

## Objective 2

**Ensure that UK policy objectives are reflected in EC legislation and that UK legislation and guidance ensures that veterinary medicines can be used effectively and safely, offering protection to human health, animal health and welfare and the environment**

**Prepare plans for Official Feed and Food Controls (OFFC) audit arrangements for medicated feed additives and residues surveillance by 1 October 2006.**

Under the OFFCs each Member State is required to prepare a 'multi-annual' national control plan. This is essentially a strategic plan setting out the national monitoring and enforcement arrangements, objectives and priorities. It describes the roles and responsibilities of the various competent authorities and provides details of how the various requirements of the Regulation are being met. The plan is a single integrated plan covering arrangements for monitoring and enforcement not only of feed and food law but also animal health and animal welfare rules, as well as plant health controls.

The feed and food elements of the plan are achieved by means of the existing monitoring returns with any necessary amendments to meet the new EU requirements. The VMD's Residues Team and its Medicated Feed Additives Team contributed by drafting the relevant sections of the plan that related to the enforcement and control activities which are consequent to the VMD's surveillance programmes and inspections carried out by the AMI. They met their deadlines and the whole plan was completed by 1 January 2007, with regular updates thereafter.

**Review of the role of the AMI by 31 March 2007.  
Approve and register manufacturers and suppliers of medicated feed additives and SQP suppliers of POM VPS medicines as required by agreed standard operating procedures (SOPs).**

The AMI became part of the VMD on 1 January 2006, following a TUPE transfer from the Royal Pharmaceutical Society of Great Britain. The Inspectorate, which was formerly a branch within the Society's Fitness to Practice and Legal Affairs Directorate, was originally formed in 1988 to register and inspect manufacturers of medicated animal feedingstuffs at the request of MAFF. The Society was already involved in the agricultural sector at that time, as it was responsible for the registration and inspection of agricultural merchants and saddlers retailing PML classified veterinary medicines, under its duty to enforce section 52 of the Medicines Act 1968 (the retail sale of medicines not on a general sales list).

The mutual agreement to transfer the AMI into the VMD was due to the Inspectorate not fitting in with plans for the restructuring of the Society and the introduction of the Veterinary Medicines Regulations 2005, which disappplied the Medicines Act 1968, and therefore the Society's duty, in relation to veterinary medicines.

The Inspectorate comprises two office staff based at its Stoneleigh Park headquarters in Warwickshire, and five regionally based Inspectors, one of whom also heads the department. Its role continues to be the approval and inspection of those businesses retailing POM-VPS and NFA-VPS medicines by Suitably Qualified Persons and those manufacturers and distributors of animal feedingstuffs' products regulated by Schedule 5 of the Veterinary Medicines Regulations. In addition, Inspectors visit trade shows and exhibitions to ensure that unauthorised products are not being marketed, as well as conducting investigations into veterinary medicines or specified feed additive residues in human foods potentially arising from deficiencies in the manufacture or distribution of animal feedingstuffs.

During the year, the Inspectorate carried out a total of 1,698 routine inspections of approved premises against a target of 1,799 (94.4%), as well as 181 other visits, including 20 visits to trade exhibitions and 11 residue investigations.

A review of the role of the AMI was carried out during the latter part of the year and the recommendations arising from the review are currently being considered by the VMD.

### Prepare antimicrobial sales data report<sup>29</sup> for 2005 and make available on the VMD website by 31 December 2006.

Antimicrobial resistance is a serious problem in human medicine resulting in increasing concerns about the use of antimicrobial products in human medicine, veterinary medicine, animal production, agriculture and horticulture. The UK Government has made clear that it takes this problem seriously and has developed a comprehensive strategy to address it so that the effectiveness of antimicrobial products in both humans and animals can be maintained. A key element of this strategy is the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK.

For the past eight years, in response to recommendations made by the Advisory Committee on the Microbiological Safety of Food (ACMSF), the VMD's Antimicrobial Resistance Team have collected, collated and published figures on UK sales volumes of active antimicrobial ingredients used in products authorised as veterinary medicines, growth promoters or coccidiostats. The report has been extended over time to include antiprotozoal and antifungal products. The 2006 sales data report was published on the VMD website according to plan. Hard copies are also available.

### Prepare the first overarching report of human and animal antimicrobial sensitivity.

Another recommendation of the ACMSF was that the organisations responsible for monitoring antimicrobial resistance in animals, people and food should work together to produce a report summarising antibiotic resistance in the food chain, in the UK.

The VMD contributes to this initiative by providing the Chair and secretariat for the Defra Antimicrobial Resistance Co-ordination (DARC) Group, which was tasked with providing support for preparation of this report. The VMD, VLA, Defra, HPA, DH, HPS, FSA, and the Devolved Administrations were all involved in drafting what is the first joint report for the UK dealing with public health and food-producing animal health. The report is awaiting clearance for publication. It brings together data on antimicrobial consumption, significant pathogens and their antimicrobial susceptibilities across both fields.

### Continue legal classification review of authorised veterinary medicines.

In March 2006 the VPC agreed to establish a Sub-Group on the Review of the Distribution Categories of Authorised Veterinary Medicinal Products, to provide advice to the VMD on the responses to the consultation on the Government's acceptance of recommendations in the report of the Independent Review of Dispensing by Veterinary Surgeons of Prescription Only Medicines (the Marsh Report) and the Competition Commission<sup>30</sup> report on the supply within the United Kingdom of prescription only veterinary medicines.

The VMD asked for seven groups of products to be considered by the VPC Sub-Group together with documents to explain working procedures. The VPC Sub-Group met in January and March to consider their recommendations for change.

### Establish an EU co-ordination team.

The increasing level of work we carry out at EU level has triggered a review of this sector of our work during the past year. This is work we carry out in conjunction with our colleagues in other Member States and the EMEA, alongside the ongoing development of the EU network of Competent Authorities through the Strategic Plan from the Heads of Medicine Agencies (HMA) and the EMEA Roadmap. We are taking forward this review as part of the VMD's Change Programme, which will lead to changes in 2007 and beyond.

29. You can access the Antimicrobial Sales Data report via [www.vmd.gov.uk](http://www.vmd.gov.uk) under Publications

30. You can find out more about the Competition Commission via the website [www.competition-commission.org.uk](http://www.competition-commission.org.uk)

Continue to publicise the work of the Enforcement Team through attendance at trade shows, county shows and by publishing articles regularly in magazines and journals.

The VMD's Enforcement Team visited sixteen county shows including visits to game fairs to publicise the illegalities of using Emtryl for game-birds. The Team worked closely with game-keeper associations in this area and produced a laminated information sheet on Emtryl which has been widely circulated. They gave a number of presentations on the work of the Enforcement Team to a variety of bodies, including representatives from other Member States, and they continued to publish reports of successful prosecutions in a variety of journals.

