

# Changes to exemptions from the Veterinary Medicines Regulations (VMR) for small pet animals

The VMD has made some changes to how you apply, to include:

- a new active substance in a medicine for a small pet animal that is exempt from the VMR under Schedule 6 (that is a medicine that does not have to be authorised)
- a new route of administration or target species for an active substance that is already approved

and how we assess the application.

Certain changes will be effective immediately and will apply to all applications for new active substances.

## **Applications**

The following must now be provided when you apply to include a new active substance, or a new route of administration or target species for an active substance that is already approved in a Schedule 6 product.

You must list the Chemical Abstracts Number (CAS) number, where one is available, on your application form. This is the unique numeric identifier designating only one substance. This can be found on the safety data sheet for the chemical/active substance.

You must send your application form to the following email address:  
[pet.exemptions@vmd.gov.uk](mailto:pet.exemptions@vmd.gov.uk).

The guidance on [Exemption from authorisation for medicines for small pet animals](#) includes the application form and the list of approved active ingredients.

## **Assessment of active substance**

The VMD considers the potential risk to the user and the environment when we assess applications. This risk assessment will now be applied to applications under the exemption scheme. As a result, warnings or restrictions may be included on the product package in addition to the current label requirements.

You do not need to provide any additional information when you apply unless we have specifically asked you to.

These changes should not cause any delays in dealing with applications.

## **Consolidated list of active substances**

We now publish a consolidated list of approved active substances, including CAS number to ensure accurate and transparent identification of the substances. Duplicate substances under different names are now listed together with one CAS number.

These changes should not have an impact on existing products marketed under Schedule 6. However, if you think they do, you should contact the VMD as soon as possible at [pet.exemptions@vmd.gov.uk](mailto:pet.exemptions@vmd.gov.uk).

## **Consultation on possible future changes to the exemptions to the VMR for medicines for small pet animals**

The VMD will be proposing further changes which will affect all products covered by the Schedule 6 exemption. These will include introducing a requirement for the VMD to be notified about all Schedule 6 products marketed in the UK.

The proposal will be open to public consultation in Autumn 2020. If, following consultation, we introduce a requirement for the VMD to be notified about all Schedule 6 products marketed in the UK, there will be a transition period before notification becomes mandatory, during which companies can notify us of products on a voluntary basis.

For further information and to be included on our mailing list for updates about the scheme, email [pet.exemptions@vmd.gov.uk](mailto:pet.exemptions@vmd.gov.uk).