VMD EXPORT CERTIFICATE SCHEME: Guidance for Exporters of Veterinary Medicinal Products (VMPs)

The VMD has recently implemented changes to its Export Certificate Scheme.

We recognise the importance of helping to facilitate international free trade and make every attempt to help you with your needs. We also continue to show due diligence regarding the certificates we issue and the assurances that these certificates provide to the authorities of importing countries. The changes to the scheme are intended to ensure both these objectives are met. We have also taken the opportunity to remove some administrative burdens.

Content of Certificates

The VMD is only able to confirm details on certificates that it knows to be true; therefore, we can only approve export certificate schedules that contain details found in the UK Manufacturing Authorisation (ManA) and / or Marketing Authorisation (MA) for the veterinary medicine(s) concerned.

The VMD is content that the information provided on its certificates and the certificate schedule are clear and transparent; stating the authorised activities of the manufacturing sites named and the authorisation status of the named exported products. However, we recognise that the authorities of the importing countries have strict rules on the paperwork they must receive from the importer and that this could include information that we cannot verify. Therefore, we have made changes to the scheme by permitting you to submit additional pages as part of Defra-1, Defra-2 and Defra-4 applications, which can be attached to an export certificate. However, the VMD won't approve documentation that is false, misleading or unsubstantiated including;

- false details about the status of the exported product, i.e. that the product is licenced, regulated or registered in the UK when it is not
- Contradictory information between documents such as the Export Certificate, Export Certificate Schedule, Summary of Product Characteristics, Product Literature, Manufacturing Authorisation or Marketing Authorisation;

In all cases, the additional pages must include the following wording in a box at the foot of each page. The VMD will sign and date this upon issue.

Wording for Defra-1 and Defra-4 certificate applications:

The VMD stamp and signature on this page confirms the site is GMP compliant and holds a Manufacturing Authorisation, but it does not independently verify any of the other information contained on this page. The Qualified Person at the site named on page one is responsible for the veracity and validity of the other information on this document.

Signed:

Name: Miss Sam Ward

Date :<*same as certificate*>

Wording for Defra-2 certificate applications:

The VMD stamp and signature on this page confirms the veterinary medicine named on page two holds a Marketing Authorisation in the same name, but it does not independently verify any of the other information contained on this page.

Signed:

Name: Miss Sam Ward

Date: <*as per certificate*>

Removal of administrative burdens

The requirement to provide Indemnity Letters and to provide an annual updated list of the personnel at each company authorised to apply for Export Certificates has been removed.

We would like to remind you to contact us BEFORE you start shipping the VMP from the UK to discuss your needs should the importing authorities request something outside of the usual scope of the Export Scheme.

Timescales

The VMD has introduced a new target of 10 working days to either issue the export documentation to you, or inform you of why a certificate will not be issued.

All applications are subject to validation, which is a check to ensure that all documentation has been provided and properly filled in. If any information is missing, you will be asked to resubmit a new application. You will not be charged for the invalid application. If the application is incomplete for minor reasons, the VMD will contact you and try to resolve the outstanding issues within the 10 day timeframe rather than asking you to resubmit.

The following are examples of reasons why applications are considered invalid.

- Not using the correct templates.
- Not using an up to date version of the SPC and /or product literature
- Not using an up to date version of the Manufacturing Authorisation

- Not providing the schedule on company headed paper

Further information and guidance

The online Export Certificates system and Veterinary Medicines Guidance Note (VMGN) No.19 will be updated to reflect these changes. An updated VMGN should be available on the VMD website in December 2014:

http://www.vmd.defra.gov.uk/pdf/vmgn/VMGNote19.pdf

https://www.vmd.defra.gov.uk/EC/Login.aspx?ReturnUrl=%2fec

For further information, please email exportcert@vmd.defra.gsi.gov.uk