SOLVING NEW ZEALAND'S COMPLEMENTARY & ALTERNATIVE MEDICINE (CAM) PRODUCT CRISIS: A RISK-BASED PROPOSAL

Peter J Harris* & Ian C Shaw†

Abstract

Complementary and alternative medicine (CAM) products have existed in a regulatory vacuum for most of the past 30 years. With the national industry now worth more than $1.4 billion/year, and in widespread breach of the few regulations that apply to their products, it is no wonder that every attempt at new legislation over the past 15 years has ultimately failed. In the face of risks to public health from unsafe CAM products, false and misleading marketing of these products, and outdated and inappropriate legislation, new measures are desperately required. This article considers the history of CAM product regulation in New Zealand, through the mechanisms of the Food Acts 1981 and 2014, the Medicine Act 1981, and the Dietary Supplement Regulations 1985. It takes examples of risk-based regulation in the new Food Act 2014 and the Medicines Act 1981, and studies the nature of this regulatory device and the possibility of its application to CAM products. This leads on to a consideration of the attempts at updating the legislation around CAM products, and the problems encountered along the way. Finally, the article outlines a new proposal for the regulation of CAM products in New Zealand – the risk-based Complementary and Alternative Medicinal Products Bill.

I. Introduction

There exists a pervasive Antipodean (if not more widespread), laissez-faire attitude towards complementary and alternative medicine (CAM) products, that they are regulated somehow; because that is just the way things are: foods are regulated, medicines are regulated, so CAM products must be regulated too. However, the truth about the regulation of CAM products in New Zealand is more limited than the public expect. The New Zealand regulations, the Dietary Supplement Regulations (DSRs) 1985 came into

* LLM (Hons), LLB, BSc (Chemistry); Legal and Research Counsel, Office of the Chief Coroner, Auckland.
harris.peterjohn@gmail.com. With sincere thanks to my supervisors, Associate Professor Debra Wilson and Professor Ian Shaw for their unyielding assistance, perseverance, and support in the conduct of this research.

† BSc (Hons), PhD, FRSC, CChem, FRCPath: Professor of Toxicology, University of Canterbury, Christchurch.

force in 1987 under the Food Act 1981.[1] The Regulations predate even the term "complementary and alternative medicine", and given their age and limited scope, the Regulations are all but redundant. Consequently, CAM products proliferate relatively unchecked throughout the New Zealand market, generating huge profits in a $1.4 billion/year industry,[2] and frequently making illegal therapeutic claims about everything from relieving headaches, to treating cancer.[3]

A. Complementary and alternative medicine products

"A clear, objective and neutral … definition of [complementary and alternative medicine] is the first requirement for any reasoned debate and discourse …",[4] however, it remains one of the major problems of this area due to disagreement on the appropriateness of the term "complementary and alternative medicine", let alone defining what the term incorporates.

It is important to note that this article is concerned with the regulation of CAM *products*, not CAM modalities or practices. Nearly every organisation, government, or regulatory body has a discrete definition of CAM products, but they commonly separate CAM products into the two branches; non-mainstream products used together with conventional medicine (complementary medicine products), and those same products used in the place of conventional medicine (alternative medicine products).[5] This article takes a broader and more flexible approach.

The World Health Organization's definition demonstrates the breadth that comes with most definitions of 'CAM':[6]

> The terms "complementary medicine" or "alternative medicine" refer to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.

1 Dietary Supplement Regulations 1985, s 1; Food Act 1981, s 42.

2 Natural Products New Zealand "Report: Natural Products Industry a Significant Contributor to NZ's Economy" (press release, 19 February 2015) at 1.

3 Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 5–6.

4 Terry SH Kaan "Traditional, complementary, and alternative medicine" in Yann Joly and Bartha Maria Knoppers (eds) *Routledge Handbook of Medical Law and Ethics* (Routledge, Oxford, 2015) 419 at 419.

5 National Center for Complementary and Integrative Health "Complementary, Alternative, or Integrative Health: What's In a Name?" (June 2016) <www.nccih.nih.gov>.

6 World Health Organization *WHO Traditional Medicine Strategy: 2014–2023* (WHO, online ed, Geneva, 2013).

CAM products are not usually conventional medicines or foods, but are commonly (although not exclusively) naturally occurring or biologically-based products.[7] These products may have some effect in treating, preventing or diagnosing illness, disease or symptoms, or promoting health and wellbeing;[8] whether that effect is real, or a placebo effect is a key point. CAM products often lack scientific evidence as to one or more of their safety, quality, or efficacy.[9] They may be categorised as CAM products by: user-identification as a CAM product,[10] their inability or lack of desire to meet the scientific and legal requirements for recognition and regulation as a medicine, or third party identification as CAM products due to their failure to meet common standards or usual definitions of foods, conventional medicines, or any other broad category of product for direct human use. From the point of view of the company developing the product, it is in their interests to categorise a product as CAM because the development costs are very significantly less than if the product was a bona fide medicine which requires a full risk assessment involving animal testing and clinical trials.

B. What is the problem with CAM product regulation in New Zealand?

There are a plethora of issues surrounding New Zealand's regulation of CAM products, but this article touches on just two: the inability of the current, outdated legislation to effectively regulate CAM products, and the failure of various proposed measures to update the regulation of CAM products over the past 20 years.

Current regulation of CAM products in New Zealand involves a complicated system, with three primary pieces of legislation: the Food Act 2014, the Medicines Act 1981, and the Dietary Supplement Regulations 1985. As such, since the end of the 1990s, attempts have been made to reform the system, with proposals like a joint regulatory agency in conjunction with Australia, or the Natural Health and Supplementary Products Bill 2011. All these proposals have prioritised stakeholder satisfaction at the expense of implementing sound, evidence-based measures around the safety, efficacy, and quality of CAM products.

This article considers the success of risk-based legislation like the Food Act 2014 and the Medicines Act 1981, in order to import similar measures into new CAM product regulation. Finally, the article culminates by proposing a risk-based CAM Products Bill involving a 'light touch" risk assessment

7 Lucinda E Jesson and Stacey A Tovino *Complementary and Alternative Medicine and the Law* (Carolina Academic Press, North Carolina, 2010) at 6–10.

8 Ministerial Advisory Committee on Complementary and Alternative Health *Complementary and Alternative Health Care in New Zealand: Advice to the Minister of Health* (Wellington, June 2004) at 1.

9 Katherine R. Ellena "The uncritical enthusiasts versus the uninformed sceptics: Regulation of complementary and alternative medicines" (2005) 13(1) JLM 106, at 106–107.

10 Ministerial Advisory Committee on Complementary and Alternative Health, above n 8, at 1.

compared with that required for medicines. This Bill aims to regulate CAM products in a manner commensurate with the risk they pose, which is likely to be low, while establishing a flexible system that promotes the collection of further evidence and information around CAM products.

II. A History of CAM Product Regulation in New Zealand

To understand the current state of CAM product regulation in New Zealand, the overlapping histories of food, medicine, and dietary supplement regulation must be considered. The Food Act 1981, the Medicines Act 1981 and the Dietary Supplement Regulations 1985 have regulated CAM products for the majority of the past three decades, with their relative antiquity explaining many of the problems which permeate New Zealand's CAM product regulation to this day.

A. The Food Acts

The Food Act 1981 was a paradigm shift from earlier food legislation that effectively focused on the purity of foods. Instead, the 1981 Act turned towards consumer protection; through the regulation of sale, advertisements, hygiene, and food safety and standards. Dietary supplements were nascent in 1981, but nevertheless, the Minister of Health at the time noted that the Food Bill intentionally allowed for cross-over of dietary supplements, slimming foods, or other special purpose foods, between food and medicine regulations on the grounds that "[o]ne man's food may conceivably be another man's medicine".[11] Consequently, the legislative position was that the particular classification of these products would ultimately rest on their presentation to the public and the manufacturer's claims.[12] This was the beginning of the systemic definitional problems between food, medicines, and dietary supplements, which continue to plague CAM product regulation.

In 2010, a new Food Bill was brought before the House.[13] This Bill radically overhauled the previous system, bringing food regulation in New Zealand into the 21st century. Notably, it included updated penalties and enforcement measures,[14] and a novel method of regulating food safety in New Zealand: a risk-based approach.[15] An important change from the 1981 Act is the expanded definition of "food".[16] Section 9 of the Food Act 2014 explicitly excludes a number of items from being foods, including "… any substances used only as medicines (within the meaning of the Medicines Act

11 (26 August 1981) 440 NZPD 2982; per Hon George Gair MP.
12 At 2982.
13 Food Bill 2010 (160–1).
14 (22 July 2010) 665 NZPD 12616.
15 See Part III.
16 Compare s 2, Food Act 1981 and s 9, Food Act 2014.

1981) …".[17] However, in practice, the expanded definition of food does little to clarify the murky overlap in the legislation between food, medicines and dietary supplements.

B. The Medicines Act 1981

New Zealand's enactment of dedicated medicines legislation arose at the tail end of global momentum for substantially more thorough medicine regulation, in the wake of the devastating thalidomide tragedy of the 1960s. The Medicines Act 1981 was one of the earliest instances in New Zealand of a risk-based approach for the regulation of products. This prescient piece of legislation has remained relevant well into the 21st century; remaining effectively unchanged from its initial enactment. Nevertheless, with developments in medicine over the last few decades, including medical devices, and cell and tissue therapies, new legislation is under construction in the form of the Therapeutic Products Bill, although details remain sparse at the time of writing.[18]

The Medicines Act 1981 defines a medicine as being a product intended to have a therapeutic purpose in humans; achieving this purpose by pharmacological, immunological, or metabolic means.[19] Section 3 Medicines Act 1981 goes on to list products not included in this definition,[20] before defining new medicines, and three other categories of medicines (Prescription, Restricted, and Pharmacy-only medicines)[21] that are further detailed in sch 1, Parts 1–3 Medicines Regulations 1984.

Under the Medicines Act, any food is specifically precluded from being a medicine.[22] This contrasts with the approach of the new Food Act 2014, wherein only products which have exclusive usage as a medicine (for example, paracetamol), cannot be classified as a food.[23] Consequently, products that may be used as a medicine or be a component of food (for example, Vitamin C), continue to exist in a regulatory limbo, with the relevant legislation usually being presumed based upon a product's appearance or presentation.[24] Furthermore, at s 2, the Medicines Act defines "herbal remedy" as a medicine, despite such herbal preparations usually being in the realm of

17 Food Act 2014, s 9(1)(c)(iii).
18 Ministry of Health, "Therapeutic products regulatory regime" (February 2018) <www.health.govt.nz>.
19 Medicines Act 1981, s 3(1)(a).
20 Section 3(1)(c).
21 Section 3(3).
22 Section 3.
23 Food Act 2014, s 9(1)(c)(iii).
24 (26 August 1981) 440 NZPD 2984.

CAM products.[25] This is another example of the aforementioned definitional overlap between these product categories.

C. The Dietary Supplement Regulations 1985

In an attempt to provide a "catch-all" for those products that did not readily fit within the definition of food or medicine, the Dietary Supplement Regulations 1985 were created under the umbrella of the Food Act 1981. However, these regulations did not clarify the distinction between foods and medicines, and nor did they establish a regulatory system which required adherence. As a result, industry and government have largely ignored the DSRs, with their limited scope[26] and toothless penalties.[27]

Regulation 2A DSRs defines a dietary supplement as a liquid, powder, tablet or lozenge intended to be taken orally, which comprises an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin, either alone or in a mixture; the intention of which is to supplement those components which may be normally derived from food. This definition does nothing to limit dietary supplements from foods or medicines, with many general-sale medicines and ingredients of foods falling squarely within that definition. Consequently, there remains a confusing, unworkable overlap between food, medicines and dietary supplements.

In practice, this means that dietary supplements, and by extension, CAM products, fall through the gaps, escaping any regulation, control, or enforcement, except where they explicitly breach other legislation, making enforcement action feasible. While some enforcement has occurred under the Medicines Act 1981,[28] the majority of the few actions taken around CAM products rely on the Fair Trading Act 1986[29] and misleading and deceptive conduct or representations.[30]

25 Providing herbal remedies neither make therapeutic claims nor contain restricted products in sch 1, Parts 1–3 Medicines Regulations 1984, they are exempt from the Medicines Act requirements.

26 Dietary Supplement Regulations 1985, Part 1 and Part 2; the DSRs broadly only control the labelling and some of the constituents of dietary supplements. They do not purport to be exhaustive on the products they permit; thus taking neither a black- nor white-list approach.

27 At reg 21(1); the maximum penalty is $500 under the DSRs.

28 See *Mega Vitamin Laboratories (NZ) Ltd v Commerce Commission* (1995) 6 TCLR 231 (HC); *Ministry of Health v Pacific Pharmaceuticals Ltd* HC Auckland A165/00, 16 February 2001; and *Diet Tea Co Ltd v Attorney-General* HC Auckland A.457/85, 25 March 1986.

29 Sections 9, 10, 12A and 13.

30 See *Commerce Commission v New Zealand Nutritionals (2004) Ltd* [2016] NZHC 832 (section 9); *Commerce Commission v Erdic (NZ) Ltd* DC Tauranga CRI-2006-070-006303, 15 August 2008 (section 10); *Commerce Commission v John Graham Godwin and Anor* DC Tauranga CRI-2007-070-0007795, 14 January 2009 (section 13); *Commerce Commission v Silberhorn Ltd* DC Dunedin, 2018, currently before Judge Phillips.

D. Problems with the current regulation of CAM products

There clearly exists a lack of clarity around what constitutes a dietary supplement, let alone a CAM product, but the problems with the current regulations are broader than this; making new legislation imperative.

In 2003, 1,600 products produced by Australian company Pan Pharmaceuticals were recalled due to serious adverse reactions to a Pan medicinal product, Travacalm, with 19 people requiring hospitalisation from life threatening reactions.[31] This occurred due to a huge variation in the active ingredient present in the product, ranging from 0–700 percent of the advertised amount.[32] The problems that lead to this incident were found to be endemic throughout the manufacturing and testing of Pan Pharmaceuticals products,[33] raising an especial issue for New Zealand, given Pan Pharmaceuticals also manufactured CAM products for a number of companies in New Zealand, including Red Seal, Nutralife and Thompson Nutrition.[34] The uniquely New Zealand problem in this instance was the difficulty with which the recall was executed.

The fact that the Australian regulator identified this problem with Pan products is testament to the thorough post-marketing surveillance and adverse event reporting that exists in Australia; something sorely lacking from the DSRs. The lack of a register of dietary supplements or CAM products made the recall in New Zealand exceedingly difficult.[35] Of the 219 products initially recalled, three were medicines, while 216 had to be classified as food in order to recall under s 40 Food Act 1981, on the basis they were unsound or unfit for human consumption.[36] Ultimately, there was substantial confusion around the recall in New Zealand, with the process taking days to be clarified, and several different recall documents, until it was found that 642 dietary supplements required recalling in New Zealand.[37]

The Pan Pharmaceuticals case illustrates not only the problems with the lack of a clear, well organised and effectively managed regulatory scheme for CAM products, but also highlights the dangers of contamination in CAM products. This is a problem that is widely recognised internationally[38] and

31 Bebe Loff and Helen McKelvie "Australia shaken by complementary medicines recall" 2003 361 The Lancet 1710.

32 Thomas Faunce and Esme Shirlow "Recent Legal Developments and the Authority of the Australian Therapeutic Goods Administration" (2009) 16 JLM 764.

33 Loff and McKelvie, above n 31.

34 Reuters "NZ orders recall for Pan products" *The New Zealand Herald* (2 May 2003).

35 Annette King "Australian Recall of Pan Pharmaceutical Products" (press release, 30 April 2003).

36 Lynne Eagle and others "Regulatory Oversight or Lack of Foresight? Implications for product recall policies and procedures" (2005) 28 Journal of Consumer Policy 433.

37 The New Zealand Herald "List of Pan Pharmaceuticals products sold in NZ released" *The New Zealand Herald* (3 May 2003).

38 Steven G Newmaster and others "DNA barcoding detects contamination and substitution in North American herbal products" 2013 11 BMC Medicine 222.

has arisen as an issue in New Zealand in recent years with the contamination of bodybuilding supplements.[39] With no post-market monitoring in New Zealand of the contents of CAM products, let alone whether the information on the label is correct, the health of all those taking CAM products is put at risk by a lack of information, and the government's refusal to effectively regulate these products.

III. Risk-based Regulation

Risk-based regulation of products has become increasingly common; both nationally and internationally over the past few decades.[40] Science and law take similar approaches in their interpretation of risk, enabling especially streamlined regulation of products like food and medicines. Regulating products based on their risk is a proven and effective platform to be transposed across to CAM product regulation; especially where proponents of CAM products are so vocal as to the safety of their products.

A. A legal and scientific concept of risk

Risk is defined as "[a] situation involving exposure to danger".[41] Risk from a scientific and legal perspective is often represented by different terms but, in application, the concepts broadly have the same effect.[42] This is crucial, as in the regulation of products, scientific research forms the basis for determining the risk of ingredients and products, relative to other products within the broad categories of foods or medicines. Subsequently, in the drafting of legislation and its eventual enforcement, a legal approach to risk is generally taken. If these two concepts of risk were incompatible, the creation and application of legislation designed on the basis of scientific information would be confusing and impracticable.

Scientific risk is perhaps the simpler of the two, as it is readily represented using a basic formula:[43]

39 Steve Deane "'It was like a drug, it was addictive. You had to wean off it' - The damaging effects of the gym-drug roundabout" *The New Zealand Herald* (online ed, Auckland, 9 February 2015).

40 Misuse of Drugs Act 1975, Medicines Act 1981, and Food Act 2014; see also Julia Black "Risk-based Regulation: Choices, Practices and Lessons Being Learnt", in Gregory Bounds and Nikolai Malyshev (eds) *Risk and Regulatory Policy: Improving the Governance of Risk* (OECD Publishing, Paris, 2010) at Ch 6.

41 "Risk" Oxford Dictionaries <oxforddictionaries.com>.

42 *New Zealand Pork Industry Board v Director-General of the Ministry for Primary Industries* [2013] NZSC 154, [2014] 1 NZLR 477 at [23]–[24].

43 Jos CS Kleinjans "Principles in toxicological risk analysis" (2003) 140–141 Toxicology Letters 311.

Risk = Hazard x Exposure

Equation 1: Toxicological Risk Equation

In toxicology, this formula is used to determine the risk of a compound, ingredient, or product. Although this equation is quantifiable, it is intended to operate as an empirical formula for weighing the risk of something against its benefit.[44] "Hazard" in this formula is generally the intrinsic toxicity of a substance. "Exposure" is a measure of the duration and dose of a substance. For example, the risk of contracting *Salmonella* from chicken eggs can be considered by looking at the hazard of *Salmonella* (relatively high – it causes serious gastroenteritis), balanced against the exposure (very low – even more so when eggs are cooked which kills the organism). Consequently, the risk of *Salmonella* infection is low and, when subsequently balanced against the benefit of eating eggs, it is usually regarded as an acceptable risk.

In contrast to the comparatively settled scientific definition of risk, the legal theory of risk has engendered a variety of opinions.[45] Nevertheless, it is possible to strike a balance between various formulae for legal risk with a basic equation like the following:[46]

Risk = Probability x Legal Consequences

Equation 2: Legal Risk Equation

"Legal consequences" in this equation encompasses positive, neutral or negative outcomes, allowing financial calculi to inform the measure, but not requiring them to do so, as some other formulae do.[47] Probability is to this equation as exposure is to the scientific equation: effectively the likelihood of an event occurring. Ultimately, the measure of these two factors allows analysis of the risk, which can then be balanced against the benefit of a particular event to determine whether it is worthwhile (for example, the ramifications from allowing imported eggs, which might be contaminated with *Salmonella*, into the country).

Although similar, the primary distinction between the scientific and legal approaches to risk is where they best fit temporally. The scientific approach to risk is better suited to looking at a problem *ab initio*, whereas the legal approach more naturally operates within a prescribed sphere where the risk

44 Ian C Shaw *Food Safety: The Science of Keeping Food Safe* (Wiley-Blackwell, Somerset, 2012) at 15.

45 For two examples see: Mark Little "How to Measure and Manage Legal Risk" (2 May 2014) Berkman Solutions <www.berkmansolutions.com>; and International Organization for Standardization *ISO 31000:2009 Risk Management – Principles and guidelines* (online loose-leaf ed, ISO, 2009, accessed 18 August 2016) at 2.1.

46 Richard Moorhead and Steven Vaughan "Legal Risk: Definition, Management and Ethics" (2015) Social Science Research Network <www.ssrn.com> at 5–11.

47 Little, above n 45.

from particular events is being considered. Both scientific and legal approaches to risk play a vital role in the foundation and implementation of risk-based legislation respectively.

B. Risk in the Medicines Act 1981

The Medicines Act 1981 and the Misuse of Drugs Act 1975 were some of the earliest instances of risk-based legislation in New Zealand. These two Acts operate in a very similar way, but most importantly, a toxicological evaluation of the risk of individual medicines and drugs is the cornerstone of them both.

The Medicines Act 1981 and Medicines Regulations 1984 employ a permissive "white list" approach in categorising medicines into prescription medicines, restricted medicines or pharmacy-only medicines.[48] In some cases, the same product will arise in two or more of these categories, but with differing dose restrictions depending on the category; a perfect example of managing the risk of a product through control of potential exposure.[49]

Medicines are usually categorised into those three classes, or that of "general sale medicines" based upon the research and data provided in the application for the registration of that medicine. This demonstrates the application of a risk-based approach to ensure public safety and wellbeing, while balancing the competing interests of public benefit and access to medication.

C. Risk in the Food Act 2014

The 1981 Food Act required management of hazards to reduce risk. Hazard-based approaches to risk management can cause over-regulation, as every potential consequence is a rationale for regulation.[50] This created a system under the old Act that focused to a greater degree on microbiological hazard in the form of the control of food premises, rather than controlling the safety of the food itself.[51]

The Food Act 2014 takes a more integrative, risk-based approach to food safety.[52] As with medicines regulation, this fundamentally involves the use of the toxicological risk equation, identifying a particular foodborne hazard, and considering the exposure level in order to determine the risk.[53] Substantial research was carried out in New Zealand from the early 2000s by scientists

48 Medicines Regulations 1984, sch 1.

49 See Equation 1: Toxicological Risk Equation.

50 Eirini Tsigarida "Risk-based Approaches to Food Safety (Abstract)" (11 May 2016) International Association for Food Protection's European Symposium on Food Safety <www.iafp.confex.com>.

51 (13 May 2014) 698 NZPD 17750.

52 (22 July 2010) 665 NZPD 12615.

53 Tsigarida, above n 50.

at the Institute of Environmental Science and Research (ESR) on the best method for ranking the risks of food.[54]

Although food regulation is broader than that for medicines, a similar structure for its risk-based regulation was eventually settled upon. This involves three broad classes for food sectors, based on their risk.[55] Because of the breadth of the subject matter, the middle class is subdivided into three further risk levels; requiring national programmes to control, mitigate and manage risks, in line with their level. To summarise, the entire system operates by regulating food sectors in a manner commensurate with the risk that they pose to the public.

D. Where is "risk" in the regulation of CAM products?

It should be immediately evident that the DSRs are not risk-based regulations. They arise under the umbrella of the 1981 Food Act and thus, at best, the DSRs regulate the few named dietary supplements therein according to a hazard-based approach.

Since the parliamentary debates in the early 1980s on the Food and Medicines Acts, it has been well recognised that dietary supplements, and certainly CAM products, are distinct from foods, and yet do not require regulation at a level akin to medicines. In short, CAM products sit between food and medicines on the regulatory spectrum. Therefore, it would appear only natural to utilise the same risk-based approach to regulation seen in both the Food Act 2014 and the Medicines Act 1981, when designing regulation for CAM products.

Some proponents of CAM products maintain they are low risk and, therefore, require either no, or very limited regulation. There are two main issues with this position. Firstly, there is a systemic lack of data and information to support the assertion that CAM products are always low risk and, secondly, in the event that such products are shown to be safe, then risk-based regulation, as a malleable and adaptable tool, would be the best way of managing these products anyway.

Those who avidly advocate the risk-free nature of CAM products commonly cite both personal experiences, and the matter of traditional medicines as evidence for the products' safety. In this field, the misquote "the plural of anecdote is not data" is more relevant than ever.[56] Traditional medicines pose a more complex example. A longstanding history of safe use, as many traditional medicines have, is a good indication of the relative

54 Peter Cressey and Rob Lake *Ranking Food Safety Risks: A Discussion Document* (Institute of Environmental Science and Research Ltd, June 2003).

55 Food Act 2014, ss 8 and 20(2)(a).

56 The actual quote "the plural of anecdote is data" is commonly attributed to Berkeley Political Scientist, Raymond Wolfinger, however, the negation of this quote, as used above, has arguably become the more common version, especially when considering reporting bias in statistics; see David Smith "The plural of anecdote is data, after all" <www.blog.revolutionanalytics.com>.

safety of a product.[57] That being said, data and scientific research into these products provides a much bigger picture of a product's risk profile, including its potential reaction with other products, the doses at which the product might be safe and the potential for adverse effects in certain populations or individual situations.

One of the defining features of risk-based regulation is that it aims to regulate products in accordance with the risk they pose. This balances the competing interests of safety and widespread availability; two of the leading concerns surrounding CAM products. In addition, risk-based regulation can be designed in such a way as to allow reclassification of products, should new information show that a product's risk is higher or lower than where the product is currently categorised.[58]

To its credit, the Natural Health and Supplementary Products Bill (NHSPB) 2011 (324-2) took some steps towards a risk-based strategy; however, these were ultimately overshadowed by an array of problems with that proposed legislation. Perhaps the biggest problem for the NHSPB was its failure to acknowledge the lack of information or evidence surrounding CAM products, and the Bill's inability to remedy this situation due largely to a lack of flexibility in the legislation.

IV. The Natural Health and Supplementary Products Bill: An attempted solution

The most promising development in CAM product regulation in the last 30 years was the NHSPB. The Bill arose from more than 10 years of failed attempts at creating a joint regulatory system with Australia for medicines and CAM products. The NHSPB was far from perfect, but it was an improvement on the *status quo* of effective deregulation.[59] Despite making it past its second reading, the Bill does not appear to have survived the travails of coalition wrangling in the formation of the 2017 Labour-New Zealand First Government. Nevertheless, the NHSPB provides a valuable opportunity to learn from both its achievements and its mistakes, in order to inform new legislation.

A. The winds of change: 1999–2014

It has been more than 30 years since the enactment of the DSRs and, during that time, there have been multiple attempts to update the legislation

57 Many such traditional medicines have in this way been synthesised and incorporated into mainstream medical practice – for example, aspirin from willow bark.

58 See Part V.

59 Barbara von Tigerstrom "Globalisation, harmonisation and the regulation of therapeutic products: the Australian New Zealand Therapeutic Products Authority in global context" (2007) 13 Canterbury Law Review 287 at IV.

and regulations around CAM products. There were four milestones in the development of new CAM product regulation in the period 1999–2014 and, although nothing came to fruition, traits of all four are present in the NHSPB, making their history a valuable place to start.

The first of these was the Australia-New Zealand Therapeutic Products Agency (ANZTPA); a manifestation of the late 20th century drive for a closer relationship with Australia, on the back of the Closer Economic Relations and Trans-Tasman Mutual Recognition Agreements. Beginning in 1999, the ANZTPA was a proposal to amalgamate New Zealand and Australia's regulation of therapeutic products; namely medicines and CAM products. Implementing legislation in the form of the Therapeutic Products and Medicines Bill 2006 (103-1) was introduced to Parliament, but it lacked support and was abandoned in 2007 before its second reading. Due to negative public opinion, CAM products were eventually taken out of the ambit of this proposal. In 2011, the National Government signalled a restart to implementation of the joint-Agency approach, limiting its scope to medicines.[60] However, sufficient support was never engendered for regulation with Australia and, finally, in 2014, both Governments issued a joint statement spelling an end to the ANZTPA.[61]

In the midst of this process, a Ministerial Advisory Committee on Complementary and Alternative Health was convened to conduct a wide-scale review of CAM healthcare between 2001 and 2004. Two important proposals from this Committee were eventually implemented; a CAM Database with reliable information for consumers on the evidence surrounding CAM products and treatments, and a New Zealand unit that could facilitate the evaluation of the safety and efficacy of CAM products.[62] Unfortunately, government support for these initiatives waned, and the Committee report had little long-term effect.

As mentioned above, the Therapeutic Products and Medicines Bill 2006 (103-1) was introduced to Parliament as part of the ANZTPA initiative. The idea behind the legislation was that it was an omnibus Bill which would later be subdivided into two distinct Bills: Parts 1–5 containing the Therapeutic Products Act 2006, and Parts 6–7 to become the Medicines Act 2006. The Bill sought to address two problems that it identified in this area: outdated legislation and an insufficient regulatory capacity.[63] There was inadequate support in Parliament and in the wider public for the Bill, partly due to widespread concern that it would unduly restrict access to CAM products.[64]

60 John Key "Australia, NZ announce intention on ANZTPA" (press release, 20 June 2011).

61 Peter Dutton and Jonathon Coleman "Joint Statement regarding ANZTPA" (joint media statement, 20 November 2014).

62 Ministerial Advisory Committee on Complementary and Alternative Health *Complementary and Alternative Health Care in New Zealand: Advice to the Minster of Health* (Wellington, June 2004) at 1.

63 Therapeutic Products and Medicines Bill 2006 (103-1) (explanatory note) at 3.

64 (12 December 2006) 636 NZPD 7079–7081, 7083 and 7091.

This has generated an unfortunate situation wherein issues of a capacity deficit and outdated legislation are magnified by every passing year without new legislation.[65]

Finally, in 2009, a joint industry taskforce comprising a number of consumer and industry groups heavily invested in CAM products put forward the "Joint Industry Natural and Traditional Health Products Bill" Proposal.[66] This never gained traction, however, it was published as a submission on the NHSPB in 2012.

B. A brief history of the Natural Health and Supplementary Products Bill 2011

With the demise of the Therapeutic Products and Medicines Bill in 2007, it became apparent that such products would require their own legislation, separate from any ANZTPA approach. Consequently, when the National Party took power following the 2008 election, they signed a memorandum of understanding with the Green Party that included an agreement to develop a new Natural Health Products Bill.[67]

Between 2009 and 2011, work was carried out around the development of the Bill, including a public consultation eliciting 1,500 responses.[68] In June 2011, a regulatory impact statement for the new legislation was released.[69] This highlighted the systemic problem of an information deficit around CAM products in New Zealand; including the lack of any empirical data on the use or safety of CAM products.[70]

The pressing need for new legislation around CAM products is well illustrated by the overwhelming cross-floor support the Bill received at its first and second readings. Between readings, the Health Select Committee considered 739 submissions on the Bill; many of which were polarised. On one hand was industry and consumers who decried the costs and controls to be placed on CAM products. Whereas, on the other hand, the scientific, medical and healthcare communities questioned whether the Bill went far enough; suggesting that it relied on unsubstantiated assumptions about the safety of CAM products and the good-will of the industry to follow loose regulations.[71]

65 See Tigerstrom, above n 59, at IV.

66 Natural Health Alliance "Joint Industry Natural and Traditional Health Products Bill" (February 2009) New Zealand Health Trust <www.nzhealthtrust.co.nz>.

67 "Memorandum of Understanding Between The New Zealand National Party and The Green Party of Aotearoa New Zealand" (8 April 2009) at 1–2.

68 Ministry of Health *The Development of a Natural Health Products Bill: Consultation Paper* (19 March 2010).

69 Ministry of Health, above n 3.

70 At 3–6.

71 Natural Health and Supplementary Products Bill 2011 (324-2) (select committee report).

In a minority opinion published alongside the Select Committee report, the Green Party raised concerns around the clarity of some of the lists and permitted activities within the Bill, and notably, the lack of inclusion of the Treaty of Waitangi within the Bill.[72] Nevertheless, the Bill passed its second reading 120–1 votes in favour.[73]

Two years passed, with no further developments on the NHSPB, and no explanation for this delay. Finally, in 2015, substantial work began on practical measures for the implementation of the Bill, including the development of guidance documents[74] and the formation of a committee for the assessment of products.[75]

In August 2017, when Parliament dissolved before the 2017 General Election, the Bill was very much on the back-burner of the National Government's priorities, despite waiting more than four years for its third reading. With a change of Government following the 2017 election from a National-led Government to a Labour-New Zealand First Government, the Bill was not renewed, and consequently lapsed on 22 August 2017. Although no reason has been offered for this decision or oversight, disparaging comments about the Bill made by now Deputy Prime-Minister, the Rt Hon Winston Peters, in the months before the election offer a potential explanation.[76]

C. An overview of the legislation

The NHSPB aimed to regulate CAM products via a range of reactive mechanisms, rather than a pure risk-based approach. This included: product licensing requirements, regulation of ingredients, export and manufacturing controls, restrictions on the nature of products' claims, labelling and advertising regulation and the development of penalties in the event of a breach of any part.[77] The framework for the Bill was broadly modelled on the Canadian approach in the Natural Health Product Regulations 2003 (Canada), which comes under the umbrella of the Food and Drugs Act 1985 (Canada). In a similar way to the Canadian system, the NHSPB employed a white list and a black list in respectively permitting and prohibiting CAM products.[78]

The Bill started life as the Natural Health Products Bill, but following the Select Committee's changes, became the Natural Health *and Supplementary* Products Bill, in an effort to indicate regulation of a broader array of products. "Natural health and supplementary products" was defined at cl 6 of the Bill by their purpose and then by what they are or what they include: namely

72 At 11–14.

73 (20 March 2013) 688 NZPD 8817–8818.

74 Ministry of Health *Natural Health Products Draft Papers* (November 2015).

75 Medsafe *Background on the Natural Health Products Bill* (June 2016) at 3.

76 Winston Peters "Scrap Natural Health Products Bill" (press release, 17 May 2017).

77 Natural Health and Supplementary Products Bill 2011 (324-2), cls 11–34 and 36–40C.

78 Natural Health Products Regulations (Canada), schs 1 and 2.

permitted ingredients.[79] Clause 6 goes on to explicitly exclude a natural health and supplementary product from being either a food or a medicine. This was a radical change from the confusing position promulgated by legislation up until this point.

Despite this added clarity, the unrestrained and undefined use of the polyseme "natural" in the Bill remained a problem. This issue was best summarised by the Chief Science Advisor to the Prime Minister at the time, Professor Sir Peter Gluckman, who noted in his submission on the Bill that: "The use of 'natural' draws on the naturalistic fallacy that what is found in nature is somehow better – even though many 'natural products' are highly toxic."[80]

Although the Bill was relatively broad in its scope, the Select Committee decided that homeopathic products should not be regulated under the Bill. The Committee's reasons for this were that the quantities of active ingredient were too small to measure, and there was a lack of scientific evidence surrounding the efficacy of homeopathic products. In contrast, the Bill did regulate traditional medicine, although excluded regulation of CAM products that were dispensed by a practitioner to an individual. This was an attempt to avoid the regulation of rongoā – Māori traditional medicine.

Two aspects comprise the practical provisions of the Bill: the permitted and prohibited substances list, and the permitted conditions and allowable claims. These were to be implemented and managed by the Natural Health and Supplementary Products Regulatory Authority and Advisory Committee.

As previously mentioned, the Bill would operate with a white and black list, formally known as the permitted and prohibited ingredients lists respectively.[81] If a product or its ingredients were not in the permitted list, it would have to apply for inclusion according to the set criteria, before it could be sold. Conversely, if an ingredient was on the prohibited ingredients list, it would not receive approval. There were already problems showing with this system, as discussed at section D below.

The permitted conditions and allowable claims content in the Bill signalled a radical change from the DSRs. Instead of CAM products being prohibited from making "therapeutic claims" about the products, the Bill allowed products to make "health benefit claims" where they were supported by scientific or traditional evidence.[82] "Allowable claims" were to be a sub-group of health benefit claims. These would be approved by the Authority before being used, and would relate to the use of CAM products for "named conditions". The exact operation and structure of this system remained unclear, but a proposed list of conditions raised concerns. The list included

79 Natural Health and Supplementary Products Bill 2011 (324-2), cls 6(1)(b); Unless an exception in either cl 22(2)(b)(i) applies, or the product is a dietary supplement.

80 Professor Sir Peter Gluckman "Submission to the Health Committee on the Natural Health Products Bill 2011" (February 2012) at 1.

81 Natural Health and Supplementary Products Bill 2011 (324-2), cls 20 and 21.

82 At cl 4(d).

conditions for which there is no successful medical cure (for example, Alzheimer's disease and arthritis), as well as conditions for which there is sound and simple medical treatment (for example, diabetes).[83] The issue with this was that people would take CAM products (which may not be effective) in place of taking safe, highly effective medication, like insulin for their diabetes, for example.

The NHSPB provided for a Regulatory Authority under the Director-General of Health at cl 8. It also established an Advisory Committee which would offer non-binding advice to the Authority.[84] Although neither had been formally established at the time of the Bill's demise, a Permitted Substances List subcommittee had been created, with a worrying composition; one of the problems discussed below.

D. On promise and problems: lessons from the proposed legislation

As alluded to above, there were a number of problems with the NHSPB, but these now provide a valuable opportunity to avoid making the same mistakes in future CAM legislation. Conversely, some aspects of the NHSPB were promising or much needed developments in this regulatory sphere.

That draft permitted substances list that had been released prior to the Bill lapsing, concerningly included "permitted ingredients" that are well-recognised as being harmful. Two examples illustrate this point. The first is the colourant brilliant black; widely banned, most notably in the USA.[85] Brilliant black was included on the permitted ingredients list,[86] despite evidence of allergic reactions and exacerbation of some conditions.[87] Similarly, the colouring agent tartrazine was set to be included on the permitted ingredients list. A Southampton study showed tartrazine to affect hyperactivity and cause impulsive behaviour in children.[88] These two examples pose serious questions about the permitted substances list, when products whose only purpose was to colour CAM products are included on the list, despite evidence of their risk, and when some international authorities put restrictions on their use.

Another problem touched on above was the concerning composition of the subcommittee charged with deciding what products should be on the

83 Ministry of Health *Proposed list of conditions about which claims can be made* (Ministry of Health, Natural Health Products Consultation document, November 2015).

84 Natural Health and Supplementary Products Bill 2011 (324-2), cl 10.

85 The Feingold Association of the United States "List of Colorants" (2017, online) <www.feingold.org>.

86 Ministry of Health "Permitted Substance Search" (May 2017) <www.medsafe.govt.nz>.

87 Panel on Food Additives and Nutrient Sources added to Food "Scientific Opinion on the re-evaluation of Brilliant Black BN (E 151) as a food additive" (2010) 8(4) European Food Safety Authority Journal 1540.

88 Donna McCann and others "Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial" (2007) 370(9598) The Lancet 1560.

permitted ingredients list. The subcommittee comprised 18 people, 11 of whom currently work, or have worked in the CAM product industry. This extremely close relationship to the industry in a committee that effectively decided what products and ingredients could be readily sold under the new Bill, raised substantial concerns for the perceived impartiality of the committee.

Despite these problems, the NHSPB proposed to include a publicly accessible register of CAM products.[89] Such a register would provide consumers with basic information on a product, enabling both consumer and industry buy-in to ensure unregistered products are not on the market. Furthermore, this register would have made Government-mandated recall a simple procedure, in contrast to the Pan Pharmaceuticals situation discussed at Part IID, above.

Another promising development in the NHSPB was the introduction of adverse event reporting: a scheme that has been present in medicines regulations for years.[90] Logically, such a system for CAM products should see few detractors for, if CAM products are as safe as the industry claims, such a reporting system should show no adverse events from CAM products. However, the inclusion of adverse event reporting in the NHSPB could be developed further in future legislation, with it being limited in this Bill to "serious adverse reactions". The standard for such a reaction in the Bill was hospitalisation, death, disability, congenital abnormality or allergic reaction; an absurdly high standard (higher than that for medicines), for products that are purportedly so safe.[91]

The NHSPB was far from perfect. While there is no doubt it was an improvement on the status quo, the achievements in the Bill are tempered by the problems and flaws that it perpetuates, fails to consider or insufficiently addresses: some of which are touched on above. With the Bill now lapsed, it is time to turn towards the future. Having taken account of all that has come before, and with the benefit of hindsight, a new proposal must be considered for the regulation of CAM products in New Zealand.

V. A Novel Risk-Based Proposal for CAM Product Regulation

The following proposal draws upon an exhaustive study of New Zealand food, medicine, and CAM product legislation. It is informed by a study of the wider legislative and judicial framework which affects CAM products; primarily the Fair Trading Act 1986 and enforcement actions taken thereunder. Finally, two empirical studies form part of the foundation for

89 Natural Health and Supplementary Products Bill 2011 (324-2), cl 11.

90 At cl 17.

91 At cl 17(2).

this proposal. These studied public perceptions around CAM products and the labelling and packaging of CAM products.[92]

A. An overview of the Complementary and Alternative Medicinal Products Bill

This proposal goes beyond merely attempting to regulate in the heavy-handed, over prescriptive manner of previous iterations of CAM product legislation like the NHSPB. Instead, it aims to put forward a mechanism by which, over time, scientific evidence can be obtained that establishes the efficacy of particular CAM products; ultimately creating a safer, more effective, and more transparent marketplace for the benefit of all stakeholders.

This proposal presents an evidential, risk-based approach to the regulation of CAM products. It divides products into three tiers, commensurate with their risk and the evidence available as to their effects and benefits. Alongside this, there will be a black-list, which prohibits ingredients or products known to have unacceptable risk (for example, allergenicity), which also have an overall risk profile that is not balanced by the benefit of a CAM product. To manage this proposed legislation, a regulator would be created, which would oversee pre-approval screening, classification and reclassification of products, and post-market surveillance.

This system would be partly government-funded and partly industry-funded, with a sliding fee scale which promotes safety and efficacy in CAM products through reduced costs depending on the tier classification. The proposal adopts a number of specific policies which aim for a more harmonised approach with international regulators in recognition of New Zealand's size and limited capacity. At the same time, the proposed legislation upholds and respects the principles of the Treaty of Waitangi and the rights of Māori as tangata whenua.

Key excerpts of this Bill are discussed below. These are selected definitions, an outline of the risk-based approach, and some ancillary matters. These excerpts relate to the problems and background raised in this article, and serve to demonstrate a solution and way forward for the regulation of CAM products in New Zealand.

B. Selected definitions and a solution to the food-medicine-CAM product overlap

Clause 5 of the proposed Bill provides some of the more important definitions. This includes a list of information that amounts to scientific evidence for the purpose of supporting CAM products in the risk-based scheme discussed below. A black-list is also defined, as:

92 Peter Harris "The Regulation of Complementary and Alternative Medicine in New Zealand" (LLM (Hons) Thesis, University of Canterbury, 2017).

> … the register of prohibited products or ingredients, listed in sch 1 and declared by the Regulatory Authority under section 10 to be a prohibited substance on the basis of a risk assessment.

Rongoā Māori is also defined in the Bill as the practice of Māori traditional medicine. The Bill does not propose to regulate CAM practices, much like the NHSPB. Consequently, rongoā Māori will not be regulated under the Bill, thereby avoiding one of the problems that proved fatal for the Therapeutic Products and Medicines Bill 2006. However, where traditional Māori remedies are produced on a commercial scale for sale or supply outside the practice of rongoā Māori, this Bill will apply to them, as if they are traditional medicine products. In contrast to the NHSPB, this Bill notes at cl 7 that the principles of the Treaty of Waitangi must be taken into account when carrying out the purposes of the Bill.

Traditional medicine products, as well as dietary supplements, herbal medicines or herbal remedies and homeopathic products are all noted to be sub-groups of "complementary and alternative medicinal products" as defined in cl 6 of the Bill. The individual definitions of these terms in cl 5 is broadly uncontroversial, being largely imported from existing legislation. Herbal medicines or herbal remedies are noted not to be medicines, which will also require amendment of the Medicines Act 1981 to remove them from its ambit. Traditional medicines include "any traditional or indigenous medicine which has a longstanding history of use", but as will be seen below, there are checks on the classification of these products depending on the evidence presented with them when they seek approval. In contrast to the NHSPB, homeopathy will be regulated in this Bill but, due to the simple scientific evidence surrounding homeopathic products, they will be limited in the claims they can make within the risk-based classification system, as seen in Table 1. Homeopathic remedies are probably very low risk and equally likely very low benefit which indicates that their only harm is arguably deception.

Food products are defined in cl 5 according to two metrics: the product's appearance and its intended use. Food products must appear to be food or drink products as ordinarily understood, and they must be intended for human consumption as food or drink, or else as an ingredient of food or drink. This definition is intended to be narrower than that in the Food Act 2014, to remove much of the overlap which currently exists with CAM products.

Medicine is defined in the Bill along similar lines to that proposed in the NHSPB at cl 6(2). Additionally, this Bill requires that medicines are products used for a therapeutic purpose within the meaning of s 4 of the Medicines Act 1981. This differentiates them from CAM products, which will not be required to have a therapeutic benefit.

With the definition of food products and medicines neatly corralled in the Bill, it then defines CAM products at cl 6. This definition includes

the subgroups previously mentioned and explicitly excludes any product or ingredient on the black-list, any CAM practice, food product and any medicine. Clause 6 also establishes that a CAM product must be intended for human use, show either scientific or traditional evidence for its safety, have a risk commensurate with the product's benefit and be approved for sale by the Bill's regulatory authority.

These definitions of food products, medicines and CAM products not only explicitly exclude each other, but they define their respective products in terms of characteristics unique to that type of product. This two-fold system is created to prevent overlap between the products and avoid much of the confusion and ensuing regulatory grey areas which have existed for the last 30 years.

C. A risk-based approach

The following table is taken directly from the proposed legislation. It is a companion to cl 9, which details "the classification of CAM product tiers for the purpose of assigning applicable risk-based approaches". This table is intended to be a part of the proposed legislation in a similar way to the flowcharts in the Income Tax Act 2007, for example.[93] If required, there may be scope for the examples seen in the table to be used in the proposed legislation, in a similar way to those in the Companies Act 1993 or the Patents Act 2013.[94]

93 Income Tax Act 2007, Part B.

94 See Companies Act 1993, ss 199 and 207L; and Patents Act 2013, ss 11, 15 and 282.

	Tier 1 Top tier	**Tier 2** Middle tier	**Tier 3** Bottom tier
General	High benefit, low risk	High benefit, Moderate risk Moderate benefit, low risk	Low benefit, very low risk No benefit, very low risk
	Can make strong efficacy claims	Can make weak efficacy claims	Cannot make efficacy claims
	May be required to specify purpose	May be required to specify purpose	Cannot specify purpose
	No packaging restrictions	May be limit on amount of product per package	Products cannot be packaged in boxes
	Lowest annual licencing fees	Moderate annual licencing fees	High annual licencing fees
Labelling Requirements	Labelled with a (green dot) and 'Tier 1 CAM product' on primary display	Labelled with a (orange dot) and 'Tier 2 CAM product' on primary display	Labelled with a (red dot) and 'Tier 3 CAM product' or 'Tier 3 Homeopathic product' on primary display
	Must make healthcare advisory statement	Must make healthcare advisory statement. Must list side-effects	Must make healthcare advisory statement
	Must list all ingredients	Must list all ingredients	Must list all ingredients
Evidence Requirements for Classification	Must supply a copy of the label	Must supply a copy of the label	Must supply a copy of the label
	Must have scientific evidence on safety. Biochemical basis for mode of action and toxicological safety assessments likely required - traditional evidence is insufficient.	Must show sound evidence of safety – traditional evidence unlikely to be enough alone	Must show some evidence of safety – traditional evidence will suffice
	Must show biochemical mode of action, and provide sound scientific evidence for efficacy claims, e.g. monographs, peer reviewed research of clinical studies	Must hold scientific evidence for any efficacy claims. Monographs, peer reviewed research, or clinical studies all accepted. Theoretical basis may be acceptable.	No proof of efficacy required
	Must provide evidence of GMP, Quality Control and product testing	Must provide evidence of GMP and Quality Control plans	Must provide evidence of GMP and Quality Control plans
	Must provide evidence of structural similarity assessments	Must provide evidence of structural similarity assessments	No structural similarity assessment necessary
Examples	Iron products	Olive Leaf	Arnica 6X Drops (Homeopathic)

Table 1: A Proposed Risk-based Approach for CAM Product Regulation

Table 1 provides an outline of the three tiers into which CAM products can be classified under this risk-based proposal. The table contains a precis of the labelling and evidence requirements for each tier. The regulatory authority will classify products in one of the three tiers based upon the evidence provided in the product's application, before it can be marketed in New Zealand. This proposal adopts similar tenets to the risk-based measures of the Food Act 2014 and the Medicines Act, in their respective classification of food sectors or medicines according to risk.

The structure and design of this scheme is intended to incentivise manufacturers and importers to attain the highest possible status for their CAM products. It does this by allowing stronger claims on safer, more beneficial products, by decreasing the number of restrictions around packaging and presentation of these products, and, most importantly, by having the lowest annual licencing fees corresponding to the higher tiers. In order to reach the higher tiers, products must provide scientific evidence of safety and efficacy, depending on the tier and the claims the product wishes to make. This measure not only demonstrates to the regulatory authority that the product is safe and befitting regulation within a particular risk-tier, but it also starts the process of gathering sound evidence on the safety and efficacy of CAM products to address the aforementioned information deficit. There will be established processes in the proposed legislation and regulations for registration, ongoing licencing and reclassification, with transitional provisions for the early years of the Bill's enactment.

Homeopathic products like arnica (an extract of a plant in the sunflower family) are good examples of products that will certainly be in Tier 3. As a homeopathic product, an applicant seeking classification would need to show that there was virtually no arnica remaining in the mixture and that the excipients are safe. As there is no scientific evidence for the efficacy of homeopathic products, and no benefit beyond the placebo effect, then the only option is Tier 3 classification. Consequently, no efficacy claims or statement of purpose will be able to be made on the packaging.

Olive leaf is an excellent example of a potential Tier 2 product, as it shows some evidence of efficacy as an antioxidant or diuretic,[95] but there is also a suggestion of adverse effects associated with its use.[96] This balance of benefits and risks will likely result in olive leaf's categorisation as a product with moderate benefit and low risk, making it suitable for Tier 2 classification. Evidence of safety will be required and the applicant will need to hold scientific evidence for all efficacy claims that the product makes.

Tier 1 requires the greatest amount of evidence of safety and efficacy, yet it comes with the associated benefits of low fees and permissive regulation around the labelling and marketing of the particular product. Iron supplements are

95 Health Canada *Olive Leaf – Olea europaea* (Health Canada, online, 8 December 2015).

96 Ian C Shaw "Possible toxicity of olive leaf extract in a dietary supplement" (2016) 129(1432) New Zealand Medical Journal 86.

one example of a possible Tier 1 product; they have a high benefit due to their efficacy in addressing iron deficiency leading to anaemia, while having a relatively low risk at the doses used to ameliorate iron deficiency.

Finally, it is important to note that products will be able to be registered in different tiers, depending on the evidence presented or claims which a manufacturer wishes to make. For example, Vitamin C may be registered in Tier 1 for the relief of scurvy, where there is irrefutable evidence of safety and benefit. However, another manufacturer may wish to make claims on packaging and advertising about Vitamin C for use in treating the common cold, where the evidence is not sound. Consequently, they would likely seek Tier 2 status for this product and, thus, be allowed to make weak efficacy claims, which do not require as strong evidence as that for a Tier 1 product.

There are many nuances which will certainly arise in a product category as diverse as CAM products, but this risk-based regulatory scheme is designed to be adaptive, such that the regulatory authority will be able to manage such issues, within the risk-based structure set out in Table 1.

D. Ancillary matters

Several other matters must be briefly touched upon regarding this proposed legislation. As already noted, there will be a black-list alongside the Bill. This will prohibit a substance with a risk that is too high when balanced against its benefit. Examples of such products would most certainly include brilliant black and tartrazine, as discussed above, as they have no benefit aside from colouring CAM products and have documented health risks.

There will be strong post-marketing surveillance carried out by the Bill's regulatory authority. This will involve a number of activities, including monitoring the packaging, labelling and sale of CAM products in a physical setting and in an online environment, ensuring licence holders comply with the terms of their tier. The Bill will also have a similar system to medicines in place for reporting adverse events. It may be possible that the reporting of adverse events for CAM products could simply slot into the existing adverse event reporting service which Medsafe operates, or that it is run by the University of Otago's Centre for Adverse Reactions Monitoring.

Finally, this Bill also adopts the strategy included in the NHSPB to have publicly accessible registers. Notably, there will be a searchable database of licenced CAM products, which will include the details a licence holder relies upon in their classification application and any safety, quality and efficacy information as applicable.

This article merely touches upon key parts of a proposed Complementary and Alternative Medicinal Products Bill. Nevertheless, it demonstrates a new legislative regime which will bring New Zealand's CAM product regulations into the 21st century. The Bill employs a risk-based system that encourages the collection of data on the safety and efficacy of CAM products, regulating them in a flexible manner that takes accounts of the nuances of individual

products. Furthermore, the proposed legislation links the cost of regulating CAM products, with their risk; thereby incentivising industry to seek higher classification for their products. This also allows licence holders to reap the benefits of demonstrably safer, more effective products when they can also advertise themselves as such. This system rewards innovation and research, while being flexible enough to adapt to the ever-changing demands of this area for the next 30 years.

VI. Conclusion

CAM product regulation in New Zealand began with the regulation of "herbal remedies" in the Medicines Act 1981. In 1985, the DSRs came about under the Food Act 1981, and 30 years later they remain in force under the Food Act 2014. Despite multiple proposals for reform of CAM product regulation, nothing has succeeded. The NHSPB was the best attempt at updating this area, despite its issues and lack of understanding of the market it was seeking to regulate. Nevertheless, with this Bill lapsing in August 2017, CAM products remain effectively unregulated, with widespread breaches of the regulations acknowledged the by the Ministry of Health itself.[97]

This article has focused on the persisting problem with New Zealand's regulation of CAM products; namely the inability of current or proposed legislation to effectively regulate them such that there is clarity around the safety, efficacy and quality of these products. In an effort to address this problem, Part III looked at risk-based approaches to regulation. This demonstrates the application of risk-based regulation to food and medicines and, by extension, how it could apply to CAM products.

The status quo of an effectively unregulated CAM products sector is unsatisfactory. The NHSPB has lapsed and was unwieldy and likely to struggle with ensuring safe, effective, high quality CAM products, while not being overly restrictive. As such, the CAM Products Bill (an outline of which is presented in this article) is proposed as the best solution to this regulatory problem facing New Zealand.

The Bill takes elements that have proven effective in other legislation and endeavours to create a Bill that will effectively regulate CAM products in a manner commensurate with their risk. It prioritises the safety, efficacy and quality of CAM products, and incentivises further scientific research and evidence collection. The CAM Products Bill provides a simple, flexible and evidence-based scheme for regulation of CAM products in New Zealand.

In general, the public is sufficiently confident that the government ensures the safety of both their food and of their medicines. They should also be able to be assured that, at minimum, the government ensures the safety and quality of their CAM products, through comprehensive regulation. Sound,

97 Ministry of Health, above n 3, at 1–5.

risk-based CAM product legislation benefits all stakeholders; removing ineffective or dangerous products from the market and demonstrating the safety, efficacy and benefits of the remaining products. If the endless claims of the industry that CAM products are safe, effective and of high quality are true, then regulation in line with the proposed CAM Products Bill will be a straightforward, cost-effective way to support these claims; inspiring consumer confidence, and providing substantial opportunities for the global potential of New Zealand CAM products.