SCHEDULE 1

Marketing authorisations

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.