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Chief Executive’s Foreword

The VMD is an organisation comprising highly trained scientists working alongside colleagues with highly developed competences in non scientific areas. The VMD had another very successful year in 2012/13. We fully delivered the business plan, with in-year savings and reduced costs to both business and the taxpayer, while maintaining services independently assessed as excellent, decreased sickness absence, retaining Investors in People Silver Award and a staff engagement index within the top 20 out of 95 in the Civil Service.

The Annual Review describes our key achievements in assuring the availability of veterinary medicines that can be used safely and with a high degree of expectation that the animal will benefit from the treatment. That the VMD delivers such important work consistently well, often in the face of some serious challenges, is testament to the work of the VMD’s staff and our successful collaboration with all those with an interest in protecting and improving the health of animals.

Professor SP Borriello
Chief Executive
12 August 2013
IMPROVING ANIMAL WELFARE

UK farmers first to get Schmallenberg vaccine

The Schmallenberg virus causes serious birth defects in sheep and cattle that has affected many farms in the UK. When the disease emerged, the pharmaceutical industry in the UK reacted quickly to develop a vaccine against the virus. Our role in the response to the threat that the virus poses to UK livestock has been to work closely with companies developing vaccines to ensure maximum efficiency in the review process. By expediting our assessment processes, the VMD was able to authorise in May 2013 a safe and effective vaccine, ready for use this summer. This meant that UK farmers were the first in the EU to have access to a vaccine against this disease.

New Foot and Mouth Disease (FMD) vaccine

The VMD led work in Europe on an application for an FMD vaccine that used a multi-strain dossier approach, which allows the vaccine to be adapted to the variant of the virus causing the disease outbreak. This was the first time that a recommendation for authorisation across the European Union has been made using this novel approach.

Reducing the need for the testing of vaccines on animals

The VMD has been at the heart of an EU initiative to remove the unnecessary requirement for testing of batches of vaccines on animals before they are approved for supply. This rule change to remove the target animal batch safety test came into effect on 1 April 2013. Well ahead of the change, the VMD encouraged UK marketing authorisation holders to take the necessary steps to comply. To incentivise this work, we simplified the process for varying marketing authorisations to remove the animal testing for batch release and waived the fee. As a result, for UK nationally authorised products the changes have been implemented for most vaccines. This will mean significantly fewer animals a year – about 5,000 fewer a year - will be used in testing.
CONFIDENCE FOR CONSUMERS

Regulating the manufacture, distribution and retail supply of medicines

The VMD provides reassurance that veterinary medicines manufactured and supplied in the UK comply with the law by inspecting premises in the supply chain. During the year we inspected 619 vet practices, 290 retailers, 347 manufacturers and distributors of medicated feeds and undertook 39 investigations into allegations of unlawful activities.

Clamping down on illegal activity - the VMD’s enforcement role

Our aim is to assure the quality, safety and effectiveness of veterinary medicines. Our enforcement activities play an important part in protecting consumers, their animals and the environment from the risk of harm from illegal medicines. The types of enforcement action we take include: simple advice and guidance on how to comply with the law; warning letters; improvement letters and seizure notices. In the most serious cases we will seek to prosecute offenders through the courts.

This year we have been involved in several cases brought under the Proceeds of Crime Act (POCA) to confiscate the proceeds of criminal activity associated with the illegal sale of veterinary medicines. For example, an individual involved in the illegal supply of antibiotics and pigeon products was ordered by the court to pay £31,570. As part of the ongoing work from last year’s successful prosecutions in the Eurovet case, six individuals have been ordered to pay in total over £200,000.

The misuse of veterinary prescriptions is a growing concern. In 2012/13, we dealt with approximately 140 cases of forgery and unauthorised amendments to prescriptions. The purchase of veterinary medicines in this manner is against the law. It also carries a risk to the animal treated since the clinical need for the medicine will not have been professionally diagnosed. In the majority of these cases, we have sent warning letters. In the more serious ones where fraud has been suspected, we have investigated the cases with a view to prosecution. As a result a number of individuals have been convicted; two received jail sentences.

Details of VMD prosecutions, improvement notices and seizure notices are published on our website www.vmd.defra.gov.uk/public/enforcement_notices.aspx.
Helping you to buy safe and effective medicines on the internet – the VMD’s Accredited Internet Retailer Scheme

The VMD launched its Accredited Internet Retailer Scheme (AIRS) on 25 May 2012 in response to concerns about the growth of internet retailing, in particular, the degree to which consumers can be confident that any medicines they buy online to treat their animals are authorised, appropriate, safe and effective. As far as we are aware, this is the first scheme of its kind in Europe. We understand that a number of other countries and the European Commission are keen to learn from the VMD’s example.

The Scheme is free of charge and allows those retailers who meet the accreditation scheme’s criteria to display a special ‘VMD Internet Retailer logo’ with a unique accreditation number on their website. In 2012/13 the VMD accredited 25 websites. The companies whose websites have been accredited include some prominent large retailers of veterinary medicines. This means that a significant number of customers can now have more confidence that they are buying from reputable retailers and have reduced the risks of buying unauthorised, inappropriate, unsafe, or ineffective veterinary medicines. There is further information on the Scheme on the VMD website www.vmd.defra.gov.uk/vet/internetretailers.aspx.

Helping ensure your food is safe to eat – residues surveillance

In the aftermath of the horsemeat scandal at the start of 2013, the VMD led a number of actions with our EU partners to clarify the situation on the presence of the veterinary medicine, phenylbutazone (known as ‘bute’) that had been found in horsemeat and to respond to public concerns about any food safety issues. The VMD was involved in preparing a joint European Medicines Agency/European Food Safety Authority statement clarifying - on the basis of robust scientific evidence - that there were no significant food safety concerns arising from the very low traces of phenylbutazone found in some horsemeat samples.

The Food Standards Agency decided that all horses presented for slaughter for human consumption from 31 January should be tested for the presence of ‘bute’. The VMD liaised with the Agency and the laboratory to ensure that this accelerated testing procedure started efficiently and in accordance with EU requirements.
RESPONSIBLE USE OF MEDICINES

Helping to fight antibiotic resistance

Antimicrobial resistance (AMR) in animals is an issue we take very seriously. It is a complex issue. One thing is certain: responsible use is essential in both human and veterinary medicine. Antibiotics are a key part of the veterinary toolbox for treating disease in farm and in companion animals. From the vets who prescribe them to the animal owners who administer them, everyone should use antibiotics responsibly.

Driving changes in use

We have taken a number of actions this year to ensure the responsible use of antibiotics

- We banned imports of virginiamycin which is used to control laminitis in horses
- We announced a ban on the advertising of antimicrobial products to animal keepers, to come into effect in October 2013
- We issued advice on the use of chlortetracycline (CTC) as an antibiotic in calf milk replacer, confirming its incorporation as an oral powder is illegal.

Educating and persuading

We are working with others to promote responsible use to vets, farmers and pet owners. While we defend the vet’s right to prescribe antibiotics in order to protect animal health and welfare, we emphasize that their use should not replace good farm management and animal husbandry systems. We have published information on our website and in relevant journals about antibiotic use.

We co-sponsored and chaired the debate at the ‘Antimicrobial resistance in human and veterinary medicine: one medicine, one problem?’ symposium which took place in October 2012. The symposium brought together researchers, practitioners and policy makers from both the human and veterinary medical fields to explore the evidence base for antibiotic resistance.

We also worked closely with ‘Farmers Weekly’ to help them prepare their ‘Responsible Use of Medicines’ campaign by providing background information and endorsing their campaign. This campaign was launched in April and attracted a lot of interest from the farming community, generating a productive debate about the importance of using antibiotics responsibly.
Evidence gathering

In October 2012 we published our annual report on the ‘Sales of Antimicrobial products authorised for use as veterinary medicines in the UK in 2011’. This report illustrates the pattern and trends in volumes of antimicrobials sold and is a useful proxy measure for antibiotic use. The report can be seen on our website www.vmd.defra.gov.uk/pharm/antimicrobial_pubs.aspx.

We are aware that we need to build a stronger and clearer evidence base. Emerging findings from research suggest that some longstanding husbandry practices commonly in place in the UK and EU may need to be revised. In addition, incidences of resistance in animal pathogens which have a serious impact on animal health and welfare – e.g. swine dysentery – underscore the importance of taking effective action. We need to make sure any activities we undertake are based on evidence in order to ensure that they have maximum impact with minimal unintended consequences.

Linking across government and across Europe

Defra and the VMD work closely with other government departments and the devolved administrations, including the Department of Health and Food Standards Agency, to provide a coherent approach on the issue of AMR. This has included close collaboration on developing the new cross-government AMR strategy which will bring a greater focus to human and veterinary work to combat antimicrobial resistance. The strategy, which will be published later this year, aims to limit the risks associated with AMR and minimise its impact on human and animal health.

As part of our role in Europe we have led on the initiative to revoke the marketing authorisation of certain combination antibiotic products, chair the new European Committee to assess the impact on human and animal health of antibiotic use in animals and have led on establishing the principles and components of a European scheme for surveillance of antibiotic resistance in bacteria causing animal infections.
DELIVERING A QUALITY SERVICE

Continuing to perform excellently against our published standards for authorising medicines

The VMD’s performance in relation to its published standards for new marketing authorisation applications, variations and renewals were all rated as excellent against our published targets.

During 2012/13 the VMD issued 155 new marketing authorisations, approved 60 renewals and approved a total of 504 variations. 1,759 sets of documentation were issued of which 1,707 were right first time, giving an effective rating at 97%.

To give a flavour of the types and numbers of other applications processed, the VMD issued 2,243 immunological batch release requests, 22 animal test certificates and 85 specific batch control requests. All 32 targets and key steps relating to centralised, mutual recognition and decentralised procedures met the excellent criterion.

At the end of the assessment procedure for a new marketing authorisation or a variation to a marketing authorisation, product literature reflecting the authorisation must be signed off by the VMD. To help applicants submit such literature in a way that avoids some common pitfalls, the VMD produced a literature standard. As a result of improved processes the VMD was able to reduce assessment times for sign-off.

At an operational level, the VMD held 50 company meetings and from the resulting questionnaires it is clear that industry welcomes the VMD’s open approach and values the advice offered by VMD staff across all disciplines. We secured the primary assessment role for the submission of applications for new veterinary medicines submitted under European procedures across all the Member States in nearly a third of cases. This is more than any other country and reflects the industry confidence in our scientific assessment and ability to facilitate the procedures in an effective and efficient way.

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The VMD’s Special Import Schemes

In February, the VMD launched the latest upgraded version of its Special Import Site on its website. This site makes it even easier for vets to apply online and free of charge to import a veterinary medicine into the UK from the EU and elsewhere where there is no suitable UK product available and subject to the necessary rigorous checks in place for safe use. During the year we issued a total of 15,920 import certificates. Of these, 11,638 were successfully applied for online.

Supply issues: keeping vets informed and helping them find alternatives

When the VMD becomes aware of a supply issue with a particular product, we work closely with the companies involved in order to identify how long the product will be unavailable, the likely impact, the alternative available product, and communicate this to those using veterinary medicines.

During 2012/13, we dealt with a number of availability issues for products affecting a range of domestic and farm animals. Where supply problems persisted, the VMD permitted the import of an alternative authorised product where necessary either from within the EU or elsewhere. We put information about availability prominently on our website as well as publishing it in the ‘Veterinary Record’ for veterinary surgeons to see.
Improving how we keep you informed

We have a publicity stand which is manned by VMD volunteers. We attended and gave presentations at a number of events, for example - the Animal Health Distributors Association (AHDA) conference, the British Small Animal Veterinary Association (BSAVA) Congress; the Dairy and Livestock event; the British Veterinary Nursing Association (BVNA) Congress; the Pharmacy Show, the London Pet Show, the London Vet Show and Crufts.

These events have been very successful opportunities to engage with a range of our stakeholders (e.g. vets, farmers, animal owners) to explain what we do and to answer their questions. At these events we have also intervened successfully to stop illegal advertising or sale.

We have also given lectures to third year veterinary students at the UK’s vet schools to provide an overview on the regulation of veterinary medicines.

We have continued the routine publication of relevant information tailored to the relevant audience on our website, such as:

- UK Public Assessment Reports (UKPARs)
- Product Update reports published in the Veterinary Record aimed at veterinary surgeons
- MAVIS - VMD’s quarterly publication for industry
- VMD Annual Report and Business Plan
- Information Leaflets and Guidance Notes
- Details of Freedom of Information requests

We have continued this year to keep our stakeholders up to date with what we are doing on issues that affect them including through articles in the veterinary and farming press. We have also responded to high volumes of press and media enquiries regarding topical issues such as the Schmallenberg vaccine, ‘bute’ in horsemeat, organophosphates and antimicrobial resistance.
Reducing burdens on farmers

In order to reduce the burden of inspections on farmers, we entered into a partnership with the Centre for Environment Fisheries and Aquaculture Science (Cefas). Cefas now inspect fish farmers manufacturing medicated feeds on our behalf as part of its fish health inspection visits.

Improving value for money through internal efficiencies

The VMD implemented business change during the year through its Efficiency and Partnership Project Programme (E&PP), its Investors in People re-assessment in June 2012 and the findings from the Civil Service People Surveys in 2011 and 2012. By the end of 12/13, the E&PP had yielded some £120,000 of on-going staff savings.

We achieved additional ‘cash’ and other cross-agency efficiencies through the re-structuring of our corporate and information management support teams. This led to:

- savings by creating a small pool of flexible staff to cover urgent work requirements, long term sickness absence, maternity cover and other resource gaps across the VMD – work that we had historically covered with more expensive short term ‘agency’ staff;
- savings through buying and using our stationery more smartly
- more efficient invoicing and sample delivery in our residues surveillance programmes and
- savings from circulating scientific periodicals to staff electronically.

We also continued to become more efficient and productive by streamlining and digitizing our working methods. We now issue authorisation documents electronically and have rolled out e-filing across the VMD. This demonstrates how we are delivering the Government’s digital initiative as well as making a difference for our stakeholders.

Through this rigorous attention to improving our operational efficiency we have further helped to reduce the administrative burden on industry, deliver reduced annual fees for industry and improve the service we provide to our stakeholders.
Annex 1

Finance

Income:

- £7.3m
- £2.9m
- £3.8m

Expenditure by type:

- £7.3m
- £3.7m
- £0.8m

- Veterinary Pharmaceutical Industry
- Food Industry
- Government
- Staff
- Sub-contracted residues surveillance
- Defra overheads
- Sub-contracted AMR surveillance
- Depreciation
- IT systems maintenance
- Travel
- Legal Fees
- Stationery and publications
- Communications
- Independent expert committees
- Other
The year at a glance

April to June 2012

- Accredited Retailer Scheme launched on the 25 May 2012
- New VMD information leaflet: Veterinary Medicines Advice for Pharmacists
- VMD Business Plan for 2012/15 received Ministerial approval
- VMD Residues Unit visited Bosnia Herzegovinia – leading to improvement in their surveillance programme

July to September 2012

- Study visit from the Croatian Veterinary Institute to help them prepare for accession to the EU
- Launch of upgraded online Product Information Database
- Authorisation for import of E.coli O157 vaccine for use on open farms via the Special Treatment Certificate Scheme
- Publication of Best Practice guidance for Medicated Feedingstuffs Prescriptions

October to December 2012

- Published summary of Pharmaceutical Industry Customer Survey: Update on addressing areas of improvement
- Published summary of information gathering exercise on misuse of veterinary prescriptions: Next steps
- The VMD and Veterinary Products Committee Open meeting
- Colleagues from the Residues Surveillance Unit visit to Jordan on a TAIEX (Technical Assistance and Information Exchange Agreement) Mission on behalf of the European Commission

January to March 2013

- Upgraded Special Imports website launched 4 February 2013
- Published results of VMD Website User Survey
- Launch of formal public consultation on revision to 2013 Veterinary Medicines Regulations
- Launch of new VMD export certificate online application site

This annual review highlights just some of what the VMD has achieved in 2012/13. You can read more about the overall performance of the VMD in our Annual Report and Accounts.