SCHEDULE 2

The manufacture of veterinary medicinal products

PART 3

Authorisation of blood banks

Authorisation of blood banks

20.—(1) The Secretary of State may authorise blood banks for—

(a) the collection, storage and supply of blood, or

(b) the storage and supply of blood constituents obtained by the physical separation of donor blood into different fractions within a closed-bag system,

for the treatment of non-food-producing animals.

(2) The authorisation may be for either or both of these activities.

(3) In order to be authorised a blood bank must be under the supervision of—

(a) a veterinary surgeon named in the authorisation; or

(b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the blood bank.

(4) Before authorising a blood bank, the Secretary of State must be satisfied—

(a) that the welfare of animals used in the collection of blood will be respected; and

(b) that the production process will produce a consistent, safe product.

(5) The Secretary of State may suspend, vary or revoke an authorisation of a blood bank if—

(a) the holder no longer uses fit and proper processes;

(b) the premises in which the blood bank is being or is to be operated are not suitable;

(c) the equipment is not suitable; or

(d) the holder has not complied with these Regulations.

(6) Blood may only be collected under the responsibility of a veterinary surgeon.

(7) No person may operate a blood bank for treatment of animals other than in accordance with such an authorisation.

Supply and administration of blood from a blood bank

21.—(1) The operator of a blood bank may only supply blood to a veterinary surgeon.

(2) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer blood.

(3) No person may administer blood to a food-producing animal.

Labelling

22.—(1) The operator of a blood bank must ensure that every container used for the blood is labelled with—

(a) the identification of the donor animal;

(b) the date of collection;

(c) the authorisation number of the blood bank;

(d) any necessary warnings;

(e) the expiry date.

(2) There must be no specific therapeutic indication on the label or on any information relating to the product.

Records

23. The operator of a blood bank must, as soon as is reasonably practicable, record—

(a) the date of collection;

(b) the identification of the donor animal;

(c) the veterinary surgeon who collected it;

(d) the expiry date;

(e) the date the blood was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied;

and must keep the records for at least five years.

Inspection of premises

24. The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 3.