



Subject: Re: Medicines Amendment Regulations 2011 - Controlled drugs

Hi

When the Schedule was updated, we went through the MODA lists to identify those substances that have a therapeutic use. They were then included in the appropriate part of the First Schedule (most were therefore in Part One). This was done because if a medicines is also a CD then the MA and MODA both apply to it except if there is a conflict between the 2 statutes. In that case MODA trumps. We had realised that for substances scheduled only in MODA some of the MA controls that should apply to a prescription medicine would not, because prescription medicine is defined in relation to the first schedule entry, not whether MODA says its only available on prescription. As a consequence things like labelling or advertising requirements get mucked up because they are eouched in terms of the MA classification entry. MODA only dealt with some aspects of labelling but not the full set so it push came to shove we could probably not enforce.

The rationale for the change was not publicised. The classification database on our website has dual entry statements for CDs to make this more visible.

Hope that helps!

cheers.

Prinicipal Advisor Regulation Regulatory Analysis and Delivery

Medsafe

Clinical Leadership, Protection & Regulation

Ministry of Health

http://www.moh.govt.hz

Can you remember the...

11/09/2014 05:07:53 p.m.

Bate: Subject: 11/09/2014 05:07 p.m.

Medicines Amendment Regulations 2011 - Controlled drugs

Hi

Can you remember the last amendment to the First Schedule of the Medicines Regulations 1984, Medicines Amendment Regulations 2011.

A number of controlled drugs were included. Is there any information any where about why this was done? For example on the Medsafe website?

Thanks.

Advisor Science (Secretariat - MAAC and MCC) Product Regulation

Medsafe Clinical Leadership, Protection & Regulation Ministry of Health

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(Please note I am out of the office every Wednesday)

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