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Dear Ms Shelley,

Re: Public Consultation on the Veterinary Medicines Regulations 2010

Thank you for the opportunity to comment on the proposed changes to the Veterinary Medicines Regulations (VMR) 2010.

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.

Whilst in the main the RCVS is satisfied with the proposed changes to the Veterinary Medicines Regulations, the College has a number of concerns, outlined below, relating specifically to the Veterinary Medicines Directorate (VMD) proposals numbered one, two and seven.

PROPOSAL ONE: TO AMEND THE VMR TO INDICATE THAT ANTIMICROBIALS SHOULD ONLY BE ADVERTISED TO VETERINARY SURGEONS, VETERINARY NURSES AND PHARMACISTS.

Resistance to antimicrobials and anti-parasitic drugs

The RCVS is deeply concerned by the increased resistance developing to antimicrobials and anti-parasitic drugs, and considers that this is a priority issue for the profession to address. Consequently, the College supports proposals that can be scientifically shown to ameliorate the situation regarding the development of such resistance.

Practice Newsletters

The College is aware that many veterinary practices produce regular newsletters for their clients. It is imperative that the changes to the VMR do not affect the ability of veterinary surgeons to use these newsletters to provide information to their clients on local animal

health and welfare issues, and that practices can continue to use their newsletters to recommend certain antimicrobials where localised resistances may have developed. The RCVS therefore seeks assurances that the restrictions on the advertising of antimicrobials will not restrict communication between veterinary surgeons and their clients where the primary aim is educational and not promotional.

PROPOSAL TWO: AMEND THE VMR TO ALLOW ACCEPTANCE OF PRESCRIPTIONS FROM EEA VETERINARIANS BY UK PHARMACISTS AND VETERINARIANS.

The RCVS has grave concerns regarding the proposed change to the VMR to allow the acceptance of prescriptions from EEA veterinarians by UK pharmacists and veterinarians, and considers that the current proposals could create significant problems relating to the regulation of veterinary surgeons and more importantly that the proposals have the potential to increase the misuses of drugs, promote the development of resistance, adversely affect the health and welfare of animals and impact on human food safety.

Fundamental differences between human and veterinary medicine

The driver behind the proposed changes to the VMR appears to be the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 (as amended) which made changes allowing EEA prescriptions for human medicines to be dispensed in the UK. There are, however, very significant differences between veterinary medicine and human medicine and it does not follow that a change in the law in relation to the regulation of human medicines should lead to a change in the law relating to veterinary medicines. There is, for example, a unique risk presented to human health and animal welfare if an EEA veterinary surgeon is prescribing medicines for a food-producing animal that they have not seen.

Relationship between prescribing veterinary surgeon and animal being treated

In veterinary medicine it is imperative that there is a close relationship between the prescribing veterinary surgeon and the animal they are treating. Such a relationship is important on welfare grounds because, unlike in human medicine, animals cannot choose by whom or how they are treated or communicate relevant information about their condition or past treatments. Consequently, it is important that a veterinary surgeon has a detailed understanding of the animal's present condition and relevant medical history. Furthermore, for food producing animals it is important on food safety grounds that a veterinary surgeon can work with the owner to assist them in making the necessary declarations as to what medicines the animal has been prescribed or has taken.

Indeed, the RCVS considers that such a relationship is so important that the RCVS *Guide to Professional Conduct*, the provisions of which all veterinary surgeons practising the UK must observe, requires that an animal must be under a veterinary surgeon's care before he/she can prescribe medicines for it.

The RCVS has very serious concerns that under the proposed change to the VMR there appears to be no requirement that an animal is under a veterinary surgeons care before medicines can be prescribed. Without such a requirement it is possible that a veterinary surgeon could be operating in one Member State and prescribing medicines for an animal, that he/she may never have seen, that was located in a different Member State. Such a situation has the potential to lead to an increase in the misuse of drugs, may serve to increase resistance to antimicrobials and anti-parasitic drugs, and could adversely impact on the human food chain.

Risk to food chain

Due to the risk presented to human health by veterinary medicines entering the food chain, Europe Regulation (EC) No 853/2004 requires that slaughterhouses must 'request, receive, check and act upon food chain information' (FCI) which includes information on 'veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods'. Providing such information to slaughterhouses requires a close working relationship between the owner of a particular animal and the prescribing veterinary surgeon. It seems unlikely that accurate compliance with the FCI requirements could be achieved in a situation where a veterinary surgeon was prescribing medicines for an animal in another country that he/she may never have seen, as could occur under the proposed change to the VMR.

If UK pharmacists and veterinarians were required to dispense medicines against prescriptions from EEA veterinarians, then the RCVS would advocate a situation whereby prescriptions could only be accepted in cases where the medicines were to be used in the country where the prescription originated. Such a system could serve to ameliorate the problems associated with the food chain by making it easier to establish what medicines a particular animal may have taken or have been prescribed.

Companion animals

The situation for human medicines is also quite different from animal medicines because it involves a single species and human medicine is currently more harmonised across Europe. As people travel freely and frequently across Europe, in a way that food-producing animals do not, there also is an increased rationale for imposing a system whereby a person is able to have medicines dispensed by a pharmacist in a country other than their own. As the movement of companion animals is more similar to humans and there is not the same risk to the food chain, the RCVS would support a more limited change to the VMR, whereby there was an exemption that allowed pharmacists and veterinary surgeons to dispense against a prescription from an EEA veterinary surgeon where a companion, non-food-producing, animal is being treated.

Resistance to antimicrobials and anti-parasitic drugs

The proposal to allow the acceptance of prescriptions from EEA veterinarians by UK pharmacists and veterinarians also seems to be contrary to current moves across Europe to impose greater restrictions on the use of antimicrobials by veterinary surgeons. Under the proposals, it would appear that EEA veterinary surgeons may be able to use the proposed system to procure medicines, which may be restricted in their own country, from another Member State.

Internet pharmacies

The RCVS also has concerns that the proposals could lead to increased misuses of drugs and a further promotion of the development of resistance to antimicrobials and anti-parasitic drugs as a result of internet pharmacies using EEA veterinary surgeons to write prescriptions for animals they have never seen, in order to permit the pharmacy to sell drugs to clients.

Acts of veterinary surgery

The Veterinary Surgeons Act (VSA) 1966 stipulates that in order for someone to legally perform an act of veterinary surgery in the UK, such as prescribing POM-V medicines, they must be registered as a Member of the Royal College of Veterinary Surgeons (MRCVS). Under the proposed changes, the prescriptions of any EEA veterinary surgeon would need to be accepted in the UK, whether or not the veterinary surgeon in question was registered with the RCVS. Furthermore, it would also appear that under proposals a pharmacist in the UK would be required to dispense against the prescriptions of a veterinary surgeon that may have been struck off the Register in the UK, but was practising in another country.

Given that prescribing POM-V medicines is classified as an act of veterinary surgery it is not at all clear how the proposed change to the VMR would fit with the current legislation and regulation governing veterinary surgeons and acts of veterinary surgery in the UK.

Powers of dispensing pharmacist or veterinary surgeon

In human medicine, UK pharmacists must satisfy themselves that a prescription has been written by an EEA practitioner and this will involve checking with the relevant European country's regulator. If they are not satisfied, they do not dispense. The RCVS seeks assurances that should the VMD proposal relating to the dispensing of veterinary prescriptions be adopted, pharmacists and veterinary surgeons would not be required to dispense medicines unless they could satisfy themselves that the prescription came from an appropriately qualified veterinary surgeon who had the right to practise.

Prescription feedback system

The RCVS is strongly in favour of a system whereby prescribing veterinary surgeons are provided with information from pharmacies that allows them to make checks to ensure that the animals under their care are provided with the correct drugs and that the prescriptions they write are being fulfilled and collected. Such a system could also improve the collection of data on adverse reactions as checks could be made on the precise drugs that were issued to the client, the quantity of medicine issued and whether the prescription was collected at all. The RCVS considers that the proposed change to the VMR would significantly increase the difficulties associated with the introduction of such a system.

PROPOSAL SEVEN: REMOVAL OF THE '5% RULE' PERMITTING THE SUPPLY OF PRODUCTS BETWEEN RETAILERS.

The RCVS has significant concerns regarding the proposed removal of the '5% rule' and considers that its removal would be detrimental to animal health and welfare. The '5% rule' allows retailers to act in a wholesale capacity and supply small amounts of products to each other in emergency situations, so long as the amount supplied does not exceed 5% of the medicine related turnover of the retailer.

The current '5% rule' wholesale derogation is routinely used by veterinary surgeons when they need to treat an animal, but, for whatever reason, may have run out of a particular medicine and cannot immediately procure new stock. In such situations veterinary surgeons will often borrow medicines from other local practices or retailers so that they may treat the animal in question. The ability for veterinary surgeons to borrow medicines from one another is especially important in situations where a veterinary surgeon may be dealing with the sudden outbreak of a disease at a weekend or bank holiday.

The RCVS is also aware that some practices effectively use the '5% rule' derogation to put in place arrangements with other local practices whereby they 'share' certain expensive and rarely used medicines, which are more likely to go out of date than to be used. Under such arrangements one practice in the area may buy and store a particular medicine on the understanding that the other local practices would have access to it if necessary.

The RCVS considers that the removal of the '5% rule' would be detrimental to animal health and welfare as it could result in a situation whereby a veterinary surgeon might find themselves unable to treat a particular animal due to having run out of the necessary medicine. Furthermore, removal of the derogation could potentially limit the availability to animals of expensive medicines used for the treatment of rarer conditions.

In the Impact Assessment accompanying the proposals, the VMD states that the reason for proposing the removal of the derogation is that 'some retailers of veterinary medicinal products are making routine use of the 5% exemption and effectively operating a wholesale dealer's business without meeting the relevant requirements and safeguards set out in the VMR and accompanying guidance'. The VMD appears to suggest therefore that the main problem with the '5% rule' is that retailers are not meeting the relevant requirements and safeguards associated with use of the rule. If the RCVS understanding of the issue is correct, then it seems illogical to remove the derogation, which has a positive impact on animal

health and welfare, if the problem relates to non-compliance with the requirements placed on the use of the rule. The College would therefore propose that a form of the '5% rule' should be kept, but that the VMD should find ways to ensure that the requirements related to its use are better enforced and more clearly laid out.

Thank you again for the opportunity to comment on the proposed changes to the VMR, if you require any clarification our comments above, then 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.

Yours sincerely,

Anthony Roberts
RCVS Policy and Public Affairs Officer