

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

Classification Database

Database updated: 18 August 2017

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

OR select a classification:

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

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NEW ZEALAND MEDICINES
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Welcome to Medsafe

Medsafe is the **New Zealand Medicines and Medical Devices Safety Authority**. We are responsible for the regulation of medicines and medical devices in New Zealand. We ensure that medicines and medical devices are acceptably safe.

For Consumers

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

[Information leaflets](#)

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.

[Current Regulatory Guidelines](#)
[Forms and templates](#)

News and Events

27 September 2016	Committees	Medicines Classification Committee - Agenda for the 57th Meeting - Items 6.2 and 6.3 have been updated
23 September 2016	Medical Devices	Surgical Mesh - Implementation of Government Response to Health Committee Recommendations
22 September 2016	Consultations	Change to warning statements on labels of OTC loratadine and desloratadine medicines
22 September 2016	Committees	Summary of recommendations from the 103rd Medicines Assessment Advisory Committee meeting - 4 August 2016
20 September 2016	About Medsafe	Notice of Medsafe Office Closure Christmas/New Year 2016/2017
15 September 2016	Recent Official Information Act Releases	Request for comments on the Nordic Cochrane Group complaint to the European Medicines Agency (Adobe PDF 3036 KB, 6 pages)
9 September 2016	Alert Communication	Consumer Level Recall - GlaxoSmithKline HypoKit 1 mg solution for injection
5 September 2016	Committees	The 56th Medicine Classification Committee meeting on Natural Health Products has been postponed until the Natural Health Products Bill has its third reading
1 September 2016	Medicines	Label Statements Database - Edition 1.17 (August 2016)
1 September 2016	Publications	Prescriber Update Vol. 37 No. 3 - September 2016
31 August 2016	Committees	Medicines Classification Committee - Dates and Deadlines
31 August 2016	Committees	Medicines Classification Committee - Recent New Zealand Gazette Notices Relating to Classification
31 August 2016	Alert Communication	Heater-cooler devices used during cardiac surgery: risk of infection with Nontuberculous Mycobacterium species - advice and recommendations

I want to...

- login to the medical device database (WAND)
- 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
- look for safety alerts
- find the classification of an ingredient**
- report a problem

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