Guidance

Apply for Specific Manufacturing Authorisations

Apply for an authorisation to manufacture extemporaneous preparations, autogenous vaccines, stem cell products or blood products for non-food animals

You need a specific manufacturing authorisation:

- to manufacture extemporaneous preparations for administration to named animals under the prescribing cascade, also known as ‘specials’
- to manufacture an autogenous vaccine
- to authorise a non-food animal stem cell centre for the collection, storage and supply of autologous stem cell treatments
- to authorise a non-food animal blood bank for the collection, storage and supply of blood products for the treatment of non-food animals

If you wish to apply for an authorisation to manufacture:

- an authorised veterinary medicine
- a veterinary medicine marketed under Schedule 6 of the Veterinary Medicines Regulations (Exemptions for small pet animals)

go to: Authorisations to manufacture veterinary medicines.

General Requirements

If you are the holder of a specific manufacturing authorisation you must comply with the principles of good manufacturing practice (GMP), which are included in Eudralex volume 4.

Your manufacturing activities must be carried out under the supervision of an appropriately qualified and experienced person, known as the person responsible for release (PRR).

Labelling

You must ensure that every container of product that you supply 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

In the case of:

- an autogenous vaccine or an extemporaneous preparation for administration under the cascade, the product label must also include the name of the veterinary surgeon who ordered the product

- blood or a stem cell product, the product label must also include the identification of the donor animal and the date of collection

- blood or blood products there must be no specific therapeutic indication on the product label or any information related to the product

- an unauthorised veterinary medicine for administration under the cascade, the words “This veterinary medicinal product does not hold a marketing authorisation” must be included on the label.

Records

You must keep detailed records of each batch of veterinary medicine you manufacture, as required by GMP.

When you supply a product that you’ve manufactured, you must, as soon as is reasonably practicable, record the expiry date of the product and the following:

(a) in the case of an unauthorised veterinary medicine for administration under the cascade-

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

(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 you must keep those records for at least five years.

Adverse events

You must notify us of any adverse event in relation to a product that you've produced within 30 days of learning of the event.

Extemporaneous preparations (ManSA)

You need a ManSA to manufacture and supply an unauthorised extemporaneous preparation for use as a veterinary medicine.

We will only grant a ManSA if we are satisfied that you will comply with the general requirements for holding a specific manufacturing authorisation and that:

- the product has been specifically ordered by a veterinary surgeon who is registered with the Royal College of Veterinary Surgeons (RCVS), for use in accordance with the cascade.
- the product is formulated in accordance with the veterinary surgeon's requirements
- the product is for administration to an animal under the veterinary surgeon's care and their direct personal responsibility

The order and distribution of an extemporaneous preparation should be in response to a clinical need in a specific animal. This should be a direct process between the prescribing veterinary surgeon and you, the manufacturer, and you cannot supply the product via a third party, such as a wholesale dealer.

Everyone involved in the supply chain should be aware of the unauthorised status of the product. It should be clear from the product's packaging that the product is unauthorised as it won't display a marketing authorisation (MA) number or have a trade name. Any product name may only be a precise description of that product, such as the name of the active substance, strength and pharmaceutical form.

A ManSA does not normally permit you to manufacture an unauthorised extemporaneous preparation that is the pharmaceutical equivalent of an available authorised medicine. We consider a medicine to be a pharmaceutical equivalent if:

- it contains the same amount of the same active substance(s) or, for liquid dosage forms the same concentration
- it is in the same dosage form
- it meets the same or comparable standards considered in the light of the clinical needs of the patient at the time of use of the medicine

We consider an authorised veterinary medicine to be available if it can be obtained from normal distribution channels in a reasonable time. However, if an otherwise suitable authorised veterinary medicine becomes unavailable, you may manufacture and supply an unauthorised pharmaceutical equivalent of that product if it is ordered by a veterinary surgeon but this should only be a temporary measure. You should not take supply in these circumstances as justification for long term prescription and you should cease supply as soon as is possible following the authorised product becoming available again.

Requirements for ManSA holders

The same requirements broadly apply to the manufacture of extemporaneous preparations by ManSA holders as they do for authorised veterinary medicines by the holder of a ManA, although extemporaneous preparations will not possess an MA.

You must take adequate precautions to ensure that the extemporaneous preparation is of the quality required for its intended purpose and that it complies with any relevant pharmacopoeial monograph standards.

You must keep written records of extemporaneous preparations that you have manufactured and supplied for five years and make those records available to us on request.

You must comply with the guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via veterinary medicinal products.

Where possible you should use GMP-assured active substances (also referred to as active pharmaceutical ingredients or APIs) to manufacture extemporaneous preparations.

You must ensure that any information you provide to us relating to the evaluation of the safety, quality or efficacy of any medicine which you import, handle, store or distribute is not false or misleading.

Requirements for testing extemporaneous preparations

You should conduct appropriate testing to ensure your product meets its in-house specification.

If you only manufacture an unauthorised extemporaneous preparation on an ad hoc basis, you

- must demonstrate consistency of manufacture. As a minimum there should be a standard process that can be validated even if the end product itself cannot be. However, there should be confirmation of homogeneity if this is appropriate to the preparation
- should be able to provide justification for the specified shelf life. Such products should have a short shelf life to reflect the fact there are no data to substantiate the validity of the stated expiry date

If you are producing more regularly prescribed extemporaneous preparations that may store for a length of time in anticipation of an order from a veterinary surgeon, you should undertake real-time stability studies to justify the specified shelf-life. Depending on the nature of the products being manufactured, data may be required to support the proposed shelf-life and on-going stability studies in accordance with GMP principles may also be required.

Advertising extemporaneous preparations

You must not advertise or promote the specific substances that you can manufacture. However, you may

- provide lists of active substances and formulations with prices to a veterinary surgeon but only on request
- advertise the services you provide and the different types of dosage forms that are available, for example capsules, syrups
- provide placebo samples to a veterinary surgeon enquiring about your services

For specific information on advertising extemporaneous preparations, read our 2023 blog. For more general guidance on advertising, read our guidance Advertise veterinary medicines legally.

Autogenous Vaccine Authorisation (AVA)

You must hold a valid autogenous vaccine authorisation (AVA) to manufacture autogenous vaccines from pathogens or antigens obtained from an animal/s to be used for the treatment of that animal and/or other animals within the same epidemiological unit or in the same rearing chain. Your AVA will include specific details of your manufacturing site and the method of production.

We will only grant an AVA if, following an assessment, we are satisfied that you will comply with the general requirements for holding a specific manufacturing authorisation and that:

- 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
- that the production process will produce a consistent, safe product
- a veterinary surgeon has confirmed a need and fully justified the use of the autogenous vaccine in preference to a UK authorised product

Viral Autogenous Vaccines

In the case of a viral autogenous vaccine, there is a need for a technical framework to give assurance that the associated risks are suitably controlled and that the final vaccines are free from contamination.

The requirements for the authorisation of viral autogenous vaccines are:

- compliance with the required manufacturing standard, such as by holding a full GMP certificate or by an inspection by us. If you produce a viral vaccine at a GMP compliant site within the EU, we retain the right to address specific manufacturing issues with the national competent authority and if necessary to carry out a site inspection. This is because production is not conducted to a harmonised set of requirements such as extraneous agent testing and validation of inactivation kinetics

- assurance that the vaccine is an autogenous vaccine, for example, the vaccine is manufactured from pathogens or antigens obtained from an animal/s and will be used for the treatment of that animal and/or other animals within the same epidemiological unit or in the same rearing chain. The nature of the animal production industry where the vaccine is intended to be used should be taken into account. The use of the same isolate to produce further batches of vaccine would be on a quality risk basis and tested to determine similarity
- complete testing of cell seed to European Pharmacopoeia requirements
- inactivation kinetics validation. This must cover the agent in the vaccine but also all possible sources of contamination from the isolate itself as well as potential sources of cross contamination. A risk assessment approach to those viruses which are not likely to be present can be conducted taking into account the geographical source of the isolate, the health status of the animals from which the isolate originated, other isolates handled in the plant and the range of extraneous agents testing of starting materials. A condition of authorisation will include the obligation to update this assessment and validation as appropriate, when any new isolates/starting materials are handled at the plant
- extraneous testing of the final product to European Pharmacopoeia requirements where not justified by inactivation kinetics. It may be possible to have derogations on the degree of testing depending on the range of agents covered by the inactivation kinetics validation package and the risk assessment
- batch safety test using a double dose of vaccine to be conducted on the site of use of the vaccine with satisfactory results before use of the vaccine batch in the entire group of animals
- pharmacovigilance reporting
- validation of any tests used for extraneous agents testing should be provided

Additional requirements

You must not release an autogenous vaccine onto the market before you have conducted a target animal safety test on the premises on

which it is intended to administer the vaccine and achieved a satisfactory test result.

You must notify us every time you place a batch of autogenous vaccine onto the market.

Non-Food Animal Stem Cell Centre Authorisation (ASCCA)

You must hold a non-food animal stem cell centre authorisation (ASCCA) if you collect, store, process, produce and administer stem cells for use as an autologous treatment for non-food animals in Great Britain. In Northern Ireland the requirements only apply to non-food producing equines, for which you must hold an equine stem cell centre authorisation (ESCCA).

An ASCCA is required to operate a cryo-storage facility, or bank non-food animal derived stem cells, or manufacture stem cells derived products.

We will only grant an ASCCA if we are satisfied that you will comply with the general requirements for holding a specific manufacturing authorisation and that:

- the welfare of the animals used in the collection of non-food animal stem cells will be respected
- the production process will produce a consistent, safe product

Non-Food Animal Blood Bank Authorisation (NFABBA)

You must hold a non-food animal blood bank authorisation (NFABBA) to collect and store blood for supply to a veterinary surgeon for the treatment of non-food producing animals. Collected blood may be stored and supplied as whole blood or blood constituents.

An NFABBA permits you to place the blood or blood constituents onto the market without the need for a marketing authorisation (MA) as

long as no medicinal claims are made. However, blood constituents must be obtained by the physical separation of donor blood into different fractions within a closed-bag system to be acceptable under this scheme. The production of blood products by any other means should only be carried out by the holder of a manufacturing authorisation (ManA) and in accordance with an MA.

Blood collected under an NFABBA will normally be processed at a UK-based non-food animal blood bank. Exceptionally, we may permit blood collected from animals at a UK NFABBA site to be processed outside the UK and then returned, if we are satisfied that all activities will be performed in accordance with the requirements for an NFABBA and that the quality and safety of the blood is maintained.

We will only grant an NFABBA if we are satisfied that you will comply with the general requirements for holding a specific manufacturing authorisation and that:

- the welfare of the animals used in the collection of blood will be respected
- the production process will produce a consistent, safe product

Blood collection from donor animals

In setting up a blood bank we expect that the animals used as donors will be client owned pet animals, rescue animals waiting for re-homing, or camelids from the same herd as recipients. We also expect that the blood donation procedure will not require animal sedation or chemical restraint.

If the donor animals are a colony of animals kept for the specific purpose of blood donation then an application for a Home Office Licence under the Animals (Scientific Procedures) Act (ASPA) 1986 as well as an NFABBA from us will be required.

Donor animals should be free from certain infectious agents that may pose a potential risk to transfusion recipients. A risk assessment should be conducted to determine any necessary testing. Donor animals should be tested for those infectious agents whose presence cannot be excluded during the risk assessment in order to ensure that the risk of disease transmission from donors to transfusion recipients

is minimised. Retesting of repeat donors may be necessary and should be performed at suitable intervals based on the risk assessment (but not less than 8 weeks).

You must ensure that the health and welfare of the donor animals is not compromised. At the time of donation, the attending veterinary surgeon must certify that each donor animal is suitable for use in the collection of blood.

Supply and administration of blood from a blood bank

The NFABBA holder may only supply blood or blood constituents from the blood bank to a veterinary surgeon. These blood products may only be administered by a veterinary surgeon or someone acting under a veterinary surgeon's responsibility. In addition, the following rules must be followed in relation to the use of blood:

- no person may administer blood to a food-producing animal
- any unused collected blood product should be disposed of as waste material.

The RCVS has reviewed this guidance, which includes criteria for suitable blood donors, additional species-specific criteria, and guidance concerning blood donation procedures. The RCVS considers these blood donation procedures and criteria to be consistent with routine veterinary practice (RVP).

This guidance for blood banks has been agreed by the RCVS, Home Office and us.

Criteria for suitable blood donors under a NFABBA

1. Identification: All donors should be uniquely identified, and records kept of all donations to ensure that donors that present problems at donations can be identified and excluded from further donations where appropriate.
2. Travel: Donor cats and dogs must have no history of travel outside the UK and Ireland. In the case of camelids, the travel history should be documented. Any camelid imported from outside of the UK and Ireland within the preceding 12 months should not be used as a donor.

3. Medical history: The examining vet must consider the donor's available medical history before allowing the donation to proceed. Blood should only be collected from animals with; a) no history of receiving a blood transfusion, b) no history of medical conditions (and not currently receiving medication), c) no history of taking any medication that could have a detrimental effect on the subsequent recipients of blood products from this donor, and d) no history of having had any surgical procedures that could impact on the safe collection of blood from the donor.
4. Temperament: A careful evaluation of donor temperament is important when selecting potential donor animals, especially donor cats. Only animals that do not appear stressed, are compliant and settled, and can be handled without excessive restraint will be able to donate. Donors must not be chemically restrained or sedated to facilitate collection of blood under the NFABBA scheme.
5. Health status: The donor should be examined by a vet prior to blood collection to ensure it is in a good state of general health and therefore able to donate. This health assessment must take into consideration the donor animal's species, breed, activity level, and haematological status before allowing the donation to proceed.
6. Haematological status: The donor's haematological status should be assessed to establish its suitability for donation (for example a measurement of packed cell volume and/or haemoglobin levels). It must be determined that the relevant haematological parameters are within the acceptance ranges pre-defined in the company's approved procedures. Assessment of haematological status must also include checks to ensure that the planned volume of blood for donation can be removed safely without adverse effects, for example, induction of anaemia.
7. Vaccination: Consideration should be given to any recent vaccinations received by the donor and whether this affects their ability to donate.
8. Pregnancy and lactation: Animals that are pregnant or nursing are not permitted to be blood donors.
9. Bodyweight: At the initial donation, the minimum bodyweight permitted is dependent on species as follows: 4.5 kg in cats, 25

kg in dogs, and 50 kg in camelids. At subsequent donations, blood may be collected from a donor animal weighing not more than 5% less than the bodyweight recorded at the initial donation.

10. Age: Donor animals should be skeletally mature adults (fully grown). Geriatric animals should not be used. For example, eligible donor dogs should not be more than 8 years old and eligible donor cats should not be more than 9 years old.
11. Repeat donors: In the case of repeat donors, the vet is responsible for ensuring no changes have taken place since the last donation that could have a detrimental effect on the donor or subsequent recipient.
12. Interval between donations: The minimum interval between donations should be at least 8 weeks. Furthermore, the number of donations within a calendar year should be restricted to a level that would ensure there is no risk of significantly depleting the donor's iron reserves. This could be supported by the re-evaluation of relevant haematological parameters before donation to confirm that they have returned to within their normal range.

Additional criteria for cats

1. Cardiac assessment: Donor cats should have no heart murmur on auscultation when assessed pre-donation. Prior to the first donation, and once annually thereafter, a heart scan (echocardiogram) should be performed to confirm the cat's cardiac health status.
2. Blood pressure: Before collecting blood, the attending vet should assess the donor cat's blood pressure, and this should fall within normal reference ranges.
3. Routine flea and worm treatments: When assessing the history of the donor, consideration should be given to as to whether appropriate levels of worming and flea treatment have been performed.
4. Maximum donation volume: The maximum amount of blood that can be collected from a donor cat is 10% total blood volume (equivalent to approximately 6.6 ml blood per kilogram bodyweight), up to an absolute maximum volume of 60 ml of

blood. When calculating the maximum volume in overweight cats, the animal's lean bodyweight should be used.

Donor bodyweight	Maximum donation volume
4.5kg – 9.1 kg	Maximum volume (ml) = Bodyweight (kg) x 6.6 (ml)
Above 9.1 kg	Maximum volume = 60 ml per cat

For example, a cat with a bodyweight of 5.0 kg at the initial donation will be able to donate a maximum of 33 ml of blood (that is 5.0 kg x 6.6 ml = 33 ml).

Additional criteria for Dogs

1. Maximum donation volume: 450 ml +/-10%.
2. The donor dog must have a minimum bodyweight of 25 kg at the initial donation. This will allow the collection of a volume of up to 450 ml +/-10%.

Additional criteria for New World Camelids (Alpaca, Vicuna, Llama and Guanaco)

1. Herd health status: Only donors that are in a good state of health should be used to donate. Herd health information including known disease status (absence of certain infectious agents) should be reviewed.
2. Maximum donation volume: 450 ml +/-10%. The donor must weigh a minimum weight of 50 kg at the initial donation. This will allow the collection of a volume of up to 450 ml +/-10%.
3. Supply and administration of camelid blood: Blood collected from camelids, including blood constituents, should only be used within the herd where the donating camelid resides.

Blood donation procedures

1. Blood collection should take place under the supervision of a vet, in premises including but not limited to a veterinary practice, farm or specifically adapted vehicle. The location should provide the appropriate standard of hygiene for the procedures being performed. 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 and be conducted with the owner's informed consent.
3. Owners should be permitted to be present throughout the donation process. Measures should be taken to prevent blood collection from being a negative experience for the donor animal.
4. When calculating the volume of blood that can be collected from a donor animal the attending vet must take into consideration all relevant factors. These factors must include the donor's haematological status and the maximum donation volume set for the specific species (see the additional criteria set for cats, dogs, and New World camelids).
5. The donor should be closely monitored during the donation process. Measures should be taken to reduce risk of haematoma and infection as a consequence of blood donation.
6. Donors should be clinically examined after donating and monitored for signs of adverse effects. First time donors should remain under observation for at least 30 minutes post donation and repeat donors for no less than 15 minutes post donation.
7. Post donation, instructions should be given to the owner. This information must include the contact details of an emergency vet available in the event of a delayed adverse reaction.
8. Donors must not be routinely administered replacement fluids by injection under the NFABBA scheme. The need for this type of fluid replacement therapy must be determined by the attending vet and should be reserved for those animals experiencing adverse effects from blood collection. Animals that had previously experienced adverse effects of this kind following blood collection must not be allowed to donate blood under the NFABBA scheme in the future.

Application Procedure

- Application for an AVA (ODT, 35.7 KB)
- AVA Annex 1 - Veterinary surgeon justification declaration (ODT, 30.9 KB)

Complete and submit your application for a new AVA to us via our Veterinary Medicines Digital Service

- Application form for a ManSA (ODT, 98.6 KB)
- Application for an ASCCA (ODT, 38.1 KB)
- Application for a NFABBA (ODT, 38.7 KB)

To apply for a ManSA, ASCCA or NFABBA, you may either email your application form to inspections@vmd.gov.uk or submit it via our Veterinary Medicines Digital Service.

Assessment Procedure for an AVA

We will validate your new and variation applications within 10 days of receiving it, provided you have submitted all required information. The validation time will be extended if we need further information from you, or a third party, and if an inspection of the premises is needed.

Once the application has passed validation, it will proceed into the assessment phase. We will notify you if an inspection is required.

If the outcome is to approve your application, we will issue your authorisation documentation at the end of the application procedure.

Timelines

The following timescales apply for the assessment of new and variation AVA applications:

- Validated within 10 days of receipt
- Approved or refused within 45 clock days of validation passed

- Following approval, updated authorisation documentation will be issued within 10 days

Where an inspection is required during the assessment phase (post-validation) the clock will be stopped to await the outcome of that inspection, which we will carry out within 90 days.

Assessment procedure for a ManSA, ASCCA or NFABBA

We will validate your application within 10 days of receiving it, provided you have submitted all required information. The validation time will be extended if we need further information from you, or a third party, and if an inspection of the premises is needed.

Once the application has passed validation, we will conduct the pre-authorisation inspection of your site within 90 days.

Timelines

- Validated within 10 days of receipt
- Inspection of site within 90 days of validation
- Issue of Inspection Deficiency Report within 30 days of completed inspection
- Company response to Inspection Deficiency Report within 30 days
- Issue of final Inspection Report and authorisation document within 90 days of inspection

Application refusal and appeal

We may refuse to grant an authorisation or may grant an authorisation that is different to that you applied for. In such cases we will notify you of the reason and how you can appeal our decision.

Validity of Specific Manufacturing Authorisations

Your authorisation will be valid continuously subject to satisfactory re-inspection of your manufacturing site.

The frequency of inspections is risk-based and derived from the compliance findings of the previous inspection.

Variation, Suspension and Revocation of an Authorisation

Voluntary variations to a ManSA, ASCCA or NFABBA

You must submit a variation application to us if you intend to make any changes to an authorisation that could impact upon the quality, safety or efficacy of the products manufactured, for example registered personnel changes, premises alterations, change of site.

For ManSA, ASCCA and NFABBA holders, there are two types of variation - administrative and scientific.

Administrative variations do not require assessment by an inspector. Examples include:

- change of company name/trading name
- change of owner
- change of site address (administrative rather than site location, for example postcode change)
- removal of a PRR (providing that there is more than one)
- removal of a named site
- removal of a product type

Scientific variations require assessment by an inspector and may also require an inspection. Examples include:

- addition of a new manufacturing activity
- addition of categories of products handled at the site
- addition of new site
- change of site location
- change or addition of a PRR

- Application form to vary a ManSA (ODT, 94.5 KB)
- Application form to vary an ASCCA (ODT, 40.9 KB)
- Application form to vary an NFABBA (ODT, 40.9 KB)

Voluntary variations to an AVA

AVA variation applications are split into three categories with different fees for each. Examples of the types of AVA variation application that fall under each classification include, but are not limited to, the following:

- Complex variations, these are considered to be significant changes to manufacturing processes, such as introduction of new or changes to existing antigens or adjuvants
- Simple variations, these are considered to be minor changes to manufacturing processes/procedures, such as changes to personnel/PRR or containers
- Administrative variations, these are considered to be changes to the administrative aspects of your authorisation such as name/address of holder (where the legal entity remains the same).

Applicants are encouraged to contact VMD to discuss AVA variation classification in instances where this is not clear.

Complete and submit your application to vary your AVA via our Veterinary Medicines Digital Service

Compulsory variation, suspension and revocation

We may compulsory vary, suspend or revoke your specific manufacturing authorisation if:

- you have not complied with the VMR
- you have manufactured a type of veterinary medicine which is not authorised by your specific manufacturing authorisation
- your premises or equipment is no longer suitable
- your registered PRR is not fulfilling their duties

- you have not carried out the activity specified in your authorisation for 5 years or more

- you have not paid a required fee.

In all cases, we will notify you of the reason for varying, suspending or revoking your authorisation and how you can appeal the decision.

Inspections

Pre-authorisation inspection

Before issuing a specific manufacturing authorisation, we will normally carry out a pre-authorisation inspection of your site, and any site(s) where quality control testing or other activity is contracted to a third party unless that site has already been inspected by us or the MHRA.

Scheduled inspection

We will periodically inspect your site(s) to ensure that you're complying with the VMR.

Inspectors are authorised under the VMR to:

- inspect the site, organisational arrangements and procedures used in the storage and distribution of veterinary medicines
- interview key personnel named on the authorisation
- take samples
- have access to, and inspect and copy or seize any documentation or records (in whatever form they are held) relating to the manufacture, assembly, storage and distribution of veterinary medicines

We conduct inspections on a risk basis, taking into account the products manufactured and the compliance findings of the previous inspection, although inspections will normally take place at least every 3 years.

We will agree with you an inspection date and share the main areas that will be covered during the inspection to help you prepare.

After the inspection, we will send you an inspection deficiency report within 30 days. You should respond to any deficiencies cited within 30 days of receiving it.

Once we are satisfied with your response, we will issue a final GMP inspection report and a GMP certificate within 90 days following the end of the inspection.

Deficiencies

Deficiencies are categorised as other, major and critical

Other Deficiencies:

These are:

- unlikely to pose a potential risk to human or animal health, or the environment
- does not indicate a significant deviation from the requirements of the VMR, Codes of Practice or Guidance
- cannot be classified as either critical or major because there is insufficient information to classify it as such

Major Deficiencies:

These are:

- non-critical but has produced, or has the potential to produce, a possible risk to human or animal health or the environment
- a major deviation from the requirements of the VMR
- a failure to carry out satisfactory procedures to ensure that products are manufactured, stored or distributed in accordance with their specific requirements
- a combination of a number of related other deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such

- other deficiencies that have been brought to the attention of the business on previous occasions but have not been resolved

Critical Deficiencies:

These are:

- deficiencies that have produced, or have the potential to produce, a significant risk to human or animal health, or the environment
- a significant deviation from the requirements of the VMR through serious negligence or intent.

Inspections are scheduled at intervals based on the number and type of deficiencies noted during an inspection, as follows:

- sites with no critical or major deficiencies are rated Good and given a next inspection interval of 33 months
- sites with no critical deficiencies and less than 6 major deficiencies are rated Acceptable and given a next inspection interval of 24 months
- sites with at least one critical deficiency or 6 or more major deficiencies are rated Poor and given a next inspection interval of 12 months.

We may inspect sites in countries outside of the UK that we do not have a Mutual Recognition Agreement (MRA) with.

Fees

Fees are payable for:

- processing an application for a new specific manufacturing authorisation
- a pre-authorisation inspection of each site and subsequent risk-based inspections

- an annual fee
- processing a variation application for a specific manufacturing authorisation.

Fees are not refundable or transferable.

There are separate fees for GB Fees and NI Fees

Registers

Your details will be published in the relevant register:

- Register of Veterinary-Only manufacturers of extemporaneous preparations for use under the cascade (ManSA)
- Register of Specific Manufacturing Authorisation Holders (NFABBA, ASCCA, AVA)

Contact Us

You can email us at: inspections@vmd.gov.uk.