

Memorandum of Understanding between the Veterinary Medicines Directorate and AMTRA

Introduction

1. This memorandum of understanding (MoU) is between the Veterinary Medicines Directorate (VMD) and AMTRA.
2. The MoU is not legally binding and it does not supersede the statutory duties and powers of the participating bodies.

Purpose

3. The purpose of the MoU is to establish an arrangement for the enforcement of the Code of Practice for the registration of premises and suitably qualified persons (SQPs) by the VMD's Animal Medicines Inspectorate (AMI).

Roles & Responsibilities

VMD

The VMD is an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). Its main aim is to protect public health, animal health and promote animal welfare by ensuring the safety, quality and efficacy of all aspects of veterinary medicines in the UK.

The VMD is responsible for the assessment, issue and maintenance of all national marketing authorisations for veterinary medicines in accordance with European and domestic legislation.

The VMD is also responsible for controls on the manufacture and distribution of veterinary medicinal products, and the surveillance for residues of veterinary medicines in animals and animal products. It also provides policy advice to Ministers on matters relating to veterinary medicines.

4. **Animal Medicines Inspectorate (AMI)**
The AMI is part of the VMD with responsibility for approving and inspecting premises that retail supply veterinary medicinal products classified as POM-VPS and NFA-VPS by Suitably Qualified Persons (SQPs), on behalf of the Secretary of State.
5. **AMTRA**
AMTRA is recognised by the Secretary of State as a body that is suitable to maintain a register for suitably qualified persons (SQPs) to prescribe and supply veterinary medicinal products classified POM-VPS and supply veterinary medicinal products classified NFA-VPS. As such, the Secretary of State is satisfied that AMTRA—
 - (a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;

- (b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;
 - (c) maintains a programme of continuing development for persons registered with it;
 - (d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register;
- and that those SQPs registered with AMTRA have passed examinations specified by that body.

Legislation

7. The Veterinary Medicines Regulations.

The classification and retail supply of veterinary medicinal products is regulated by the current Veterinary Medicines Regulations. Veterinary medicines classified POM-VPS and NFA-VPS may only be supplied by a veterinary surgeon, pharmacist or suitably qualified person (SQP) and, in the case of POM-VPS medicines, must be prescribed by one of those persons.

The supply of products permitted to be supplied by an SQP must take place from premises approved by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products. When supplying POM-VPS or NFA-VPS medicines, a suitably qualified person must either—

- a) hand over or despatch the product himself;
- b) ensure that, when the product is handed over or despatched, he is in a position so that he can intervene if necessary; or
- c) check the product after it has been allocated for supply to a customer, and satisfy himself that the person handing over or dispatching it is competent to do so.

The SQP must also comply with record-keeping and storage requirements set out in the Regulations.

8. Code of Practice for the Registration of Retail Premises and Suitably Qualified Persons (SQPs).

The Veterinary Medicines Regulations state that the Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph shall ensure that a suitably qualified person registered with it complies with the Code of Practice.

The Code of Practice sets down the standards that must be complied with by:-

- i. bodies that have been approved to be suitable to provide training and registration for Suitably Qualified Persons (SQPs) by the Secretary of State;
- ii. SQPs who are registered with an approved body having passed the required examinations and who may therefore supply veterinary medicinal products classified as POM - VPS and NFA - VPS, or
- iii. retail businesses with premises that are approved to be able to hold and supply veterinary medicinal products.

It also sets down guidance on the ways in which approval or registration can be obtained.

Arrangements for enforcement of the COP by the AMI

9. Whilst the AMI has responsibility of approving and inspecting premises from which SQPs may retail supply POM-VPS and NFA-VPS medicines, it is AMTRA's responsibility for ensuring that suitably qualified persons comply with the Code of Practice. This MoU:
 - b. extends the inspection role of the AMI under the Regulations to those additional requirements set out in the Code of Practice; and
 - c. permits an Inspector who has reasonable cause to believe that an SQP is failing to comply with the Regulations or Code of Practice, to refer that person to AMTRA.
10. Where an Inspector refers an SQP to AMTRA under b. above, the referral will be made in writing and set out the Inspector's grounds for believing that the SQP is failing to comply with the Regulations or Code of Practice.
11. AMTRA will deal with the referral according to its "disciplinary procedures" and inform the AMI of its outcome. [If required Inspectors will attend disciplinary hearings by prior agreement and will carry out visits to premises on behalf of AMTRA to check on compliance with the Code of practice, subject to suitable financial reimbursement].

Other Issues:

12. On a monthly basis AMTRA will provide a list of registered SQPs to the VMD and the AMI in an agreed format. The list provided to the VMD will be published on the VMD website. The list provided to the AMI will be used for the purpose of enforcing the Veterinary Medicines Regulations and Code of Practice. The VMD and AMI will treat the lists provided in confidence and not disclose it to any other party except with the express agreement of AMTRA. AMTRA will provide the information in the form of a Microsoft Access database and/or Microsoft Excel spreadsheet. Changes to this format will only be made in agreement with the VMD.

Costs:

13. The costs of attendance of AMI Inspectors at AMTRA disciplinary hearings or visits made by AMI Inspectors to a premises on behalf of AMTRA will be charged at actual salary, travelling and subsistence costs as set out in Appendix A (or could be a fixed daily rate?).

Review of the MoU

14. The MoU will be reviewed as part of the annual review of the Veterinary Medicines Regulations or upon request.

Signed

Signed

On behalf of VMD

On behalf of AMTRA

Appendix A

Reimbursement of costs incurred by the AMI in meeting the arrangements set out in the MoU

Travel:

Car 10ppm

Rail – actual cost of 2nd class travel

Buses/taxis – actual costs not exceeding £10 per journey

Air – actual cost of travel

Subsistence

Salary *

Overnight accommodation – actual costs up to £75 (£100 in London)

Overnight subsistence £25

Lunch allowance £4.25

*Alternatively – a flat rate allowance per day/half-day of attendance