

## Objective 2

**Ensure the field use of veterinary medicines is safe and effective by monitoring use by using best practice in pharmacovigilance.**

### Prompt recording of all reports of SARs

#### Expected outcome

To enter human reports onto the database within two working days, serious animal reports within two working days, non-serious reports within ten working days, and forward reports on centrally authorised products to the EMEA within 14 working days.

#### Outcome

These targets were met.

#### Evaluated by

Performance was monitored by monthly performance reports to the CEO and senior staff, and reports to the Management Board.

### Detection and reporting of trends and signals from SAR reports

#### Expected outcome

To monitor the database for emerging trends and signals, reporting results to the VMD's Alert Group and the VPC on a bi-monthly basis together with ad hoc reports as required.

#### Outcome

Reports of all serious and non-serious SARs in animals, cases involving suspected lack of efficacy, and human SARs were collated and presented for consideration by the Alert Group and the VPC on alternate months throughout the year. Ad hoc reports on the following subjects were also considered by the Alert Group during the year:

- animal SARs involving immune system disorders;
- SARs in dogs involving immune system disorders associated with a particular vaccine;
- animal SARs involving a palatable tablet presentation of a non-steroidal anti-inflammatory drug (NSAID);
- blindness in rabbits associated with a particular antibiotic;
- SARs in llamas;
- SARs in cats following treatment with an anti-hormone agent;
- human SARs involving oral and gastro-intestinal tract reactions to two pour-on products.

As a result of the discussion on the palatable NSAID tablet, the Marketing Authorisation holder was consulted and advice on how to minimise the possibility of accidental ingestion of tablets by dogs and cats was published in The Veterinary Record and made available on the VMD's website.

#### Evaluated by

Prompt and proportionate action was taken in consultation with Marketing Authorisation holders in response to any adverse trends and signals, and the VPC's assessment of reports in terms of accuracy and scientific quality.

## Effective enforcement of regulatory controls on the manufacture, release and distribution of veterinary medicines

### Expected outcome

Regular inspection, to an agreed timetable, of manufacturers of Immunological Veterinary Medicinal Products (IVMPs) to ensure compliance with the principles of Good Manufacturing Practice (GMP), and maintain efficient cost-effective systems for the batch release of immunological products. Prompt responses to requests for specific batch control.

### Outcome

The UK's Quality Assurance/Quality Control (QA/QC) batch release scheme came to an end in 2005 with the last inspection being completed in October. There is currently no EU legislative base for QA/QC audits but the VMD still considers them to be an effective and cost-effective means for controlling the batch release of immunological products in the EU. The team continued to promote the scheme within the EU to highlight the advantage over re-testing batches of immunological products. Re-testing has a significant number of disadvantages including increasing costs and animal usage and adds little value to the tests performed by manufacturers. The VMD has been successful in negotiating a harmonised batch release system for the EU which includes an administrative element of batch control review under Article 81 of the amending Directive. The harmonised scheme is in a pilot phase for 12 months to enable the European Commission, Member States and Industry to evaluate the impact of proposed changes.

Seventeen QA/QC audits were completed in 2005 in the UK, Europe, USA and Canada. A number of these were performed in the presence of observers from other national authorities.

Eight GMP inspections were completed and in addition three test sites and two autogenous vaccine producers were inspected. All were found to comply with the required standards in 2005. One facility in the USA was found not to be in compliance with the EU standards for GMP and the product is no longer accepted from this manufacturer.

Batch release figures for 2005/2006 are listed in the accompanying table:

### Overview of Batch release in 2005/2006

Release Type	Releases
UK	1458
UK EU	130
EU other	21
Emergency Product Licence	78

### Evaluated by

Performance was monitored by monthly performance reports to the Chief Executive and senior staff, and reports to the Management Board.

## Publish summary of SARs information on a quarterly basis on the VMD website

### Expected outcome

The publication of summaries of SARs information on the VMD website on a quarterly basis.

### Outcome

Quarterly summaries of SARs information were published on the VMD website.

### **Evaluated by**

Performance was monitored by the publication of quarterly summaries of SARs information on the VMD website before the end of the month after the end of the previous quarter.

## **Work with the EU network on the implementation of electronic reporting of SARs both from users and industry, and between Member States**

### **Expected outcome**

The implementation of an electronic system within the EU for the exchange of information about suspected adverse reactions between Marketing Authorisation holders, competent authorities and the EMEA.

### **Outcome**

Progress was made in 2005 towards establishing a link between the UK database and the European system. Numerous technical and security issues were overcome.

### **Evaluated by**

The electronic submission of suspected adverse reaction reports via the European network was tested in the latter half of the year and progress reported to the Chief Executive and senior staff.