



# Veterinary Medicines Guidance Note

## Authorisations for Manufacturers

Autogenous Vaccines, Non-food  
Animal Blood Banks, Equine Stem Cell  
Centres and products for  
administration under the 'cascade'

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ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



**THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE**

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**INVESTOR IN PEOPLE**

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**ANNEX**

**CRITERIA FOR USE OF BLOOD DONORS FOR  
NON-FOOD ANIMAL BLOOD BANKS**

**16-17**

### INTRODUCTION

1. This is one of a series of guidance notes explaining the requirements under the Veterinary Medicines Regulations. The Regulations are revoked and replaced every year, so the references to the Regulations should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument has not been detailed in this guidance note. These guidance notes will be updated as necessary and the date of the most recent update is shown on the front cover. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. The purpose of this note is to provide guidance for authorisations for Manufacturers; this includes manufacturing authorisations for veterinary medicinal products, Autogenous Vaccines, Non-food Animal Blood Banks, Equine Stem Cell Centres and the manufacture of products for administration under the “cascade”.

### AUTOGENOUS VACCINE AUTHORISATION (AVA)

3. In order to place on the market an autogenous vaccine manufactured from pathogens or antigens obtained from an animal and used for the treatment of that animal and/or other animals within the same epidemiological unit or in the same rearing chain, an Autogenous Vaccine Authorisation (AVA) is required. The vaccine may only be supplied to a veterinary surgeon, who is responsible for the use of the product and for reporting any suspected adverse reaction to the authorisation holder (see paragraph 64). The authorisation holder is responsible for pharmacovigilance reporting to the VMD.
4. An AVA will only be granted if the product has been inactivated. It is expected that most authorisations will relate to the manufacture of bacterial vaccines. Additional safeguards will be required in respect of most viral vaccines.

### HOW TO APPLY FOR AN AVA

5. Applications for AVAs are handled by the VMD and should not be submitted to the MHRA. The application form for an AVA is available on the VMD website under Industry Information/Applications Page. Two copies of the application form and any supporting data should be submitted to the following address:

Information Management Section  
Veterinary Medicines Directorate  
Woodham Lane  
New Haw  
Addlestone  
Surrey  
KT15 3LS

6. It would help the VMD to process your application more efficiently and speedily if, in addition to paper copies, you could provide an electronic copy of the application or of any parts of it that are available electronically. All word processing formats are acceptable but Microsoft Word held on a CD-ROM is preferred.

### **LABELLING AND RECORD KEEPING REQUIREMENTS**

7. AVA holders must ensure that the product is labelled with the following, together with any additional information required by the terms of the authorisation:
  - the name of the veterinary surgeon who ordered the vaccine;
  - a precise description of the vaccine;
  - the date the vaccine was produced;
  - the name of the authorisation holder and address of the authorised premises;
  - the expiry date;
  - any necessary warnings;
  - instructions for use.
8. Autogenous vaccine authorisation holders must keep at least the following records, together with any other records required by the terms of the authorisation:
  - the name and address of the veterinary surgeon who ordered the vaccine;
  - the identification of the source animal;
  - the expiry date;
  - the date of supply to the veterinary surgeon.
9. These records must be kept for at least five years.

### **TYPES OF AVAS**

10. Manufacturers of autogenous vaccines may apply for two different types of authorisation:- AVA (Standard Process) and AVA (Individual). These are both details below.

### **AUTOGENOUS VACCINES AUTHORISATION (STANDARD PROCESS) (AVA – S)**

11. This type of authorisation will be valid continuously, subject to satisfactory re-inspection every two years. It relates to the method of production and the premises used to make such vaccines. A list of vaccines against specified diseases will be included in the terms of the authorisation.
12. A variation to the terms of the authorisation must be granted before any change may be made to it. The terms include the data and other information that were submitted in support of the application. This includes the premises, equipment and production processes as well as the list of products, which are directly listed on the authorisation.

13. Holders of AVA-S are required to notify VMD of each production batch that they produce before it is placed on the market. A batch protocol with the results of the control tests should be submitted to the VMD Batch Release Section before the product is placed on the market. The protocol should include the results of the QC tests, site(s), the number of animals, which are to be treated and name and address of the veterinary surgeon responsible for administering the product.
14. Autogenous vaccines may not be released before a target animal safety test has been conducted on the premises on which it is intended to administer the vaccine and the results of that safety test and other required information submitted to VMD.

### AUTOGENOUS VACCINE AUTHORISATION (INDIVIDUAL) (AVA – I)

15. Autogenous vaccine manufacturers, who do not wish to use a standard production process, may apply for individual authorisations for each batch of product they wish to manufacture. This type of authorisation will be valid for a single batch of vaccine to be manufactured and placed on the market within one year.
16. It will be a condition of an individual authorisation that the autogenous vaccines may not be released before a target animal safety test has been conducted on the premises on which it is intended to administer the vaccine and the results of the safety test and other required information submitted to VMD.

### EQUINE STEM CELL CENTRES (ESCC)

17. This type of authorisation relates to the method of collection, storage, processing, production and administration of stem cells as an autologous treatment of equine patients under the care of a veterinary surgeon. It will be valid continuously, subject to satisfactory re-inspection at least every two years, and more frequently if the risk assessment for the site suggests more frequent inspection is warranted.
18. If work is to be carried that does not clearly fit under the Equine Stem Cell authorisation scheme, please contact the VMD for advice and guidance.
19. The Authorisation includes manufacturers that operate in the UK a cryo-storage facility or “bank” of equine derived stem cells or manufacture stem cell derived products.
20. The authorisation will only cover multipotent equine stem cells derived from horses or cells derived from the umbilical cord of newborn foals. The authorisation does not cover stem cells derived from embryonic tissues.
21. Treated horses must be declared as non-food producing horses in accordance with the national horse passport scheme.

22. The authorisation covers the premises in the UK used to store, process and manufacture cultures of equine mesenchymal stem cell products and lists the Qualified Person (QP) responsible for the production and release of the product and the QP responsible for pharmacovigilance. A list of stem cell derived products and the treatments, for which they are supplied, will be included in the terms of the authorisation.
23. Equine stem cells may only be supplied to a veterinary surgeon for administration by him or under his responsibility in accordance with a prescription.
24. An application for an ESCC should include:
  - the name and address of the Authorisation holder and list of sites involved in the processing, storage, manufacture and Quality Control (QC) testing of equine stem cell products and any other sites involved in providing technical advice or training to the veterinary surgeon(s) involved in the collection and administration of stem cells;
  - method(s) of collection of cells to minimise the risk of contamination;
  - premises, facilities, resources and equipment;
  - operation of a Quality Assurance / Quality Control scheme;
  - the Qualified Person (QP) responsible for manufacture and release of the product(s);
  - the Qualified Person (QP) responsible for pharmacovigilance;
  - action taken to assure animal welfare is respected;
  - action taken to minimise the risk of spreading disease during the collection, storage, manufacture and administration of equine stem cells;
  - Action taken to ensure complete traceability of the stem cells.

### **HOW TO APPLY FOR AN ESCC**

25. Applications for ESCCs are handled by the VMD and should not be submitted to the MHRA. An application form for an ESCC is available on the VMD website under Industry Information/Applications Page. Two copies of the application form and any supporting data should be submitted to the following address:

Information Management Section  
Veterinary Medicines Directorate  
Woodham Lane  
New Haw  
Addlestone  
Surrey  
KT15 3LS

26. It would help the VMD to process your application more efficiently and speedily if, in addition to paper copies, you could provide an electronic copy of the application or of any parts of it that are available electronically. All word processing formats are acceptable but Microsoft Word held on a CD-ROM is preferred.

### **LABELLING AND RECORD KEEPING REQUIREMENTS**

27. ESCC Authorisation holders must ensure that the product is labelled with the following, together with any additional information required by the terms of the authorisation:
- the identification of the donor animal;
  - the date of collection;
  - the authorisation number of the ESCC;
  - any necessary warnings;
  - the expiry date.
28. ESCC Authorisation holders must keep at least the following records, together with any other records required by the terms of the authorisation:
- the identification of the donor animal;
  - the date of collection;
  - the veterinary surgeon who collected it;
  - the expiry date;
  - 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.
29. These records must be kept for at least five years.

### **NON-FOOD ANIMAL BLOOD BANK AUTHORISATION (NFABBA)**

30. Applicants who wish to collect and store blood for use in non-food producing animals and place it on the market to meet unforeseen or exceptional needs may apply for a Non-Food Animal Blood Bank Authorisation (NFABBA) in respect of their premises. The VMD considers that the separation of whole blood into its constituent parts i.e. plasma, red cells, cryo-precipitate and cryo-supernatant by physical means within a single closed system, is acceptable under this scheme. Any other means of production of blood products should only be done via a full manufacturing and marketing authorisation.
31. This authorisation will also permit the blood or its constituent products (see 30.) to be placed on the market without a veterinary medicinal product marketing authorization. No medicinal claims should be made for blood or its constituent products.. A NFABBA will be valid continuously subject to satisfactory re-inspection. A variation to the terms of the authorisation must be granted before any change may be made to them. A variation may only be submitted if a further inspection will not be required. If it is necessary for an inspection to be carried out, an application must be made for a new authorisation.
32. It is clearly impossible for blood, and associated blood products which have to be

produced from individual animals, to be produced as a consistent medicinal product as is required for a marketing authorisation for a veterinary medicinal product. Therefore an application for a non-food animal blood bank authorisation should include data relating to:

- the name of the veterinary surgeon supervising the blood bank;
- method of the collection process to ensure consistency of the product;
- premises, facilities, resources and equipment;
- operation of a Quality Assurance / Quality Control scheme;
- action to be taken to assure animal welfare is respected;
- action to be taken to ensure the specific disease free status of the donor animal that may be a risk to recipients;
- the method of collection to ensure the blood is collected in an aseptic manner.

33. Blood may only be supplied to a veterinary surgeon for administration by him or under his responsibility. The authorisation holder is responsible for pharmacovigilance reporting to the VMD.

Animal welfare is paramount (please see section below Animal welfare). In setting up a blood bank, it is anticipated that the animals used as donors will be pet dogs or rescue dogs waiting for rehoming and that the blood donation procedure will not require sedation of the animal.

If you wish to set up a blood bank and the donor animals are kept in a colony, maintained for that specific purpose or blood donations require sedation of the animal, then you will need to apply for both a Home Office Licence under the ASPA and an NFABB Authorisation from the VMD. Please contact the VMD for further information

### **HOW TO APPLY FOR A NFABBA**

34. Applications for NFABBAs are handled by the VMD and should not be submitted to the MHRA. An application form for an NFABBA is available on the VMD website under Industry Information/Applications Page. Two copies of the application form and any supporting data should be submitted to the following address:

Information Management Section  
Veterinary Medicines Directorate  
Woodham Lane  
New Haw  
Addlestone  
Surrey  
KT15 3LS

35. It would help the VMD to process your application more efficiently and speedily if, in addition to paper copies, you could provide an electronic copy of the application

or of any parts of it that are available electronically. All word processing formats are acceptable but Microsoft Word held on a CD-ROM is preferred.

### **LABELLING AND RECORD KEEPING REQUIREMENTS**

36. Non-Food Animal Blood Bank Authorisation holders must ensure that the product is labelled with the following, together with any additional information required by the terms of the authorisation:

- the identification of the donor animal;
- the date of collection;
- the authorisation number of the blood bank;
- any necessary warnings;
- the expiry date.

37. Non-Food Animal Blood Bank Authorisation holders must keep at least the following records, together with any other records required by the terms of the authorisation:

- the date of collection;
- the identification of the donor animal;
- the identity of the veterinary surgeon
- the expiry date;
- 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.

38. These records must be kept for at least five years.

### **ANIMAL WELFARE**

39. Holders of Non-Food Animal Blood Bank Authorisations should ensure that the animal health and welfare of donor animals is respected. Please see Annex Criteria for use of blood donors for non-food animal blood banks.

40. Donor animals should be tested for the absence of certain diseases that may pose a potential risk to transfusion recipients. These tests should be conducted in accordance with veterinary guidelines or following an appropriate risk assessment to ensure that the risk of disease transmission to transfusion recipients is minimised.

41. Donor animals must be certified by the attending veterinary surgeon in relation to their health status at the time of donation.

## INSPECTIONS FOR AVA, NFABBA AND ESCC

### PRIOR INSPECTION

42. It is a pre-requisite for these authorisations that an inspection of the premises, equipment and production processes is carried out. Further inspections will be carried out at two yearly intervals during the life of the authorisation. Manufacturers that have previously been granted an AVA - I and have not been inspected within the past two years, must also have a satisfactory inspection of their premises etc. before an authorisation can be granted.
43. Valid applications will be processed within 45 days during which time the clock may be stopped when responses to questions are awaited. The clock will also be stopped while waiting for an inspection to take place. Applicants are advised to contact the VMD inspections team to arrange an inspection in good time so as to avoid delay in processing their application.
44. The Secretary of State may refuse, vary, suspend, withdraw or revoke an authorisation at any time on grounds of:
  - operating outside the terms of the authorisation;
  - insufficient data;
  - insufficient facilities, resources or equipment;
  - unsuitability of premises;
  - deficiencies of the QA / QC scheme;
  - insufficient account taken of animal welfare;
  - adverse reaction reports;
  - significant risk of disease transmission from donor animals to recipients for blood.
45. Applicants or authorisation holders may appeal against such a decision. The appeal will be heard by an appointed person who will make a recommendation to the Secretary of State. Details of the appeals regime are set down in VMG Note 11.

## GENERAL PRINCIPLES OF INSPECTIONS

46. The general principles of Manufacturing Practice that form the basis for the inspection of AVA's, ESCCs and NFABBs are as follows:

### MANUFACTURE

47. All necessary facilities shall be provided including:
  - appropriately trained staff;
  - adequate premises and space;
  - suitable equipment and services;
  - correct materials, containers and labels;
  - approved procedures and instructions;

- suitable storage and transport.
48. Records are made.
  49. A system is available to recall any batch of product.
  50. Complaints are examined and the cause of quality defects investigated.

### **QUALITY MANAGEMENT**

51. The manufacturer must manufacture products in accordance with the terms of the authorisation granted by the Secretary of State so as to ensure that they are fit for their intended use and do not place animals at risk due to inadequate safety or quality. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff. To achieve the quality objective reliably there must be a basic system of Quality Assurance (QA) and Quality Control (QC). It should be fully documented and its effectiveness monitored.

### **QUALITY ASSURANCE**

52. Manufacturers should operate an appropriate system of QA that assures:
  - Production and control operations are clearly specified and fully validated.
  - Managerial responsibilities are clearly specified.
  - Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials.
  - All necessary controls on intermediate products, and any other in-process controls are carried out.
  - The finished product is correctly processed and checked according to defined procedures.
  - Autogenous vaccines or blood are not sold or supplied before an appropriately qualified person has certified that the vaccine or blood has been produced and controlled in accordance with the requirements of the authorisation.
  - Satisfactory arrangements exist to ensure, as far as possible, that the products are stored, distributed and subsequently handled so that the quality is maintained throughout their shelf life.
  - There is a procedure for self-inspection to appraise effectiveness of the QA system.

### **QUALITY CONTROL**

53. QC is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials/products are not released for use until their quality has been judged to be satisfactory.

The basic requirements of QC are that:

- Adequate facilities, trained personnel and approved procedures are available.
- Samples are taken by personnel and by methods approved by QC.
- Test methods are validated.
- Records are made.
- The autogenous vaccine contains active substances complying with the qualitative and quantitative composition of the authorisation.
- Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures.
- Sufficient reference samples are retained to permit future examination of emergency vaccines if necessary and that the emergency vaccine is retained in its final pack.
- Autogenous vaccines are not sold or supplied before a target animal safety test has been conducted on the premises on which it is intended to administer the vaccine. The results of the safety test must be submitted to VMD.

### **PERSONNEL**

54. There must be sufficient qualified personnel to carry out all the tasks. Individual responsibilities should be clearly understood and recorded. All personnel should be aware of the principles that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs. Training records should be kept.
55. Steps should be taken to ensure as far as practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of these products. Persons entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.

### **PREMISES AND EQUIPMENT**

56. Premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. They should permit effective cleaning and disinfection to minimise the risk of errors.
57. The production area should be laid out in a logical order in accordance with the sequence of operations. Restrictions on access of personnel or materials to some or all areas may be imposed within the terms of an authorisation. The temperature and humidity (where appropriate) in storage areas for materials, vaccines and blood should be appropriately controlled, monitored and checked to demonstrate compliance with specifications.

### **DOCUMENTATION**

58. Good documentation constitutes an essential part of the QA system. Clearly written documentation prevents errors and permits tracing of batch history.

Specifications, manufacturing instructions, procedures, and records must be free from errors and available in writing. The legibility of documents is of paramount importance. Batch specific documentation should be retained for at least one year after the expiry date of the product.

### **PRODUCTION**

59. Production operations must be in accordance with the relevant authorisation and follow clearly defined procedures in order to obtain products of the requisite quality that can be released by the veterinary surgeon who carries out the site safety test.

### **CONTRACT MANUFACTURE**

60. Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings, which could result in a product or work of unsatisfactory quality. There must be a written contract, which clearly establishes the duties of each party.
61. The Contract Acceptor should understand that he is subject to inspection by the competent authorities.

### **COMPLAINTS AND PRODUCT RECALL**

62. All complaints and other information concerning potentially defective products must be reviewed carefully according to written procedures. A system should be designed to recall, if necessary, promptly and effectively products suspected to be defective from the market.

### **SELF INSPECTION**

63. Authorisation holders are expected to carry out self-inspection in order to monitor the implementation and compliance with the manufacturing principles and propose necessary corrective measures. Self-inspections should be recorded including observations made during the inspections, any proposals for corrective measures and details of subsequent action taken.

## **GENERAL REQUIREMENTS FOR MANUFACTURERS**

### **PHARMACOVIGILANCE**

64. Any suspected adverse reactions (SAR) to veterinary medicinal products, autogenous vaccines, blood products or products manufactured for administration under the “cascade” should be made to the VMD at the following address:

Department for Environment, Food and Rural Affairs (Defra)  
Veterinary Medicines Directorate  
FREEPOST KT 4503  
Woodham Lane  
New Haw  
Addlestone

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Surrey, KT15 3BR

65. For more information relating to pharmacovigilance reporting please see Veterinary Medicines Guidance Note 13 Supplementary Guidance on Pharmacovigilance.

### FEES

66. A fee is normally charged for the assessment of an application for an ManA, 'Specials' Manufacturing Authorisation(ManSA), AVA, ESCC or an NFABBA. Details on the relevant fees can be found in the Veterinary Medicines Regulations, which are available on the VMD website.

### FURTHER INFORMATION

67. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618 or E-mail: [VMGNotes@vmd.defra.gsi.gov.uk](mailto:VMGNotes@vmd.defra.gsi.gov.uk). Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website ([www.vmd.gov.uk](http://www.vmd.gov.uk)).

**CRITERIA FOR USE OF BLOOD DONORS FOR  
NON-FOOD ANIMAL BLOOD BANKS**

**This criteria has been agreed with the Home Office and the Royal College of  
Veterinary Surgeons**

1. Donations should take place under the supervision of a veterinary surgeon in premises (including specifically adapted vehicles) that provide the appropriate standard of hygiene for the procedures being performed. In addition the appropriate emergency backup must be available should it be required.
2. All donations should adhere to the strict procedures detailed in the company's approved procedures.
3. All donors should be uniquely identified and records kept of all donations to ensure that dogs that present problems at donations can be identified and excluded from further donations where appropriate.
4. Dogs should donate at no greater frequency than 3 monthly intervals.
5. Only dogs that are in a good state of health, do not appear stressed, are compliant and settled and can be handled without excessive restraint will be able to donate. The donors should be examined by a veterinary surgeon prior to each blood collection to ensure the dog is in a good state of general health. A packed cell volume or haemoglobin level should be measured prior to each donation and must be within normal limits for donation to proceed.
6. Blood should not be taken from dogs with a recent history of surgery or adverse medical conditions. It is not possible to define precise timeframes for all possible scenarios; but it is the responsibility of the attending veterinary surgeon to ensure the donor animal is in a good state of general health at the time of donation. Blood should also not be taken from dogs which are on medication (other than routine preventative healthcare) or that are pregnant or whelping or nursing pups at the time of donation.
7. Dogs should not have ever travelled outside the UK.
8. Any blood product not used should be disposed of as waste material.
9. Dogs must not be sedated to facilitate donations.
10. The donors must be a minimum weight of 25kgs to allow up to 450mls of blood to be withdrawn at any one session.

- 11.** The donor should be closely monitored during the donation process. After donating, measures should be taken to reduce risk of haematoma and infection.
- 12.** Donors should be clinically examined after donating to ensure they remain healthy and there are no adverse reactions. The owner or guardian of the donor must be given clear advice on where to seek veterinary help should they become concerned about the welfare of the donor in the hours following donation.

# VETERINARY MEDICINES GUIDANCE NOTE

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