SCHEDULE 2

The manufacture of veterinary medicinal products

[F1PART 2A

Active Substances]

Textual Amendments

F1 Sch. 2 Pts. 2A (paras. 26-31), 2B (para. 32) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **93**

[F1Prohibition on manufacture, importation or distribution of active substances unless registered E+W+S

26.—(1) No person may manufacture, import or distribute an active substance unless the person is registered in the register maintained under sub-paragraph (2).

(2) The Secretary of State must establish and maintain a register of manufacturers, importers and distributors of active substances and the sites occupied by them for the purposes of manufacturing or holding active substances.**]**

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Labelling N.I.

26. The authorised person must ensure that, before a veterinary medicinal product is supplied, every container is labelled with—

(a) the name of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the name of the authorisation holder and the address of the authorised premises;

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

Extent Information

E7 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F1Application for registration E+W+S

27.—(1) An applicant for registration under paragraph 26 must, at least two months before commencing an activity mentioned in paragraph 26(1) or, in the case of an existing manufacturer, within two months of the date on which this provision comes into force, submit the following to the Secretary of State—

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

(b) the name of the relevant active substance;

(c) a description of the activity proposed to be engaged in in relation to the relevant active substance; and

(d) particulars in relation to the site at which the relevant active substance is to be manufactured or held (as the case may be).

(2) Information may be submitted to the Secretary of State pursuant to sub-paragraph (1) prior to the date on which this provision comes into force, and in such a case—

(a) as regards an applicant for registration who is not an existing manufacturer, the relevant period of two months is to be treated as having started on the date of submission;

(b) as regards an applicant for registration who is an existing manufacturer, the information is to be treated as having been submitted within the relevant period of two months.**]**

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Records N.I.

27. The authorised person must, as soon as is reasonably practicable, record—

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

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the expiry date; and

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

and must keep the record for at least five years.

Extent Information

E8 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F1Good manufacturing or distribution practice E+W+S

28. A manufacturer, importer or distributor of active substances must comply with good manufacturing practice or good distribution practice, as applicable.**]**

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Adverse reactions N.I.

28. The authorised person must notify the Secretary of State of any adverse reactions to a product manufactured by that person within 15 days of learning of the reaction.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F1Supply of information E+W+S

29.—(1) A person registered under paragraph 26 must immediately inform the Secretary of State on receipt of any new information that might adversely affect the quality and safety of the active substance.

(2) A person registered under paragraph 26 must immediately inform the Secretary of State of any prohibition or restriction in relation to the active substance imposed by the competent authorities of any country other than the United Kingdom in which the active substance is authorised.**]**

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Inspection of premises N.I.

29. 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.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F1Inspection of sites E+W+S

30. The Secretary of State may, from time to time, inspect sites registered under paragraph 26, basing the frequency of the inspections on the risks associated with each site's history and the nature of the substances handled at the site.**]**

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Authorisation of stem cell centres N.I.

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.

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F1Report following inspection E+W+S

31.—(1) After each inspection of a site for the purposes of this Part, the inspector must make a written report to the Secretary of State on whether the requirements in this Part are being complied with.

(2) The Secretary of State must inform the inspected registered person of the content of such reports.**]**

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Supply and administration of stem cells N.I.

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.

Extent Information

E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 2A.