

## 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 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.

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(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).