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Dear Jo

The Veterinary Medicines Regulations 2005
Code of Practice for the Registration of Retail Premises and Suitably Qualified Persons

Thank you for your letter of the 4 October 2005 ref: VMD 9656 seeking comments on the draft Code of Practice for the Registration of Retail Premises and SQPs. I have pleasure in outlining below, the views and comments of the Animal Medicines Inspectorate (AMI).

The AMI welcomes the Code and believes that it is a clearly set out, pragmatic Code with which registered merchants and SQPs will, on the whole, be able to understand and comply with.

The Inspectorate does, however, believe that as this is a Code of Practice for the Registration of *Retail Premises* and SQPs, the requirements for the premises, (sections 35-40 inc) should precede those of the SQP and the SQPs duties and responsibilities etc.

With regard to the specific issue of extending the definition of premises to include registered vehicles, the AMI remains opposed to this proposal for the reasons set out in my letter of 23 June 2005 (copy attached). Set against recent European and domestic legislation aimed at tightening controls on the distribution of veterinary medicines, the Inspectorate believes that this would be a retrograde step with particular enforcement difficulties.

The Code of Practice.

The numbering below follows that of the draft COP.

1 (iii) should the word “registered” be replaced by “approved” in accordance with the term used in the Regulations (Schedule 3 section 9(4)) ?

5. 4th bullet point. The Inspectorate believes that this paragraph could be misleading and suggests that it is clarified to clearly state that an SQP cannot *supply* a POM-VPS or NFA-VPS medicine for use off-label, even if this has been prescribed by a veterinary surgeon.

The Heading – “VMD Interpretation” might be more appropriately called “Recognition of Training & Registration Bodies”

8. The AMI welcomes the clear guidance issued to SQP training and registration bodies regarding the subjects to be included on a syllabus but would suggest that:

2nd and 3rd bullet points – the sentences are preceded by the word “detailed” as we believe these are the most important elements of the training that should be provided to SQPs.

4th bullet point. The AMI suggests that this is amended from “how to obtain knowledge of a farm” to “what information is required and how it is obtained to enable etc..” There may be medicines categorised POM-VPS for animals other than farm livestock.

7th bullet point. Clarification on when to refer *what* to a Vet

11th bullet point. Clarification on the limits of knowledge and competence *of the SQP*..

12. The charges should be fully transparent and fully justifiable, in particular with regard to the requirement for mandatory CPD.

14. It should be clarified that supply relates *to retail supply*.

16. POM-V. Omission of the word *by* after the word Prescribed.

19. The consequences of failing to comply with the Code and the Regulations should be outlined.

20. Whilst the Inspectorate recognises the good work of AMTRA and understands that it is currently the only training/registration body recognised by the Secretary of State, we do not believe that it or any other individual training/registration body should be named in this, a universal COP.

22. The Inspectorate suggests that the COP specifies a registration numbering system that should be used by all training/registration bodies and which clearly identifies with whom the SQP is registered, the SQPs qualification and individual registration number. For example, an SQP registered with AMTRA could be given the registration number AMT-R12345.

23. 3rd bullet point. The minimum amount might be smaller than the smallest pack size. Therefore the AMI suggests that the wording be amended to “*prescribe the minimum pack size sufficient to provide the necessary treatment*”.

26. The AMI suggested that perhaps for the sake of consistency, the categories listed in paragraphs 26 and 21 be the same.

29. The Inspectorate believes that the paragraph relating to CPD should be expanded and clarified. For example, are the means of acquiring CPD listed in the paragraph a definitive list ? How will CPD be recorded by the SQP and forwarded to and validated by the

training/registration body ? Could a satisfactory inspection/advice from an Inspector during an inspection count towards CPD ?

30. It should be clarified that the Regulations require an SQP to be present when the sale/supply of a POM-VPS medicine is made. The term *present* should be fully explained to avoid individual interpretation.

31. Re: sheep dips. The Inspectorate would suggest that when the sale of a sheep dip is made to someone acting on behalf of the holder of a Dip Certificate both the purchaser's details and the details of the Certificate holder, including that person's Certificate number, are recorded on the sales record. In addition, guidance on the issuing of gloves and the laminated notice should be included.

32. In the example given of individual boluses being supplied, could clarification be given to whether one package leaflet is required per product or per transaction. In addition, the AMI would appreciate clarification on the supply of foil wrapped tablets that come in strips of 2 or more. Can such strips be cut/broken in order to supply individual tablets which are remain in packaging ?

33. As pointed out in previous correspondence to the VMD, the AMI believes that individual batch numbers should be recorded on each sales record. The AMI has enforced this position since 1998 and currently registered Agricultural Merchants selling PML medicines fully comply.

36. The Inspectorate notes the word *registered* in the 2nd sentence. Should this be *approved ?*

The renewal of approval should be clarified as to whether this is on a fixed date or whether it is on the anniversary of the initial approval.

As outlined in the beginning of this letter, the AMI opposes the extension of approval of a premise to a vehicle. However, the Inspectorate accepts that medicines sold from an approved premise should be able to be delivered on a vehicle but would suggest that there is a requirement for *a dated, itemised delivery note, a copy of which is left at the supplying premise, to accompany the medicines on the delivery vehicle*.

The Inspectorate notes that there are no provisions in either the Regulations or the COP for a premise's approval to be suspended or revoked for failure to comply with the requirements of them. Furthermore, there is no Appeals procedure (which would also be required if suspension/revocation was catered for) in the case of a refusal to approve a premise.

38. The Inspectorate believes that areas within domestic dwellings should be permitted to be approved subject to them:
- being separate and distinct parts of the dwelling, with a separate entrance so that access through any part of the private residence is not necessary. In such circumstances, the merchant should have to declare that they accept that the part of the premise is used for business and not residential purposes and that an Inspector has the right to enter at any

reasonable time. Failure to permit an Inspector access would lead to suspension or revocation of approval.

4th bullet point. We would suggest that the premise should be capable of being securely closed to unauthorised personnel, as all premises are capable of being made secure (i.e. at some time in the future).

8th bullet point. It appears that the word *not* my have been omitted.

9th bullet point. The Inspectorate suggests that the word *human* is deleted. (Inspectors have observed large quantities of milk in vaccine 'fridges over the years that are allegedly intended for the cat !!)

15th bullet point. We would suggest that this is reworded to "*prohibit smoking, eating and drinking in medicines storage areas*".

We would also suggest that appropriate staff facilities (i.e. toilet and washing facilities) should be required and that these should be kept clean and tidy. These facilities must not be used for the storage of medicines.

39. 1st bullet point. This may require some sheep dips to be stored within approved pesticides stores.

40. This could be simplified to (or incorporated into paragraph 39) "Products must be stored in accordance with any specific directions given on their labels. Products requiring storage at room temperature must be stored below 25.C. Thermolabile products must be stored within the temperature range stated on their labels which is normally between 2.C and 8.C. Daily temperatures for all storage areas should be recorded.

42. The 2nd sentence should begin with the words *"For the purpose of enforcing the regulations, Inspectors ".*

The powers (if any) of Inspectors to enforce the Code of Practice should be specified as well as the route by which SQPs can be referred to their respective registration bodies if they fail to comply with the Code.

Reference could also be made to Obstruction and Possession offences.

Further Comments.

The Inspectorate would welcome a requirement for merchants to document, implement and observe Standard Operating Procedures (SOPs) relating to the acquisition, intake, storage and supply of veterinary medicines.

The Inspectorate also believes that it would be helpful if the Code provided clear guidance on the disposal of out of date/damaged POM-VPS and NFA-VPS medicines.

I hope that you find the views of the Inspectorate helpful. If you have any further queries or require clarification of any point, please do not hesitate to contact me.

Yours sincerely

John J Millward

Head of Animal Medicines Inspectorate