Veterinary medicines — a not-to-be-missed opportunity for pharmacy

At a time when traditional over-the-counter business for community pharmacy has been in decline for many years, Andrew Evans takes a look at how veterinary medicines are fast becoming a professional range that may fill the gap

Community pharmacies are in search of something to offer customers to fill the gap left by toiletries and, recently, medicine sales, which are drifting away to grocery retailers. Once a niche market, veterinary medicines are fast becoming a professional range that may fill that gap.

Veterinary medicines are not a unique range of new compounds. A pharmacist's knowledge is equally as valid when it comes to veterinary medicines as it is in human medicines. Of course, the knowledge about their application within different animal species is something you will have to investigate. However there are excellent resource materials and postgraduate courses (see p340) that will help accomplish this competency.

Community pharmacies are visited by a huge number of pet owners every day. These are not new customers, but regular patients. Veterinary medicines can sell in many different places (eg, market towns, housing estates or city centres, literally anywhere).

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What types of product should I sell?

You should start with the obvious animals. Dogs and cats are ubiquitous. Concentrate on the main prophylactic medicines for fleas and worms. These do not require diagnosis (which only a veterinary surgeon or pet owner is allowed to do) and represent some of the veterinary products with the largest market share.

The cat and dog wormer market is estimated to be worth £39m at retail prices, while the cat and dog flea market is estimated to be £113m. Other simple, common ailments should also be considered: oral and aural hygiene, and digestion and skin products can all complement your range. Once your cat and dog pet section becomes established, you will find that requests for products from other pet owners will more than likely follow.

Try to pick products and brands that the customer would associate with veterinary surgeries and not products that they would associate with the supermarket. This will help reinforce the professionalism with which you sell all types of medicine.

Pharmacy business

Selling veterinary medicines can help strengthen the message that a pharmacy is the place to go to buy medicines and obtain professional advice. The margins available on most veterinary medicines are comparable to or better than those on human over-the-counter medicines. According to an independent survey on veterinary medicines prices published in September 2010 by The Best Organisation, pharmacy prices faired extremely well against those of competitors such as veterinary surgeons, whose prices often exceeded those in pharmacies by 100 per cent, so you can be profitable and competitive.

Pharmacies that have embraced veterinary medicines enthusiastically can achieve remarkable sales, with this category often being in their top five OTC departments, and often out-selling more traditional sections, such as hay fever.

Where to start?

The full line national pharmaceutical wholesalers may carry one or two lines, but none carries a range of veterinary medicines. However, the National Pharmacy Association carries a list of licensed wholesalers that specialise in the wholesale of veterinary medicines. Often, these wholesalers will also offer support and advice on setting up a veterinary section in a community pharmacy, as well as possibly training and promotional material.

Although there is no legal training requirement involved in selling veterinary medicines, there is the obvious obligation for pharmacists to carry out continuing professional development, encompassing areas covered by their practice. A comprehensive selection of courses is available through the Royal Pharmaceutical Society's Veterinary Pharmacy Education Programme. Further information is available at www.vpep.net.

Certain providers of counter staff training also include some modules on veterinary medicines and the importance of your pharmacy assistants feeling confident when selling these cannot be overstated. Initial promotion of your veterinary medicines section should concentrate on informing your existing pharmacy customers that you now stock this product range. Promotional information should be handed out to patients visiting your pharmacy. In fact, many of the major manufacturers have free-of-charge materials available. Your staff could ask regular customers whether they have a pet when engaging them during other services. The combination of these activities, plus window displays and posters, can help raise awareness quickly, leading to successful sales in a new and exciting product category.

Special feature

The quality of veterinary medicines — what is it and why does it matter?

Sarah Cockbill examines how the UK Veterinary Medicines Regulations came about, how consistent quality is ensured in the production of veterinary medicinal products and safeguards that ensure the quality of new veterinary medicines is maintained

In the UK, standards for the safety, quality and efficacy of animal medicines, as for human medicines, were first identified under the auspices of the 1968 Medicines Act. The manufacture, quality control, registration, distribution and packaging of veterinary medicines are now controlled by a plethora of European regulations and directives. These are separate from those pertaining to human medicinal products, but no less demanding. The original Directives 81/851 and 81/852 reflected in many ways the existing UK controls required under the Medicines Act. Since then there have been many changes and new legislation to try to introduce better ways of producing a single process for bringing human and veterinary medicines to the European market. Things began to move on in May 1994, when the Commission of the European Union and the Council of Europe decided to create a network of official medicines control laboratories (OMCLs), designed to be a new collaboration in the area of quality control of marketed medicinal products for human and veterinary use. In 1995, the European Directorate for the Quality of Medicines took on the responsibility of establishing this network.

The OMCLs test the quality of medicinal products for human and veterinary use independently from manufacturers, thus avoiding any conflict of interest. This testing is done in either member and observer states of the convention on the elaboration of a European pharmacopoeia involved in the general activities of the network, or member states of the EU and the European Economic Area and Switzerland, where appropriate.

(Aprescindere/Dreamstime.com)

UK Veterinary Medicines Regulations

It was in 2005, in accordance with EU law and recommendations from the Marsh Report and the Competition Bill — both of which indicated the necessity to make veterinary medicines more accessible to the public — that the UK Veterinary Medicines Regulations were first drafted. As of 30 October 2006, the Medicines Act was disapplied to veterinary medicines and now all aspects related to the licensing and control of animal medicines are defined by the Veterinary Medicines Regulations, which are revised annually. (The 2010 revisions have been delayed due to an extended consultation.)

Safety and efficacy

The issues of safety and efficacy with regard to veterinary medicinal products are beyond the scope of this feature but are, of course, of relevance to those manufacturers that are applying for marketing authorisations for both human and animal medicines. It is a fact that, if appropriate and consistent quality is ensured in the production of medicinal products, then this will also ensure their safety and efficacy.

There are several reference sources used to ensure that the materials used in the manufacture of the products conform to recognised standards and that the products made from these materials are of a quality that can be guaranteed from batch to batch. Quality assurance is defined as "a programme for monitoring the stages of a project to ensure that standards of quality are being met". Products should be manufactured to standards of good manufacturing practice and their production should also be controlled to standards appropriate for their intended use.

GMP, defined as "that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate for their intended use", is largely governed by the Orange Guide, which brings together EU directives and guidance.

Also, existing manufacturing authorisations and the Medicines and Healthcare products Regulatory Agency inspectors dealing with pharmaceutical veterinary medicines have an influence in this area.

Assorted pharmacopoeias are consulted. The European Pharmacopoeia is the most influential and incorporates individual monographs for both active substances and excipients, as well as general monographs covering standards for substances for pharmaceutical use and products, such as tablets. Other pharmacopoeias used include the British Pharmacopoeia, those from other member states such as France and Germany, and those from other parts of the globe such as China and the US.

The Committee for Medicinal Products for Veterinary Use (CVMP) was established by EC Regulation 726/2004 and is responsible for preparing the European Medicines Agency's reports on all questions relating to veterinary medicinal products. The CVMP publishes guidelines related to:

- The form, function and rationale of the product and its development pharmaceutics, which includes decision trees on the selection of any sterilisation method
- Any packaging (eg, pack size, rubber closure integrity and dosing devices)
- The method of manufacture, process validation, use of ionising radiation and the

limitation of use of ethylene oxide in the manufacture of medicinal products

The above list is not exhaustive. There are also CVMP guidelines to cover the starting materials (active substances): where and how they are made and making sure that they are the same each time. Certificates of suitability and the drug master file, together with data related to the material, are required for these ingredients. CVMP guidelines cover the summary of requirements for active substances and the chemistry of any new active substance. There are also guidelines from the International Co-operation on Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH), which is a trilateral (EU-Japan-US) programme launched in 1996, with the aim of harmonising technical requirements for veterinary product registration. VICH guidelines cover residual solvents and impurities in any new active substance, as well as many other areas.

As may be expected, manufacturers are required to demonstrate that the product is made the same way each time so, in any marketing authorisation application, there will need to be a description of the product formula, its method of manufacture, evidence that there has been validation of this method at intervals during the process and at the end. There are many guidelines to cover these. They will also be expected to illustrate that they have carried out transmissible spongiform encephalopathies evaluations on all components, they have used a control, they have done functionality tests for all excipients and they have certificates of analysis for the product. Also, they will need, if necessary, to test intermediate products. This is rare, but is needed if the product is manufactured at a different site from that where it will be put into its final container. In this instance, manufacturers will need to provide evidence of the stability of the product in the temporary container and during storage. They will need to give evidence of the tests performed on the finished product, such as all methods plus their validation, as well as batch analysis data. The manufacturer will also need to provide evidence of the stability of the product. This means checking the product at the end of its shelf-life to confirm that it is still safe and still works. There are VICH and CVMP guidelines to cover tests on the active substance, the finished product, the shelf-life, storage conditions during the stated shelf-life and the retest interval.

Safeguards

It is comforting to know that there are so many safeguards around to ensure that the quality of new veterinary medicines reaching the market is maintained. Apart from obvious animal welfare considerations, it is essential that the human food chain is protected and that undesirable residues in the environment are kept to a minimum. It is only to be hoped that the undeniable high costs of generating data related to the safety, quality and efficacy of new pharmaceutically active veterinary ingredients will not serve to deter manufacturers from progressing their research and marketing new products into a relatively small market place, where a return on their investment may not be seen for many years.

Do you want to learn more? Read on . . .

The Royal Pharmaceutical Society and Harper Adams University College have produced a selection of veterinary pharmacy programmes for those involved with the provision of animal health. Steven Kayne, the course director, explains

There is an ever growing number of companion animals (including horses) in the community, all of which require regular prophylactic treatment in order to control and contain many naturally occurring internal and external parasites, both for animal welfare and public health reasons.

Many aspects of veterinary pharmacy are analogous to mainstream human-oriented pharmacy, although, of course, major pharmacological differences occur between animal species and must be taken into account. Diagnosis and therapeutic treatments are the main perogative of veterinarians for animals under their care, but disease prevention and prophylactic control is not so limited. Recent changes in veterinary Regulations allow pharmacists and suitably qualified persons to prescribe certain veterinary medicines. Pharmacists are in a key position to act as a link between pet and livestock owners and other appropriate health professionals. Professional co-operation with veterinary surgeons and their practices is important and is of especial benefit to the animal "patient" and animal owner.

The Royal Pharmaceutical Society and Harper Adams University College (HAUC) have joined together to produce a selection of innovative veterinary pharmacy programmes designed to attract individuals involved with the provision of animal health. These may include pharmacists, pharmacy technicians, pharmacy support staff, veterinary nurses or university lecturers. The modular course is highly flexible, offering the following professional and HAUC-accredited awards:

- Professional certificate in companion animal and equine health care
- Professional certificate in large animal health care
- HAUC University College diploma in veterinary pharmacy (UCDip)
- HAUC postgraduate diploma in veterinary pharmacy (PgD)
- HAUC master of science in veterinary pharmacy (MSc)

Some areas where pharmacists can contribute include:

- Public health issues associated with keeping and eating animals
- Legal issues associated with the supply of veterinary medicines
- Formulation and quality of veterinary medicinal products
- Routine prophylactic treatment of internal and external parasites
- Advice on improving hygiene and issues about zoonoses
- Guidance on dosage and administration
- Information on welfare issues and travel
- The need for prompt referral to a veterinary surgeon when necessary

The courses comprise four modules. The 2011 cohort began its studies with modules 1–3 in January. The module 4 residential week will be held at HAUC in Newport, Shropshire, in July. It may still be possible to sign up for this.

Details of the programme may be viewed at www.vpep.net.

Steven Kayne is the editor of 'An introduction to veterinary medicine for pharmacists and suitably qualified persons' (published by Saltire Books, February 2011)

RPS EVENT

The Royal Pharmaceutical Society is running a conference on veterinary pharmacy on 2–3 July 2011 at the Royal York Hotel, York. For more information, visit the RPS events page online at www.rpharms.com/events.

Zoonoses: public health issues with keeping animals or eating them

Zoonoses can become major public health threats if they become uncontrolled. Martin Shakespeare looks at the factors that can lead to unexpected zoonotic disease outbreaks and how they can be controlled

Zoonoses are diseases and infections that are transmitted naturally between vertebrate animals and man. The transmission can occur by a variety of routes: direct contact with animals or infected material (such as blood, faeces or urine) or by aerosol, bites or ingestion of infected or contaminated produce (eg, meat, milk or other foods).

Uncontrolled zoonotic disease poses a massive public health threat, with brucellosis, tuberculosis and other serious zoonoses being historically major causes of illness and death in the UK. Large outbreaks in past decades have influenced current controls through the recommendations of public inquiries and an identified need for better practice. Control measures, therapeutic advances and best practice for animal owners (both for pets and commercial animal enterprises) have led to a massive reduction in the health burden associated with these diseases.

However, changes in husbandry practice and a widening of the variety of species kept as pets can lead to unexpected outbreaks. For example, the emergence of bovine spongiform encephalopathy in cattle and new variant Creutzfeldt-Jakob disease in humans is linked to changes in feed processing and butchery practice. And the recent outbreak of Q fever in The Netherlands followed a repositioning of the Dutch dairy industry from cattle to milking goats, associated with a lack of understanding of a need for changes in associated husbandry measures.

The trend for keeping exotic animals as pets can also lead to unexpected disease, with reptiles being now recognised as a major source of unusual salmonella infections.

Cow infected with bovine spongiform encephalopathy (BSE): the emergence of BSE in cattle and new variant Creutzfeldt-Jackob disease in humans is linked to changes in feed processing and butchery practice (C. V. L. /Eurelios/Science Photo Library)

Control

The control of disease in commercial animal enterprise is based on risk-management through the Hazard Analysis Critical Control Points process. This is underpinned by statutory requirements from the Health and Safety Executive, Department for Environment, Food and Rural Affairs, and the Food Standards Agency. The "Farm to fork" initiative focuses on safeguarding the general public from the risks associated with food, and ensures that quality and safety are maintained.

Control measures provide protection in depth, with good hygiene, herd testing, culling of diseased animals, vaccination and therapeutic intervention all ensuring that milk is safe and that animals go to slaughter in the best condition possible. Slaughter controls and carcass inspection, coupled with good butchery, refrigeration and sell-by dates, ensure consumer protection up to the retailer-consumer interface for meat.

The food processing, retailing and restaurant trades are bound by public health measures that ensure the products they deliver should be safe. Breakdown of best practice or compromise of control can lead to outbreaks of food-borne zoonoses, such as the *Escherichia coli* outbreak in Wishaw in 1996, with 496 suspected cases, 272 confirmed cases and 21 deaths. Another outbreak of *E coli* in Wales in 2005, traced to school catering, infected 157 children, one of whom died.

Risks and hazards

Farmers and livestock workers are usually well informed about the hazards they must face and control, especially given the protection measures. However, this is not always true for pet owners, who are either ignorant of, or choose to ignore, the risks that can be associated with their animals. There is also a lack of understanding and education related to the risks posed by zoonotic disease in adults and children who come from predominantly urban areas. Disease outbreak may also occur at petting farms, zoos and other places where they come into contact with animals, without recognition of the profound need for good hygiene.

Education

There is a need for the gap between veterinary care and traditional GP-led community services, where there may be little linkage between the pet and the patient, to be bridged. The problem of health education relating to zoonotic disease is an issue that must be grasped to protect the health of all.

Individually, members of the general public are responsible for ensuring their own health, and they often require education and information to assist them to understand the risks and benefits of pet ownership and make informed choices. General advice is available from a wide variety of sources (Government departments, animal charities and other bodies), many of which provide online advice or information leaflets. This is an important field of health promotion, where pharmacists are well placed to be effective advocates for both patients and their pets, signposting their customers to appropriate resource.

It is important that pharmacists should consider rapid referral of any patient suspected of having a zoonotic condition to a doctor as soon as is practicable because most of these conditions will not respond to self-medication.