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 must 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 must 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;

(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;

(**1**) OJ No L 211, 28.11.2001, p. 1 as last amended by Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ No L152, 16.6.2009, p. 11). Annex I was inserted by Commission Directive 2009/9/EC (OJ No L 44, 14.2.2009, p. 10).

(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 Regulation (EC) No 470/2009 of the European Parliament and of the Council 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 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 in Commission Regulation (EU) No 37/2010, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.

(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 must include the following information, set out in the same format—

	Summary of product characteristics
1	Name of the veterinary medicinal product, followed by 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.
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, 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 Regulation (EC) No 470/2009 of the European Parliament and of the Council.

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 the applicant 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) The applicant 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, the applicant 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 Secretary of State may, with the permission of the holder, use the 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 the applicant 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 are 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 the Secretary of State to be satisfied of this, the Secretary of State 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 may 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 are 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 submitted 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 protection period is extended by one year for each additional food-producing species added to the marketing authorisation.

(3) The total period may 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 on being 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 a product authorised in another country

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 must ensure that the procedure for granting an 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 for testing 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, the Secretary of State must 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 must 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 must inform the applicant of the summary of product characteristics that has been approved, and the distribution category of the product.

Marketing authorisations for food-producing species

23.—(1) The Secretary of State must not grant a marketing authorisation for a veterinary medicinal product for food-producing species unless all its pharmacologically active substances appear in Table 1 in the Annex to Commission Regulation (EU) No 37/2010.

(2) This does not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption; but in this case the product must not include an active substance that appears in Table 2 in the Annex to Commission Regulation (EU) No 37/2010 and must not be intended for the treatment of a condition for which a veterinary medicinal product is already authorised for horses.

Refusal of a marketing authorisation

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

(2) In addition, the Secretary of State must 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 Regulation (EC) No 470/2009 of the European Parliament and of the Council 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 to grant a marketing authorisation—

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

(b) if additional data have been requested and those data are not provided within such time limit as may be stipulated.

(4) If the Secretary of State, on the grounds of safety, quality or efficacy, intends to refuse an application, or proposes to grant a marketing authorisation that is different from the one applied for, the Secretary of State must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee.

Publication following the grant of a marketing authorisation

25.—(1) On granting a marketing authorisation the Secretary of State must publish—

(a) the notice granting the marketing authorisation;

(b) the summary of the product characteristics;

(c) the assessment report that has already been prepared but with any commercially confidential or personal information deleted.

(2) The Secretary of State must 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) The Secretary of State must send a copy of the assessment report, and any update, to the holder of the marketing authorisation before publication to enable the holder to make representations concerning any confidential or personal information that may be in it, and may specify a date by which representations must be made.

Marketing authorisations in exceptional circumstances

26.—(1) In exceptional circumstances, and if there is no other product with a full marketing authorisation for the indicated condition in the target species, the Secretary of State may grant an exceptional marketing authorisation consisting of—

(a) a provisional marketing authorisation subject to a requirement for the applicant to provide further data; or

(b) a limited marketing authorisation for a product with a limited market.

(2) The Secretary of State must reassess each provisional or limited marketing 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 technical expertise to facilitate any analysis of the product.

Supply of information

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

(2) The holder 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.

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

29.—(1) Before placing an immunological product on the market the holder of the marketing authorisation must either—

(a) notify the Secretary of State asking for written approval to do so; or

(b) if the holder has already received written approval from another member State permitting the release of the product, send a copy of that approval to the Secretary of State.

(2) If notified under sub-paragraph (1)(a) the Secretary of State must give or refuse a written approval as soon as is reasonably practicable.

(3) No person may place an immunological product on the market without a written approval issued by the Secretary of State or (if the approval was issued by another member State) without sending a copy of that approval to the Secretary of State.

Control tests

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

Placing on the market

31.—(1) A holder of a marketing authorisation must notify the Secretary of State when the veterinary medicinal product is first placed on the market in the United Kingdom, and the date on which it was placed on the market.

(2) A holder of a marketing authorisation who removes the veterinary medicinal product from the market in the United Kingdom must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before doing so.

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

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

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

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) An applicant who applies for the renewal of the marketing authorisation must enclose a list of all documents concerning the product that the applicant 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

33.—(1) The Secretary of State is the competent authority for the purposes of Commission Regulation (EC) No 1234/2008(**2**).

(2) The holder of a marketing authorisation may apply to the Secretary of State for a variation of that marketing authorisation.

(3) An application for a variation under paragraph (2) may only relate to a "single variation" unless the application is submitted in accordance with—

(a) Article 7 of Commission Regulation (EC) No 1234/2008 ("grouped variations"), or

(b) Article 20 of Commission Regulation (EC) No 1234/2008 ("workshare variations").

(4) The Secretary of State, when granting a variation of a veterinary medicinal product, may (unless there are exceptional circumstances necessary to protect human or animal health or the environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

Refusal of a variation of a marketing authorisation

34.—(1) This paragraph applies in relation to the refusal by the Secretary of State of an application for a variation unless the procedure following the refusal of a variation is one of those set out in Article 13 of Regulation 1234/2008.

(2) The grounds on which the Secretary of State may refuse an application for a variation of a marketing authorisation are those set out in paragraph 24 of this Schedule (refusal of a marketing authorisation).

(3) The Secretary of State must give written reasons for refusing to grant a variation; and if—

(a) those reasons are on the grounds of safety, quality or efficacy; and

(b) the variation is Type II or an extension application (whether or not in each case as part of an application for a worksharing or grouped application),

the applicant may appeal to the Veterinary Products Committee.

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, the Secretary of State may notify the marketing authorisation holder, require the holder to submit an application for a variation enabling data to be assessed and revoke the administrative variation.

(**2**) OJ No L334, 12.12.2008, p. 7.

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, for any of the reasons for suspending a marketing authorisation specified in paragraph 38, or because the classification of a veterinary medicinal product should be changed, that a variation to a marketing authorisation is necessary, the Secretary of State must by a notification in writing to the holder of the marketing authorisation require that person to apply for a variation of the marketing authorisation, giving reasons for requiring the application to be made.

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

(3) If the variation is on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

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

PART 5

Suspension, etc. of a marketing authorisation

Suspension of a marketing authorisation: grounds

38.—(1) The Secretary of State may suspend a marketing authorisation at any time on being 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; or

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

(2) The Secretary of State may also suspend a marketing authorisation on being 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 the veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(3) The Secretary of State must suspend a marketing authorisation on being 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 Regulation (EC) No 470/2009 of the European Parliament and of the Council;

(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; or

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

Suspension of a marketing authorisation: procedure

39.—(1) If a marketing authorisation is suspended the Secretary of State must notify the holder immediately, and, unless the Secretary of State directs otherwise, the suspension has immediate effect, and continues in effect unless the marketing authorisation is reinstated.

(2) If the suspension is on the grounds of safety, quality or efficacy, the holder may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(3) If the veterinary medicinal product is authorised in more than one member State, the Secretary of State—

(a) must immediately refer the matter to the Agency, and must comply with a decision of the Commission within 30 days of the decision; and

(b) may suspend the marketing and the use of the veterinary medicinal product in the United Kingdom pending a decision of the Agency, but must inform the Commission and the other member States no later than the following working day of the reasons for the action.

(4) When a marketing authorisation is suspended, the Secretary of State may in addition prohibit the supply of the veterinary medicinal product, and if necessary require the marketing authorisation holder to recall the product.

Revocation

40. The Secretary of State may revoke any marketing authorisation that has been suspended for more than 28 days unless there is a current appeal to the Veterinary Products Committee, and may publicise a revocation in such manner as the Secretary of State sees fit.

Prohibiting the supply of veterinary medicinal products

41.—(1) In addition to the powers to suspend a marketing authorisation, the Secretary of State, on being satisfied that a product has not been manufactured in accordance with the marketing authorisation, may prohibit the supply of a veterinary medicinal product, and if necessary require the marketing authorisation holder to recall it.

(2) The prohibition on supply and the requirement for recall may be confined 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 the Secretary of State 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

42.—(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) An applicant applying in more than one member State must supply the Secretary of State with a list of all the States in which the applicant is applying.

(5) The Secretary of State must obtain an assessment report from the reference member State and, where appropriate, an explanation of any extension of the period of data protection.

(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 they have not been approved, and provide the reference member State with a detailed statement of the reasons.

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

(8) If the assessment report, the summary of product characteristics, the labelling and the package leaflet are approved, the Secretary of State must ensure that a decision whether or not to grant a marketing authorisation can be made within 30 days of the approval.

(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 must 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 must 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

43.—(1) When the Secretary of State has granted a marketing authorisation for a veterinary medicinal product and is notified by the marketing authorisation holder that the marketing authorisation holder has applied to have that veterinary medicinal product authorised in another member State, the Secretary of State must 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 the Secretary of State need take no further action.

(3) If not all the other member States concerned so agree within a further 90 days the Secretary of State must 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 must 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

44.—(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"), the applicant 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 applications have been made; 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 must 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 must 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 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 the Secretary of State will not approve it, and provide the reference member State with a detailed statement of the reasons.

(4) The Secretary of State may 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 must ensure that a decision whether or not to grant a marketing authorisation can be made 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) must 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 must 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, the Secretary of State may grant the marketing authorisation even though not all member States have agreed to grant it, but must 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

45. The Secretary of State, when issuing a marketing authorisation, must approve all containers, packaging, labels and package leaflets.

Reference to being authorised

46. 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

47.—(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 responsibility of that same veterinary surgeon.

Labelling with all the information on the immediate packaging

48.—(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

49.—(1) If it is not reasonably practicable to have all the required 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 required information as is reasonably practicable.

(4) The outer packaging must contain all the required information 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

50.—(1) If it is not reasonably practicable to have all the required information 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 required information 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 must relate solely to the veterinary medicinal product with which it is included.

(4) It must be written in plain English.

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

Ampoules

51.—(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 required information 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

52. As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the required information, all the required information 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

53.—(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

54. 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

55. A marketing authorisation holder must have permanently and continuously the services of an appropriately qualified person responsible for pharmacovigilance ("a qualified person (pharmacovigilance)") who resides in a member State.

Duties relating to the qualified person

56. 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 the information was requested, 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.

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

57.—(1) A marketing authorisation holder must act in accordance with this paragraph on learning 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) The holder must make a record of what happened.

(3) The holder 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, the holder must supply to the Secretary of State all relevant veterinary pharmacovigilance information that the holder possesses 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, 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.

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

58.—(1) A marketing authorisation holder for a veterinary medicinal product authorised in the United Kingdom must act in accordance with this paragraph on learning 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) The holder must make a record of what happened.

(3) The holder 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, the holder must supply to the Secretary of State, the competent authorities of all other member States where the product is authorised and the Agency, all relevant veterinary pharmacovigilance information in the holder's possession relating to the reaction as in the preceding paragraph.

Periodic safety update reports

59.—(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) A marketing authorisation holder who has not yet placed a product on the market in the United Kingdom 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 for each year of the report, 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)(c) 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.

Release of information by the marketing authorisation holder

60.—(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.

Action taken on account of pharmacovigilance

61.—(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,

the Secretary of State must 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 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 must comply with that request immediately on a temporary basis.

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

PART 9

Homeopathic remedies

Meaning of "homeopathic remedy"

62. 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(**3**) 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

63.—(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.

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

Application for registration

64.—(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;

(**3**) ISBN 9287145873.

(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 Regulation (EC) No 470/2009 of the European Parliament and of the Council 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 Table 1 in the Annex to Commission Regulation (EU) No 37/2010 and complies with any requirements in that Table 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 on being satisfied that it is reasonable to do so.

Procedure for registration

65.—(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 efficacy;

(b) the product is not required to have a summary of product characteristics;

(c) the Secretary of State is not required to 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

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

Classification

67. 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.

Offences

68. It is an offence to fail to comply with—

(a) a requirement made under paragraph 27(1);

(b) a request made under paragraph 27(2);

(c) paragraph 28(1) or (2);

(d) a requirement made under paragraph 28(3);

(e) paragraph 29(3);

(f) paragraph 30;

(g) paragraph 31(1) or (2);

(h) a request made under paragraph 31(3);

(i) a prohibition or requirement made under paragraph 39(4);

(j) a prohibition or requirement made under paragraph 41(1);

(k) paragraph 55;

(l) paragraph 56;

(m) paragraph 57;

(n) paragraph 58;

(o) paragraph 59; or

(p) paragraph 60.