

Review of Veterinary Medicines Legislation

Introduction

Veterinary Ireland, the representative organisation of the profession, has been invited to meet Department of Agriculture & Food officials on Thursday 19 February 2004 to review Department proposals on revisions to Veterinary Medicines Legislation, which were circulated on 16 February 2004.

We note that following this round of meetings with stakeholders that the Department will outline its proposals to the Animal Remedies Consultative Committee.

Veterinary Ireland has serious concerns about these proposals and has outlined these below – and has also presented alternative proposals where considered appropriate.

(1) Department Proposal

- Removal of the general requirement on veterinary practitioners to clinically examine animals before prescribing, thus according greater weight to professional judgement in relation to diagnosis and prescription. At the same time, it is intended to retain the requirement for a 'bona fide' relationship between practitioner and client as the context within which prescriptions will be issued;

Veterinary Ireland Comments

Veterinary Ireland is wholly unhappy with this proposal. Nobody could conclude that removing the requirement for clinical examination accords greater weight to professional judgement. It might accord greater weight to judgement of the farmer but that's about all. This statement removes the link between diagnosis and treatment which is unjustifiable and possibly encourages inappropriate use of medicines which is in conflict with good veterinary practice to say nothing about consumer protection and minimising onset of increased resistance to antibiotics and anti-parasitics.

Veterinary Ireland Proposal

A provision should be made in the Animal Remedies Regulations for a veterinarian and their bona fide client (as defined in S.I. 179 of 1996 and in Regulation 44 thereof) to put in place an audited animal health programme for food producing animals. The animal health programme would require visits sufficiently often to allow the veterinarian to be aware of the current animal health status of animals on the farm of his / her bona fide client.

Two divisions should be made for animal remedies supplied under prescription control:

- Class 1 POM would require the veterinarian to meet all of the criteria outlined in Regulation 45 taking into account Regulation 44 and other relevant regulations.
- Class 2 POM would require advice by the veterinarian without the need for meeting the requirements of Regulation 45 c(i) (i.e. without the need for immediate prior clinical examination) before the sale is completed. These Class 2 POM category medicines to be used within the next stated period in the animal health programme should be written and signed into the programme by the vet. The supply of such medicines could be



completed either by the bona fide vet or by a pharmacist, from a pharmacy, on foot of the protocol agreed in the programme.

(2) Department Proposal

- A new requirement that veterinary practitioners must in all cases issue written prescriptions and if the practitioner supplies the medicine that he/she issues the client with an invoice for supplying the product which is distinct from the invoice in respect of the provision of professional services;

Veterinary Ireland Comments

This is a workable way of providing a paper trail for all animal medicines for use in food-producing species. Under the current system, the animal remedies register is the most unused document on the farm except the herd register part of it. Whether or not this additional paper work is charged for, is a matter, which will probably be dealt with subsequently.

Veterinary Ireland Proposal

Full consideration should be given to this added element of bureaucracy as it could result in increased costs (such as an additional charge or a higher rate of VAT) for farmers.

(3) Department Proposal

- Amendment of the 1996 Regulations to remove the exception for intramammaries from the general rules on antibiotics and also to decouple intramammaries from controls under Poisons legislation;

Veterinary Ireland Comment

Veterinary Ireland foresees no difficulty with this as long as they are categorised as class 2 POM's and can only be supplied if there is an operational mastitis control programme on the farm as part of the Herd Health Management Programme.

Veterinary Ireland Proposal

Intramammaries to be treated as Class 2 POM's.

(4) Department Proposal

- Provision that prescribed veterinary medicines may, with certain exceptions, henceforth be supplied by Licensed Merchant outlets (with appropriately trained personnel) as well as by pharmacies and veterinarians. Such exceptions would, for example, apply to injectible antibiotics and sedatives. In addition, breaking of packaging on non-sterile products would continue to be reserved to pharmacies. Provide for improved record-keeping in respect of medicines;



Veterinary Ireland Comments

Veterinary Ireland does not support this proposal under any circumstances. The filling of prescriptions is too serious an issue to allow it to be dealt with by merchants who have been given minimal training. Vets and pharmacists spend many years studying pharmacology etc. and this proposal completely white washes this and demeans the whole concept of writing a prescription. Prescribing products carries quite a degree of legal responsibility and to have merchants fill scripts would, in our opinion, be irresponsible. It could place client animals at risk from incorrectly interpreted prescriptions and cannot be supported in light of our oath to uphold the welfare of animals. It also places the consumer at risk if inappropriate medicines were supplied. On certain occasions, in human medicine, pharmacists refuse to supply scripts on the basis of doctors making errors in dosage, product name etc. Presumably it is conceivable when supply is divorced from the vet, the same could happen, so the double check system, where the vet is supported by another professional interpreting their prescription, is just as essential on the veterinary side, especially in circumstances where supply is divorced from the vet. Improved record keeping is of course a desirable objective.

Veterinary Ireland Proposal

This change should not be implemented.

(5) Department Proposal

- In the light of the foregoing changes, removal of the 'Prescription Only Exempt' category from the sales categories provided for in the legislation;

Veterinary Ireland Comment

Veterinary Ireland agrees with this as long as the proposals for a two-tier POM system are implemented.

Veterinary Ireland Proposal

Prescription Only Exempt medicines should all be treated as Class 2 POM's. Similarly LM category medicines should be treated as Class 2 POM's

(6) Department Proposal

- Designation of the Irish Medicines Board (IMB) as competent authority for veterinary vaccines, in addition to its existing role for other medicines. The Minister for Agriculture and Food would, however, continue to exercise control on the use of vaccines for certain diseases in accordance with SI No. 528/2002.

Veterinary Ireland Comment

Veterinary Ireland agrees with this proposal.