Even the most conscientious Koi keeper will encounter poor health in their stock at some point. There will be times when treatment is unavoidable and there’s a lot of confusion among hobbyists about the testing a product must undergo before it can be placed on sale, what approval is needed and the type of information that medical products must display.

The laws governing medicines cover both human and veterinary medicines and they’re designed to ensure that any products sold or supplied for medicinal purposes are made to a standard and do ‘what it says on the tin’. The Veterinary Medicinal Products Directive 2001/82/EC sets out in great detail the specific requirements and controls for the manufacture, authorisation, marketing, distribution and general surveillance of veterinary medicines and is in force in all Member States of the EU. This may sound a bit heavy – and it is!

It starts with the definition of a veterinary medicinal product as, “1) Any substance or combination of substances presented as having properties for treating or preventing disease in animals. 2) Any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis.” ‘Substance’ is defined as ‘any matter irrespective of origin’, while ‘Animals’ include fish.

Therefore, it doesn’t really matter how a label is phrased, so all the clever wording of ‘may assist in’ or ‘can affect’ won’t make any difference to the regulators. If the product does something to an animal, then it’s a veterinary medicinal product and will come under some part of the European Regulations. Even water treatments, if they have a direct effect on the fish, will be considered as veterinary medicines.

**The regulators**
These regulations define exactly what is required in three general areas, so let’s look at each of these in turn. We’ll start with quality, or how the product is manufactured.
The factories that manufacture veterinary medicines have to work to very high standards, with detailed record keeping. They’re also subject to inspection by the Regulatory Authorities. This is all to ensure that the products are made to exactly the same high quality in each batch, will last for at least the expiry date on the label, and that the manufacturers (and owners of the licences to sell the products) monitor the way the products work once they are out in the marketplace.

Secondly, in order for a veterinary medicinal product to obtain a Marketing Authorisation (permission to sell), it must have been shown to be safe for the animal or fish that receives it, and safe for the human handler administering it, as well as for the environment and also the consumer who might end up eating a treated animal.

Last – and as they say, by no means least – the regulations look at the efficacy of the product. In other words, does it work in the manner it claims? The authorities need to be satisfied by extensive clinical trials that the product actually works. As you can imagine, the amount of time and money required to gather all of this data is huge, which goes some way to explain the financial cost to purchase both veterinary and human medicines.

The sale of these veterinary medicines is also controlled and the products themselves are grouped into a number of different categories. These include ‘Prescription-only Medicine-Veterinarian’ (POM-V), which is a...
KOI KEEPING

A SAFE BET FOR A SAFE VET

The title ‘Veterinary Surgeon’ has been protected in law by The Veterinary Surgeons Act 1966 and it is a criminal offence for anyone to call themselves a vet or veterinary surgeon, either directly or by implication. You might wonder why the police need to be involved, but the ultimate aim is animal protection and welfare.

In this Act, the term ‘animals’ includes birds and reptiles, but not fish, so it’s still perfectly legal for someone other than a vet to diagnose diseases in fish at the moment. This is likely to change though, as the British Veterinary Association have accepted that fish – and other vertebrates – should be given the same professional protection as reptiles and birds. Watch this space...

It is considered to be an act of veterinary surgery to perform operations on fish though, so it’s illegal for anyone other than a vet to carry out operations on fish such as the removal of tumours from the abdomen. According to the exact wording of the act, you may only undertake, “Any minor medical treatment given to an animal by its owner, by another member of the household of which the owner is a member or by a person in the employment of the owner”.

Although anyone can legally diagnose fish diseases, treating them can still be a tricky proposition, since only a vet may prescribe POM-V products. In order to practise work as a vet in the UK, you must be a member of the Royal College of Veterinary Surgeons (MRCVS). Some vets can become Fellows of the Royal College of Veterinary Surgeons (RCVS) by virtue of their experience and contribution to veterinary knowledge and science, or by very strict examinations.

Vets must pay an annual fee to the Royal College to be retained on the Register of Practising Vets, and anyone can find out about a vet’s qualifications by contacting the Royal College via the website www.rcvs.org.uk. Vets must abide by the strict rules and regulations that form what is known as the Professional Code of Conduct and any vet who doesn’t abide by these rules can find themselves up before the Disciplinary Committee. This is somewhat like a Court of Law that can impose serious sanctions including ‘striking off’ the register, meaning that the vet in question is no longer entitled to practise.

LOCAL CUSTOMS

One of the advantages of the internet is the instant access it can give you to worldwide information, including websites around the world offering a wonderful array of exotic medicines for your fish – usually just the very product that you need and that you can’t get anywhere else at home. However, there is a catch: if the product is not authorised here then it’s illegal for you to import it. As a general rule, it is the responsibility of the person buying the medicine to ensure that it is legal in their country, not the responsibility of the company selling the product. However, quite a few companies show a very responsible attitude and will enquire as to the ultimate destination of the product and then may refuse to supply it to another country where it is potentially illegal. Also, Customs may inspect packages on entry and impound anything that is potentially illegal – and the result is no parcel… and no refund of whatever you spent to get it into the hands of the Customs officers.

For the love of Koi, don’t re-use needles or medication from other keepers on your own Koi
dealer must be able to demonstrate a system is in place to cope with a batch recall, or how to get the product back if there was a problem with it.

Nobody expects the Veterinary Medicines Directorate!

Although this may seem to be a bit heavy-handed for these medicines, it is in place to protect the most important end users: your Koi. This is also why there has been a recent crackdown by the regulatory authority, the Veterinary Medicines Directorate, on the use of chemicals which have not been through this SAES process, and so will not have the guarantee of quality and the traceability that goes with a SAES product.

It’s worth bearing in mind that a very popular and well-used product, malachite green is, in fact, a dyestuff. Malachite green is used in the dyeing of shoe leather to make green shoes, for instance. It has no formal specification to confirm how much it might contain in the way of impurities, or even in the case of malachite and formalin combination products how much malachite these contain if they are not SAES products.

All veterinary medicinal active ingredients have to conform to a set of formal standards, such as the European Pharmacopoeia, and must have what is called a Drug Master File, or DMF. This is basically the recipe of how to make the drug and what impurities it might contain, if any, as well as how long it lasts, or its stability profile. You should note that raw chemicals do not have this legal control.

The information that is written on a veterinary product’s label is also strictly controlled by law. This law applies to SAES products, even though they are exempt from other legal requirements. Labels must include full details of the name and strength of each active ingredient, as well as the shelf life after the product has first been opened.

IT ISN’T GOOD TO SHARE

If a vet has prescribed a POM-V product such as an injectable antibiotic for your friend’s Koi, it is illegal (as well as unsafe) for you to use it on your fish. It’s both illegal for your friend to supply it and illegal for you to possess it. This is ultimately to protect your fish since a vet will have prescribed the antibiotic for a particular situation for fish under his care – which yours are not. If anything goes wrong, you have no comeback, whereas in the case of your friend who had the product legitimately, there is a route back through the prescribing vet right back to the manufacturer, taking in the Adverse Reactions branch of the VMD on the way.

Left: don’t take our word for it – this is straight from the horse’s mouth! Well, the VMD, anyway