REGULATING MEDICINES

Sanya Ram, LLB, BPharm, NZRegPharm

LEARNING OUTCOMES

By the end of this lecture students should be able to:

Describe how and why medicines are regulated?

Outline the purpose of key legislation in regulating Medicines

Define what a medicine is and explain how medicines are classified.

Describe the role of Medsafe.

Discuss the importance of pharmacovigilance.

Explain Pre-marketing approval and Post-marketing surveillance activities.

WHAT IS A MEDICINE?

Medicines Act 1981 regulates medicines, related products and medical devices in New Zealand.

The Act:

- defines what a medicine is

Activity:

Why are some of these medicines and others are not?

SECTION 3 MEDICINES ACT 1981

1(a) medicine means any substance or article that—

(i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and

(ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and

b) includes any substance or article—

(i) that is manufactured, imported, sold, or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or

(ii) of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act; but

(c) does not include—

(i) a medical device; or (ii) any food within meaning of s2 of the Food Act 1981; or

any radioactive material, animal food , animal remedy; or any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act.

SECTION 4 MEDICINES ACT 1981

4 Meaning of therapeutic purpose

- (a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
- (b) influencing, inhibiting, or modifying a physiological process; or
- (c) testing the susceptibility of persons to a disease or ailment; or
- (d) influencing, controlling, or preventing conception; or
- (e) testing for pregnancy; or
- (f) investigating, replacing, or modifying parts of the human anatomy.

MISUSE OF DRUGS ACT 1975

Some (narcotic and psychotropic) products that are used for therapeutic purposes are classified as controlled drugs.

These products are therefore regulated under both the Medicines Act and the Misuse of Drugs Act 1975

Eg codeine, morphine etc

CLASSIFICATION OF MEDICINES

CLASSIFICATION OF MEDICINES

The Medicines Act 1981 defines three classification categories for medicines.

- Prescription medicine
- Restricted medicine (also referred to as pharmacist-only medicine)
- Pharmacy-only medicine.
- General Sale Medicines

CLASSIFICATION OF MEDICINES

- Medicines are classified according to their active ingredients.
- If the medicine has more than one active ingredient, the active with the most restrictive classification determines the classification of the medicine
- The First Schedule to the Medicines Regulations 1984 is a list of active ingredients grouped under their respective classifications.
- Classification changes occur approximately every six months.

PRESCRIPTION MEDICINE

Prescription medicine means a medicine that is declared by regulations or by a notice given under section 106 to be one that, except as may be permitted by regulations, may be—

(a) sold by retail only under a prescription given by an authorised prescriber, veterinarian, or delegated prescriber; and

(b) supplied in circumstances corresponding to retail sale only—

- (i) under a prescription given by an authorised prescriber, veterinarian, or delegated prescriber; or
- (ii) in accordance with a standing order; and

(c) administered only in accordance with—

(i) a prescription given by an authorised prescriber, veterinarian, or delegated prescriber; or

(ii) a standing order

RESTRICTED MEDICINE

Restricted medicine means a medicine that is declared by regulations made under this Act or by a notice given under section 106 to be one that, except as may be permitted by the regulations, may be—

(a) sold by retail only by a pharmacist in a pharmacy or hospital; or

(b) supplied in circumstances corresponding to retail sale only—

- (i) by a pharmacist in a pharmacy or hospital; or
- (ii) in accordance with a standing order.]

PHARMACY ONLY MEDICINE

Pharmacy-only medicine may be—

(a) sold by retail only—

- (i) in a pharmacy or hospital; or
- (ii) in any shop described in section 51(2) and in accordance with a licence issued under Part 3; or

(b) supplied in circumstances corresponding to retail sale only—

- (i) in a pharmacy or hospital; or…..

WHERE DO YOU FIND THE CLASSIFICATIONS

Medicines Regulations 1984:

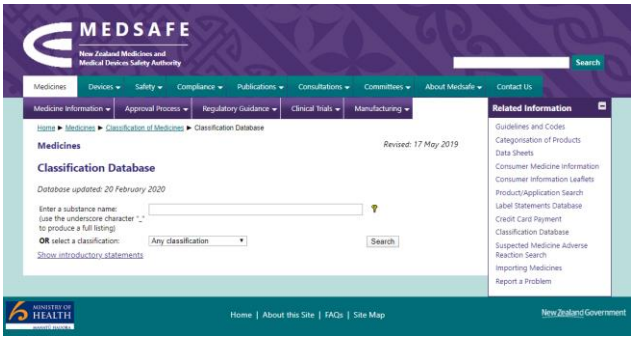
Regulation 3: Classification of medicines

- (1) All medicines and classes of medicines specified in Part 1 of Schedule 1 are hereby declared to be prescription medicines.
- (2) All medicines and classes of medicines specified in Part 2 of Schedule 1 are hereby declared to be restricted medicines.
- (3) Subject to subclause (4) of this regulation, all medicines and classes of medicines specified in Part 3 of Schedule 1 are hereby declared to be pharmacy-only medicines.

GENERAL SALE MEDICINES

Medicines not listed in the classification schedules are referred to as general sale medicines.

These medicines may be sold from any outlet.



Ingredient	Conditions (if any)	Classification
Ranitidine	***except*** when specified elsewhere in this schedule; ***except*** in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply	Prescription
Ranitidine	in medicines for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in the manufacturer's original pack containing not more than 14 days' supply; **except** in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply	Pharmacy Only
Ranitidine	in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply	General Sale

ACTIVITY

Consider a medicine such as …...

Assuming you are a member of the NZ Medicines Classification Committee, outline what classification you would recommend for sumatriptan.

What factors did you consider?

FACTORS TO CONSIDER

- Indications and dose
- Presentation
- Consumer benefits
- Contraindications and precautions
- Undesirable effects
- Overdose
- Medication errors and abuse/misuse potential
- Communal harm
- Benefit/risk
- Risk mitigating strategies

WHY REGULATE MEDICINES

Photo taken from https://smra.gov.lk/index.php?option=com_content&view=article&id=92&Itemid=232&lang=en

ACTIVITY: EXAMEZE

Assurance of:

Quality (stability, purity)

Safety

Efficacy

Pre-market evaluation and approval

Pharmacovigilance

HISTORY OF REGULATING MEDICINES

The 1937 Elixir Sulfanilamide Incident

http://pubs.acs.org/subscribe/archive/mdd/v07/i01/pdf/104timeline.pdf

MEDICINES REGULATIONS

Manages the risk of avoidable harm associated with the use of medicines by ensuring that:

- medicines meet acceptable standards of safety, quality and efficacy;
- personnel, premises and practices used to manufacture, store and distribute medicines comply with requirements designed to ensure that products meet acceptable standards right up until they are delivered to the end-user; and
- information about the selection and safe use of medicines is provided to health professionals and consumers.

MEDICINES ACT 1981

The Medicines Act sets out:

- requirements for the
  - approval,
  - classification,
  - manufacture,
  - sale,
  - distribution,
  - advertising, prescribing and
  - dispensing of medicines
- licensing requirements for the medicines distribution chain, including wholesalers and pharmacies
- requirements for the approval of related products
- post-market controls on medicines and medical devices.

REGULATORY AUTHORITIES

Federal Drug Agency (USA)

Therapeutic Goods Administration (Australia)

Medicines & Healthcare products Regulatory Agency (UK)

Medsafe: New Zealand Medicines and Medical Devices Safety Authority (NZ)

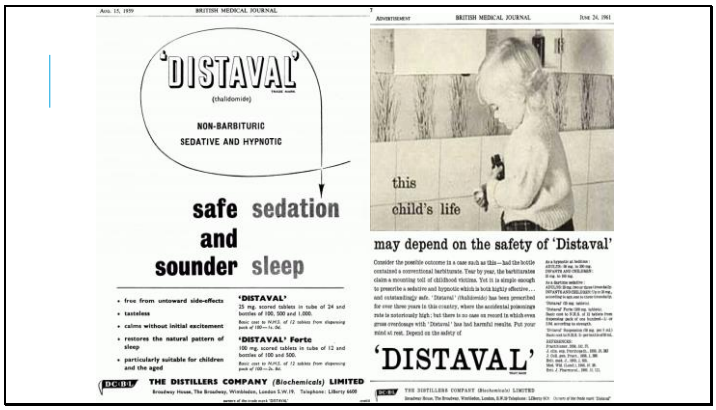
MEDSAFE

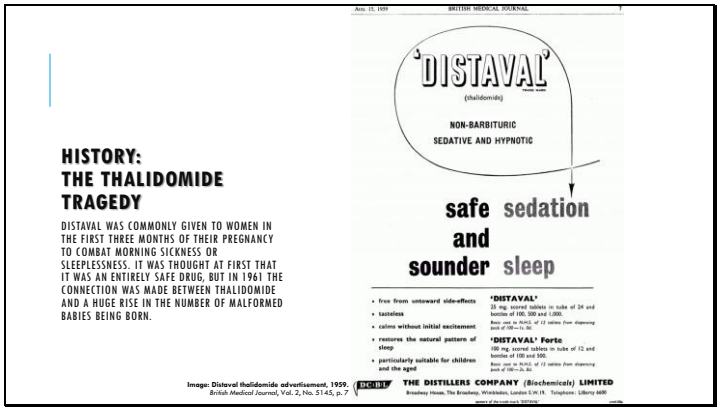
Medsafe is responsible for administering most aspects of the Medicines Act 1981 and its associated regulations in New Zealand including:

- approval of new and changed medicines and related products
- audit and licensing of medicine manufacturers
- approval of clinical trials of new medicines
- classification of medicines
- pharmacovigilance
- surveillance and monitoring
- border control and enforcement
- administration of a database of medical devices in New Zealand
- oversight of medicine and medical device recalls.

http://www.medsafe.govt.nz/

POST- MARKETING SURVEILLANCE





HISTORY: THE THALIDOMIDE TRAGEDY

DISTAVAL WAS COMMONLY GIVEN TO WOMEN IN THE FIRST THREE MONTHS OF THEIR PREGNANCY TO COMBAT MORNING SICKNESS OR SLEEPLESSNESS. IT WAS THOUGHT AT FIRST THAT IT WAS AN ENTIRELY SAFE DRUG, BUT IN 1961 THE CONNECTION WAS MADE BETWEEN THALIDOMIDE AND A HUGE RISE IN THE NUMBER OF MALFORMED BABIES BEING BORN.

Image: Distaval thalidomide advertisement, 1959. *British Medical Journal*, Vol. 2, No. 5145, p. 7

POST-MARKETING SURVEILLANCE

Post-marketing surveillance monitors the safety of medicines and medical devices in use. Products shown to be unsafe are removed from use, and prescribers are advised about new safety information for products. Post-marketing surveillance is achieved through activities such as:

Pharmacovigilance: monitoring adverse reactions to medicines used in New Zealand and monitoring the international literature and other information sources;

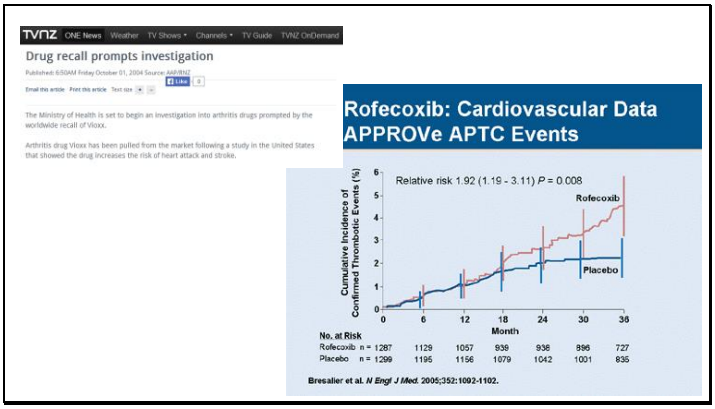
- testing marketed medicines against product quality standards;
- handling complaints and investigations; and
- auditing and licensing medicine manufacturers

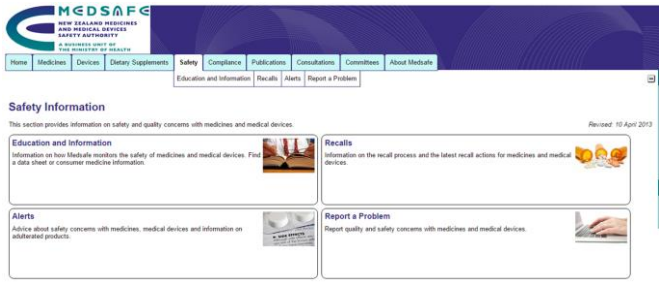
WHAT IS PHARMACOVIGILANCE?

"Monitoring of the safety of marketed medicines and taking action to reduce risk and promote safe use, thereby protecting public health"

Goals

- To identify previously unrecognised hazards (or signals)
- To evaluate changes in risk and benefits
- To take action to promote safer use of medicines
- To provide optimal information to health professionals





CARM REPORTING

CARM
CENTRE FOR ADVERSE REACTIONS MONITORING

What?
- Adverse drug reaction only has to be suspected
- You do not need to have evidence of association or cause

Who?
- Health professionals
- Pharmaceutical companies
- Consumers (but where possible an attempt is made to involve the patient's practitioner)

How?
- Record patient details, details of medicine and of the event
- Yellow form on ward
- Download from both the CARM and Medsafe web sites
- Return by email, post or fax.

https://nzphvc.otago.ac.nz/carm/

REGULATION OF MEDICINES

Key activities:

- Control of the manufacturing chain
- Control of the distribution chain
- Pre-market evaluation and approval
- Post-market surveillance
- Control of access to medicines

FUNDING OF MEDICINES

PHARMAC
Pharmaceutical Management Agency

http://www.pharmac.health.nz/

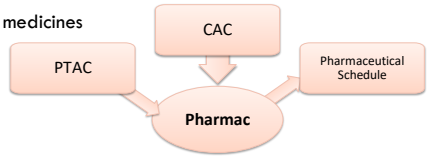
PHARMAC

Manages the pharmaceutical schedule

Manages the subsidy of medicines in public hospitals

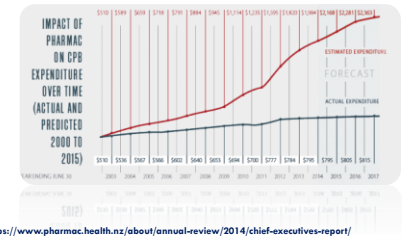
Manages special access programmes

Promotes best use of medicines



NZ PUBLIC HEALTH AND DISABILITY ACT 2000

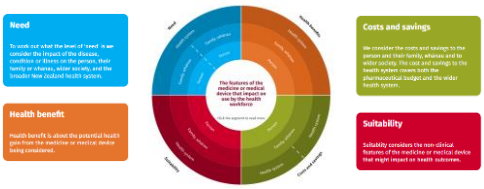
"To secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceutical treatment within the funding available"



https://www.pharmac.health.nz/about/annual-review/2014/chief-executives-report/

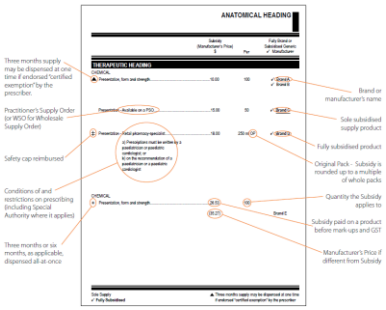
FUNDING OF MEDICINE BASED ON A SET OF CRITERIA

In deciding which medicines to fund, Pharmac seeks to balance the needs of patients' access to healthcare against its responsibilities to the taxpayer.



https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/factors-for-consideration/

HOW CAN I TELL IF A MEDICINE IS SUBSIDISED?



CONCLUSION

The Medicines legislation manages the risk of avoidable harm associated with the use of medicines by ensuring that:

- medicines meet acceptable standards of safety, quality and efficacy;
- personnel, premises and practices used to manufacture, store and distribute medicines comply with requirements designed to ensure that products meet acceptable standards right up until they are delivered to the end-user; and
- information about the selection and safe use of medicines is provided to health professionals and consumers in a timely manner

KEY QUESTIONS DISCUSSED

Define what a medicine is

Describe how and why medicines are regulated?

Outline the purpose of key legislation in regulating Medicines

Define what a medicine is and explain how medicines are classified.

Describe the role of Medsafe.

Discuss the importance of pharmacovigilance.

Explain Pre-marketing approval and Post-marketing surveillance activities.

What is the role of Pharmac and how medicines are funded.