SCHEDULE 2 Regulation 5(2)

The manufacture of veterinary medicinal products

PART 1

Manufacturing authorisations

[F1Manufacturing authorisation E+W+S

1.—(1) No person may carry out any activity mentioned in sub-paragraph (2) otherwise than in accordance with an authorisation granted under this Schedule (a "manufacturing authorisation").

(2) For the purposes of sub-paragraph (1) the activities are—

(a) the manufacture of veterinary medicinal products (whether for use in Great Britain or another country);

(b) the carrying out of any part of the manufacturing process or of bringing a veterinary medicinal product to its final state, including the processing, assembling, packaging or repackaging, labelling or relabelling, storing, sterilising or releasing for supply of a veterinary medicinal product;

(c) the importation of any veterinary medicinal product for use in Great Britain.**]**

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

Textual Amendments

F1 Sch. 2 para. 1 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **80**

Application N.I.

1. An application for a manufacturing authorisation must be made to the Secretary of State.

Extent Information

E33 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F2Application for authorisation E+W+S

2.—(1) An application for a manufacturing authorisation must be submitted to the Secretary of State electronically and must include the matters mentioned in sub-paragraph (2).

(2) For the purposes of sub-paragraph (1) the matters are—

(a) the name of the person who will hold the manufacturing authorisation and that person's address or registered place of business;

(b) the names and addresses of the sites (including any site where work is undertaken on behalf of the proposed holder under contract) where—

(i) each stage of the manufacturing process or of bringing a veterinary medicinal product to its final state, including processing, assembling, packaging or repackaging, labelling or relabelling, storing or sterilising, is carried out;

(ii) any imported products are held; or

(iii) any control or batch release is carried out;

(c) a description of the veterinary medicinal products or pharmaceutical forms proposed to be manufactured or imported under the authorisation;

(d) the name of the proposed qualified person (manufacture) for the purposes of paragraph 9;

(e) the name of the person proposed to have responsibility for quality control;

(f) the qualifications and a description of the relevant experience of the person proposed to have responsibility for quality control;

(g) the name of the person proposed to have responsibility for production;

(h) the qualifications and a description of the relevant experience of the person proposed to have responsibility for production;

(i) a declaration that the applicant complies with good manufacturing practice and any relevant legislation; and

(j) a declaration that any site mentioned in paragraph (b) is ready for inspection.**]**

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

Textual Amendments

F2 Sch. 2 para. 2 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **81**

Time limits N.I.

2.—(1) The Secretary of State must process an application for a manufacturing authorisation within 90 days of receiving it.

(2) The Secretary of State must process an application for a variation of a manufacturing authorisation within 30 days unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

Extent Information

E34 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F3Procedure for grant of authorisations and time limits E+W+S

3.—(1) The Secretary of State must process an application mentioned in paragraph 2 within 90 days of validating the application.

(2) The Secretary of State must inspect the sites mentioned in paragraph 2(2)(b) within 90 days of validating the application.

(3) The Secretary of State must grant the manufacturing authorisation if satisfied, following the inspection mentioned in sub-paragraph (2), that—

(a) the sites are suitable for the intended purposes;

(b) the applicant has—

(i) suitable and sufficient staff, technical equipment and facilities for the proposed activities; and

(ii) a documented quality management system in place.

(4) Where the Secretary of State is not satisfied in relation to one or more of the matters mentioned in sub-paragraph (3), the Secretary of State may—

(a) reject the application; or

(b) grant a conditional manufacturing authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(5) The Secretary of State may extend the period for which a conditional manufacturing authorisation is granted under sub-paragraph (4)(b).

(6) Where a conditional manufacturing authorisation is granted under sub-paragraph (4)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect without those conditions.**]**

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

Textual Amendments

F3 Sch. 2 para. 3 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **82**

Granting the authorisation N.I.

3. The Secretary of State must grant a manufacturing authorisation on being satisfied that the applicant has suitable and sufficient premises, staff, technical equipment and facilities for the manufacture, control and storage of the products, and will comply with these Regulations.

Extent Information

E35 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

The authorisation E+W+S

4.—(1) The manufacturing authorisation must specify—

(a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured **[**[F4], controlled**]** or imported;

[[F5](b) the name and address of the site where the products are to be manufactured or controlled, or to which they are to be imported;**]**

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the names of all qualified persons nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

(3) The holder of a manufacturing authorisation must notify the Secretary of State, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used.

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

Textual Amendments

F4 Word in Sch. 2 para. 4(1)(a) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **83(a)**

F5 Sch. 2 para. 4(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **83(b)**

The authorisation N.I.

4.—(1) The manufacturing authorisation must specify—

(a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured or imported;

(b) the place where they are to be manufactured or controlled;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the names of all qualified persons nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

(3) The holder of a manufacturing authorisation must notify the Secretary of State, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used.

Extent Information

E36 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F6Application for variation to the authorisation

4A.—(1) The holder of a manufacturing authorisation must notify the Secretary of State, and apply for a variation of the authorisation, before—

(a) making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used;

(b) changing the qualified person (manufacture), the person with responsibility for quality control or the person with responsibility for production.

(2) The Secretary of State must process an application under sub-paragraph (1) within 30 days of receiving it unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

(3) The Secretary of State must grant the application under sub-paragraph (1) if satisfied in respect of the matters in paragraph 3(3) as regards the proposed variation.

(4) The Secretary of State may inspect any site to which the manufacturing authorisation or proposed variation relates in connection with the application.

(5) Where the Secretary of State is not satisfied for the purposes of sub-paragraph (3), the Secretary of State may—

(a) reject the application; or

(b) grant a conditional variation to the manufacturing authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(6) The Secretary of State may extend the period for which a conditional variation to the marketing authorisation is granted under sub-paragraph (5)(b).

(7) Where a conditional variation to the manufacturing authorisation is granted under sub-paragraph (5)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect as so varied without those conditions.**]**

Textual Amendments

F6 Sch. 2 para. 4A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **84**

[F7Suspension, revocation etc] of the authorisation E+W+S

5.—(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder—

(a) has not complied with these Regulations;

(b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;

(c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; F8...

(d) no longer has suitable premises or equipment.

[F9(e) has failed to carry out the activity specified in the authorisation for a period of five years or more; or

(f) has not paid any fee required under these Regulations**]**

[F10(2) The Secretary of State may also suspend, vary or revoke the authorisation on being satisfied that the qualified person (manufacture), the person responsible for quality control or the person with responsibility for production is not fulfilling that person's duties under these Regulations.

(3) In particular, the Secretary of State may—

(a) suspend the manufacture or import of veterinary medicinal products;

(b) suspend, revoke or vary the manufacturing authorisation for one or more pharmaceutical forms;

(c) suspend, revoke or vary the manufacturing authorisation for one or more activities in one or more manufacturing sites.**]**

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

Textual Amendments

F7 Words in Sch. 2 para. 5 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **85(c)**

F8 Word in Sch. 2 para. 5(1) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **85(a)(i)**

F9 Sch. 2 para. 5(1)(e)(f) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **85(a)(ii)**

F10 Sch. 2 para. 5(2)(3) substituted for Sch. 2para. 5(2) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **85(b)**

Suspension, variation or revocation of the authorisation N.I.

5.—(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder—

(a) has not complied with these Regulations;

(b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;

(c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; or

(d) no longer has suitable premises or equipment.

(2) The Secretary of State may also suspend, vary or revoke it on being satisfied that the qualified person (manufacture) is not fulfilling their duties under these Regulations.

Extent Information

E37 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F11Good manufacturing practice certificates and inspection of sites] E+W+S

6.—(1) The Secretary of State must, from time to time, inspect **[**F12sites**][**F13authorised**]** under paragraph 3, basing the frequency of the inspection on the risks associated with each **[**F14site's history**]** and the nature of the products handled at the **[**F12sites**]**.

[F15(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection establishes that the manufacturer has complied with the requirements of these Regulations in respect of the site to which the inspection relates.

(2A) Where the Secretary of State does not consider that compliance is established after inspection in accordance with sub-paragraph (2), the Secretary of State must enter that fact in the register mentioned in paragraph 12(a).

(2B) The Secretary of State may carry out an inspection on a site occupied by a manufacturer established in a country other than the United Kingdom notwithstanding any arrangements that may have been entered into between the United Kingdom and that country.

(2C) The importer of a veterinary medicinal product must ensure before importation that the manufacturer of that product has—

(a) a valid certificate of good manufacturing practice issued by the Secretary of State; or

(b) an equivalent certificate issued by a regulatory authority—

(i) with which the Secretary of State has an agreement or arrangement for such purposes; or

(ii) which the Secretary of State considers to have demonstrated equivalent standards to those in the United Kingdom.**]**

F16(3) . . . . . .

F16(4) . . . . . .

F16(5) . . . . . .

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

Textual Amendments

F11 Sch. 2 para. 6 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **86(c)**

F12 Word in Sch. 2 para. 6(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **86(a)(i)**

F13 Word in Sch. 2 para. 6(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **86(a)(ii)**

F14 Words in Sch. 2 para. 6(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **86(a)(iii)**

F15 Sch. 2 para. 6(2)-(2C) substituted for Sch. 2para. 6(2) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **86(b)**

F16 Sch. 2 para. 6(3)-(5) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Inspection of premises N.I.

6.—(1) The Secretary of State must, from time to time, inspect premises registered under paragraph 3, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection established compliance with the principles and guidelines on good manufacturing practice in accordance with Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**1**).

(3) If an inspection is carried out at the request of the European Pharmacopoeia to establish compliance with a monograph, the Secretary of State must issue a certificate of compliance with the monograph, if appropriate.

(**1**) OJ No L 228, 17.8.91, p. 70.

(4) The Secretary of State must provide details of each certificate of good manufacturing practice issued to the Agency for entry into a database.

(5) If the outcome of the inspection is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice, the Secretary of State must provide details to the Agency for entry into the database.

Extent Information

E38 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Report following inspection

7.—(1) After each inspection of manufacturing premises, the inspector must make a written report to the Secretary of State on whether the principles and guidelines on good manufacturing practice and the conditions of these Regulations are being complied with.

(2) The Secretary of State must inform the inspected manufacturer of the content of such reports.

Duties on the holder of a manufacturing authorisation E+W+S

8.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

[F17(2) The holder must have permanently at the holder's disposal the services of—

(a) staff complying with any legal requirements in relation to manufacture of veterinary medicinal products; and

(b) at least one qualified person (manufacture).

(2A) The holder must place at the disposal of any qualified person (manufacture) all necessary documents, premises and technical and other facilities in order to enable that person to discharge their duties as the qualified person.

(2B) Where any qualified person (manufacture) ceases to be available to provide services to the holder, the holder must give notice of the fact to the Secretary of State—

(a) at least 30 days in advance of the person's ceasing to be so available; or

(b) where such notice is not possible, at the earliest opportunity.**]**

[F18(3) The holder must—

(a) comply with good manufacturing practice and have a valid certificate of good manufacturing practice;

(b) use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice and distributed in accordance with good distribution practice for active substances;

(c) verify that each manufacturer, distributor or importer from whom the holder obtains active substances and to which paragraph 26 applies is registered with the Secretary of State under that paragraph;

(d) carry out audits based on a risk assessment in relation to the manufacturers, distributors and importers from which the holder obtains active substances;

(e) have in place a system of quality assurance and quality control; and

(f) give to the Secretary of State, on request, proof of any control test specified by the Secretary of State which has been carried out on the veterinary medicinal product or the

constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(3A) The holder of a manufacturing authorisation must inform the Secretary of State and the holder of any relevant marketing authorisation where the holder obtains information that veterinary medicinal products which fall within the scope of its manufacturing authorisation are falsified, or are suspected of being falsified, irrespective of whether those products were distributed within the legal supply chain or by illegal means.**]**

(4) A holder who makes up a bulk package of veterinary medicinal products must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

(a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;

(b) the batch number;

(c) the expiry date;

(d) any storage requirements; and

(e) any other warning necessary for the safe handling of the package.

(5) A holder must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if required in writing to do so.

[F19(6) A holder must keep detailed records of all veterinary medicinal products which the holder supplies.**]**

Extent Information

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

Textual Amendments

F17 Sch. 2 para. 8(2)-(2B) substituted for Sch. 2para. 8(2) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **87(a)**

F18 Sch. 2 para. 8(3)(3A) substituted for Sch. 2para. 8(3) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **87(b)**

F19 Sch. 2 para. 8(6) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **87(c)**

Duties on the holder of a manufacturing authorisation N.I.

8.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

(2) The holder must have permanently at their disposal the services of at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State and must place all necessary facilities at the qualified person's disposal.

(3) The holder must—

(a) have a current Certificate of Good Manufacturing Practice;

(b) have in place a system of Quality Assurance and Quality Control; and

(c) give to the Secretary of State on request proof of all control tests carried out on the veterinary medicinal product or the constituents and intermediate products of the

manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(4) A holder who makes up a bulk package of veterinary medicinal products must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

(a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;

(b) the batch number;

(c) the expiry date;

(d) any storage requirements; and

(e) any other warning necessary for the safe handling of the package.

(5) A holder must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if required in writing to do so.

Extent Information

E39 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F20Good manufacturing practice

8A.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with this paragraph, whether the manufacturing is performed by the holder or another person.

(2) The manufacturing operations must be conducted in accordance with a written methodology, to be known as the "pharmaceutical quality system" or "PQS".

(3) The PQS must be—

(a) clear;

(b) systematically reviewed from time to time in the light of experience; and

(c) capable of consistently manufacturing veterinary medicinal products which are of the required quality and which meet the requirements of the relevant marketing authorisation.

(4) The critical steps of the manufacturing process set out in the PQS must be validated.

(5) Any significant amendments to the PQS must be validated.

(6) The PQS must provide for—

(a) appropriately qualified and trained personnel;

(b) adequate premises and space;

(c) suitable equipment and access to services;

(d) suitable materials, containers and labelling;

(e) relevant procedures and instructions;

(f) suitable storage and transport;

(g) investigation into complaints and defects.

(7) The PQS must provide for any significant deviations from its provisions to be—

(a) fully recorded, and

(b) investigated, with appropriate corrective and preventative action implemented.

(8) The holder of a manufacturing authorisation must ensure that records of the manufacturing process, including distribution, are kept in a comprehensible and accessible form until the later of—

(a) the date which is five years after the date on which the veterinary medicinal product is placed on the market;

(b) the date which is one year after the expiry date of the batch of veterinary medicinal product.

(9) In this paragraph, a process (or part of a process) is "validated" if scientific evidence is assembled which demonstrates that it is capable of consistently delivering expected results.**]**

Textual Amendments

F20 Sch. 2 paras. 8A, 8B inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **88**

[F20Recalled and counterfeit products

8B.—(1) The holder of a manufacturing authorisation must comply with any requirement by the Secretary of State to recall a veterinary medicinal product and must record the details of the recall operation.

(2) The holder of a manufacturing authorisation must record any veterinary medicinal product which is—

(a) recalled (whether or not the holder physically receives the recalled product); or

(b) discovered to be counterfeit.

(3) Where any veterinary medicinal product is recalled and physically received, the qualified person (manufacture) must assess the recalled product in order to determine whether—

(a) the product has been stored (including during transport) in accordance with the summary of product characteristics;

(b) the product is a genuine product and not counterfeit.

(4) Where the qualified person (manufacture) determines that a recalled veterinary medicinal product does not satisfy sub-paragraph (3)(a) or (b), or where it is not possible for the qualified person (manufacture) to determine whether the product does so, the product may not be re-sold.

(5) The qualified person (manufacture) must record any assessment and determination made under sub-paragraphs (3) and (4).

(6) Any veterinary medicinal products which may not be re-sold must be identified, held separately and destroyed and the holder of a manufacturing authorisation must develop a suitable procedure to set out the steps to be taken in accordance with this sub-paragraph.

(7) The holder of a manufacturing authorisation must keep any information recorded under this paragraph for five years.**]**

Textual Amendments

F20 Sch. 2 paras. 8A, 8B inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **88**

Qualified persons for manufacture

9.—(1) The Secretary of State may appoint as a qualified person (manufacture) any person **[**F21(including the manufacturer of a veterinary medicinal product)**]** who is—

(a) a member of the Royal Pharmaceutical Society or registered with the Pharmaceutical Society of Northern Ireland;

(b) a Chartered Chemist or a Fellow, Member or Associate Member of the Royal Society of Chemistry; or

(c) a Chartered Biologist or a Fellow, Member or Associate Member of the Society of Biology;

[F22(1A) For the purposes of sub-paragraph (1), a person has sufficient practical experience if they have been engaged in one or more of the activities mentioned in sub-paragraph (1B) for at least two years in the provision of services to the holder of a manufacturing authorisation.

(1B) For the purposes of sub-paragraph (1A) the activities are—

(a) quality assurance of medicinal products;

(b) qualitative analysis of medicinal products;

(c) quantitative analysis of active substances.

(1C) The Secretary of State may treat the reference in sub-paragraph (1A) to two years of practical experience as a reference to—

(a) one year, where the person's formal course of study lasted for at least five years;

(b) six months, where the person's formal course of study lasted for at least six years.**]**

who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent and who has sufficient practical experience to carry out the duties under this Schedule.

(2) The Secretary of State may exceptionally appoint a person who is not a member of one of those institutions to act as a qualified person (manufacture) on being satisfied that that person has the educational qualifications or practical experience to carry out the duties under this Schedule.

Textual Amendments

F21 Words in Sch. 2 para. 9(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **89(a)**

F22 Sch. 2 para. 9(1A)-(1C) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **89(b)**

[F23**Refusal, revocation, suspension or variation of appointment]** E+W+S

10. The Secretary of State may refuse **[**F24, revoke, suspend or vary**]** an appointment if the Secretary of State is not satisfied that a person has fulfilled or will fulfil duties under these Regulations.

Extent Information

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

Textual Amendments

F23 Sch. 2 para. 10 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **90(b)**

F24 Words in Sch. 2 para. 10 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **90(a)**

Refusal or revocation of appointment N.I.

10. The Secretary of State may refuse or revoke an appointment if the Secretary of State is not satisfied that a person has fulfilled or will fulfil duties under these Regulations.

Extent Information

E40 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duties on a qualified person E+W+S

11.—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from **[**F25another**]** country,F26..., the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested F27..., including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) Sub-paragraph (2) does not apply **[**F28where the exporting country has demonstrated equivalent standards to those of the United Kingdom or **]** where appropriate arrangements have been made F29...with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

Extent Information

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

Textual Amendments

F25 Word in Sch. 2 para. 11(2) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 Words in Sch. 2 para. 11(2) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F27 Words in Sch. 2 para. 11(2) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(iii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F28 Words in Sch. 2 para. 11(3) inserted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU

Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(c)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F29 Words in Sch. 2 para. 11(3) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(c)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Duties on a qualified person N.I.

11.—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from a third country, including a product manufactured in a member State, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested in a member State, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) Sub-paragraph (2) does not apply where appropriate arrangements have been made by the European Union with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

Extent Information

E41 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Register

12. The Secretary of State must maintain and publish a register of—

(a) holders of manufacturing authorisations; and

(b) qualified persons (manufacture) appointed under paragraph 9(2).

Test sites E+W+S

13.—(1) The Secretary of State may authorise **[**F30a site**]** to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The **[**F31site**]** must have a current certificate of good manufacturing practice.

[F32(2A) The site must be specified in an existing manufacturing authorisation.**]**

(3) **[**F33Inspection of the site is**]** the same as for a manufacturing authorisation.

Extent Information

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

Textual Amendments

F30 Words in Sch. 2 para. 13(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **91(a)**

F31 Word in Sch. 2 para. 13(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **91(b)**

F32 Sch. 2 para. 13(2A) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **91(c)**

F33 Words in Sch. 2 para. 13(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **91(d)**

Test sites N.I.

13.—(1) The Secretary of State may authorise premises to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The premises must have a current certificate of good manufacturing practice.

(3) Authorisation and inspection of the premises are the same as for a manufacturing authorisation.

Extent Information

E42 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34PART 2

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

Textual Amendments

F34 Sch. 2 Pt. 2 (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for Sch. 2 Pt. 2 (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), Pt. 3 (paras. 20-24 entitled "Authorisation of blood banks"), Pt. 4 (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and Pt. 5 (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **92**

[F34Authorisation to manufacture specific veterinary medicinal products E+W+S

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.**]**

Extent Information

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

Authorisation to manufacture autogenous vaccines N.I.

14.—(1) The Secretary of State may authorise a person to manufacture autogenous vaccines and may authorise premises for the purpose of such manufacture by that person.

(2) In order to be authorised the premises must be under the supervision of—

(a) a veterinary surgeon; or

(b) a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before authorising the premises, the Secretary of State must be satisfied that the production process will produce a consistent, safe product.

(4) No person may manufacture an autogenous vaccine other than in accordance with an authorisation under sub-paragraph (1).

Extent Information

E43 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Prohibition E+W+S

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).**]**

Extent Information

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

Types of authorisation N.I.

15.—(1) The authorisation must specify the products that may be manufactured.

(2) It may either be for the production of a single batch of product or for ongoing production of the products specified in the authorisation.

(3) If it is for a single batch it must be time limited.

(4) Only the products specified in the authorisation may be manufactured, and in the case of an authorisation for a single batch the product may only be manufactured before the expiry of the authorisation.

Extent Information

E44 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Personnel E+W+S

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.**]**

Extent Information

E13 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.

16. The operator of the premises must ensure that every container containing autogenous vaccine is labelled with—

(a) the name of the veterinary surgeon who ordered the vaccine;

(b) a precise description of the vaccine;

(c) the date the vaccine was produced;

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

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

Extent Information

E45 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Process of authorisation E+W+S

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.**]**

Extent Information

E14 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.

17. The operator of the premises must, as soon as is reasonably practicable, record—

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

(b) the identification of the source animal;

(c) the expiry date;

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

and must keep the records for at least five years.

Extent Information

E46 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Authorisation in relation to blood banks E+W+S

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.**]**

Extent Information

E15 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.

18. The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine within 15 days of learning of the reaction.

Extent Information

E47 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Authorisation in relation to stem cells E+W+S

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.**]**

Extent Information

E16 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.

19. 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

E48 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Authorisation in relation to products for administration under the cascade **E+W+S**

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.**]**

Extent Information

E17 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 blood banks **N.I.**

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.

Extent Information

E49 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Suspension, compulsory variation or revocation of authorisation E+W+S

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.**]**

Extent Information

E18 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 blood from a blood bank N.I.

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.

Extent Information

E50 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Labelling E+W+S

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.**]**

Extent Information

E19 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.**

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.

Extent Information

E51 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Records **E+W+S**

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.**]**

Extent Information

E20 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.**

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.

Extent Information

E52 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Adverse events E+W+S

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.**]**

Extent Information

E21 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.

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.

Extent Information

E53 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F34Inspection of sites E+W+S

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.**]**

Extent Information

E22 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Authorisation to manufacture products for administration under the cascade N.I.

25.—(1) The Secretary of State may authorise a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade.

(2) In order to be authorised the premises must be under the supervision of a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before authorising the premises, the Secretary of State must be satisfied that the production process will produce a safe product.

(4) The authorisation must specify what types of product it covers.

(5) No person may manufacture an unauthorised veterinary medicinal product other than in accordance with an authorisation under sub-paragraph (1).

Extent Information

E54 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35PART 2A

Active Substances]

Textual Amendments

F35 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**

[F35Prohibition 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

E23 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

E55 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35Application 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

E24 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

E56 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35Good 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

E25 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

E57 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35Supply 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

E26 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

E58 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35Inspection 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

E27 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

E59 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35Report 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

E28 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

E60 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F35PART 2B

Schedule 2 Offences]

[F35Offences **E+W+S**

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

(a) paragraph 1;

(b) paragraph 4(3);

(c) paragraph 8;

(d) paragraph 11;

(e) paragraph 15;

(f) paragraph 18;

(g) paragraph 19;

(h) paragraph 20(1), (3) or (4);

(i) paragraph 22;

(j) paragraph 23;

(k) paragraph 24;

(l) paragraph 26;

(m) paragraph 28;

(n) paragraph 29.**]**

Extent Information

E29 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.**

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.

Extent Information

E61 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Records **E+W+S**

33. [F34] . . . . . .

Extent Information

E30 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F34 Sch. 2 Pt. 2 (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for Sch. 2 Pt. 2 (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), Pt. 3 (paras. 20-24 entitled "Authorisation of blood banks"), Pt. 4 (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and Pt. 5 (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **92**

Records **N.I.**

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.

Extent Information

E62 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Inspection of premises E+W+S

34. [F34] . . . . . .

Extent Information

E31 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F34 Sch. 2 Pt. 2 (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for Sch. 2 Pt. 2 (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), Pt. 3 (paras. 20-24 entitled "Authorisation of blood banks"), Pt. 4 (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and Pt. 5 (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **92**

Inspection of premises N.I.

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 E+W+S

35. [F34] . . . . . .

Extent Information

E32 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F34 Sch. 2 Pt. 2 (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for Sch. 2 Pt. 2 (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), Pt. 3 (paras. 20-24 entitled "Authorisation of blood banks"), Pt. 4 (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and Pt. 5 (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **92**

Offences N.I.

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.

Extent Information

E63 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, SCHEDULE 2.