Royal College of Veterinary Surgeons

EUROPEAN COMMISSION CONSULTATION ON THE BETTER REGULATION OF VETERINARY PHARMACEUTICALS: HOW TO PUT IN PLACE A SIMPLER LEGAL FRAMEWORK, SAFEGUARDING PUBLIC AND ANIMAL HEALTH WHILE INCREASING THE COMPETITIVENESS OF COMPANIES

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.

1. Data Exclusivity

Data Protection

The RCVS considers that in the main the level of data protection provided by the current legal framework is appropriate. The RCVS is concerned, however, that the current framework applies uniformly to all products and that this can have a detrimental effect on the development of new products for small markets. In the case of medicines for minor species and minor uses, where there is a reduced chance of the pharmaceutical company recouping its research and development costs, a data protection period of at least 13 years may be more appropriate. Such an extended period of data protection could help to improve animal health and welfare by serving to promote the development of new medicines.

Generics

With appropriate data protection periods, the RCVS maintains that generic drugs increase the availability of veterinary pharmaceuticals without adversely affecting research and development and without compromising animal welfare. It is imperative, however, that generic drugs are exact replicas of the original reference products. Furthermore, they must only be issued to clients under suitably controlled conditions such as by an appropriate prescription. This will ensure that the use of generics does not serve to reduce the effectiveness of certain drugs as a result of increased resistance caused by unnecessary use.

2. Authorisation

The RCVS is in principle supportive of the proposal of the Federation of Veterinarians of Europe (FVE) for a 1.1.1.1 system of centralised European-wide authorisation of veterinary medicines. Under this system there would be one dossier, one application and one approval system in one single market. Thus any veterinary medicine that received authorisation would be automatically available throughout Europe.

The RCVS maintains, however, that impact assessments should be made to establish how the implementation of a centralised authorisation system might affect pharmaceutical SMEs that may not currently market certain products in all 27 Member States and the impact that this may in turn

have on the availability of certain existing medicines, and the development and authorisation of new medicines.

ANTIMICROBIALS AND ANTHELMINTICS

The RCVS is concerned that the current legislative framework does not provide adequate controls on the use of antimicrobials or anthelmintics and that this has the potential to adversely affect animal and human health as a result of increased resistance to such products. The RCVS would like to see evidence-based and proportionate controls being placed on the use of antimicrobials and anthelmintics to ensure that their effectiveness is preserved.

The RCVS is particularly concerned that there is widespread evidence of extensive, multiple resistance to anthelmintics in cattle, sheep and horses. Therefore the RCVS maintains that Member States should be given additional powers to place restrictions on the use of certain antimicrobials and anthelmintics in certain circumstances, as resistance to such products often occurs in specific, often small, geographic areas or even within individual herds or farms.

3. Packaging and Labelling

The RCVS considers that that the current labelling requirements should be simplified and made more flexible. The current regulations may be viewed as being unnecessarily burdensome especially in cases where medicines are dispensed under the direct supervision of veterinary surgeons or pharmacists and where it can be established that directions are understood and that the medicines are being dispensed appropriately. More detailed labelling and direction, however, may be useful where internet pharmacies are concerned and verbal directions cannot be given and the comprehension of the recipient cannot be assessed.

The RCVS proposes that the use of universal symbols and the standardisation of labelling across Member States could simplify distribution and reduce unnecessary variations in packaging. This could reduce costs for manufacturers and increase the availability of medicines for clients.

PACK SIZES

The RCVS supports a system whereby the licensing requirements relating to changes in pack sizes are made more flexible and the burdens upon pharmaceutical companies wishing to introduce new pack sizes are reduced. The RCVS maintains that greater flexibility of pack sizes would have a positive impact on animal health and welfare as it would help to ensure that clients are only provided with the correct dosage of medicines required for their animals. Thus reducing incidents of clients 'self-prescribing' left-over drugs to the same or other animals and reducing the inappropriate disposal of leftover medicines. Furthermore, more flexible pack-sizes could lead to improvements in pharmacovigilance as it would be easier to establish the quantity of medicines that are actually used by animals in addition to the amount of medicines that have been prescribed.

4. PHARMACOVIGILANCE AND MONITORING

The RCVS supports the view of the VMD that a pharmacovigilance master file should be introduced as this would serve to rationalise the submission of periodic safety update reports. The RCVS also supports the VMD proposal that member states should be able to request information on resistance that may have developed to antimicrobials and other products.

5. DISTRIBUTION CHANNELS

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. In the UK a similar system is already in operation for the distribution of prescription medicines for human use.

6. Off-label Use

The cascade system remains an important tool for veterinary surgeons and serves to allow the treatment of minor species or conditions where the size of the market may have precluded the development of specific medicines. The current cascade system is not, however, applied uniformly to all products in all member states. The RCVS considers that the system needs to be updated and applied in a fashion that reflects risk assessments, especially where animal health and welfare can be improved with very little risk to human health.

The RCVS considers that there should be greater leniency across Europe when it comes to the off-label usage of medicines for non-food species. Furthermore, the RCVS is supportive of proposals for greater flexibility and a risk-based approach to withdrawal periods for off-label medicine use in food-animals. Standard withdrawal periods should be set in such as way as to protect human health, whilst at the same time ensuring the withdrawal period is not so long as to preclude the use of the medicine.

7. Existing Products

The RCVS is concerned that an unnecessary burden should not be placed on drugs which were authorised under older, less rigorous regimes, but which have been used in veterinary medicines for many years with no significant reported side-effects, as this could have the potential to result in effective medicines, for which there may be no substitute available, being withdrawn from the market. To this end the RCVS supports the proposal of the VMD that some authorised medicines should undergo risk-based harmonisation, but that this should not be compulsory for all products.

.