SCHEDULE 1

Marketing authorisations

PART 8

Pharmacovigilance

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.