

# The Law

## NZ Legislation



# What would you do?

- A farmer you have never seen before walks into the clinic, says he has a problem with *Staph aureus* masitis and asks for a box of tubes.



- a. sell him six months supply of your most expensive 4th generation cephalosporin tubes
- b. tell him to go to Farmlands and get some penicillin tubes
- c. tell him to give intramammary gin as it is all the rage at the moment
- d. tell him to get his milking machine serviced as *Staph. aureus* is spread by the machine
- e. give him a leaflet about the SAMM plan
- f. tell him just to cull the high cell count cows
- g. examine his herd, check that his management is reasonable then write a prescription for cloxacillin tubes
- h. tell him to wait until he gets his first case of clinical mastitis then bring in a sample for culture and sensitivity testing
- i. tell him to use a cider vinegar teat dip as the price for organic milk is higher



# legislation

- Acts of Parliament
- Statutory 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



# 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
  - public health
- **domestic food standards**
- **consumer information**



# ACVM Act

- definitions
- registration
- abolished ARB
- human drugs?
- horses?
- chemicals?



# ACVM Act

- **veterinary medicine**
  - “any substance used in the direct management of animals”



# ACVM Act

- definitions
- registration
- abolished ARB
- human drugs?
- horses?
- chemicals?



# ACVM Act

- registration
- risks to
  - trade
  - animal welfare
  - agricultural security
  - public health
- 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**
  - RVMS (PARs)
  - species



# restricted veterinary medicines

- **must be authorised by vet**
  - can be given by anyone
    - can be restrictions on use
  - must be given by vet
  - must be used only under an approved plan



# 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

- **separate prescribing from dispensing**
- **allow prescribing over the phone without examining animal**
- **relax PAR classification**
  - standing orders (veterinary operating instructions)



# 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 or the environment



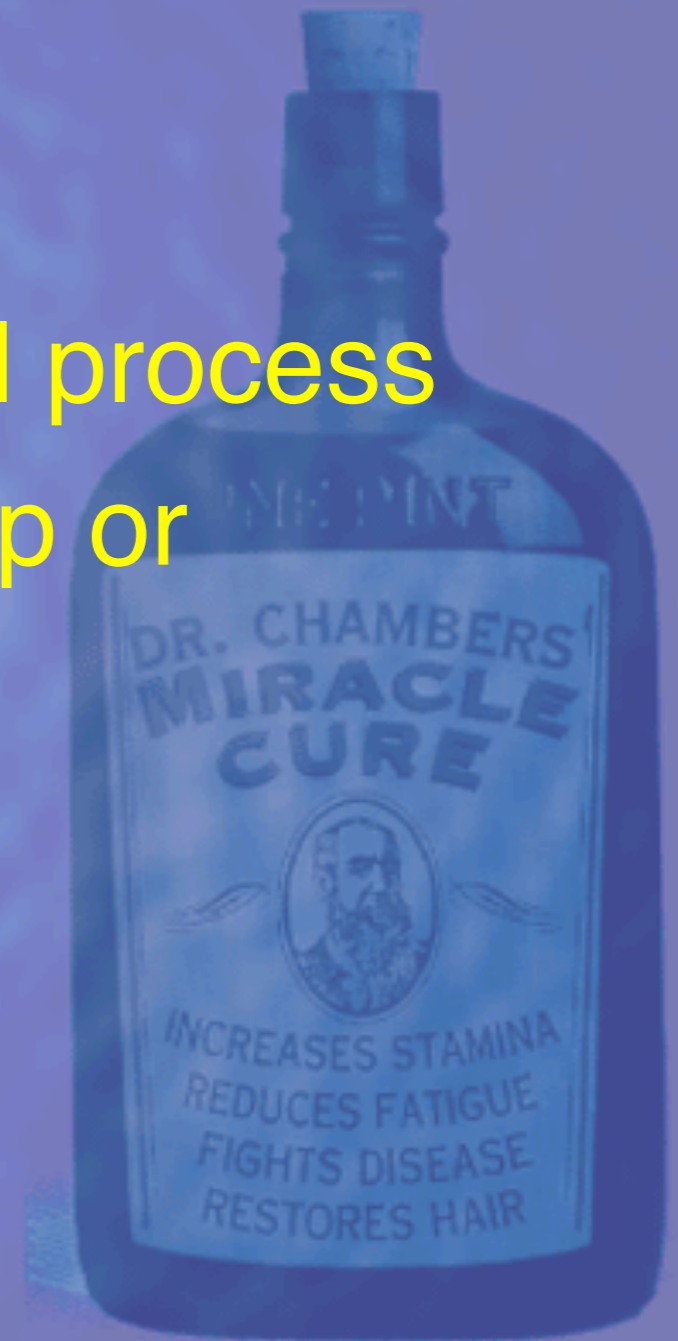
# HSNO Act

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



# HSNO Amendment

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



# food standards

- **ACVM Act? - NZFSA**
- **HSNO Act? - MfE**
- **Medicines Act? - MoH**
- **Misuse of Drugs Act? - MoH**
- **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





# 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**

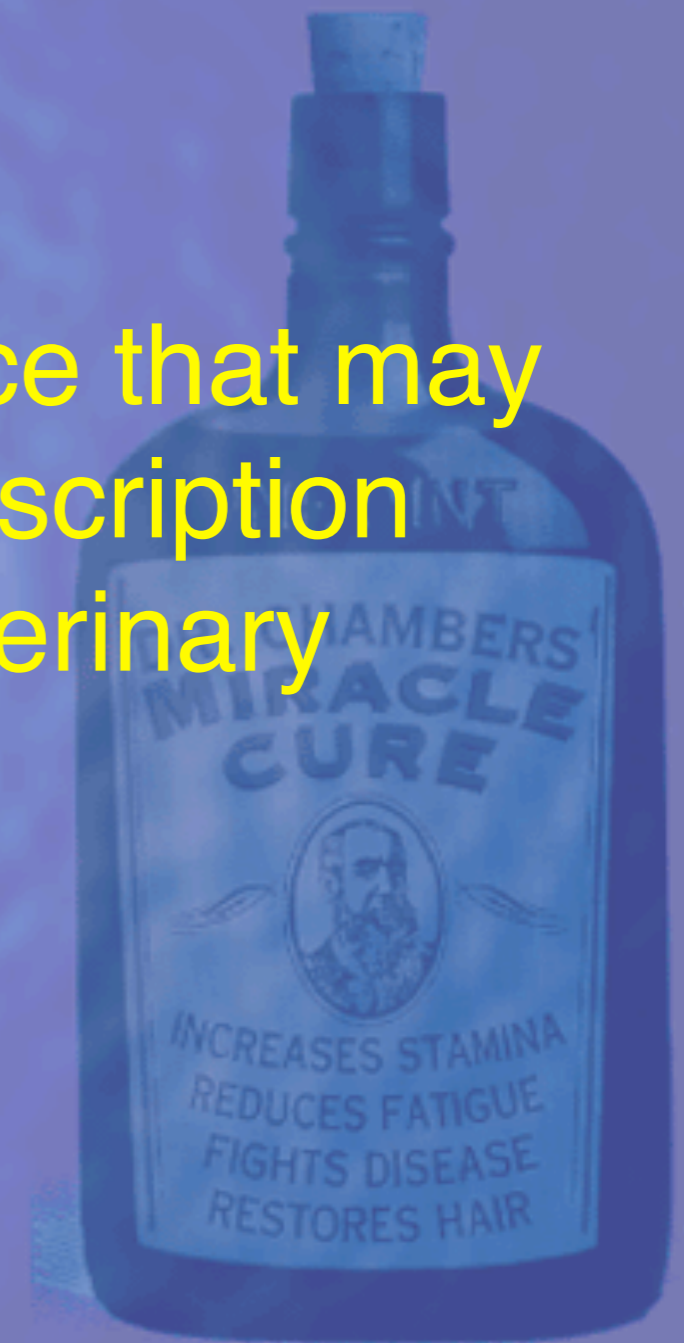
- declared by regulation or notice that may only be sold in a pharmacy or hospital, or a licensed shop.



# 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**

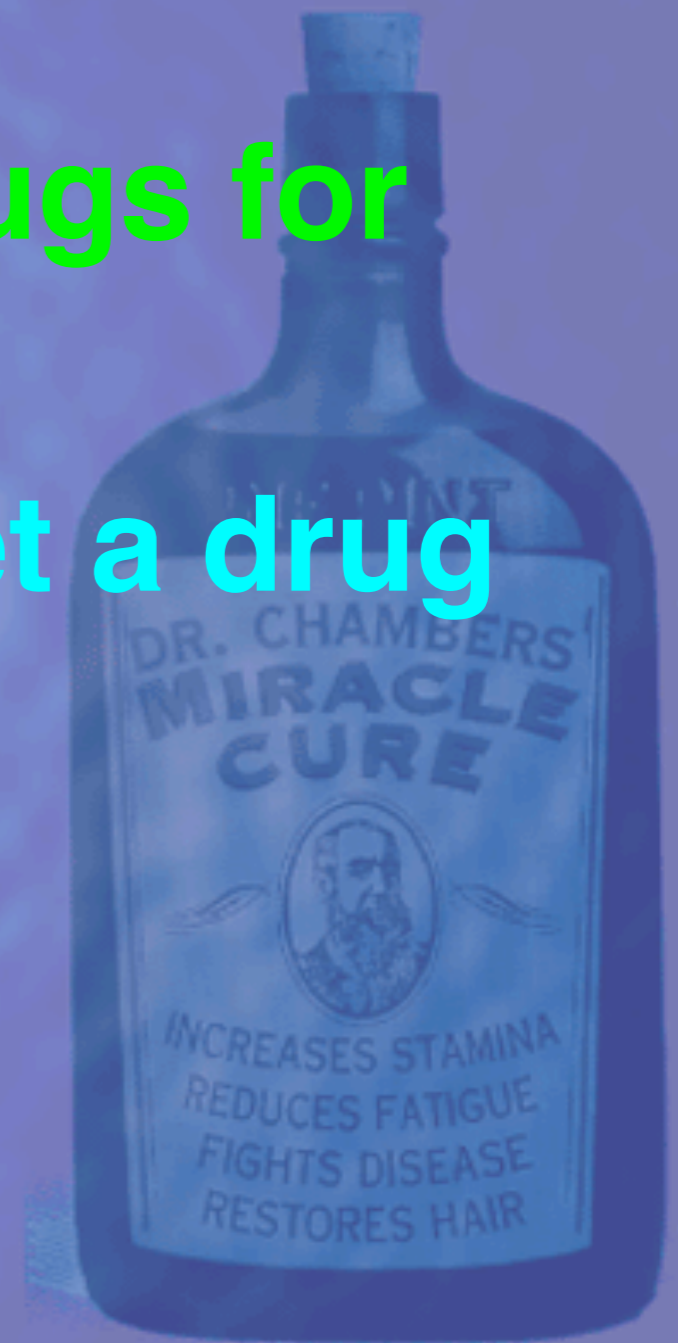
- declared by regulation or notice that may only be sold only by a pharmacist in a pharmacy or hospital.

- (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



<b>class</b>	<b>drugs</b>	<b>restrictions</b>
<b>A (&amp;B1 except morphine, B2)</b>	etorphine, phenylpropanolamine ephedrine, pseudoephedrine (heroin, thalidomide etc)	controlled drug safe controlled drug register permission from MoH
<b>B</b>	morphine pethidine fentanyl alfentanil methadone	controlled drug safe controlled drug register
<b>C2 &amp; C4</b>	codeine buprenorphine pentobarbitone ketamine (from early 2007)	locked up controlled drug safe
<b>C5</b>	benzodiazepines phenobarbitone	locked cupboard
<b>C6</b>	dilute solutions	none
<b>C7</b>	carfentanil (designer drugs)	controlled drug safe controlled drug register
not controlled at present	butorphanol nalbuphine pentazocine	locked cupboard

# Misuse of Drugs Act

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



# 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
16/10/02	<i>From Baxter's</i>	<i>order no. 1234</i>	<i>10</i>		<i>10</i>		<i>A. Scuffham</i>	<i>JPC</i>
16/10/02	<i>Dog Smith</i>	<i>123456</i>		<i>1</i>	<i>9</i>	<i>Barter</i>	<i>Linda</i>	<i>JPC</i>

must be written out

animal's name

case no.

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

# Misuse of Drugs Act

- **drugs of abuse**
  - classification
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  - prescriptions





Temgesic  
Injection  
1 ml - 300µg  
(0.3mg)

**Morphine Sulfate Injection**  
Morphine Sulfate BP  
**30 mg in 1 mL**  
50 ampoules

**Morphine Sulfate Injection**  
Morphine Sulfate BP  
**10 mg in 1 mL**  
50 ampoules

**Pethidine Injection BP**  
Pethidine Hydrochloride BP  
**100 mg in 2 mL**  
50 Ampoules

100-500

# 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**

