

## SCHEDULE 1

### Marketing authorisations

## PART 8

### Pharmacovigilance

#### **Qualified persons responsible for pharmacovigilance**

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

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

#### **Duties relating to the qualified person**

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

- (a) establishes and maintains a system that ensures that information about all suspected adverse reactions reported to the marketing authorisation holder is collected and collated in order to be accessible at least at one point in a member State;
- (b) answers any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product fully and within any time limit imposed by the Secretary of State when she requested the information, including the volume of sales of the veterinary medicinal product concerned and, if available, details of prescriptions;
- (c) provides to the Secretary of State any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; and in this paragraph “post-marketing surveillance studies” means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying and investigating a safety hazard relating to an authorised veterinary medicinal product.

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

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

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

- (a) serious adverse reaction;
- (b) human adverse reaction; or
- (c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in the United Kingdom.

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

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

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(4) In addition, he must supply to the Secretary of State all relevant veterinary pharmacovigilance information in his possession relating to the reaction, giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology<sup>(1)</sup>, 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/birth defect, or that results in permanent or prolonged signs in the animals treated.

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

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

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

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

(b) human adverse reaction; or

(c) unintended transmission of an infectious agent through a veterinary medicinal product, following the administration of the product in a third country.

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

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

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

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

### **Periodic safety update reports**

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

(2) If the marketing authorisation holder has not yet placed a product on the market in the United Kingdom, he must submit a periodic safety update report immediately upon request of the Secretary of State or 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 —

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

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- (a) at least every six months during the first two years following the initial placing on the market;
  - (b) once a year for the following two years; and
  - (c) thereafter, at three-yearly intervals.
- (4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the periods of notification.
- (5) The periodic safety update report must include a scientific evaluation of the risk benefit balance of the veterinary medicinal product.
- (6) The periodic safety update report must include—
- (a) the volume of the product sold in each year covered by the report, calculated on an annual basis beginning 1st January;
  - (b) the number of adverse reactions for each year of the report;
  - (c) the ratio of adverse reactions to volume of product sold together with an explanation of the basis of the calculation;
  - (d) differentiation of data based on—
    - (i) target species (if the product is authorised for use in more than one species);
    - (ii) reaction type (such as serious, non-serious, human, suspected lack of efficacy, unauthorised use or other);
    - (iii) the country of origin of the report.
- (7) If the product is indicated for more than one species, the information in sub-paragraph (6) must be based so far as is practicable on the estimated use of the product.
- (8) Data relating to different formulations (either different dosage forms or different strengths) must be provided in separate reports.
- (9) It is an offence to fail to comply with this paragraph.

#### **Release of information by the marketing authorisation holder**

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

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

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

#### **Action taken on account of pharmacovigilance**

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

- (a) suspended;
- (b) revoked; or
- (c) varied so as to—
  - (i) restrict the indications;
  - (ii) change the distribution category;
  - (iii) amend the dose;
  - (iv) add a contraindication; or

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(v) add a new precautionary measure,

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

(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 she must inform the Agency, the Commission and the other member States within one working day.

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

(4) The Secretary of State shall take final measures in accordance with the Decision of the Commission in accordance with Article 78(3) of Directive [2001/82/EC](#).