

Review of the Veterinary Medicines Regulations

Who we are

BVA is the national representative body for the veterinary profession in the United Kingdom and has over 19,000 members. Our primary aim is to represent, support and champion the interests of the veterinary profession in this country, and we therefore take a keen interest in all issues affecting the profession, including animal health and welfare, public health, regulatory issues and employment matters. In producing this response, we have consulted carefully with our divisions and branches to ensure we are representing as wide a cross-section of the veterinary profession as possible. Some of those divisions have co-badged this response, others have chosen to respond separately, but there has been general support across the profession for the views expressed.

The Fish Veterinary Society is a forum for vets with an interest in fish as well as Fish Health Professionals and veterinary students. It also promotes fish welfare and has an increasing stake in the health management of fish whether farmed, in public aquaria or in the ornamental sector including fish kept as pets.

The British Veterinary Poultry Association (BVPA) is an active non-territorial division of the British Veterinary Association. Its membership is open to poultry veterinarians and scientists working with poultry.

The Association of Government Veterinarians (AGV) is a Specialist Division of the British Veterinary Association representing the views of vets working in UK Government Departments and Executive Agencies.

The Goat Veterinary Society was formed to promote interest in and improve knowledge of goats within the veterinary profession. It is a professional society and specialist species division of the British Veterinary Association (BVA)

The Society of Practising Veterinary Surgeons is a not-for-profit organisation for professionals within the veterinary industry which provides a wide range of excellent advice, guidance and support for its members.

The Sheep Veterinary Society is a division of the British Veterinary Association and includes members from around the World and from all areas of the sheep industry; membership is open to veterinary surgeons and scientists working in the sheep sector.

BVA notes that, while this consultation applies only to Great Britain, we must ensure that the benefits of better regulations of veterinary medicines must also be extended to Northern Ireland. Every effort must be made to ensure that any divergence from EU regulations does not exacerbate structural supply issues, or the availability of veterinary medicines in Northern Ireland.

Chapter 1 – General

- 1. Do you agree with the proposal for the VMD to be able to require information on request? (1.4-5)**

BVA agrees with this proposal, provided that requests to vets are proportionate and justified, noting that, unlike most MA holders, smaller practices have limited administrative resources. Vets are happy to provide information, but cost and administrative burdens need to be taken into account. It would be helpful if requests are aligned with PMS outputs.

- 2. Do you agree with this approach for the “as soon as reasonably practical” issuing of records by vets? (1.6)**

Neutral. In most cases this is already being done through recording in the farm’s medicine book for example. In many cases the information is given before administration, where this is done by the keeper, rather than the vet. The proposed wording does not give a clear timeline and therefore in practice adds little to the current version.

- 3. Do you agree with the proposed approach to advertising of veterinary medicines? (1.7-12)**

Disagree. We would like to see the exemption for immunological medicines extended to include other preventative medicines such as vaccines, parasiticides (as long as this is in conjunction with tighter regulation), and non-steroidal anti-inflammatories. As with immunologicals, in consultation with a vet, use of these products may reduce disease and contribute to a reduction in use of antimicrobials. A ban on advertising to farmers, may limit the dissemination of information to clients, including through information sessions, which can be sponsored by pharmaceutical companies.

We would like the terms “inexpensive” and “animal health professionals” to be defined more clearly. Also does “professional keeper of animals” refer to dog breeders for example, or owners of kennels/stables who may not own the animals in their care? Provision 10A needs to be clearer on what constitutes a financial inducement. It’s not clear how this impacts sponsorship of professional development events, or whether it applies to things such as bulk discounts for example. There also needs to be clarity over events which include a mixture of animal keepers and veterinary professionals (agricultural shows for example).

- 4. Do you agree with this approach to the changes in inspectors’ powers, including the introduction of an offence? (1.13 – 14)**

Agree

- 5. 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?**

Chapter 2 – Marketing Authorisations

- 6. 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)**

Agree, although we do have some concerns that the requirements are too broad and may inhibit innovation, particularly of new antimicrobials. It is important to include environmental impact, particularly for parasiticides.

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

Agree in principle but have some concerns regarding reduced availability of medicines when products have supply issues.

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

Neutral. This may compound supply problems if imports have to be authorised to counter shortages, causing delay.

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

Agree

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

Disagree with decoupling the addition of species where the product is packaged separately. Products for minor species are already limited as it is not cost-effective for manufacturers to apply for separate MAs. This is placing an additional barrier to increasing the availability of authorised medicines for those species.

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

Agree

12. 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)

Agree

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

Neutral

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

Strongly agree, this is important to facilitate informed decision-making for vets. However the information needs to be handled in such a way as to avoid panic-buying, exacerbating shortages. Anecdotally however, there appears to be some discrepancy between shortages experienced by vets, and what manufacturers report as a shortage. Possibly this is because of a supply chain issue which would not be covered by this measure.

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

Agree

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

Neutral

17. Do you agree with this approach to suspension and revocation of MAs prohibiting supply or restricting (immunological) medicines? (2.32-35)

Agree provided that this is not done for political rather than clinical reasons.

18. Do you agree with this approach to the labelling and package leaflet? (2.36-39)

Agree. In particular we would support the inclusion of information on the potential environmental impact of a medicine, in line with recommendations in the [BVA position on small animal parasiticides](#). Our recommendations 11 and 12 are:

- Recommendation 11: Data on the annual sales of parasiticide products and actual frequency of use on companion animals should be collected, and sales data published annually, as the VMD does for antimicrobials.

- Recommendation 12: The VMD should review the requirements for environmental impact assessment of companion animal parasiticide products.

19. Do you agree with allowing electronic package information leaflets? (2.40)

Agree However small animal vets are concerned about accessibility for pet owners (as opposed to professional keepers.) We would also like to see the GTIN number included as this facilitates cross-referencing and upload to the Medicines Hub.

20. Do you agree with this approach to pharmacovigilance? (2.41-44)

Agree, in particular the provision at 2.42 to allow urgent safety restrictions in the event of a risk to animal or human health.

21. Do you agree with this approach for homeopathic remedies? (2.45-48)

Neutral. Homeopathic remedies should be subject to the same efficacy requirements as other medicines.

22. 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?

23. 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.

Chapter 3 – Manufacture

24. Do you agree with this approach for manufacturing authorisations? (3.3-5)

Neutral

25. Do you agree with this approach for specific manufacturing authorisations? (3.6-3.8)

Neutral

26. Do you agree with this approach for regulatory oversight of active substances? (3.9-10)

Agree

27. Do you agree with this approach for products manufactured under the cascade? (3.11-13)

Agree, although we would like “pharmacologically equivalent” to be more tightly defined, for example does this cover dose and formulation? Restrictions on autogenous vaccines could potentially increase costs of these essential medications.

28. Do you agree with this approach to stem cell centres? (3.14)

Agree, but would like clarity on how this applies to kits sold to vets to collect, process, and inject autologous stem cells.

29. 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?

- 30. 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.**

Chapter 4 – Classification and Supply

- 31. Do you agree with the proposed additions to the POM-V classification? (4.2-3)**

We strongly agree. We would also like to see anthelmintics reclassified as POM-V, due to the [increasing body of evidence](#) that there is growing resistance to parasiticides. There is also emerging evidence of fluke resistance in humans which can be linked to overuse of parasiticides. Responsible provision of anthelmintics needs to sit alongside knowledge of pasture management and diagnostic data in the specific case, requiring these products to be more closely regulated than currently. BVA supports responsible antibiotic, vaccine and anthelmintic use, and strongly agrees that all these products should be POM-V

The term “hormonal” needs to be defined here, and we are unclear why “thyrostatic” has been singled out over, for example, adrenostatics. This does not allow for future development of other drugs that inhibit hormonal glands.

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

Agree, but we would like to see regularisation of GTIN codes for all medicines to ease the recording process. There’s an opportunity for the contents and format of the Product Information Database to be reviewed and the requirements of a Wholesaler Dealers Licence to be modified, along the lines of:

When an authorised veterinary medicine is supplied from a Marketing Authorisation Holder to other authorised dealers or retailers then that body should also then incorporate the GTIN code for that product in all transaction documentation and systems. The use of other currently used identification codes, as defined and used by the individual holder of the WDA will still be permitted but it will be required for that to be cross referenced to the unique product GTIN

- 33. Do you agree with the requirement for wholesale dealers to investigate stock discrepancies and keep records for five years? (4.7-8)**

Agree

- 34. 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)**

Agree

- 35. Do you agree with this approach for medicines distributed for promotional purposes? (4.11)**

Agree. This is important to support efforts to tackle AMR.

- 36. Do you agree with the requirement for online retailers to register?(4.12-13)**

Strongly agree. We would also like to see steps taken to reduce prescription fraud – where a prescription is filled multiple times at different pharmacies, facilitated by the online market. We propose placing a requirement on dispensers to close the loop by reporting the dispensation to the prescriber so that unauthorised repeat prescriptions can be identified and acted on. Although this would be an additional

administrative burden on pharmacies, we feel it is justified by the well-recognised and significant risk of prescription fraud to animal health and welfare, public health, and the environment.

- 37. Do you agree with this approach to audits, record-keeping and storage by retailers? (4.14-5)**

Agree

- 38. 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? (4.16-17)**

Disagree. We support the addition of “group of animals” and would like this to be explicitly defined as an epidemiological unit. However, the phrase “other proper assessment” introduces another unnecessary and undefined term. We would prefer to retain the existing term, “clinical assessment”, allowing the RCVS to interpret what that means in practice. This is a key term within the regulations that is undefined, and so it is essential that the regulations are clear about where the responsibility for interpreting the term lies. We would like the explanatory notes to state clearly that the RCVS are empowered to interpret “clinical assessment.”

- 39. Do you agree with the changes to the requirements for prescribing medicines?(4.18-19)**

Agree, but these measures do not go far enough to tackle prescription fraud. We propose placing a requirement on dispensers to close the loop by reporting back to the prescriber so that repeat fills can be identified and acted on. Although this would be an additional administrative burden, we feel it is justified by the significant risk of prescription fraud to animal health and welfare; public health; and the environment.

References to “oral prescriptions” should be changed to “verbal” to avoid confusion with orally-administered medications. It should also be clarified that this does not include instructions to colleagues during surgery for example.

It needs to be clarified that the requirement for prescribers to keep records for five years refers to the prescribing practice, not the individual vet (who may be a locum or move practices within that timeframe). This is more practical both for vets and auditors.

- 40. Do you agree with this approach to products prescribed and supplied under the cascade? (4.21)**

Strongly agree

- 41. Do you agree with this approach to remote supplying by SQPs? (4.22)**

Agree

- 42. 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?**

The impact assessment setting out the benefit to rural vets of remote prescribing does not agree with the feedback we are getting from our members in those jobs. They have expressed serious concerns about the negative impact of the changes at 4.16 and 17. We would be grateful for further clarity on this point.

- 43. 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.**

Chapter 5 – The Cascade

44. Do you agree with this approach to ensuring appropriate use of the cascade? (5.5)

Disagree. We understand the intent behind this measure, but it is tackling the symptom, rather than the cause. While vets should always prescribe within the steps of the cascade, there are many factors which need to be considered on a case-by-case basis. These factors relate to the animal, the owner, and the condition being treated and include a significant degree of subjective assessment. Vets also need to be able to prescribe generics where a licensed product is beyond an owner's means. The issue is not about inappropriate use of the cascade, but with the licensing process, which puts barriers in place to licensing products for additional species (particularly minor species). This means the available licensing options are insufficient for vets to apply best clinical practice.

We would like to remove the word “encourage” from the new offence as this is too open to interpretation, and potentially criminalises vets for providing advice to owners, and other vets, and for following best clinical practice. It does not allow for scientific developments that overtake the authorised products. It has the potential to restrict clinical judgement in cases where the choice of a medicine under the cascade is influenced by the clinical context, such as underlying conditions or an animal keeper's ability to administer treatment etc. Vets treating minor species or exotics are particularly concerned that this new offence would make them very reluctant to use the steps of the cascade, which they are reliant on, due to severely limited authorised medicines for these species.

Restrictions on use of autogenous vaccines is also of serious concern as these can play a significant role in reducing antimicrobial use through preventing infection, particularly when used against strains of microbes where authorised vaccines are ineffective. We would like this provision reworded as follows: “Autogenous vaccines should only be used if no commercial vaccine is available for the particular pathogen or strains present, or if the use of the commercial vaccine has proved ineffective.”

45. Do you agree with this approach to the statutory minimum withdrawal periods? (5.7)

Agree

46. 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?

We are also concerned about the impact of changes to minimum residue levels (at 5.4) on minor species, particularly food-producing minor species (goats and deer). Medications for these animals are already very limited, and the additional requirements may restrict the use of cascade medicines to treat them.

Chapter 6 – Medicated Feedingstuffs

47. Do you agree with this approach to prescriptions for medicated feed? (6.3-4)

Agree, but needs to allow for syndromic diagnosis. The term veterinary medicinal product should be retained, as premix is ambiguous and can refer to nutritional supplements such as vitamins.

48. Do you agree with this approach to labelling? (6.5)

Neutral. We urge caution around the use of the term “premix” which commonly refers to a nutritional supplement, rather than a medicine. We would prefer to retain “veterinary medicinal product”.

49. Do you agree with this approach to storage and disposal of medicated feed? (6.6-9)

Neutral, although we note that manufacturers have some concerns about the practicalities of this.

50. Do you agree with this approach to cross-contamination and carryover? (6.10-11)

Agree

51. Do you agree with this change to the tolerance table? (6.12)

Agree

52. 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?

53. 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.

Chapter 7 – Exemptions for Small Pet Animals

54. 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?

Agree

55. 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?

Agree

56. 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?

57. 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 requirements would be applied immediately upon the revised VMR coming into force.

Chapter 8 – Antimicrobial Resistance

58. 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, but there may be implications for practice management systems and the ability to do this without additional administrative burden. The proposal needs to be properly costed.

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

We agree with the intentions of these changes, but some clarifications are necessary. The use of the term “exceptional circumstances” would appear to preclude use of antibiotics for common surgeries (such as castrations, debudding, and orthopaedics) where the risk of infection can be high. Small animal vets have similar concerns about prevention of post-surgical infection if administration of antibiotics post-surgery is classed as prophylactic use. It would also be important to be clear that this would not affect the use of antibiotic trials in the treatment of a disease (e.g. for diarrhoea before performing endoscopy under anaesthesia, or for urinary tract infections before performing cystocentesis under sedation). We would prefer “evidence-based” or “risk-based” instead of the word “exceptional”, to allow for clinical judgement of risk to be taken into account.

We are also concerned about the impact on metaphylactic use of antibiotics, where only some of a herd or flock are showing symptoms. We know that treating epidemiologic units on first isolation of a primary bacterial pathogen, rather than waiting for clinical signs to develop in the population, can be effective in controlling morbidity and mortality at population level in that unit, but this would appear to be precluded by these changes.

**60. Do you agree with this approach to medicated feed containing antibiotics?
(8.7-8)**

We broadly agree but have some specific concerns with the changes. In-feed medications are an important tool for treating pigs and farmed fish in particular. Limiting prescriptions to one antibiotic per batch of feed is a major concern. There are cases where more than one is needed either to treat more than one condition, or because the second medication is needed for the first to be effective. (e.g, research shows that use of two antibiotics can lower MIC in swine dysentery). In cases of multiple conditions, this will mean the second treatment will have to be administered by another method, which is unduly onerous and potentially stressful for the animals.

We are also concerned about the 5 day limit. Does this refer to the time between prescribing and mixing, or prescribing and starting treatment? If the latter, we would like this to be extended to 7 days (or 5 working days) to allow for weekends (when mills are closed) and delivery of the feed to more remote locations (notably fish farms). This also means that a two-week course of treatment would require two prescriptions and two separate feed orders, which seems to be adding administrative burden for little benefit.

Chapter 9 – Fees

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

We support the need for VMD to recover costs and accept the need to increase fees. We are pleased to see that in the clinical academic practice the setting of fees for small-scale non-commercial trials at £40, which is a change from the current fee for applications (£30), renewals (£130) and variations (£265). This is good news for the development of clinical research within a variety of settings.

We are not clear how fees are calculated however, and would like to understand why there is a flat rate for each type of practice, not taking into account the size and complexity of the practice and number of vets employed.

We are also slightly concerned that increasing licensing costs will limit innovation and compound the issues with licensing products for minor species, which we outlined in the section on the cascade.