



The big ban

» Natural health | By Lynda Wharton

Just why is the government trying so hard to legislate regulation for the natural health industry?

Lynda Wharton looks at the history and issues behind Medsafe's new initiatives

{ To quote Charles Dickens, these are “the best of times and the worse of times” when it comes to natural health in New Zealand. They’re the best of times, because we have the opportunity to create a sensibly regulated natural health sector that could be a world leader. They’re the worse of times, because – so far – we seem to be sliding towards the imminent introduction of a regulatory system that could effectively sound a death knell for the natural health industry in New Zealand.

Last year saw a collective sigh of relief and moment of celebration amongst Kiwi natural health practitioners, following a fierce and successful battle to overthrow the proposed harmonisation of our regulator, Medsafe, and Australia’s Therapeutic Goods Administration (TGA). Called the Trans-Tasman Therapeutic Goods and Medicines Bill, the government-led move was designed to bring our natural health industry under the legislative control of the draconian TGA, which works on the Napoleonic “guilty until proven innocent” principle.

The New Zealand natural health sector and health consumers alike were fervent in their resistance to the idea, fearing the same kind of rapid restriction in choice that has been

witnessed across the Tasman. Their opposition inspired street marches, thousands of visits to MPs from angry constituents, and – ultimately – the stalling of the proposed Bill. The failure of the Labour party to secure parliamentary ratification was a huge political embarrassment; but one year on, industry euphoria has evaporated, to be replaced by incredulity at the turns taken by the latest developments in the ongoing saga.

New Zealand, 2008 – and we are in the middle of a new, potentially more threatening, battle to protect the health freedom of New Zealanders. This time, the fight is against a more stealthy threat. There is none of the media frenzy that documented every fresh development of the last struggle and – to date – most ordinary Kiwis are even unaware of its very existence.

Contrary to general belief, the natural health manufacturing industry in New Zealand has always been subject to control and regulation; as indeed it should be. Not one single Act, but four, govern the industry: Fair Trade, Manufacturing Safe Practice, Dietary Supplements, and Medicines.

Overlooking all this is Medsafe, the business unit of the Ministry of Health, and the authority responsible for regulating medicines and medical

devices in New Zealand. It is Medsafe’s job to administer and enforce the Medicines Act 1981. Its stated mission is to “enhance the health of New Zealanders by regulating medicines and medicinal devices to maximum safety and benefit”.

For 26 years, natural therapies in this country have apparently been successfully governed by the existing Acts, with no prosecutions by Medsafe – or any other government agency – in that time. Further, there are no records of any deaths resulting from natural supplements, in contrast with the average 1400 New Zealanders a year who die as a result of pharmaceutical drugs and doctors’ mistakes.

So what’s this current, silent crisis all about? Many natural health practitioners and their clients are dubbing it a witch-hunt, claiming it is a direct backlash from the defeat of last year’s proposed legislation. And once you examine the facts closely, it’s easy to see validity in their argument. However, to properly understand the situation, it’s necessary to wade through the dry and dusty 1981 Medicines act, so brace yourself for some legal intricacies!

The 1981 Medicines Act is the legislation that defines and regulates medicines in New Zealand. According to Medsafe – and the Act – the composition of a product, its presentation and its promotion, determine whether or not it is a medicine and therefore whether it falls under regulation.

The Act has never considered natural

products, dietary supplements, nutraceuticals, cosmetic creams and balms to be medicines, as long as their labeling and advertising material make no therapeutic assertions. That means that as long as a vitamin, herb or supplement does not claim to treat or prevent disease, it is not classified as a medicine and falls outside the scope of the Act. Similarly, natural therapists are not covered by the Act, as long as they do not claim to be diagnosing or treating any medical condition covered

in Schedule 1 of the legislation.

And remember that this has been the case since 1981. There has been no legislative change since then whatsoever – or cause for any such amendment. Yet, suddenly, we are seeing a drive towards radical new interpretation and enforcement of the same old law, which will see natural remedies considered medicines. Why?

Nicola Grace, spokesperson for health consumer advocacy group Health Freedom, says: “the implication

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is obvious... why would an agency deliberately recruit people to enforce flawed regs? Obviously, not for public safety. That leaves retaliation. Won’t join up with the Aussies? Let’s see how you like this”.

Whatever its intention, Medsafe recently published a document entitled *Therapeutic Claims: Guidelines on Compliance with the Medicines Act*, in which it sets out a whole new interpretation of the words ‘therapeutic claim’ and ‘medicine’. This forbids any practitioners, advertisers and website owners – natural or conventional – from making any of

the following claims for their non-registered products or services:

- Treats or prevents disease (including colds, flu and parasite).
- Assists with general ailments, including inflammation and pain
- Alters the size, shape, structure, or weight of the body
- Prevents or interferes with the normal operation of a physiological function.
- Relieves, prevents, or treats a disease or symptom of a disease.
- Has – in itself or its ingredients – been used traditionally for therapeutic purpose.

It is also now forbidden to use testimonials or personal statements on a website or brochure to suggest the product has a therapeutic purpose. However, you may be thinking that there are still ways around such limitations for the creative mind... but wait, there’s more!

Websites can no longer carry information articles regarding disease prevention or other therapies, which include any product brand name. What about quoting research or clinical trials to support the efficacy of a product? No, that’s forbidden too. What about having a link on your website that takes you to other sites that may verify the efficacy or historical use of a product? You guessed it, that’s illegal as well.

It’s also not permitted to claim that a natural product is in any way an alternative to a medicine or group of medicines. And, if you manufacture herbal creams or lotions, you can’t say “apply to the affected area”, as this implies a therapeutic effect, and makes

your product a medicine and therefore subject to the controls of the Medicines Act. Similarly banned is any suggestion that the product may relieve symptoms (even temporarily), assist in the treatment of, or be useful in clearing up any condition.

As a result of this more stringent enforcement of policy, numerous natural health websites have already been forced offline or to comply more rigorously with the dictates of the Act. Health stores have been raided and products confiscated. In fact, to date, at least 57 business and website owners have been contacted and required to comply.

Then, there’s the precarious situation in which registered natural health practitioners now find themselves. Under the Medicines Act, Section 4 – Therapeutic Use, if you are not a medically qualified practitioner, you cannot purport to diagnose, cure, treat, or prevent any medical disease listed in Schedule 1 of the act. And that effectively covers every conceivable human condition.

While Medsafe argues that it is simply fulfilling the requirements of the Act, and protecting the health and wellbeing of New Zealanders, those involved in the natural health industry have quite a different viewpoint. Health Freedom believes that Medsafe is attempting to intimidate the industry into accepting the proposed, but temporarily shelved, Trans-Tasman harmonisation. It points to the fact that – for the first time in its history – Medsafe is specifically seeking out and remedying even the smallest breaches of the Act. Given the timing – hot on the heels of governmental embarrassment – it may well have a point.

And, the irony of the whole situation is that the natural health industry has always been the first to recognise the need for effective self-regulation. It has spent 27 years trying to achieve a fair, effective legislative structure, but current lobbying to the NZ Health Trust is all but being ignored by government. «

WHAT DO YOU THINK? Do you agree with Medsafe’s current actions? Will good health become more of a challenge? Email your opinion to fit@fitnesslife.co.nz.

For more information on the Medsafe crackdown go to www.healthfreedom.co.nz or www.nzhealthtrust.co.nz.