DRAFT VETERINARY MEDICINES REGULATIONS 2013 CONSULTATION RESPONSE FORM

The closing date for this consultation is: 18 February 2012

You may find it helpful to set out your responses to the Consultation using this form.

<table>
<thead>
<tr>
<th>Name</th>
<th>Rachael Gledhill</th>
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<tbody>
<tr>
<td>Organisation (if applicable)</td>
<td>British Veterinary Association</td>
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| Address               | 7 Mansfield Street  
                          | London  
                          | W1G 9NQ |
| Please return completed forms to: | Lorna Shelley  
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Please tick one box from the following list of options that best describes you.

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<th>Small to Medium Enterprise</th>
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1 Proposal: Amendment to the provisions relating to importation and possession of unauthorised veterinary medicines which will allow enforcement action to be taken where necessary.

Do you support this clarification of the legislation? Will this change aid businesses’ with compliance?

Comments

We support this proposal.

2 Proposal: Amendment to Regulation 35 (2) to permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine.

Do you support this change to the legislation? Will this change aid businesses’ with compliance?

Comments

We support this proposal.

3 Proposal: Introduction of a clause within Schedule 3 to allow the removal of a veterinary practice premise from the register if the practice is not up to the standards.

Do you support this change to the legislation?

Comments

We support this change and encourage a joined-up approach with the RCVS Practice Standards Scheme.
4 Proposal: Clarification of fees for applications for Marketing Authorisations relating to biological products.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

Increasing fees for bio-similars may have the effect of reducing availability of generic vaccines. BVA supports measures to increase medicines availability.

5 Proposal: Introduction of a fee for the renewal of a registration of a homeopathic remedy.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

We support this proposal.

6 Proposal: Amendment of category descriptions for extensions to Marketing Authorisations to align them with EU legislation.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect? Does this change bring more clarity to the fee structure for extending Marketing Authorisations?

Comments

No comment.

7 Proposal: Simplification of the fees for appeals to the Veterinary Products Committee.
How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

**Comments**

We support this proposal.

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**8 Proposal**: Removal of the fee for additional member States on application for a Marketing Authorisation relating to a Parallel Import.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

**Comments**

We support this proposal which we hope will increase medicines availability.

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**9 Proposal**: Reduction to fees for Decentralised applications for Marketing Authorisations where the UK is Concerned member State or for recognition of a product authorised in another member State.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

**Comments**

We support this proposal which we hope will increase medicines availability.

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**10 Proposal**: Rebalancing of fees for manufacturers and wholesale dealers.
How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

No comment

11 Proposal: Increase to the charge for inspections of veterinary practice premises to achieve full cost recovery for this work.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

A 40% increase in inspection fees is a considerable rise when businesses can ill afford increased costs. It is likely that an increase in costs would result in vets increasing their prices, although this would be difficult in some sectors, such as the pig sector, where competition is fierce.

A flat fee will always favour larger practices that can absorb or recover the costs. We believe that a graded fee would be preferable, potentially based on medicines turnover.

12 Proposal: Changes to fee structure for inspections of Manufacturers and Distributors of Feedingstuffs and Suitably Qualified Persons Premises.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

No comment
13 Proposal: Increase for the application and subsequent annual fee for fees relating to manufacturers and distributors of feedingstuffs in Northern Ireland.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

No comment

14 Proposal: Reduction to the fees applied by the Royal College of Veterinary Surgeons for the registration veterinary practice premises.

How will this change to the legislation affect your business, either directly or indirectly? What costs or benefits would it present? Or will it have no effect?

Comments

Given the size of the increase in inspection fees, a reduction in the fees applied by the RCVS for the registration of veterinary practice premises will have little impact.

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Comments

There are a number of clauses which no longer make sense as they have been amended. These are para 32(2) on page 14, and para 34(6) on page 15.

In relation to para 48(r) on page 39 we suggest that the requirement to include disposal advice on packaging could be removed. The information given for most products is misleading, and waste disposal channels are under constant review, so any disposal information on the packaging or indeed the package leaflet, could well be out of date and thus lead to the user inadvertently breaking the law.

In relation to para 7(6) on page 73, clarification should be given as to whether ‘1kg of veterinary medicinal product’ refers to 1kg of the product as manufactured, or 1kg of active ingredient.
Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below:

Please acknowledge this reply  ☒

Here at the Veterinary Medicines Directorate we carry out our research on many different topics and consultations. As your views are valuable to us, can we contact you again from time to time either for research or to send through consultation documents?

☒  Yes   ☐  No