SCHEDULE 1

Marketing authorisations

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;

(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

(**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).

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

(**2**) OJ No. L224, 18.8.1990, p. 1 as last amended by Commission Regulation (EC) No. 869/2005 (OJ No. L 145, 9.6.2005, p. 19).

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 Council Regulation (EEC) No. 2377/90.