Q&A – Medicated Feedingstuffs

Introduction

We have provided responses to questions received to further aid consideration of the proposals for the review of the Veterinary Medicines Regulations 2013 (VMR).

We may have paraphrased or consolidated similar questions from the focus sessions held in early March to make the document easier to navigate. If your question has not been answered, email vmr@vmd.gov.uk.

Please submit comments on the proposed changes as part of your official consultation response using citizen space. It is helpful to include details about any impacts these changes may incur in your response, for example costs and savings, environmental impacts, social impacts or any other impacts.

You can also include comments on the implementation of these changes in your response, for example your views on what guidance would be needed or how long it would take you to put any changes into practice.

If you have any specific questions on the proposed changes, email vmr@vmd.gov.uk.

You can also find more information about the consultation and supporting documents on gov.uk and VMD Connect

The Q&As from the other sessions are available on VMD Connect and GOV.UK.

Contents

Introduction 1
Definitions 2
Prescription 2
Antibiotics 3
Impacts 4
Tolerance, Cross-contamination and Disposal 4

Definitions

Q) Is a medicated feedingstuff considered as expired under the VMR if the medicine has expired or if any of the ingredients have expired?

A feedingstuff will be considered as expired if any of the material contained in it has expired.

Q) Why are veterinary medicines now been referred to as a ‘premix’?

The rationale for this change was to reflect the naming of veterinary medicines for incorporation into feedingstuffs. All authorised medicines that can be incorporated into a medicated feed have “premix” in the name.

Q) What is meant by diagnosed disease? Where a disease is syndromic and multifactorial, what would be considered sufficient?

This means the disease that the prescription has been written to treat or prevent.

The intention is to capture in writing the reason for using the veterinary medicine to ensure they are being used appropriately and responsibly. It will be the vet’s responsibility to determine if their diagnosis is sufficient for the use of the veterinary medicine.

Prescription

Q) Will the VMD provide examples of new medicated feedingstuffs prescriptions, including prescriptions for medicated feedingstuffs used under the cascade?

We will provide new guidance and amending existing guidance to provide advice on complying with the proposed changes as part of the implementation.

This will include guidance for medicated feedingstuffs prescriptions and may include templates.

Please provide any comments on the implementation of these changes in your response.

Q) Will there be the ability to write repeat prescriptions for medicated feedingstuffs?

No, repeat prescriptions for medicated feedingstuffs are not allowed under the VMR.

Q) Why does a prescription need to include a statement that the premix should not be reused?

This is a drafting error and should say the “prescription should not be reused”. This will be amended in the final version of the legislation.

Antibiotics

Q) Will the proposed changes prevent vets from prescribing antibiotics under the cascade?

A vet will still be able to prescribe products for use in medicated feedingstuffs under the cascade, including for antibiotics, provided this complies with other provisions in the VMR. This includes the duties when prescribing antibiotics set out in paragraph 7A in Schedule 3 and the requirement for the product to be authorised for incorporation into feedingstuffs in accordance with Schedule 5, paragraph 20(3).

Q) Will the validity of a medicated feedingstuffs prescription of 5 days be 5 working days?

Q) When does the validity of a prescription start, is it in hours or days?

Q) Will this result in farms having to have separate feed deliveries where vets write multiple prescriptions?

We appreciate the complexity of the supply chain for medicated feedingstuffs. The intention is to ensure antibiotics prescribed to treat infections in animals are administered within an effective and appropriate timeframe.

A medicated feedingstuffs prescription's period of validity would begin on the date issued by a vet and would be measured in days.

We are seeking information from industry in their consultation feedback on how this measure can be implemented in a practical way.

Q) Is it possible for a vet to prescribe more than one antibiotic to be incorporated into a single feed where there are different pathogens and disease challenges that cannot be treated by a single antibiotic?

No, the proposal only allows for one such product to be administered at one time. If you are aware of a situation that would require more than one to be administered at one time, please include this as part of your consultation response.

Q) Will the restrictions on use of antibiotics in medicated feedingstuffs be the same as those on veterinary medicines in Schedule 3?

Yes, the restrictions in Schedule 3 paragraph 7A on prophylactic use of antibiotics apply to medicated feedingstuffs.

Q) How will the 2-week duration of treatment for antibiotics without specific wording in the SPC be implemented alongside the 5-day validity for prescriptions?

The prescription validity will mean that the medicated feedingstuffs must be supplied within the 5-day period.

The duration of treatment should be 2-weeks from the point at which the product is first administered.

Impacts

Q) Have the costs for training new staff and implementing the changes being considered in the impact assessments?

Impacts, including costs and savings, of the proposed changes have been included in the Impact Assessment where these are known. Where the exact costs are not known we have provided a qualitative analysis.

If you are aware of additional impacts or can provide more data on the costs and savings the proposed changes may have, please include them in your consultation response.

Tolerance, Cross-contamination and Disposal

Q) Will there be any mechanism to allow tolerance results that are over ±30% where this is due to variable recovery rates for veterinary medicines?

No, this isn't part of the proposed changes. We considered this when we decided on the proposed levels and it was one of the reasons we have diverged from EU Regulation 2019/4, to allow for some variation to recovery rates for the medicine.

Please provide feedback on the proposed tolerance table as part of your consultation response.

Q) Will there be guidance available on the testing frequency expected for sampling for cross-contamination and root-cause analysis?

We will provide new guidance and amending existing guidance to provide advice on complying with the proposed changes.

Please provide any comments on the implementation of these changes in your response.

Q) Will disposal requirements result in more waste going to hazardous waste? Will there be more options for mills to be able to reduce, reuse and recycle waste?

The rationale for these changes is to ensure that where there is excess medicated feedingstuffs on farms, due to unforeseen circumstances, the feed is disposed of responsibly to reduce risk of AMR in animals and the environment.

If you are aware of additional impacts or can provide more data on the costs and savings the proposed changes may have, please include them in your consultation response.