Review of the Veterinary Medicines Regulations-PVS response

We have tried to pull out the most relevant questions for PVS. However, please feel free to review the entire document and supporting papers that can be found on the VMD website Veterinary Medicines Regulations Consultation (vmdconnect.uk). VMD held a number of Q&A sessions – responses are in the process of being uploaded to their website. They cover each of the chapters in the consultation.

How to review this document

VMD text *is in the text in italics and is blue in colour*
Questions from the consultation **are in bold and black**
PVS responses are in normal text. Where we are asking for input, text is highlighted

We welcome your views on the proposed changes, as to whether they will achieve the intended objectives. We also seek information on the time and cost of familiarising your business with the new requirements, and the impact of the proposed changes on you, your business and wider aspects (such as social or environmental impacts). We are looking for the positive and negative impacts, as well as direct and indirect costs. We will use the information received to update and improve the pre-consultation impact assessment that is provided with the consultation.

For PVS members, we have indicated where examples would be particularly useful. Please send any examples and costs to Mandy Nevel, secretary@pigvetsoc.org.uk

Annex A – Consultation questions

About you

1. Would you like your response to be confidential? No

2. Who are you responding as? An organisation, Pig Veterinary Society, a specialist division of the BVA

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). Other: membership group of pig veterinary surgeons

4. What is the name of your organisation? Pig Veterinary Society

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

    - Northern Ireland
    - England
    - Scotland
    - Wales

Pig Veterinary Society (PVS) is a scientific organisation and a specialist division of the BVA. Our members comprise practicing vets as well as those from industry, government and pharmaceutical companies. We also have associate members (non-veterinary) largely from nutrition and pharmaceutical industries. We have discussed widely on the consultation with our members and would like to make some general comments as well as answering the specific questions in the consultation.

Chapter 1 – General

Providing information upon request

1.4 *The VMD is responsible for ensuring that safe and effective medicines of high quality are available in the UK. To fulfil our regulatory obligations, we currently have powers to request specific information from certain businesses, for example information on the benefit-risk balance of a product from marketing authorisation holders or information from wholesale dealers.*

1.5 We propose to extend the requirement to provide the Secretary of State with information upon request to all businesses or persons regulated by the VMR. We would provide a justification for our request and ensure that any requests for information are reasonable.

Do you agree with the proposal for the VMD to be able to require information on request? *(1.4-5)*
PVS agrees in principle with changes that help achieve responsible antibiotic use. This proposal may future proof regulations, but it is an open door to request more information and whether requests are categorised as reasonable will depend on the workload required to answer these. As these requests are not yet specified and no timeline indicated, it is impossible to assess impact. The limit of what is reasonable – PVS suggests the minimum legal requirement- and the justification of the requests, as well as an agreed appeals procedure would need to be put in place.

Do we have any costs?

1.6 *We want to ensure that a food-producing animal owner or keeper receives in a timely manner relevant information about the medicine administered to their animal by the vet, including the withdrawal period. This information helps ensure that food-producing animals do not enter the food chain until after the medicine's withdrawal period has passed, which will help ensure food safety. Currently, the legislation does not state when a vet must provide this information to the animal owner or keeper. We therefore propose that a vet who personally administers a medicine to a food-producing animal should provide records to the animal owner or keeper "as soon as reasonably practical" (regulation 18 in the VMR).*

Do you agree with this approach for the "as soon as reasonably practical" issuing of records by vets? *(1.6)*
Strongly agree. Pig vets will do this already and there is a duty to make sure administered drugs go in the meds record. Does this more precise wording than timely

Advertising

1.7 *Advertising of veterinary medicines has changed and progressed since 2013, with more publication platforms and media available than previously. The VMD's enforcement officers regularly deal with usually unintended breaches of the VMR related to advertising. We want to ensure compliance with the VMR.*

1.8 We therefore propose changes which are part of a suite of changes that we are introducing to improve the system of prescription and supply. We propose to adjust the regulations on advertising to make explicit what is allowed and required in terms of the advertising of a veterinary medicine (regulation 10 in the VMR). Specific changes include a requirement that the advertisement makes clear that the message is an advertisement for the purpose of promoting the supply, sale, prescription, distribution or use of the veterinary medicine, intermediate feedingstuff or compound feedingstuff.

1.9 We propose to make explicit that a medicine may only be advertised if it has a marketing authorisation, which is not suspended. This change would not apply to medicines marketed in accordance with Schedule 6 to the VMR (exemptions for small pet animals).

1.10 We also propose to introduce a regulation setting out the conditions for inducements and hospitality in relation to veterinary medicines (new regulation 10A).

1.11 We believe that there are specific training and knowledge requirements for prescribing and using veterinary medicines. Advertising medicines to people who cannot properly assess the risks associated with the use of the medicine may lead to misuse or abuse of medicines. This in turn may lead to risks to the animal, the people treating the animal and / or to the environment. This is why we restrict the advertising of prescription- only medicines to certain audiences.

1.12 With regard to POM-V medicines advertising targeted at professional keepers of animals, we propose to only allow this for immunological medicines (regulation 11) as the use of immunological products can help reduce disease and may contribute to a reduction in the use of antibiotics in farm animals. An advert for a POM-V immunological product aimed at professional keepers of animals must state that the professional keeper of animals will need to consult a vet before using the medicine. Companies would continue to be able to advertise POM-V medicines specifically targeted to vets, veterinary nurses and pharmacists.

Do you agree with the proposed approach to advertising of veterinary medicines? *(1.7-12)*
[Note: VMD have clarified that they already have guidelines on advertising, many of which will still apply.] Neutral. Please explain “inexpensive” and “animal health professionals”. Provision 10A needs to be clearer on what constitutes a financial inducement. It is not clear if this is this going to affect practice meds training and CPD sponsorship. The new wording in the VMR includes terms such as premix to mean those with antibiotics. Premix is a commonly used term in the feed industry for vitamins and minerals. Using premix to denote antibiotics would therefore be confusing and could lead to inadvertent inclusion of incorrect products in feeds. We recommend that VMD discuss with the feed industry to achieve a workable alternative (see section on in feed medication).

PVS supports responsible use of immunological products. PVS supports having a single veterinary surgeon/practice overseeing all medicine use, including immunologicals. PVS is aware that this is not the case in other sectors. Can we put in costs? Note: see Q&A responses on VMD website.

Do you agree with this approach to the changes in inspectors’ powers, including the introduction of an offence? *(1.13 – 14)*
Strongly agree. However, PVS is concerned that removal of products from market could be swift and without notice and ask for reassurance that this would not happen.

Batch testing and batch release

1.15 Veterinary medicines that are to be placed on the market must be batch tested and certified by a

Qualified Person before they can be released to the market. Since EU Exit, we have adopted a transitional approach to the batch testing and release of imported products. We intend to launch a separate consultation which will set out our proposals for batch testing and batch release of products to be marketed in Great Britain. We intend to make changes on batch testing and release at the same time as the other changes to the VMR.

This needs to be carefully co-ordinated to avoid unintended consequences of misaligning the documents. PVS seeks reassurance that further consultation will not delay or interrupt supply of medicines.

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? What would be the consequences if we did not make these changes? Can you provide examples and can we put in costs?

Chapter 2 – Marketing Authorisations

Do you agree with the proposed changes to the requirements for the summary of product characteristics and data requirements for a marketing authorisation application? *(2.2-6)*

Neutral. These requirements need to be visionary to take into account alternatives to antibiotics e.g. phages and antimicrobial peptides which may not need the same requirements. Innovation should be encouraged, not stifled.

Do you agree with this approach to generic/generic hybrid products? *(2.9-11)*

Agree in principle but concerns regarding reduced availability of medicines when products have supply issues. PVS is concerned that this may add cost to generic products. Reducing regulatory burden without compromising safety or adding to the cost of production is important.

Do you agree with the proposed removal of the option have marketing authorisations for parallel import? *(2.12-13)*

Neutral. If outages occur there must not be a delay in obtaining product or animal welfare will be compromised. Disagree. PVS is concerned that there may be difficulties in sourcing alternatives when there are supply chain issues. SIC can add to unacceptable delay in treating animals and therefore could raise welfare issue.

This may have impact on the pharmaceutical companies' ability to source product from other countries.

Do you agree with the proposal of assessing applications for MAs and MRLs at the same time?*(2.14-15)*

Strongly Agree. This will save time during the licensing process.

Do you agree with the proposal for amending the current data protection periods? *(2.16)*

Neutral. PVS supports changes that encourage innovation. However, this may increase the burden when marketing a product for other species. This may inhibit manufacturers applying for an MA thereby having a disproportionate impact on minor species.

Do you agree with the proposal for introducing flexibility into the assessment timeline? *(2.17)*

Strongly agree

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? *(2.18)*

Neutral

Do you agree with this approach for publishing assessment reports? *(2.20-21)*

Neutral

Do you agree with this approach on making it mandatory for MAHs to report supply shortages to the Secretary of State? *(2.25)*

Agree/Strongly agree. This will facilitate planning.

Do you agree with the proposed changes for renewing MAs? *(2.26)*

Agree

Do you agree with the proposed changes for variations to MAs?*(2.27-31)*

Neutral

Do you agree with this approach to suspension and revocation of MAs prohibiting supply or restricting

(immunological) medicines? *(2.32-35)*
Agree, but on the understanding that political pressure will not be allowed to result in suspend use/supply.
Do you agree with this approach to the labelling and package leaflet? *(2.36-39)*
Agree as long as the requirements do not exceed those of EU regs as will this increase costs and so reduce range of products.

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.*

Please provide any costs/comments

Electronic package information leaflet

2.40 We propose allowing an electronic package information leaflet (EPIL) to be provided, where appropriate, as an alternative to a physical package leaflet (Schedule 1 paragraph 51(5-6) in the VMR). There must be clear reference to the EPIL on the packaging and the necessary links. We would require that an MAH must be able to provide the physical package leaflet where necessary.

Please provide additional information, especially on the impact this may have on you, your business and wider aspects.
Do you agree with allowing electronic package information leaflets?
Strongly agree
Please provide any costs/comments

Do you agree with this approach to pharmacovigilance? *(2.41-44)*
Agree
Do you agree with this approach for homeopathic remedies? *(2.45-48)*
Strongly Disagree PVS believes that Homeopathic remedies are basically a confidence trick and should be subject to the same regulations as other veterinary medicinal products.

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

We will make transitional arrangements to cover applications already being processed for (variation of) a marketing authorisation or registration or registration of a veterinary homeopathic remedy, changes in labelling or 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.
Please provide any costs/comments

Chapter 3 – Manufacture

Do you agree with this approach for manufacturing authorisations? *(3.3-5)*
Neutral
Do you agree with this approach for specific manufacturing authorisations? *(3.6-3.8)*
Agree but we have concerns about cost and extemporaneous products
Do you agree with this approach for regulatory oversight of active substances? *(3.9-10)*
Agree
Do you agree with this approach for products manufactured under the cascade? *(3.11-13)*
Agree [VMD have clarified that 3.13 relates to commercial companies and not to vets]

~~Disagree. Extemporaneous products are often made by vets so meds with MAs can be more easily given to sick animals and this can be on an individual or farm basis. Is this actually what they mean? If so we need examples that will be affected.~~
Do you agree with this approach to stem cell centres? *(3.14)*
This is not within PVS remit

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? What would be the consequences if we did not make these changes?
We will make transitional arrangements to cover applications already being processed for a (variation of) a manufacturing authorisation 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.
Please provide any costs/comments

Chapter 4 – Classification and Supply

4.2 There are four categories of authorised veterinary medicines:
- *Prescription-only medicines to be prescribed by a vet (POM-V).*
- *Prescription-only medicines to be prescribed by a vet, pharmacist or SQP (POM- VPS).*
- *Medicines for non-food animals (NFA) that do not require a prescription but still need to be supplied by either a vet, pharmacist or SQP (NFA-VPS).*
- *Authorised veterinary medicines that are available on the general sales list (AVM- GSL).*

4.3 We propose to adjust the requirements so that the categories of medicines that must be classified as POM-V include medicines that contain antibiotics or beta-agonists, or that are used for euthanasia, or that are immunological or hormonal (Schedule 3 paragraph 1 in the VMR). Immunological products currently classified as POM-VPS would remain POM-VPS, subject to established procedures and regulation (for example assessment by the Veterinary Product Committee).

Do you agree with the proposed additions to the POM-V classification? *(4.2-3)*
Strongly agree. We would support anthelmintics being made POM-V in line with antibiotics. Resistance to anthelmintics is an extremely significant welfare risk to many food producing animals.
However, we are slightly concerned that having some vaccines as POM-V and others as POM-VPS will result in farmers opting of the POM-VPS in cases where they are easier to buy (geographically). This could result in inappropriate vaccine use. PVS supports responsible antibiotic, vaccine and anthelmintic use and strongly agrees that all these products should be POM-V.

Do you agree with the proposed changes for wholesale dealers, including the proposed offences? *(4.4-6)*
Strongly agree.

Do you agree with the requirement for wholesale dealers to investigate stock discrepancies and keep records for five years? *(4.7-8)*
Strongly agree
Do you agree with the proposal for an MAH to hold a WDA to wholesale products (including products for which they are the MAH)? *(4.9)*
TBA.
Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.
Please provide comments

Special Import Scheme

4.10 We want to reduce barriers for a vet to obtain medicines under the special import scheme (regulation 25 in the VMR). Therefore, we propose to amend the regulation to clarify that a pharmacist does not need a wholesale dealer's authorisation to supply an unauthorised veterinary medicine imported under the scheme to a vet provided the vet holds the appropriate special import certificate.
Please provide comments Note, there is no question or agree/disagree with 4.10.

Do you agree with this approach for medicines distributed for promotional purposes? *(4.11)*
Strongly agree.
Do you agree with the requirement for online retailers to register?*(4.12-13)*
Strongly agree.
Do you agree with this approach to audits, record-keeping and storage by retailers? *(4.14-5)*
Strongly agree

Assessment by vet before prescribing POM-V

4.16 We want to reduce burden on vets, in particular those in remote areas, whilst supporting responsible, safe and effective prescribing. One way to achieve this may be to enable vets to prescribe medicines remotely and more efficiently without reducing the oversight required for responsible and safe prescribing.

4.17 We therefore propose to amend the requirements for prescriptions by a vet to allow vets the option of performing a "clinical examination or other proper assessment" of an animal or group of animals under their care when prescribing POM-V medicines (Schedule 3 paragraph 4 in the VMR). The current requirement is for the vet to carry out a 'clinical assessment'. Note that the Royal College of Veterinary Surgeons provides an interpretation of the term 'clinical assessment'.

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?
PVS is seeking views on this question. We could request further clarity from RCVS on the term 'under our care'. However, the VMR is the legislation (not guidance) and therefore should be the appropriate place for clarity. There may be merit in looking at the BVA vet-client relationship guidance to inform. For food producing animals, the herd plan should be at the heart of 'under our care' that all vets prescribing for that have should adhere to. We have asked for clarification of this and awaiting a response.

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

Do you agree with the changes to the requirements for prescribing medicines?*(4.18-19)*
Strongly agree. This is currently normal practice. However, with regard to retaining records for 5 years, it should be noted that prescribers (vets/SQPs) may not stay within that employment for 5 years so the requirement should be the employer.
Do you agree with this approach to products prescribed and supplied under the cascade? *(4.21)*
Strongly agree

4.22 The current VMR places disproportionate regulatory burden on SQPs when supplying veterinary medicines in comparison to vets or pharmacists, as it does not allow the remote supply of products by the SQP. We propose to amend the VMR in relation to the supply of POM-VPS and NFA-VPS medicines by SQPs to be consistent with the requirements for vets and pharmacists. The proposed change would mean that an SQP who has correctly prescribed / advised on a product and who has authorised its supply in advance, does not necessarily have to be physically present when the product is selected and / or handed over to the customer. They can delegate that process to a competent person (Schedule 3 paragraph 14).
Do you agree with this approach to remote supplying by SQPs? *(4.22)*
PVS to add response -comments please

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? What would be the consequences if we did not make these changes? comments please Need costs please. also if we have to add in strength and formulation to labels and prescriptions please indicate if you will we need to change PMS?

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

Chapter 5 – The Cascade

5.3 We propose a suite of changes to improve the system of prescription and supply, which includes assurance that vets make responsible prescribing decisions under the cascade. Medicines prescribed under the cascade carry a higher risk than authorised medicines used within the terms of their marketing authorisation. In the case of food- producing animals there is the additional risk to human health through the food chain. We believe that the requirement in the VMR needs to be adjusted to further reduce the risk of inappropriate or unsafe medicines being used in food-producing species under the cascade.

5.4 The current requirement is that pharmacologically active substances included in medicines administered to food-producing animals need to be substances for which a maximum residue limit is established. We propose to expand this requirement to all substances in that medicine to have an established maximum residue limit or to be included on the out-of-scope list (Schedule 4 paragraph 1 in the VMR).

Appropriate use of the cascade

5.5 We are aware that some vets are being encouraged to use the cascade inappropriately (for example, when UK-authorised medicines for that species and condition are available). We propose to introduce a new offence of encouraging or facilitating the illegal use of the cascade (new paragraph 9A in Schedule 4 to the VMR).

5.6 We also propose to explicitly state that an autogenous vaccine should only be used in exceptional circumstances and when there is no authorised immunological veterinary medicine for the target species, in accordance with the cascade (new paragraph 6A).

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

Disagree with 5.6. Autogenous vaccines are an important tool to help reduce antibiotic use. Autogenous vaccines may be used when there is an authorised product available but where strain differences occur. For example, there are licenced vaccines for APP, Strep suisi and so on, but on some farms, the strains vary so the vaccine does not provide cover. We are also aware that some marketed vaccines show poor efficacy on some farms and an autogenous vaccine may be preferable. Where there is concurrent disease, MAs will not permit the use of vaccines together and again, an autogenous vaccine may be preferable. PVS recommends the wording is changed to say 'and when there is no authorized immunological veterinary medicine covering the appropriate strains, evidence of non-efficcy or combination of pathogens'

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

Do you agree with this approach to the statutory minimum withdrawal periods? *(5.7)*
Agree
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? What would be the consequences if we did not make these changes?
Please provide comment/examples Loss of the ability to tailor autogenous vaccines to the specific strain of a pathogen on a particular farm will likely result in increased antibiotic use. This would have animal welfare and cost implications.

Chapter 6 – Medicated Feedingstuffs

Definitions

6.2 We want to ensure a clear and consistent understanding of the VMR which is shared by stakeholders and the regulator. Therefore, we propose to introduce additional definitions in Schedule 5, such as for batch, complementary / complete / compound feed and intermediate feedingstuffs (Schedule 5 paragraph 1 in the VMR). We also propose to refer specifically to premix as the veterinary medicine incorporated into feed and replace the confusing term 'premixture' with 'intermediate feedingstuff' throughout the schedule.

Do you agree with this approach to prescriptions for medicated feed? *(6.3-4)*
Disagree. The change from VMP to premix will cause confusion at the mill as use this term for vitamin mixtures. Do we have a preferred term VMD should use instead of 'premixture'? Diagnosis needs to allow syndromes and not be prescriptive. [note: there is a typo and it should refer to repeat prescription not repeat premix]
Do you agree with this approach to labelling? *(6.5)*
Agree. Note the comment above about terminology of premix.
Storage and disposal of medicated feed

6.6 There are currently no requirements under the VMR to provide adequate assurances that medicated feed is being used safely and responsibly by keepers of animals. There is a risk to animal health, public health and the environment if medicated feed is not responsibly used, stored and disposed of, especially in the case of medicated feed containing antibiotics.

6.7 We propose to require keepers of animals to store any product regulated by Schedule 5 in accordance with the summary of product characteristics. They should also ensure that there is no contamination of products, feed material and environment (Schedule 5 paragraph 26 in the VMR). Products should be administered only to the correct animal and the withdrawal period should be complied with.

6.8 We need to ensure unused, expired and waste feed is disposed of correctly and responsibly, particularly when it contains antimicrobials. We propose to introduce a new requirement for feed business operators and professional keepers of animals to have a collection and disposal system in place for expired or unused medicated feed (new paragraph 26A).

6.9 We also propose to state explicitly that medicated feed that has passed its expiry date may not be fed to an animal (new paragraph 26A). We propose to introduce an offence for failure to comply with this requirement

Do you agree with this approach to storage and disposal of medicated feed? *(6.6-9)*
Agree in principle – please comment and give specifics if this is an issue.

Do you agree with this approach to cross-contamination and carryover? *(6.10-11)*
Agree
Do you agree with this change to the tolerance table? *(6.12)*
Agree
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? What would be the consequences if we did not make these changes?
We will make transitional arrangements for new requirement, 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.
please comment The above questions ignore both 5 day length of script, various issues with length of treatment feed going to several batches of pigs for short periods after weaning and the use of only one product at a time. We need clinical examples to argue our case.

Chapter 7 – Exemptions for Small Pet Animals

PVS is not answering this section specifically, except to say that we support a level playing field.

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?
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?
If all changes to Schedule 6 were made, as set out in this chapter, would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make the changes?
We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or any other measures which might help address problems if the new requirement s would be applied immediately upon the revised VMR coming into force.

Chapter 8 – Antimicrobial Resistance

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 with such a request? *(8.2-4)*

Agree. The pig sector records antibiotic use in 95% of slaughter pigs. We have reduced use by approximately 70% since 2015. This was done voluntarily. We support the other sectors being able to demonstrate responsible use voluntarily. Please comment. Is there any desire to make recording compulsory in the pig sector e.g. to force those not recording to do so?

Prophylactic use

8.5 Prophylaxis is defined as "the administration of a medicinal product to an animal or group of animals before clinical signs of a disease in order to prevent the occurrence of disease or infection". We do not support routine preventative use (prophylaxis) of antibiotics in animals or poor farming practices which rely on routine or predictable antibiotic use to be viable. Our proposal constitutes a significant increase in restriction and scrutiny of all antibiotic prophylaxis, in particular where it is used in groups of animals, with a view to dramatically reducing it. We are therefore proposing that use of antibiotics for prophylaxis is only allowed in exceptional circumstances, where the risk of an infection or an infectious disease is very high and the consequences are likely to be severe (new paragraph 7A in Schedule 3 to the VMR). We propose to introduce an offence for failure to comply with this requirement. When considering groups of animals, we are additionally proposing that prophylaxis would only be allowed if the use is not routine or predictable, the rationale is clearly recorded by the prescribing veterinary surgeon and a management review carried out as soon as reasonably practicable which identifies factors and implements measures to help control the infection of infectious disease, with the aim of eliminating the future or recurring need to administer antibiotics prophylactically to groups of animals. We would monitor the effectiveness of these measures through antimicrobial consumption and resistance surveillance programmes, and through continued engagement with stakeholders. A similar provision is introduced for prescribing medicated feed containing antibiotics (Schedule 5 paragraph 19).

8.6 We are not proposing a full, blanket ban on group prophylactic use as, if there is an infection or infectious disease on the farm, making improvements to farm infrastructure and management practices to reduce or eliminate this can take time. Banning group prophylaxis while these changes are being implemented could be harmful to animal welfare (as you would need to wait until some animals become clinically ill before treating) and increase the risk of the disease spreading (which would subsequently require higher antibiotic use and thus increase the risk of AMR developing). We believe it is better to take a stepwise approach that helps the UK farming industry, with the support of the veterinary

profession, continue to make sustainable changes towards reducing prophylactic use to groups of animals.

Do you agree with our proposals to restrict prophylactic use? *(8.5-6)*

[note: we are awaiting clarification on 'exceptional circumstances' but VMD have indicated it should be absolutely exceptional]. Please give examples of prophylactic use e.g. depops

In-feed antibiotics

8.7 In-feed antibiotics can be a convenient way of administering antibiotics but currently account for a third of antibiotics prescribed to food-producing animals. Furthermore, animals should be treated within a relevant time-frame, for the treatment to be effective.

8.8 We propose including the following restrictions relating to medicated feed containing antibiotics (Schedule 5 paragraph 19):

- *the duration of treatment must comply with the SPC. If it is not specified in the SPC, the duration of treatment must be less than two weeks.*
- *the prescription would be valid from the date it is issued for a maximum period of five days.*
- *a vet may not prescribe medicated feed with more than one antibiotic premix.*
- *a vet may not prescribe medicated feed containing antibiotics for prophylactic purposes, but the exceptions set out in paragraph 8.5 apply here too.*

Do you agree with this approach to medicated feed containing antibiotics? *(8.7-8)*
Disagree. The first point removes the ability of the vet to prescribe in feed under the cascade.
We recommend changing the 5 day limit to 5 working days. Production and delivery of medicated feed e.g. to remote farms and over a weekend is difficult to complete in 5 days. We acknowledge the intent to treat animals as soon as possible after the decision to use antibiotics is made. However, animals would not be left untreated in the interim period even if this resulted in a mass injection plan. Please give clarity on the time interval start (prescription feed leaves mill?) There will be increased bureaucracy with the increased need for prescriptions each week.
There are a significant number of times when two antibiotics are needed to be included in the feed. Anecdotal evidence in EU suggest that vets are having to 'get around' this by providing one in feed and another, often not the ideal one, in water. This is an unintended consequence we should avoid as it results in irresponsible antibiotic use.

Note in the Q&A on VMD there is this response:
Medicated Feedingstuffs Q) Will the validity of a medicated feedingstuffs prescription of 5 days be 5 working 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. We are seeking information from industry in their consultation feedback on how this measure can be implemented in a practical way which upholds the intention, to ensure antibiotics prescribed to treat infections in animals are administered withing an effective and appropriate timeframe. 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? The aim of including this in the consultation is to avoid antibiotic use that is not targeted towards a specific pathogen. However, if there are specific situations where you think there is a need to add two veterinary medicines for in-feed use at the same time due to concurrent pathogens/ disease challenges, then please provide specific examples as part of the consultation. Please provide examples

Chapter 9 – Fees

Please provide information as to how the proposed changes to fees will impact you/your business (including familiarisation costs).
Please provide any estimates of costs of any of the changes outlined. Specific examples are particularly welcome.
PVS is concerned that fees for autogenous vaccines and inspections of those manufacturing them are going to rise substantially also for meds produced under the cascade.