INTRODUCTION

The BVA is pleased to offer the following comments on the financial implications for members arising from proposed changes to legislation arising out of Review 2001. We would like to point out, however, that consultation with members has been difficult and based on oral presentations from VMD rather than written documents other than the amending Directive 2004/28/EC and the Marsh and Competition Commission Reports. In the circumstances our submission can be neither detailed nor definitive.

COST IMPLICATIONS

1. The BVA represents veterinary surgeons in all areas of veterinary activity but this submission is primarily intended to reflect the cost implications for veterinary surgeons in different types of practice – farm animal, equine, companion animal and other. Most of these are small businesses, and because of this only regulatory change that increases costs will have an affect on a large section of the profession, and on the animal owning public. Although we are not making significant comment on behalf of those employed in the pharmaceutical industry the BVA is concerned that anything that increases the cost of producing veterinary medicines will have an adverse effect on their availability. The BVA would like every care taken to minimise the financial and regulatory burden on veterinary pharmaceutical companies in order to ensure the continued production and availability of veterinary medicines that satisfy the requirements of safety, quality and efficacy.

2. Consultation with some of our key specialist divisions raised the following issues with regard to possible cost implications of the Review of Veterinary Medicines Legislation.

Prescriptions

3. A veterinary consultation may, but does not inevitably, result in the administration, prescribing or dispensing of a medicine: they have to be considered separately as separate actions. BVA considers that the administration, prescription or dispensing of veterinary medicines should be regarded as being an addition to a consultation and that the veterinary surgeon concerned should have the right to charge a separate fee.

4. The BVA strongly supports the maintenance and reinforcement of prescribing controls particularly in view of the importance of antibiotic resistance and the increasing problem of anthelmintic resistance. The BVA view is that the person “professionally qualified” to prescribe must be a veterinary surgeon. This stance is based on ethical, welfare and public health considerations, but it should be recognised that any deviation from this requirement would have a negative impact on income for veterinary businesses, and therefore the viability of veterinary practices in some of the more rural areas of the country.

Medicines Classification

5. While BVA has not seen any firm proposals with regard to medicines classification we are firmly of the view that any dilution of the current definition of a POM would have
a negative impact on veterinary income. BVA is considering this issue and will be making further representations.

Medicines Availability

6. The BVA is encouraged that the opening paragraphs of EU Directive 2004/28/EC demonstrate a clear understanding of the problems associated with availability of veterinary medicines. We would like to make the following additional points:

(a) in terms of medicines availability both the cascade and the clause in the Directive allowing for importation of medicines from other EU countries are useful (Article 10, para 1b ii and Article 11, para 1c) for the veterinary surgeon, and there is likely to be minimal impact on costs for veterinary practices;

(b) Article 6 of Directive 2004/28/EC relates to Marketing Authorisations for veterinary medicinal products and how they are issued. It states that “A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appear in Annexes I, II or III to EEC Regulation 2377/90.” This is a threat to the availability of medicines for horses unless the “non-food horse” is deemed a separate species by means of passport legislation. It should therefore be possible for the VMD to maintain marketing authorisations for most veterinary medicines that are currently available for non-food horses.

There are however restrictions and Article 6 goes on to state that “such veterinary medicinal products shall neither include active substances that appear in Annex IV …nor be intended for use in the treatment of conditions, as detailed in the datasheet, for which a veterinary medicinal product is authorised for animals of the equidae family.” This creates a risk in that existing products may be lost if there is an alternative which does have an MRL and has the same indications. This may lead to market contraction, loss of competition and increased costs for veterinary surgeons and horse owners.

Furthermore, issuing market authorisations for veterinary medicinal products containing substances in Annex IV, even for non-food horses, is precluded under Article 6. It is possible that this will mean the loss of the currently licensed equine Metronidazole and although the substance might continue to be accessible under the cascade for non-food horses, the cost is likely to be higher.

Record Keeping Requirements

7. The record keeping requirements in Article 66 of Directive 2004/28/EC are likely to impose a cost burden on veterinary businesses, though the significance of that burden will depend on the interpretation of “adequate records” under the Directive. If we interpret this as keeping of invoices and other paperwork generated as part of normal business activities the impact will be minimal. On the other hand, if the veterinary surgeon is required to set up a special recording system to enable him/her to separately record activities then there will be set up costs for systems, costs for staff training, internal audits etc.

8. Of all the proposed changes, that for batch number recording potentially has the largest financial impact. A requirement to record batch numbers for all companion animal medicines would require a major investment by most British small animal
practices (which are, of course, the great majority of British practices). We perceive this to be a major expense. Manual recording would be cumbersome and time consuming, and also expensive. A bar code system, if practical, would be prohibitively expensive for a small practice to install. Most existing computer systems would need major upgrades or replacement or change to a new system. The minority of practices without a computer system would probably have to purchase one. All systems would require a considerable input of staff time. Overall, the capital and administration costs, which would have to be passed on to clients, would be considerable. We understand that such a recording system is currently not even a requirement for human medicines and, whilst we understand the need for detailed recording in the case of food animals, we consider the costs far outweigh any benefits in the case of non-food animals.

9. If further controls are placed on the disposal of unwanted medicines there will be additional costs in terms of time, payments to contractors and (potentially) technology for record keeping.

CONCLUSION

10. The issues that we have identified in this submission are, at your request, not that detailed but nevertheless we hope they provide a useful indication of our memberships initial concerns. What is clear is that any cost burden placed on the veterinary surgeon will be passed down the line to the animal owner and, given that veterinary surgeons may only prescribe for animals under their care, there are limits to the economies of scale that can be achieved. One estimate we have received suggests that the dispensing fee for each item would have to rise by £1.60 to cover additional record keeping costs.

NOTE

The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom and represents over 10,000 members. Our chief interest is to protect and promote the interests of the veterinary profession in this country and we therefore take a keen interest in all issues affecting the veterinary profession, be they animal health, animal welfare, public health or employment concerns.

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