Laboratory Animals Veterinary Association

Information to Establishment Licence Holders and Licensees

The control of acquisition, supply, administration (use), storage and disposal of medicines in establishments designated under the Animals (Scientific Procedures) Act1986

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 the Regulations also allow researchers themselves to legally acquire and use the medicines needed in the course of their research provided they are used in the course of a procedure licensed under the Animals (Scientific Procedures) Act (ASPA). This authority has important 'knock on' consequences that Establishment Licence Holders should be aware of.

There are circumstances when there are restrictions to the administration of products even in the course of a procedure licensed under ASPA and these are listed in the box below.

Researchers acquiring and using medicines assume responsibility for directing 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.

This document offers some suggestions to Establishment Licence Holders with some advice on how these requirements may be implemented within their Licensed User, Breeder and Suppler Establishment. It is the responsibility of those who administer veterinary medicinal products during the course of a procedure to ensure that appropriate controls and records are in place. As the Project Licence Holder is responsible for directing the program of work, he/she would assume this responsibility for the direction of medicines used. The Named Veterinary Surgeon is responsible for the control, supply and use of medicines for therapeutic use on protected animals within the establishment. The Laboratory Animals Veterinary Association (LAVA) has produced guidance to assist Named Veterinary Surgeons when prescribing medicines at Licensed User, Breeder and Supplier Establishments.

For reference, Regulation 3 of the VMR states '*They do not apply in relation to a product intended for administration in the course of a procedure licensed under the Animals (Scientific Procedures) Act 1986, except that, if the animals are to be put into the human food chain, the only products that may be administered to the animals are (a) authorised veterinary medicinal products administered in accordance with their marketing authorisation; or (b) products administered in accordance with an animal test certificate.'*

The combination of Regulations 3, 26 and 27 exempt researchers from the VMR for all aspects of the chain of acquisition, supply and use of medicines. As acquisition, supply, administration is permitted it therefore follows that the researchers are also responsible for the safe storage and disposal of such medicines.

The only exception to the disapplication of the VMR is the acquisition of medicines from abroad and that is partly because the Veterinary Medicines Directorate (VMD) has a responsibility for control of imported products and particularly needs to track antimicrobials and banned substances. It also permits the VMD to facilitate research by providing a route to import a product or substance to be used in research. If a medicine is not available in the UK a Project Licence Holder may apply on-line for a Research Import Certificate (RIC) by searching for VMD on GOV.UK.

The role of the Establishment Licence Holder

- The Establishment Licence Holder represents the governing authority of the establishment. He or she is responsible for the performance of Named Veterinary Surgeons and Named Animal Care and Welfare Officers. He or she must also ensure that appropriate care is provided for each animal, which includes the appropriate use of medicines, and must take steps to prevent unauthorised procedures, which would include administration of medicines by researchers without project licence authority.□
- Establishment Licence Holders may wish to remind Project Licence Holders that medicines used in the course of regulated procedures fall under ASPA and therefore researchers are responsible for acquisition, supply, administration (use), storage and disposal of such medicines. As Project Licence Holders have overall responsibility for the programme of work, this extends to the medicines used in the course of licensed work. Project Licence Holders should also be aware that although they might delegate the ordering of medicines to other researchers, they hold responsibility and are therefore strongly advised to keep adequate records
- To ensure high standards of welfare and care and to promote good science Establishment Licence Holders should ensure that NVS advice is sought during the planning of studies and at other times when appropriate or necessary (Ref. 3.13.7 and 5.23.1 of the Guidance to ASPA). NVS advice is particularly necessary regarding the appropriate use of medicines used to facilitate the conduct of procedures, such as anaesthetics, or to control adverse effects, such as analgesics. Establishment Licence Holders should ensure that Project Licence Holders are obliged to seek and take heed of such advice unless there are compelling scientific reasons for not doing so.

Other points

- Licensees should be aware that the disapplication of the VMR is very specific (i.e. medicines that are used in the course of a procedure licensed under ASPA) and that the VMR do apply in any other contexts e.g. in respect of stock animals, and failure to comply would constitute a breach of the VMR. In addition, misuse or abuse of medicines might constitute a breach of the VMR.
- Adequate facilities should be available for the correct storage and disposal of all medicines and drugs administered to animals at the establishment, irrespective of purpose. Under the VMR, dispensing of medicines that have passed their expiry date is an offence. Under ASPA the Secretary of State expects and requires that all of those who are entrusted with authorities under ASPA work to high standards. The Home Office would consider the use of medicinal products after the stated expiry date to be evidence of low standards and poor practice
- Licensees should be aware that the Home Office medicines branch places additional requirements to Controlled (CD) Drugs.
- Although the VMR do not apply to medicines used in the course of regulated procedures it is possible that wholesalers may be unwilling to supply to personnel other than veterinary surgeons. This is an internal issue which should be discussed and resolved locally.

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. 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

4. Veterinary Medicines Regulations 2013