Guidance

Apply to register as a manufacturer, importer or distributor of active substances for veterinary medicines

Register as a manufacturer, importer or distributor of active substances for use in veterinary medicines.

You must be registered with us if you are located in Great Britain (GB) and you manufacture, import or distribute an active substance for use in a veterinary medicine.

Active Substances

In this guidance, an “active substance” means any substance or mixture of substances intended to be used in the manufacture of veterinary medicine, that, when used in its production, is responsible for the activity of that veterinary medicine.

Manufacture, importation or distribution of an active substance

If you manufacture, import or distribute an active substance for use in a veterinary medicine, you must be registered with us and the details of all sites where your activities take place must be listed in the Register of Manufacturers, Importers and Distributors of Active Substances for Veterinary Use.

In relation to these requirements, you must register as

- a manufacturer, if you manufacture an active substance to use in a veterinary medicine that you manufacture yourself, or to supply to an authorised veterinary medicines manufacturer or a registered distributor
- an importer, if you bring an active substance into GB from another country for use in a veterinary medicine that you

manufacture yourself, or to supply to an authorised veterinary medicines' manufacturer or a registered distributor
- a distributor if you supply a third party's active substance to an authorised veterinary medicines manufacturer or another registered distributor.

As a registered manufacturer of active substances, you may supply your own products to an authorised veterinary medicines manufacturer or registered active substance distributor without being additionally registered as a distributor. However, you do require additional registration as an importer or distributor (as applicable) if you deal in a third party's products.

You must register with us if you manufacture, import or distribute an active substance, even if you hold an authorisation to manufacture or wholesale veterinary medicines; or you are registered as a veterinary practice or pharmacy.

Manufacturers of active substances that are located outside GB do not need to register with us. However, the finished product manufacturer of the relevant veterinary medicine is responsible for audit of these sites in line with GMP requirements.

Registration procedure

You must apply for registration at least two months before commencing an activity by sending us your completed registration form (existing manufacturers, importers and distributors of active substances must register with the VMD within two months of the amended VMR coming into force).

To register, complete and submit the registration form to us by email: inspections@vmd.gov.uk.

Duties on registered manufacturers, importers or distributors

Good manufacturing or distribution practice

As a registered manufacturer, importer or distributor of active substances you must comply with good manufacturing practice (GMP) or good distribution practice (GDP), as applicable.

For GMP see Eudralex Volume 4, Part II.

For GDP see the site, storage, transport and record-keeping requirements for veterinary medicines wholesale dealers

To ensure traceability, you should make and retain appropriate records of your activities in relation to active substances, that meet the requirements of GMP or GDP.

Inspection of sites

We may, from time to time, inspect your registered site basing the frequency of the inspection on the risks associated with the site's history and the nature of the substances handled at the site.

We may also inspect your site as a follow up to a GMP inspection of a finished product manufacturer that uses an active substance manufactured or handled at your site, or in the event of a quality defect or recall involving a finished product where a potential cause may be due to the manufacture or handling of the active substance.

If you hold an authorisation issued by us (or you are registered with the RCVS as a veterinary practice premises) and you are also registered to manufacture, import or distribute an active substance, we may include active substances in the scope of any inspection we conduct in relation to your authorisation (or registration).

If you are authorised to manufacture active substances, for example for active substances used in veterinary vaccines and other biological veterinary medicines, existing requirements for scheduled GMP inspection will continue to apply.

If you manufacture active substances, you may voluntarily request an inspection for the purpose of formal GMP certification of your site. In this event we will try to accommodate your request. We may also

inspect your site in response to a formal request to do so by an MRA partner.

If we do inspect your site, we will provide you with a written report stating whether you are complying with the requirements of GMP or GDP.

Supply of information

You must immediately inform us if you receive or become aware of any new information that might adversely affect the safety or quality of any active substance that you manufacture, import or distribute.

This includes any prohibition or restriction in relation to the substance imposed by the competent authority of another country in which the active substance is used.

Otherwise you should notify us on an annual basis of any changes that have taken place as regards the information provided in your registration form.

Fees

There is no fee for registering as a manufacturer, distributor or importer of an active substance.

For voluntary inspections of active substance manufacturers and those requested by an MRA partner in accordance with the terms of an MRA, a fee will apply. This will normally be the same as for a non-sterile finished product manufacturing site of the same size but will be clarified in advance of the inspection. No fees will be charged for other inspections related to manufacturers, importers or distributors of active substances.

Register

Your details will be published in the register of Manufacturers, Importers and Distributors of Active Substances for Veterinary Use

Contact Us

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