Target 2

To ensure that UK policy objectives are reflected in EC legislation and guidance and that UK legislation and guidance enables veterinary medicines to be used responsibly, effectively and safely.

Revoke and re-make the Veterinary Medicines Regulations (VMRs) and associated guidance to come into force on 1 October 2007 and initiate the project to revoke and remake the Regulations for 2008

The Veterinary Medicines Regulations 2007 came into force on 1 October.

The project for the 2008 Regulations is well underway with the final drafting instructions being completed prior to consultation. Key issues will include whether legislation for controlling the use and storage of controlled drugs post Shipman should be included in the VMRs and formalising the details for veterinary practice registration. Discussions have been held on these with the RCVS, British Veterinary Association (BVA) and Home Office.

Progress the legal classification review of authorised veterinary medicines and implement agreed changes following consultation with stakeholders according to the project plan

Good progress is being made in this complex exercise. All 30 product groups have been reviewed by the VPC sub-group. Consultations on their proposals have either begun or the responses are being considered.

Encourage the responsible use of veterinary medicines through the implementation of a risk-based enforcement strategy working in conjunction with other agencies

Enforcement activity on illegal medicines usage is based on risk assessment in accordance with Hampton. The strategy paper has yet to be published. The paper is drafted; however we are now considering the implementation of risk based inspections, details of which will need to be included within the paper. Publication of the results of Court cases has been implemented in line with the strategy. The number of cases referred to the Defra Investigation Service (DIS) for subsequent legal action is reducing as a result of the introduction of the 'seize and destroy' policy which is also part of the strategy.

Monitor sales of veterinary antimicrobials in the UK by publishing the Antimicrobial Sales Data Report for 2006

The report[27] was published in December 2007.

Ensure the appropriate quality of feedingstuffs containing veterinary medicinal premixes and/or specified feed additives and ensure the appropriate supply of such feedingstuffs and POM-VPS and NFA-VPS medicines, through the approval and risk-based inspection of relevant businesses

The AMI undertook a total of 1,673 visits during 2007/08, comprising 1,379 routine inspections and 294 "other" visits.

The AMI therefore achieved 81% of the planned 1,703 routine inspections. The shortfall was partly due to the significant increase in other visits which are not accounted for in the AMI's planned inspection statistics. The statistics only reflect routine inspections of approved premises.

27. You can access the Antimicrobial Sales Data report via www.vmd.gov.uk under Publications

The 294 other visits were as follows:

153 were investigations into unlawful activities e.g. the illegal importation of VMPs and the unlawful marketing of Small Animal Exemption Scheme (SAES) products; and the investigation of food safety incidents i.e residues of specified feed additives or VMPs in foodstuffs or non-target animal species.

26 visits were made to trade fairs, exhibitions and livestock markets to look for unlawful products.

The remaining 115 were neither a "routine inspection" nor an investigation. Investigations are visits to those persons or businesses allegedly committing serious breaches of the Regulations. These included: "follow up visits" e.g. visits to check that deficiencies drawn to a business' attention at an earlier routine inspection had been rectified; "special visits" e.g. to a feed manufacturer to discuss a labelling deficiency noted on a bag of their feed; visits made at the request of a business e.g. to discuss the Regulations or relevant procedures arising from them; and "check" visits to premises that failed to renew their approval, to establish that they were not operating unlawfully.

The planned number of routine inspections was therefore not achieved for several reasons:

(i) the greater than envisaged number of investigations conducted. Investigations generally take longer to conduct than routine inspections and require far more planning and administration time;

(ii) inspection of "on-farm" feedingstuffs manufacturers i.e. livestock premises was suspended between 8 August 2007 and 5 November 2007 due to FMD; and

(iii) the size of the Inspectorate means that any absences or failure to undertake the required number of inspections by an inspector has a significant effect on inspection figures. During 2007/08, the Head of AMI who has an inspection role, was unable to undertake the required number of inspections due to a greater involvement in Corporate and Policy issues.

A business case for an additional inspector has been made and agreed and is included in the 2008/09 budget.

A Defra audit in March provided substantial assurance that the control framework for Official Feed and Food Controls implemented by the AMI adequately managed and controlled the risks in this area confirming the quality of the AMI's work.

Work with EU colleagues to improve the availability of veterinary medicines to develop and prepare for implementation of an agreed EU strategy and, specifically in the UK, by continuing to implement with industry the exemption scheme for products marketed for use in non-food species as detailed in the legislation

The VMD has continued to participate in the discussions at CVMP linked to defining products that would fall under the definition of limited market and also the discussions surrounding the extension of the EMEA scheme offering free scientific advice.

Comments have been sought from interested parties within the VMD and these have been incorporated into a VMD action plan following up the recommendations of the Task Force on Availability of Veterinary Medicines. A separate action plan for VMD actions is being compiled that will allocate resources and deadlines. The action plan has yet to be completed.

An article has been published in MAVIS highlighting those medicines regularly imported into the UK with the aim of encouraging companies to submit MA applications in the UK.

Industry have been consulted on a paper to identify forms of assistance including financial and non-financial incentives for companies wishing to obtain authorisations for minor market products in the UK. Comments have been analysed and proposals made for the areas to be explored first including: designated personal advisors, VMD training courses for industry, wider use of provisional MAs and staged assessment.

The Schedule 6 SAES was fully implemented in November 2007 in accordance with the VMRs.

Reduce the risk of pollution from sheep dip by implementing agreed actions from the joint VMD/Environment Agency Pollution Reduction Programme for sheep dip

The Pollution Reduction Programme is now nearing completion. Two research studies which investigated ways in which cypermethrin dips could pollute during dipping have been made available to the Pollution Reduction Programme for sheep dip steering group and published on the VMD website. The VMD has also contributed to the development of a Policy Options Appraisal for sheep dip. We have commented on a paper costing the policy options appraisal and a further R&D study to investigate the effects of drying sheep after dipping is underway.

Open negotiations with other Member States and the European Commission to take forward the Cabinet Office initiative on the reduction of administrative burdens to industry

A presentation was made to the Veterinary Pharmaceutical Committee in March and Defra contacts have been asked to attempt to get the changes to the Directive added to their simplification workplan.

The VMD has asked Defra to attempt to add the review of this legislation to proposals for the Commission Simplification Workplan. A meeting with the Defra Regulation team took place on 11 July to provide an update on the Better Regulation initiatives at the VMD. The information was well received and it was noted that this is a long term exercise which will progress slowly.

An agenda item on Simplification of Administrative Burdens in the EU in respect of veterinary medicines has been added to the agendas for meetings with Romania and Poland over the next few months.