Response ID ANON-FCE5-76G3-A

Submitted to Review of the Veterinary Medicines Regulations 2013
Submitted on 2023-03-21 12:59:46

About you

1 Would you like your response to be confidential?

No

If you answered Yes to this question, please give your reason.:

2 Who are you responding as? (Select one option only)

Campaign group/NGO – In an official capacity as the representative of a non-governmental organisation / trade union / other organisation

Other (please specify)::

3 Which of the following best describes the role or field you belong to? (If you have multiple roles, please select the one which best represents your interests in this consultation response) (select one option only)

Not Answered

Other, please state::
Campaigner for more responsible antibiotic use in farming

4 What is the name of your organisation?

Organisation:
Alliance to Save Our Antibiotics

5 Please select where you/your organisation is based (select all that apply):

England

Executive summary

Introduction

Chapter 1 - General (regulations)

6 Do you agree with the proposal for the VMD to be able to require information on request?

Strongly agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Record keeping for vets and food-producing animal owners/keepers

7 Do you agree with this approach to the “as soon as reasonably practical” issuing of records by vets?

Strongly agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Advertising

8 Do you support this approach to advertising of veterinary medicines?

Agree

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes to update the advertising requirements.:

Powers of an inspector

9 Do you agree with this approach to the changes in inspectors’ powers?

Strongly agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects, and your views on the introduction of an offence.:

Batch testing and batch release

Chapter 1 summary questions

10 If all changes to the regulations were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?

If all changes to Regulations were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?:

11 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

Chapter 2 – Marketing authorisations in GB

12 Do you agree with the proposed changes to the requirements for the summary of product characteristics and data requirements for a marketing authorisation application?

Agree

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed change with regard to paragraph 2.3.:

The Alliance strongly supports the proposal for a requirement to supply information on the direct or indirect risks to public or animal health or to the environment arising from use of the antimicrobial product in animals.

Although not covered by the terms of reference of this consulation, we also believe that this requirement should be extended to coccidiostat feed additives, including the ionophore antibiotics.

Bibliographic applications

Generic / generic hybrid products

13 Do you agree with this approach to generic / generic hybrid products?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Marketing authorisation for parallel import

14 Do you agree with the proposed removal of the option to have marketing authorisations for parallel import?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Parallel assessment of application for maximum residue limit and MA

15 Do you agree with the proposal of assessing applications for MAs and MRLs at the same time?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Data protection periods

16 Do you agree with the proposal for amending the current data protection periods?

Not Answered

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.:

Parallel assessment with other regulators

17 Do you agree with the proposal for introducing flexibility into the assessment timeline?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

MAH location

18 Do you agree with the proposal for a UK-based local representative instead of the requirement for the MAH to be established in the UK?

Agree

Please provide additional information, including any positive or negative impacts on you / your business / wider aspects.:

The granting of an MA

Withdrawal of an MA application

19 Do you agree with this approach for publishing assessment reports?

Agree

Please provide additional information, especially if you have any concerns around this proposal.:

Ther Alliance strongly supports Schedule 1 Paragraph 22(4) which gives the option for the Secretary of State to require, in relation to medicines containing antimicrobials, MAHs to conduct post-authorisation studies to ensure that the benefit-risk balance remains positive.

Refusal of an MA

Samples

Information on shortages

20 Do you agree with this approach for making mandatory that to MAHs report supply shortages to the Secretary of State?

Strongly agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Renewal of marketing authorisations

21 Do you agree with the proposed changes for renewing MAs?

Strongly disagree

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.:

When a new antimicrobial product is placed on the market, evidence may appear that the use of the product in animals is contributing to resistance in human infections. This evidence may go against earlier claims that resistance would not appear in bacteria from animals or would not result in resistance in human infections (as for example had been incorrectly suggested by some before fluoroquinolones were licensed for use in poultry in the 1990s).

If there is no automatic review of the safety of the use of the product in animals, then use is likely to continue even if it is harmful to human health. The Alliance realises that Schedule 1 Paragraph 22(4) would enable the Secretary of State to require the Marketing Authorisation Holder "to conduct post authorisation studies in order to ensure that the benefit-risk balance remains positive in relation to the development of antimicrobial resistance", however there is no guarantee that the SoS would require these studies to be carried out. Therefore removing an automatic 5-year review of the risk-benefit balance could compromise safety.

Variations

22 Do you agree with the proposed changes for variations to MAs?

Not Answered

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.:

Grounds for suspension of MA, prohibiting supply and temporary restrictions

23 Do you agree with this approach to suspension and revocation of MAs, prohibiting supply or restricting (immunological) medicines?

Agree

Please provide additional information, especially on the impacts on you / your business / wider aspects from these proposed changes.:

Labelling and package leaflets

24 Do you agree with this approach to the labelling and package leaflet?

Agree

Please provide additional information, especially on the impact (especially costs and savings) on you / your business / wider aspects of the proposed changes. We are specifically seeking information on the following: potential savings for joint labelling, printing costs, redesigning (for example of artwork) costs, costs of disposal of out-of-date packaging material, risks associated with reduction of information on labelling, and the balance of this information being available through QR codes etc, and increasing availability of minor use and minor species medicines.:

Electronic package information leaflet

25 Do you agree with allowing electronic package information leaflets?

Neutral

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Pharmacovigilance (post-authorisation monitoring)

26 Do you agree with this approach for pharmacovigilance?

Disagree

Please provide additional information, especially on the impact (especially costs and savings) on you / your business / wider aspects of the proposed changes for streamlined reporting, the PSMF and the required actions in response to adverse events. :

If there is a serious human or animal adverse reaction to a medicine, there does not seem to be any good reason for extending the period of time for this to be reported to the Secretary of State from 15 days to 30 days. Sending an email about a serious adverse reaction should not take this amount of time. We do not support extending this time period from 15 days to 30 days, particularly since the legislation also clearly says that if all the relevant information is not available at the time of the initial report that it can be sent later.

Registered homeopathic remedies

27 Do you agree with this approach for homeopathic remedies?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Chapter 2 summary questions

28 If all changes to Schedule 1 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?

f all changes to Schedule 1 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?:

29 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

30 We will make transitional arrangements to cover applications already being processed for a marketing authorisation (either a new MA or a variation) or registration of a veterinary homeopathic remedy, changes in labelling and packaging requirements, and other new requirements, as appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

We will make transitional arrangements to cover applications already being processed for a (variation of a) marketing authorisation or registration of a veterinary homeopathic remedy, changes in labelling and packaging requirements, and other new requirements, as appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.:

Chapter 3 – Manufacture

31 Do you agree with this approach for manufacturing authorisations?

Agree

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.:

Consistent approach for specific manufacturing authorisations

32 Do you agree with this consistent approach for specific manufacturing authorisations?

Agree

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.:

Active substances

33 Do you agree with this approach for regulatory oversight of active substances?

Agree

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes, and views on the proposed offence.:

Manufacturers of products for administration under the cascade

34 Do you agree with this approach for products manufactured under the cascade?

Not Answered

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change, including views on the proposed offence.:

Stem cell centres

35 Do you support this approach to stem cell centres?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Chapter 3 summary questions

36 If all changes to Schedule 2 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?

If all changes to Schedule 2 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?:

37 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

38 We will make transitional arrangements to cover applications already being processed for a (variation of a) manufacturing authorisation and other new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

We will make transitional arrangements to cover applications already being processed for a (variation of a) manufacturing authorisation and other new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.:

Chapter 4 – Classification and supply, wholesale dealers and sheep dip

39 Do you agree with the proposed additions to the POM-V classification?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

We strongly support antibiotics being classified as POM-V.

Requirements for wholesale dealers

40 Do you agree with the proposed changes for wholesale dealers?

Agree

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes, especially with regard to reporting suspected counterfeit or falsified medicines or supply shortages, and your views on the offences.:

Wholesale dealers' audits and record-keeping

41 Do you agree with the requirement for wholesale dealers to investigate stock discrepancies and keep records for five years?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Wholesale dealing by MAHs

42 Do you agree with the proposal for a MAHs to hold a WDA to wholesale products (including products for which they are the MAH)?

Agree

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.:

Special Import Scheme

Distribution for promotional purposes

43 Do you agree with this approach for medicines distributed for promotional purposes?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects, including views on the proposed offence.:

We strongly agree that the distribution of medicines containing antimicrobials for promotional purposes should not be permitted.

Registration of online retailers

44 Do you agree with requirement for online retailers to register?

Strongly agree

Please provide additional information, including views on the proposed offences, and the impacts on you / your business / wider aspects from this proposed change.:

Retailer supply

45 Do you agree with this approach to audits, record-keeping and storage by retailers?

Strongly agree

Please provide additional information, including views on the proposed offences, and the impacts on you / your business / wider aspects from this proposed change.:

Assessment by vet before prescribing POM-V

46 Do you agree with this approach to the assessment made of an animal/animals by the vet before the vet prescribes a POM-V medicine?

Neutral

Please provide additional information, including any concerns raised by the proposed changes and impacts on you / your business / wider aspects from this proposed change.:

We do not object to allowing vets to prescribe remotely, so long as the animals are properly under the vets care and a proper clinical examination or other appropriate assessment has been made.

However, such remote prescribing should never be permitted for group prophylaxis with antibiotics. The Alliance believes that all group prophylaxis with

antibiotics should be prohibited, but if the government decides to allow such irresponsible antibiotic use to continue, at a very minimum the remote prescribing of group prophylactic treatments with antibiotics should not be permitted.

Prescriptions

47 Do you agree with the changes to the requirements for prescribing medicines?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Wholesale supply of premix by feed business operators

Products supplied under the cascade

48 Do you agree with this approach to products prescribed and supplied under the cascade?

Strongly agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Remote supply by SQPs

49 Do you agree with this approach to remote supplying by SQPs?

Not Answered

Please provide additional information, especially on the impacts on you / your business from this proposed change.:

SQP registration bodies

Sheep dip

Chapter 4 summary questions

50 If all changes to Schedule 3 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?

If all changes to Schedule 3 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?:

51 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

52 We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.:

Chapter 5 – Administration under the cascade

Cascade prescribing for food-producing animals

Appropriate use of the cascade

53 Do you agree with this approach to ensuring appropriate use of the cascade?

Neutral

Please provide additional information, especially on the impact this may have on you, your business and wider aspects, including views on the proposed offence.:

The Alliance believes that, for food-producing animals, the use of the cascade should be exceptional because of the increased risk to human health. This should be made clear in
Schedule 4 Paragraph 1 (2) which should begin:
"If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in

particular to avoid unacceptable suffering, exceptionally treat the animal concerned with the following ("the cascade"), cascaded in the following order [...]"

The exclusion of the word "exceptionally" in this Paragraph is one reason why completely inappropriate routine uses of the cascade can occur in food-producing animals in the UK.

In the EU, the corresponding article of Regulation 2019/6 makes clear that use of the cascade should be exceptional.

Withdrawal periods

54 Do you agree with this approach to the statutory minimum withdrawal periods?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Chapter 5 summary questions

55 If all changes to Schedule 4 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?

If all changes to Schedule 4 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?:

56 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

Chapter 6 – Medicated feed

Definitions

Prescription for medicated feed

57 Do you agree with the approach to prescriptions for medicated feed?

Not Answered

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.:

Labelling

58 Do you agree with this approach to labelling?

Agree

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.:

Storage and disposal of medicated feed

59 Do you agree with this approach to storage and disposal of medicated feed?

Strongly agree

Please provide additional information, including views on the proposed offence and the impacts on you / your business / wider aspects from the proposed changes.:

Cross-contamination and carryover

60 Do you agree with this approach to cross-contamination and carryover?

Disagree

Please provide additional information, including views on the proposed offence and the impacts on you / your business / wider aspects from the proposed changes.:

Paragraph 22A in Schedule 5 does not prohibit a feed company from continuing to produce a feed with significant cross-contamination with antibiotics in it, from continuing to produce that feed. As long as the company carries out an investigation for high levels of cross contamination, and records the results, they may continue to produce feed contaminated with antibiotics.

It is well known that low-levels of antibiotics in animal feed can select for antibiotic resistance, since the Minimum Selective Concentration for many antibiotics is far below the Minimum Inhibitory Concentration. Allowing feed companies to continue to produce feed contaminated with antibiotics at these levels may therefore contribute to the selection of antibiotic resistance.

Tolerance table

61 Do you agree with this change to the tolerance table?

Not Answered

Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.:

Chapter 6 summary questions

62 If all changes to Schedule 5 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?

If all changes to Schedule 5 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business?:

63 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

64 We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.:

Chapter 7 – Exemptions for small pet animals

Registration and supply of information

65 Do you agree with our approach to register companies that market products under the exemption for small pet animals and require them to provide information annually?

Not Answered

Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.:

Reporting of adverse events by retailers

66 Do you agree with our approach to remove the requirement for retailers to record and report adverse events for products sold under the exemption for small pet animals?

Not Answered

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Chapter 7 summary questions

67 If all changes to Schedule 6 were made, as set out in this chapter, what would be the impact on your business?

If all changes to Schedule 6 were made, as set out in this chapter, what would be the impact on your business?:

68 What would be the consequences if we did not make these changes?

What would be the consequences if we did not make these changes?:

69 We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.:

Chapter 8 – Antimicrobial resistance

Antibiotic usage data

70 Do you agree with the collection of species or sector specific antibiotic use data remaining a voluntary initiative but that the Secretary of State can request such data if insufficient progress is made, and that it would be an offence to fail to comply which such request?

Strongly disagree

Please provide additional information, especially on the impact (for example costs and savings) on you / your sector if usage data collection were made mandatory, including your views on the introduction of an offence.:

The Alliance recognises the positive contribution that voluntary industry antibiotic-use data collection has made towards achieving a better understanding of farm antibiotic use, and ultimately achieving reductions in use.

However, the Alliance is strongly in favour of a statutory system of antibiotic-use data collection as it would lead to greater understanding of current UK farm antibiotic use and contribute to greater reductions in use.

Statutory data collection is superior to voluntary industry-led data collection for a number of reasons:
- statutory data collection is simpler and much faster to set up. Within a short period of time, full coverage of all major farm-animal species would be established under a statutory system. This is what occurred in the Netherlands a decade ago when they set up their statutory system. In contrast, despite the successes in the UK, the UK voluntary system only has about 90% coverage of the UK poultry industry, 95% of the pig industry, and does not cover most of the beef, dairy or sheep sectors.
- statutory antibiotic-use data collection by animal species allows for easier, and more complete, benchmarking of farms and veterinary practices, as occurs in the Netherlands. This has led to faster and larger reductions in farm antibiotic use in the Netherlands compared with the UK. Antibiotic use per pig in Denmark and the Netherlands, where statutory antibiotic-use data collection has existed for years, is less than half of the level in the UK pig industry.
- statutory antibiotic-use data collection allows for the setting of accurate targets by sector, as occurs in countries like the Netherlands and Denmark. The UK farming industry has attempted to set targets, but the lack of data in some sectors limits the ability to set meaningful targets (particularly for beef, dairy and sheep).
- statutory antibiotic-use data collection makes it much easier for sectors, such as the organic sector, which wish to obtain information on their own antibiotic use to do so. Current voluntary systems are not currently set up to do this and obtaining comprehensive data for organic farmers for all major animal species is likely to take many years of efforts.
- setting up a statutory antibiotic-use data collection system would make it far easier for companies buying and selling animal foods, such as supermarkets or catering companies, to obtain antibiotic-usage data from their suppliers. This would enable these companies to more accurately set their own antibiotic targets and monitor usage in their supply chain. Action by supermarkets has already contributed to more responsible use, and the wider availability of antibiotic-usage data would improve supermarket policies and enable catering companies, which often are unable to collect antibiotic-usage data, to do so.
- antibiotic-use data collected on a statutory basis is publicly owned and can therefore be examined a lot more easily by scientists are others interested in how use varies by farming system or by husbandry method (farm-level data is of course anonymised). In Denmark, statutory data collection has enabled comparison of antibiotic use by farming system to be made and published in the peer-reviewed scientific literature (https://pubmed.ncbi.nlm.nih.gov/33556801/) and in the Netherlands statutory data collection enables the authorities to easily compare antibiotic use in fast-growing broilers with slower-growing broilers (https://cdn.i-pulse.nl/autoriteitdiergeneesmiddelen/userfiles/sda%20jaarrapporten%20ab-gebruik/ab-rapport-2021/uk-appendix-sda-report-usage-of-antibiotics-i). In contrast, voluntary industry systems are ultimately privately owned and while some data is published a lot of the data remains privately owned.

Continuing to rely on voluntary data collection will mean that, unlike the EU which is beginning statutory data collection for pigs, poultry and cattle this year, the UK will continue to struggle to obtain comprehensive data for years to come. While the UK currently has better data on its antibiotic use than many EU countries, this will likely soon no longer be the case because of the government's refusal to back statutory antibiotic-use data collection.

The Alliance supports the regulation (new regulation 24A in the VMR) which allows the Secretary of State to require vets, manufacturers, marketing authorisation holders or wholesale dealers to provide information in relation to sales and use of antibiotics, but believes this should be put into practice immediately instead of waiting to see if voluntary data collection delivers.

Prophylactic use

71 Do you agree with our proposals to restrict prophylactic use?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects, including views on the proposed offence.:

The Alliance strongly supports the proposals to:
- ban routine farm antibiotic use (Schedule 3 Paragraph 6(1)(B)(a))
- ban using antibiotics " to compensate for poor hygiene, inadequate animal husbandry, or poor farm management practices" (Schedule 3 Paragraph

6(1)(B)(b))
- restrict prophylactic antibiotic use to "exceptional circumstances where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the product are likely to be severe" (Schedule 3 Paragraph 7A(2)).

However, the Alliance believes that there should be a full, blanket ban on group prophylactic use with antibiotics, as is the case in the EU since January 2022.

Several European countries have had such a ban for many years (Sweden, Norway, Iceland, , Denmark, Finland, Netherlands) and this has not led to significant animal-welfare problems. In fact, in October 2015 the Nordic farming unions wrote to their governments calling on them to agree such a ban with the EU
(https://www.bondelaget.no/getfile.php/13714520-1445601556/MMA/Dokumenter/15-00773-1%20Brev%20til%20nordiske%20ministere%20om%20profylaktisk%2
which indicates that Nordic farmers do not think such a ban has had a negative effect on their animals' health and welfare.

Allowing prophylactic group treatments to continue will mean that certain farms, which currently use antibiotics routinely, are likely to continue to do so because of a lack of clarity in the legislation. Although the legislation says that group treatments should not be routine or predictable, it also says that purely prophylactic group treatments are legal.

Schedule 3 Paragraph 7(4) says that, if antibiotics are used for a prophylactic group treatment, a management review must be carried out. However, no information is given about who should carry out the management review, whether it needs to be submitted for assessment or not, nor who would assess the review. It is therefore unclear how such a review process can be expected to reliably lead to future group prophylactic use being avoided.

A further weakness in the proposed approach is that there are no specific proposals for limiting metaphylactic group treatments with antibiotics.

Whereas EU Regulation 2019/6, which came into force in the EU on 28 January 2022, aims to ensure that prophylaxis and metaphylaxis represent "a smaller proportion of the total use of antimicrobials in animals", the UK proposals aim only to dramatically reduce group prophylaxis. The UK should be trying to ensure that group treatments only represent a small percentage of total farm antibiotic use.

Responsible farm antibiotc use tends to be targeted rather than blanket. In countries like Sweden, Norway and Iceland, which have the lowest levels of antibiotic use in Europe, individual antibiotic treatments account for 90% or more of farm antibiotic use, whereas in the UK group treatments account for about 75% of use.

There is therefore a need to drastically reduce all group treatments with antibiotics (although we acknowledge that for poultry virtually all use will have to be group treatments). Therefore there need to be specific restrictions on metaphylactic use, so that metaphylactic use does not simply replace reduced prophylactic group treatments.

The Alliance believes that new wording needs to be included to restrict metaphylactic antibiotic use. Metaphylactic antibiotic use should only be permitted if:
- the use of the product is not routine or predictable
- when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available.

While ionophore coccidiostats are not currently classified as Veterinary Medicinal Products, growing scientifc evidence suggests that the use of ionophores can co-select for resistance to medically important antibiotics (Pikkemaat et al. 2022 https://edepot.wur.nl/565488, Naemi et al. 2020 https://pubmed.ncbi.nlm.nih.gov/32117133/, Simm et al. 2019 https://pubmed.ncbi.nlm.nih.gov/31830083/).

Dutch scientists, who have found significant evidence of ionophore co-selection for resistance to medically important antibiotics in enterococci have said "Abandoning of prophylactic use of ionophores will be inevitable" (Pikkemaat et al. 2022). It is therefore imperative that the VMD review the current routine prophylactic use of ionophores in much of the poultry industry. Ionophores should be re-classified as prescription-only medicines, as recommended by the Federation of Veterinarians of Europe
(https://fve.org/cms/wp-content/uploads/FVE-position-paper-on-coccidiostats-or-anticoccidials.pdf).

Finally, the Alliance believes that the increased restrictions on farm antibiotic use in the UK need to also ultimately apply to imported animal foods. From a human-health point of view, since antibiotic resistance can spread through the food chain, it makes no scientific sense to focus only on UK production, particularly since antibiotic use per livestock unity in many other countries is often higher than it is in the UK. Furthermore, focusing only on UK production puts UK farmers at an unfair competitive disadvantage.

The Alliance believes that there should be an immediate ban on the importation of animal foods produced with antibiotic growth promoters. The EU will be implementing such a ban in coming years.

Furthermore, restrictions on all forms of routine farm antibiotic use, including routine prophylactic use, should be phased in for imported produce.

In-feed antibiotics

72 Do you agree with this approach to medicated feed containing antibiotics?

Agree

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.:

Our comments, in reply to the previous question, about the need to end all prophylactic antibiotic group treatments and the need to include specific restrictions on metaphylactic antibiotic treatments are also applicable for in-feed antibiotics.

Chapter 9 – Fees

73 It would help us to improve this assessment if you are able to provide detailed information on the impact (including positive and negative) of these proposed changes to the fees on you / your business / wider aspects.

It would help us to improve this assessment if you are able to provide detailed information on the impact (including positive and negative) of these proposed changes to the fees on you / your business / wider aspects.:

74 Please provide information as to how the proposed changes to fees will impact you / your business (including familiarisation costs).

Please provide information as to how the proposed changes to fees will impact you / your business (including familiarisation costs).:

Annex A - Consultation questions

Annex B – Main areas impacting each business area

Annex C – Assessment of the matters set out in Section 10 of the Medicines and Medical Devices Act 2021

Annex D – Proposed changes to fees