

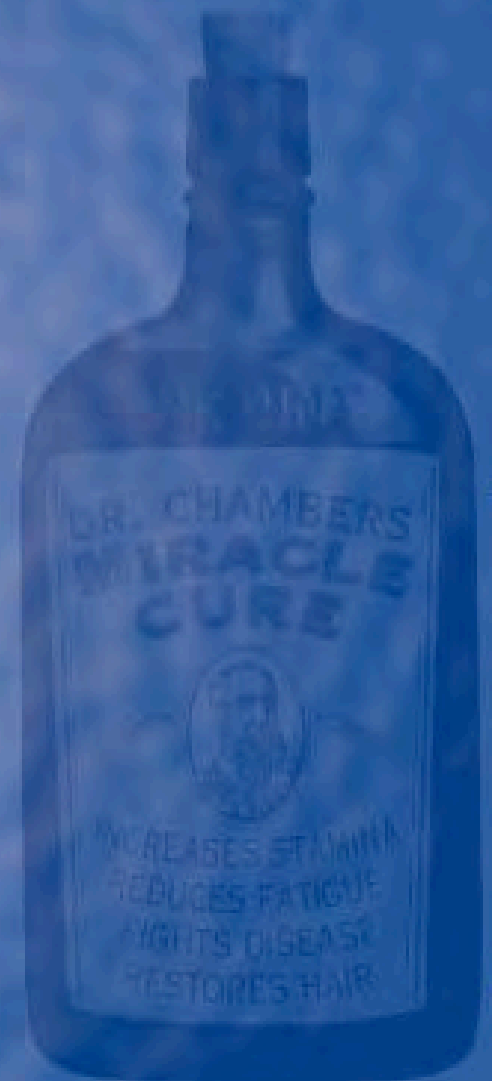
The Law

NZ Legislation



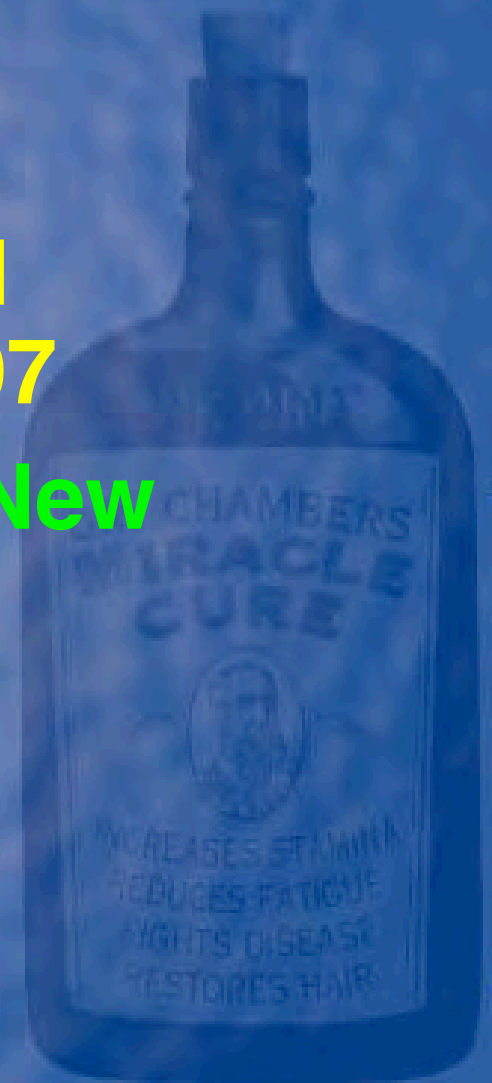
legislation

- Acts of Parliament
- Statutory Regulations
- Codes of Conduct



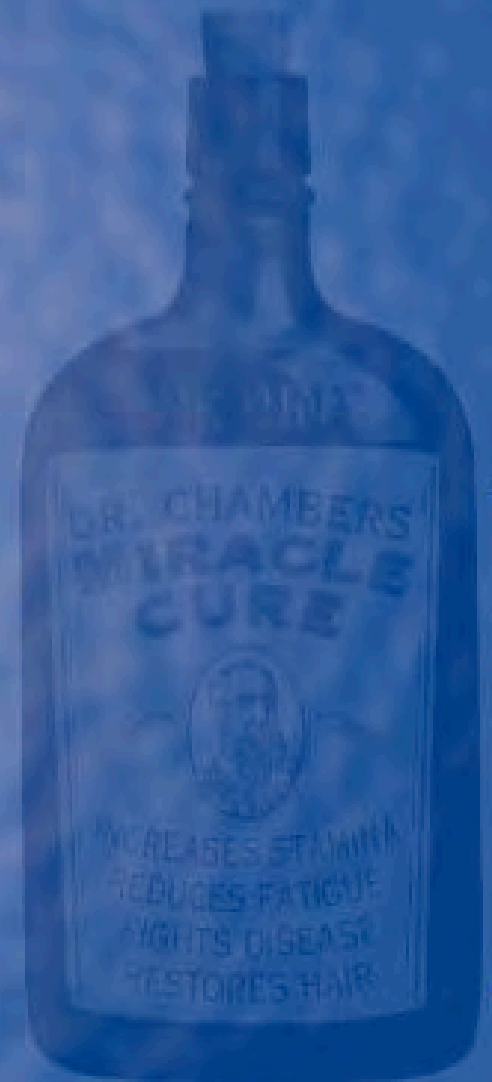
Acts

- 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



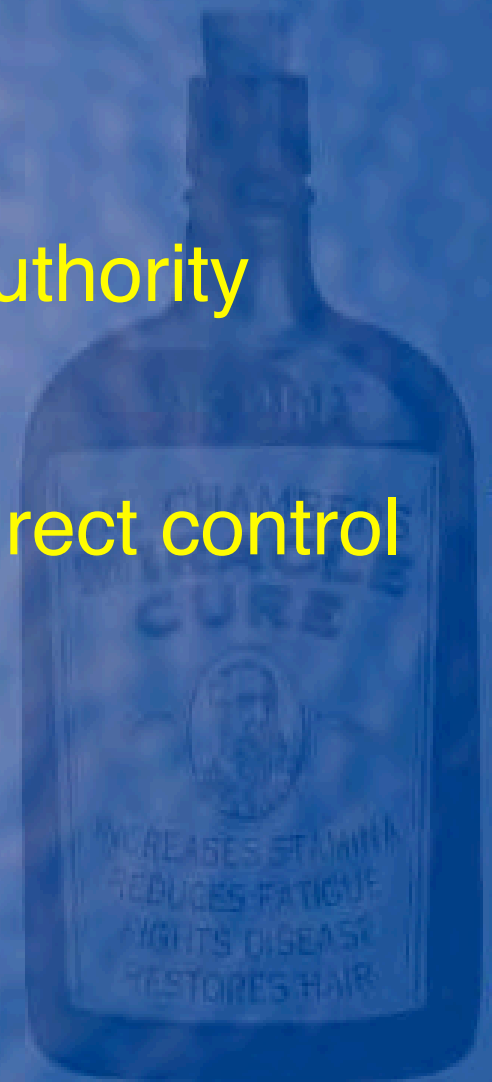
Animal Remedies Act

- definitions
- Animal Remedies Board
- registration
- classification



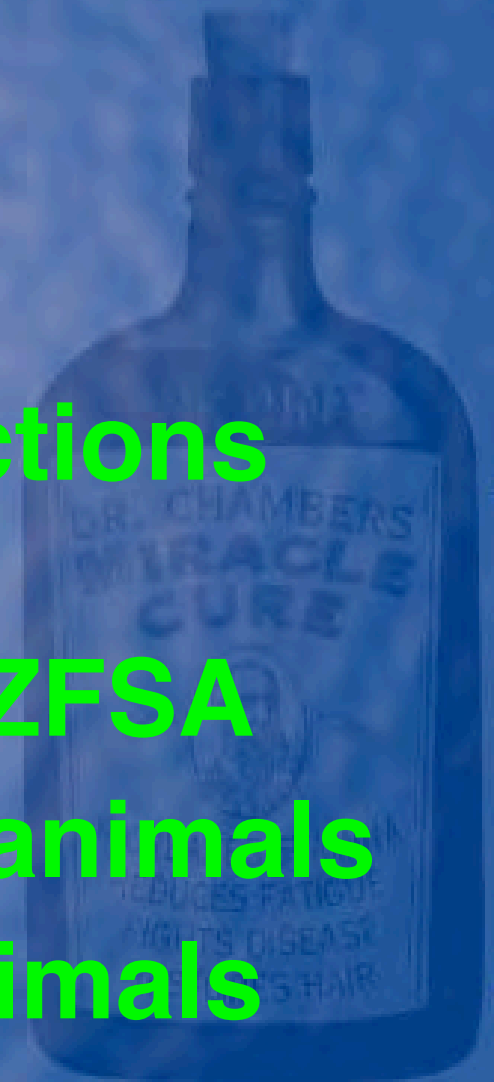
prescription animal remedies

- **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



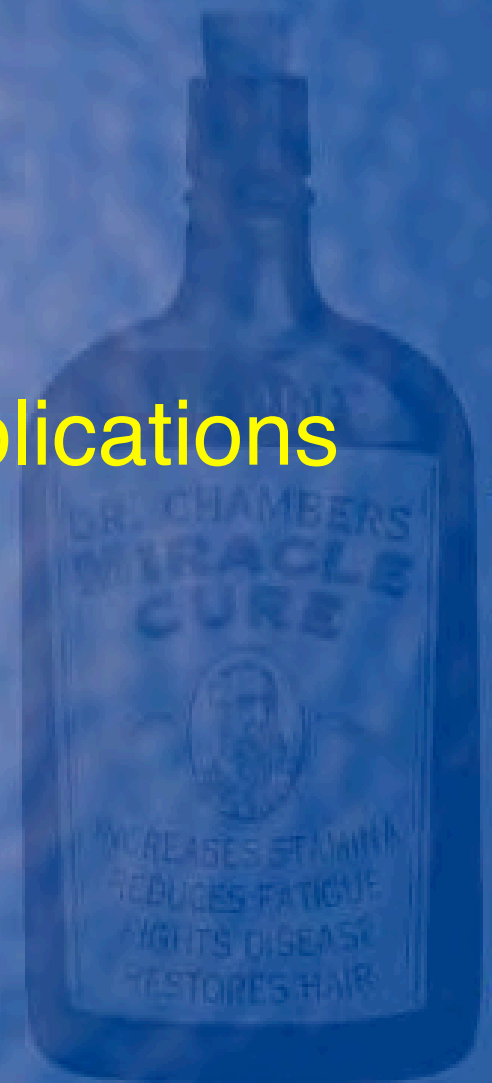
PAR1 antibiotics

- 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



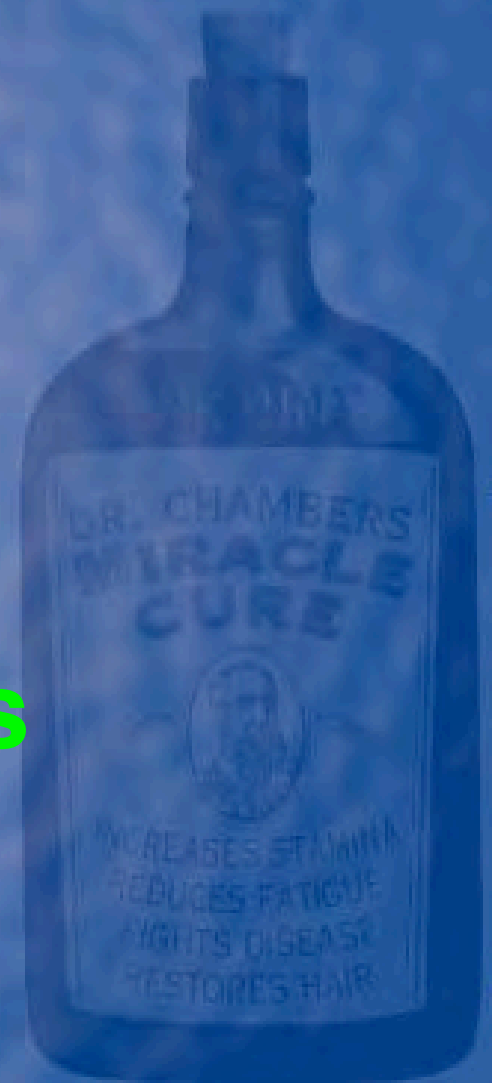
Animal Remedies Act

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



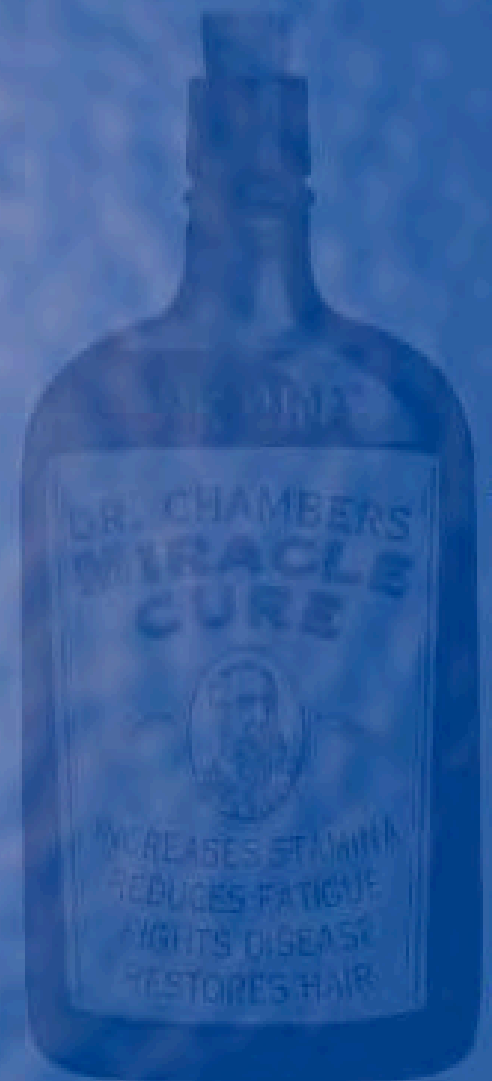
ACVM Act

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



ACVM Act

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



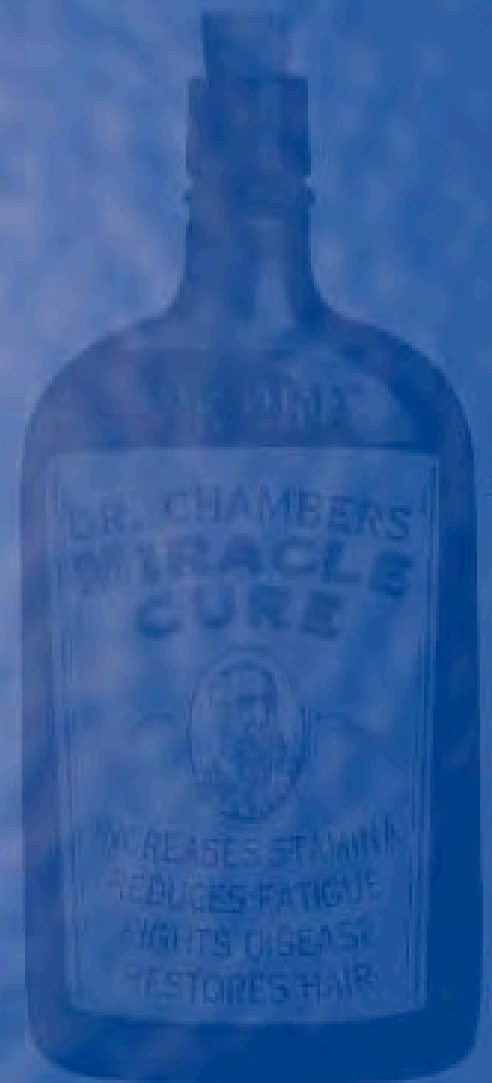
ACVM Act

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



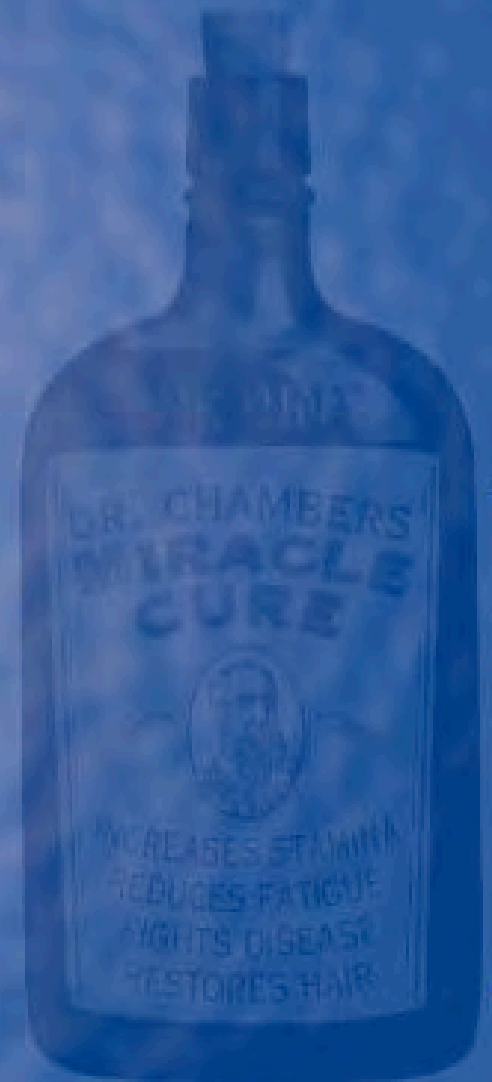
ACVM Act

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



ACVM Act

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



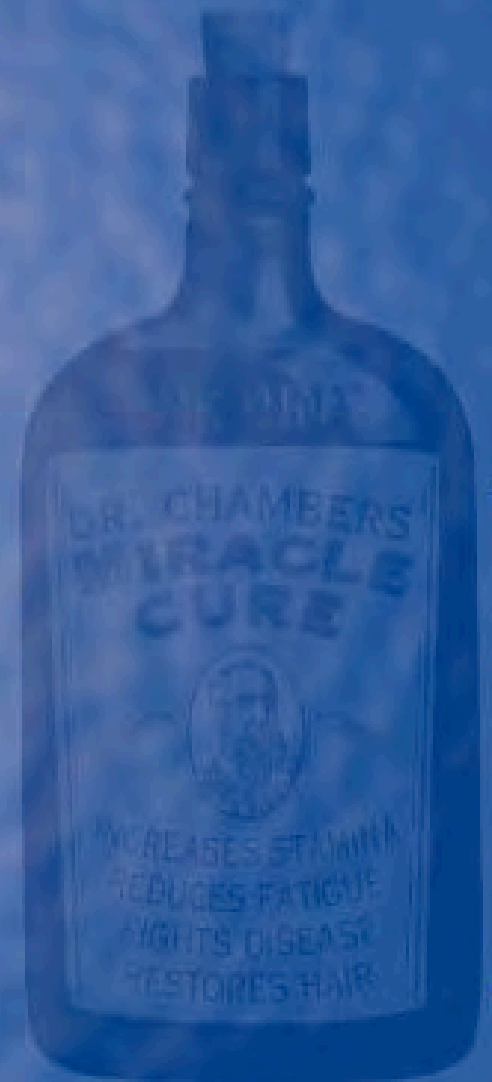
ACVM Act

- 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



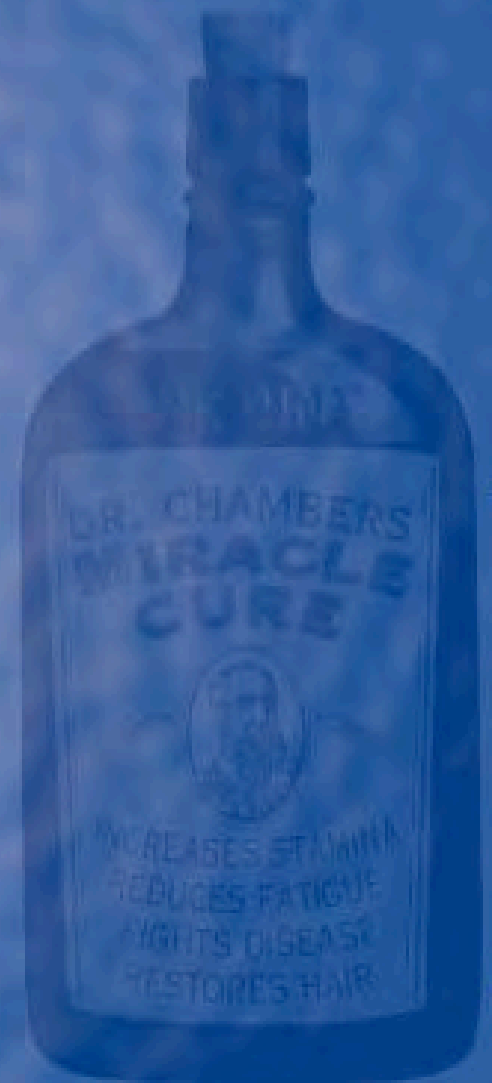
ACVM Act - future?

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



HSNO Act

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



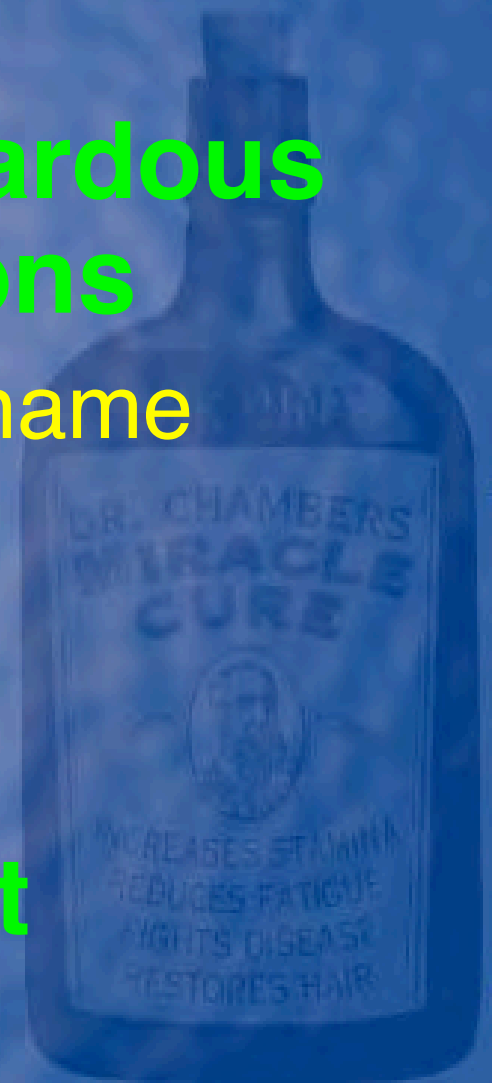
HSNO Act

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



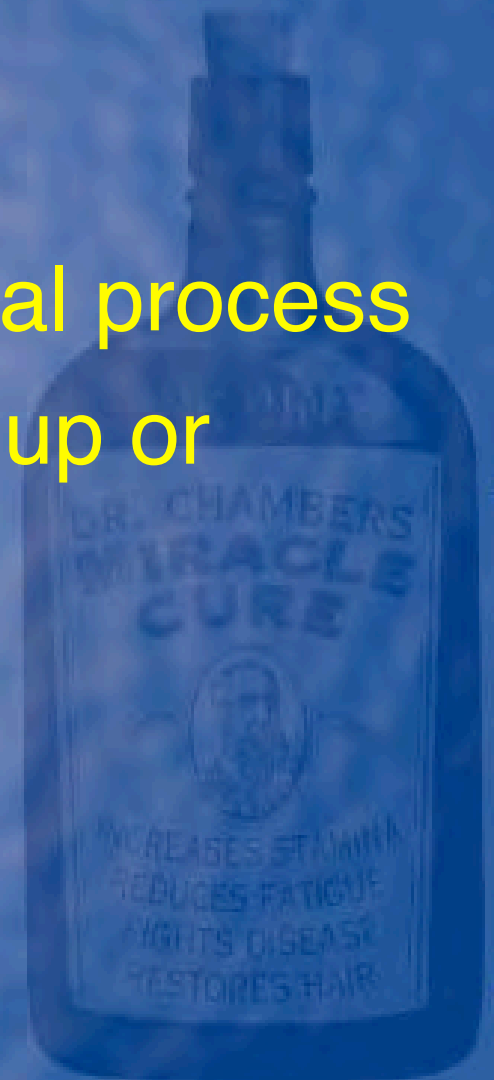
HSNO Act

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



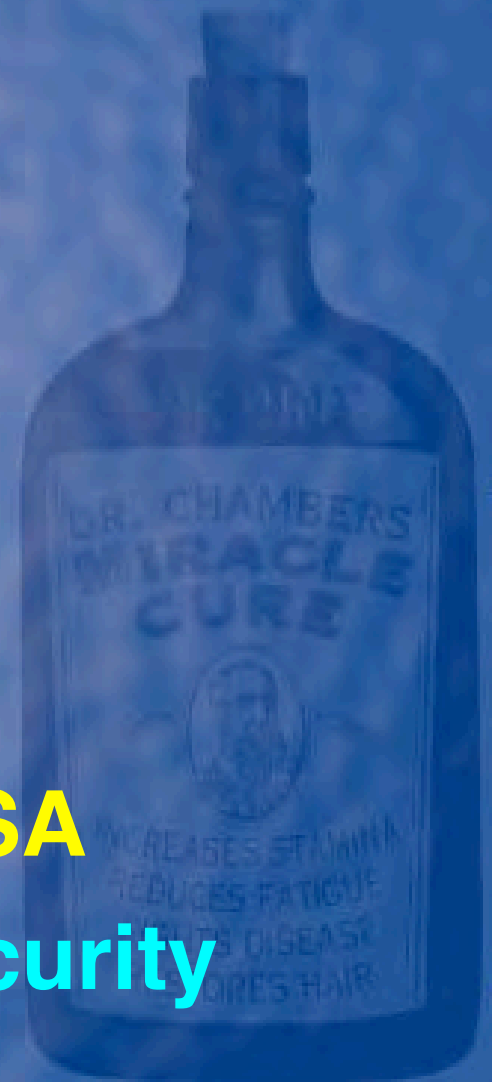
HSNO Amendment Bill

- **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**



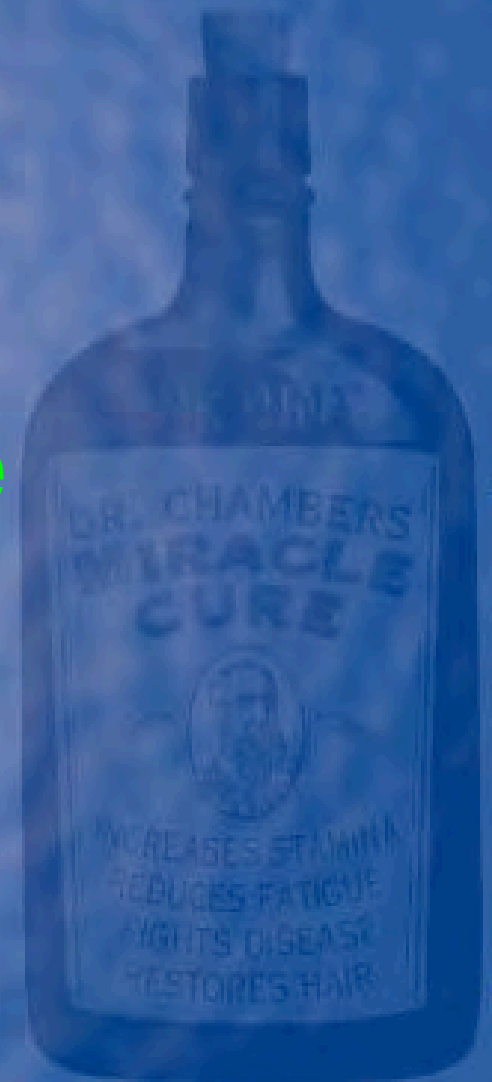
Medicines Act

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



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

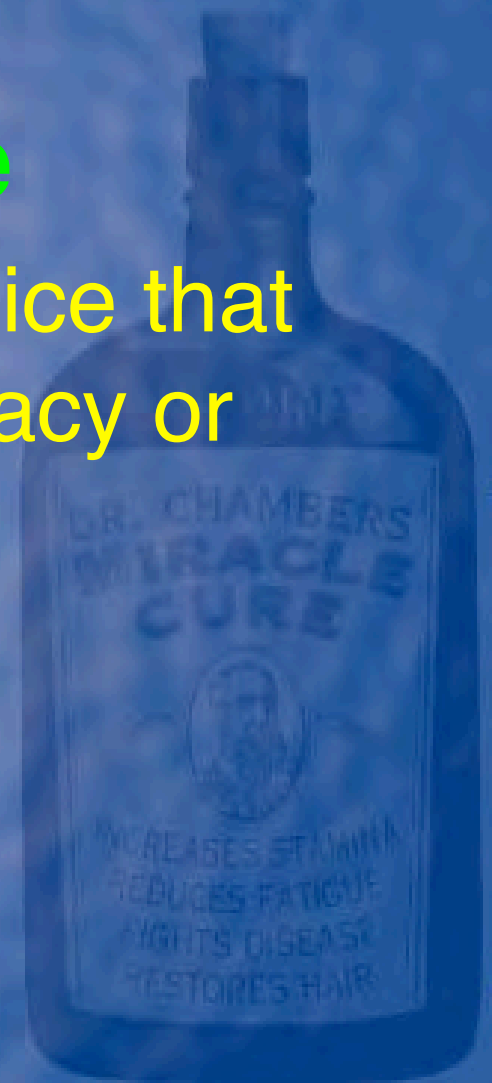
- **New medicine**

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



classification

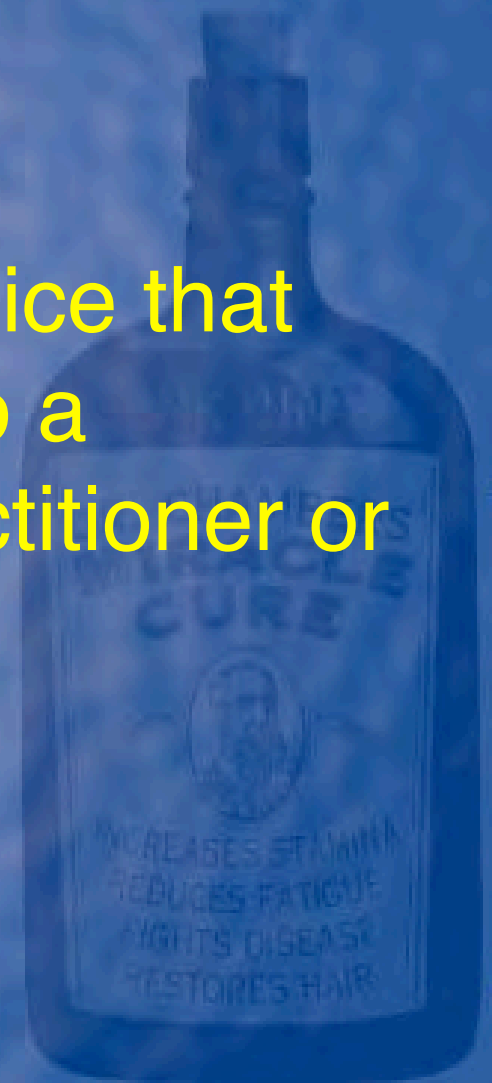
- **Pharmacy only medicine**
 - declared by regulation or notice that may only be sold in a pharmacy or hospital, or a licensed shop.



classification

- **Prescription medicine**

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



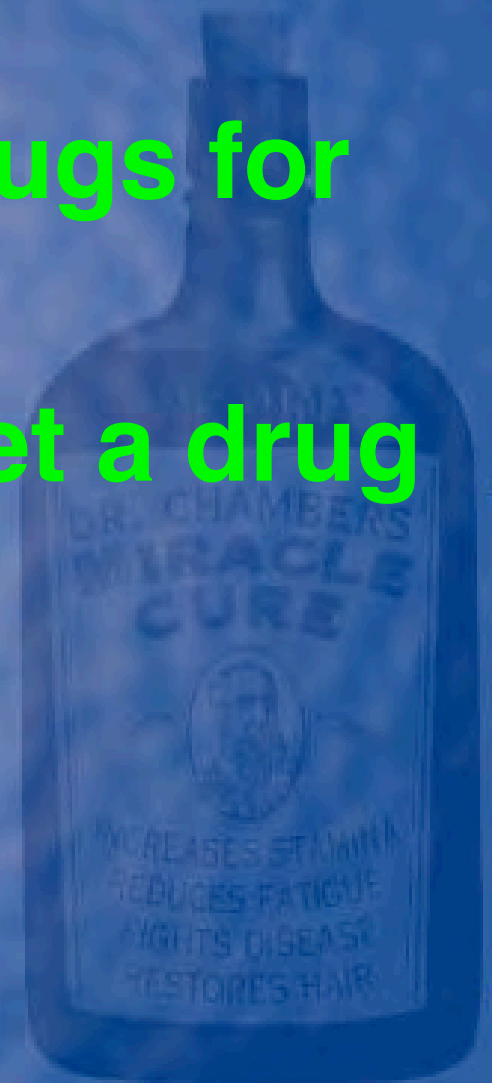
classification

- **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



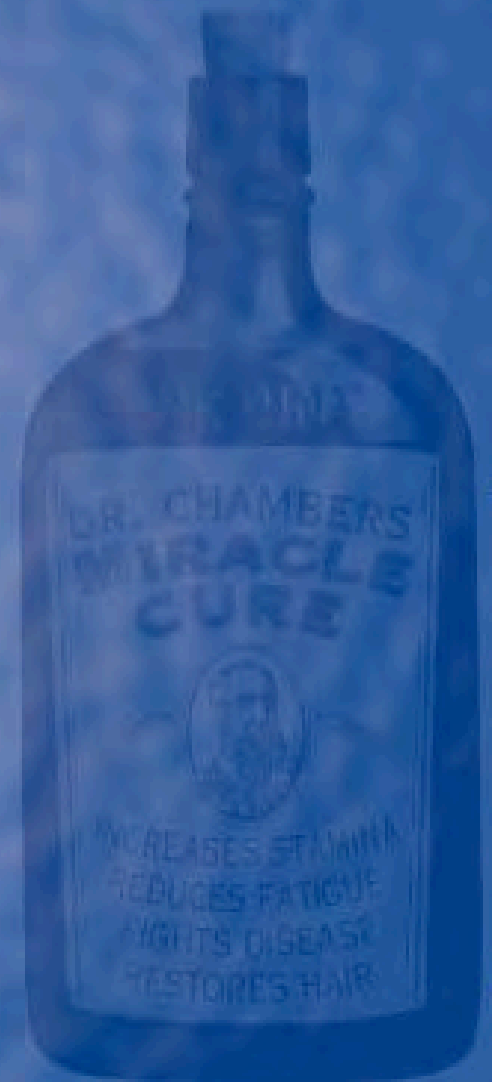
Medicines Act

- 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

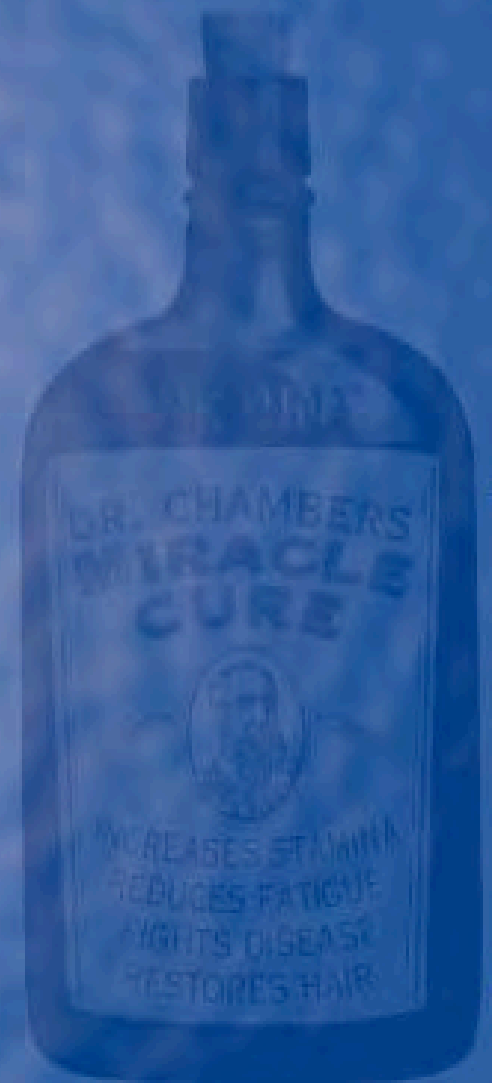
- drugs of abuse
 - classification
 - records
 - storage
 - prescriptions



class	drugs	restrictions
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	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



CONTROLLED DRUGS REGISTER

page 1

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>IPC</i>
16/10/02	<i>Dog Smith</i>	<i>123456</i>		<i>1</i>	<i>9</i>	<i>Barter</i>	<i>Linda</i>	<i>IPC</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!

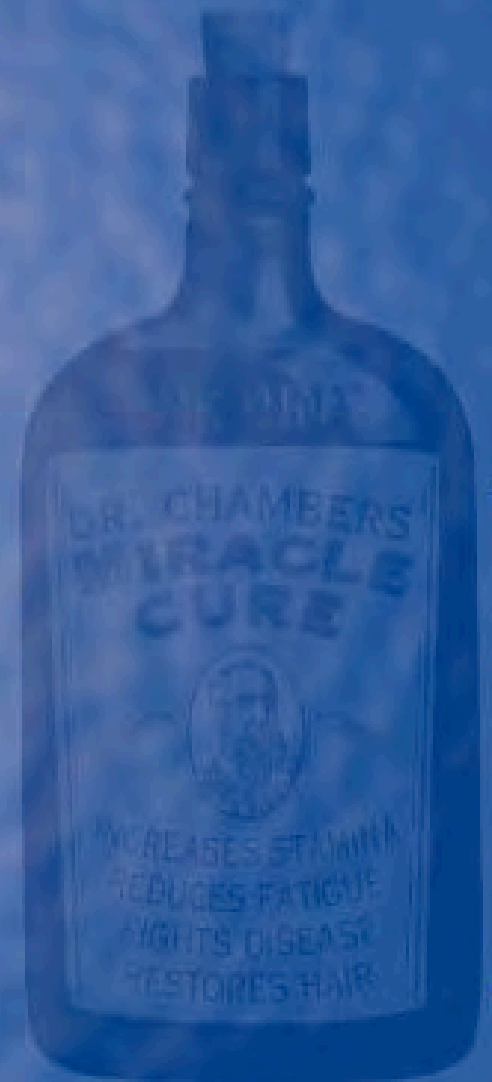
name of vet
who authorised
use

signature of person
giving drug

signature of
person checking
balance

Misuse of Drugs Act

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



Temgesic
Injection
100 µg (0.3 mg)
1 ml - 300 µg (0.3 mg)
1 ml - 300 µg (0.3 mg)

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

DBL
Morphine Sulfate Injection
100 µg (0.3 mg)
1 mL
50 ampoules

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

clonidine

...

...

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

