Reclassifying medicines in New Zealand

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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

**Database updated: 18 August 2017**

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

OR select a classification:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Conditions (if any)</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>except when specified elsewhere in this schedule</td>
<td>Prescription</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>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</td>
<td>Pharmacy Only</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>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</td>
<td>General Sale</td>
</tr>
</tbody>
</table>
Medsafe website

Welcome to Medsafe

For Consumers
Information that everyone should know about medicines and medical devices including updates on staying safe and healthy.

For Healthcare Professionals
Information about medicines and medical devices. Updates on safety information and how to report problems.

For Industry
Guidance on the New Zealand regulatory processes for suppliers of medicines and medical devices.

News and Events
- 27 September 2016: Committees
- 23 September 2016: Medical Devices
- 22 September 2016: Consultations
- 22 September 2016: Committees
- 20 September 2016: About Medsafe
- 15 September 2016: Recent Official Information
- 9 September 2016: Alert Communication
- 5 September 2016: Committees
- 1 September 2016: Medicines
- 1 September 2016: Publications
- 31 August 2016: Committees
- 31 August 2016: Alert Communication

I want to...
- find a medicine data sheet
- find consumer medicine information
- search the product/application database
- search for adverse reactions to medicines
- search for recalls of medicines and medical devices
- read Prescriber Update articles
- report for quality data
- report a problem

Find the classification of an ingredient