

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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