Detailed guide: Apply for a Manufacturing authorisation for veterinary medicines

Updated: Updated register of specials manufacturing sites

Manufacturers are required to comply with the principles of Good Manufacturing Practice (GMP) where appropriate in relation to the following types of authorisation:

- manufacturing authorisation (ManA)
- manufacturing extemporaneous products (Specials) authorisation (ManSA)
- autogenous vaccine authorisation (AVA-I/S)
- non food animal blood banks authorisation (NFABBA)
- equine stem cell centre authorisation (ESCCA)
- exemptions for small pet animals (Schedule 6)

Guidance

For information about the requirements for veterinary only manufacturers.

Applications forms

- Application form for manufacturers authorisation
  (MS Word Document, 96.1KB)
- Application form for variation to manufacturers authorisation
  (MS Word Document, 101KB)
- Application form for manufacturers special authorisation
  (MS Word Document, 90.8KB)

- Application form for
  variation to manufacturers special authorisation
  (MS Word Document, 86KB)

- Application form for, or variation to
  schedule 6 manufacturer
  (MS Word Document, 68.7KB)

An application for a ManA or ManSA should be accompanied by a Site Master File.

To help process your application more efficiently you should provide, in addition to paper copies, an electronic copy of the application or any parts of it. These should be in MS Word if possible, although other formats are acceptable.

You must submit your application to the Veterinary Medicines Directorate (VMD).

Timelines

The VMD will validate your application within 10 days of receipt although this time will be extended if the VMD has to ask you for further information.

After validation we will carry out the pre-approval inspection within 90 days.

Fees

The VMD charges a fee for:

- a manufacturers authorisation
- a manufacturers authorisation variation
- the initial inspection of each site
- duplicate or multiple GMP Certificates
- on-going annual and inspection fees

The application and annual fees are not refundable or transferable.

Application refusal and appeals

We may refuse to grant an authorisation or may grant an authorisation that is different than that applied for. In such cases we will notify you.

Manufacturers of human and veterinary products

Where a site handles both human and veterinary medicines you should also refer to guidance published by the Medicines and Healthcare products Regulatory Agency (MHRA).

Any queries should be directed to the Regulatory Information Service on 020 3080 7400 or via their website.

Contact

You can contact the Inspections administration team by email at inspections@vmd.defra.gsi.gov.uk.or by phone on 01932 338426 or 338328.

EudraGMDP

Details of authorised manufacturing sites (ManA holders) and Good Manufacturing Practice (GMP) Certificates can be accessed by searching the European database, EudraGMDP. See
guide to using the EudraGMDP
(PDF, 87.4KB, 2 pages)

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Registers

Approved Specific Manufacturing Authorisations – AVAS

Approved Specific Manufacturing Authorisations – Non-Food Animal Blood Banks, and Equine Stem Cell Centre Authorisations

Authorised specials manufacturing sites
(PDF, 130KB, 3 pages)

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Guidance: Vaccination of dogs

Updated: Vaccines table updated

The Veterinary Medicines Directorate's (VMD) position on the authorised vaccination schedule for dogs has been published to help you make an informed decision on the vaccination schedule for your dog.

The table of vaccines lists vaccine products which have been authorised by the VMD.

Vets will use vaccination schedules that are based on the authorised summary of product characteristics (SPC).

However a vet may make the decision to use either a shorter or longer revaccination schedule based on the age, health, or vaccination history of the animal. This is considered to be off-label use of the product and the vet takes responsibility for the decision.

It is recommended that the course of action is agreed with the animal owner.

Guidance: IsItWaste tool: for advice on the by-products and end of waste tests

Updated: We've updated information on how to use our Definition of Waste Service to get an opinion on whether your waste derived material can be classed as non-waste.

Use the user guide to:

- access the IsItWaste tool
- do a self assessment to help you decide whether your material is likely to be waste
- ask the Environment Agency Definition of Waste Service for an opinion

The IsItWaste tool is for England only. It's based on English and Welsh case law. Northern Ireland and Wales may have similar tools.

Collection: Forestry Commission statistical release announcements

Updated: Quarterly update.

Forestry Commission statistical release announcements.

Guidance: Statutory market values for oil

Updated: The daily values for all Category 1 crude oils for September 2018 have been added.

If you're a participator in a UK oil field, you must use these defined market value rates if you dispose of:

- crude oil
- liquefied petroleum gases (LPGs)
- condensate

Each taxable crude blend has a separate market value. There's 2 types of crude oil for valuation purposes.

Do not use these rates for arm's length sales.

Category 1 oil

These are the crude oils valued using Price Reporting Agency data.

The crudes for category 1 are:

- Brent
- Ekofisk
- Flotta
- Forties
- Statfjord

This publication shows category 1 values from 2015 to 2018. Earlier years are on the
National Archives website.

Category 2 oil

All other blends (including LPGs and condensates) are classed as category 2.

Category 2 oils are valued using deal data supplied to the Large Business (LB) Oil and Gas Sector in Petroleum Revenue Tax Returns.

The valuation methods used are similar to the way each particular blend is sold at arm's length, and are agreed with industry.