Reclassifying medicines in New Zealand

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October 2017

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Outline

- Classifications in New Zealand
- Reclassification/switch process
- Criteria considered
- Risk mitigation/follow up
- Challenges

Classifications

- Prescription medicine
- Restricted medicine
- Pharmacy only medicine
- General sales

Prescription except when…

- Access only within specific criteria
- Restrict to certain healthcare professionals
- Mandate specific training
- Mandate wider health standards
- Mandate legislative requirements

Reclassification/Switch

- Call for submissions/applications
- Consultation period
- All comments and applications published
- Medicines Classification Committee
- Minutes published & objection period
- Medsafe considers impact of change
- Decision by Minister/Delegate

Medicines Classification Committee

- Ministerial Advisory Committee
- Composition determined by Medicines Act
  - 2 x NZ Medical Association
  - 2 x Pharmaceutical Society of NZ
  - 2 x Ministry of Health (includes Chair)
- Considers new chemical entities & reclassifications

Criteria considered

- Patient access – time & location
- Accuracy
- Efficacy
- Precedent
- Therapeutic index
- Toxicity

Criteria considered

- Inappropriate use
- Abuse potential
- Precautions
- Communal harm/benefit
- Harmonisation

What is not considered?

- Cost implications
- Products available in a small market
  - Sildenafil vs naloxone
- Impact on healthcare professionals business model
  - Oral Contraceptives
  - Sildenafil

Risk mitigation/Follow up

- Objections before decision by delegate
- Risk based audit
- Impact of change
  - Sildenafil
- Secret Shopper initiatives
- Feedback from professional groups
- Prescription except when....

Challenges

- Prescriptive composition of committee
- Encouraging products into a small market
- Period of exclusivity
- Transparency of submission
- Mandating specific training for each substance

Questions?

Classification database

Classification Database

Database updated: 18 August 2017

Enter a substance name:
(use the underscore character "_"
to produce a full listing)

paracetamol

OR select a classification:

Any classification

Search

Ingredient	Conditions (if any)	Classification
Paracetamol	**except** when specified elsewhere in this schedule	Prescription
Paracetamol	in liquid form; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams and not more than 50 grams; in slow-release forms containing 665 milligrams or less and more than 500 milligrams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack	Pharmacy Only
Paracetamol	in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; in powder form in sachets containing 1 gram or less and not more than 10 grams	General Sale

Medsafe website