SCHEDULE 1

Marketing authorisations

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 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 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 he has 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 Annex I, II or III to Council Regulation (EEC) No. 2377/90.

(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

on Annex IV to Council Regulation (EC) 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.

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, he 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 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 to grant 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.

(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, he must notify the applicant accordingly, and the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

Publication following the grant of a marketing authorisation

25.—(1) When he grants 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 he has already prepared but with any commercially confidential or personal information deleted.

(2) He 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) He must 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.

(2) The Secretary of State must 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) Before the holder of a marketing authorisation for an immunological product places that product on the market he must either—

(a) notify the Secretary of State and ask for his written approval to do so, or

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

(3) It is an offence to 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 he has carried out all control tests required under the marketing authorisation, and the results of those tests, and failure to do so is an offence.

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).