The Law

NZ Legislation

legislation

- Acts of Parliament
- Statutary Regulations
- Codes of Conduct

Acts

- Animal Remedies Act 1967
- Agricultural Compounds and Veterinary Medicines Act 1997
- Hazardous Substances and New Organisms Act 1996
- · Biosecurity Act 1993
- Medicines Act 1981
- Misuse of Drugs Act 1975

Animal Remedies Act

- definitions
- · Animal Remedies Board
- registration
- · classification

.

prescription animal remedies

- · class 1 (PAR 1)
 - given by a vet or under a vet's authority
- class 2
- given by a vet or under a vet's direct control
- · class 3
 - given by a vet

PAR1 antibiotics

- · level 1 no controls
- · level 2 as current PAR1
- level 3 for serious infections after C&S
- · level 4 as L3 + notify NZFSA
- · level 5 banned in food animals
- · level 6 banned in all animals

Animal Remedies Act

- · does not cover
 - -implications for trade
 - -deadlines for processing applications
 - -prescriptions
 - -storage & labelling
 - -data sheets

ACVM Act

- · manages risks to
 - -trade
 - -animal welfare
 - -agricultural security
- domestic food standards
- consumer information

ACVM Act

- definitions
- registration
- · abolishes ARB
- human drugs?
- horses?
- · chemicals?

ACVM Act

- · veterinary medicine
 - "any substance used in the direct management of animals"

ACVM Act

- definitions
- registration
- · abolishes ARB
- human drugs?
- · horses?
- · chemicals?

ACVM Act

- registration
- · risks to
 - -trade
 - -animal welfare
 - -agricultural security
- efficacy???

ACVM Act

- all drugs used in animals must be registered unless
 - -exempted under ACVM Regs
 - -a s28 code of practice is followed
- conditions can be applied to registration
 - -PARs
 - -species

ACVM Act

- s28 codes of practice
 - -NZVA code of practice
 - human prescription drugs
 - -prescription writing standard

ACVM Regs

- exempted with conditions
 - -human GSL drugs
- -shampoos, hoof treatments etc
- -drugs compounded by a vet for animals under his care
- -substances generally recognised as safe

ACVM Act - future?

- separate prescribing from dispensing
- allow presribing over the phone without examining animal
- · relax PAR classification
 - -standing orders

HSNO Act

- · ERMA
- · manages risk to
 - -environment
 - -public health
- definitions?

HSNO Act

- new organisms
 - -genetically modified
 - -exotic animals / plants
 - -newly evolved pathogens???
- hazardous substances
 - anything which may be detrimental to human health

HSNO Act

- detailed regs listing hazardous substances and conditions
 - active ingredients not trade name products
- vet drugs are hazardous substances
- human drugs are exempt

HSNO Amendment Bill

- · sets thresholds
 - -above threshold full approval process
 - below threshold ACVM Group or Medsafe can approve

food standards

- ACVM Act? NZFSA (MAF)
- · HSNO Act? MfE
- · Medicines Act? MoH
- · Misuse of Drugs Act? MoH
- Meat Act? NZFSA
- · Animal Products Act? NZFSA
- · Biosecurity Act MAF Biosecurity

Medicines Act

- · as AR Act plus
- prescriptions, labels, containers etc
- · data sheets
 - -now on the web
 - -http://www.medsafe.govt.nz
- · classification

22

medicines classification

- · prescription medicine
- · restricted medicine
- · pharmacy only medicine
- (general sales medicine)

classification

- Medicine
 - anything for administration to people for a therapeutic purpose (treating or preventing disease, diagnosing disease, contraception, inducing anaesthesia, altering the human body, interfering with physiological functions or cleaning contact lenses) or for pregnancy testing. Does not include animal remedies.

classification

New medicine

 any medicine which has not been generally available in NZ in the last five years.

classification

· Pharmacy only medicine

 declared by regulation or notice that may only be sold in a pharmacy or hospital, or a licensed shop.

classification

Prescription medicine

 declared by regulation or notice that may only be sold pursuant to a prescription written by a practitioner or veterinary surgeon.

classification

- · Restricted medicine
 - declared by regulation or notice that may only be sold only by a pharmacist in a pharmacy or hospital.
- (nb. drugs controlled under the Misuse of Drugs Act 1975 are not classified under this act.)

Medicines Act

- s25 vets may procure drugs for named patients
- s29 anyone may sell a vet a drug for a named patient

Medicines Act

- in both Europe and USA, veterinary & human medicines are regulated under the same law
- · Oz different laws in each state
- drugs not licensed in NZ are often licensed overseas

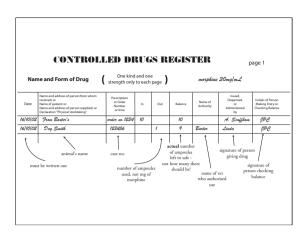
Misuse of Drugs Act

- · drugs of abuse
 - -classification
 - -records
 - -storage
 - -prescriptions

class	drugs	restrictions
А	etorphine (heroin, cocaine, LSD etc)	controlled drug safe controlled drug register permission from MoH
B1	morphine	controlled drug safe controlled drug register
В3	alfentanil fentanyl pethidine methadone	controlled drug safe controlled drug register
C2	codeine	controlled drug safe
C4	buprenorphine pentobarbitone	controlled drug safe
C5	benzodiazepines phenobarbitone	locked cupboard recom- mended
C6	dilute solutions/forms	none
C7	carfentanil (designer drugs)	controlled drug safe controlled drug register
not controlled at pres- ent	ketamine butorphanol nalbuphine pentazocine ephedrine	locked cupboard

Misuse of Drugs Act

- · drugs of abuse
 - -classification
 - -records
 - -storage
 - -prescriptions



Misuse of Drugs Act

- · drugs of abuse
 - -classification
 - -records
 - -storage
 - -prescriptions



cd prescriptions

- same as medicine prescriptions but
 - -no abbreviations
 - -no repeats
 - -must be hand written
- only rarely necessary for class C drugs in vet practice