SCHEDULE 1

Marketing authorisations

PART 8

Pharmacovigilance

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.