Laboratory Animals Veterinary Association

Guidance to Named Veterinary Surgeons

The control of acquisition, supply, administration (use), storage and disposal of medicines in establishments licensed under the Animals (Scientific Procedures) Act 1986

Several pieces of legislation control medicinal products and other drugs to be administered to animals. Generally the Veterinary Medicines Regulations (VMR) restrict the final supply and direction for use of many drugs and prescription only medicines to veterinary surgeons. However, these restrictions in do not apply in respect of medicines used in the course of a procedure licensed under the Animals (Scientific Procedures) Act (ASPA). The Veterinary Medicines Regulations allow researchers themselves to legally acquire and use the medicines needed in the course of their research.

This exemption in the VMR requires that the researchers assume responsibility for the acquisition, directions for use, storage and safe disposal of these medicines. Therefore, controls should be in place at Licensed User Breeder and Supplier Establishments to ensure that medicines are used appropriately, and that there are adequate arrangements for handling, storage, disposal, stock control and auditing. Since all the involved parties are responsible to the Establishment Licence Holder, he or she is best placed to ensure that appropriate controls are implemented.

Named Veterinary Surgeons (taken here to include their veterinary clinical colleagues working within Licensed User, Breeder and Supplier Establishments) should be aware of issues that may arise. Particular issues for the NVS include

- Responsibility for acquisition, storage and disposal of medicines.
- Circumstances in which researchers may or may not use medicines independently of veterinary control.

This Guidance is intended only to assist the NVS in interpretation of the current regulations.

The role of the NVS in relation to use of medicines

- Establishment Licence Holders should be aware that the NVS has primary responsibility for medicines for use in all animals that are not being used under the authority of a project licence. Researchers may not authorise any administration of medicine to stock animals.
- Before dispensing medicines, the NVS should have clear knowledge of the animals in which the medicines will be used and should have given advice on the circumstances in which they will be used. The NVS should clearly inform any member of animal care staff to whom the medicines are dispensed on how they should be administered, stored and ultimately disposed of. The recipient of the medicines should then assume these responsibilities. The NVS should record the transactions. In cases where an animal is under procedure it would be prudent for the NVS to consult with licensees before treatment is administered to ensure scientific objectives will not be compromised by such treatments
- Where medicines or other substances are central to the scientific purpose and not given for the benefit of the animal it may be inappropriate or not necessary for the NVS to advise. In this situation the responsibility for use of the medicine rests entirely with the Project Licence Holder. Where medicines are used during regulated procedures to facilitate their conduct, such as anaesthetics, the advice of the NVS should be obtained by the Project Licence Holder during the planning stage and a management plan agreed. However, the responsibility for the use of the medicines in this situation rests with the Project Licence Holder.
- Management of expected adverse effects of a procedure, such as pain, is an integral part of the scientific procedure. The advice of the NVS should be obtained by the Project Licence Holder during the planning stage and a management plan agreed, which may include the administration of medicines. However, the responsibility for the medicines rests with the

Project Licence Holder and authority for their use should exist in the project licence. NVS advice may be needed to assess whether the expected adverse event and treatment as stated in the project licence is consistent with the observed clinical signs.

- When it is appropriate to treat unexpected adverse effects of a scientific procedure (which will require an assessment/ diagnosis by the NVS), the NVS should provide such treatment, including necessary medicines. In such circumstances it would be prudent, as noted above, for the NVS to consult with licensees before treatment is administered to ensure scientific objectives will not be compromised by such treatments.
- In animals that are being used in scientific procedures under project licence authority the NVS is responsible for medicines for the treatment of incidental illness or injury. In such circumstances it would be prudent, as noted above, for the NVS to consult with licensees before treatment is administered to ensure scientific objectives will not be compromised.
- At places other than licensed establishments (POLEs) used for licensed programmes of work (for example, farms), when animals are not being used in scientific procedures under project licence authority they will be under the care of a veterinary surgeon (who will not necessarily be the NVS).
- The VMR regulations do not prevent the NVS from acquiring some or all medicines on behalf of researchers. Should the NVS and the Establishment Licence Holder agree to allow such arrangements the NVS should obtain unequivocal statements on the transfer of responsibilities for the medicines to the researcher during the chain of acquisition, receipt, storage, giving directions for use, administration and disposal.

References

1. Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (2014)

2. RCVS Guide to Professional Conduct (current edition)

3. LAVA Information to Establishment Licence Holders and Licensees: The control of acquisition, supply, administration (use), storage and disposal of medicines in establishments licensed under the Animals (Scientific Procedures) Act 1986

4. Veterinary Medicines Regulations 2013