Law Society of Scotland

Consultation Response

Review of the Veterinary Medicines Regulations 2013

30 March 2023

Introduction

The Law Society of Scotland is the professional body for over 12,000 Scottish solicitors.

We are a regulator that sets and enforces standards for the solicitor profession which helps people in need and supports business in Scotland, the UK and overseas. We support solicitors and drive change to ensure Scotland has a strong, successful and diverse legal profession. We represent our members and wider society when speaking out on human rights and the rule of law. We also seek to influence changes to legislation and the operation of our justice system as part of our work towards a fairer and more just society.

Our Rural Affairs sub-committee welcomes the opportunity to consider and respond to the Department for Food, Environment, and Rural Affairs consultation: Review of the Veterinary Medicines Regulations 2013.[1] The sub-committee has the following comments to put forward for consideration.

General comments

In general, changes which deliver enhanced control on use of antimicrobials, and which may assist in the reduction of AMR are desirable. However, anything which impacts on the ability of the veterinary surgeon to make clinically justifiable decisions on treatment, and which will improve animal health and welfare, where the risk of AMR is mitigated by careful and considered use, would not be beneficial to the production animal sector.

The requirement for registration and enhanced powers of inspectors to deal with un-registered medicine supply is welcomed, and the harmonisation with the EU arrangements on medicines will assist flow of trade and is also welcomed.

Professional animal keepers have been aware of the impact of AMR for some time, and whilst the introduction of changes to the advertising regime may support a reduction in inappropriate medication, this has not been evidenced and should be approached with caution, as it could lead to under-reporting of disease and associated animal health and welfare impacts.

The principles around marketing authorisation provide for good control of medicines, and it is appreciated that there is a need for early information on supply chain issues which could lead to animal welfare issues. There should be flexibility in, for example, use of generic products to deal with these types of issue.

The guidance on remote prescribing for both veterinary surgeons and SQPs is welcomed, however the restriction on wholesale of medicines to only authorised premises may impact on veterinary surgeons being able to prescribe for their own livestock, and needs consideration.

Likewise regulation of the cascade system could restrict options for veterinary surgeons to deal with emerging disease, and whilst the system is supportive of a safe and evidenced use of medicines with

[1] Review of the Veterinary Medicines Regulations 2013 - Defra - Citizen Space

appropriate withdrawal periods, however caution is needed to not stifle innovation and development of new treatments, including extemporaneous presentations, by rigid application where this may impact on animal health and welfare.

Chapter 1 - General (regulations)[2]

Providing information upon request

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

There is a need to be more transparent with information, and there is an area of concern around supply chain fragility for production animal medicines, one which the government via the VMD will have a need for access to information.

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?

It is of importance that the information on withdrawal periods is available as soon as reasonably practicable. However, veterinary surgeons should not be placed in a position where they are solely accountable for the provision of relevant information to enable compliance with the withdrawal periods for medicines. The detail of the medicines prescribed in many cases will be available to the professional animal keeper (e.g. from the packaging and data sheet) and clarification on what constitutes the provision of this information for the keeper's record in this context would be welcomed.

Advertising

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

There are a number of tenets to this change. To identify the advertisement as being for the safe use, supply etc. of a veterinary medicine is sensible. The advertising of medicines should be limited to those with a current marketing authorisation.

With regard to further regulation over hospitality, we would query whether this is already sufficiently covered by anti-bribery and corruption legislation, and further restriction may impact on development of marketing for important medicines which could advance animal health and welfare, whilst promoting the education of the veterinary prescriber.

In general, control over marketing which could lead to inappropriate use is desirable. However, this follows an assumption that the advertising to animal keepers will lead to misuse or abuse of medicines, when POM-V/POM-VPS medicines should always be prescribed by a veterinary surgeon/SQP. There are two suppositions in the argument:

1. that the animal keeper can procure the medicine; and

[2] We have included responses to questions 1-5 under the "Introduction" heading above and in our covering email.

2. that they misuse it with recklessness of intent of causing harm to the animal or wider human population by development of resistance.

This could be better addressed by education rather than censure. There are a number of key POM-V medications which have significantly improved animal health and welfare and have not intrinsically been harmful to the animal or wider public health concern, and which have been advertised to professional animal keepers for a number of years.

There is insufficient information on some of the proposals on the restriction of prescribing to give a full view. We understand that there is a lack of understanding around the role of the professional animal keeper in terms of withdrawal periods and advertising and that this will have a significant impact on veterinary business. In addition, any "tightening" of the cascade system in animals needs to have consideration for the current cost-crisis and consequential impact on animal welfare.

Powers of an inspector

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

Enhanced powers where there is a real risk are desirable, to protect human and animal health. However, this must be evidence based, balanced, and follow an agreed hierarchy of enforcement in lower risk cases, to avoid detrimental impact on the supply chain and possible animal welfare issues.

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?

We have no comments in response to this question.

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

We have no comments in response to this question.

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?

We would make the following general comments:

- The harmonisation with the EU is desirable, as this will potentially permit the flow of medicines.
- Information on the direct and indirect risks to public or animal health or to the environment should be clarified – e.g. whether this is in terms of the product, the risk of AMR, or the risk of not treating the condition – because this is not clear from the consultation.
- In respect of the methods of mitigating the development of antimicrobial resistance as a result from the use of the antimicrobial product in animals, this is likely to be very similar for most anti-microbials and revolve around using other treatment modalities first, length/dose of treatment and continued monitoring. It is unclear what benefit there would be in forming part of the SPC or dossier for authorisation and seems an unduly onerous burden which could stifle innovation.
- The rationale is not clear for the proposal to introduce the requirement that the SPC submitted for a generic veterinary medicine must be essentially similar to that for the reference product. E.g., whether it would be sufficient if the generic product does not contain some of the same inactive ingredients, or if some of the data for the active compound is taken from the current licenced version and validated. This seems to bring additional reporting requirements without any additional protective benefit for human or animal health.

Generic / generic hybrid products

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

On balance the provision of the information around the difference seems sensible. However, the provision to protect the reference product could stifle innovation.

Whilst the rights of the manufacturer of the reference product should rightly be protected, we would suggest that there should be a safeguarding provision, meaning that the placing on the market could happen where there were significant animal health or welfare benefits to doing so.

The flexibility in delivery for VMA for immunological products is sensible given disease epidemiology.

Marketing authorisation for parallel import

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

We consider that in terms of supply chain fragility and food supply integrity this would be an extremely dangerous backward step with no safety reason to implement this – other than protecting the rights of the parent product.

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?

We have no comments in response to this question.

Data protection periods

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

There is unconvincing evidence that extension of the data protection period should be within the VMD remit, as this should be based on the disease, species, and supply chain risks.

The decoupling of additional species etc. does appears to be a sensible and balanced approach.

Parallel assessment with other regulators

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

We have no comments in response to this question.

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?

With our departure from the EU this is a completely necessary step to preserve future authorisations and enhance animal health and welfare.

Withdrawal of an MA application

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

We have no comments in response to this question.

Information on shortages

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

We have no comments in response to this question.

Renewal of marketing authorisations

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

We consider that this should be extended, although do not consider that a no-review policy is of benefit. There are instances where alterations to disease patterns and enhancements in research mean that at the

review amendments can be sought. However, this will not place any incentive on the MAH to advance understanding if there is no review period.

Variations

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

We have no comments in response to this question.

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?

The process for revocation should involve a period where the SoS provided with the impact assessment and the company is given a chance to make representations. We consider that this is not clear from the proposal.

Labelling and package leaflets

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

We consider that this is necessary for reducing waste and improving environmental credentials.

Electronic package information leaflet

25. Do you agree with allowing electronic package information leaflets?

We have no comments in response to this question.

Pharmacovigilance (post-authorisation monitoring)

26. Do you agree with this approach for pharmacovigilance?

Whilst the risk benefit report is a welcome addition, there is a benefit also to the submission of periodic safety reports to ensure that there are not trends in adverse reactions.

The remainder of the provisions to allow safety restrictions and the action against same active substances are sensible, and the increased inspection requirements are also a welcome addition.

Registered homeopathic remedies

27. Do you agree with this approach for homeopathic remedies?

We have no comments in response to this question.

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?

We have no comments in response to this question.

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

We have no comments in response to this question.

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 have no comments in response to this question.

Chapter 3 – Manufacture

Manufacturing authorisation

31. Do you agree with this approach for manufacturing authorisations?

We consider that there should be some consideration for veterinary special manufacturers who supply medicines in a format not otherwise available.

Consistent approach for specific manufacturing authorisations

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

We have no comments in response to this question.

Active substances

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

This step possibly adds unnecessary burden to manufacture. We consider that this should be covered by demonstration and audit of GMP.

Manufacturers of products for administration under the cascade

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

The extemporaneous route has been used by practitioners to address a number of issues, including the strength and product presentation of veterinary medicines which have not been formulated for a small market. We consider that there has not been detail of how this improves animal health or welfare and will add to the already increased risk of animals not being treated for conditions which there is a rationale for doing so.

Stem cell centres

35. Do you support this approach to stem cell centres?

We have no comments in response to this question.

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?

We have no comments in response to this question.

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

We have no comments in response to this question.

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 have no comments in response to this question.

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

Classification of POM-V medicines

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

We are unclear of the benefit of escalating some VPS product to POM - V and this may decrease availability and treatment options, e.g. the risk of SQP prescription of hormonal products is not clear.

Requirements for wholesale dealers

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

The registration of wholesalers is welcomed. As part of the traceability requirements for the supply chain, the restriction of supply to only authorised premises will restrict the ability of, for example, veterinary practitioners to treat their own production animals.

The wording needs to be clear that there should only be onward prescribing to other animal keepers to ensure the right to prescribe and supply for a vet's own animals is not impacted.

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?

We have no comments in response to this question.

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)?

This could have a market impact, for example it could force more business into the corporate wholesalers, limiting competition.

Distribution for promotional purposes

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

When a product comes to market it is safe, but the compliance of the animal owner has not been established, therefore there is no evidence of benefit in removing the use of medicines to promote or to remove antimicrobials as products which can be used for promotion, as the same prescribing rules should apply in all cases.

Registration of online retailers

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

We have no comments in response to this question.

Retailer supply

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

We have no comments in response to this question.

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?

Given the severe workforce shortage in the remote and rural areas, this is a necessary and welcome step. Previous requirement for a clinical examination has been over-exaggerated by practices as an animal welfare impact and has led to some protectionist and anti-competitive behaviours which have no impact on animal welfare, either positive or negative.

Prescriptions

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

It is not clear that there can always be a rationale for prescription of some VPS products, other than at the owner's/keeper's request, e.g., horse wormers and certain anthelmintics or parasiticides. Whilst we consider that the requirement should be written, it should not be prescriptive in its application.

We strongly support the creation of an offence to alter prescriptions.

Products supplied under the cascade

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

We consider that the benefit to the animal is unclear here. This appears overly prescriptive and reduces a clinician's ability to make a judgement. In addition, the record keeping requirement adds nothing to the safety margin.

Remote supply by SQPs

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

We have no comments in response to this question.

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?

We have no comments in response to this question.

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

We have no comments in response to this question.

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 have no comments in response to this question.

Chapter 5 – Administration under the cascade

Appropriate use of the cascade

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

Anything which reduces information flow on possible novel treatment modalities for new and emerging diseases should be avoided. There is a risk that this approach will severely stifle innovation. Creation of an offence for advocating “off licence” use for example could lead to a backward step in animal health and welfare.

Withdrawal periods

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

We have no comments in response to this question.

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?

We have no comments in response to this question.

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

We have no comments in response to this question.

Chapter 6 – Medicated feed

Prescription for medicated feed

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

We consider that medicated feed may be used in the absence of a full diagnosis and on a presumptive basis, although to require a diagnosis could possibly limit use and impact on animal health and welfare.

Labelling

58. Do you agree with this approach to labelling?

We have no comments in response to this question.

Storage and disposal of medicated feed

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

We have no comments in response to this question.

Cross-contamination and carryover

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

We consider that much of this could also be achieved if a policy decision was taken to implement the requirement for all primary producers to have a validated HACCP plan. This would not require additional legislation.

Tolerance table

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

We have no comments in response to this question.

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?

We have no comments in response to this question.

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

We have no comments in response to this question.

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 have no comments in response to this question.

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?

We have no comments in response to this question.

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?

We have no comments in response to this question.

Chapter 6 summary questions

67. 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?

We have no comments in response to this question.

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

We have no comments in response to this question.

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 have no comments in response to this question.

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?

We consider that whilst there is a benefit in access to the data, it is not clear that creating a further offence will ensure quality information.

Prophylactic use

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

We consider that the restriction of antibiotics is a positive step. However, we should be alive to the potential for emerging disease and not remove the option from vets to use these to deal with possible large-scale outbreaks.

In-feed antibiotics

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

We have no comments in response to this question.

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.

We consider that the impact for most businesses will be minimal, however the charging for destruction of drugs could lead to clandestine disposal.

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

We have no comments in response to this question.

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