

VMD Informal Consultation - Amended Veterinary Medicines Guidance Notes

1. The following response is made on behalf of the Royal College of Veterinary Surgeons (RCVS). The RCVS is the regulatory body for veterinary surgeons in the UK. The role of the RCVS is to safeguard the health and welfare of animals committed to veterinary care through the regulation of the education, and ethical and clinical standards, of veterinary surgeons and nurses, thereby protecting the interests of those dependent on animals, and assuring public health. It also acts as an impartial source of informed opinion on relevant veterinary matters.
2. The College is broadly supportive of the amended Veterinary Medicines Guidance Notes (VMGNs) and the consolidation that has occurred. The Guidance notes are, in the main, clear and well-written, and represent an improvement on the previous VMGNs.
3. As a regulatory body, the RCVS will limit its comments to those areas where there are clear indications of relevance to the College's role and where the new policy may require the Government, the veterinary profession or the public to seek assistance from the College. Representatives of the College have reviewed all of the amended VMGNs, but the College will only seek to provide comment on those VMGNs where there are issues that fall within our regulatory remit.
4. The College notes that in relation to issues concerning veterinary medicines, the British Veterinary Association (BVA) Veterinary Medicines Group acts as an expert and authoritative voice on behalf of the profession. The response of the BVA Veterinary Medicines Group to the consultation exercise will cover issues that fall out-with the regulatory remit of the RCVS.

Guidance for Retailers (Note 3)

5. Page 3 of the 'Quick Start' to Note 3 states 'prescribing is considered to be the action of deciding, instructing and recording which treatment should be administered to an animal and may be oral or put in writing'. The RCVS notes that true prescribing involves diagnosis and is therefore considered to be the practise of veterinary surgery. The College therefore urges the VMD to include a reference to compliance with the Veterinary Surgeons Act in this section.
6. In the main body of Note 3, paragraph 5 refers to POM-V and notes that such medicines may only be 'prescribed by a veterinary surgeon following a clinical assessment of an animal, or group of animals, under a veterinary surgeon's care'. The Guidance goes on to set out the RCVS interpretation of 'clinical assessment', but does not refer to the RCVS interpretation of an animal being 'under his (the prescribing veterinary surgeon's) care'.
7. As the VMRs do not define the meaning of 'under his care', the RCVS considers that it is imperative that the RCVS guidance on this matter is referred to in this VMGN.

8. The College interpretation of 'under his care' is available in section 2H of the *Guide to Professional Conduct* and is as follows:

a. the veterinary surgeon must have been given the responsibility for the health of the animal or herd by the owner or the owner's agent

b. that responsibility must be real and not nominal

c. the animal or herd must have been seen immediately before prescription or,

d. recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe.

e. the veterinary surgeon must maintain clinical records of that herd/flock/individual

What amounts to 'recent enough' must be a matter for the professional judgement of the veterinary surgeon in the individual case.'

9. The RCVS also considers that a reference to the College interpretation of 'under his care' should be included in paragraph 75, relating to prescriptions made by EEA and Swiss veterinary surgeons for animals in the UK.
10. Paragraph 76 refers to labelling requirements and states that label information on a product 'must not be obscured by any additional labelling or amendments made to the packaging'. The College notes that this guidance presents significant practical problems to veterinary surgeons when labelling smaller products with prescription information for their clients.
11. The College commends the recognition of the RCVS Practice Standards Scheme (PSS) in this VGMN and welcomes the risk-based approach that the VMD adopts towards the inspection of premises, whereby veterinary practice premises that are PSS members and therefore subject to PSS inspections are not subject to additional inspections by the VMD.
12. The RCVS questions, however, the requirement that non-PSS veterinary practices are inspected at least every four years, the same as PSS practices, whereas inspections of SQP retailers' premises are carried out on a risk basis and the frequency varies from once every four to six years.

Controls on Advertising (Note 4)

13. The RCVS is concerned that paragraph 15 (see below) is potentially misleading:

'Selection and supply of VMP must be based on clinical suitability rather than economic incentive. All advertising campaigns must reflect this responsibly. Discounts and other types of promotions (such as "buy one, get one free") must not be a consideration when prescribing or supplying a veterinary medicinal product. Any promotion that attempts to influence the decision of the prescribing professional, especially for financial gain, is inappropriate.'

14. Whilst the RCVS is fully in agreement that the selection of VMP must be based on clinical suitability rather than economic incentive, the RCVS is concerned that as the paragraph is

currently phrased it may prevent the selection of one identical formulation from another on the basis of economic considerations. This does not, however, appear to be the intended goal, nor should it be.

Animal Test Certificates (ATC) (Note 6)

15. Paragraph 12 states that 'placebos can be included within an ATC provided use does not compromise animal welfare as a result of withholding treatment'. The RCVS questions, however, whether placebos could ever have a place in treating client animals.
16. If there are indeed such circumstances where placebos may be used on client animals the RCVS considers that more guidance is required.

Exemption Scheme for Small Pet Animals (Note 12)

17. The College has concerns that Note 12 on the Exemption Scheme for Small Pet Animals could be open to misinterpretation. Furthermore, certain phrases used in this VMGN, such as 'there are no restrictions on the retail supply of products under this Scheme' are confusing and could cause the public to think that such medicines are not regulated.
18. The College would urge the VMD to consider redrafting Note 12 to provide a fuller explanation of the purpose, limited nature and terms of the Exemption Scheme for Small Pet Animals, so as to provide public assurance that provisions are in place to ensure the safety, quality and efficacy of medicines marketed under this Scheme.
19. The College also considers that the requirement in paragraph 20 that 'any serious adverse reactions should be reported by manufacturers, importers or retailers to the VMD within 15 days of learning of the reaction', should be linked to Note 11: 'Pharmacovigilance Guidance on Adverse Events', and that reference to this requirement should also be incorporated into Note 11.

Guidance on the Use of the Cascade (Note 13)

20. Paragraph 53 notes:

'It is not a legal requirement for veterinary surgeons to report adverse reactions to medicines prescribed under the Cascade. However, we encourage reporting of any adverse events to the Marketing Authorisation Holder (MAH) or to the VMD as this will provide us with knowledge of the use of the medicine in the field. Unless such reports are received the incidence and severity of side effects, and the ongoing efficacy of products, cannot be assessed, and consequential action, for example, to amend product literature, cannot be taken.'

21. The College urges the VMD to lead a communications campaign to ensure that practising veterinary surgeons are aware of the importance of reporting not only the adverse events caused by medicines used under the cascade, but also the efficacy of these medicines, and considers that such a campaign could lead to significant improvements in pharmacovigilance. The College notes that anecdotal evidence would suggest that there is a lack of appreciation within the profession that the lack of efficacy of a medicine should be reported as an 'adverse event'.

Record-Keeping Requirements for Veterinary Medicinal Products (Note 14)

22. The RCVS notes that the audit requirements for those who retail or wholesale supply prescription VMP, referred to in paragraphs 28-33, would present real practical difficulties for those who did not operate a computerised system of stock control and may require a disproportionate investment of time compared to the benefit of such an audit. Moreover there are significant difficulties in enforcing such audits.
23. If you require clarification on the above comments, please do not hesitate to contact me. Alternatively, representatives from the RCVS would be happy to meet with you to discuss and expand upon our position.

RCVS
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