(r) disposal advice;

(s) full indications;

(t) dosage instructions;

(u) contra-indications;

(v) further information required in the marketing authorisation;

(w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.

(2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.

Products with immediate and outer packaging

48.—(1) If it is not reasonably practicable to have all the information on the immediate packaging then this paragraph applies.

(2) The immediate packaging must have at least the following information—

(a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;

(b) the name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription";

(g) the words "Keep the container in the outer carton".

(3) In addition, the immediate packaging must have as much of the information in paragraph 47 as is reasonably practicable, in the order set out in that paragraph.

(4) The outer packaging must contain all the information in paragraph 47 if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product in accordance with the following paragraph.

Package leaflets

49.—(1) If it is not reasonably practicable to have all the information in paragraph 47 on the immediate packaging or all of this information on the outer packaging, there must be a package leaflet supplied with the product, containing all the information in paragraph 47 except for the batch number and the expiry date, and including the name of both the marketing authorisation holder and, if different, the name of the distributor named in the marketing authorisation.

(2) If there is a package leaflet, the immediate packaging and the outer packaging must both refer the user to it.

(3) A package leaflet shall relate solely to the veterinary medicinal product with which it is included.

(4) It must be written in terms that are comprehensible to the general public.

(5) Only a package leaflet approved in the marketing authorisation may be included with the veterinary medicinal product.

Ampoules

50.—(1) In the case of ampoules or other unit dose forms, where the container cannot bear legibly the required information, only the following information must be shown on the immediate packaging—

(a) the name of the veterinary medicinal product;

(b) the name and strength of the active ingredient;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription".

(2) The outer packaging must contain all the information in paragraph 47 if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product, except that the ampoule need not refer to the package leaflet.

Small containers other than ampoules

51. As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in paragraph 47, all the information in paragraph 47 must appear on the outer packaging or outer packaging and package leaflet, but the immediate packaging must be labelled with the batch number and the expiry date and, if there is room, the other information in the preceding paragraph.

Homeopathic remedies

52.—(1) A homeopathic remedy registered under these Regulations must be labelled in accordance with this paragraph.

(2) There must be no specific therapeutic indication on the labelling or in any information relating to it.

(3) The labelling (or labelling and package leaflet) must contain the following and no other information—

(a) the words "homeopathic remedy without approved therapeutic indications for veterinary use";

(b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used (if the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks);

(c) the name and address of the registration holder and (on the package leaflet) of the manufacturer;

(d) the method and, if necessary, route of administration;

(e) the expiry date;

(f) the pharmaceutical form;

(g) the contents of the pack;

(h) any special storage precautions;

(i) the target species;

(j) any necessary special warnings;

(k) the batch number; and

(l) the registration number.

Variations

53. The Secretary of State may permit variations in the above in any individual marketing authorisation if this is necessary for public or animal health purposes or the protection of the environment.

PART 8

Pharmacovigilance

Qualified persons responsible for pharmacovigilance

54.—(1) A marketing authorisation holder must have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance ("a qualified person (pharmacovigilance)") who resides in a member State.

(2) It is an offence to fail to comply with this paragraph.

Duties relating to the qualified person

55.—(1) The marketing authorisation holder must ensure that the qualified person (pharmacovigilance)—

(a) establishes and maintains a system that ensures that information about all suspected adverse reactions reported to the marketing authorisation holder is collected and collated in order to be accessible at least at one point in a member State;

(b) answers any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product fully and within any time limit imposed by the Secretary of State when he requested the information, including the volume of sales of the veterinary medicinal product concerned and, if available, details of prescriptions;

(c) provides to the Secretary of State any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; and in this paragraph "post-marketing surveillance studies" means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying and investigating a safety hazard relating to an authorised veterinary medicinal product.

(2) It is an offence to fail to comply with this paragraph.

Adverse reactions to a veterinary medicinal product administered in the United Kingdom

56.—(1) A marketing authorisation holder must act in accordance with this paragraph if he learns of any suspected—

(a) serious adverse reaction;

(b) human adverse reaction; or

(c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in the United Kingdom.

(2) He must make a record of what happened.

(3) He must without delay and in any event within 15 days report it (electronically if this is practicable) to the Secretary of State.

(4) In addition, he must supply to the Secretary of State all relevant veterinary pharmacovigilance information in his possession relating to the reaction, giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology(**8**), either with the report or, if the information becomes available after the report has been sent, as soon after it becomes available as is reasonably practicable.

(5) In this and the following paragraph—

"human adverse reaction" means a reaction that is noxious and unintended and that occurs in a human being following exposure to a veterinary medicine;

"serious adverse reaction" means an adverse reaction that results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly or birth defect, or that results in permanent or prolonged signs in the animals treated.

(6) It is an offence to fail to comply with this paragraph.

Adverse reactions to a veterinary medicinal product administered in a third country

57.—(1) A marketing authorisation holder for a veterinary medicinal product authorised in the United Kingdom must act in accordance with this paragraph if he learns of any suspected—

(a) serious, unexpected adverse reaction (for these purposes a reaction is unexpected if its nature, severity or outcome is not consistent with the summary of the product characteristics);

(b) human adverse reaction; or

(c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in a third country.

(2) He must make a record of what happened.

(3) He must without delay and in any event within 15 days report the suspected reaction or transmission (electronically if this is practicable) to the Secretary of State, the competent authorities of all member States in which the product is authorised, and the Agency.

(4) In addition to the report, he must supply to the Secretary of State, the competent authorities of all other member States where the product is authorised and the Agency, the information required under paragraph 56(4) in the manner set out in that paragraph.

(5) It is an offence to fail to comply with this paragraph.

(**8**) A list of clinical terms for reporting suspected adverse reactions to veterinary medicinal products (the Veterinary Dictionary for Drug Regulatory Activities) is published by the Committee for Medicinal Products for Veterinary Use. It is available at www.veddra.org

Periodic safety update reports

58.—(1) The marketing authorisation holder must submit to the Secretary of State records of all adverse reactions (including nil reports) in the form of a periodic safety update report for each marketing authorisation in accordance with this paragraph, including a summary of each incident and a list of all the symptoms using internationally recognised veterinary and medical terminology.

(2) If the marketing authorisation holder has not yet placed a product on the market in the United Kingdom, he must submit a periodic safety update report immediately upon request of the Secretary of State and at least every six months after authorisation.

(3) Following the placing on the market in the United Kingdom, the marketing authorisation holder must submit a periodic safety update report to the Secretary of State immediately upon request and—

(a) at least every six months during the first two years following the initial placing on the market;

(b) once a year for the following two years; and

(c) thereafter, at three-yearly intervals.

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the periods of notification.

(5) The periodic safety update report must include a scientific evaluation of the risk benefit balance of the veterinary medicinal product.

(6) The periodic safety update report must include—

(a) the volume of the product sold in each year covered by the report, calculated on an annual basis beginning 1st January;

(b) the number of adverse reactions for each year of the report;

(c) the ratio of adverse reactions to volume of product sold together with an explanation of the basis of the calculation;

(d) differentiation of data based on—

(i) target species (if the product is authorised for use in more than one species);

(ii) reaction type (such as serious, non-serious, human, suspected lack of efficacy, unauthorised use or other);

(iii) the country of origin of the report.

(7) If the product is indicated for more than one species, the information in sub-paragraph (6) must be based so far as is practicable on the estimated use of the product.

(8) Data relating to different formulations (either different dosage forms or different strengths) must be provided in separate reports.

(9) It is an offence to fail to comply with this paragraph.

Release of information by the marketing authorisation holder

59.—(1) A marketing authorisation holder must not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised veterinary medicinal product without giving prior or simultaneous notification to the Secretary of State.

(2) The marketing authorisation holder must ensure that such information is presented objectively and is not misleading.

(3) It is an offence to fail to comply with this paragraph.

Action taken on account of pharmacovigilance

60.—(1) Where, as a result of the evaluation of veterinary pharmacovigilance data, the Secretary of State considers that a marketing authorisation should be—

(a) suspended;

(b) revoked; or

(c) varied so as to—

(i) restrict the indications;

(ii) change the distribution category;

(iii) amend the dose;

(iv) add a contraindication; or

(v) add a new precautionary measure,

he shall forthwith inform the Agency, all other member States (irrespective of whether the product is authorised in another member State) and the marketing authorisation holder.

(2) If urgent action is necessary for protecting human or animal health, the Secretary of State may suspend the marketing authorisation of a veterinary medicinal product, but he must inform the Agency, the Commission and the other member States within one working day.

(3) If, following the opinion of the Agency, the Commission requests the Secretary of State to suspend, withdraw or vary the marketing authorisation, the Secretary of State shall comply with that request immediately on a temporary basis.

(4) The Secretary of State shall take final measures in accordance with the Decision of the Commission.

PART 9

Homeopathic remedies

Meaning of "homeopathic remedy"

61. For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia(**9**) or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State.

Placing a homeopathic remedy on the market in accordance with a registration

62.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological product.

(3) The route of administration must be as described in the European Pharmacopoeia or, if it is not described there, by a pharmacopoeia currently used officially in any member State.

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(**9**) ISBN 9287145873.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

Application for registration

63.—(1) An applicant for registration must submit the following to the Secretary of State—

(a) the scientific name or other name of the homeopathic stock given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;

(b) a dossier describing how the homeopathic stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate bibliography;

(c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;

(d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;

(e) a copy of the manufacturing authorisation for the product;

(f) copies of any registrations or authorisations obtained for the same homeopathic remedy in other member States;

(g) a mock-up of the outer packaging and immediate packaging;

(h) stability data;

(i) the proposed withdrawal period necessary to ensure that the provisions of Council Regulation (EEC) No. 2377/90 are complied with together with all necessary justification.

(2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one that appears in Annex II to Regulation (EEC) No. 2377/90 and complies with any requirements in that Annex relating to that substance.

(4) If a product is registered in another member State, the Secretary of State may waive some or all of the requirements of this paragraph if he is satisfied that it is reasonable to do so.

Procedure for registration

64.—(1) The procedure for registration is the same as the procedure for granting a marketing authorisation in accordance with Part 3, except—

(a) the applicant is not required to provide proof of therapeutic effect;

(b) the product shall not have a summary of product characteristics;

(c) the Secretary of State shall not publish an assessment report.

(2) The procedure for variation, suspension and revocation is the same as for a marketing authorisation.

Products on the market before 1994

65. A homeopathic remedy that was on the market before 1st January 1994 may be placed on the market without being registered.

Classification

66. The registration must specify the classification of the homeopathic remedy, which must be one of the classifications specified for a veterinary medicinal product in Schedule 3.

SCHEDULE 2 Regulation 5(2)

THE MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS

CONTENTS

PART 4

Authorisation of manufacturers of products for administration under the cascade

PART 1

Manufacturing authorisation

Application

1. An application for a manufacturing authorisation shall be made to the Secretary of State.

Time limits

2.—(1) The Secretary of State shall process an application for a manufacturing authorisation within 90 days of receiving it.

(2) He shall process an application for a variation of a manufacturing authorisation within 30 days unless he notifies the applicant in writing that he is extending the time to 90 days.

Granting the authorisation

3. The Secretary of State shall grant a manufacturing authorisation if he is satisfied that the applicant has at his disposal suitable and sufficient premises, staff, technical equipment and facilities for the manufacture, control and storage of the products, and will comply with his duties under these Regulations.

The authorisation

4.—(1) The manufacturing authorisation shall specify—

(a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured or imported;

(b) the place where they are to be manufactured or controlled;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the name of the qualified person nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

Suspension or revocation of the authorisation

5.—(1) The Secretary of State may suspend or revoke a manufacturing authorisation if the holder—

(a) has not complied with these Regulations;

(b) has manufactured a veterinary medicinal product not authorised by his manufacturing authorisation;

(c) has produced a veterinary medicinal product outside the terms of a marketing authorisation;

(d) no longer has suitable premises or equipment.

(2) He may also suspend or revoke it if he is satisfied that the qualified person (manufacture) is not fulfilling his duties.

Representation to the Secretary of State

6.—(1) A person may make representations against a refusal, suspension or revocation of a manufacturing authorisation to a person appointed for the purpose by the Secretary of State.

(2) The appointed person shall consider the representations and report in writing to the Secretary of State.

(3) The Secretary of State shall give written notification of his final determination and the reasons for it.

Inspection of premises

7.—(1) The Secretary of State shall inspect the premises relating to a manufacturing authorisation on a regular basis to ensure compliance with good manufacturing practice.

(2) Within 90 days after an inspection, the Secretary of State shall issue a certificate of good manufacturing practice to the manufacturer if the inspection established that he is complying with the principles and guidelines on good manufacturing practice in accordance with Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**10**).

(3) If an inspection is carried out at the request of the European Pharmacopoeia to establish compliance with a monograph, the Secretary of State shall issue a certificate of compliance with the monograph, if appropriate.

(4) The Secretary of State shall provide details of each certificate of good manufacturing practice that he issues to the Agency for entry into a database.

(5) If the outcome of the inspection is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice, he shall provide details to the Agency for entry into the database.

Report following inspection

8.—(1) After each inspection of manufacturing premises, the inspector shall make a written report to the Secretary of State on whether the principles and guidelines on good manufacturing practice and the conditions of these Regulations are being complied with.

(2) The Secretary of State shall inform the inspected manufacturer of the content of such reports.

Duties on the holder of a manufacturing authorisation

9.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

(**10**) OJ No. L 228, 17.8.91, p. 70.

(2) He must have permanently at his disposal the services of at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State.

(3) He must hold a current Certificate of Good Manufacturing Practice.

(4) He must have in place a system of Quality Assurance and Quality Control.

(5) He must give to the Secretary of State on request proof of all control tests carried out on the veterinary medicinal product or the constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(6) If he makes up a bulk package of veterinary medicinal products he must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

(a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;

(b) the batch number;

(c) expiry date;

(d) any storage requirements; and

(e) any other warning necessary for the safe handling of the package.

(7) He must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if he requires it in writing.

Qualified persons for manufacture

10.—(1) The Secretary of State may appoint as a qualified person (manufacture) any person who is—

(a) registered as a pharmaceutical chemist with the Royal Pharmaceutical Society of Great Britain or with the Pharmaceutical Society of Northern Ireland;

(b) a Chartered Chemist or a Fellow, Member or Associate Member of the Royal Society of Chemistry; or

(c) a Chartered Biologist or a Fellow, Member or Associate Member of the Institute of Biology,

who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent and who has sufficient practical experience to carry out the duties under this Schedule.

(2) The Secretary of State may exceptionally appoint a person who is not a member of one of those institutions to act as a qualified person (manufacture) if he is satisfied that he has the educational qualifications or practical experience to carry out the duties under this Schedule.

Refusal or revocation of appointment

11.—(1) The Secretary of State may refuse or revoke an appointment if he is not satisfied that a person has fulfilled or will fulfil his duties.

(2) A person may make representations against a refusal or revocation to a person appointed for the purpose by the Secretary of State, and the procedure in paragraph 6 applies.

Duties on a qualified person

12.—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under his responsibility is manufactured and checked in compliance with

these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from a third country, including a product manufactured in a member State, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested in a member State, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) The preceding paragraph does not apply where appropriate arrangements have been made by the European Community with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

(5) It is an offence to fail to comply with this paragraph.

Register

13. The Secretary of State shall maintain and publish a register of holders of manufacturing authorisations and qualified persons (manufacture).

Test sites

14.—(1) The Secretary of State may authorise premises to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The premises must have a current certificate of good manufacturing practice.

(3) Authorisation and inspection of the premises are the same as for a manufacturing authorisation.

PART 2

Authorisation of manufacturers of autogenous vaccines

Authorisation to manufacture autogenous vaccines

15.—(1) The Secretary of State may authorise a person and premises to manufacture autogenous vaccines.

(2) In order to be authorised the premises must be under the supervision of—

(a) a veterinary surgeon, or

(b) a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before he authorises the premises, the Secretary of State must be satisfied that the production process will produce a consistent, safe product.

(4) The procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.

(5) It is an offence to manufacture an autogenous vaccine other than in accordance with such an authorisation.

Types of authorisation

16.—(1) The authorisation shall specify the products that may be manufactured.

(2) It shall either be for the production of a single batch of product or for on-going production of the products specified in the authorisation.

(3) If it is for a single batch the authorisation shall be time-limited.

(4) Only the products specified in the authorisation may be manufactured, and in the case of an authorisation for a single batch the product may only be manufactured before the expiry of the authorisation.

Labelling

17.—(1) The operator of the premises must ensure that every container containing autogenous vaccine is labelled with—

(a) the name of the veterinary surgeon who ordered the vaccine;

(b) a precise description of the vaccine;

(c) the date the vaccine was produced;

(d) the name of the authorisation holder and address of the authorised premises;

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

(2) It is an offence to fail to comply with this paragraph.

Records

18.—(1) The operator of the premises must, as soon as is reasonably practicable, record—

(a) the name and address of the veterinary surgeon who ordered the vaccine;

(b) the identity of the source animal;

(c) the expiry date;

(d) the date of supply to the veterinary surgeon.

(2) He must keep the records for at least five years.

(3) It is an offence to fail to comply with this paragraph.

Adverse reactions

19.—(1) The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine of which he becomes aware within 15 days of learning of the reaction.

(2) It is an offence to fail to comply with this paragraph.

Inspection of premises

20. The Secretary of State shall inspect the authorised premises every two years.

PART 3

Authorisation of blood banks

Authorisation of blood banks

21.—(1) The Secretary of State may authorise blood banks for the collection, storage and supply of blood for the treatment of non-food-producing animals.

(2) In order to be authorised a blood bank must be under the supervision of—

(a) a veterinary surgeon named in the authorisation; or

(b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the blood bank.

(3) Before he authorises a blood bank, the Secretary of State must be satisfied—

(a) that the welfare of animals used in the collection of blood will be respected; and

(b) that the production process will produce a consistent, safe product.

(4) The procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.

(5) Blood may only be collected under the supervision of a veterinary surgeon.

(6) It is an offence to operate a blood bank for treatment of animals other than in accordance with such an authorisation.

Supply and administration of blood from a blood bank

22.—(1) The blood may only be supplied to a veterinary surgeon.

(2) It may only be administered by a veterinary surgeon or under his supervision.

(3) It may only be administered to non-food-producing animals.

(4) It is an offence to fail to comply with this paragraph.

Labelling

23.—(1) The operator of a blood bank must ensure that every container used for the blood is labelled with—

(a) the identity of the donor animal;

(b) the date of collection;

(c) the name of the veterinary surgeon who collected it;

(d) any necessary warnings; and

(e) the expiry date.

(2) It is an offence to fail to comply with this paragraph.

Records

24.—(1) The operator of a blood bank must, as soon as is reasonably practicable, record—

(a) the date of collection;

(b) the identity of the donor animal;

(c) the veterinary surgeon who collected it;

(d) the expiry date; and

(e) the date the blood was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied.

(2) He must keep the records for at least five years.

(3) It is an offence to fail to comply with this paragraph.

Inspection of blood banks

25. The Secretary of State shall inspect a blood bank every two years.

PART 4

Authorisation of manufacturers of products for administration under the cascade

Authorisation to manufacture products for administration under the cascade

26.—(1) The Secretary of State may authorise a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade.

(2) In order to be authorised the premises must be under the supervision of a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before he authorises the premises, the Secretary of State must be satisfied that the production process will produce a safe product.

(4) The procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.

(5) The authorisation shall specify what types of product it covers.

(6) It is an offence for the holder of an authorisation to manufacture a product other than in accordance with the authorisation.

Labelling

27.—(1) The authorised person must ensure that, before a veterinary medicinal product is supplied, every container is labelled with—

(a) the name of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the name of the authorisation holder and the address of the authorised premises;

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

(2) It is an offence to fail to comply with this paragraph.

Records

28.—(1) The authorised person must, as soon as is reasonably practicable, record—

(a) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the expiry date; and

(e) the date of supply to the veterinary surgeon.

(2) He must keep the records for at least five years.

(3) It is an offence to fail to comply with this paragraph.

Adverse reaction

29.—(1) The authorised person must notify the Secretary of State of any adverse reaction to a product manufactured by him within 15 days of learning of the reaction.

(2) It is an offence to fail to comply with this paragraph.

Inspection of premises

30. The Secretary of State shall inspect the authorised premises every two years.

SCHEDULE 3 Regulation 7

CLASSIFICATION AND SUPPLY, WHOLESALE DEALERS AND SHEEP DIP

CONTENTS

PART 1

Classification and supply of authorised veterinary medicinal products

Classification of veterinary medicinal products

1.—(1) There shall be the following categories of authorised veterinary medicinal products—

(a) Prescription Only Medicine—Veterinarian (abbreviated to POM-V);

(b) Prescription Only Medicine—Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);

(c) Non-Food Animal—Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);

(d) Authorised Veterinary Medicine—General Sales List (abbreviated to AVM-GSL).

(2) The Secretary of State shall specify the classification of the veterinary medicinal product when he grants the initial marketing authorisation.

(3) He may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).

(4) When he grants the marketing authorisation the Secretary of State must classify the following as POM-V—

(a) products containing narcotic or psychotropic substances;

(b) products intended as treatments following a precise prior diagnosis.

(5) When he grants the marketing authorisation he must classify the following as POM-V or POM-VPS—

(a) (after 1st January 2007) products for food-producing animals;

(b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—

(i) the target species;

(ii) the person administering the products to the animal; and

(iii) the environment;

(c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; and

(d) new veterinary medicinal products containing an active substance that has not been included in an authorised veterinary medicinal product for five years.

Wholesale supply of veterinary medicinal products

2.—(1) Only a holder of a marketing authorisation, the holder of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.

(2) They may only supply a veterinary medicinal product if their authorisation relates to that product, and they may only supply it to another person who may supply that product under these Regulations, either wholesale or retail.

(3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 13.

(4) It is irrelevant whether or not the supply is for profit.

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer provided that in any one year the amount supplied by a retailer does not exceed five per cent in terms of value of turnover of veterinary medicinal products of that retailer.

(6) It is an offence to fail to comply with this paragraph.

Retail supply of veterinary medicinal products

3.—(1) This paragraph applies in relation to retail supply of veterinary medicinal products.

(2) A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

(3) A veterinary medicinal product classified as POM-VPS may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 13,

and must be in accordance with a prescription from one of those persons.

(4) A veterinary medicinal product classified as NFA-VPS may be supplied without prescription, but may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 13.

(5) There are no restrictions on the supply of AVM-GSL products.

(6) In this paragraph—

(a) "retail supply" means any supply other than to or from the holder of a wholesale dealer's authorisation, and whether or not for payment; and

(b) a person may supply a product irrespective of who owns it.

(7) It is an offence to fail to comply with this paragraph.

Prescriptions by a veterinary surgeon

4. A veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V must first carry out a clinical assessment of the animal, and the animal must be under his care, and failure to do so is an offence.

Prescriptions

5.—(1) A prescription may be oral or written, but a veterinary medicinal product classified as POM-V or POM-VPS may only be supplied—

(a) by the person who prescribed it, or

(b) under a written prescription that complies with paragraph 6.

(2) A person supplying such a product under a written prescription—

(a) may only supply the product specified in that prescription,

(b) must take all reasonable steps to satisfy himself that the prescription has been written and signed by a person entitled to prescribe the product; and

(c) must ensure that it is supplied to the person named in the prescription.

(3) It is an offence to fail to comply with this paragraph.

Written prescriptions

6.—(1) A written prescription must include—

(a) the name, address and telephone number of the person prescribing the product;

(b) the qualifications enabling the person to prescribe the product;

(c) the name and address of the owner or keeper;

(d) the species of animal, identification and number of the animals;

(e) the premises at which the animals are kept if this is different from the address of the owner or keeper;

(f) the date of the prescription;

(g) the signature or other authentication of the person prescribing the product;

(h) the name and amount of the product prescribed;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(k) the withdrawal period if relevant.

(2) A written prescription for a controlled drug as specified in the Misuse of Drugs Regulations 2001(**11**) is valid for 28 days.

(3) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.

(4) If the prescription is a repeatable prescription that does not specify the number of times the product may be supplied, the prescription may only be repeated once.

Duties when a product is prescribed or supplied

7.—(1) When a person prescribes a product classified as POM-V or POM-VPS, or supplies a product classified as NFA-VPS—

(a) before he does so, he must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised;

(b) when he does so, he must advise on its safe administration and on any warnings or contra-indications on the label or package leaflet; and

(**11**) S. I. 2001/3998; relevant amending instruments are S.I. 2003/1432 and 2005/1653.

(c) he must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the treatment; but it is a defence for him to show that—

(i) the product prescribed or supplied by him was in a container specified in the marketing authorisation;

(ii) the manufacturer does not supply that veterinary medicinal product in a smaller container; and

(iii) he is not a person authorised to break open the package before supply.

(2) It is an offence to fail to comply with this paragraph.

Supply by a pharmacist

8.—(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS from premises registered as a pharmacy with the Royal Pharmaceutical Society of Great Britain or with the Pharmaceutical Society of Northern Ireland, or (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises registered under paragraph 13.

(2) A pharmacist may supply a homeopathic remedy prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy that he is permitted to supply under these Regulations) provided that it is prepared in accordance with paragraph 61 of Schedule 1 for an individual customer.

(3) It is an offence to fail to comply with this paragraph.

Supply by a veterinary surgeon when he is not present

9.—(1) A veterinary surgeon supplying a veterinary medicinal product need not be present when it is handed over, but if he is not present—

(a) he must authorise each transaction individually before the product is supplied;

(b) he must have satisfied himself that the person handing it over is competent to do so.

(2) It is an offence to fail to comply with this paragraph.

Supply of products for incorporation into feedingstuffs

10.—(1) In the case of a veterinary medicinal product where the marketing authorisation specifies that it must be incorporated into feedingstuffs, the marketing authorisation holder, an authorised manufacturer of that product or an authorised wholesale dealer may supply it to—

(a) an approved premixture manufacturer; or

(b) a feedingstuffs manufacturer where the approval so permits.

(2) A veterinary surgeon, pharmacist or suitably qualified person who supplies a veterinary medicinal product for the purposes of incorporating it into a premixture or feedingstuff may only supply it to a person specified in paragraph 10(1)(a) or (b).

(3) In addition, an approved premixtures manufacturer or feedingstuffs manufacturer may supply a veterinary medicinal product to another approved premixtures manufacturer or feedingstuffs manufacturer provided that the amount supplied does not exceed five per cent in terms of value of veterinary medicinal product used annually.

(4) It is an offence to fail to comply with this paragraph.

Labelling at the time of retail supply

11.—(1) If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it is an offence to supply it if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

(2) Sub-paragraph (1) does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription from a veterinary surgeon, provided that the unamended information remains clearly visible.

(3) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely, and failure to do so is an offence.

Supply of veterinary medicinal products for use under the cascade

12.—(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product supplies the product himself and administers it to the animal himself, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

(a) the name and address of the pharmacy or veterinary surgery supplying the veterinary medicinal product;

(b) the name of the veterinary surgeon who has prescribed the product;

(c) the name and address of the animal owner;

(d) the identification of the animal or group of animals;

(e) the date of supply;

(f) the expiry date of the product, if applicable;

(g) the name or description of the product which should include at least the name and quantity of active ingredients;

(h) dosage and administration instructions;

(i) any special storage precautions;

(j) any necessary warnings for the user, target species, administration or disposal of the product.

(3) It is an offence to fail to comply with this paragraph.

Supply by a suitably qualified person

13.—(1) The Secretary of State shall recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

(2) In order to recognise such a body, the Secretary of State must be satisfied that the body—

(a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;

(b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;

(c) maintains a programme of continuing development for persons registered with it;

(d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.

(3) To become a suitably qualified person it is necessary to pass examinations specified by such a body, and to be registered with such a body.

(4) The supply of products permitted to be supplied by a suitably qualified person must take place from premises approved by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products.

(5) A suitably qualified person must either—

(a) hand over or despatch the product himself;

(b) ensure that, when the product is handed over or despatched, he is in a position so that he can intervene if necessary; or

(c) check the product after it has been allocated for supply to a customer, and satisfy himself that the person handing over or dispatching it is competent to do so.

(6) If a suitably qualified person considers that the premises in which he is operating no longer comply with the approval granted by the Secretary of State, he must notify the Secretary of State without unreasonable delay, and failure to do so is an offence.

(7) The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph shall ensure that a suitably qualified person registered with it complies with the Code of Practice.

(8) The Secretary of State shall publish a list of—

(a) suitably qualified persons; and

(b) the trading names and the addresses of premises approved under this paragraph.

(9) The procedure for the suspension or revocation of the authorisation of the premises is the same as for the holder of a manufacturing authorisation.

Annual audit

14.—(1) At least once a year every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products shall be reconciled with products currently held in stock, any discrepancies being recorded.

(2) It is an offence to fail to comply with this paragraph.

PART 2

Requirements for a wholesale dealer's authorisation

Application

15. An application for a wholesale dealer's authorisation shall be made to the Secretary of State.

Time limits

16. The Secretary of State shall process an application for a wholesale dealer's authorisation within 90 days of receiving it.

Granting the authorisation

17.—(1) The Secretary of State shall grant a wholesale dealer's authorisation if he is satisfied that this paragraph is complied with.

(2) The authorised site must be—

(a) weatherproof;

(b) secure and lockable;

(c) clean; and

(d) free from contaminants.

(3) If the veterinary medicinal products covered by the authorisation are subject to specific storage conditions, the site must be capable of fulfilling those requirements.

(4) The authorisation holder must—

(a) have at his disposal the services of technically competent staff; and

(b) have an effective emergency recall plan.

The authorisation

18.—(1) The wholesale dealer's authorisation shall specify—

(a) the types of veterinary medicinal products and pharmaceutical forms that may be dealt in;

(b) the place where they are to be stored;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates; and

(e) the name of the qualified person nominated to act under the Guidelines on Good Distribution Practice under paragraph 21.

(2) It may cover more than one site.

(3) It shall lapse if the holder does not deal in veterinary medicinal products for five years.

Suspension or revocation of the authorisation

19. The Secretary of State may suspend or revoke a wholesale dealer's authorisation if the holder—

(a) has not complied with these Regulations; or

(b) no longer has suitable premises or equipment.

Representations

20.—(1) A person may make representations against a refusal, suspension or revocation of a wholesale dealer's authorisation to a person appointed for the purpose by the Secretary of State.

(2) The appointed person shall consider the representations and report in writing to the Secretary of State.

(3) The Secretary of State shall give written notification of his final determination and the reasons for it.

Duties on the holder of a wholesale dealer's authorisation

21.—(1) The holder of a wholesale dealer's authorisation must store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product.

(2) He must comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use(**12**) as if the veterinary medicinal products were products for human use.

(3) He must carry out a detailed stock audit at least once a year.

(4) He must supply information and samples to the Secretary of State on demand.

(5) He must notify the Secretary of State if there are any changes to the information held by him.

(6) It is an offence to fail to comply with this paragraph.

PART 3

Sheep dip

Supply of sheep dip

22.—(1) If the veterinary medicinal product is a sheep dip of any type the provisions of this paragraph apply, and it is an offence to supply the product by retail other than in accordance with this paragraph.

(2) The supply must be to a person (or a person acting on his behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed and issued by—

(a) in England, Wales, and Northern Ireland by the National Proficiency Tests Council, or by NPTC Part of the City & Guilds Group; or

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

(3) The supplier must make a record of the Certificate number as soon as is reasonably practicable, and keep it for at least three years.

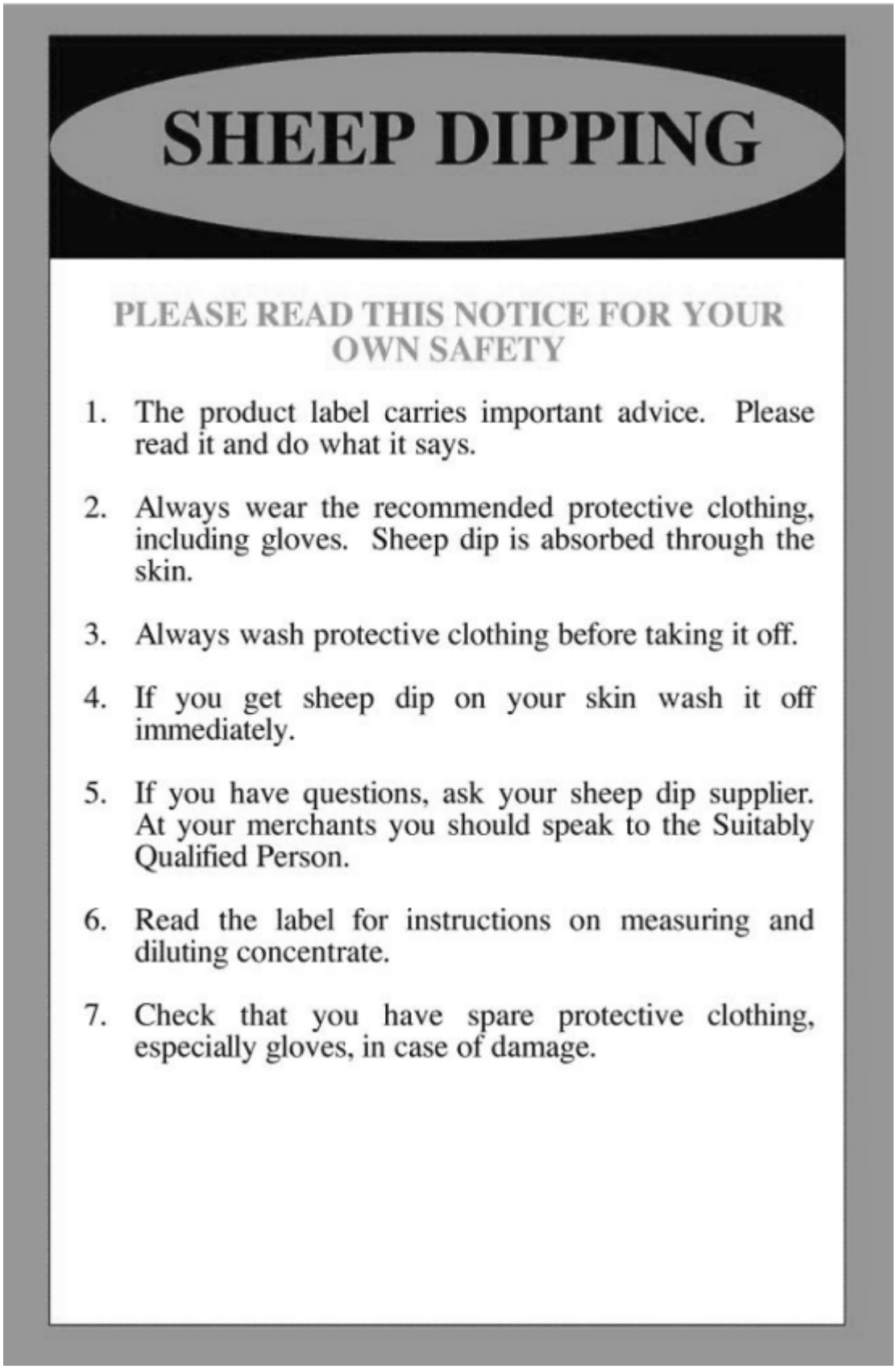
(4) If the active ingredient of the veterinary medicinal product is an organophosphorus compound, the supplier must give to the buyer—

(a) a double sided laminated notice meeting the specifications in the following sub-paragraph (unless the notice has been provided to the buyer within the previous twelve months and the supplier knows or has reasonable cause to believe that the buyer still has it available for use); and

(b) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described.

(5) The notice shall be at least A4 size with a laminated transparent cover, coloured and printed to scale on front and back substantially in accordance with the following two diagrams, except that in Wales it may be in Welsh as well as in English—

(**12**) OJ No. C 63, 1.3.94, p. 4.


SHEEP DIPPING
PLEASE READ THIS NOTICE FOR YOUR OWN SAFETY
1. The product label carries important advice. Please read it and do what it says.
2. Always wear the recommended protective clothing, including gloves. Sheep dip is absorbed through the skin.
3. Always wash protective clothing before taking it off.
4. If you get sheep dip on your skin wash it off immediately.
5. If you have questions, ask your sheep dip supplier. At your merchants you should speak to the Suitably Qualified Person.
6. Read the label for instructions on measuring and diluting concentrate.
7. Check that you have spare protective clothing, especially gloves, in case of damage.

A well designed sheep dip, with splash screens to limit contamination, reduces the risks, makes the job easier and makes wearing protective clothing more practical.

Everyone doing the job must be adequately trained. If they are not absolutely sure how to dip safely consider a training course.

The recommended protective clothing is:

Face Shield (when handling dip concentrate)

Bib apron (over boiler suit) **or waterproof coat** (PVC or nitrile)

Gloves (non-lined, PVC or nitrile, heavy duty gauntlet style – 0.5 mm thick and at least 300 mm long)

Waterproof leggings/trousers (PVC or nitrile)

Wellington boots

For more information you are recommended to read the Government's leaflet 'Sheep dipping' (AS29rev2).

Use of sheep dip

23.—(1) It is an offence to use sheep dip unless this is done by, or under the supervision and in the presence of, a person who holds a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed and issued by—

(a) in England, Wales and Northern Ireland by the National Proficiency Tests Council, or by NPTC Part of the City & Guilds Group; or

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

(2) In the case of a person who has had practical experience of sheep dipping before 1st October 2006, this paragraph does not apply until 31st December 2008, and in any other case does not apply until 1st April 2007.

SCHEDULE 4 Regulation 8

ADMINISTRATION OF A VETERINARY MEDICINAL PRODUCT OUTSIDE THE TERMS OF A MARKETING AUTHORISATION

CONTENTS

Administration under the cascade

1.—(1) A veterinary surgeon acting under this paragraph may either administer a veterinary medicinal product prescribed by him personally or may direct another person to do so under his responsibility.

(2) If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following ("the cascade"), cascaded in the following order—

(a) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or

(b) if and only if there is no such product that is suitable, either—

(i) a medicinal product authorised in the United Kingdom for human use; or

(ii) a veterinary medicinal product not authorised in the United Kingdom but authorised in another member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or

(c) if and only if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) In the case of a veterinary medicinal product imported from another member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting him to import it, he must obtain a certificate from the Secretary of State before he administers it.

(4) For the purposes of this paragraph a food-producing animal includes an animal belonging to the equidae family unless it has been declared, as not being intended for slaughter for human consumption in accordance with—

(a) the Horse Passports (England) Regulations 2004(**13**);

(b) the Horse Passports Regulations (Northern Ireland) 2004(**14**);

(c) the Horse Passports (Scotland) Regulations 2005(**15**); or

(d) the Horse Passports (Wales) Regulations 2005(**16**).

(5) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Annex I, II or III to Council Regulation (EEC) No. 2377/90.

Withdrawal periods

2.—(1) A veterinary surgeon administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

(2) The withdrawal period must ensure that, if there is a maximum residue limit specified for the active substance in Council Regulation (EEC) No. 2377/90, the level of residue of the active substance does not exceed that limit.

(3) In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit is specified in Council Regulation (EEC) No. 2377/90) must not be less than—

(a) 7 days for eggs;

(b) 7 days for milk;

(c) 28 days for meat from poultry and mammals including fat and offal;

(d) 500 degree days(**17**) for fish meat.

(4) In the case of a homeopathic remedy in which active principles figure in Annex II to Council Regulation (EEC) No. 2377/90, the withdrawal period is zero.

Immunological products for serious epizootic disease

3.—(1) In the event of serious epizootic diseases, the Secretary of State may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

(**13**) S.I. 2004/1397.
(**14**) S.R. (NI) 2004 No. 497.
(**15**) S.S.I. 2005/223.
(**16**) S.I. 2005/231 (W. 21).
(**17**) The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

(2) He shall publicise any permit as he sees fit.

Immunological products for an imported or exported animal

4. If an animal is imported from, or exported to, a third country, the Secretary of State may permit the administration to that animal of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the United Kingdom but is authorised under the legislation of the third country.

Administration by veterinary surgeons from other member States

5.—(1) Veterinary surgeons practising in another member State may bring into the United Kingdom and administer to animals small quantities of veterinary medicinal products that are not authorised for use in the United Kingdom if—

(a) the quantity does not exceed the requirements for the treatment of specific animals;

(b) the product is authorised in the member State in which the veterinary surgeon is established;

(c) the product is transported by the veterinary surgeon in the original manufacturer's packaging;

(d) in the case of administration to food-producing animals, there is a veterinary medicinal product authorised in the United Kingdom that has the same qualitative and quantitative composition in terms of active substances;

(e) the veterinary surgeon has acquainted himself with the Guide to Professional Conduct issued by the Royal College of Veterinary Surgeons(**18**).

(2) The veterinary surgeon must only supply to the owner or keeper enough veterinary medicinal product to complete the treatment of animals concerned.

(3) He must—

(a) ensure that the withdrawal period specified on the label of the product is complied with, or the United Kingdom withdrawal period for the equivalent product authorised in the United Kingdom if this is longer than the one on the label; and

(b) keep detailed records of the animals treated, the diagnosis, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and shall keep them in the United Kingdom for at least three years, and failure to comply with this sub-paragraph is an offence.

(4) The overall range and quantity of veterinary medicinal products carried by the veterinary surgeon must not exceed that generally required for the daily needs of good veterinary practice.

(5) This paragraph does not apply in relation to immunological veterinary medicinal products.

Treatment in exceptional circumstances

6.—(1) the health situation so requires, and where there is no suitable veterinary medicinal product available either as an authorised product or under the cascade, a veterinary surgeon may treat an animal with a medicinal product authorised in a third country; but if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting him to import it, he must obtain a certificate from the Secretary of State before he treats the animal.

(2) The certificate may be granted subject to any condition the Secretary of State thinks fit.

(**18**) Published at www.rcvs.org.uk/PrintFullArticle.asp?NodeID=89642

Administration of a homeopathic remedy

7.—(1) A registered homeopathic remedy or a homeopathic remedy prepared and supplied by a pharmacist under paragraph 8 of Schedule 3 may be administered to an animal by anyone, subject to any restrictions specified in its registration.

(2) A homeopathic remedy that was on the market before 1st January 1994 may be administered by anyone.

(3) A veterinary surgeon may administer, either himself or under his responsibility—

(a) a homeopathic remedy authorised for human use, or

(b) a homeopathic remedy prepared extemporaneously by a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

SCHEDULE 5 Regulation 14

MEDICATED FEEDINGSTUFFS AND SPECIFIED FEED ADDITIVES

CONTENTS

Scope and interpretation

1.—(1) This Schedule applies in relation to the following (referred to in this Schedule as "specified feed additives") when used as feed additives—

(a) coccidiostats;

(b) histomonostats; and

(c) all other zootechnical additives except—

(i) digestibility enhancers;

(ii) gut flora stabilisers; and

(iii) substances incorporated with the intention of favourably affecting the environment.

(2) It also applies in relation to the manufacture and placing on the market of feedingstuffs containing a veterinary medicinal product.

(3) In this Schedule—

"premixture" means a mixture of a veterinary medicinal product or a specified feed additive with feedingstuffs materials, intended for further mixing with feedingstuffs before being fed to animals;

"zootechnical additive" means any additive used to maintain animals in good health or favourably affect their performance.

Enforcement of Regulation (EC) No. 178/2002

2.—(1) For the purposes of Regulation (EC) No. 178/2002 (of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**19**)) the competent authority is the Secretary of State.

(2) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

(a) Article 11 (requirements relating to imports);

(b) Article 12 (requirements relating to exports);

(c) Article 15 (1) (prohibition on the placing on the market or feeding unsafe feedingstuffs);

(d) Article 16 so far as it prohibits misleading labelling, advertising or presentation of feedingstuffs;

(e) Article 18 (2) and (3) (requirements of traceability) in so far as it relates to feed business operators; and

(f) Article 20 (responsibilities of feed business operators).

Enforcement of Regulation (EC) No. 1831/2003

3.—(1) For the purposes of Regulation (EC) No. 1831/2003 (of the European Parliament and the Council on additives for use in animal nutrition(**20**)) the competent authority is the Secretary of State.

(2) When he grants an authorisation under Article 3(2) of that Regulation, the authorisation shall be in writing.

(3) It is an offence to be in possession of a specified feed additive, or a premixture or feedingstuffs containing a specified feed additive, unless the specified feed additive has been authorised under Regulation (EC) No. 1831/2003 or is for export to a third country.

(**19**) OJ No. L 31, 1.2.2002, p. 1.
(**20**) OJ No. L 268, 18.10.2003, p. 29.

(4) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

(a) Article 3(1) or Article 3(3) (the authorisation, conditions of use and labelling of specified feed additives);

(b) Article 12(1) or (2) (conditions relating to specified feed additives);

(c) Article 16(1) (labelling);

(d) Article 16(3) (additional labelling requirement);

(e) Article 16(4) (premixtures containing specified feed additives);

(f) Article 16(5) (packaging).

Enforcement of Regulation (EC) No. 882/2004

4. For the purposes of Regulation (EC) No. 882/2004 (of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(**21**)) the competent authority is the Secretary of State.

Enforcement of Regulation (EC) No. 183/2005

5.—(1) For the purposes of Regulation (EC) No. 183/2005 (of the European Parliament and of the Council laying down requirements for feed hygiene(**22**)) the competent authority is the Secretary of State.

(2) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

(a) Article 5(2), (5) or (6) (specific obligations);

(b) Article 6(1) as read with (2) and (3) (HACCP system);

(c) Article 7(1) (documents concerning the HACCP system);

(d) Article 9(2) (official controls, notification and registration);

(e) Article 11 (prohibition on operating without approval or registration);

(f) Article 17(2) (exemption from on-site visits);

(g) Article 18(3) (declaration of compliance);

(h) Article 23(1) (conditions relating to imports from third countries);

(i) Article 25 (feedingstuffs produced for export to third countries).

(3) A manufacturer must ensure that, so far as is reasonably practicable, the active ingredient is evenly incorporated throughout the feedingstuffs and failure to do so is an offence.

(4) In the case of the refusal, suspension or revocation of an approval under the Regulation the representations procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 applies.

Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products

6.—(1) It is an offence to incorporate a veterinary medicinal product into a premixture or feedingstuffs, or to act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Secretary of State.

(**21**) Corrected version at OJ No. L 191, 28.5.2004, p. 1.
(**22**) OJ No. L 35, 8.2.2005, p. 1.

(2) The requirements of this paragraph do not apply in relation to a person who incorporates a veterinary medicinal product into feedingstuffs in domestic premises for feeding, on those premises—

(a) non-food-producing animals, or

(b) food-producing animals kept purely for domestic consumption.

(3) The provisions of Regulation (EC) No. 183/2005 apply to those producers and distributors in the same way as to persons approved under Article 9 of that Regulation.

(4) A manufacturer must ensure that, so far as is reasonably practicable, the veterinary medicinal product is evenly incorporated throughout the feedingstuffs and failure to do so is an offence.

(5) In the case of the refusal, suspension or revocation of an approval under this paragraph the representations procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 applies.

Incorporation of a veterinary medicinal product into a premixture

7.—(1) Any person who incorporates a veterinary medicinal product into a premixture—

(a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there; and

(b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive.

(2) It is an offence to fail to comply with this paragraph.

Incorporation of a veterinary medicinal product into feedingstuffs

8.—(1) Any person who incorporates a veterinary medicinal product (or a premixture containing a veterinary medicinal product) into feedingstuffs—

(a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there;

(b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive;

(c) must ensure that the veterinary medicinal product is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the prescription;

(d) must ensure that the daily dose of the veterinary medicinal product is contained in a quantity of medicated feedingstuffs corresponding to at least half the daily feedingstuffs ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs.

(2) It is an offence to fail to comply with this paragraph.

Additional record keeping requirements relating to veterinary medicinal products

9.—(1) Any person who—

(a) incorporates a veterinary medicinal product into a premixture;

(b) incorporates a premixture containing a veterinary medicinal product into feedingstuffs; or

(c) incorporates a veterinary medicinal product into feedingstuffs,

must make a daily record of—

(i) the types and quantities of all veterinary medicinal products (and specified feed additives, if any) and premixture used in the manufacturing process; and

(ii) the quantity of feedingstuffs and premixture containing veterinary medicinal product manufactured that day.

(2) An approved distributor must make a daily record of—

(a) the types and quantities of all premixtures and feedingstuffs containing veterinary medicinal products bought and sold that day;

(b) the quantity held.

(3) A manufacturer and distributor must also record, as soon as reasonably practicable, for each consignment supplied—

(a) the date of delivery;

(b) the name and address of each consignee (or, in the case of a manufacturer supplying to a distributor, the name and address of the distributor);

(c) the type of feedingstuffs or premixture supplied;

(d) the quantity;

(e) the type of veterinary medicinal product incorporated into the feedingstuffs; and

(f) the expiry date.

(4) Records must be kept for five years.

(5) It is an offence to fail to comply with this paragraph.

Labelling a premixture containing a veterinary medicinal product

10.—(1) A premixture containing a veterinary medicinal product must be clearly and legibly labelled with the following—

(a) the words "MEDICATED PREMIXTURE" in upper case letters;

(b) the proprietary name of the veterinary medicinal product and the authorisation number;

(c) the name and amount of the active substance (mg/kg) in the premixture;

(d) the inclusion rate into the feedingstuffs (or, where liquid is to be incorporated into the final feedingstuffs, the words "typical inclusion rate but refer to the prescription for the exact inclusion rate" or equivalent wording);

(e) the level of the active ingredient in the final feedingstuffs;

(f) warnings and contra-indications;

(g) withdrawal period;

(h) the expiry date;

(i) any special storage instructions;

(j) where a prescription is required, a statement to this effect.

(2) If the premixture also contains a specified feed additive to which this Schedule applies it must also contain the information required under Article 16 of Regulation (EC) No. 1831/2003.

(3) It is an offence to supply such a premixture not labelled in accordance with this paragraph.

Labelling of feedingstuffs containing a specified feed additive

11.—(1) Feedingstuffs containing a specified feed additive must be clearly and legibly labelled with the following—

(a) the name of the specified feed additive;

(b) the name and amount of the active substance (mg/kg) in the feedingstuffs;

(c) the withdrawal period if one is specified in the authorisation;

(d) the expiry date;

(e) the name and approval number of the manufacturer or the distributor;

(f) any particulars concerning the proper use of the feedingstuffs specified in the authorisation of the specified feed additive.

(2) It is an offence to supply such feedingstuffs not labelled in accordance with this paragraph.

Labelling of feedingstuffs containing a veterinary medicinal product

12.—(1) Feedingstuffs containing a veterinary medicinal product must be clearly and legibly labelled with the following—

(a) the words "MEDICATED FEEDINGSTUFFS" in upper case letters;

(b) the proprietary name, authorisation number and inclusion rate (kg/tonne or mg/kg) of the veterinary medicinal product incorporated into the feedingstuffs;

(c) the name and amount of the active substance (mg/kg) in the feedingstuffs;

(d) the species of animal for which the feedingstuffs are intended;

(e) warnings and contra-indications;

(f) the withdrawal period;

(g) the expiry date;

(h) any special storage instructions required by the marketing authorisation;

(i) a statement to the effect that the feedingstuffs must only be fed in accordance with its prescription;

(j) the name and approval number of the manufacturer or the distributor.

(2) It is an offence to supply feedingstuffs not labelled in accordance with this paragraph.

Supply of specified feed additives

13.—(1) A manufacturer or distributor of specified feed additives may only supply them to a person approved to hold them in accordance with this Schedule.

(2) It is an offence to fail to comply with this paragraph.

Supply of premixture

14.—(1) A manufacturer or distributor of a premixture may only supply it to a person approved to hold it in accordance with this Schedule.

(2) It is an offence to fail to comply with this paragraph.

Supply of feedingstuffs containing a veterinary medicinal product

15.—(1) A manufacturer (if his approval so permits) or distributor of feedingstuffs containing a veterinary medicinal product may only supply those feedingstuffs to—

(a) a person approved to hold them in accordance with this Schedule, or

(b) in accordance with a prescription as specified in paragraph 22, a person who keeps animals.

(2) He must keep the prescription for five years.

(3) It is an offence to fail to comply with this paragraph.

Possession

16.—(1) It is an offence for any person other than a person holding the appropriate approval under this Schedule to be in possession of any—

(a) specified feed additive or veterinary medicinal product to which this Schedule applies;

(b) premixtures containing such an additive or a veterinary medicinal product; or

(c) feedingstuffs containing such an additive or a veterinary medicinal product unless supplied under these Regulations.

(2) It is an offence for any person other than a manufacturer or distributor to be in possession of feedingstuffs incorporating a veterinary medicinal product unless it has been supplied under a prescription.

Sampling and analysis

17.—(1) If any enforcement action is taken under this Schedule based on a sample, that sample must have been taken and analysed in accordance with Council Directive 76/371/EEC (establishing Community methods of sampling for the official control of feedingstuffs(**23**)).

(2) Unless otherwise specified in the marketing authorisation, it is a defence if the active substance in the sample is within the following tolerances—

(a) not exceeding 50 mg/kg of active ingredient: ±50%;

(b) exceeding 50 mg/kg but not exceeding 500 mg/kg: ±40%;

(c) exceeding 500 mg/kg but not exceeding 5g/kg: ±30%;

(d) exceeding 5g/kg but not exceeding 50g/kg: ±20%;

(e) exceeding 50g/kg: ±10%.

Storage

18.—(1) Any person who stores veterinary medicinal products intended for incorporation into feedingstuffs, or a premixture or feedingstuffs containing such veterinary medicinal products, shall do so in a suitable storage area that is locked when not in use or in hermetic containers designed to store those products.

(2) It is an offence to fail to comply with this paragraph.

Packages and other containers

19.—(1) Any person placing feedingstuffs containing a veterinary medicinal product on the market in packages or containers must ensure that they are sealed in such a way that, when the package or container is opened, the seal is damaged.

(2) It is an offence to fail to comply with this paragraph.

Transport

20.—(1) In the case of feedingstuffs distributed by road tankers or in bulk the labelling requirements must be given in a document accompanying the feedingstuffs, and the transporter must hand over details when he delivers the feedingstuffs unless these have already been provided to the purchaser.

(**23**) OJ No. L 102, 15.4.76, p. 1.

(2) Any person transporting feedingstuffs containing veterinary medicinal products or specified feed additives in road tankers or similar containers must ensure that the vehicle or container is cleaned before any re-use if this is necessary to prevent undesirable interaction or contamination.

(3) In the case of feedingstuffs containing a veterinary medicinal product he must ensure that the vehicle is accompanied by documentation stating this.

(4) Any person operating an undertaking transporting feedingstuffs containing veterinary medicinal products or specified feed additives must give written instructions to drivers on how to load and unload vehicles so as to avoid cross-contamination, and take reasonable steps to ensure that the driver complies with those instructions.

(5) It is an offence to fail to comply with this paragraph.

Possession, placing on the market and use of feedingstuffs

21.—(1) It is an offence for any person to possess, place on the market or feed to animals any feedingstuffs incorporating veterinary medicinal products or specified feed additives unless they have been incorporated in accordance with this Schedule.

(2) It is an offence to feed to any animal, or buy or possess for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless that veterinary medicinal product or specified feed additive is authorised for that species of animal and for the purpose for which it is used (unless prescribed under the cascade).

(3) This paragraph shall not apply in relation to feedingstuffs if the veterinary medicinal product has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

Prescriptions for feedingstuffs containing a veterinary medicinal product

22.—(1) A prescription for feedingstuffs containing a veterinary medicinal product must be in writing (notwithstanding the provisions of paragraph 5 of Schedule 3) and must contain the following—

(a) the name and address of the person prescribing the product;

(b) the qualifications enabling the person to prescribe the product;

(c) the name and address of the owner or keeper of the animal;

(d) the species of animal, identification and number of the animals;

(e) the premises at which the animals are kept if this is different from the address of the owner or keeper;

(f) the date of the prescription;

(g) the signature or other authentication of the person prescribing the product;

(h) the name and amount of the product prescribed;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(k) the withdrawal period;

(l) the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);

(m) a statement that, if the validity exceeds one month, not more than 31 days supply may be provided at any time;

(n) the name, type and quantity of feedingstuffs to be used;

(o) the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;

(p) any special instructions for the stockfarmer; and

(q) the percentage of the prescribed feedingstuffs to be added to the daily ration.

(2) A prescription for feedingstuffs is valid for three months or such shorter period as may be specified in the prescription.

(3) The prescription must be sufficient for only one course of treatment.

(4) If the prescription is for a period of longer than one month, the supplier may not provide more than one month's supply at any one time.

(5) The person who writes the prescription must—

(a) give a copy to the person incorporating the veterinary medicinal product into the feedingstuffs or to the distributor of the feedingstuffs;

(b) give one copy to the keeper of the animals to be treated;

(c) keep a copy himself.

(6) The person who writes the prescription must be satisfied that—

(a) there is no undesirable interaction between the veterinary medicinal product and any feed additive used in the feedingstuffs; and

(b) the active substance of the veterinary medicinal product is not the same as an active substance in any feed additive used in the feedingstuffs.

(7) For the avoidance of doubt, a veterinary surgeon may prescribe either a veterinary medicinal product authorised for that species and condition, or under the cascade.

(8) It is an offence to fail to comply with this paragraph.

Imports from third countries

23. No person shall import feedingstuffs containing a veterinary medicinal product from a third country, and it is an offence to fail to comply with this paragraph.

Trade between member States

24.—(1) No person shall bring in feedingstuffs containing a veterinary medicinal product from another member State unless—

(a) they have been manufactured in accordance with the provisions of Council Directive 90/167/EEC (laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**24**)) and Regulation (EC) No. 183/2005; and

(b) they only contain a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in the United Kingdom.

(2) It is an offence to fail to comply with this paragraph.

(**24**) OJ No. L 92, 7.4.90, p. 42.

SCHEDULE 6 Regulation 15(3)

EXEMPTIONS FOR SMALL PET ANIMALS

CONTENTS

Animals to which this Schedule applies

1. This Schedule applies in relation to veterinary medicinal products intended solely for the following animals kept exclusively as a pet—

(a) aquarium fish;

(b) cage birds;

(c) ferrets;

(d) homing pigeons;

(e) rabbits;

(f) small rodents; and

(g) terrarium animals.

Placing on the market, importing and administering the product

2.—(1) A veterinary medicinal product intended solely for an animal to which this Schedule applies may be placed on the market or imported without a marketing authorisation if it complies with this Schedule.

(2) There are no restrictions on its administration to the target species.

Manufacture

3.—(1) The product must have been manufactured by—

(a) the holder of a manufacturing authorisation if manufactured in the United Kingdom;

(b) the holder of a manufacturing authorisation issued under Directive (EC) No. 2001/82 if manufactured in another member State;

(c) in the case of Australia, Canada, New Zealand, or Switzerland, the holder of an authorisation from the competent authority permitting him to manufacture medicinal products;

(d) in the case of any other country, a manufacturer whose premises have been inspected and approved by an officer of the Secretary of State.

(2) This paragraph does not apply until 1st November 2007.

Approval of the active substance

4.—(1) The Secretary of State may approve an active substance for use in a veterinary medicinal product manufactured under this Schedule.

(2) The Secretary of State must grant an approval if he is satisfied that the substance does not require veterinary control.

(3) The approval must specify the animals for which it is approved, and may specify how it or a product containing it is to be administered.

(4) The Secretary of State may suspend or revoke the approval (or limit it to a smaller number of species) if—

(a) it is demonstrated that the substance requires veterinary control;

(b) serious adverse reactions are reported making suspension or revocation necessary; or

(c) it is demonstrated that the substance—

(i) is carcinogenic;

(ii) is genotoxic; or

(iii) shows developmental toxicity (including teratogenicity).

The product

5.—(1) The active substance in the veterinary medicinal product must be approved under paragraph 4.

(2) The veterinary medicinal product must not be an antibiotic.

(3) It must not contain any narcotic or psychotropic substance.

(4) If it contains an active substance contained in a veterinary medicinal product authorised in the United Kingdom as a product that can only be prescribed by a veterinary surgeon, a product containing that active substance must have been so authorised for at least five years.

(5) It must not be intended for treatments or pathological processes that require a precise prior diagnosis or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures.

(6) The requirement that a veterinary medicinal product may only contain an active substance approved under paragraph 4 does not apply until 1st November 2007 in relation to a veterinary medicinal product on the market on 30th October 2005.

Labelling

6.—(1) The product must be clearly labelled as being exempt from the requirements of these Regulations in relation to a marketing authorisation.

(2) The labelling must show the following—

(a) the name of the veterinary product, including, if it is part of the name, its strength and pharmaceutical form;

(b) the name and strength of each active substance;

(c) the route of administration;

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only";

(g) the contents by weight, volume or number of dose units;

(h) the name and address of the manufacturer;

(i) the target species;

(j) the words "Keep out of reach of children";

(k) storage instructions;

(l) the shelf-life after the immediate packaging has been opened for the first time;

(m) disposal advice;

(n) full indications, including—

(i) therapeutic indications;

(ii) contra-indications;

(iii) interaction with other medicines and other forms of interaction; and

(o) dosage instructions.

(3) If there is insufficient room on the label, the information may instead be in a package leaflet, but the leaflet must contain all the information in the preceding sub-paragraph other than the batch number and the expiry date, but the label on the product must contain at least the following—

(a) the name of the veterinary medicinal product;

(b) its active substance and its strength;

(c) the route of administration;

(d) the batch number;

(e) the expiry date; and

(f) the words "For animal treatment only".

(4) This paragraph does not apply until 1st November 2007 in relation to a veterinary medicinal product on the market on 30th October 2005.

Administration

7. The method of administration must be oral or topical or (in the case of a product for fish) addition to the water.

Pack size

8. The pack size must only be sufficient for a single course of treatment or, in the case of a veterinary medicinal product for aquarium fish, sufficient for a single treatment of an aquarium of 25,000 litres.

Adverse reactions

9.—(1) The manufacturer or importer of a product must notify the Secretary of State of any serious adverse reactions (as defined in paragraph 56 of Schedule 1) of which he becomes aware within 15 days of learning of the reaction.

(2) It is an offence to fail to comply with this paragraph.

SCHEDULE 7 Regulation 16

FEES

CONTENTS

PART 1

Introduction

Interpretation of Schedule 7

1. In this Schedule—

"national application" means an application for a marketing authorisation that does not involve another member State;

"pharmaceutical product" means any veterinary medicinal product other than an immunological product;

"simultaneous application" is an application in which, at the time an authorisation for a product is applied for, one or more additional applications are submitted for products that are identical to the first product except that—

(a) in the case of an immunological product, they have a lesser number of antigens than the first product, but only contain antigens contained in the first product; and

(b) in the case of a pharmaceutical product, they have different strengths of the active substance, and, in the case of an application involving more than one member State, the additional applications do not include a member State that was not included in the first application.

Payment of fees

2. All fees under this Schedule are payable to the Secretary of State.

Time of payment

3. All fees are payable on invoice unless otherwise specified.

Multiple inspections

4. If a site is inspected for more than one type of authorisation at the same time, only one fee (the highest) is payable.

Translation

5. All translation costs are charged additionally.

PART 2

Fees relating to marketing authorisations

Fees for specified pharmaceutical applications

6. The following table sets out the fees relating to a pharmaceutical veterinary medicinal product for—

(a) a national application for a marketing authorisation that is—

(i) a full application under Part 1 of Schedule 1;

(ii) a bibliographic application; or

(iii) an application based on pharmacological equivalence;

(b) an application for a marketing authorisation using the decentralised procedure where the United Kingdom is a concerned member State;

(c) an application for the mutual recognition of a product authorised in another member State.

Fees for specified pharmaceutical applications

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
Base Fee: The following fees are in addition to the base fee—	910	1,800	1,800	2,320	460
Quality assessment (if quality data are assessed):	3,810	3,230	2,710	3,470	1,810
Safety assessment (if safety data are assessed):	3,810	3,030	1,030	1,330	1,810
Efficacy assessment (if efficacy data are assessed):	3,810	3,030	1,030	1,330	1,810
Ecotoxicology assessment (if ecotoxicology data are assessed):	640	520	320	410	390
Additional fee if any of the target species is a food-	3,740	3,420	2,070	2,650	1,350

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
producing animal (not payable if neither safety data nor ecotoxicology data are assessed):					
Reduced by—					
if no safety data are assessed:	2,100	2,100	1,290	1,650	640
if no ecotoxicology data are assessed:	990	760	290	370	290
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—					
food-producing animal:	7,170	6,330	5,610	7,200	2,520

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
non-food-producing animal:	6,260	5,620	5,360	6,870	2,200
Additional fee for each additional pack type:	720	720	590	740	330
Reduced by—					
if no quality data are assessed:	350	350	350	450	120
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	60	60	60	70	60
if no ecotoxicity data are assessed:	60	60	—	—	60
Additional fee for each additional active ingredient (food-producing animal):	6,210	5,870	3,880	4,960	2,000

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
Reduced by—					
if no quality data are assessed:	1,400	1,400	1,400	1,790	470
if no safety data are assessed:	2,630	2,630	1,580	2,020	820
if no efficacy data are assessed:	880	700	530	670	290
if no ecotoxicity data are assessed:	700	580	—	—	230
Additional fee for each additional active ingredient (non-food-producing animal):	4,140	3,940	3,110	3,960	1,430
Reduced by—					
if no quality data are assessed:	1,400	1,400	1,400	1,790	470
if no safety	1,400	1,400	880	1,120	470

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
data are assessed:					
if no efficacy data are assessed:	880	700	530	670	290
if no ecotoxicity data are assessed:	60	60	—	—	60
Additional fee if there is more than one target species, for each additional species (food-producing animal):	3,820	3,430	2,330	2,980	1,240
Reduced by—					
if no quality data are assessed:	180	180	180	220	60
if no safety data are assessed:	1,400	1,400	880	1,120	470
if no efficacy data are assessed:	1,750	1,400	1,050	1,350	530

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
if no ecotoxicity data are assessed:	120	120	—	—	60
Additional fee if there is more than one target species, for each additional species (non-food-producing animal):	2,400	2,010	1,490	1,900	780
Reduced by—					
if no quality data are assessed:	180	180	180	220	60
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	1,750	1,400	1,050	1,350	530
if no ecotoxicity data are assessed:	60	60	—	—	60

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application*		*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
			Reference product authorised in UK (£)	*Reference product not authorised in UK (£)*	
Additional fee for each additional recommended route of administration (food-producing animal):	2,590	2,390	1,560	1,980	910
Reduced by—					
if no safety data are assessed:	1,400	1,400	880	1,120	470
if no efficacy data are assessed:	880	700	530	670	290
if no ecotoxicity data are assessed:	60	60	—	—	60
Additional fee for each additional recommended route of administration (non- food-producing animal):	1,170	970	720	910	390
Reduced by—					

Menu	*Full national application under Part 1 of Schedule 1 (£)*	*Bibliographic national application (£)*	*Pharmacologically equivalent national application* *Reference product authorised in UK (£)*	*Reference product not authorised in UK (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	880	700	530	670	290
Simultaneous applications: fee for each additional product in the application:	2,780	2,780	2,780	3,560	1,610

Decentralised pharmaceutical application where the United Kingdom is the reference member State

7.—(1) The fee for a decentralised application for a pharmaceutical product where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 6, with the addition of the fees in the following table.

Decentralised pharmaceutical application where the United Kingdom is the reference member State

Application	*Additional fee (£)*
Food-producing animal: one concerned member State:	3,560
Non-food-producing animal: one concerned member State:	3,100
Each additional concerned member State:	510

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,400 for one concerned member State and £110 for each additional concerned member State.

Application for a marketing authorisation for an immunological product

8.—(1) The fee for a national application for a marketing authorisation relating to an immunological product, a decentralised application where the United Kingdom is the concerned member State or the mutual recognition of a product authorised in another member State is in accordance with the following table.

Fees for specified immunological applications

Menu	*National application for a marketing authorisation (£)*	*Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)*
Base fee:	11,310	5,560
The following fees are in addition to the base fee—	7,100	2,390
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:		
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,300	640
More than one antigenic component—fee for each additional component:	1,290	390
More than one species—fee for each additional species:	5,170	1,550
More than one route of administration—fee for each additional route of administration:	5,170	1,550
Simultaneous application—fee for each additional product in the application:	2,780	1,610

(2) The fee for an application for a marketing authorisation for an immunological product that is identical to a product already authorised in the United Kingdom but with a lesser number of antigens and which only contains antigens contained in the product already authorised is £10,020 (United Kingdom only) or £5,170 (decentralised application where the United Kingdom is a concerned member State).

Decentralised immunological application where the United Kingdom is the reference member State

9.—(1) The fee for a decentralised application for a marketing authorisation for an immunological product where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 8(1), with the additions of £3,330 for one concerned member State and £510 for each additional concerned member State.

(2) In the case of a simultaneous application the fee for each additional product in the application is £6,400 for one concerned member State and £110 for each additional concerned member State.

Application for a marketing authorisation using identical data

10. The fee for an application for a marketing authorisation using identical data is in accordance with the following table.

Identical data

Application	*Fee (£)*
Any application other than decentralised where the United Kingdom is the reference member State:	910
Decentralised application where the United Kingdom is the reference member State—	
one concerned member State:	4,000
each additional concerned member State:	510

Application for a provisional marketing authorisation

11. The fee for an application for a provisional marketing authorisation is the same as that for a full national marketing authorisation in paragraph 6 (in the case of a pharmaceutical product) or the fee for a national application in paragraph 8 (in the case of an immunological product), and the fee for its conversion into a full marketing authorisation is—

(a) if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation—

(i) £8,130, or

(ii) if the application for the provisional marketing authorisation was made before 1st October 2006, £10,705; and

(b) in any other case the same fee as for the provisional marketing authorisation.

Application for a marketing authorisation relating to a parallel import

12. The fee for a marketing authorisation for a parallel import is in accordance with the following table.

Parallel imports

Application	*Fee (£)*
Application where the imported product has been authorised in accordance with the mutual recognition procedure or decentralised	

Application	*Fee (£)*
procedure, and the United Kingdom is included in these procedures—	
import from one member State:	1,690
each additional member State:	340
Any other application—fee for each member State from which the product is imported:	2,050

Application for a variation

13.—(1) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change) and the appropriate fee is payable for each application.

(2) As an exception from sub-paragraph (1), if an applicant applies for more than one variation to the quality data in a marketing authorisation on the same application form, he may elect to pay a total fee of £4,440; but this sub-paragraph does not apply—

(a) if one or more of the variations relates to a new source of an active substance and the applicant does not submit a Certificate of Suitability issued by the European Pharmacopeia relating to the new source, or

(b) if a significant formulation change is applied for that requires a new assessment of the safety or efficacy of the veterinary medicinal product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £440 for a variation specified as Type 1A in that Annex.

(4) If the variation is specified as Type 1B in that Annex, the fee is £835 except in accordance with the following table.

Reductions to Type 1B fees

Variation	*Conditions*	*Fee (£)*
Identical changes to a number of products—	All the products are from the same marketing authorisation holder Supporting data are identical All applications are submitted at the same time	First product 835 Each subsequent product 440

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No.1084/2003 is £2,220 except in the following cases, where the fee is as specified.

Reductions to Type II fees

Change	*Conditions*	*Fee (£)*
(a) (a) Identical changes to a number of products—	All the products are from the same marketing authorisation holder Supporting data are identical	First product 2,220 Each subsequent product 440

Change	*Conditions*	*Fee (£)*
	All applications are submitted at the same time	
(b) (b) Change of distributor—	No other aspect of the dossier is changed and the marketing authorisation holder remains the same	835
(c) (c) Change of legal entity of marketing authorisation holder—	No other aspect of the dossier is changed	835
(d) (d) Simple dosage instruction changes intended to remove ambiguity—	The change is not as a result of safety concerns No new studies are required to support the change The dosage regime remains the same	835
(e) (e) Addition or change to safety warnings—	No other aspects of the dossier are changed No safety warnings are removed No new studies are required to support the change and the proposed warnings serve to increase the protection of the user/ environment/target species as appropriate	835
(f) (f) Corrections or simple text layout changes to summary of product characteristics and/or product literature. Included in this is the introduction of multilingual labelling—	The changes are not a result of safety concerns No new studies are required to support the change and no other aspect of the dossier is changed The legibility of the current English labelling is not compromised The indications and warnings are the same in all languages	835
(g) (g) Abbreviated resubmission of a previously refused Type II variation—	At the time of refusal of a Type II variation, the Secretary of State has given written permission for resubmission under this category	835

Change	*Conditions*	*Fee (£)*
	The application has been resubmitted within 3 months of the date the refusal advice was issued	
(h) (h) Submission made following the formal advice of the Secretary of State—	The Secretary of State has already assessed the relevant data and formed an opinion on these The change is not required as a result of the holder failing to keep the Part II (quality) data in accordance with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**25**)	835
(i) (i) Approval of a mock-up for an authorised pack size—	The pack size is already authorised No new studies are required to support the change and no other aspect of the dossier is changed	835
(j) (j) Changes to the summary of product characteristics and product literature of a Marketing Authorisation for Parallel Import as a direct consequence of the approval of a variation to the summary of product characteristics and product literature for the United Kingdom authorised product—	The only changes to the summary of product characteristics and product literature are those required to bring the marketing authorisation for parallel import back in direct line with those of the United Kingdom authorised product	835

Application for a variation to a marketing authorisation that has been issued in other member States

14.—(1) In this paragraph the types of variation are those specified in Commission Regulation (EC) 1084/2003.

(2) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change).

(3) The fee is in accordance with the following table.

(**25**) The Committee was established by Article 30 of Regulation (EC) No. 762/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ No. L 136, 30.4.2004, p. 1.

Variations

Type of variation	*UK is the reference member State (£)*	*UK is a concerned member State (£)*
Type II variation:	8,990	2,220
If a marketing authorisation holder applies for a Type II variation for a number of marketing authorisations, and— — all the applications have identical supporting data — all the changes are identical — all the applications are submitted at the same time the fee payable is—		
— for the first variation:	8,990	2,220
— for each subsequent variation:	1,555	440
If a marketing authorisation holder— — applies for a Type II variation to correct the Summary of Product Characteristics or product literature or where variations are required for simple text layout changes — the change is not a result of safety concerns — no new studies are required to support the change — no other aspects of the dossier are changed the fee payable is:	2,455	475
Type 1A variation:	1,555	440
Type 1B variation:	2,455	475
If a marketing authorisation holder applies for a Type 1B variation for a number of marketing authorisations, and— — all the applications have identical supporting data — all the changes are identical — all the applications are submitted at the same time the fee payable is—		
— for the first variation:	2,455	475

Type of variation	*UK is the reference member State (£)*	*UK is a concerned member State (£)*
— for each subsequent variation:	1,555	440

Application for an extension to a marketing authorisation

15. The fee for an application for an extension to a marketing authorisation is in accordance with the following table.

Extension to a marketing authorisation

Extension	*Fee if the marketing authorisation is UK only (£)*	*Fee for a decentralised application where the United Kingdom is a concerned member State or the mutual recognition of an extension authorised in another member State (£)*
Change of strength or potency or the addition of a new strength or potency:	6,400	3,180
Change of pharmaceutical form or the addition of a new pharmaceutical form:	8,080	3,690
Change of route of administration, or the addition of a new one, of—	5,170	2,790
— an immunological product, or a pharmaceutical product for a non-food-producing animal:		
— a pharmaceutical product for a food-producing animal:	6,850	3,300
Change or addition of target species:	9,240	4,080
Change of active substance:	8,080	3,690
Other:	8,080	3,690
Simultaneous application —fee for each additional product in the application:	2,780	1,610

Decentralised application for an extension where the United Kingdom is the reference member State

16.—(1) The fee for a decentralised application for an extension where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 15, with the additions of the fees in the following table.

Decentralised application for an extension where the United Kingdom is the reference member State

Application	*Additional fee (£)*
Pharmaceutical product for a food-producing animal—one concerned member State:	3,560
Pharmaceutical product for a non-food-producing animal—one concerned member State:	3,100
Immunological product—one concerned member State:	3,300
Each additional concerned member State:	510

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,400 for one concerned member State and £110 for each additional concerned member State.

Provision of information relating to the recognition of a United Kingdom marketing authorisation

17.—(1) Where an application is made for the Secretary of State to provide information to other member States to enable them to recognise a marketing authorisation already granted by the United Kingdom the following fees are payable.

(2) Where a valid application to provide information to another member State is received within six months of the original grant of the marketing authorisation, or where the Secretary of State has already provided the information to a member State, and a further valid application is made for him to provide the information to an additional member State within six months of the date he last provided the information the fees are—

Type of application	*Fee (£)*
Pharmaceutical product for a food-producing animal—one member State:	2,345
Pharmaceutical product for a non-food-producing animal—one member State:	1,820
Immunological product—one member State:	2,050
Each additional member State:	510

(3) In any other case the fees are—

Type of application	*Fee (£)*
Pharmaceutical product for a food-producing animal—one member State:	10,105
Pharmaceutical product for a non-food-producing animal—one member State:	7,080

Type of application	*Fee (£)*
Immunological product—one member State:	8,595
Each additional member State:	510

(4) In the case of simultaneous applications, the above fees are payable for each additional product in the application for one member State, with a fee of £110 for each additional product for each additional member State.

Application for the renewal of a national marketing authorisation

18.—(1) The fee for the renewal of a national marketing authorisation originally granted on or after 30th October 2005 is £1,305.

(2) In the case of a marketing authorisation originally granted before 30th October 2005—

(a) if it is the first time the marketing authorisation has been renewed, or if the renewal entails assessment of post authorisation commitments the fee is £1,305, and

(b) otherwise £295.

(3) The fee for the first reassessment of a provisional marketing authorisation is £295, and the fee for each subsequent reassessment is £1,305.

Application for the renewal of a marketing authorisation granted in more than one member State

19. The fee for the renewal of a marketing authorisation granted in more than one member State is—

(a) £1,765 if the United Kingdom is the reference member State, and

(b) £1,175 where the United Kingdom is a concerned member State.

Registration of a homeopathic remedy

20. The fee for an application for the registration of a homeopathic remedy is in accordance with the following table.

Fee for the registration of a homeopathic remedy

Type of application	*Fee (£)*
If all stocks and the formulation have already been assessed by the Secretary of State— not more than five stocks:	155
more than five stocks:	360
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed— not more than five stocks:	440
more than five stocks:	640

Type of application	*Fee (£)*
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	730
not more than five stocks:	
more than five stocks:	945
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom or in another member State—	155
not more than five stocks:	
more than five stocks:	360

Annual fees for marketing authorisations

21.—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation shall provide him with a statement of his turnover for the previous calendar year; and, if specified in the demand, an audit certificate relating to the turnover.

(2) When he provides the statement of his turnover he shall pay an annual fee, rounded up to the next £10, of—

$$£\frac{0.67T}{100} + £220n$$

where

T is the annual turnover in the previous calendar year and *n* is the number of active marketing authorisations held at any time during the previous calendar year.

(3) In the case of an authorisation holder with a turnover relating to all marketing authorisations held of less than £220,000, the amount, rounded up to the next £10, is—

$$£\frac{0.67T}{100} + £110n$$

where

T and *n* mean the same as in the preceding sub-paragraph.

(4) In this paragraph—

"turnover" means the gross value at manufacturers' prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom;

"manufacturers' prices" means the prices charged for authorised products by manufacturers to wholesalers, except to the extent that—

(a) the products are supplied by manufacturers direct to retailers, in which case it means the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the Secretary of State, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products;

(b) a marketing authorisation holder sells or supplies products which he has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by him for those products.

Auditor's certificate

22.—(1) If the Secretary of State required an audit certificate when he sent out the demand for the statement of turnover, and the holder of the marketing authorisation has not provided it within 30 days, an additional fee is payable for that year of £10,765 plus an additional £2,155 in respect of each marketing authorisation held.

(2) If the Secretary of State is not satisfied that the audit certificate provides sufficient assurance that the figures fairly present the financial records of the company, he shall require the marketing authorisation holder to produce within 30 days a further certificate and specify what further assurances he needs; and if these are not provided within those 30 days the additional fee specified in sub-paragraph (1) is payable.

(3) Nothing in this paragraph limits the powers of an inspector to examine financial records.

Late payment of annual fees

23.—(1) Where a person fails to pay the annual fee for a marketing authorisation within 30 days from and including the date of the demand, he must pay an additional fee, rounded up to the nearest £10, of—

(a) where payment is received after 30 but before 60 days have expired from and including the due date, 1% of the annual fee;

(b) where payment is received after 60 but before 90 days have expired from and including the due date, 2% of the annual fee; and

(c) where payment has not been received after the expiry of 90 days, 5% of the annual fee.

(2) Where a marketing authorisation holder has not provided the Secretary of State with a statement of his annual turnover so that the annual fee cannot be determined before the due date, he may make a payment of an amount on account of the annual fee, in which case the additional fee is calculated on the difference between the amount paid on account and the actual amount due.

PART 3

Fees payable by manufacturers

Application for a manufacturing authorisation

24. The fee for an application for a manufacturing authorisation for a veterinary medicinal product is £2,660.

Application for a variation of a manufacturing authorisation

25. The fee for an application to vary a manufacturing authorisation is £475 where the variation requires scientific or pharmaceutical assessment, and £165 where it does not.

Application for an authorisation to manufacture an autogenous vaccine or a product for administration under the cascade

26.—(1) The fee for an application for a standard authorisation to manufacture an autogenous vaccine or a veterinary medicinal product for administration under the cascade is £3,035 for each manufacturing site, with the same fee for each subsequent inspection.

(2) In the case of an application for an individual authorisation to manufacture a single batch of autogenous vaccine, or a single batch of veterinary medicinal product for administration under the cascade the fee is £1,515.

(3) The fee to vary an authorisation is £285 if no further inspection is required, and otherwise is the full application fee.

Annual fees

27.—(1) An annual fee of £245 is payable in respect of each manufacturing authorisation held (other than a manufacturing authorisation in relation to an autogenous vaccine or a veterinary medicinal product for administration under the cascade).

(2) The annual fee for a manufacturing authorisation for an autogenous vaccine or a veterinary medicinal product for administration under the cascade is 0.67% of the turnover in the previous calendar year rounded up to the next £1, with a minimum fee of £10, and in this paragraph "turnover" has the meaning given in paragraph 21(4).

Site inspections—type of site

28. For the purposes of deciding the fee for a site inspection—

"super site" is a site at which 250 or more relevant persons are employed;

"major site" is a site at which 60 or more, but fewer than 250, relevant persons are employed;

"standard site" is a site at which 10 or more, but fewer than 60 relevant persons are employed;

"minor site" is a site at which fewer than 10 relevant persons are employed;

"relevant person" means a person employed on the premises and systems inspected.

Inspection of a site where immunological veterinary medicinal products are manufactured

29. The fees for the inspection of a site where immunological veterinary medicinal products are manufactured are in accordance with the following table.

Sites where immunological veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site:	24,615
Major site:	17,325
Standard site:	5,570
Minor site:	4,865

Inspection of a site where sterile veterinary medicinal products are manufactured

30. The following fees are payable for the inspection of a site where no immunological veterinary medicinal products are manufactured, but where sterile products are manufactured.

Sites where sterile veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site:	18,125
Major site:	10,020
Standard site:	4,925
Minor site:	3,295

Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured

31. The following fees are payable for the inspection of a site where only non-immunological and non-sterile veterinary medicinal products are manufactured—

Sites where no sterile or immunological veterinary medicinal products are manufactured

Type of site	*Fee (£)*
Super site:	10,925
Major site:	5,750
Standard site:	4,125
Minor site:	2,225

Inspection of a site where veterinary medicinal products are assembled

32. The following fees are payable for the inspection of a site where the only manufacturing process in relation to veterinary medicinal products is their assembly after the product has been put into its immediate container.

Site where medicinal products are assembled

Type of site	*Fee (£)*
Super site:	7,945
Major site:	5,365
Standard site:	2,635
Minor site:	1,360

Test sites

33. The fee for the inspection of a test site is £2,730.

Animal blood bank authorisations

34.—(1) The fee for an authorisation to operate a blood bank is £3,035, with the same fee for each subsequent inspection.

(2) The fee for a variation is £285.

Expenses

35. In addition the travel and subsistence costs of the inspectors, and any additional costs reasonably incurred by them (including, in the case of an inspection outside the United Kingdom, interpreters' fees) are payable.

PART 4

Fees relating to a wholesale dealer's authorisation

Application for a wholesale dealer's authorisation

36.—(1) The fee for an application for a wholesale dealer's authorisation is—

(a) £1,550; or

(b) £635 if the application is accompanied by an estimate that the first year's turnover will be less than £40,000.

(2) If the applicant paid a fee of £635, he shall send a declaration of his turnover for the first year of trading on the anniversary of the grant of the authorisation, and if the figure is more than £40,000 he shall pay the balance of £915 within 30 days.

(3) If the applicant paid £1,550 but his turnover for the first year of trading was lower than £40,000, if he sends a declaration certifying the turnover, the Secretary of State shall refund the excess.

(4) Nothing in this paragraph limits the powers of an inspector to examine financial records.

(5) For the purposes of this paragraph, "turnover" has the same meaning as in paragraph 38.

Variation of a wholesale dealer's authorisation

37. The fee for an application to vary a wholesale dealer's authorisation is—

(a) £475 if the variation requires scientific or pharmaceutical assessment;

(b) otherwise £165.

Annual fee for a wholesale dealer's authorisation

38.—(1) The annual fee for a wholesale dealer's authorisation, payable on the anniversary of the grant of the authorisation, is—

(a) £495, or

(b) £245 if the holder certifies when making the payment that his turnover for that year was less than £40,000.

(2) For the purposes of this paragraph, "turnover" means the gross value of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom during the previous year.

PART 5

Fees relating to feedingstuffs

Fees relating to feedingstuffs

39.—(1) Fees relating to feedingstuffs are payable with the application, or on invoice for the subsequent annual fee.

(2) Where more than one activity is carried out at one premises, only one fee (the highest) is payable.

(3) Fees are in accordance with the following table.

Fees relating to feedingstuffs

Application and annual fee	*Fee payable in Great Britain (£)*		*Fee payable in Northern Ireland (£)*	
	Standard	*Late*[(a)]	*Standard*	*Late*[(a)]
Application for the approval of an establishment to manufacture a specified feed additive, and the subsequent annual fee[(b)]:	910	1,090	489	587
Application for the approval of an establishment to manufacture a premixture, and the subsequent annual fee:	575	690	386	463
Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures, and the subsequent annual fee:	575	690	386	463
Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2 kg per tonne or more when the feedingstuffs are to be placed on the market, and the	385	460	285	342

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

Application and annual fee	*Fee payable in Great Britain (£)*		*Fee payable in Northern Ireland (£)*	
	Standard	*Late[(a)]*	*Standard*	*Late[(a)]*
subsequent annual fee:				
Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be placed on the market, and the subsequent annual fee:	195	235	152	182
Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2 kg per tonne or more when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee:	140	170	117	140
Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and	120	145	98	118

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

Application and annual fee	*Fee payable in Great Britain (£)*		*Fee payable in Northern Ireland (£)*	
	Standard	*Late*[(a)]	*Standard*	*Late*[(a)]
the subsequent annual fee:				

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

Fees relating to distributors

40. The fee for an application or subsequent annual fee to be a distributor of specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products is £135 in Great Britain (or £160 if the annual fee is not paid within 60 days of the invoice) and £62 in Northern Ireland (or £74 if the annual fee is not paid within 60 days of the invoice).

PART 6

General

Testing samples

41. The fee for testing a sample required to be submitted by the Secretary of State is the full economic cost of the test.

Animal test certificates

42.—(1) The fee for an animal test certificate is £330 in the case of—

(a) an immunological veterinary medicinal product that has been authorised in another member State for the species on which the proposed test will be conducted;

(b) a pharmaceutical veterinary medicinal product which has been authorised in another member State for use with a food-producing species on which the proposed test will be conducted where the same or similar dosage regime and method of administration is to be used in the medicinal test as is authorised; or

(c) a pharmaceutical veterinary medicinal product authorised in another member State for human or animal use where the test is to be conducted on non-food-producing animals only.

(2) In any other case the fee is £785.

(3) The fee for an application for a variation of the certificate is £255 for each change.

(4) The fee for an application to renew a certificate is £125.

Treatment under the cascade

43. The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product authorised in another member State for treatment under the cascade is £15.

Treatment in exceptional circumstances

44.—(1) The fee for a certificate to import (if necessary), be in possession of and administer a veterinary medicinal product authorised in a third country is £30 for the initial certificate and £30 for its renewal (£15 for a renewal if the certificate is renewed on-line using the website of the Veterinary Medicines Directorate) payable in respect of each animal treated.

(2) In the case of administration to and treatment of a discrete group of animals, the Secretary of State may notify the applicant in writing that a fee for only one animal is payable.

Specific batch control

45. The fee for an authorisation to release a veterinary medicinal product under specific batch control is £535.

Submission of control tests of an immunological product

46. The fee for the submission of the results of tests carried out on a batch of immunological products prior to release is £80.

Export certificates

47. The fee for an application for an export certificate is £30, and £15 for each certified copy.

Fees relating to premises for supply by suitably qualified persons

48.—(1) The fee to approve premises for the retail supply of veterinary medicinal products by suitably qualified persons is—

(a) £245, or

(b) if the premises are only authorised to supply veterinary medicinal products for the treatment of horses and companion animals, £135.

(2) The subsequent annual fee is—

(a) £175, or £205 if the fee is not paid within 60 days of the invoice, or

(b) if the premises are only authorised to supply veterinary medicinal products for the treatment of horses and companion animals, £90, or £110 if the fee is not paid within 60 days of the invoice.

Application to the Veterinary Products Committee

49.—(1) If the Secretary of State refuses to grant a marketing authorisation or an animal test certificate, or grants one that is different from what was applied for, the fee for making representations to the Veterinary Products Committee is in accordance with the following table.

Application to the Veterinary Products Committee: authorisations and animal test certificates

Type of application	*Fee (£)*
Application involving a new active substance:	1,865
Standard application:	495
Application for a pharmacologically equivalent product:	495
Application using identical data:	195

Type of application	*Fee (£)*
Application for an animal test certificate:	650

(2) If the holder of a marketing authorisation applies for a variation and the Secretary of State refuses it, the fee for making representations to the Veterinary Products Committee is in accordance with the following table—

Application to the Veterinary Products Committee: variations

Type of application	*Fee (£)*
Type 1A variation:	195
Type 1B variation:	195
Type II variation:	260

Non-payment of fees

50. Where fees (other than fees relating to a manufacturing authorisation or wholesale dealer's authorisation) are not paid, the Secretary of State may, after giving one month's written warning, suspend the authorisation to which the fee relates.

Waiver or reduction of fees

51.—(1) If the Secretary of State is satisfied that for reasons of human or animal health or the protection of the environment it is desirable that a product should be authorised for veterinary use or that an authorised product should remain on the market he may waive or reduce any fees payable under these Regulations.

(2) An applicant or the holder of a marketing authorisation must provide full written justification for any waiver or reduction.

Reduction of application fee

52.—(1) Where an application for a marketing authorisation is withdrawn before determination, or refused on the grounds that data requested by the Secretary of State have not been supplied within the time limit specified in the request, the applicant may request a refund of a proportion of the fee (or, if the fee has not yet been paid, a reduction of the fee) in accordance with this paragraph.

(2) The request for a reduced fee must be made in writing within two months of the withdrawal of the application, or of the date of notification of a refusal.

(3) No reduction is payable if the application is withdrawn after all the data have been fully assessed, or if the application has been referred to the Veterinary Products Committee.

Reduction in fees where an application is withdrawn

Stage at which application is withdrawn	*Percentage reduction or refund*
The assessment (veterinary, scientific or pharmaceutical) has not yet begun:	90%
The assessment has begun but the Secretary of State has not yet requested further data:	50%

Stage at which application is withdrawn	*Percentage reduction or refund*
The Secretary of State has requested further information but it has not yet been provided:	25%
The Secretary of State has been supplied with further information requested but has not yet fully assessed it, or the application has not been referred to the Veterinary Products Committee:	10%

SCHEDULE 8 Regulation 44(2)

AMENDMENTS TO THE MEDICINES ACTS ETC.

PART 1

Consequential amendments to the Medicines Acts 1968 and 1971

The Medicines Act 1968

1. The Medicines Act 1968(**26**) shall be amended as follows.

2. In section 1 (Ministers responsible for administration of the Act)(**27**)—

(a) in subsection (1)—

(i) in paragraph (a), for "the Health Ministers", in both places those words appear, substitute "the Ministers" and omit "concerned with health in England", and

(ii) omit paragraph (b) and the words following that paragraph; and

(b) omit subsection (2).

3. In section 3 (functions of the Commission)(**28**), in subsection (1), for "any one or more of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act" substitute "either or both of the Ministers".

4. In section 4 (establishment of committees)(**29**)—

(a) in subsection (1), omit ", the Health Ministers or the Agriculture Ministers";

(b) in subsection (5), omit "by whom a committee is established under this section"; and

(c) omit subsection (5A).

5. In section 5 (supplementary provisions as to Commission and committees)—

(a) in subsection (2), omit "specified in paragraphs (a) and (b) of section 1(1) of this Act"; and

(b) in subsection (3), omit "specified in paragraphs (a) and (b) of section 1(1) of this Act".

6. In section 6 (the licensing authority)—

(**26**) 1968 c. 67. The Act does not apply in relation to veterinary medicinal products—see regulation 44(1) of S.I. 2005/2745.
(**27**) Section 1 was amended by Schedule 1 to S.I. 1969/388, the Schedule to S.I. 1999/3142 and paragraph 15 of Schedule 1 to S.I. 2002/794.
(**28**) Section 3 was substituted by regulation 4 of S.I. 2005/1094 and amended by paragraph 1 of Schedule 1 to S.I. 2005/2754.
(**29**) Section 4 was amended by paragraph 2 of Part 1 of Schedule 10 to S.I. 2004/1031, regulation 5 of S.I. 2005/1094 and paragraph 2 of Schedule 1 to S.I. 2005/2754.

(a) in subsection (1), for the words from "a body of Ministers" to the end substitute "a body consisting of the Ministers";

(b) in subsection (2), for the words from "by any one" to the end substitute "by either of the Ministers acting alone or both of them acting jointly"; and

(c) in subsection (3), for "any one or more of those", in both places those words appear, substitute "either or both of the".

7. In section 7 (general provisions as to dealing with medicinal products)(**30**)—

(a) in subsection (1), omit paragraph (b);

(b) in subsection (5)(b), omit ", a ready-made veterinary drug" and "other than a veterinary drug";

(c) in subsection (6A), omit the words from "Where the product" to "veterinary drug,";

(d) omit subsection (6B); and

(e) in subsection (7)—

(i) at the end of the definition of "radiopharmaceutical", omit "and", and

(ii) omit the definition of "ready-made veterinary drug".

8. In section 8 (provisions as to manufacture and wholesale dealing)(**31**)—

(a) in subsection (1), for "(a) to (c)" substitute "(a) and (c)";

(b) in subsection (3)(b), omit ", ready-made veterinary drug" and "other than a veterinary drug";

(c) in subsection (4), omit the words from "Where the product" to "veterinary drug,";

(d) omit subsection (5); and

(e) in subsection (6), for the words from ""homoeopathic" to "veterinary drug"" substitute ""proprietary medicinal product" and "radiopharmaceutical"".

9. In section 9 (exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners)(**32**)—

(a) omit subsections (2) and (3); and

(b) the heading of section 9 accordingly becomes "Exemptions for doctors and dentists".

10. In section 10 (exemptions for pharmacists)(**33**)—

(a) in subsection (1), omit "Subject to the next following subsection,";

(b) omit subsection (2);

(c) in subsection (3), omit paragraph (b) and the word "or" before it;

(d) omit subsection (6A);

(e) in subsection (7A), omit "Health".

11. In section 15 (provision for extending or modifying exemptions)—

(a) in subsection (1), omit "appropriate"; and

(**30**) Section 7 was amended by regulation 2(2) of S.I. 1977/1050, regulation 2 of S.I. 1983/1724, regulation 2 of S.I. 1992/604, regulation 3 of S.I. 1994/276, paragraph 3 of Part 1 of Schedule 10 to S.I. 2004/1031, regulation 25(1)(a) of S.I. 2005/50 and paragraph 1 of the Schedule to S.I. 2005/2753.

(**31**) Section 8 was amended by regulation 3 of S.I. 1977/1050, regulation 3(3) of S.I. 1992/604, regulation 2 of S.I. 1993/834, regulation 4 of S.I. 1994/276, regulation 2(a)(i) of S.I. 2002/236, paragraph 4 of Part 1 of Schedule 10 to S.I. 2004/1031, regulation 25(1)(b) of S.I. 2005/50 and paragraph 1 of Part 1 of Schedule 5 to S.I. 2005/2789.

(**32**) Section 9 was amended by regulation 10 of S.I. 1994/2987.

(**33**) Section 10 was amended by paragraph 5 of Schedule 3 to the Regulation of Care (Scotland) Act 2001 (asp 8)), article 3 of S.I. 1971/1445, regulation 3 of S.I. 1993/384, regulation 11 of S.I. 1994/2987 and section 26(1) of the Health Act 2006 (c. 28).

(b) in subsection (3), omit "appropriate".

12. In section 18 (application for licence), omit subsection (3)(**34**).

13. In section 23 (special provisions as to effect of manufacturer's licence)(**35**)—

(a) in subsection (1), omit "the provisions of this Part of this Act relating to medicinal tests on animals and to";

(b) in subsection (2)—

(i) omit "Subject to the next following subsection,", and

(ii) omit paragraph (b) and the word "or" before it; and

(c) omit subsection (3).

14. In section 28 (general power to suspend, revoke or vary licences), omit subsection (3)(i)(**36**).

15. Sections 32 to 36 and 38 to 40 shall be omitted.

16. In section 44 (provision of information to the licensing authority)(**37**)—

(a) in subsection (1), omit "or for an animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act)";

(b) in subsection (2), omit ", or of an animal test certificate,";

(c) in subsection (3), omit "or certificate"; and

(d) in subsection (4)—

(i) omit ", or of a certificate issued in pursuance of section 37(4) of this Act,",

(ii) omit "or certificate", in each place those words appear,

(iii) in paragraph (a), for "sections 25 and 37(4)" substitute "section 25", and

(iv) in paragraph (b), omit "or issue".

17. In section 45 (offences under Part II)(**38**)—

(a) in subsection (1)—

(i) for ", section 8, section 32, section 34 or section 40" substitute "or section 8",

(ii) omit "or animal feeding stuff", and

(iii) for "any of those sections" substitute "either of those sections";

(b) in subsection (2)—

(i) omit "or animal feeding stuff",

(ii) omit ", section 32 or section 40", and

(iii) omit "or feeding stuff";

(c) in subsection (3)—

(i) omit "or of an animal test certificate", and

(ii) omit "or certificate", in both places those words appear; and

(d) omit subsections (4) and (5).

(**34**) Section 18(3) was substituted by regulation 4 of S.I. 1983/1724 and amended by regulation 2(b) of S.I. 2002/236.
(**35**) Section 23 was amended by paragraph 5 of Part 1 of Schedule 10 to S.I. 2004/1031.
(**36**) Section 28(3)(i) was inserted by regulation 2(2) of S.I. 1975/1169 and amended by Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40).
(**37**) Section 44 was amended by paragraph 12 of Part 1 of Schedule 10 to S.I. 2004/1031 and paragraph 9 of Schedule 1 to S.I. 2005/1094.
(**38**) The relevant amendments to section 45 were made by paragraph 13 of Part 1 of Schedule 10 of S.I. 2004/1031.

18. In section 46 (special defences under s45)(**39**)—

(a) in subsection (1)—

(i) omit "or of an animal test certificate", and

(ii) omit "or certificate"; and

(b) in subsection (2)—

(i) omit "or of an animal test certificate" in the first place those words appear,

(ii) in paragraph (a), omit "or of an animal test certificate applicable to them",

(iii) in paragraph (b), omit "or certificate".

19. In section 47 (standard provisions for licences or certificates)(**40**)—

(a) in subsection (2), omit "or any animal test certificate" and "or issued";

(b) in subsection (4)—

(i) omit ", or any animal test certificate,", and

(ii) omit "or certificate", in both places those words appear;

(c) in subsection (5)—

(i) omit ", or in any certificate issued in pursuance of section 37(4) of this Act,", and

(ii) omit "or certificate", in both places those words appear;

(d) in subsection (6), omit "or certificate", in both places those words appear;

(e) in subsection (8), omit "or certificate"; and

(f) in subsection (9), omit "or certificate", in both places those words appear.

The heading accordingly becomes "Standard provisions for licences".

20. In section 48 (postponement of restrictions in relation to exports), in subsection (1), for "sections 49 and 49A" substitute "section 49".

21. In section 49 (special provisions in respect of exporting certain products)—

(a) in subsection (1), for "the Health Ministers or the Agriculture Ministers" substitute "the Ministers"; and

(b) in subsection (2)—

(i) for "the Health Ministers or the Agriculture Ministers" substitute "the Ministers", and

(ii) for "the Ministers making the order" substitute "them".

22. In section 51 (general sale lists)—

(a) in subsection (1), omit "appropriate"; and

(b) in subsection (3), omit "appropriate".

23. In section 52 (sale or supply of medicinal products not on general sale list), in subsection (2)(**41**), omit "Health".

24. In section 53 (sale or supply of medicinal products on general sale list), in subsection (2)—

(a) omit "either"; and

(b) omit paragraph (b) and the word "or" before it.

(**39**) Section 46 was amended by paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40) and by paragraph 14 of Part 1 of Schedule 10 to S.I. 2004/1031.

(**40**) Section 47 was amended by paragraph 15 of Part 1 of Schedule 10 to S.I. 2004/1031.

(**41**) Subsection (2) was inserted by section 26(2) of the Health Act 2006 (c. 28).

25. In section 54 (sale of medicinal products from automatic machines), in subsection (2), omit "appropriate".

26. In section 55 (exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners)(**42**)—

(a) in subsection (2)—

(i) in paragraph (a), omit "Health", and

(ii) in paragraph (b), for "Health Ministers" substitute "Ministers"; and

(b) omit subsection (3).

The heading of section 55 accordingly becomes "Exemptions for doctors and dentists etc".

27. In section 56 (exemptions in respect of herbal remedies), in subsection (3), omit "appropriate".

28. In section 57 (power to extend or modify exemptions)(**43**)—

(a) in subsection (1), omit "appropriate";

(b) omit subsections (2A) to (2D); and

(c) in subsection (3), omit "appropriate".

29. In section 58 (medicinal products on prescription only)(**44**)—

(a) in subsection (1), for "appropriate Ministers" substitute "Ministers";

(b) in subsection (1A), in paragraph (h), for "appropriate Ministers", in both places those words appear, substitute "Ministers";

(c) omit subsection (1B);

(d) in subsection (3), omit paragraph (b) and the word "or" before it;

(e) in subsection (4), for "appropriate Ministers" substitute "Ministers"; and

(f) in subsection (6), for "appropriate Ministers" substitute "Ministers".

30. In section 58A (requirement to specify certain products for human use as prescription-only products)(**45**)—

(a) in subsection (1), omit "appropriate";

(b) in subsection (3), omit "appropriate";

(c) in subsection (4), omit "appropriate"; and

(d) in subsection (5), omit "and section 58B of this Act".

The heading of section 58A accordingly becomes "Requirement to specify certain products as prescription-only products".

31. Section 58B (requirement to specify certain products for veterinary use as prescription-only products)(**46**) shall be omitted.

32. In section 59 (special provisions in relation to new medicinal products), in subsection (2)(b), omit "appropriate".

(**42**) Section 55 was amended by paragraph 128(1) of Schedule 4 to the National Health Service Reorganisation Act 1973 (c. 32) and paragraph 10(b) of Part 1 of the Schedule to S.I. 2004/1771.
(**43**) Section 55 was amended by section 14 of the Animal Health and Welfare Act 1984 (c. 40).
(**44**) Section 57 was amended by section 1 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 63 of the Health and Social Care Act 2001 (c. 15), paragraph 2 of Schedule 5 to S.I. 2002/253 and paragraph 10 of Schedule 1 to S. I. 2005/1094.
(**45**) Section 58A was inserted by regulation 2 of S.I. 1992/3271 and amended by regulation 2(a)(v) of S.I. 2002/236.
(**46**) Section 58B was inserted by regulation 2 of S.I. 1992/3271.

33. In section 60 (restricted sale, supply and administration of certain medicinal products)(**47**)—

(a) in subsection (1), omit "appropriate", in both places that word appears;

(b) in subsection (3), omit "appropriate";

(c) in subsection (4), omit "appropriate";

(d) in subsection (5)—

(i) omit "appropriate", in each place that word appears, and

(ii) for "those Ministers" substitute "the Ministers"; and

(e) in subsection (7), for "appropriate Ministers" substitute "Ministers".

34. In section 61 (special restrictions on persons to be supplied with medicinal products), omit "appropriate".

35. In section 62 (prohibition of sale or supply, or importation, of medicinal products of specified description, or of animal feeding stuffs incorporating such products)(**48**)—

(a) in the heading, omit ", or of animal feeding stuffs incorporating such products";

(b) in subsection (1)—

(i) omit "appropriate", and

(ii) omit paragraph (b);

(c) in subsection (3)—

(i) for "appropriate Ministers" substitute "Ministers", and

(ii) omit ", whether of human beings or of animals";

(d) in subsection (5)—

(i) for "appropriate Ministers", in each place those words appear, substitute "Ministers", and

(ii) for "those Ministers", in both places those words appear, substitute "the Ministers"; and

(e) in subsection (6), omit "appropriate".

36. In section 65 (compliance with standards specified in monographs in certain publications)—

(a) in subsection (4), omit ", the British Veterinary Codex";

(b) in subsection (5), in paragraph (c), omit "or the British Veterinary Codex"; and

(c) in subsection (7), omit "Health".

37. In section 66 (further powers to regulate dealings with medicinal products), in subsection (1), omit "appropriate".

38. In section 72A (the responsible pharmacist)(**49**)—

(a) in subsection (2), omit "Health";

(b) in subsection (4)(b), omit "Health";

(c) in subsection (5)(b), omit "Health"; and

(d) in subsection (6), omit "Health".

39. In section 73 (power to extend or modify conditions)—

(a) in subsection (1), omit "Health"; and

(**47**) Section 60 was amended by paragraph 11 of Schedule 1 to S.I. 2005/1094.
(**48**) Section 62 was amended by paragraph 12 of Schedule 1 to S.I. 2005/1094.
(**49**) Section 72A was inserted by section 30(1) of the Health Act 2006 (c. 28).

(b) in subsection (3), omit "Health".

40. In section 76 (supplementary provisions as to registration of premises), omit subsection (6).

41. In section 79 (provision for modifying or extending restrictions under section 78)—

(a) in subsection (1), omit "Health";

(b) in subsection (2), omit "Health"; and

(c) in subsection (3), omit "Health".

42. In section 85 (labelling and marking of containers and packages), in subsection (1), omit "appropriate".

43. In section 86 (leaflets)(**50**), in subsection (1), omit "appropriate".

44. In section 87 (requirements as to containers), in subsection (1)—

(a) omit "appropriate"; and

(b) for "those Ministers" substitute "the Ministers".

45. In section 88 (distinctive colours, shapes and markings of medicinal products), in subsection (1)—

(a) omit "appropriate"; and

(b) for "those Ministers" substitute "the Ministers".

46. In section 89 (display of information on automatic machines), in subsection (1), omit "appropriate".

47. Section 90 (provisions as to medicated animal feeding stuffs) shall be omitted.

48. In section 91 (offences under Part V, and supplementary provisions)(**51**)—

(a) in subsection (1), for ", section 86(3) or (4) or section 90(2)" substitute "or section 86(3) or (4)";

(b) in subsection (2), omit "or any of those provisions as applied by section 90(1) of this Act"; and

(c) in subsection (3), omit ", and any power to make regulations conferred by those sections as applied by section 90(1) of this Act shall be exercisable in a corresponding way".

49. In section 95 (powers to regulate advertisements and representations)(**52**)—

(a) in subsection (1), omit "appropriate", in both places that word appears; and

(b) in subsection (3), omit "appropriate".

50. In section 99 (new editions of British Pharmacopoeia, and other compendia)(**53**)—

(a) in subsection (4), in paragraph (a), for "veterinary drugs" substitute "veterinary medicinal products";

(b) in subsection (6)—

(i) for "subsection (3)(a)" substitute "subsection (3)",

(ii) omit "Health", and

(iii) omit the words from "; and where the appropriate body has prepared" to the end; and

(c) in subsection (7)—

(**50**) Section 86 was amended by regulation 7(1) of S.I. 1994/276 and regulation 2(a)(vi) of S.I. 2002/236.
(**51**) Section 91 was amended by section 32(2) of the Magistrates' Courts Act 1980 (c. 43) and regulation 8 of S.I. 1994/267.
(**52**) Section 95 was amended by section 32(2) of the Magistrates' Courts Act 1980 (c. 43).
(**53**) Section 99 was amended by Part 17 of Schedule 1 to the Statute Law (Repeals) Act 2004 (c. 14).

(i) after "In this Part of this Act" insert "—",

(ii) for ", and "relevant" substitute ";

"relevant"; and

(iii) at the end insert

"veterinary medicinal product" has the same meaning as in the Veterinary Medicines Regulations 2006

51. In section 101 (other publications), in subsection (2)—

(a) for "the Health Ministers or the Agriculture Ministers" substitute "the Ministers"; and

(b) omit "concerned".

52. In section 102 (supplementary provisions)—

(a) in subsection (2)—

(i) omit "Health", and

(ii) for "those Ministers" substitute "the Ministers";

(b) in subsection (4), omit "appropriate";

(c) in subsection (5), omit "appropriate";

(d) in subsection (6), omit "appropriate"; and

(e) in subsection (7), omit the words from ""the appropriate Ministers"" to "to be published, and".

53. In section 103 (construction of references to specified publications)(**54**), in subsection (1), omit paragraph (d).

54. In section 104 (application of Act to certain articles and substances)(**55**), in subsection (1), omit ", the Health Ministers or the Agriculture Ministers".

55. In section 105 (application of Act to certain other substances which are not medicinal products)(**56**), in subsection (1), in paragraph (b), omit ", or of causing danger to the health of animals generally or of one or more species of animals".

56. In section 108 (enforcement in England and Wales)(**57**)—

(a) in subsection (6), in paragraph (a), omit "40," and "and of any regulations made under section 40 of this Act";

(b) omit subsection (8);

(c) in subsection (9), for "(2) to (8)" substitute "(2) to (7)";

(d) in subsection (10), as amended by section 31(1)(d) of the Health Act 2006(**58**), omit "and (8)"; and

(e) in subsection (11)—

(i) omit paragraph (a), and

(ii) in paragraph (b), omit "in all other respects,".

57. In section 109 (enforcement in Scotland), in subsection (2), omit paragraph (d).

(**54**) Section 103 was amended by section 22 of the Health and Medicines Act 1988 (c. 49).
(**55**) Section 104 was amended by paragraph 17 of Part 1 to Schedule 10 to S.I. 2004/1031.
(**56**) Section 105 was amended by paragraph 18 of Part 1 to Schedule 10 to S.I. 2004/1031.
(**57**) Section 108 was amended by Schedule 30 to the Local Government Act 1972 (c. 70), paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40), paragraph 8 of Schedule 3 to the Food Safety Act 1990 (c. 16), paragraph 33 of Schedule 16 to the Local Government (Wales) Act 1994 (c. 19), article 5(4) of S.I. 1968/1699 and article 2 of S.I. 1988/1955.
(**58**) 2006 c. 28.

58. In section 110 (enforcement in Northern Ireland)—

(a) in subsection (1), as amended by section 31(3)(a) of the Health Act 2006, for "subsections (3C) and (4)" substitute "subsection (3C)";

(b) omit subsection (4); and

(c) in subsection (5)—

(i) in paragraph (a), for "(2) to (8)" substitute "(2) to (7)", and

(ii) in paragraph (b), as amended by section 31(3) (d) of the Health Act 2006, omit "and (8)".

59. In section 116 (liability to forfeiture under Customs and Excise Management Act 1979)(**59**), in subsection (3), omit "or are, or normally are, animal feeding stuffs in which medicinal products have been incorporated".

60. Section 117 (special enforcement and sampling provisions relating to animal feeding stuffs) shall be omitted.

61. In section 121 (contravention due to default of other person), in subsection (4), for "85 to 90" substitute "85 to 89".

62. In section 122 (warranty as defence), in subsection (2), omit "and section 90".

63. In section 125 (prosecutions), in subsection (4)—

(a) omit "or subsection (8)"; and

(b) for "either of those subsections" substitute "that subsection".

64. In section 126 (presumptions)(**60**)—

(a) in subsection (1)—

(i) omit paragraph (a),

(ii) omit "animal feeding stuff or", in both places those words appear, and

(iii) omit "animal feeding stuffs or";

(b) in subsection (2)—

(i) omit "or animal feeding stuff", in each place those words appear, and

(ii) omit "or of animal feeding stuffs in which medicinal products have been incorporated";

(c) in subsection (3), omit the words from ", to any of those provisions" to the end; and

(d) in subsection (4)—

(i) omit ", or of so much of subsection (2) of section 90 of this Act as relates to leaflets",

(ii) omit "or of animal feeding stuffs in which medicinal products have been incorporated", and

(iii) for the words from "in his possession" to the end, substitute "in his possession for the purpose of supplying it with a medicinal product".

65. In section 129 (orders and regulations)(**61**)—

(a) in subsection (2), omit ", paragraph 5";

(b) in subsection (3), in paragraph (a), omit ", 35(2)(b)" and ", 117"; and

(c) omit subsection (6A).

(**59**) Section 116 was amended by paragraph 12 of Schedule 4 to the Customs and Excise Management Act 1979 (c. 2).
(**60**) Section 126 was amended by paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40).
(**61**) Section 129 was amended by paragraph 15 of Part 3 of Schedule 3 to the Food Standards Act 1999 (c. 28).

66. In section 130 (meaning of "medicinal product" and related expressions)(**62**)—

(a) in subsection (1), omit "or animals", in both places those words appear;

(b) omit subsections (3A) to (3C);

(c) in subsection (4)—

(i) omit "or (3A)",

(ii) omit "or animals", and

(iii) in paragraph (c), omit the words from ", or beneficial to" to the end of the paragraph;

(d) in subsection (5), in paragraph (c), omit ", the Health Ministers or the Agriculture Ministers";

(e) in subsection (6)—

(i) omit "or (3B)", and

(ii) for "the relevant subsection", in both places those words appear, substitute "that subsection"; and

(f) in subsection (9)—

(i) omit "or an animal", and

(ii) omit "or feeding", in both places those words appear.

67. In section 132 (general interpretation provisions)—

(a) in subsection (1)—

(i) omit the definitions of the following expressions—

"animal",

"animal feeding stuff"(**63**),

"animal test certificate",

"the appropriate Ministers",

"the 1981 Directive"(**64**),

"herd",

"medicinal test on animals",

"poultry", and

"veterinary drug",

(ii) in the definition of "manufacture", omit "and does not include the incorporation of the product in any animal feeding stuff", and

(iii) after the definition of "the Marketing Authorisation Regulations" insert the following definition—

""the Ministers" shall be construed in accordance with section 1(1) of this Act;";

(b) in subsection (2)—

(i) in paragraph (a), omit ", or of causing danger to the health of animals generally or of one or more species of animals", and

(ii) omit paragraph (b); and

(c) in subsection (3), omit the words from ", and any reference" to the end.

(**62**) Section 130 was amended by section 13(2) of, and paragraph 3 of Schedule 1 to, the Animal Health and Welfare Act 1984 (c. 40), by regulation 2 of S.I. 1994/3119 and regulation 25(1)(c) and (d) of S.I. 2005/50.

(**63**) The definition of "animal feeding stuff" was inserted by section 13(2) of the Animal Health and Welfare Act 1984 (c. 40).

(**64**) The definition of "the 1981 Directive" was inserted by regulation 3 of S.I. 1992/3271.

68. In Schedule 3 (sampling), in paragraph 17—

(a) omit paragraph (a); and

(b) in paragraph (b), omit "in any other case".

69. In Schedule 4 (provisions relating to Northern Ireland)(**65**)—

(a) omit paragraphs 2 to 5;

(b) in paragraph 6—

(i) for "The appropriate Northern Ireland Minister or Ministers" substitute "The appropriate Northern Ireland Minister",

(ii) for "appropriate Ministers" substitute "Ministers",

(iii) omit ", section 35", and

(iv) omit "or their";

(c) omit paragraph 7;

(d) in paragraph 8—

(i) omit ", or the Minister of Agriculture for Northern Ireland, or both those Ministers,", and

(ii) omit ", paragraph 5";

(e) in paragraph 9—

(i) for ""the appropriate Northern Ireland Minister or Ministers"" substitute ""the appropriate Northern Ireland Minister"",

(ii) in paragraph (a), omit the words from "for the purpose" to "of animals,",

(iii) omit paragraphs (b) and (c), and

(iv) omit the words after paragraph (c); and

(f) in paragraph 10—

(i) omit "or to the Minister of Agriculture for Northern Ireland",

(ii) for "either or both of those Ministers" substitute "that Minister",

(iii) omit the words from "or, as the case may require" to the end.

The Medicines Act 1971

70. In section 1 of the Medicines Act 1971 (fees payable for the purposes of Part II of the Medicines Act 1968)(**66**), in subsection (1A), in the definition of "medicinal product", omit paragraph (b) and the word "and" before it.

(**65**) Schedule 4 was amended by paragraph 3 of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40), paragraph 10 of Schedule 4 to S.I. 1979/1573 and paragraph 8 of Schedule 5 to S.I. 1976/2713.

(**66**) 1971 c. 69; section 1 was amended by section 21 of the Health and Medicines Act 1988 (c. 49) and paragraph 20 of Part 1 of Schedule 10 to S.I. 2004/1031, and its effect modified by regulation 9(12)(a) of S.I. 1994/3144.

PART 2

Consequential amendments to secondary legislation

The Medicines (Surgical Materials) Order 1971

1. In the Medicines (Surgical Materials) Order 1971(**67**), in article 3 (application of specified provisions of the Medicines Act 1968 to surgical materials), omit "Health".

The Medicines (Specified Articles and Substances) Order 1976

2. In the Medicines (Specified Articles and Substances) Order 1976(**68**), in article 2 (application of specified provisions of the Medicines Act 1968 to articles and substances specified in Schedule 1), omit "Health".

The Medicines (Radioactive Substances) Order 1978

3. In the Medicines (Radioactive Substances) Order 1978(**69**), in article 2 (application of specified provisions of the Medicines Act 1968 to certain substances or articles consisting of or containing radioactive substances), omit "Health".

The Medicines (Administration of Radioactive Substances) Regulations 1978

4. In the Medicines (Administration of Radioactive Substances) Regulations 1978(**70**), for "the Health Ministers", in each place those words appear, substitute "the Ministers".

The Medicines (Cyanogenetic Substances) Order 1984

5. In the Medicines (Cyanogenetic Substances) Order 1984(**71**), in article 2 (application of specified provisions of the Medicines Act 1968), omit "Health".

The Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986

6. In the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986(**72**), in rule 2 (interpretation), in paragraph (b), in the definition of "relevant Minister", in sub-paragraph (ii), for "the appropriate Ministers as defined in section 1(2)" substitute "the Ministers as defined in section 1(1)".

The Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992

7. In the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992(**73**), in the Schedule—

(a) in the entry relating to section 44(1) to (3)—

(i) for the first entry in column (2) substitute "as though in subsection (1) "(including a licence of right)" were omitted",

---

(**67**) S.I. 1971/1267; relevant amending instrument is S.I. 2004/1031.
(**68**) S.I. 1976/968, amended by S.I. 1994/3199 and 2004/1031.
(**69**) S.I. 1978/1004.
(**70**) S.I. 1978/1006, amended by S.I. 1994/2147 and 2005/2754.
(**71**) S.I. 1984/187.
(**72**) S.I. 1986/1761, amended by S.I. 2005/2745.
(**73**) S.I. 1992/605, amended by S.I. 2004/1031 and 2005/2754.

(ii) omit the second entry in column (2), and

(iii) in the third entry in column (2), omit "and the words "or certificate" were omitted";

(b) in the entry relating to section 45(1), (2) and (6) to (9)—

(i) for the first entry in column (2) substitute "as though in subsection (1) the words ", section 8" were omitted and for "any of those sections" there were substituted "that section"", and

(ii) omit the second entry in column (2);

(c) in the entry relating to section 46(1), omit

""or of an animal test certificate" and "or certificate" were omitted and";"

(d) in the entry relating to section 47, omit the second, third and fourth entries in column (2);

(e) in the entry relating to section 91—

(i) for the first entry in column (2) substitute "as though in subsection (1) for "section 85(5), section 83(3) or (4) or section 90(2)" there were substituted "section 86(3) or (4)",

(ii) in the second entry in column (2) for "section 90(1)" substitute "section 87(2)", and

(iii) in the third entry in column (2), omit "and the words from "and any power to make regulations conferred by those sections" to the end of the subsection were omitted"; and

(f) for the entry relating to section 126(4), substitute "as though the words "or subsection (3)" were omitted".

The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

8. In the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**74**)—

(a) in regulation 6 (grant of a certificate), omit "appropriate"; and

(b) in Schedule 4 (application of the provisions of the Medicines Act 1968)—

(i) omit the entries relating to sections 23, 58A, 121, 122 and 126,

(ii) in the entry relating to section 44—

(aa) omit "or for an animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act",

(bb) omit "and as though ", or of an animal test certificate," were omitted", and

(cc) for "as though "licence or" were omitted" substitute "as though for "licence" there were substituted "certificate"",

(iii) in the entry relating to section 108, omit the words from "as though in subsection (8)" to the end, and

(iv) in the entry relating to section 110, omit "as though subsection (4) were omitted".

The Medicines (Advertising) Regulations 1994

9. In the Medicines (Advertising) Regulations 1994(**75**), in regulation 2 (interpretation), for paragraph (4) substitute the following paragraph—

(**74**) S.I. 1994/105; relevant amending instruments are S.I. 2004/1031 and 2005/2753.
(**75**) S.I. 1994/1932; relevant amending instrument is S.I. 1999/267.

"(4) In these Regulations, "the Health Ministers" means the Ministers specified in section 1(1) of the Act, and the functions of the Health Ministers under these Regulations may be performed by either of them acting alone or both of them acting jointly.".

The Medicines (Monitoring of Advertising) Regulations 1994

10. In the Medicines (Monitoring of Advertising) Regulations 1994(**76**), in regulation 2 (interpretation and application), for paragraph (3) substitute the following paragraph—

"(3) In these Regulations, "the Health Ministers" means the Ministers specified in section 1 of the Act, and the functions of the Health Ministers under these Regulations may be performed by either of them acting alone or both of them acting jointly.".

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

11. In the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**77**), in Schedule 4 (modifications of enforcement provisions of the Medicines Act 1968)—

(a) in paragraph 9, in paragraph (b), for "85 to 90" substitute "85 to 89"; and

(b) in paragraph 10, in paragraph (b), for "sections 85 to 88 and section 90" substitute "and sections 85 to 88".

The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

12. In the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**78**), in Schedule 1 (funded operations), in paragraph 1, in sub-paragraph (a), omit "the Health Ministers,".

The Herbal Medicines Advisory Committee Order 2005

13. In the Herbal Medicines Advisory Committee Order 2005(**79**), in article 2 (Herbal Medicines Advisory Committee), in paragraph (b), omit "Health".

The Medicines (Advisory Bodies) (No. 2) Regulations 2005

14. In the Medicines (Advisory Bodies) (No. 2) Regulations 2005(**80**), in regulation 1 (citation, commencement and interpretation), in paragraph (3), for the definition of "the appropriate Ministers" substitute the following definition—

""the appropriate Ministers" means the Secretary of State for Health and the Department for Health, Social Services and Public Safety acting jointly;".

(**76**) S.I. 1994/1933, to which there are amendments not relevant to this instrument.
(**77**) S.I. 1994/3144, to which there are amendments not relevant to this instrument.
(**78**) S.I. 2003/1076 as amended by S.I. 2005/2061.
(**79**) S.I. 2005/2791.
(**80**) S.I. 2005/2754.

SCHEDULE 9 Regulation 44(3)

OTHER CONSEQUENTIAL AMENDMENTS

PART 1

Consequential amendments to primary legislation

The Pharmacy Act 1954

1. In subsection (1) of section 13I of the Pharmacy Act 1954(**81**) (effect of suspension of registration)—

(a) in paragraph (b) omit "31, 33";

(b) at the end of paragraph (e) omit the word "and"; and

(c) add at the end the following—

"and

(g) the Veterinary Medicines Regulations 2006.".

The Trade Descriptions Act 1968

2. In subsection (5) of section 2 of the Trade Descriptions Act 1968(**82**) (trade description) add at the end the following—

"(c) where any description of a veterinary medicinal product is required to be applied to the product by an authorisation for the product granted under the Veterinary Medicines Regulations 2006, that description, when applied to the product, shall be deemed not to be a trade description.".

The Poisons Act 1972

3. After subsection (1)(a) of section 11 of the Poisons Act 1972(**83**) (interpretation) add—

"(aa) a veterinary medicinal product as defined by regulation 2 of the Veterinary Medicines Regulations 2006, nor".

The City of London (Various Powers) Act 1977

4. Section 23 of the City of London (Various Powers) Act 1977(**84**) (animal feeding stuffs) shall cease to have effect.

The Sporting Events (Control of Alcohol etc.) Act 1985

5. In subsection (3) of section 2 of the Sporting Events (Control of Alcohol etc.) Act 1985(**85**) (offences in connection with alcohol, containers, etc. at sports grounds) after "(within the meaning of the Medicines Act 1968)" add "or any veterinary medicinal product (within the meaning of the Veterinary Medicines Regulations 2006)".

(**81**) 1954 c. 61.
(**82**) 1968 c. 29.
(**83**) 1972 c. 66.
(**84**) 1977 c. xv.
(**85**) 1985 c. 57.

The Animals (Scientific Procedures) Act 1986

6. In section 2 of the Animals (Scientific Procedures) Act 1986(**86**) (regulated procedures) substitute for subsection (6) the following subsection—

"(6) The administration of any substance or article to an animal is not a regulated procedure if the substance or article is administered for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2006.".

The Consumer Protection Act 1987

7. In subsection (1) of section 19 of the Consumer Protection Act 1987(**87**)(interpretation of Part II) in the definition of "licensed medicinal product"—

(a) at the end of paragraph (a) omit the word "or"; and

(b) at the end of paragraph (b) add—

"or

(c) a veterinary medicinal product that has a marketing authorisation under the Veterinary Medicines Regulations 2006."

The Environmental Protection Act 1990

8. In subsection (7) of section 142 of the Environmental Protection Act 1990(**88**) (powers to obtain information about potentially hazardous substances)—

(a) omit the word "and" where it appears after the words "Part III of the Food and Environment Protection Act 1985;"; and

(b) after the words "the Food Safety Act 1990;" add—

"the Veterinary Medicines Regulations 2006;".

The Sunday Trading Act 1994

9. In Schedule 1 to the Sunday Trading Act 1994(**89**) (restrictions on Sunday opening of large shops)—

(a) in paragraph 1 after the definition of "stand" add—

""veterinary medicinal product" has the same meaning as in regulation 2 of the Veterinary Medicines Regulations 2006."; and

(b) in paragraph 3(1)(d)(ii) after the words "medicinal products" add the words ", veterinary medicinal products".

The Value Added Tax Act 1994

10. In Group 15 in Part II of Schedule 8 to the Value Added Tax Act 1994(**90**) (zero rating)—

(a) in item 9 insert the words "or veterinary medicinal product" after the words "medicinal product"; and

(b) in Note (11)—

(**86**) 1986 c. 14.
(**87**) 1987 c. 43.
(**88**) 1990 c. 43.
(**89**) 1994 c. 20.
(**90**) 1994 c. 23.

(i) omit the words "or animals" (in both places) from the definition of "medicinal product"; and

(ii) after paragraph (c) add—

"(d) "veterinary medicinal product" has the meaning assigned to it by regulation 2 of the Veterinary Medicines Regulations 2006."

The Criminal Law (Consolidation) (Scotland) Act 1995

11. In subsection (8) of section 20 of the Criminal Law (Consolidation) (Scotland) Act 1995(**91**) (sporting events: controls)—

(a) in the definition of "controlled container", after "medicinal product" insert "or veterinary medicinal product"; and

(b) after the definitions of "medicinal product" and "medicinal purpose" insert—

""veterinary medicinal product" has the meaning assigned to that term by regulation 2 of the Veterinary Medicines Regulations 2006.".

The Food Standards Act 1999

12. For subsection (2) of section 29 of the Food Standards Act 1999(**92**) (consultation on veterinary products) substitute—

"(2) In this section "veterinary products" means—

(a) veterinary medicinal products as defined in regulation 2 of the Veterinary Medicines Regulations 2006; or

(b) specified feed additives as defined in paragraph 1 of Schedule 5 to those Regulations."

The Licensing Act 2003

13. In section 191 of the Licensing Act 2003(**93**) (meaning of "alcohol")—

(a) at the end of subsection (1)(e) add "or a veterinary medicinal product"; and

(b) at the end of subsection (2) add—

""veterinary medicinal product" has the same meaning as in regulation 2 of the Veterinary Medicines Regulations 2006".

PART 2

Consequential revocations of and amendments to secondary legislation

Revocations

1. The following are revoked—

(a) the Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1994(**94**);

(**91**) 1995 c. 39.
(**92**) 1999 c. 28.
(**93**) 2003 c. 17.
(**94**) S.I. 1994/3143.

(b) the Medicines (Animal Feeding Stuffs) (Enforcement) Regulations 1985(**95**);

(c) the Medicines (Feeding Stuffs Limits on Variation) Order 1976(**96**).

Importation of Animal Pathogens Order 1980

2. In article 5 of the Importation of Animal Pathogens Order 1980(**97**) after the words "section 7 of the Medicines Act 1968 or section 32 of that Act" add "or in accordance with the Veterinary Medicines Regulations 2006".

The Warble Fly (England and Wales) Order 1982

3. In article 2 of the Warble Fly (England and Wales) Order 1982(**98**) for the definition of "dressing" substitute—

> ""dressing" means a product that has a marketing authorisation under the Veterinary Medicines Regulations 2006 permitting its sale and supply for systemic use to kill the warble fly;".

The Environmental Protection (Prescribed Processes and Substances) Regulations 1991

4. In Section 4.8 of Schedule 1 to the Environmental Protection (Prescribed Processes and Substances) Regulations 1991(**99**) after the words "one of the ways specified in section 130(1) of the Medicines Act 1968" add "any veterinary medicinal product to which the Veterinary Medicines Regulations 2006 apply".

The Products of Animal Origin (Import and Export) Regulations 1996

5.—(1) The Products of Animal Origin (Import and Export) Regulations 1996(**100**) are amended in accordance with this paragraph.

(2) In regulation 11(1) for the words "a licence issued under section 8 of the Medicines Act 1968" substitute "a manufacturer's authorisation granted under the Veterinary Medicines Regulations 2006".

(3) In regulation 12(1) for the words "licence issued under section 8 of the Medicines Act 1968" substitute "manufacturer's authorisation granted under the Veterinary Medicines Regulations 2006".

(**95**) S.I. 1985/273.
(**96**) S.I. 1976/31.
(**97**) S.I. 1980/1212.
(**98**) S.I. 1982/234.
(**99**) S.I. 1991/472.
(**100**) S.I. 1996/3124 to which there are amendments not relevant to these Regulations.