STATUTORY INSTRUMENTS

2024 No. 567

The Veterinary Medicines (Amendment etc.) Regulations 2024

PART 4

Amendments to Schedule 2 to the 2013 Regulations

Amendment to Parts 2 to 5

92. For Parts 2 to 5 substitute—

"PART 2

Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade

Authorisation to manufacture specific veterinary medicinal products

14.—(1) The Secretary of State may authorise a person to—

(a) manufacture—

(i) autogenous vaccines; or

(ii) an unauthorised veterinary medicinal product for administration under the cascade;

(b) collect, store and supply blood in connection with the treatment of non-food animals;

(c) collect, store and supply blood constituents obtained by the physical separation of donor blood into different fractions within a closed bag system, for the treatment of non-food animals; or

(d) collect, process and store stem cells for use as an autologous treatment in non-food animals,

and may authorise sites for the purpose of carrying out those activities by that person.

(2) A single authorisation under sub-paragraph (1) may confer permission to carry out the activities mentioned in both paragraph (b) and (c) of that sub-paragraph.

(3) In this paragraph, a "closed bag system" means a system in which the blood pack assembly is manufactured under clean conditions, sealed to the external environment and sterilised.

Prohibition

15. No person may carry out any activity mentioned in paragraph 14 otherwise than—

(a) in accordance with an authorisation mentioned in that paragraph; or

(b) pursuant to paragraph 1(2) of Schedule 4 (administration under the cascade).

Personnel

16. In order to be authorised the site mentioned in paragraph 14(1) must be under the supervision of a named person responsible for release (a "PRR") who in the opinion of the Secretary of State has sufficient qualifications and experience to manufacture the product safely.

Process of authorisation

17.—(1) An applicant for authorisation under paragraph 14 must, at least two months before commencing an activity mentioned in that paragraph, submit the following to the Secretary of State—

(a) the name and address of the proposed holder of the authorisation;

(b) a description of the activity in which the applicant for authorisation proposes to be engaged;

(c) particulars (including the name and address) in relation to the site at which the relevant activity is to be carried out (whether in the occupation of the proposed holder or otherwise) and a description of the technical equipment on the site;

(d) particulars in relation to the qualifications and experience of the proposed PRR who will supervise the activities at the site.

(2) The application must include a declaration that the applicant will comply with the requirements of these Regulations and confirmation that the site is ready for inspection.

(3) Before granting an authorisation in relation to a site, the Secretary of State must be satisfied that the production process carried out there will produce a consistent, safe product and, in the case of a blood bank or a stem cell centre, that the welfare of the animals involved in the processes will be respected.

Authorisation in relation to blood banks

18.—(1) No person may collect blood for the purposes of a non-food animal blood bank other than a veterinary surgeon or a person acting under the responsibility of a veterinary surgeon.

(2) The holder of an authorisation to carry out an activity under paragraph 14(1)(b) or (c) may only supply blood or blood constituents to a veterinary surgeon.

(3) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer blood to a non-food producing animal.

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

Authorisation in relation to stem cells

19.—(1) No person may collect stem cells for the purposes of treating animals other than a veterinary surgeon or a person acting under the responsibility of a veterinary surgeon.

(2) No person may collect stem cells from embryonic tissues.

(3) No person may administer any product grown from stem cells to a food-producing animal.

Authorisation in relation to products for administration under the cascade

20.—(1) Subject to sub-paragraph (2), no person may manufacture a product for administration under the cascade that is the pharmaceutical equivalent of an authorised veterinary medicinal product.

(2) The Secretary of State may authorise the manufacture of a product notwithstanding sub-paragraph (1) where there is difficulty in relation to the supply of the authorised veterinary medicinal product.

(3) The holder of an authorisation under paragraph 14(1)(a)(ii) may not supply a product manufactured in accordance with that sub-paragraph other than to a veterinary surgeon who has prescribed the product under the cascade.

(4) The holder of an authorisation under paragraph 14(1)(a)(ii) must—

(a) provide a list of products manufactured in accordance with that sub-paragraph to the Secretary of State annually or at the request of the Secretary of State;

(b) provide sales data for products supplied under sub-paragraph (3) at the request of the Secretary of State.

(5) For the purposes of this paragraph, a product is the pharmaceutical equivalent of an authorised veterinary medicinal product if—

(a) it has the same qualitative and quantitative composition in active substances; and

(b) it has the same pharmaceutical form.

Suspension, compulsory variation or revocation of authorisation

21. The Secretary of State may by notice suspend, vary or revoke an authorisation under paragraph 14 if the Secretary of State is satisfied that—

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

(b) the site at which the activity takes place is not suitable;

(c) the equipment is not suitable;

(d) the PRR has not carried out adequately the PRR's responsibilities under these Regulations;

(e) in the case of a person authorised under paragraph 14(1), that person has manufactured a veterinary medicinal product pursuant to that authorisation that is not within its scope;

(f) the holder has not conducted an activity relating to the authorisation for five years or more;

(g) the holder has not paid any fee required under these Regulations; or

(h) the holder has not complied with any other provision in these Regulations.

Labelling

22.—(1) The holder of an authorisation under paragraph 14 must ensure that every container used is labelled with—

(a) a precise description of the product;

(b) the date on which the product was produced;

(c) the name and address of the authorisation holder;

(d) the address of the site named under the authorisation and its authorisation number;

(e) the instructions for use;

(f) the expiry date;

(g) any necessary warnings;

(h) in the case of an autogenous vaccine or an unauthorised veterinary medicinal product for administration under the cascade, the name of the veterinary surgeon who ordered the product;

(i) in the case of blood or a stem cell product—

(i) the identification of the donor animal; and

(ii) the date of collection.

(2) In the case of blood or blood constituents there must be no specific therapeutic indication on the label or on any information related to the product.

(3) In the case of an unauthorised veterinary medicinal product for administration under the cascade the words "this veterinary medicinal product does not hold a marketing authorisation" must appear on the label.

Records

23. The holder of an authorisation under paragraph 14 must, as soon as is reasonably practicable after the product is supplied, in addition to the expiry date of the product, record the following—

(a) in the case of an unauthorised veterinary medicinal product for administration under the cascade—

(i) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;

(ii) a precise description of the product;

(iii) the date of production;

(iv) the date of supply to the veterinary surgeon;

(b) in the case of stem cells or blood—

(i) the identification of the source animal;

(ii) the name of the veterinary surgeon who collected the product (or under whose responsibility it was collected);

(iii) the date of collection of the product;

(iv) the date that the product was used or if the product was supplied to another veterinary surgeon, the name and address of that veterinary surgeon and the date the product was supplied;

(c) in the case of an autogenous vaccine—

(i) the name and address of the veterinary surgeon who ordered the vaccine;

(ii) the identification of the source animal;

(iii) the date of supply to the veterinary surgeon,

and must keep the records for at least five years.

Adverse events

24. The holder of an authorisation under paragraph 14 must notify the Secretary of State of any adverse event in relation to a product produced by that person under that authorisation within 30 days of learning of the event.

Inspection of sites

25. The Secretary of State must inspect any site authorised under paragraph 14, basing the frequency of the inspection on the risks associated with each site's history and the nature of the products handled at the site.".