10 The Law

Introduction

There are several different levels of legislation:

•*Acts of Parliament* - must be discussed and debated before being passed by Parliament. The modern tendency is for them to contain general outlines of the legislation with the details hidden within

•*Subsidiary legislation* (usually Regulations in NZ) These have to be laid before Parliament (after they come into force) but are not subject to the same (any?) scrutiny and debate. Politicians like these because they give them control over the details of the operation of the law and minimise public debate. They are still law.

•*Codes of Conduct* such as the NZVA policies are not generally legally binding but are well worth following. If the worst happens and you end up in court, it is useful to be able to claim that you were doing what a consensus of the profession believed should be done. There are lots of grey areas where the law is not defined and the test of legality is likely to be what the rest of the profession consider reasonable.

Successive NZ governments have become very keen on Codes of Conduct, since these are written by the organisations being regulated and the government does not have to pay someone to write them. If they have too many unintended effects they can always be quietly abandoned without troubling Parliament. Many CoPs now have the same status as regulations, ie, they are law.

For instance, the *Agricultural Compounds and Veterinary Medicines Act (1997)* section 75 says that the government can make regulations to cover all aspects of veterinary medicines, the *Agricultural Compounds and Veterinary Medicines Regulations (2001)* say that vets can use human medicines in animals under their care provided that a suitable code of practice is followed, and the NZVA *Code of Practice for the Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians* specifies the conditions of use of human medicines in animals.

Overview

The situation is confused at present. A new law, the Agricultural Compounds and Veterinary Medicines Act (1997) (ACVM Act) started to come into effect in July 2001, and is supposed to have been fully implemented by July 2004. This says that everyting sold for use in animals must be registered (with a few exceptions) and conditions are imposed on registration, which can cover use among other things. This Act is supposed to fit in with the Hazardous Substances and New Organisms Act (1996) (HSNO Act) and the Biosecurity Act (1993) so that everything to do with agriculture is covered by these Acts. This may have sounded like a good idea over a beer in the Backbencher's Bar, but it appears that very little thought went into the details. In particular, none of the politicians seems to have realised that veterinary medicines are given to small animals as well as farm animals, and that human medicines are given to both. The Animal Produce Act (1999) requires standards for foods to be contained in separate regulations, but at present, MRLs are covered by New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards (2010) made under the Food Act (1981). However, where these are different to EU MRLs, the EU MRLs are used for veterinary medicines! Everything to to with food is supposed to be administered by the NZ Food Safety Authority, which has recently been hived off from MAF, and reports to the Minister of Health. The ACVM Act is administered by the NZFSA, which shows clearly where their priorities lie. Confused? So is every vet in NZ, but ignorance of the law is not a defence for breaking it (in most cases - that is not very clear either).

The ACVM Act, while full of flaws, is relatively straightforward compared to the HSNO Act. Since all veterinary medicines fit into the category of hazardous substances (human medicines do too, but they have been given an exemption), they are supposed to be registered under the HSNO Act. This involves public consultation, which can be mind-bogglingly expensive. This is likely to mean that there will be very few new veterinary medicines registered. The status of the large volumes of human medicines used in animals does not appear to have been considered, but this volume is likely to increase as the price differential caused by double registration of veterinary medicines increases.

In the meantime, while people try to get to grips with the new law, things carry on much as they did under the Animal Remedies Act (1967). This is similar to veterinary medicines legislation in many other countries, where everything to do with veterinary medicines is contained in one Act. Drug companies are familiar with this sort of legislation and there was a rush to get drugs licensed under the old system before July 2001. There have been very few applications to register new drugs since, which may only be temporary.

The Animal Remedies Act was one of the first main pieces of animal medicines legislation in the world and had to be extensively modified over the years. The Medicines Act (1981) only deals with human medicines, but veterinary surgeons using human medicines in animals must stick by its provisions. There was a rash of medicines legislation around the world following the thalidomide affair in the late 1950s; by waiting and basing its legislation on what was done elsewhere, NZ got it right first time. There are significant differences from the Animal Remedies and ACVM Acts.

The Misuse of Drugs Act (1975) is designed to stop people abusing addictive drugs. It contains a number of sensible provisions which increase the burden of paperwork.

Most countries have similar legislation.

Both these Acts are under review as part of a harmonisation process with Australia (but don't hold your breath). There is tighter control of discretionary use of drugs there, so expect the worst.

The Dairy Industry Regs (1990) made under the Dairy Industry Act (1952) require farmers to follow Product Safety Programmes to ensure that contaminated milk does not enter the supply chain. MAF Standard D105 "Milking Animal Health" requires farmers to keep records of drugs given to their animals. This information usually comes from vets, on a standard form (treatment form 2).

Animal Remedies Act (1967)

This has now been repealed, but you still need to have an idea of its provisions as most traditional practice is based on it.

It defined an animal remedy, made it illegal to sell an unregistered animal remedy, established the Animal Remedies Board which had control of drug registration and use. Drugs had to be safe and effective to be registered, and the ARB could refuse registration or impose conditions on use to take into account public health and environmental issues.

Most vets assume that the ACVM Act must be similar, but it is not.

Classification of Animal Remedies

Class I prescription animal remedy (PAR): may be administered to an animal only by a

•veterinary surgeon

•under and in accordance with authority or prescription of veterinary surgeon.

Class II PAR: administered only by a

•veterinary surgeon or

•in the presence and under the direct control of a veterinary surgeon.

Class III PAR: administered only by a veterinary surgeon

(Most drugs in this category have recently been made PAR2s.)

Other drugs can be purchased without a prescription, sometimes called over the counter drugs (OTC).

This classification was continued under the ACVM Act until 2010. The term "prescription animal remedy" was retained since the ACVM Act defines the more sensible term "veterinary medicine" in such a silly way.

Note that the Animal Remedies Act covered all aspects of veterinary medicines (including public health and environmental issues) in contrast to the ACVM Act.

Agricultural Compounds and Veterinary Medicines Act (1997)

"Veterinary Medicine" is defined as anything used in the direct management of animals, and this wide definition has caused problems. NZFSA have gradually reduced the working definition to something sensible. Tractors and sheds are now excluded (although the position of stockmen is unclear), and the idea of registering hypodermic needles and surgical instruments has been dropped. Grass is a veterinary medicine, although it is generally recognised as safe (GRAS in ACVMspeak). To get round this problem, NZFSA are again referring to what the rest of the world knows as "veterinary medicines" as "animal remedies".

The ACVM Act is designed to manage specific risks: **trade in primary produce, agricultural security and animal welfare**. Domestic food standards are mentioned as an afterthought. Benefits such as efficacy are not considered (you are supposed to sue the manufacturer under consumer legislation if the drug does not work) and safety is only considered as it affects animal welfare. Inaccurate labelling (exaggerated claims) is also a matter for the Fair Trading Act (1986). The act has recently been amended to include public health (eg, antibiotic resistance). In practice, drug companies submit the same dossier of information they have compiled for overseas registration, so most drugs have evidence of efficacy and safety, however, the ACVM Group keeps all this secret, so you cannot tell for sure.

Under the ACVM Act, the Animal Remedies Board (which controlled drug registration and use) has been abolished and drug registration is now carried out by civil servants subject to political control.

It is illegal to use drugs in animals which are not registered with NZFSA or specifically exempted from registration (either with or without conditions). To comply with international treaties, nearly all drugs for use in food animals have to be registered (eg, antibiotics). Registration can involve conditions on use. Drugs which pose a low risk are exempted (eg hoof treatments, oxygen, shampoos, human over the counter medicines). Many drugs for small animals are fall into the "exempted with conditions" category, in most cases, the conditions are that a code of practice is followed, although in some cases the conditions may be related to the manufacturing process, or packaging and labelling, and do not directly affect vets. The relevant code of practice for vets will usually be the **NZVA Code of Practice for the Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians** (more on this below).

Horses are treated as companion animals, provided a long withholding period (6 months) is observed.

The PAR classification persisted until 2010 but has been modified and remodified back again several times. Most vets still refer to PARs. Currently all drugs which used to be PARs are Restricted Veterinary medicines, roughly equivalent to PAR1. This system was imposed as conditions on registration. The ACVM Group periodically decides that this is too simple and that every individual drug will have different conditions on registration. Even the drug companies cannot keep up with this vacillation and most drugs now have something on the label like "See the ACVM website for conditions". These conditions are compulsory but are usually totally unknown to vets in practice.

The latest classification is:

unrestricted = OTC

restricted class A = PAR1

restricted class B = PAR3 (no drugs in this class)

restricted class C = a means of allowing corporate farmers to use prescription veterinary medicines without veterinary interference in their money making

How long this will last is anyone's guess.

The NZFSA has also separated prescribing from

trading in veterinary medicines, which allows anyone with a trader's licence to fill prescriptions written by a vet. Vets have to register as traders, but are not subject to some of the vetting that others are.

One of the big problems with the ACVM Act is that since the Act itself contains so little useful information, the civil servants in the ACVM Group of the NZFSA have had to make up the rules as they go along. It can be very difficult to determine what is actual law and what is only ACVM Group policy. Very little of this legislation has been tested in court.

The NZVA have published their summary of the ACVM Act in their Guide to Veterinary Pharmacy and Dispensing, which all vets should read: `http://www.vets.org.nz/Vetzone/Forms/infoforms.htm`

Agricultural Comounds and Veterinary Medicines Regs (2001)

These list the "veterinary medicines" which are exempt from registration under the ACVM Act (medicines made up for use on someone's own animals, medical gases, hoof and skin perparations, etc, etc), and specify the conditions for those which are exempt with conditions (homoeopathic preparations, herbal medicines, antiseptics, human medicines and medicines compounded by vets).

The regs also include a list of banned poisonous plants, and a list of substances generally recognised as safe. There are also specifications for labels.

Schedule 8

A list of banned drugs; mostly things like DDT and strychnine, which have not been used for years. However, like the rest of this legislation, it is badly written. Many of the drugs are acronyms: it is not clear if DDD stands for "Donald Duck Drug" or is a synonym for mitotane.

Hazardous Substances and New Organisms Act (1996)

As the name suggests, this is designed to regulate hazardous substances (environmental and human effects) and new organisms (anything not already present in NZ). It established the Environmental Risk Management Agency (ERMA) which spent a long time bogged down in trying to regulate genetically engineered organisms. All veterinary medicines have to be registered under this act too, but the hazardous substances part is mind-bogglingly complicated and has been amended many times so far. On the day the Act was passed, someone realised that it would be illegal to fill a car up with petrol, so the first amendment was rushed through. This process continues.

The HSNO Act is different from other Acts by registering generic substances: thus if a company spends megabucks registering their new drug, other companies can freeload on this registration once the patent runs out. Understandably, this does not encourage registration. A sensible compromise has emerged, where ERMA delegates registration of low risk compounds to more appropriate people, such as the ACVM Group of the NZFSA.

Vets are deemed to be "approved handlers" for some drugs but need specific licences for others, or large quantities of them.

ERMA regards drugs with potential environmental effects, such as avermectins, as high risk. It is not out of the question that drenches will have similar restrictions to nuclear waste!

The hazard classification and controls in the HSNO Act and Regs are truly of mind-boggling complexity, I seriously doubt if anyone in NZ who handles chemicals understands them fully. This Act has the potential to cause complete chaos; if it was enforced as it is, all industry in NZ would stop. This does not mean it can be ignored. the NZVA has material to help guide vets through it.

Medicines Act (1981)

Medicines Regulations (1984/143)

Regulates the manufacture, supply and use of human medicines. Drugs must be approved for sale, and must meet standards for purity, safety and efficacy. Covers prescriptions, labelling and storage requirements (see below). Veterinary surgeons may prescribe and dispense drugs **for animals under their care**. Classifies drugs into "Prescription only medicines", "Restricted medicines" and "Pharmacy medicines", which are subject to different controls. Drugs not specifically classified are "general sales medicines".

Administered by Medsafe, who have an excellent web site - `http://www.medsafe.govt.nz/profs.htm`

Misuse of Drugs Act (1975)

Misuse of Drugs Regulations (1977/37)

The main legislation designed to control the use of addictive drugs. Most countries have something similar; the NZ act is based on the UK one. Classifies controlled drugs - mainly important for illegal possession. Vets are permitted to supply, prescribe and administer controlled drugs Class B or C for animals under their care. Specifies the more stringent requirements for prescriptions, labelling and storage of controlled drugs. Allows the Minister of Health to ban specific vets from prescribing controlled drugs, ensures that the Veterinary Council is informed of any convictions concerning controlled drugs so that convicts can be struck off.

Class A controlled drugs

Drugs of addiction such as LSD, heroin, cocaine, most amphetamines; drugs with no clinical use such as thalidomide (and Spanish fly!). The only drug of veterinary interest is etorphine. It is probably included here as it is highly dangerous to people. Permission from the Minister of Health is required to use Class A drugs. You should not come across these drugs in practice in NZ.

Class B controlled drugs:

Most opioids, including diphenoxylate (but also ecstasy and cannabis for some reason). In veterinary practice it is never necessary to prescribe or dispense Class B drugs:

they should be kept in the clinic and administered to the animal as needed.

Class C controlled drugs

Codeine, barbiturates, buprenorphine, meprobamate; very dilute solutions of morphine, < 2.5mg diphenoxylate (also cannabis plant and coco leaf!). Ketamine has recently been classified as C4. Benzodiazepines, which are the class of drugs most widely abused by people, have recently been added to class C. "Designer drugs" (analogues of drugs of abuse) are in class C 7. This includes carfentanil (!?).Some drugs commonly used in small animal practice such as pseudoephedrine (used illegally to make methamphetamine) are likely to be made class C soon.

Security

Controlled Drugs from classes B and C 1 - 4 and 7 must be secured when not in use. Secured means locked in a metal or concrete cabinet bolted down to the building and keys kept elsewhere. These drugs should not be left unattended in vehicles. Remember that pentobarbitone is class C 4. Class C 5 do not need to be locked up, but it is still a good idea.

Records

Class B drugs must have records kept of their use. A Controlled Drugs Register must be kept on the premises (usually with the drugs). It must be a bound book with consecutively numbered pages with details of one form of one drug per page. Entries must be legible and indelible, and filled in within 24 hours of the use of the drug. A full audit of drugs obtained and used is to be carried out at the end of June and December. The Controlled Drug Register must be available for inspection by the police or Ministry of Health officers.

class	drugs	restrictions
A	etorphine (heroin, cocaine, LSD etc)	controlled drug safe controlled drug register permission from MoH
B1	morphine	controlled drug safe controlled drug register
B3	alfentanil fentanyl pethidine methadone	controlled drug safe controlled drug register
C2	codeine	controlled drug safe
C4	buprenorphine pentobarbitone ketamine	controlled drug safe
C5	benzodiazepines phenobarbitone	locked cupboard recommended
C6	dilute solutions/forms	none
C7	carfentanil (designer drugs)	controlled drug safe controlled drug register
not controlled at present	butorphanol nalbuphine pentazocine ephedrine	locked cupboard strongly recommended

Summary of controlled drugs requirements. If these drugs are prescribed, the prescription requirments are more stringent (see below).

CONTROLLED DRUGS REGISTER

Name and Form of Drug (One kind and one strength only to each page) *morphine 30mg/mL*

Date	Name and address of person from whom received; or Name of patient; or Name and address of person supplied; or Declaration "Physical stocktaking"	Prescription or Order Number or time	In	Out	Balance	Name of Authority	Issued, Dispensed, or Administered by	Initials of Person Making Entry or Checking Balance
30/2/06	*From pharmacy*	*9.30 am*	*10*		*10*		*P. Chambers*	*ABC*
30/2/06	*Dog Smith*	*123456*		*1*	*9*	*Barter*	*Linda*	*JPC*

must be written out

animal's name

case no.

leave blank

number of ampoules used, not mg of morphine

actual number of ampoules left in safe - not how many there should be!

name of vet who authorised use

signature of person giving drug

signature of person checking balance

Form of controlled drugs register. Different drugs and different forms of the same drug (eg morphine 30mg/mL) should be recorded on different pages.

Prescriptions

A prescription is a set of instructions to a pharmacist to make up and supply a medicine. They are usually only used in veterinary practice for infrequently used medicines. Animal owners can also ask for a prescription so that they can get it filled by another vet, if they think that this will be cheaper. The legal requirements for a prescription vary, but it is good practice to write all presriptions in the same way. Pharmacists have a legal responsibility to verify a prescription: if they don't like it they will not fill it.

Prescriptions for veterinary medicines are a grey area in the law. The requirements for presecriptions for human drugs are set out in the Medicines Regs, and vets prescribing human drugs must stick to these. It is good practice to follow the same requirements for veterinary medicines. There is an ACVM code of practice written by the NZVA for writing prescriptions, but it is not clear if it is a legal requirement. The NZFSA has issued the snappily entitled "Veterinarians Recognised (under s 62, ACVM Act) to Issue a Valid Authorisation for Purchase and Use of Restricted Veterinary Medicines Requiring Veterinary Authorisation Perfromance and Technical Standard" but it is not clear if this is actually law either. See: `http://www.nzfsa.govt.nz/acvm/registers-lists/cop.htm`

"Authorisation" is a term used by the ACVM Group where most people would talk about a prescription. They usually take the form of a note in the case records of an animal or farm to the effect that the client can be supplied with drugs, although the definition is constantly changing. Note that this is a different definition from other countries. Bear in mind that authorisations for veterinary medicines will probably be filled by someone who knows nothing about pharmacy.

Requirements for a prescription

A prescription must be written in ink and should include:

•*Name and address* of the prescriber and the veterinary practice

•*Date* of prescription

•*Name, initials and address of the client* (include animal's name or species)

•*Superscription*

•*Name of drug(s) and strength*. This is usually the approved name, in which case the pharmacist may dispense any suitable product, but you may use a tradename for a particular product. This is compulsory for veterinary medicines.

•(*Directions to pharmacist* - how to prepare any preparation which needs to be made up)

•*Amount* to be dispensed. For controlled drugs this must be in words and figures to stop people altering it.

•*Directions* you wish to appear on the label. Dose, directions for use, "for animal treatment only", "keep out of the reach of children" and any precautions or warnings

•Veterinary surgeon's *signature*

•Policy on *repetition*. If nothing is put down here the prescription cannot be repeated, but it is possible to specify one or two repeat prescriptions. This is very rarely necessary in veterinary practice.

Printed prescriptions are a grey area too. Currently, the drug, the amount and the signature should be handwritten, but the MoH are reconsidering this, and fully electronic presriptions may be allowed soon. The NZVA have prescription forms available at: `http://www.vets.org.nz/Vetzone/Forms/infoforms.htm`

Abbreviations

Prescriptions used to be written in Latin, and some Latin abbreviations are still seen. However, they should be written without abbreviation and in English these days. Abbreviations are illegal in prescriptions for controlled drugs.

for information only:

Veterinary - may not be recognised by pharmacists

sid	*semel in die*	once daily
bid	*bis in die*	twice daily
tid	*ter in die*	three times daily
qid	*quater in die*	four times daily
q12h	*quaque 12 hora*	every 12 hours
q6h		every 6 hours
qd	*quaque dies*	every day
q2d		every 2 days
qs	*quantum sufficiat*	as much as needed
ad lib	*ad libitum*	freely available

Human

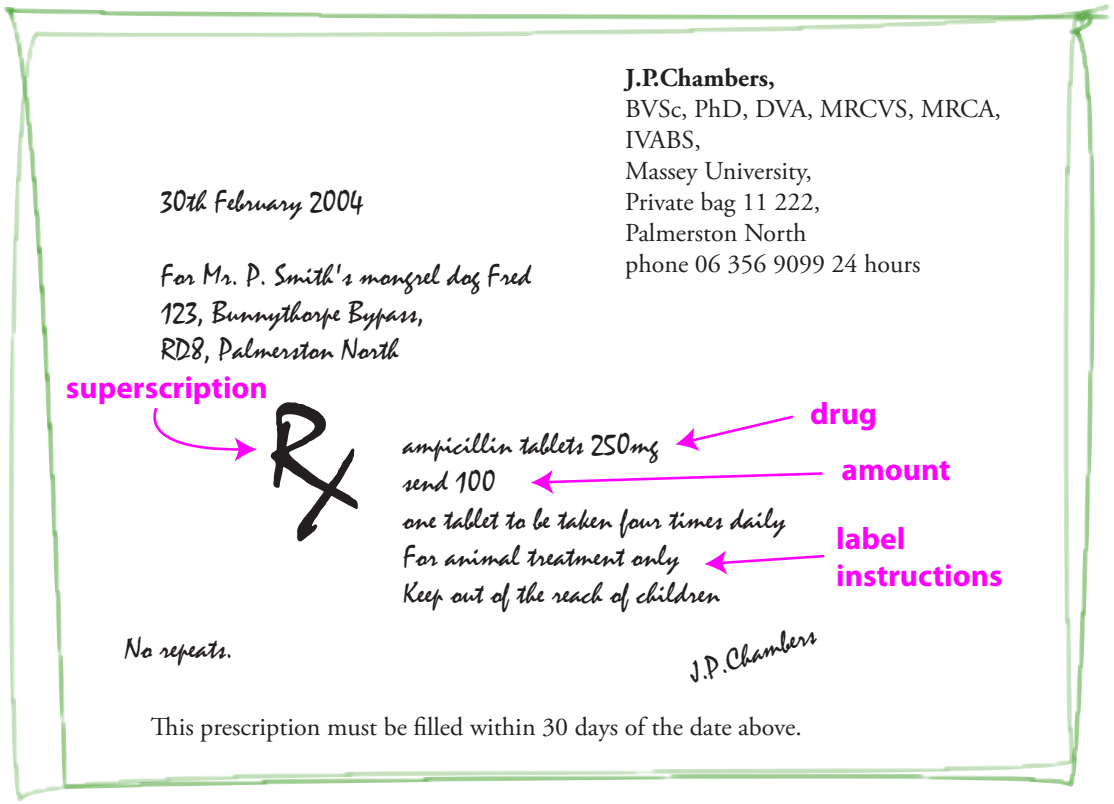
ac	*ante cibum*	before food
bd	*bis die*	twice daily
od	*omni die*	every day (daily)
om	*omni mane*	in the morning
on	*omni nocte*	at night
pc	*post cibum*	after food
prn	*pro re nata*	when required
qds	*quater die sumendus*	four times daily
qqh	*quarta quaque hora*	every four hours
stat	*statim*	immediately
tds	*ter die sumendus*	three times daily

Directions to include drugs in feed

This is a form of prescription, and the requirements are much the same. Bear in mind that all animals to which medicated feed is given are food animals. The manufacturer is not allowed to make up the feed until he receives the written directions. Use the NZVA production animal prescription pad: `http://www.vets.org.nz/Vetzone/Forms/infoforms.htm`

Things to be included:

- Name and address of veterinary practice
- Name of prescribing veterinary surgeon
- Name and address of client
- Date
- Name of drug, form and concentration
- Inclusion rate
- Final concentration of active ingredient in food



Typical form of a prescription

- The feed to which the drug is to be added
- The quantity of medicated feed to be supplied
- The species to be treated
- Number of repeats allowed
- Precautions, including withholding period
- Contact phone number
- Signature

Keep a record!

Labelling drugs

Every package of any sort of prescription animal remedy dispensed must be clearly labelled with the following information:

- Name and address of veterinary practice
- Contact phone number
- Emergency phone number
- Name of prescribing veterinarian
- Date dispensed
- Name and address of owner
- Name / no. and species of animal
- Name, strength and quantity of drug
- Directions for use: dose, method of administration and frequency
- Any relevant warnings (e.g. "wear gloves when handling")
- Witholding period for food animals
- In bold print "**for animal treatment only**"
- "Keep out of reach of children"

If the drug is in a container inside another container, eg, a tube inside a box, put the label on the container with the drug in it.

For over the counter sales of animal remedies in the manufacturer's original packaging, this label is not necessary but still a good idea.

It is difficult to fit all the necessary information on a label, even if your writing is very small. It is likely in the near future that computer printed labels will be required. They are certainly a good idea.

Prescription writing goes back a long way. The superscription is usually taken to be an abbreviated form of the Latin recipe *= take, but could also be a representation of the Eye of Horus, supposed to enlist his aid in making the drug work!*

Storage of medicines

Drugs should not be kept anywhere that food is stored. If you want to keep vaccines and milk in the fridge, you need two fridges. It is also illegal to prepare or pack drugs in any room where food or drink is prepared or consumed. Children and unauthorised people must not have access to the drug storage area. Buildings or vehicles containing drugs must not be left unattended unless they are properly secured.

Many drugs have specific storage requirements; many must be refrigerated. Most drugs will have a longer shelf life if stored in a cool dry place out of direct sunlight. The back of a car is about the worst possible place to store drugs.

J.P.Chambers, MRCVS
IVABS, Massey University
phone 06 356 9099

24/1/01
for Mr. Smith's dog Fred
123, Bunnythorpe Bypass,
RD8, Palmerston North
100 tablets ampicillin 250mg
give one tablet four times daily

For animal treatment only
Keep out of the reach of children

J.P.Chambers, MRCVS
IVABS, Massey University
phone 06 356 9099

24/1/01
for Mr. Smith's weaner pigs
123, Bunnythorpe Bypass,
RD8, Palmerston North
Zaquilan 20% injection 100mL
give 2mL intramuscularly and repeat in 2 days
withholding period 28 days
For animal treatment only
Keep out of the reach of children

J.P.Chambers, MRCVS
IVABS, Massey University
phone 06 356 9099

24/1/01
for Mr. Smith's horse Jim
123, Bunnythorpe Bypass,
RD8, Palmerston North
Dr. Chambers' patent horse medicine 1 pint
rub on the affected area once a week

For external use only

Wear full protective clothing

For animal treatment only
Keep out of the reach of children

Some examples of labels for dispensed drugs.

Discretionary (off label) use of drugs

All licensed animal remedies have been approved by the NZFSA for certain species, uses and at certain doses. These are written on the label. Vets may use almost any drug they consider helpful but this use is unapproved and discretionary or "off label". If a registered veterinary medicine is used in the approved way and something goes wrong, it is the drug company's responsibility. If it is used in an unapproved way, the prescribing veterinary surgeon is responsible. All veterinary use of human drugs is discretionary.

Under the new legislation, a vet can presribe almost any drug but it is a legal requirement to comply with the **NZVA Code of Practice for the Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians**. This says that before using drugs in a discretionary way, a veterinary evaluation must be made, and certain requirements must be met.

A veterinary evaluation involves several consecutive steps:

The animal must be in your immediate care, and you must have sufficient information anout the animal to decide that treatment is justified. It is a good idea to clinically examine the animal and make a diagnosis.

Assess if there is a veterinary medicine available which is likely to work at the doses stated on the label. If there is, use it.

If there is a veterinary medicine available which is likely to work at doses outside those on the label, this should be used.

If no veterinary medicine is available which is likely to work, then a human medicine or a medicine made up on a one off basis can be used.

Requirements for discretionary use:

Ensure that the drug is not banned. No drugs are banned at the moment, but the ACVM Act allows the Minister of Agriculture to ban specific drugs. Some drugs have conditions on their use which mean that they cannot be used as you might want. Check before use: `http://www.nzfsa.govt.nz/acvm/registers-lists/acvm-register/index.htm`

Assess the scientific information available. Have you enough information to use it safely and effectively? Information can be obtained from the drug company (the drug may be licensed overseas for your use), from the literature or from colleagues (preferably ones you can trust as the responsibility is still yours). You must be sure that the drug will not cause unnecessary pain or suffering. Remember species differences - particularly in pharmacokinetics.

Keep in contact with the owner to check for adverse reactions.

For food animals, think about the possibility of drug residues in food. You have to have a very good reason to give an unapproved drug to a food animal. You also have to calculate witholding periods, or use the defaults (see table).

Assess if there is a risk to agricultural security. This boils down to the development of resistance in pathogens.

Give the owner the following information in writing and keep a record for two years:

animal	meat	milk	eggs
ruminants	91	35	
pigs	63		
horses	180		
birds	63		10
camelids	63		
rabbits and hares	63		

Default withholding times in days used as a guide by the ACVM Group. nb. these have no basis in law (or science).

(i) Name of owner or owner's agent

(ii) The identity of the animal or group to be treated

(iii) The established name of the drug, the active ingredient (if compounded for discretionary use) and the concentration

(iv) The dose rate and frequency of treatment

(v) The route and method of administration

(vi) The duration of treatment

(vii) The withholding time (for food animals)

(viii) The date of treatment

(ix) The name of the prescribing veterinarian and the name, address and contact phone numbers of that veterinarian's practice.

Ensure that the following information is conveyed to the animal's owner or agent:

(i) Any special considerations in regard to operator safety;

(ii) Specific advice that adverse reactions should be reported immediately to the prescribing veterinarian or in the absence of that veterinarian to other veterinarians in the practice;

(iii) Provide the information that this use is discretionary use

This code of practice has been approved by the Minister of Agriculture under the ACVM Act. Note that there are major differences from the situation in our major trading partners. In the USA, there is a list of drugs which are banned in food animals; in Europe, it is illegal to give a drug to a food animal unless the active ingredient is licensed in some food animal species (ie, an MRL has been established). This means that there may be political pressure to change the NZVA code of practice.

Making up your own drugs

All animal remedies sold commercially must be registered with the NZFSA or exempted from registration, but you are allowed to make up your own drugs **for animals under your care**, ie, you must have examined the animal and have been given responsibility for its treatment by the owner. As this is an discretionary drug use, all the considerations above apply. You cannot put home made medicines on general sale without going through the registration process (which is a serious exercise in filling in forms and spending money).

Making up mixtures requires knowledge of the chemical compatibility and stability of drugs, and is best avoided. If it must be done, it may be better to write a prescription and get a pharmacist to do it.

If registered animal remedies are bought in bulk and repackaged, they must only be used for animals under your care. Once the seal on the original container is broken, the drug company is unlikely to take responsibility for any problems with the drug (there is usually something on the label along the lines of "use within two days of opening"). Particular attention must be paid to labelling.

Repackaging bulk drugs because you anticipate a requirement for small lots is acceptable: doing it to save money is not.

Dispensing of medicines

The exact legal requirements for packaging animal remedies are unclear, but veterinary surgeons dispensing human medicines must comply with the same regulations as medical practitioners and pharmacists. The veterinary profession cannot afford to be sloppy in this, or the right to dispense drugs may be removed. Child proof safety containers for all dispensed drugs are highly recommended. Envelopes are not acceptable.

Unopened manufacturer's packaging is usually acceptable - stick the label where it will not obscure any warnings etc.

Foil wrapped / blister packed tablets are legally regarded as childproof containers and may be dispensed in resealable plastic bags; loose tablets must be in a proper childproof rigid container.

If preloaded syringes are dispensed, the needle should be supplied separately and the syringe should be capped to prevent leakage.

All packages (no matter how small or awkwardly shaped) must be properly labelled. Most drugs given to animals will also affect people; anyone handling the drugs must be properly trained and appropriate safeguards taken. This is the responsibility of the veterinary surgeon. The HSNO Act is likely to make this more onerous.

Disposal of unwanted drugs

Do not just tip them down the sink or throw them in the bin! The veterinary surgeon is directly responsible for safe disposal of drugs - think about their possible effects on the environment. In most cases the drugs should be incinerated at high temperatures (do not just throw them in the fire either!). Talk nicely to your local chemist or hospital, or pay for them to be disposed of properly.

Adverse drug reactions

An adverse drug reaction is an undesirable, unintended or unexpected response to the clinical use of a drug, including injury, toxicity, sensitivity reaction or lack of efficacy.

possible causes of adverse reactions:

•anaphylactic / anaphylactoid reactions

•misreading instructions - double dosing, incorrect dilution, miscalculation

•use of an unlabelled product

•known side effects of a drug

•use of expired product

•interactions of one or more animal remedies

•idiosyncratic reactions

Adverse drug reactions should be reported to the ACVM Group on forms provided by them. If you do not have a form handy, collect as much information as possible at the time and organise the form later from:

`http://www.nzfsa.govt.nz/ACVM/publications/forms/adrform.doc`

or contact MAF ACVM Group, PO Box 2526, Wellington. Fax: (04) 460 8771 phone (04) 460 8750

The info you will need is likely to include at least:

Your name and contact details

The name, batch no., licence no. and expiry date of the product

The animal's owner's name and contact details

The actual dose given and the route of administration

The number of animals treated and the number reacting

The date and nature of the reaction

Animal details: species / breed, age, sex, weight

Other products given

Immediate treatment

Samples taken for analysis

Keep any remaining drug for analysis!

Reporting of adverse reactions is a condition of registration of all veterinary medicines, ie, compulsory, but only for the drug company. It is an ethical requirement under the Code of Professional Conduct. Reactions in people handling the drugs should also be reported to the ACVM Group.

As a matter of professional courtesy, the drug company should also be informed. Adverse reactions to off label use of drugs should also be reported.

The future?

The present fluid situation makes prediction difficult, with the only certainty that the amount of paperwork involved will inevitably increase. Every use of drugs of any sort will probably have to be recorded in an auditable way. The most up to date information on what is happening can be found at the ACVM Group's web site: `http://www.nzfsa.govt.nz/acvm/`

Clients are likely to want more information about drugs given to their animals: this may well be enshrined in law.

For instance, in Europe, human patients have a right to prescribing information and prescribers have a duty to explain all the relevant information in non technical language. The same thing is **recommended** in NZ (for people). You may have to learn some pharmacology!