SCHEDULE 2

The manufacture of veterinary medicinal products

PART 5

Authorisation of equine stem cell centres

Authorisation of stem cell centres

30.—(1) The Secretary of State may authorise equine stem cell centres for the collection, storage, processing, production and administration of equine stem cells for use as an autologous treatment for horses.

(2) In order to be authorised a centre 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 centre.

(3) Before authorising a centre, the Secretary of State must be satisfied—

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

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

(4) Equine stem cells may only be collected under the responsibility of a veterinary surgeon.

(5) The Secretary of State may suspend, vary or revoke an authorisation of an equine stem cell centre if—

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

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

(c) the equipment of the centre is not suitable; or

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

(6) No person may operate an equine stem cell centre other than in accordance with such an authorisation.

Supply and administration of stem cells

31.—(1) The operator of an equine stem cell centre may only collect equine stem cells.

(2) The operator of an equine stem cell centre may not collect stem cells from embryonic tissues.

(3) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer any product grown from collected equine stem cells.

(4) No person may administer any product grown from collected equine stem cells to a food-producing horse.

Labelling

32.—(1) The operator of an equine stem cell centre must ensure that every container used for the stem cell product is labelled with—

(a) the identification of the donor animal;

(b) the date of collection;

(c) the authorisation number of the equine stem cell centre;

(d) any necessary warnings;

(e) the expiry date.

(2) The operator of an equine stem cell centre must ensure that no specific therapeutic indication is included on the label or on any information relating to the product.

Records

33. The operator of an equine stem cell centre must, as soon as is reasonably practicable, record for each stem cell product—

(a) the identification of the donor animal;

(b) the date of collection;

(c) the veterinary surgeon under whose responsibility the stem cells were collected;

(d) the expiry date;

(e) the date the product 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

34. 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.

Offences

35. It is an offence to fail to comply with—

(a) paragraph 4(3);

(b) paragraph 11;

(c) paragraph 14(4);

(d) paragraph 16;

(e) paragraph 17;

(f) paragraph 18;

(g) paragraph 20(6) or (7);

(h) paragraph 21;

(i) paragraph 22;

(j) paragraph 23;

(k) paragraph 25(5);

(l) paragraph 26;

(m) paragraph 27;

(n) paragraph 28;

(o) paragraph 30(4) or (6);

(p) paragraph 31;

(q) paragraph 32; or

(r) paragraph 33.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 5.