Australian Natural Therapists Association

Submission to
Chair, Health Workforce Principal Committee
Registration of Naturopathy, Western Herbal Medicine and Nutritional Medicine

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Introduction

This submission prepared on behalf of ANTA[1] presents evidence for the statutory regulation of Naturopathy, Western Herbal Medicine and Nutritional Medicine (Nat/WHM/NM) in Australia under the National Registration and Accreditation Scheme for the Health Professions (NRASHP). This submission applies the process outlined in Attachment B of The Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions (IGA), which outlines six criteria to be met before registration of any health profession is considered.[2] The IGA states 'it was envisaged that other health professions would be added over time.'[3] This submission will focus on all of these criteria with a special focus on Criterion 2 which requires that the occupations' practice presents a serious risk to public health and safety which could be minimised by regulation. This submission seeks to demonstrate that registration of these three health professions is justified and will provide evidence of the risk to public health and safety and the reasons why current regulatory mechanisms are insufficient in minimising this risk. In achieving that goal, this submission will be cognisant of the COAG Best Practice Regulation Guidelines (COAG guidelines)[4] which requires any regulatory response to first find a case for action, any decisions made should consider self-regulation, co-regulation and non-regulatory options and it should provide the greatest net benefit for the community which is proportional to the issue being addressed.[5]

Although this submission is primarily focussed on the Australian context, information has been accessed from other jurisdictions such as the USA and Canada. The use of international evidence is justified on the basis that the types of therapies used in Nat/WHM/NM in Australia are applied in these other jurisdictions and evidence of harm reported in those jurisdictions provides lessons about the potential risk of the provision of Nat/WHM/NM in Australia. In all examples used in this submission adverse outcomes involve only unlicensed or unregistered practitioners using Nat/WHM/NM.

Risks associated with clinical judgments are inherent in any health profession. This submission will outline some of the documented examples of any type of injury that has been reported to have occurred in relation to Nat/WHM/NM in Australia, the USA and Canada. This submission will draw from data found in the significant La Trobe University Report, *The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine November 2005* (School of Public Health – La Trobe University), V Lin, A Bensoussan, S P Myers, P McCabe, M Cohen, Sophie Hill and G Howse[6] (the La Trobe report) which is the most authoritative and comparatively recent research about Nat/WHM and the regulatory requirements for these modalities. This submission will discuss other issues and update information, events and regulatory responses that have occurred since 2005 including data about nutritional medicine which has emerged as a significant modality since 2005. The 484 pages of the La Trobe report

[1] View the profile of ANTA under Schedule C of this submission.

[2] Criterion 1: It is appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?
Criterion 2: Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
Criterion 3: Do existing regulatory or other mechanisms fail to address health and safety issues?
Criterion 4: Is regulation possible to implement for the occupation in question?
Criterion 5: Is regulation practical to implement for the occupation in question?
Criterion 6: Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

[3] The Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions (26 March 2008), p 22, 1.1

[4] Council of Australian Governments, *Best Practice Regulation Guidelines: A Guide for Ministerial Councils and National Standard Setting Bodies*, October 2007.

[5] Ibid pp 4-6.

[6] http://health.vic.gov.au/__data/assets/pdf_file/0004/320188/naturopathy-final1106.pdf

provides an evidence-based analysis of the regulatory structure of naturopathy and western herbal medicine applying the AHMAC criteria (which are the same as the IGA criteria).

Significantly, 11 years ago the La Trobe report recommended that based upon AHMAC criteria that statutory regulation is warranted[7] for the following reasons:[8]

- 'there is a level of risk in naturopathy and WHM comparable to other regulated professions;
- there is a particular risk related to the interaction of herbal medicine and pharmaceutical drugs and the need for appropriate prescribing frameworks;
- existing regulatory frameworks are insufficient to protect against professional misconduct
- variable arrangements currently exist for professional practice standards among professional associations and professional associations have been unable to come to common arrangement; and
- variable standards exist among education and training institutions with no evidence of movement towards common standards (including the failure of current regulatory frameworks to ensure basic standards for education).'

Although there have been changes in the regulatory structure for Nat/WHM/NM since 2005, the factual basis for the conclusions reached by the La Trobe report is still relevant in 2016. Although the focus of the La Trobe report is on Nat/WHM it is clear from the definitions below, the data provided by the La Trobe report and the examples of negative outcomes specified in Category A, there is a substantial degree of overlap between these three health professions including data about the use of both nutritional medicine and Western Herbal Medicine by naturopaths and vice versa.

Definitions for Western Herbal Medicine Nutritional Medicine and Naturopathy

For the purpose of this submission, it is worthwhile to describe definitions of each of these three professions.

Western Herbal Medicine

Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations.

Herbs: crude plant material such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

Herbal materials: in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other materials.

[7] A similar recommendation arose from the Minister for Health and Ageing, *Complementary Medicines in the Australian Health System, Report to the Parliamentary Secretary*, (September 2003), 129.
[8] La Trobe report, above n 6, 305-306.

Herbal preparations: the basis for finished herbal products may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.

Finished herbal products: herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.[9]

Nutritional Medicine

'Nutritional medicine is defined as the study of interactions of nutritional factors with human biochemistry, physiology and anatomy and how the clinical application of a knowledge of these interactions can be used in the modulation of structure and function for the prevention and treatment of disease as well as the betterment of health.[10]

'Nutrition can be defined as the sum of all processes involved in the intake, assimilation and utilisation of nutrients. The clinical nutritional medicine approach is based on a wide range of published scientific information and is essentially integrative, deriving concepts and knowledge from many disciplines including physics, chemistry, anatomy, physiology, biochemistry, pathology, pharmacology, toxicology, genetics, anthropology, palaeontology, microbiology, molecular biology, environmental science, nutrition, food science, psychology and sociology.'[11]

The "nutritional factors" assessed and addressed by nutritional medicine include diets, food substances, non-food dietary components and isolated nutritional compounds. These compounds may be synthetic or of natural origin and may involve varying degrees of processing and refinement. Therapeutic interventions may involve the withdrawal or administration of any such compounds, potentially at supraphysiological levels.

Naturopathy

Naturopathy is a distinct type of primary care medicine that blends age-old healing traditions with scientific advances and current research. Naturopathy is guided by a unique set of principles that recognise the body's innate healing capacity, emphasise disease prevention, and encourage individual responsibility to obtain optimal health. Naturopathic treatment modalities include diet and clinical nutrition, behavioural change, hydrotherapy, homoeopathy, botanical medicine and physical medicine.[12]

'In general, naturopathy emphasises prevention, treatment and the promotion of optimal health through the use of therapeutic methods and modalities which encourage the self-healing process – the vis medicatrix naturae. The philosophical approaches of naturopathy include prevention of

[9] World Health Organisation, Definitions http://www.who.int/medicines/areas/traditional/definitions/en/ (Accessed 13th August 2016)

[10] Stephen Davies, 'Scientific and Ethical Foundations of Nutritional Medicine Part 1 – Evolution, Adaption and Health,' (1991) 2 *Journal of Nutritional Medicine* 227-247, 227.

[11] Ibid

[12] Fleming, S, & Gutknecht, N (2010), 'Naturopathy and the Primary Care Practice', (2010) 37 *Primary Care*, 119-136, 119.

disease, encouragement of the body's inherent healing abilities, natural treatment of the whole person, personal responsibility for one's health and education of patients in health-promoting lifestyles. Naturopathy blends centuries-old knowledge of natural therapies with current advances in the understanding of health and human systems. Naturopathy, therefore, can be described as the general practice of natural health therapies.'[13]

Naturopathic philosophy of practice is succinctly stated in the six principles of naturopathic medicine. These principles guide naturopathic medical treatments and could be applied in integrative settings to organise the use of conventional treatments with CAM therapies:

1. The Healing Power of Nature (Vis Medicatrix Naturae). The body has an inherent capacity to maintain health and treatments guide and support this capacity.

2. Identify and Treat the Causes (Tolle Causam). The naturopathic physician promotes healing by addressing the root cause of an illness.

3. First Do No Harm (Primum Non Nocere). Interventions should be as non-invasive as possible and proceed to more disruptive and potentially harmful treatments only when necessary.

4. Doctor as Teacher (Docere). The role of the naturopathic physician includes educating the patient, involving him or her in the healing process and establishing an essential physician/patient partnership.

5. Treat the Whole Person (Tolle Totum). All aspects of an individual's health, including mental/emotional, behavioural, genetic, structural, environmental, social, and spiritual factors, need to be taken into account.

6. Prevention. Prevention of future illnesses and optimising wellness is imperative. Prevention is more cost-effective health care and less stressful to patients than treating chronic diseases.[14]

Methods applied by Nat/WHM/NM

In Nat/WHM/NM a variety of methods can be used to evaluate potential causative factors. Some of the more common tools used in the clinical evaluation process include a thorough medical history (including family history of disease), dietary analysis (including eating habits and food intake), lifestyle analysis (including exercise, stress burden, sleeping patterns), clinical signs and symptoms (such as blood pressure, body composition and tissue condition). Laboratory tests, such as blood, stool, hair and urine analyses for vitamin and mineral levels as well as body metabolite balances, can also be employed to determine nutrient deficiencies, heavy metal toxicity, fat and protein imbalances, immune status, blood sugar balance, kidney, liver and digestive function.

[13] World Health Organization, 2010, "Benchmarks for training in traditional / complementary and alternative medicine. Benchmarks for Training in Naturopathy," 1.

[14] AP Litchy, (2011), 'Naturopathic physicians: holistic primary care and integrative medicine specialists', (2011) 8 *Journal Of Dietary Supplements*, 369-377, 370.

This information (regarding nutrient adequacy, food quality, dietary behaviours, lifestyle and environment factors, as well as the causes of dysfunction), is assessed by the practitioner and used to educate the patient, create a personalised diet and lifestyle plan and prescribe focussed supplementation for the individual where necessary. Scientific evidence, ethics and sound clinical reasoning guide practice to ensure that treatment recommendations are efficacious and safe.[15]

Criterion 1:
Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?

Complementary and Alternative Medicine (CAM), a considerable part of which would involve expenditure on Nat/WHM/NM, now constitutes a significant part of the Australian health care sector. A 2007 study suggested that the estimated number of patient visits to CAM practitioners is similar to the number of visits to conventional medical providers (69.2 million v. 69.3 million) with national out-of-pocket expenditures on CAM products of over $4.1 billion.[16] In some areas of Australia, CAM practitioners providing primary care services out number conventional primary care physicians.[17] It has been calculated that nearly 10% of the Australian female population see a naturopath or western herbal medicine practitioner and this increases to 16% when dealing with complex conditions.[18] Accordingly, it is important that, along with orthodox medicine, the regulation of Nat/WHM/NM is given careful consideration. As the use of Nat/WHM/NM is a multi-billion dollar industry in Australia and it is demonstrated that these three professions are providing a substantial level of health services to Australians alongside orthodox medicine, it is appropriate for Health Ministers to exercise responsibility for these occupations rather than the occupations being regulated by another Ministry. If the IGA is appropriately within the portfolio of the Health Ministers then there is no reason why the regulation of these occupations should fall within any other Ministry domain. While the number of Nat/WHM/NM practitioners in Australia is not clear, there may be as many as 10,000 Naturopaths and Western Herbalists in Australia.[19] Although the type of therapies, substances and health philosophy applied in Nat/WHM/NM may be different from orthodox medicine, the focus is upon clients' health and it is appropriate that Health Ministers consider regulation of these occupations.

[15] Ian Kerridge, Michael Lowe and Cameron Stewart, *Ethics and law for the health professions,* (4th Edition, The Federation Press 2013) pp 822-828.
[16] Charlie C Xue et al, 'Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey' (2007) 13 (6) *Journal of Alternative and Complementary Medicine* 643, 643.
[17] Jon Wardle et al, 'Distribution of Complementary and Alternative Medicine (CAM) Providers in Rural New South Wales, Australia: A Step towards Explaining High CAM Use in Rural Health?' (2011) 19(4) *Australian Journal of Rural Health* 197, 199.
[18] Jon Wardle, 'The National Registration and Accreditation Scheme: what would inclusion mean for Naturopathy and Western Herbal Medicine', (2010) 22 (4) *Australian Journal of Medical Herbalism* 113,114.
[19] Submission from The Australian Naturopathic Practitioners Association in Australian Health Ministers' Advisory Council, *Options for Regulation of Unregistered Health Practitioners*, 3.

Criterion 2:
Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?

The following should be considered when assessing whether there is significant risk of harm to the health and safety of the public:

- the nature and severity of the risk to the client group;
- the nature and severity of the risk to the wider public; and
- the nature and severity of the risk to the practitioner.

Areas which could be explored to identify a risk to public health and safety are:

- to what extent does the practice of the occupation involve the use of equipment, materials or processes which could cause a serious threat to public health and safety;
- to what extent may the failure of a practitioner to practice in particular ways (that is, follow certain procedures, observe certain standards, or attend to certain matters), result in a serious threat to public health and safety;
- are intrusive techniques used in the practice of the occupation, which can cause a serious, or life threatening danger;
- to what extent are certain substances used in the practice of the occupation, with particular emphasis on pharmacological compounds, dangerous chemicals or radioactive substances; and
- is there significant potential for practitioners to cause damage to the environment or to cause substantial public health and safety risk.

Risks associated with Nat/WHM/NM

The discussion of the risk of harm to the health and safety of the public will involve a discussion of the types of risks normally encountered in the practice of Nat/WHM/NM. This submission will then consider specific examples of when adverse events have occurred in the provision of Nat/WHM/NM and views expressed by practitioners and GPs and the evidence of health complaints bodies in the frequency of health care complaints about Nat/WHM/NM. Details of negative outcomes associated with the provision of Nat/WHM/NM are documented in **Schedule A** to this submission.

Type of Risk of Treatment

The risks associated with the Nat/WHM/NM might be considered to fall into two categories:[20]

a. risks associated with the clinical judgment of the Nat/WHM/NM practitioner.

This category includes two sub-categories namely (a) adverse events related to acts of commission (such as recommending cessation of medical treatment or failing to avoid known interactions with pharmaceuticals, prescribing substances not well suited to a particular client such as a diabetic, over dosage of substances which are only toxic at high levels or prescribing for prolonged periods with potential for impacts on liver function),[21] (b) acts of omission (such as misdiagnosis, failure to detect underlying pathology, failure to refer to an appropriate practitioner or insufficient advice about risks of treatment) are evidenced below. Concerns have

[20] La Trobe report, above n 6, 33.
[21] La Trobe report, above n 6, 34.

been expressed among consumers and healthcare practitioners about the nature and extent of such risks.

b. risks related directly to the consumption of nutritional and herbal medicines.[22]

In the same way that pharmaceutical substances produce unexpected impacts, herbal medicines and other substances commonly used by Nat/WHM/NM can and do produce predictable and unpredictable effects. Cases were identified in both of these areas to include direct toxicity, toxicity related to overdose of a preparation and interaction with Western pharmaceuticals. Unpredictable effects included allergic idiosyncratic impacts. In some cases, herbal substances may be adulterated with toxic substances or contain pharmaceutical substances.

The table below in **Schedule A** shows in chronological order documented examples of adverse events involving Nat/WHM/NM indicating what modality is involved, where the event occurred and the source of the report. In addition, the categories of the types of risks involved is also specified.

Health Complaints

The level of complaints about health issues may provide a profile of the risk of particular therapies and the activities of specific practitioners. There are health complaint bodies in all States and Territories in Australia which compile and publish health complaint statistics.[23] The La Trobe report looked at examples of complaints against alternative medicine practitioners to Health Complaints Commissioners in a number of jurisdictions over the period for the period 1997-2004.[24] The ACT, Tasmania and the Northern Territory health complaints body made no mention of alternative or other providers in its statistics. The difficulty with the evidence provided by health complaints bodies for the purpose of analysing the complaint profile for Nat/WHM/NM was that in most cases little detail was provided about the modalities complained against with most categorised under the term 'alternative health providers, alternative therapists, alternative health, alternative providers or other providers'.

The most complete evidence of health complaints in regard to modalities the subject of this submission in the specified period was Queensland's Health Quality and Complaints Commission which documented nine complaints in the two years to February 2004 and 20 complaints in ten years to February 2004.[25] The most common complaints for naturopathy relate to sexual misconduct, medication, misdiagnosis and treatment negligence. This data does not provide information about what resulted from these complaints namely whether they were investigated, were they dismissed or was there regulatory action such as a referral to police or other governmental authority.

More recently, the New South Wales Health Care Complaints Commission Annual Report 2013-2014 contained records of 17 complaints against alternative health providers (presumably not naturopaths, or massage therapists who are specifically covered by data) suggesting that these practitioners may include western herbal medicine and nutritional medicine. The complaints against alternative health providers dealt with issues in descending order of frequency in professional conduct (10), treatment (4) and environment and management of facilities (3).

[22] La Trobe report above n 6, 37.

[23] *Healthcare Complaints Act 1993* (NSW); *Health Complaints Act 2016* (Vic.); *Health Ombudsman Act 2013* (Qld); *Health and Disability Services (Complaints) Act* 1995 (WA); *Health Complaints Act 1995* (Tas); *Health and Community Services Complaints Act 2004* (SA); *Human Rights Commission Act 2005* (ACT); *Health and Community Services Complaints Act 1998* (NT).

[24] La Trobe report above n 6, 35.

[25] Ibid, 36

Under the category of natural therapist there were two complaints related to professional conduct. In relation to naturopaths there were five complaints about professional conduct (3), communication/ information (2) in New South Wales in the 2013-2014 financial year.[26]

Recent data provided by the New South Wales Health Care Complaints Commission Annual Report 2014-2015 contained records of 12 complaints against alternative health providers (presumably not naturopaths, homoeopaths and massage therapists who are specifically covered by data) suggesting that these practitioners may include western herbal medicine and nutritional medicine.[27] The complaints against alternative health providers dealt with issues in descending order of frequency in professional conduct (6), treatment (2), communication/ information (3), fees/costs (1). In relation to naturopaths there were in New South Wales in the 2014-2015 financial year seven complaints about treatment (2), communication/ information (2), medication (3) and fees/costs (1).[28]

Practitioner reported adverse events in Nat/WHM/NM

An impressive workforce survey dealing with adverse events was published in 2004 by A Bensoussan et al.[29] Data was obtained using a national survey of practitioners in various alternative modalities. Five questions on the survey related to adverse events in naturopathy, nutritional medicine and herbal medicine. The survey requested an indication of the number of times an adverse event had occurred over their time in practice.[30] Naturopathy often involves the use of herbal medicine, homoeopathy, massage therapy and nutritional medicine. The results of this survey suggest that the respondent best described one of their practice descriptors as herbalism 62%; naturopathy 76%.[31]

Based upon the receipt of 859 surveys returned the authors suggested the 'estimate of the total adverse events extrapolated to all Australian practitioners who prescribe herbal, nutritional and/ or homoeopathic medicines is 16,165 events during their practice lifetimes.'[32] The types of adverse events recorded dealt with:

Nutritional medicine – mild gastrointestinal symptoms (1023); headaches (434); severe gastrointestinal symptoms (150); serious adverse events included central nervous system effects (11); significant respiratory disturbances (8); renal toxicity (1) and one death. Fourteen of these adverse events were considered serious enough to require a referral to medical practitioner or hospital.[33]

Herbal medicine – the most common adverse events for this modality reported were mild gastrointestinal symptoms (1952); headaches (870); menstrual irregularities (322); significant skin reactions (307) and severe gastrointestinal symptoms (296); serious adverse events included central nervous system effects (17); hepatotoxity (9) and significant respiratory disturbances (9). 82 of these adverse events required a referral to a medical practitioner or a hospital.[34]

The survey suggested that 33% of practitioners reported their adverse events to third parties though only 27% of the respondents were aware of the Australian adverse drug reaction reporting procedures.[35] Overall, the number of adverse events suggests that naturopathy, herbal

[26] New South Wales, *Health Care Complaints Commission Annual Report 2013-2014*, 117.
[27] New South Wales, *Health Care Complaints Commission Annual Report 2014-2015,* 112.
[28] Ibid
[29] A Bensoussan, SP Myers, SM Wu and K O'Connor, Naturopathic and Western Herbal Medicine practice in Australia – a workforce survey, (2004) 12 *Complementary Therapies in Medicine*, 17-27.
[30] Ibid 22
[31] Ibid 19
[32] Ibid 22
[33] Ibid 22
[34] Ibid 22
[35] Ibid 23

medicine practitioners and nutritional medicine practitioners will need to deal with a significant number of adverse events (some serious) in their practice.[36]

The authors of the study analysed the results of this study and (excluding mild gastrointestinal symptoms) suggested that a herbalist will have 1.1 adverse events per year of full time practice, .0020 adverse events per consultation and 500 consultations per adverse event.[37] Naturopaths were said to have 1.2 adverse events per full time practice and .0025 adverse events per consultation and 400 consultations per adverse event. The authors exclude mild gastrointestinal symptoms to focus 'on potentially more serious adverse reactions that may be distinctly associated with naturopathic or herbal medicine practice.'[38] The authors conclude 'The risks and the adequacy of the regulatory arrangements to protect public health and safety warrant review in terms of the needs for statutory occupational regulation. The minimisation of risks should be a priority of the herbal and naturopathic professional working with government policy makers.'[39]

The Bensoussan study provides good evidence from the perspective of naturopathy, herbal medicine and nutritional medicine practitioners. The value of the data from this study is enhanced by the further data obtained by a separate workforce study involving a survey of general practitioners discussed in the La Trobe report. In this study general practitioners were asked to report adverse events associated with complementary medicine generally, interactions with complementary medicine and orthodox medicine and events such as withdrawal from conventional treatment or delay of diagnosis involving the intervention of a complementary medicine practitioner.[40] The general practitioners were asked to identify over the comparatively short period of the previous four weeks adverse events they had encountered involving complementary medicine or a complementary medicine practitioner. Responses were received from 402 doctors who noted that there were 1,548 adverse events over that period. The authors have suggested caution about this data owing to the difficulty in remembering after the event which may result in an underestimation of adverse events and may involve an assumption of causality. Of the modalities quoted, herbal medicine (15.6%) and naturopathy (13.2%) were the leading modalities in this research data. The highest level of serious adverse events related to herbal medicine (4.1%) and naturopathy (3.6%) just below chiropractic (4.7%). Herbal medicine was considered to have resulted in 72 adverse events, 82 interaction issues, 39 withdrawals from treatment, 48 delays in diagnosis with a total of 241 of adverse events.[41] Naturopathy was seen as involved in 33 adverse events, 34 interaction issues, 67 withdrawals from treatment, 71 delays in diagnosis totalling 205 adverse events.[42] As the GP's reported that they saw 121 patients per week, this is suggestive of one adverse event for every 125 patient consultations or one adverse event per week.

The La Trobe report noted only naturopathy, chiropractic, herbal medicine, massage, and acupuncture featured in medical practitioner handwritten comments in relation to serious cases. GPs generally considered the harm caused by CAM was primarily related more to the scope of practice, that is, the broad range of clients and conditions treated and a lack of recognition of the limitations to practice. [43] This was seen as contributing to incorrect, inadequate, or delayed diagnoses rather than to the specific risks of the therapies themselves. The GPs considered

[36] Ibid
[37] Ibid 24
[38] Ibid
[39] Ibid 26
[40] La Trobe report above n 6, 50-52.
[41] Ibid 51
[42] Ibid
[43] La Trobe report above n 6, 51-52; refer also to Jon Wardle and Jon Adams, 'Naturopaths: Their Role in Primary Health Care Delivery' in, (eds): Jon Adams, Parker Magin, Alex Broom , *Primary Health Care and Complementary and Integrative Medicine: Practice and Research*, Chapter 4, Imperial College Press, (2013) pp.73-92, 73,76.

naturopathy and WHM offered an alternative health service to that offered by GPs and were accordingly primary care practitioners. As a result they saw patients with the full spectrum of health complaints potentially including serious illnesses. As primary care practitioners, these practitioners are necessarily involved with diagnosis and subsequent treatment.[44]

Some of the comments from the GP respondents relate to the following matters:[45]

Naturopathy

'Death from superficial melanoma treated by naturopath
Naturopath delayed conventional breast cancer treatment for nine months—now inoperable
Woman with widespread breast cancer metastases had ineffective naturopathy and herbal treatment instead
Wrong diagnosis by naturopath
Inappropriate investigations suggested by naturopath
Allergic reaction from naturopathy
Serious allergic skin reaction from naturopathy
Two cases of detox reaction by naturopath using homoeopathy
Severe cystic acne as a result of diet manipulation by naturopath

Herbal Medicine

Herbal interactions with contraceptive pill
Aplastic anaemia after taking kelp tablets
Serious interaction between Ginkgo and aspirin/NSAID causing iron deficiency
Anaemia and angina requiring hospital admission and transfusion
Two near-fatal reactions to St John's Wort in combination with Ginkgo reported to ADRAC
Serious interaction between St John's Wort and Warfarin

General Comments

Many serious reactions due to complementary therapies too difficult to remember
Many delayed or incorrect diagnoses due to complementary therapies
Many patients do not tell doctors what complementary medications they are taking
Some doctors requested a database of interactions between herbal and traditional medicines
Some doctors suggested that profit motive overrides clinical judgment in complementary therapies.'

Risks associated with practice[46]

All healthcare involves risks from decisions made by the practitioner involving clinical judgment which can involve both risks of omission or commission. The La Trobe report suggests that, although these studies indicate there are cases of adverse events related to both commission and omission, this does not appear to represent widespread malpractice. The most significant type of complaint by clients to professional associations related to communication problems rather than with the health practice itself.[47] In regard to the adverse events from use of herbal medicine and use of nutritional supplements it is difficult to determine whether these adverse events were caused by negligence by the practitioner (such as inappropriate prescribing) or were the result of adverse reactions to the substance itself. Primarily the reports by GPs of severe adverse reactions, were more related to the scope of practice applied with a lack of understanding or

[44] La Trobe report above n 6, 52.
[45] La Trobe report above n 6, 52.
[46] Ibid 53
[47] Ibid

recognition of the limitations of their practice, contributing to incorrect, inadequate, or delayed diagnoses rather than to the specific risks of the therapies themselves. The La Trobe report suggested that there was a '*prima facie*, risk associated with a workforce of clinicians who consult directly with patients who present with a full range of health conditions' and 'whose principal tools of trade involve ingestible medicines'.[48]

Risks associated with the consumption of herbal and nutritional medicines[49]

Herbal and nutritional medicines can produce unexpected reactions in people including direct toxicity, overdose toxicity, and toxicity associated with interaction with pharmaceuticals. Also possible are idiosyncratic, allergic and anaphylactic reactions to herbal medications. Some herbs have well known potential for causing toxic reactions only some of which are restricted by current legislation while a number of less toxic substances are available for practitioners to prescribe. Risks can arise related to the inappropriate handling or manufacture of herbal and nutritional medicines especially in the context of the permissible supply, sale and manufacturing of herbal substances for some Nat/WHM/NM practitioners under the exemptions from the manufacturing, listing and registration provisions of the *Therapeutic Goods Act 1994* discussed below. To date, few examples of injury caused by these practices exist in Australia or overseas. Numerous examples of injurious interactions between pharmaceutical drugs and herbal and nutritional medicines have been documented though the level of this risk is unknown.[50]

Implications of the risk profile for Nat/WHM/NM [51]

The number of adverse events associated with WHMs and nutritional medicines recorded in Australia is significant including matters such as severe gastrointestinal symptoms, palpitations and hepatotoxicity. 'The workforce survey data suggests that practitioners will experience one serious adverse event every 11 months of full time practice and 2.3 adverse events for every 1,000 consultations (excluding mild gastrointestinal effects).'[52] Although one third of practitioners reported that they notify adverse events, these reports were generally made to the manufacturer or supplier of the product, rather than reporting adverse events to the TGA Adverse Drug Reaction Reporting System (ADRS). Although the ADRS database does refer specifically to complementary medicine the reporting system appears not to be widely used by unregistered practitioners.[53] Nearly half of the 22 categorised complaints from patients acknowledged by Nat/WHM/NM professional associations related to poor communication by practitioners which seems to be a more significant problem than adverse events from the commission of treatment which reflects in only five of the 22 complaints.[54] The La Trobe report suggests this pattern of complaints is likely to represent significant under-reporting requiring an educational response for Nat/WHM/NM educators. One unpublished thesis suggested that the reported incidences of adverse reactions for CAM will rise significantly when greater clarity for reporting is understood.[55] ANTA maintains a Natural Therapy Adverse Events Register.[56]

[48] Ibid
[49] Ibid
[50] Ibid
[51] La Trobe report above n 6, 54-55.
[52] Ibid 54
[53] https://www.tga.gov.au/report-side-effect-medicine.
[54] La Trobe report above n 6, 54.
[55] Wardle, 'Why run a risk agenda for CAM regulation?', (2008) 20 *Australian Journal of Medical Herbalism* 136, 137 from G Moses, *Increasing the Frequency, quality and breadth of adverse drug reaction reporting by consumers and health profession,* Doctorate of Clinical Pharmacy, School of Pharmacy, Brisbane, University of Queensland (2005).
[56] Refer to Schedule C below p 58.

The degree of risk to public health and safety established in regard to the use of Nat/WHM/NM requires serious consideration about the need for more effective occupational regulation focussed on minimisation of risks.

Nat/WHM/NM Workforce

The La Trobe report provided some clarity about the parameters of the workforce based upon a questionnaire for which there were 432 respondents. A total of 76.1% of practitioners suggested that they practiced under more than one area of practice supporting the view that there is overlapping in the modalities practiced 'with naturopaths including herbal medicine in their practice up to 44% of the time and herbalists regularly practising both homoeopathy and nutritional medicine.'[57] This data suggested that the workforce was predominantly female with the intensity of practice very variable with the mean number of hours per week being 24, which is suggestive of 22 consultations per week.[58] If a calculation is made across the Naturopathy and WHM workforce in Australia that suggests nearly two million consultations in 2003 involving costs of $85 million dollars. In terms of education, the level of education was from six months to six years with most having at least three years of education in herbal or naturopathic practice with some (11%) having other health related qualifications. Many (88%) were involved in continuing education.[59] More than half of the workforce belonged to two or more professional associations with a large number of professional associations being identified. [60]

Until recently, the minimum educational standard to commence practice in Nat/WHM/NM was at the level of Advanced Diploma under Health Training Package (HLT07). Since December 2015, the required educational standard for Nat/WHM/NM is a Bachelor degree subject to the teach-out period for existing students that ceases in December 2018. It should be noted that even when the AQF level 7 bachelor degree level of education impacts on the level of education of the Nat/WHM/NM workforce this will not stop practice in Nat/WHM/NM by an uneducated or virtually uneducated practitioner. Although an untrained person might have difficulty in attaining membership with most professional associations; there would be difficulty in gaining access to health fund rebates and professional indemnity insurance, these matters would not make the practice of Nat/WHM/NM impossible unless the practitioner falls foul of the negative licensing regime under NSW, Qld or South Australia[61] (or eventually the national scheme in due course) so as to be subject to criminal charges and or a prohibition order.

The ability of some undereducated Nat/WHM/NM practitioners to provide treatment is a somewhat alarming circumstance, as there are clear risks associated with the treatment modalities used as outlined above. In addition, the range of herbal and nutritional medicines in use continues to expand. Most Nat/WHM/NM practitioners are involved in primary care of people and necessarily participate in the diagnosis and treatment of health problems. The scope of practice of all Nat/WHM/NM and particularly naturopathy is broad and overlapping dealing with a wide range of health problems. Nat/WHM/NM practitioners do not have access to a range of diagnostic tools of orthodox medicine and need to understand when it is appropriate to refer to orthodox medicine. Another major risk of Nat/WHM/NM is the risk of misdiagnosis with the danger of this being greater if clinical training hours are inadequate and there is inadequate

[57] La Trobe report above n 6, 99.
[58] Ibid 115
[59] Ibid 116
[60] Ibid 116
[61] New South Wales and later South Australia enacting a Code of Conduct for Unregistered Health Practitioners. Queensland and Victoria are the first states to enact the national code under the *Healthcare Ombudsman Act 2013* (Qld) and in Victoria under the *Health Complaints Act 2016* (Vic) Schedule 2.

exposure to a range of health conditions, settings and demographics. This is better dealt with under the new degree standard for education of practitioners involving greater quality and volume of learning though the position of educationally non-compliant practitioners remains.

For people who use both Nat/WHM/NM and orthodox medicine, there are risks associated with interactions between and misunderstandings about the treatment modalities used and potential drug interactions between different health practitioners. This risk is exacerbated by a lack of communication regarding treatment among various providers and patients where 34% of clients consuming herbal medicine were concurrently taking pharmaceutical medications (excluding vitamin and mineral supplements).[62] This lack of communication can lead to a negative outcome for clients. The reticence to report to GPs their use of CAM was because the doctor might reject the therapy or because they felt that they should be in charge of their health. The lack of communication between consumers and practitioners is a particular cause for concern.[63]

Criterion 2, Conclusion

Based upon the level of demonstrated serious risk that applies for the practice of Nat/WHM/NM; the concerns about the current ability of under educated practitioners to practice relatively freely; the inability for consumers to readily ascertain which practitioner has the requisite education and training; and the fact that many Nat/WHM/NM practitioners practice as primary health practitioners is suggestive of the need to provide greater regulatory control over these professions.

Criterion 3:
Do existing regulatory or other mechanisms fail to address health and safety issues?

Once the particular health and safety issues have been identified, they are addressed through:

- other regulations, for example, risk due to skin penetration addressed via regulations governing skin penetration and/or the regulation of the use of certain equipment, or industrial awards;
- supervision by registered practitioners of a related occupation; and
- self-regulation by the occupation.

The health and safety risks of the provision of Nat/WHM/NM are documented above and include the reported adverse outcomes documented in **Schedule A.** These health and safety risks have resulted in some cases in very serious health outcomes. Current professional regulation of Nat/WHM/NM is primarily based upon self-regulation which is inadequate to deal with the risks of Nat/WHM/NM.[64] The regulation of Nat/WHM/NM involves both the application of general legislative provisions dealing with the activities of any health professional (such as the Australian Consumer Law) and some legislation which deals with more specific issues for Nat/WHM/NM such as the Therapeutic Goods legislation or other negative licensing provisions discussed below. The primary professional regulatory organs are professional associations which apply differing standards.

Regulation by Self-Regulation

[62] La Trobe report above n 6, 249.
[63] La Trobe report above n 6, 249.
[64] Ibid 295-296

Self-regulation has limited ability to apply minimum levels of entry to the professions through membership of a professional association applying requirements for education and training. The current regulatory framework is fragmented and lacks a level of coherence available through statutory regulation. There is little control on entry into the profession or practicing Nat/WHM/NM in Australia.[65] Even if a Nat/WHM/NM practitioner is not a member of a specific professional association because (a) the practitioner does not comply with required educational standards or (b) for financial reasons or (c) their membership is withdrawn after disciplinary action leading to expulsion, that person can either seek membership with another professional association or continue their practice with some limitations. A person stating that they are a Nat/WHM/NM practitioner or a former professional association member, deregistered health therapists such as chiropractors, osteopaths or TCM practitioners cannot be prevented from holding out they are Nat/WHM/NM practitioners.[66] This applies unless the practitioner acts in a manner that breaches consumer legislation such as indicating they have qualifications or membership they do not have resulting in a court order requiring cessation of that activity or the practitioner is subject to a prohibition order under a negative licensing regime. Many breaches may not be detected by regulators who are averse to commencing regulatory action except in cases of clear breaches.[67] This suggests that these practitioners cannot be effectively policed in the current self-regulatory setting.

Under self-regulation, professional associations normally establish standards of practice. Numerous professional associations represent Nat/WHM/NM practitioners each with its own standards of practice, minimum educational qualifications for entry and disciplinary procedures. This results in industry standards that are piecemeal and inconsistent and disciplinary procedures that lack transparency and consistency.[68] Smaller professional associations have resisted amalgamation into larger professional associations to allow an orderly movement to professional status. This has resulted in a plethora of inconsistent standards of practice and education and a lack of expertise in developing a transparent, consistent, rigorous and fair mechanism for complaints and investigation with appropriate avenues of appeal. The size of some professional associations means the complaint processes may not be properly funded.[69] Market pressures to attract membership by professional associations may result in lower standards and differences in standards and may have been a reason for splits from within professional associations exacerbating differentiation in standards.[70] Further, internal divisions within the professions tend to exacerbate these issues.[71]

It is worthwhile to consider some of the legislative provisions which specifically or generally regulate Nat/WHM/NM in Australia. The current legislative framework that exists in Australia as it applies to the practice of Nat/WHM/NM, is deficient. This regulatory structure as outlined below provides regulation for therapeutic goods, consumer legislation, health complaints and negative licensing. The integrity of this regulatory structure relies to a great extent on the professional standards of the Nat/WHM/NM practitioners who are required to satisfy these legislative standards. This standard currently also relies upon the quality of the professional

[65] Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 28.
[66] J Wardle, A Steel and J Adams, 'A Review of Tensions and Risks in Naturopathic Education and Training in Australia: A Need for Regulation,' (2012) 18 (4) *The Journal of Alternative and Complementary Medicine* 363, 364.
[67] https://www.tga.gov.au/regulatory-compliance-framework
[68] Wardle, above n 67, 364; Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 17.
[69] Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 54.
[70] Wardle, above n 67, 364, 365.
[71] Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 54.

standards required by professional associations which varies not only in the content of those standards but also in the preparedness and capacity to enforce those standards. For many Nat/WHM/NM practitioners this legislative responsibility is justified and accepted but the capacity to control level of education, training and probity of practitioners must be doubted without a more a formal process of regulation.

Therapeutic Goods

Specific provision is made for the regulation of complementary medicines in Australia. Complementary medicines including those used by Nat/WHM/NM which involve ingestive substances and therapeutic devices are regulated in Australia by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1994* and regulations.[72] The intention of this legislation is to create a national scheme, though because of constitutional limitations, this does not apply to Queensland and Western Australia other than when an activity involves the activities of a corporation related to trade and commerce or transactions across State or national borders or in relation to providing pharmaceutical or repatriation benefits.[73] State legislation adopting the *Therapeutic Goods Act* in the other states plugs the gaps in the scheme for things done *within* a State. To date, only Queensland and Western Australia have not passed legislation that applies the provisions of the Commonwealth legislation at the State level.

The limited constitutional power of the Commonwealth does to some extent impact on the effectiveness of the legislation. For example, a practitioner who prescribes a herb in Queensland or Western Australia is not affected by the *Therapeutic Goods Act 1994* and regulations if the transaction has no international or interstate aspect,[74] which would not commonly apply to most transactions of a herbalist in those jurisdictions. For practitioners within the territories, New South Wales, Victoria, South Australia and Tasmania, the *Therapeutic Goods Act 1994* and regulations and mirror state and territory legislation will apply to all of those activities.[75] The TGA applies a risk-based approach with a two-tiered system for the regulation of all medicines, including complementary medicines:[76]

- Lower risk medicines can be listed on the Australian Register of Therapeutic Goods (ARTG) which will include most ingestive substances provided by Nat/WHM/NM.
- Higher risk medicines must be registered on the ARTG which may include some substances provided by Nat/WHM/NM.

Some complementary medicines are exempt from the requirement to be included on the ARTG. The Australian Regulatory Guidelines for Complementary Medicines (ARGCM) provides detail on the regulation of complementary medicines. Nat/WHM/NM practitioners are able to take advantage of the substantial exemptions from many provisions of the TGA. TGA regulation Schedule 5 exempts from registration and listing some medicines that are dispensed or extemporaneously compounded for a particular person for therapeutic application to that person.[77] In regard to the normal obligation to have a licence to manufacture therapeutic goods, Schedule 8 of the TGA regulations exempts herbalists, nutritionists, naturopaths, practitioners of Traditional Chinese Medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation, where:[78]

- the preparation is for use in the course of his or her business, and

[72] https://www.tga.gov.au/overview-regulation-complementary-medicines-australia
[73] Weir, *Law and Ethics in Complementary Medicine,* (4th edition, Allen and Unwin, 2011), 154-155.
[74] Ibid 154
[75] Ibid 153
[76] Ibid 156,157
[77] Ibid 158,159
[78] Ibid 160, 161

- the preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public; and
- the person carrying on the business supplies the preparation for administration to a particular person after consulting with that person and uses his or her own judgement as to the treatment required.

Accordingly, within the parameters of this exemption, there is no obligation on a practitioner to comply with the requirements of Part 3-3 of the TGA, which requires the obtaining of a licence to manufacture therapeutic goods. These persons may or may not have a substantial level of training or education to professionally and safely perform these services. The basis of this legislation is the risk-based assessment of the quality of Nat/WHM/NM practitioners which relies upon the self-regulation discussed above. The extent to which this self-regulation is not effective in the provision of well credentialed practitioners impacts on the safety of the provision of therapeutic goods to consumers.

TGA post market regulatory activity of complementary medicines
The TGA undertake regulatory activities post market relating to monitoring of safety, quality and efficacy of listed, registered and included therapeutic goods.[79] The TGA also audits manufacturers to ensure compliance with good manufacturing practice. The advertising of complementary medicines including those used by Nat/WHM/NM is regulated by the Therapeutic Goods Advertising Code (TGAC) and the supporting regulations, the consumer legislation and other relevant laws to ensure that marketing promotes the use of the product is socially responsible and does not mislead or deceive the consumer. There is evidence that the funding for this auditing and oversight role is limited, as the TGA has a full cost recovery approach to this role leading to a desire to focus on low cost options suggesting a substantial reliance on the training, education and professional approach of unregulated Nat/WHM/NM practitioners.[80]

Consumer Legislation

Like any business, Nat/WHM/NM practitioners in Australia are subject to consumer legislation that imposes obligations on the practitioner as to how goods and services are advertised and supplied. The most important statutes are the *Sale of Goods Act* (SGA) (almost identical provisions in all States)[81] and the Commonwealth *Competition and Consumer Act 2010* (CCA) (similar provisions applicable in all States).[82]

The CCA includes the Australian Consumer Law (ACL), which applies across all jurisdictions in Australia. Many Nat/WHM/NM practitioners sell goods such as, herbal mixtures or herbs, vitamins and oils. These sales are also subject to the SGA legislation in each state. The SGA deals with transactions relating to 'goods' on matters such as how a contract of sale is formed, implied warranties as to quality and undertaking as to title when title to the goods passes and how the performance of the contract should occur. Goods are defined to include most items and substances sold by practitioners.

Misleading or deceptive behaviour
The ACL provides that:[83] 'A person shall not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.' This is a very broad provision that

[79] The Auditor – General Audit Report no 3 2010-2012, *Performance Audit, Therapeutic Goods Regulation: Complementary Medicine*, Australian National Audit Office, 107.
[80] Ibid 115
[81] Weir above n 74, 173,175.
[82] Ibid 175-179
[83] Ibid 176, *Australian Consumer Law* s 18.

covers many specific circumstances dealt with under other sections. A breach of this provision might include exaggerated claims of the effect of services, such as miracle slimming techniques where the claims are not verifiable. Another example is unjustified claims made about the curative effects of certain herbal substances sold by practitioners.

Unconscionable conduct

A person is obliged not to take advantage of a vulnerable client.[84] This is fundamental to appropriate professional practice and is reflected in the ACL provision that 'a supplier shall not, in trade or commerce, in connection with the supply or possible supply of goods or services to a person ("the customer"), engage in conduct that is, in all the circumstances, unconscionable'. The provision describes examples of unconscionable conduct such as the use of unequal bargaining power or where undue influence or unfair tactics were used in connection with the supply of goods or services. Liability might arise if a client under a disability, such as inexperience or limited English or understanding, was convinced to undertake a course of treatment or to purchase goods in circumstances where the practitioner used his or her position as a health professional to unfairly influence this transaction.

False representations

Goods and services should be marketed fairly without misrepresentation.[85] The ACL provides that a person shall not, in trade or commerce in connection with the supply or possible supply of goods or services or in connection with the promotion by any means of the supply or use of goods or services, make representations such as:

- falsely representing that goods are of a particular standard, quality, value, grade, composition, style or model or have had a particular history or particular previous use;
- falsely representing that services are of a particular standard, quality, value or grade;
- falsely representing that goods or services have sponsorship, approval, performance characteristics, accessories, uses or benefits they do not have; and
- making a false or misleading representation concerning the need for any goods or services.

In New South Wales, s 99 of the *Public Health Act 2010* penalises the promotion or advertisement of health services (this includes complementary medicine) which is false, misleading or deceptive, or likely to be misleading or deceptive. In addition, this provision penalises promotion or advertisement of health services that creates an unjustified expectation of beneficial treatment.

The limitations of this form of regulation is that financial injury might arise for a consumer from dealing with a practitioner who unbeknownst to the consumer is acting in a misleading or deceptive manner or any physical injury occurs before the breach of consumer legislation is established. Although a remedy for a breach of these provisions may be available through the relevant regulator the Australian Competition and Consumer (ACCC) or other state consumer bodies obtaining that remedy will be time consuming and perhaps expensive for consumers. It has been suggested that 'while consumer protection regulators have successfully prosecuted in some cases, results are mixed and relying on consumer protection legislation to deal with repeated and wilful unethical conduct of unregistered health practitioners may be insufficient to protect public health and safety.'[86]

[84] Ibid, *Australian Consumer Law* s 20.
[85] Ibid 177, *Australian Consumer Law* s 29.
[86] Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 52.

Health Complaints

Health Complaints Commissioners in Australia's States and Territories can receive complaints about the professional conduct of Nat/WHM/NM practitioners.[87] This legislation focuses on investigation, conciliation and the resolution of disputes.[88] The avenues for disciplinary action against unregistered practitioners are few, particularly if practitioners are not receptive to conciliation. The ability to enforce standards of treatment under this legislation is limited because there are no sanctions available for unregistered professions unless there are grounds for referral to the police for criminal matters or by civil litigation. The embarrassment and inconvenience of a complaint made against a practitioner may not always be sufficient to improve their performance. In New South Wales and South Australia, a complaint may result in unregistered and registered health practitioners (in a matter not relevant to their registration) being subject to a prohibition order or interim prohibition order. Refer to below. The proposed National Code of Conduct for Unregistered Health Practitioners based generally on the New South Wales model now enacted by Queensland and Victoria will provide similar enforcement powers to deal with unethical practices by unregistered practitioners across Australia.[89]

GST

Section 38.10 of the *A New Tax System (Goods and Services Tax) Act 1999* confirms that the supply of health services for chiropractic, osteopathy, acupuncture, naturopathy or herbal medicine (including Traditional Chinese Herbal Medicine) is GST free if: the supplier is a recognised professional in relation to the supply of services of that kind and the supply would generally be accepted, in the profession associated with supplying services of that kind, as being necessary for the appropriate treatment of the recipient of the supply.

A 'recognised professional' is a professional who has permission, approval or registered status under state or territory legislation, or is a member of a professional association with uniform national registration requirements in relation to the supply of services of that kind. A number of major professional associations have been acknowledged by the Australian Taxation Office as providing appropriate uniform national registration requirements so as to deem their members 'recognised professionals'.

The supply of goods associated with the supply of the exempt professional services may also be exempt from GST for chiropractic, osteopathy and acupuncture if the supply is made at the premises at which the service is supplied (the clinic). This would presumably include the supply of acupuncture needles, vitamins and supplements. For herbal medicine, including TCM and naturopathy, the supply of goods such as medicine or herbs is GST free if the goods are supplied in the course of supplying the services and if they are supplied and used or consumed at the premises. This legislation has most likely supported the advantages of membership in an association with national registration standards but it does not deal with the fact that these professional associations, as even those with a national footprint do not have the same level of educational standards.[90] Each professional association is obliged to ensure that only suitably qualified people gain practitioner status to comply with the exemption.[91]

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[87] *Health Care Complaints Act 1993* (NSW); *Health Complaints Act 2016* (Vic.); *Health Ombudsman Act 2013* (Qld); *Health and Disability Services (Complaints) Act 1995* (WA); *Health Complaints Act 1995* (Tas); *Health and Community Services Complaints Act 2004* (SA); *Human Rights Commission Act 2005* (ACT); *Health and Community Services Complaints Act 1998* (NT).

[88] *Health Complaints Act 2016* (Vic) s154*, Healthcare Ombudsman Act 2013* (Qld) s 288 and Regulation 5.

[89] COAG, *Final Report: A National Code of Conduct for Health Care workers* (17 April 2015).

[90] La Trobe report above n 6, 208.

[91] La Trobe report above n 6, 257.

Negative Licensing

Concern has been expressed in Australia with regard to the activities of some unregistered health professionals, including formerly registered health professionals who now practise in related fields after being suspended or deregistered. The discipline and enforcement provisions available under registration statutes are not available to stop some unfair, unethical, criminal and dangerous practices by a small proportion of unregistered health practitioners.[92] This gap in the legislation and a number of concerning cases of unethical and dangerous acts by unregistered health practitioners led to New South Wales and later South Australia enacting a Code of Conduct for unregistered health practitioners to regulate the activities of those health workers giving powers to grant prohibition orders against their activities.[93]

These Codes of Conduct are a form of 'negative licensing' which means there are limited controls on entry into the industry but they provide a power to prohibit a person to practice in some practice areas or prohibit practice entirely based upon a breach of the relevant code. A review of this issue by the Australian Health Ministers Advisory Council culminated in a decision by the COAG Health Council in April 2015 for a code of conduct for health workers (similar but not the same) as the New South Wales example to be enacted in all jurisdictions in Australia.[94] The implementation of this process may take some time to unfold. When fully realised this process will mean that regulation similar to the New South Wales model will apply across Australia. This regulation will include the significant remedies to apply interim or permanent prohibition orders against the practices of unregistered practitioners who are in breach of the Code of Conduct. Queensland has already enacted the National Code of Conduct for Health Care Workers (Queensland) reflecting the national model under Regulation 5 of *the Health Ombudsman Regulation 2014* as has Victoria under the *Health Complaints Act 2016* (Vic) Schedule 2. The use of this form of regulation is welcome but it provides retrospective regulation that applies only after negative outcomes have arisen and does not provide proactive prior statutory regulation of the quality of training, education and probity of Nat/WHM/NM practitioners.

[92] Wardle, above n 56, 138.

[93] http://www.health.nsw.gov.au/phact/Documents/Code_of_Conduct_unregistered_health_practitioners_-_poster_-_2012_Regulation.pdf

[94] Refer to the COAG, *Final Report: A National Code of Conduct for Health Care workers* (17 April 2015) in relation to the details of this proposed National Code of Conduct.

http://www.coaghealthcouncil.gov.au/Announcements/ArtMID/527/ArticleID/54/Final-Report-A-National Code-of-Conduct-for-health-care-workers)

Fragmented Regulatory Framework

The practice of Nat/WHM/NM is framed by a myriad of incoherent complex and confusing legislation and regulations at both State and Federal levels. These legislative and regulatory measures are based upon different policy imperatives which are significant in their own right such as the Therapeutic Goods regulation or health care complaints but it is not easy to point to clear regulatory structure for the practice of Nat/WHM/NM.

The La Trobe report suggests 'The present model—a mixture of self-regulation and statutory requirements—does not serve the public, the profession, or the industry well.[95] Under The *A New Tax System (Goods and Services) Act 1999* naturopaths, acupuncturists, and herbal medicine practitioners who are members of recognised professional associations can provide GST-free services. This is a powerful incentive for practitioners to obtain GST free status for their practice by joining a recognised association. The failure of this legislation is that the membership of professional associations is based upon the varying practice standards created by the different associations. The standards are inconsistent with one another and do not need to have regard to standards set by other bodies. The legislative scheme does not require professional associations to have matters such as specified standards of practice, a complaints mechanism, infection control guidelines, or requirements for education and qualification for practitioners. Rather they are only required to have "national standards". Many professional associations have established appropriate standards in such areas, but they are not consistent and may lack the degree of professionalism required to achieve the desired outcome of public protection. There has been a failure to determine and require national standards amongst professional associations. The result is confusion for both practitioners and the public.[96] In reality the TGA and GST exemptions are not aimed at a coherent regulatory structure but focus on the need to deal with taxation and risks in the provision of therapeutic goods. It does not provide a whole of profession coherent answer to the need for public protection. Statutory regulation would still require a role for Nat/WHM/NM professional associations in representing practitioners, supporting them in misconduct matters and the provision of advice and representing members in dealings with government but their role will focus on representing practitioners rather than being involved in difficult to achieve standard professional educational standards and discipline which would then be the province of a statutory regulator.

Consideration of overseas regulatory models such as that applying in the USA and Canada enacted after careful consideration, in the face of orthodox medicine opposition suggests some points that may be relevant to Australian policy development.[97] The protection of the consumers is best attained through the development of a register of practitioners, based upon specified standards of practitioner probity and professional practice, education and training. This will assist in prospectively avoiding adverse outcomes, but if they occur, to provide a statutory mechanism for investigating allegations of unprofessional conduct to provide a response to ensure the practitioner does not repeat that behaviour and to provide lessons that can be applied generally in the regulatory structure. This is what currently applies under the National Law in Australia for health professions subject to statutory regulation.

[95] La Trobe report, above n 6, 296.
[96] Ibid
[97] Refer to discussion below pp 32.

Criterion 4:
Is regulation practical to implement for the occupation in question?

When considering whether regulation of the occupation is possible, the following needs to be considered:

- is the occupation well defined;
- does the occupation have a body of knowledge that can form the basis of its standards of practice;
- is this body of knowledge, with the skills and abilities necessary to apply the knowledge, teachable and testable;
- where applicable, have functional competencies been defined; and
- do the members of the occupation require core and government accredited qualifications?

WHM is well established throughout Western history and can be readily understood to be the practice of herbal medicine from the traditions of Britain, Europe and North America.[98] Herbal medicine practised in the Chinese medicine tradition is already regulated under the IGA. WHM is one of the modalities used by naturopaths and these professions have overlapping identities and modalities. Naturopathy is an established body of knowledge and the boundaries of its practice are well defined, but because no barriers to entry exist, naturopaths can practice any modality and still use the title. Naturopathic modalities are also practiced as single modalities by other practitioners, WHM practitioners, homoeopaths, massage therapists, nutritionists and lifestyle counsellors. Nutritional medicine is a more recently established health profession but the new requirement for a degree standard for education will provide an underpinning to professionalisation of this profession through the required mapping of higher degrees attributes required for this degree.

Level and Nature of Education of Nat/WHM/NM

Education for Nat/WHM/NM has been offered at tertiary level for many years in Australia. There was a broad professional agreement on core competencies and curriculum requirements through the adoption of the National Health Training Package (the minimum requirements set by the Vocational Education and Training sector) which had the support of professional associations. The Complementary & Alternative Health (CAH) aspects of HLT07 relevant to Nat/WHM/NM were:

HLT60512 Advanced Diploma of Naturopathy
HLT60112 Advanced Diploma of Western Herbal Medicine
HLT61012 Advanced Diploma of Nutritional Medicine

It is significant that in 2015 the next stage of the maturation of the professionalisation has arisen for Nat/WHM/NM as a bachelor degree level previously offered by a number of university and private education providers is now the required educational standard for practitioners subject to the teach-out period that ceases in December 2018. There had been criticism of the standard of education of the advanced diploma as it focussed on VET standards and skill-based competencies as against the degree standard of higher education with a focus on critical analysis and independent thinking.[99]

[98] http://www.who.int/medicines/areas/traditional/definitions/en/
[99] Wardle, above n 67, 364.

The La Trobe report found that in 2003 there were 47 naturopathy and WHM education providers in Australia involving 104 undergraduate and postgraduate courses.[100] At that time the level of education was 47% advanced diploma, 16% bachelor degree, 15 % diploma and certificates and 13% postgraduate awards. The first bachelor degree in naturopathy commenced in 1995 at Southern Cross University though this course been discontinued in recent years. In 2003 the market was predominantly privately owned 15 colleges (52%), four TAFE (14%) and 10 universities (34%). It was estimated at that time that 3500 students were enrolled in naturopathy and WHM.[101] The La Trobe report suggested that there was concern about the need to clarify minimal education standards and for education standards to be set by an independent body.[102] It has been noted that:

'The level of education in naturopathy and WHM is evolving, but the absence of a common standard for the preparation of practitioners contributes to lack of recognition by mainstream institutions. Debate is required to reach agreement on minimum standards for naturopathy and WHM education programs, but attempts to improve educational standards are unlikely to succeed without the support of a regulatory system that can mandate minimum education requirements.'[103]

The La Trobe report suggested that courses in both naturopathy and WHM reflected a range from 2 years to 4.5 years with course contact hours (bachelor degrees and advanced diplomas combined) for naturopathy were 2265 and for WHM were 1693.[104] The content focussed on science ranged from 300 hours to 930 hours in naturopathy and from 507 hours to 923 hours in WHM with clinical experience ranging from 198 hours to 800 hours in naturopathy and 100 hours to 272 hours in WHM. 97% of courses in this study were government or university accredited.

Concern was expressed about aspects of curricula in regard to the level of time spent on matters such as: clinical practice; pharmacology and interactions among herbs, nutrients, and drugs; communication, counselling, ethics, and legal issues; critical thinking and analysis; basic research methods, literature reviews, and the role of evidence-based practice in holistic healthcare; manufacture of herbal products for extemporaneous prescribing; sociology of health and healthcare; core modalities of naturopathy and WHM; variety of forms of assessment; and input from education specialists to ensure that forms of assessment match desired outcomes with respect to subjects, courses, and graduate attributes.[105]

The upgrade in the minimum required levels of education for Nat/WHM/NM would deal with many of these concerns. Advanced Diploma qualifications for the above modalities are now in teach-out phase and students enrolled in these advanced diplomas have until December 2018 to complete these courses. Students have not been able to enrol in Advanced Diplomas of Naturopathy, Nutrition and WHM since December 2015 when the advanced diplomas ceased. As a result of advanced diplomas ceasing the new minimum educational standard for Naturopathy, Nutrition and WHM will become bachelor degree level. Since December 2015 people wanting to enrol in these modalities can now only enrol in bachelor degree programs.[106]

[100] La Trobe report above n 6, 144.
[101] Ibid
[102] Ibid 146
[103] Ibid 147
[104] ibid 144-145; Wardle, above n 56, 138.
[105] Ibid 145
[106] http://www.cshisc.com.au/develop/industry-qualifications-training-packages/qualifications-under-review/complementary-alternative-health/

The move to bachelor degree programs has seen a rationalisation of course providers. Several course providers who delivered advanced diplomas programs have decided not to deliver bachelor degree programs probably because of the cost involved in setting up bachelor degrees, the higher standards expected of that form of education and because of stricter Tertiary Education Quality and Standards Agency (TEQSA)[107] audit and quality control over colleges who deliver them. Australian Skills Quality Authority (ASQA), which is the VET sector regulator previously governed audits and quality control over advanced diplomas at a less stringent level. The move to bachelor degree programs has been supported by most associations except for ATMS (refer to discussion below).

Currently in Australia the provision of the now standard minimum level degree standard education (for four and three years) for Nat/WHM/NM includes as follows:

Naturopathy

Bachelor of Health Science (Naturopathy)

Endeavour College of Natural Health - four years full time
Paramount College of Natural Medicine - three years full time
Southern School of Natural Therapies - four years full time
Australasian College of Natural Therapies (ACNT) - four years full time

Western Herbal Medicine

Bachelor of Health Science (Western Herbal Medicine)

Paramount College of Natural Medicine - three years full time
Southern School of Natural Therapies - three years full time
Australasian College of Natural Therapies (ACNT) - four years full time

Nutritional Medicine

Bachelor of Health Science (Nutritional and Dietetic Medicine)

Endeavour College of Natural Health - three years full time
Queensland University of Technology (QUT) – four years full time

Bachelor of Health Science (Nutritional Medicine)

Paramount College of Natural Medicine - three years full time
Southern School of Natural Therapies - three years full time
Australasian College of Natural Therapies (ACNT) - four years full time
Charles Sturt University, Bachelor of Health Science (Food and Nutrition) - (six years part time distance)
Victoria University, Bachelor of Science – Nutrition Food and Health Science - three years full time

Bachelor of Human Nutrition

University of Canberra - three years full time
La Trobe University - three years full time

[107] TEQSA is the HE statutory regulator under the discussed in more detail below. http://www.teqsa.gov.au/.

The significance of the movement to a bachelor degree as the fundamental educational standard is significant as this will now mean that educational institutions will become subject to the stricter regulation requirements of TEQSA rather than ASQA especially in the case of non-self-accrediting institutions[108] which is 'a higher education provider that does not have responsibility for accrediting its own qualifications'. Most private colleges fall into that category.

The movement towards requiring bachelor degree as the minimum educational standard derived from a review of the qualifications for CAM under the 'Complementary & Alternative Health Alignment of Qualifications to the Australian Qualifications Framework Discussion Paper'.[109] This was initiated by the Community Services & Health Industry Skills Council (CS&HISC). At the time the All Complementary & Alternative Health (CAH) qualifications in the Health Training Package (HLT07) were under review.

Industry Reference Groups comprising representatives from all CAH modalities oversaw this work, with a smaller Subject Matter Expert Group (SMEG) for each modality. Issues arose about the appropriate alignment of CAH qualifications to the Australian Qualifications Framework (AQF) and whether for CAH the required minimum educational level should be adjusted to a bachelor degree level. The advanced diploma was the required educational level for Aromatic Medicine, Ayurveda, Homoeopathy, Naturopathy, Nutritional Medicine and Western Herbal Medicine.

The paper suggested:[110]

'This paper has been developed based on a range of discussion and comments, including:

- the need for substantial additional and more clearly articulated anatomy, physiology, pathophysiology and pharmacology content – especially in the advanced diploma qualifications (with some impact on Certificate IV and diploma qualifications also)
- questions around what the actual difference is between advanced diploma and bachelor degree
- the amount of learning required to achieve the qualification outcomes (e.g. views that advanced diploma outcomes not able to be achieved in less than 3 years for some modalities)
- tacit acknowledgment and / or open discussion that a degree level qualification either is, should be, or will be in the near future, the qualification required to practice.'

The paper then mapped the learning outcomes required by AQF levels for advanced diploma and bachelor degree and the knowledge and skills needs of practitioners in CAH. It was noted that issues such as professional practice; accountability for own learning and volume of learning for degree at three years were significant requirements for the bachelor degree level.[111]

The paper then asked for feedback on the issue of whether the educational level should now be at the bachelor level for CAH. After receiving feedback, in November 2014 by a unanimous recommendation of the Training Package Advisory Committee and the CS&HISC Board it was decided to remove the Advanced Diplomas of Homoeopathy, Naturopathy, Nutritional Medicine

[108] Australian Qualifications Framework Council, *Australian Qualifications Framework*, (Second Edition January 2013) p100.
[109] Community Services & Health Industry Skills Council, *Complementary & Alternative Health Alignment of Qualifications to the Australian Qualifications Framework* Discussion Paper: October, 2013.
[110] Ibid p 4
[111] Ibid pp 6-10

and Western Herbal Medicine from the Health Training Package in December 2015 with no extension.[112] This change in educational standard is significant as the clear intention was to focus the educational outcomes and training on the issue of professional practice, greater focus on anatomy, physiology, pathophysiology and pharmacology, increased volume of learning and with initiative and judgment in planning, problem solving and decision making in professional practice and/or scholarship and working in an independent professional practice context.[113]

Practitioners are currently not obliged to upgrade to bachelor degree level qualifications but over time this professional transition will to a large measure occur based upon a number of factors. For example, current members of ANTA and most likely other professional associations with only the advanced diploma qualification who have continuous membership and comply with health fund provider requirements will continue as members and as providers with health funds.[114] It is expected that the health funds will be updating educational requirements for naturopathy, western herbal medicine, homoeopathy and nutrition to bachelor level so this change will directly impact on new entries into the profession and practitioners who were former members of a professional association and seek renewed membership or after a gap in health fund accreditation.[115]

Significance of adoption of bachelor level educational standard

A useful discussion is provided by Australian Natural Therapists Association Ltd[116] in regard to the different educational standards that will apply under the newly introduced bachelor degree standard as against the standard specified under the Advanced Diploma, the differences are clear based upon the AQF specifications.[117]

Under the Advanced Diploma (AQF Level 6) the expectations of graduate outcomes are:

'Knowledge: Graduates at this level will have broad theoretical and technical knowledge of a specific area or a broad field of work and learning.

Skills: Graduates at this level will have a broad range of cognitive, technical and communication skills to select and apply methods and technologies to:

- analyse information to complete a range of activities
- interpret and transmit solutions to unpredictable and sometimes complex problems
- transmit information and skills to others

Application of knowledge and skills: Graduates at this level will apply knowledge and skills demonstrating autonomy, judgment and defined and defined responsibility:

- In contexts that are subject to change
- Within broad parameters to provide specialist advice and functions'

[112] http://www.cshisc.com.au/develop/industry-qualifications-training-packages/qualifications-under-review/complementary-alternative-health/
[113] Community Services & Health Industry Skills Council, above n 5, 6-10.
[114] Brian Coleman, 'Executive Officer Report' *March* (2016) 31 *The Natural Therapist* 5.
[115] Ibid 12
[116] ANTA, Submission to Community Services & Health Industry Skills Council on Complementary & Alternative Health Alignment of Qualifications to the Australian Qualifications Framework 26th November 2013 pp 4-6
[117] Australian Qualifications Framework (second edition January 2013) 41, 42.

Under the Bachelor Degree (AQF Level 7) the expectations of graduate outcomes are:[118]

'Knowledge: Graduates at this level will have broad and coherent theoretical and technical knowledge with depth in one or more disciplines or areas of practice.

Skills: Graduates at this level will have well-developed cognitive, technical and communication skills to select and apply methods and technologies to:

- Analyse and evaluate information to complete a range of activities
- Analyse, generate and transmit solutions to unpredictable and sometimes complex problems
- Transmit knowledge, skills and ideas to others

Application of Knowledge and Skills: Graduates at this level will apply knowledge and skills to demonstrate autonomy, well developed judgement and responsibility:

- in contexts that require self-directed work and learning
- within broad parameters to provide specialist advice and functions'

The ANTA submission suggests that:[119]

'as many natural therapists are increasingly regarded and utilised by the public as primary health care service providers, there is a growing requirement for practitioners to act as independent professionals or specialists and demonstrate in depth theoretical and technical knowledge as well as critical thinking, assessment and diagnosis skills.

The Advance Diploma AQF Level 6 qualifications has served the natural therapy profession well for a significant period of time, however, in order to achieve continuous quality improvement and meet public expectations, ANTA supports the alignment of natural therapy qualifications to bachelor degree AQF Level 7.'

A comparison of the key information outlined above in relation to advanced diploma and bachelor degree qualifications suggests that industry and also public expectations are more aligned with bachelor degree knowledge and skills requirements.[120]

'Public and industry expectations now require natural therapy practitioners to:[121]

- have skills to exercise critical thinking and problem solving
- have skills to critically review and analyse information and knowledge
- have the knowledge and ability to act independently
- be able to adapt knowledge and skills in diverse contexts

The above attributes are typically found in bachelor degree programs.'

[118] Ibid, 47, 48.
[119] ANTA submission, above n 117, 6,
[120] Ibid
[121] Ibid

Higher Education Regulation

As the basic level of education for Nat/WHM/NM will now be in the higher education space, the regulator of the educators and the quality of courses will be TEQSA which is Australia's independent national regulator of the higher education sector. TEQSA is an independent statutory agency.[122]

TEQSA indicates that its role and impact on the higher education is based upon the need to:[123]

'safeguard the interests of all current and future students studying within Australia's higher education system. It does this by regulating and assuring the quality of Australia's higher education providers. TEQSA is responsible for the registration and re-registration of providers and the accreditation and re-accreditation of courses'.

TEQSA's regulatory approach is standards and risk-based. It is guided by three regulatory principles - regulatory necessity, reflecting risk and proportionate regulation, when exercising its powers.

Standards based regulation:[124]

- 'provider entry to and continued operations within Australia's higher education sector are determined by demonstrated compliance with the Higher Education Standards Framework (Threshold Standards)
- the standards are developed and promulgated independently of TEQSA by the Higher Education Standards Panel
- the standards apply to all providers, offering courses leading to a regulated higher education award, irrespective of where and how a course is delivered
- while all providers must demonstrate adherence to the Threshold Standards, TEQSA assesses these in the context of each provider's circumstances
- the standards are applied flexibly and with regard to the diversity of teaching methods and delivery modes that exist and are emerging within the sector. The standards are not intended, or applied, to limit higher achievement'.

Education providers offering a bachelor degree will need to satisfy the Higher Education Standards Framework (Threshold Standards) including the profession specific obligations in relation to Learning Outcomes and Assessment clause 1.4 (set out in **Schedule B** to this submission) including knowledge and skills that characterise the field of education or disciplines involved, knowledge and skills required for employment; skills in independent and critical thinking suitable for life-long learning.

[122] http://www.teqsa.gov.au/
[123] http://www.teqsa.gov.au/regulatory-approach
[124] http://www.teqsa.gov.au/regulatory-approach

Risk-based Regulation

'TEQSA's risk-based approach ensures that resources are directed to areas of higher risk based on validated, quality intelligence about a provider. Key aspects of this approach include the Higher Education Standards Framework, the Case Manager model, the Agency's Regulatory Risk Framework, the use of experts and engagement with professional bodies.'[125]

This means that any higher education providers of Nat/WHM/NM are subject to TEQSA oversight and the standards required by all higher education providers. In the case of universities which are self-accrediting institutions their regulation is more light touch while in the case of non-university institutions such as private colleges, these are generally non self-accrediting institutions which are subject to greater scrutiny by TESQA including reviewing and approving courses and programs, applying performance conditions to approvals during a specified accreditation period which may relate the specific degrees or courses.[126] In regard to higher education providers for Nat/WHM/NM the heightened supervision by TEQSA against the training for industry approach of ASQA will mean that that their activities will be monitored for quality and educational outcomes at a higher standard of professional practice.

Research

The provision of Nat/WHM/NM has a well-developed and rapidly burgeoning body of knowledge that can form the basis of its standards of practice. This is reflected in the amount of funded Nat/WHM/NM research currently being undertaken by the higher education sector in Australia. Funding for research into CAM including Nat/WHM/NM comes from both the government and private funding sources.[127] The National Health and Medical Research Council (NHMRC) prompted by reports about the use of treatments, including CAM, without an adequate evidence basis to treat chronic, or serious medical conditions has placed a greater focus on this issue.[128] The increasing interest by regulators in CAM is reflected in the inclusion in the 'NHMRC Strategic Plan 2010–2012, of 'examining alternative therapy claims' as a major health issue for consideration by the organisation, including the provision of research funding. In the current Strategic Plan 2013–2015, NHMRC has broadened its focus to investigate the general issue of 'Claiming benefits for human health not based on evidence'.'

'With regard to CAM, NHMRC is undertaking a number of activities that align with its commitment outlined in its Strategic Plan 2013–2015 with the aim of assisting Australians in making informed decisions about their health care. This includes consideration of the potential benefits and risks of each option using the available evidence. Current activities include:[129]

- Developing a resource for clinicians to facilitate discussion with patients regarding their use of CAM.
- Continuing to increase knowledge through the funding of investigator-driven research on CAM through NHMRC's competitive, peer-reviewed grant application processes.
- Reviewing the effectiveness of a range of CAM using established methods for identifying and assessing evidence.'

[125] http://www.teqsa.gov.au/regulatory-approach
[126] http://www.teqsa.gov.au/regulatory-approach/teqsa-and-quality-assurance
[127] http://theconversation.com/industry-has-a-role-in-funding-alternative-medicine-research-23418
[128] https://www.nhmrc.gov.au/health-topics/complementary-medicines
[129] https://www.nhmrc.gov.au/health-topics/complementary-medicines

NHMRC, under the guidance of the Health Care Committee, has developed a resource for clinicians to facilitate discussion with patients regarding their use of CAM.

A notable research institute in Australia on issues relevant to Nat/WHM/NM is The National Institute of Complementary Medicine at Western Sydney University.[130] The Institute's website indicates it is active in clinical trials, publications, provision of scholarships, international collaborations and continuing professional development. The Institute has benefited from millions of dollars of research funding from industry and benefactors.[131]

In 2014, La Trobe University entered into Memorandum of Understanding with Swisse Wellness. Chief Executive Officer Radek Sali has confirmed that the company will be the founding partner, contributing $15 million over six years towards the commissioned research activities and establishment of the La Trobe Complementary Medicine Evidence Centre (CMEC).[132]

Another significant research centre involved in research in regard to CAM which includes Nat/WHM/NM is the Australian Research Centre in Complementary and Integrative Medicine (ARCCIM) at the Faculty of Health, University of Technology, Sydney.[133]

ARCCIM states:

'it is the world-leading critical public health research centre focusing on complementary and integrative health care. The scientific investigation of complementary and integrative medicine is paramount when addressing contemporary health systems and global health challenges. At ARCCIM, we believe this requires a synergy of critical perspectives, genuine collaboration and a commitment to produce meaningful insights.'

ARCCIM suggests it has been involved in the following research achievements:[134]

- '$11 million in external competitive grant funding, including 18 grants funded by the National Health and Medical Research Council and Australian Research Council
- 5 prestigious government-funded (NHMRC and ARC) Research Fellowships
- $3.5 million in industry/community partnership funding
- authoring 700+ peer-reviewed publications, including 11 research books with prestigious international publishing houses
- the largest concentration of PhD students focused upon complementary and integrative health care in Australia.'

ARCCIM is the first centre worldwide dedicated to conducting and promoting critical CAM research via a wide range of established methods and perspectives from public health and health services research.

There has been criticism of the lack of research outputs from private colleges.[135] One study it suggested there was dominance by public universities in CAM related research outputs and a lack of commitment to building research capacity with a drop off in research by researchers after commencing teaching at a private college.[136] The Endeavour College of Natural Health has in

[130] http://www.nicm.edu.au/

[131] http://www.westernsydney.edu.au/newscentre/news_centre/research_success_stories/leading_national_complementary_medicine_agency_to_receive_significant_funding

[132] http://www.La Trobe.edu.au/news/articles/2014/release/complementary-medicine-partnership

[133] http://www.uts.edu.au/research-and-teaching/our-research/arccim/about-centre/vision-and-mission

[134] Ibid

[135] J Wardle, above n 67, 366, 367.

[136] J Wardle, above n 67, 364.

the last two years established an Office of Research including a research committee, a research ethics committee and has funded internally and externally research projects on Nat/WHM/NM and has commenced a collaborative partnership with the ARCCIM. [137] Some major professional associations provide funding or access to participants for research projects by researchers as part of their day-to-day function.[138]

ANTA provides to its members free access to scientific resources including ESBCO Host, eMIMS, IMgateway and iTherapeutics.[139]

Institutional Recognition

Private Health Funds

The increasing popularity of Nat/WHM/NM has resulted in responses from many government and private sector organisations including health insurance, professional indemnity insurers, ATO, higher education and NHMRC. Many health insurance companies provide rebates on health practitioner fees for Nat/WHM/NM. Based upon the ANTA website[140] which regularly provides an update of health insurance rebates the following health insurers provide rebates for the provision of Nat/WHM/NM modalities namely:

Nutrition – Australian Health Management, Australian Unity, CBHS Health Fund, GMF Health, GU Health, HBF, HCF, Medibank Private, NIB

Naturopathy – 36 Health Funds

Western Herbal Medicine – 24 Health Funds

This indicates a broad acceptance of the role of Nat/WHM/NM in the provision of health care in Australia. In the absence of registration status for Nat/WHM/NM it is necessary for the health funds to provide a process to establish the credentials of Nat/WHM/NM practitioners to ensure they are appropriately qualified. Under the *Private Health Insurance (Accreditation) Rules 2011* there are specific requirements before a health practitioner can offer a rebate to clients for their services under the private health insurance policy based upon the terms of each policy. Treatment provided by complementary medicine practitioners is only eligible for coverage by private health insurance if the practitioner is duly registered such as applies to chiropractic, osteopathy and Chinese Medicine for the treatment contemplated by that registration. For other unregistered complementary medicine practitioners to be eligible for private health rebates they must be a member of a national professional association which assesses the training and education qualifications of members; the professional association must conduct a compulsory professional development scheme for members; it must have an enforced code of conduct and a formal disciplinary procedure to suspend or expel members and an appropriate complaints procedure.[141] In addition, any State or Territory premises legislative requirements must be satisfied.[142]

[137] http://www.endeavour.edu.au/research/office-of-research

[138] ANTA http://www.australiannaturaltherapistsassociation.com.au/resources/ebscohost.php. Refer to Schedule C page 62, 64.

[139] http://www.australiannaturaltherapistsassociation.com.au/resources/ebscoho Refer to Schedule C pp 55.

[140] http://www.australiannaturaltherapistsassociation.com.au/resources/healthfundlist.php

[141] *Private Health Insurance (Accreditation) Rules 2011* clause 10.

[142] Ibid clause 11.

Most private health insurers have additional requirements before recognising a complementary medicine practitioner as eligible for the health fund rebate for clients. These requirements normally relate to having suitable professional indemnity insurance, requirements about keeping good records, demonstrated participation in continuing professional education, the ability to lodge information electronically and the practitioner having a current first aid certificate. Not all health insurance companies cover complementary medicine and those that do cover these services do not cover all modalities. This suggests that as the access to health insurance rebates is a significant financial issue for practitioners that the control over access to health rebates applied by health funds is an aspect of the regulatory control over the practice of Nat/WHM/NM.[143] No doubt the move to bachelor degree status will result in a review of the required educational standards for eligibility for health rebates after a period of grand parenting. It is still possible to practice and hold out as a Nat/WHM/NM practitioner without access to health fund rebates.

Worker Compensation Insurance

There is limited access to the benefits provided by Work Cover for the provision of Nat/WHM/NM in some jurisdictions normally focussed on the potential for the provision of remedial physical therapies. Nat/WHM/NM is not specifically mentioned in workers compensation legislation though in South Australia there is provision for treatment by remedial physical therapies.[144]

Professional Indemnity Insurance

A number of insurance providers provide professional indemnity insurance for Nat/WHM/NM practitioners. It is possible for individual practitioners to approach a professional indemnity insurance company individually but most major professional associations have a negotiated indemnity arrangement with an insurance company which accepts the standard of education and training required for membership of the professional association as sufficient for acceptance of the practitioner. All major professional associations require professional indemnity insurance as a condition of membership. Some of the professional indemnity insurance companies are:

Therapy Sure[145]

Arthur J Gallagher[146]

BizCover[147]

Fenton Green[148]

If there was a national standard for education this would likely reduce the time necessary for underwriters to be satisfied about the quality of education of practitioners.[149]

[143] The details of the educational and training requirements for accreditation for health funds is outlined: http://www.atms.com.au/visageimages/Health%20Funds/Provider%20Status%20Eligibility%20Requirements%20and%20Application%20Form/ATMS%20Accredited%20Modalities%20%26%20Health%20Fund%20Requirements_Naturopathy_Nov%202015.pdfat:

[144] https://www.rtwsa.com/service-providers/supporting-recovery/non-medical

[145] http://www.therapysure.com/

[146] http://www.ajg.com.au/industries/natural-therapies-insurance

[147] http://www.bizcover.com.au/professional-indemnity/

[148] http://www.fentongreen.com.au/allied-health-practitioners.php

[149] La Trobe report, above n 6, 208.

Conclusion, Criterion 4

Nat/WHM/NM are defined professions, with understood modalities involving now a higher education level for normal acceptance into the profession. Many other institutions and bodies such as the ATO, health funds and professional indemnity insurers are prepared to regulate or endorse the practice of Nat/WHM/NM. This suggests that there is a secure basis to implement regulation. There are complexities in relation to naturopathy—because of the diversity of practices adopted by the profession and the fact that practitioners can specialise in some modalities while not practising others but this can be dealt with by the manner in which any regulatory system is designed. Although practitioners are currently permitted to access health fund rebates for the benefit of clients, professional indemnity insurance for their and their clients protection and GST discounts for lower costs to consumers the regulatory structure Nat/WHM/NM may be subject to change or exclusion as time proceeds. A much more solid basis for the continuation of high quality Nat/WHM/NM and the protection of consumers is through statutory regulation.

Criterion 5:
Is regulation practical to implement for the occupation in question?

When considering whether regulation of the occupation is practical the following should be considered:

- are self-regulation and/or other alternatives to registration practical to implement in relation to the occupation in question;
- does the occupational leadership tend to favour the public interest over occupation self-interest;
- is there a likelihood that members of the occupation will be organised and seek compliance with regulation from their members;
- are there sufficient numbers in the occupation and are those people willing to contribute to the costs of statutory regulation;
- is there an issue of cost recovery in regulation; and
- do all State Governments agree with the proposal for regulation.

Size of Nat/WHM/NM profession

There are many Nat/WHM/NM practitioners in Australia (in excess of 10,000) according to one source.[150] As indicated above, CAM practitioners provide a significant part of the provision of health care in Australia. Generally (though not all) Nat/WHM/NM practitioners and their professional associations favour statutory regulation. ANTA, founded in 1955 is the largest national democratic association of 'recognised professional' traditional medicine and natural therapy practitioners (including a large percentage of Nat/WHM/NM practitioners) who work in the areas of health care and preventive medicine. The full profile of ANTA is found at **Schedule C** of this submission.

[150] Above n 19, 3.

Professional Associations

Most professional associations favour statutory registration for Nat/WHM/NM. The ANPA,[151] Complementary Medicines Australia,[152] and ANTA strongly support statutory registration.[153] By contrast Australian Traditional Medicine Society (ATMS) does not support statutory regulation.[154] It is stated on its website that:

'ATMS adopted the self-regulation model, later to become the Co-Regulation model. This was opposed to the Statutory Registration model that was sought by TCM. It was felt this model was not appropriate for the occupations that fall under the umbrella of natural medicine. Regulation of the occupations has always been a major point of difference between ANTA, NHAA and ATMS, the former supporting statutory registration, ATMS never wavering from the opposite view.'[155]

International Models of Regulation

Practitioners of naturopathy are recognised and regulated in many other jurisdictions notably in various states of the United States including Alaska, Arizona, California, Colorado, Connecticut, District of Columbia, Hawaii, Kansas, Maine, Maryland, Minnesota, Montana, New Hampshire, North Dakota, Oregon, Utah, Vermont, Washington; and United States Territories: Puerto Rico and Virgin Islands.[156]

In Canada, five provinces register naturopaths namely Ontario, British Columbia, Manitoba, Saskatchewan, and Alberta.[157]

Chinese Medicine (including Chinese herbal medicine and acupuncture) has been successfully regulated in Victoria since 2000 and now nationally since 2011 under the National Law (which is the legislation created pursuant to the IGA for a national registration scheme for a number of health professionals including Chinese Medicine incorporating a national registration board for each regulated health profession) under the auspices of the Chinese Medicine Board of Australia. These examples demonstrate the practicality of implementing occupational regulation for CAM generally and Nat/WHM/NM specifically.

Chinese Medicine Model in Australia

For Chinese Medicine, protected titles under the National Law are Chinese medicine practitioner, Chinese herbal dispenser, Chinese herbal medicine practitioner, Oriental medicine practitioner, and acupuncturist. For the Chinese Medicine Registration Board of Victoria and now under the national board, there have been practical challenges in the normal issues involved in professionalisation. These include the limits of 'grand parenting' practitioners who may seek to obtain registration based on clinical experience; setting the appropriate standards for education including learning outcomes; educating the profession, private health funds, and the public about the role of the board. In addition, it is necessary to align standards for practice with other registration boards to ensure this regulation deals with national standards of practice and

[151] http://www.anpa.asn.au/images/stories/anpa-ahmac-submission-april-2011.pdf .
[152] http://cma.asn.au/about-cma/aims-of-cma/; http://www.cmaustralia.org.au/Registration-of-Practitioners
[153] http://www.nhaa.org.au/ Refer to ANTA profile Schedule C below, 61.
[154] http://www.atms.com.au/
[155] http://www.atms.com.au/page.php?id=26
[156] American Association of Naturopathic Physicians http://www.naturopathic.org/content.asp?contentid=57 (accessed 1 May 2016)
[157] Wardle, above n 43, 84-85; Canadian Association of Naturopathic Doctors https://www.cand.ca/Professional_Affiliations.professional.0.html (accessed 1 May 2016)

the costs of regulation in terms of the impact on practitioner and governmental costs of regulation.[158]

It is likely that similar practical issues will emerge for Nat/WHM/NM should statutory regulation be undertaken, but the problems are not insurmountable. It is likely the number of Nat/WHM/NM potential registrants could be expected to be higher than for Chinese Medicine. This may reduce the cost to government of regulation and for practitioners based upon the greater numbers of practitioner providing registration fees. In addition, some of the cost of dealing with the evidence of training and education from overseas institutions in a foreign language as well as the difficulties of cultural fit may be less problematic.

The major practical issue is the question of how to define the professions. It is clear that each of Nat/WHM/NM are definable practices and a definable profession but in terms of what Nat/WHM/NM practitioners do on a daily basis is more difficult as it includes an eclectic range of practices some of which might be considered 'risky' (involving ingestive substances) and 'non-risky' (massage or dietary advise). Herbal medicine is, however, a core practice for naturopaths and nutritional medicine is a second core practice. Another practical difficulty occurs due to the multiplicity of titles used by practitioners.[159] At present, Nat/WHM/NM practitioners in the context of where there are no protected titles any practitioner even one with limited training and education can use generic professional titles (such as natural therapist) or in terms of the individual modalities that they offer. If titles do become protected for Nat/WHM/NM, a designated generic and/or specific title will need to be determined. These protected titles might conflict with some of the titles currently being used by practitioners who may be unable to become registered for reasons of lack of education or clinical experience. This will also impact on education providers, professional associations, private health funds, and taxation authorities (under the GST exemption legislation). Although this is an issue, it was dealt under the regulation of Chinese Medicine and will no doubt result in a rationalisation of the marketplace for some non-registered practitioners. Any registration board for Nat/WHM/NM will need to make informed, responsible and evidenced based decisions about what titles should be restricted focussing on the public interest which is the primary focus of this regulation.[160]

The La Trobe reports suggests many CAM practitioners use the title 'naturopath' when applying modalities such as herbal medicine, nutritional medicine, homoeopathy, tactile therapies, and lifestyle counselling.[161] Currently practitioners can use the title of 'naturopath' if they are one or several of these modalities. If a statutory restricted title protection was established for WHM practitioners only, naturopaths practising herbal medicine may avoid this statutory mechanism. If a statutory restricted title 'naturopath' only was applied this would mean that naturopaths using modalities such as nutritional medicine and homoeopathy would be forced to choose between registration and not using the title. Depending on the restricted title applied by statute some practitioners might attempt to adopt other related terms such as 'natural therapist', 'complementary therapist', 'homoeopath', 'clinical nutritionist', and 'nutritional medicine.' Some practitioners might be refused registration (or not seek registration) on the basis they do not comply with educational and training requirements. These might continue to practise under alternative titles—including the potentially confusing title of 'natural therapist' if that is not a restricted title.[162]

[158] La Trobe report above n 6, 299-302.
[159] Ibid 301
[160] Ibid
[161] Ibid
[162] Ibid

Summary of Level of support for or against Occupational Regulation:

Concerns have been expressed no doubt by practitioners who were wary that 'statutory regulation would result in the 'medicalisation' of naturopathy including '(i) subordination to medical doctors; (ii) the effect on practice of a highly regulated environment; (iii) increased patient volume; (iv) less time with patients; (v) less individualised care; and (vi) violation of practice philosophy and stronger regulation is likely to introduce a degree of standardisation.'[163]

The La Trobe report suggested support for statutory registration from a number of stakeholders based upon:[164]

- consumer focus group responses.
- The GP survey participants from the La Trobe report suggested support for government regulation of herbal medicine and naturopathy, most likely to deal with the perceived risk of injury caused by limitations on practitioner education and training.
- The majority of naturopaths and WHM practitioners generally having a positive view of government regulation and support for greater regulation of their profession.

These conclusions are consistent with circumstances that now apply in Australia based upon recent data and is reflective of the development in the research strength in universities in developing a research basis for the provision of Nat/WHM/NM, the significant profession wide support for the bachelor degree level of education and an expressed desire from many professional associations and other practitioner bodies to protect the well-being of clients through statutory regulation discussed above.

Criterion 6:
Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?[165]

Benefits:

- The move to statutory regulation would permit by statute under the National Law access to an objective transparent and accountable system for managing complaints and professional misconduct (including access to an appeals process) which will involve community and practitioner representatives with statutory backing for determinations made including fines, conditions of practice, further education, suspension and exclusion primarily focussed on public interest considerations.[166]

- As is revealed by the GP survey discussed in the La Trobe report, a major issue appears to be a lack of preparedness to refer to orthodox medicine.[167] The use of statutory regulation is likely to result in improved quality and safety in healthcare as a result of better

[163] La Trobe report, above n 6, 301; Jon Wardle, 'The National Registration and Accreditation Scheme: what would inclusion mean for naturopathy and Western Herbal Medicine', (2010) 22 (4) *Australian Journal of Medical Herbalism* 113, 114.
[164] La Trobe report, ibid.
[165] La Trobe report, above 6, 303.
[166] For example under *Health Practitioner Regulation National Law Act 2009* (Qld) ss 155, 191 and 196
[167] La Trobe report above n 6, 7, 303.

communication and referral among qualified practitioners including orthodox medicine practitioners who will both share the status of being registered health practitioners.[168]

- The greater level of scrutiny by a well-resourced regulatory body and the role of AHPRA is likely to result in better information and protection for consumers.

- The qualification for registration will require the imposition of improved and consistent standards of education which will include policies, guidelines and requirements provided by the relevant registration board which will result in better quality assurance processes and foster greater research in the modality for the benefit of consumer safety.[169]

- Better assurance for insurers and employers of appropriate standards of training of practitioners leading to better public safety outcomes.

- The use of registration of Nat/WHM/NM will tend to support community confidence in the professions and enhanced status for practitioners.[170]

- Statutory regulation will support the process of integrating complementary and alternative healthcare practices into the health system.

- Statutory regulation will result in increased collaborations between public hospitals, universities and government institutions and private sector heath providers, educators and professional associations in the health and education sectors.

- Statutory regulation will result in decreased administrative burden for funds and insurers as the standards of training and education will be clarified and standardised with efficiencies that may lead to lower costs for funds and insurers.[171]

- Statutorily enforced compulsory professional indemnity insurance will protect patients from the financial consequences of negligent practice when injuries occur.[172]

Negative Impacts

Many of these potential negative impacts are natural consequences of limiting registration to only those practitioners who comply with registration standards.

- The potential increase in fees for practitioners (including registration costs and in addition membership of professional associations) may mean higher fees charged to consumers.[173]

- Increased restrictions to entry to practice of the profession which may result in a lessening of competition in the marketplace which may result in higher fees.[174]

- Statutory regulation may increase costs for some educational institutions to upgrade courses which may result in higher fees for students.[175]

[168] Ibid 13
[169] Ibid
[170] Ibid 303
[171] Ibid
[172] Ibid
[173] Ibid
[174] Ibid
[175] Ibid

- Statutory regulation may result in a loss (or diminution) of income for practitioners precluded from registration who are not able to use grand parenting provisions.[176]

- Statutory regulation may in due course mean loss of GST-free status for non-registrants.[177]

- Statutory regulation may require practitioners to fund what may be required to upgrade qualifications to achieve registration.[178]

- Statutory regulation may result in loss of market share or closure for educational institutions unable to upgrade to meet higher standards.[179]

The benefits of promoting public safety clearly outweigh the potential negative impacts of occupational regulation.[180]

Overall assessment against IGA Criteria

The data above dealing with the extent of involvement of CAM in the health sector shows that the use of CAM is widespread.[181] This submission concludes that:[182]

- the regulation of Nat/WHM/NM is within the appropriate responsibility of health ministers;

- evidence suggests some Nat/WHM/NM practices pose a significant risk of harm and the risks are compounded by the primary healthcare context and the broad scope of practice;

- existing regulatory mechanisms are inadequate for safeguarding and protecting consumers of Nat/WHM/NM;

- there are definable modalities within Nat/WHM/NM such that it is possible to implement a form of statutory regulation as discussed in this submission;

- there will be some practical challenges for statutory regulation, but lessons can be drawn from overseas experience and the Victorian and national statutory regulation of Chinese Medicine in Australia; and

- the benefits of protecting public safety through statutory regulation does outweigh the potential negative impacts.

Options for Regulatory Models

There may be six general models for the regulation of the health workforce:[183]

[176] Ibid
[177] Ibid
[178] Ibid
[179] Ibid
[180] La Trobe report, above n 6, 302.
[181] Charlie C Xue et al, 'Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey' [2007] (July-August) 13 (6) *Journal of Alternative and Complementary Medicine* 643, 643; Jon Wardle et al, above n 16, 199.
[182] La Trobe report, above n 6, 304.
[183] Ibid 304

- Self-regulation –membership of a professional association could provide evidence that the practitioner has suitable qualifications, is safe to practise and is subject to a disciplinary scheme to deal with unethical or unprofessional practice.

- Negative licensing – a practitioner may enter and practise a self-regulated profession unless the practitioner is shown to have breached the provisions of a code of conduct making the practitioner ineligible or limited in their ability to practise by order of the regulator.

- Co-regulation – members of a professional association are regulated by an association with government involvement.

- Reservation of title only – a statutory registration board registers members of a profession and reserves the use of restricted titles for registrants only.

- Reservation of title and core practices – certain procedures considered to be high risk normally applied in the practice of a profession are by statute restricted to registrants and other specified registered health professions.

- Reservation of title and whole practice restriction – this model restricts the use of restricted titles, within the defined scope of practice of a profession, and prohibits non registrants from practising the profession.

Self-Regulation[184]

The model of *self-regulation* assumes that the industry normally through professional association membership has appropriate mechanisms and financial capacity to monitor and discipline members of the profession. Nat/WHM/NM is self-regulated at present though the level of regulation is limited. Although the acceptance that the minimal educational standard allowing entry into the profession will now be at bachelor degree level even this substantial upgrade of this standard will be to some extent stymied by the continuation of professional associations which have wide variations in educational levels among practitioners based upon historical circumstances. This situation will not change for many years as the grand parenting of these new standards will take many years to fully impact on the market meanwhile allowing practitioners to practice with some of the TGA exemptions and health fund rebates though that will become more difficult as time goes on as the transition to a bachelor degree standard profession continues.

[184] Ibid

Co-Regulation

Co-regulation, a form of government monitored self-regulation, has been proposed by some professional associations within the sector in particular ATMS. Under such a model, there would be governmental oversight of mechanisms and procedures.[185] This would most likely require the government either to monitor numerous bodies or facilitate the establishment of a single regulatory authority separate from professional associations. This may become an intrusive process and could involve high transaction costs which may be borne by taxpayers.[186]

Negative Licensing

The La Trobe report[187] 'found no evidence that *negative licensing* has been applied in Australia in relation to regulation of the professions. It would limit regulation to those identified as failing to meet certain standards of professional conduct or education. In this context, there have been instances of deregistered health practitioners continuing to practise, using the title of naturopathy or WHM. A system of negative licensing could offer protection to the community against such behaviour. This mechanism could co-exist with other forms of health practitioner regulation. However, issues of civil liberty do arise in any such system.'

Since the La Trobe report, there have been substantial initiatives in the form of regulation as discussed and culminating in the proposal for a National Code of Conduct for Health Care Workers. Queensland has already enacted the National Code of Conduct for Health Care Workers (Queensland) reflecting the national model under Regulation 5 of *the Health Ombudsman Regulation 2014* as has Victoria under the *Health Complaints Act 2016* (Vic) Schedule 2.

The Code is a form of negative licensing which:

'sits on a continuum of regulations between self-regulation and statutory regulations. It is more targeted, less restrictive and is a less costly form of regulation than statutory regulation, since it provides the regulatory tools to deal directly with those who behave illegally or in an incompetent, exploitative or predatory manner and, if necessary prohibit them from practicing. It leaves the vast majority of ethical and competent members of an unregistered health profession to self-regulate, but provides an additional level of public protection with respect to unregistered practitioners, at minimal cost to the community.'[188]

This form of regulation means that there are few limitations on persons entering the profession but if the activity of the practitioner is deemed to breach a code of conduct there is provision for conditions to be applied to that practitioner's practice or for a suspension or prohibition order in relation to their practice. This form of regulation does not impose substantial regulatory costs upon practitioners if they comply with the Code while allowing a disqualification for specified attributes, events or offences.[189] This allows the enforcement of a minimum standard of practice without the cost of a statutory registration board.[190] Those who are shown to not be fit to provide health services can be prevented from doing so. In this way rogue practitioners can be controlled

[185] Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 19.
[186] La Trobe report above n 6, 305
[187] Ibid
[188] Australian Health Ministers Advisory Council, Final Report, *Options for Regulation of Unregistered Health Practitioners*, April 2013, 24-25.
[189] Ibid
[190] Ibid, 31; Arie Freiburg, *The Tools of Regulation* (The Federation Press, 2010), 151.

without a substantial cost to the community.[191] From a regulatory perspective, one limitation of this type of regulation is that the regulation is reactive, not proactive, as the remedies will only be available when a breach of the code of conduct has occurred, which may mean that a negative outcome has already arisen**.**[192]

Statutory Regulation

The following models are all forms of statutory regulation

- Reservation of title only;
- Reservation of title and core practices;
- Reservation of title and whole practice restriction.

The focus under the National Law has been away from any regulation involving a whole of practice restriction and a reservation of title that was up until the 1990s the normal model for the regulation of health professions in Australia. Since the Competition Policy Review, the role of the state in regulating professions was questioned owing to its potential to create anti-competitive outcomes. Statutory regulation with reservation of title only was considered by the La Trobe report to be the most practical option for Nat/WHM/NM. Statutory regulation is a well-established model for health professions across Australia. The legislative frameworks and operational arrangements used in other health professions can be readily adapted and applied to Nat/WHM/NM —as has already been done in the case of Chinese Medicine. The current National Registration and Accreditation Scheme for the Health Professions (NRASHP) framework also represents a form of co-regulation in that it is a co-operative arrangement between government and profession. A Nat/WHM/NM board could be integrated with existing boards (for example, the Chinese Medicine Registration Board) to improve efficiency of operation and reduce the cost to government and registrants. The use of a reservation of title only would appear to be the most cost effective and appropriate form of statutory regulation for Nat/WHM/NM.

[191] Australian Health Ministers Advisory Council, ibid.

[192] Freiburg, above n 192, 150.

Conclusion and Recommendations

In considering the application of the IGA criteria for health workforce regulation to the current state of Nat/WHM/NM practice within Australia, it is concluded that a negative licensing model currently becoming a national Code of Conduct is a useful regulatory mechanism. It prevents those practitioners who engage in seriously unethical or illegal conduct from continuing to practice or practising without scrutiny but it does not protect from clearly unethical and untrained practitioners from entering the workforce. Statutory regulation is desirable and warranted for the following reasons:[193]

- there is a level of risk in naturopathy and Nat/WHM/NM comparable to other regulated professions;
- there is a particular risk related to interaction of herbal medicine and pharmaceutical drugs and the need for appropriate prescribing frameworks;
- existing regulatory frameworks are insufficient to protect against professional misconduct.

'It is actually the public who are extended the right to accessible naturopathic and western herbal medicine services and they also have the right to be assured that these practitioners are bound by minimum standards of practice and training, or be easily able to make an informed choice based on these factors. Regulation is about the patient, not the practitioner.'[194]

[193] La Trobe report, above n 6, 305.

[194] Jon Wardle, above n 18,113,114.

Schedule A

Date	Facts	Type of medicine	Location	Links and citations
2016	A Sydney naturopath will face court over the treatment plan she allegedly devised for a baby boy, who police say was malnourished and close to death when he was admitted to hospital. The eight-month-old boy was suffering from eczema when his mother consulted the naturopath in April for advice about alternative health treatments for her son, police said.	Naturopathy	Sydney, NSW	http://www.smh.com.au/nsw/naturopath-charged-after-baby-boy-near-death-admitted-to-sydney-hospital-20150709-gi8jlw.html
2016	Ian Pile, a non-registered health practitioner providing services as a medical herbalist, including ayurvedic medicine, iridology, nutrition, reflexology and sports/herbal medicine. Mr Pile advised a client with metastatic colorectal cancer that he could treat the cancer by cleansing her blood and she would be "cured in a couple of weeks". Provided the client with two capsules containing anti-cancer herbs with emetic properties during a home visit, the combined effects of which made her vomit shortly after ingestion. It was also found that Mr Pile provided capsules of his own cancer-treating and liver-detoxifying herbal formulas, with instructions to take 12 capsules a day. He did so without considering any adverse reactions with her orthodox cancer treatment. The client attended the emergency department with increasingly intense abdominal pain after almost a fortnight of this treatment regime. The investigation found that Mr Pile breached the Code of Conduct for Non-Registered Health Practitioners when he: • failed to provide health services in a safe and ethical manner; • failed to demonstrate a sound understanding of any adverse interactions between the therapies and treatments he provides or prescribes and any other medications or treatments, whether prescribed or not, that he is aware a client is taking or receiving; • held himself out as qualified, able or willing to cure cancer;	Herbal Medicine, Nutrition	Sydney, NSW	http://www.hccc.nsw.gov.au/Publications/Media-releases/2016/Ian-Pile Risks related directly to the consumption of nutritional and herbal medicines Act of commission – inappropriate therapy Act of omission – failure to refer

Date	Facts	Type of medicine	Location	Links and citations
	• failed to maintain accurate and contemporaneous clinical records; • failed to ensure that appropriate indemnity insurance arrangements were in place in relation to his practice. The Commission was satisfied that Ian Pile poses a risk to the health or safety of members of the public.			
2016	Matthew Whitby took a protein powder obtained online which contained green tea extract and a supplement with garcinia cambogia (tropical fruit used in weight loss). He suffered sudden liver failure and needed an emergency liver transplant. Doctors considers it was the green tea extract, and less likely but still possible the garcinia cambogia, that caused it. [Note: this is an example of a case where the herbal medicine was not prescribed. However, it was endorsed by a number of alternative therapists].	Herbal Medicine	Perth, WA	https://www.mja.com.au/journal/2016/204/1/fulminant-liver-failure-and-transplantation-after-use-dietary-supplements No mention of practitioners but evidence of need to have good regulation for those prescribing Risks related directly to the consumption of nutritional and herbal medicines
2016	Television report of a naturopath and formerly registered chiropractor and osteopath who sought to treat a person with a suspected cancer lesion on the side of his face with dietetics. The health practitioner, a Mr George Zaphir suggested that the client Ian Booth had an 85% chance of curing the lesion. Client died.	Naturopathy	Caboolture, Qld	http://aca.ninemsn.com.au/article/9104870/cancer-quack# Act of omission – failure to refer
2015	Eight month old boy admitted to hospital near death after naturopath prescribed a treatment that left him with severe malnutrition and developmental issues. The boy lived. The naturopath was charged with grievous bodily harm. It appears the trial has not been held yet.	Naturopathy	Sydney, NSW	http://www.theguardian.com/australia-news/2015/jul/09/sydney-naturopath-arrested-after-baby-comes-close-to-death-on-treatment-plan Good discussion of need to regulate naturopaths Act of commission – inappropriate therapy
2014	A man had a hole burned into the side of his head after applying 'black salve', a herbal remedy containing bloodroot and zinc chloride, which is said to cure cancer, for a period of approximately 4 months. [Note: Complaints have been made to the Therapeutic Goods Association about Adrian Jones, a	Naturopathy, Herbal Medicine	Brisbane, QLD	http://www.smh.com.au/national/skin-cancer-warning-over-bogus-black-salve-treatment-20140410-36epv.html It is reported in the Medical Journal of Australia, April 2014

Date	Facts	Type of medicine	Location	Links and citations
	naturopath's support for black salve (which the TGA has warned against). TGA ordered Jones to publish a retraction of his endorsement. See the explanation of his website: http://www.adrianjonesnaturopath.com/retraction-explanation]			Act of commission – inappropriate therapy
2013	Robert Jarvis, a man previously deregistered by the Chiropractic and Osteopaths Tribunal and forbidden to practice naturopathy for 3 years, touched and spoke to a girl inappropriately at a meditation class. He was banned for life and put on a 2 year good behaviour bond, but allowed to keep performing administrative duties at the wellness centre where he worked.	Naturopathy	Wollongong, NSW	https://www.hccc.nsw.gov.au/Publications/Media-releases/2014/Mr-Robert-Jarvis---convicted-for-breach-of-prohibition-order http://www.abc.net.au/news/2014-10-24/naturopath-banned/5840304 Act of commission – inappropriate actions
2010	Robert Jarvis, a man previously deregistered by the Chiropractic and Osteopaths Tribunal for having sex with a patient and then practising as a naturopath, touched a female patient inappropriately and asked her inappropriate questions in the course of his work. He was forbidden to practice for 3 years. [See also other offences]	Naturopathy	Wollongong, NSW	http://www.hccc.nsw.gov.au/Publications/Media-Releases/-Public-Statement-in-relation-to-Mr-Robert-Jarvis- Act of commission – inappropriate actions
2008	A Cairns naturopath treated a man with a head injury as a result of falling off a horse. For six weeks she ineffectively treated the patient with a herbal poultice and dietary recommendations and failed to refer the patient even when the injury had progressed to a massive erosive lesion measuring 11x10 cm. At the behest of his wife, the patient finally sought medical treatment, where it was found that the lesion had eroded through the skull, soft tissue and down to the meninges of the brain.	Naturopathy	Cairns, Qld	Final Report: National Code of Conduct for Health Care Workers Appendix 2 page 79 Act of omission – failure to refer Mackinnon M. In general practice, 'always expect the unexpected'. Australian Family Physician 2008; 37: 235-6.
2008	Mrs Atkinson went to see Jeremiah Hunter, a naturopath, for her and her daughter's eczema and was as put on nine day detox diet while breastfeeding four children that left her 'thin' (though no medical evidence of serious harm). Hunter was charged under the Fair Trading Act. Judge ordered that the naturopath be permanently restrained from practicing any form of naturopathy,	Naturopathy	Manly, NSW	*Commissioner for Fair Trading, Department of Commerce v Hunter* [2008] NSWSC 277 (2 April 2008) – Act of commission – inappropriate therapy

Date	Facts	Type of medicine	Location	Links and citations
	herbalism etc. [Note: Hunter is the same person as Dummett, described below in relation to the death of a 37 year old man.]			
2007 to 2008	The Victorian Court of Appeal held that the Hope Clinic (a CAM clinic for the treatment of many diseases, mostly cancer) was guilty of misleading and deceptive conduct following an extensive inquiry by the Health Complaints Commissioner for Victoria. The conduct was that it held out to cure cancer, that its treatments were evidence based, and so on. The Hope Clinic was run by Noel Campbell (nutritional medicine), staffed largely by people with nutritional medicine qualifications, but also included a naturopath and a herbalist. The inquiry lists 9 complainants who suffered as a result of these treatments, including: • Most complainants describing thousands of dollars spent on treatment and equipment (up to $18,000); • Lack of consultation or examination; • One patient had an adverse reaction to a Vitamin C infusion, at times appearing in shock for hours or couldn't speak after receiving the treatment • One patient had an adverse reaction to ozone therapy treatment, causing the boy unable to speak, to walk and to sit unaided and drastically reduced his quality of life in his final weeks before death	Naturopathy, Western Herbal Medicine, Nutritional Medicine	Melbourne, VIC	*Noone, Director of Consumer Affairs Victoria v Operation Smile (Australia) Inc & Ors [2012] VSCA 91 (11 May 2012)* Act of commission – inappropriate therapy
2007	Dr Kathryn Mary O'Sullivan was found guilty of unsatisfactory professional conduct for complying with the course of treatment that Jill Newlands, a naturopath, requested for herself (that is, by infusing bicarbonate of soda with her breast cancer treatment), without exercising her professional responsibilities and informing Ms Newlands that there was no scientific evidence for it. Dr O'Sullivan then agreed to infuse non-therapeutic substances into two of Ms Newlands' patients, without exercising her own independent medical judgment about the treatment. [Note: it is not	Naturopathy	Brisbane, QLD	*Medical Board of Australia v O'Sullivan* [2011] QCAT 135 - Naturopathy by doctor under orders of naturopath on herself and other clients. Medical doctor disciplined by medical tribunal though naturopath not subject to proceedings Act of commission – inappropriate therapy

Date	Facts	Type of medicine	Location	Links and citations
	clear that the infusions, however, did any serious harm, just that they were unnecessary and not standard treatment.]			
2006	A 45 year old man was admitted to hospital with symmetrical maculopapular eruption on his limbs and a temperature, 2 days after taking Ginkgo Biloba for tinnitus. He was not on any other drugs and had not taken it before. The rash cured up within 10 days of withdrawal of the Ginkgo Biloba. [Note: it is not clear if this was prescribed by a herbalist or just over-the-counter.]	Western Herbal Medicine	Brisbane, QLD	Robert S Pennisi, 'Acute generalised exanthematous pustulosis induced by the herbal remedy Ginkgo Biloba', (2006) 184 *MJA*, 583-584 Risks related directly to the consumption of nutritional and herbal medicines
2006	A 51 year old woman presented to hospital with liver failure, after a history of taking black cohosh for menopause. This was consistent with international cases involving liver disease caused by black cohosh. She required a liver transplant. [Note: it is not clear if this was prescribed by a herbalist or just over-the-counter.]	Western Herbal Medicine	Adelaide, SA	Elizabeth C-Y Chow, Marcus Teo, John A Ring and John W Chen, 'Liver failure associated with the use of black cohosh for menopausal symptoms' (2008) 188 (7) *MJA* 420-422 Risks related directly to the consumption of nutritional and herbal medicines
2004 to 2006	Paul Perrett, a naturopath, was sued under the Fair Trading Act over his conduct in relation to the following victims: • Owen Holbert, a man with multiple sclerosis who suffered a severe reaction and later broke out in cold sores after Perrett gave him an intravenous drip; • Sheryl Anne Willson, a woman with breast cancer, whom Perrett convinced not to have chemotherapy and who suffered burning and swelling in her breast after Perrett gave her a black ointment to apply, severe aches and pains after an intravenous drip, and whose cancer continued to grow until she eventually had to have a bilateral mastectomy and removal of her ovaries and fallopian tubes; • Clare Denise Ellis, a women with an abnormal lump on her thyroid who Perrett convinced not to have radiation therapy. She later developed further lumps;	Naturopathy	Rutherford and Newcastle, NSW	*Commissioner for Fair Trading, Department of Commerce v Perrett* [2007] NSWSC 1130 http://www.austlii.edu.au/cgi- Act of omission – failure to refer Act of commission – inappropriate therapy

Date	Facts	Type of medicine	Location	Links and citations
	• Marilyn Jean Christie, a woman whose husband had lung, liver and bone cancer. Perrett gave her medication. Her husband died. The medication was found to contain no active ingredients. [Note: doctors could only recommend palliative care for the husband, so there was no medical treatment available]; • John Kimpton, a man with prostate cancer and a basal cell carcinoma. Perrett convinced him not to have hormone replacement therapy for the prostate cancer and put him on a strict dietary plan and gave him tablets instead which caused him to lose 27 kg; • Robyn Linette Kimpton (above man's wife) who had Huntington's disease and cystic acne. Perrett gave her some tablets and ointment to cure these (which proved ineffective in the long term) and an intravenous drip that was so painful she asked him to take it out; • Susan Allison Turner, a woman with sympathetic nerve dystrophy. Mr Perrett gave the impression to all of these people that he was a biochemist and suitably trained, and that the treatment he recommended (sometimes without even examining the patient) would cure their diseases. He was found guilty of misleading and deceptive conduct and ordered to stop holding out that he could cure or treat such diseases. [Note: the judgment itself does not say he is a naturopath, but the NSW Hansard reveals that he was listed as a Naturopath with the Australian Traditional Medicine Society.]			
2003	Barry Sheene, 52 year old motorcyclist with stomach and throat cancer, died after following the Rudolf Breuss diet marketed as curing his cancer. (Breuss was a naturopath and used nutritional medicine.) Sheene also tried microwave therapy, amongst other things.	Naturopathy, Nutritional Medicine	Gold Coast, QLD	http://news.bbc.co.uk/sport2/hi/motorsport/motorbikes/2219767.stm No naturopath involved but a naturopath regime and nutritional medicine

Date	Facts	Type of medicine	Location	Links and citations
				Risks related directly to the consumption of nutritional and herbal medicines
2003	56 year old woman died of liver failure after taking herbal anti-anxiety pills (containing kava) prescribed by her naturopath for several months. The pills were later found to contain unidentified and missing ingredients, but it was found to be unlikely that this was the cause of the death, as the death was consistent with other kava-related liver failure deaths. A later letter to the Medical Journal of Australia doubted the conclusion that it was kava that caused the death, but said that the batch of the product appears to be missing ingredients on the label and may have been contaminated.	Naturopathy, Western Herbal Medicine	Melbourne, VIC	https://www.mja.com.au/journal/2003/178/9/fatal-fulminant-hepatic-failure-induced-natural-therapy-containing-kava http://www.theage.com.au/articles/2003/05/04/1051987598205.html Naturopath prescribed substance Risks related directly to the consumption of nutritional and herbal medicines
2002	Robert Coram was a naturopath and medical herbalist who was convicted of sexually assaulting a patient when she came in for the treatment of a sore back.	Naturopathy, Herbal Medicine	Rockhampton, QLD	R v Coram [2006] QCA 313 - http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/qld/QCA/2006/313.html?stem=0&synonyms=0&query=title(%222006%20QCA%20313%22) Act of commission – inappropriate therapy
2002	Vecko Krsteski, a 37 year old man, died of heart attack and renal failure during a live-in detoxification program run by Jeffrey Dummett, a naturopath. Dummett was charged with manslaughter, although he was later found **not guilty**. [Note: Dummett is the same person as Jeremiah Hunter, described above in relation to Mrs Atkinson and charges under the *Fair Trading Act*]	Naturopathy	Sydney, NSW	http://www.smh.com.au/news/national/naturopath-in-court-over-detox-death/2006/09/01/1156817073892.html http://www.smh.com.au/news/national/naturopath-found-not-guilty-of-patients-death/2007/09/21/1189881777198.html Act of commission – inappropriate therapy

Date	Facts	Type of medicine	Location	Links and citations
2002	Boy with 60% chance of surviving cancer died after his naturopath convinced him to stop chemotherapy.	Naturopathy	Melbourne, VIC	http://www.theage.com.au/articles/2002/09/24/1032734164917.html Act of omission – failure to refer
1999	Mitchell James Little, an 18 day old boy, died of serious heart defect that was curable with surgery after Reginald Fenn, a naturopath, told Little's parents that the baby had been cured by herbal remedies. Little's parents took Fenn's advice and did not proceed with surgery. Fenn charged and convicted of manslaughter.	Naturopathy	Port Stephens, NSW	http://www.abc.net.au/news/2003-08-29/naturopath-found-guilty-of-babys-manslaughter/1471488 http://www.theage.com.au/articles/2004/02/13/1076548218504.html Act of omission – failure to refer Act of commission – inappropriate therapy
1987 to 2006	Michael Wilson, a naturopath, was convicted of 22 counts of indecent assault, 11 counts of rape, one count of sexual penetration of a child under 16 and one count of indecent acts in front of a child under 16. All of the alleged offences, with one exception, occurred in the course of the applicant's practice as a naturopath and all of the complainants were his patients. Part of his defence is that massage of pubic bones and near the breast area were part of the treatment (eg Bowen massage). Some of the convictions were quashed for technical reasons, but others remained. [Note: Wilson continued to treat patients even after he had been charged with these offences.]	Naturopathy	Various, VIC	*R v Wilson* (2011) 33 VR 340; [2011] VSCA 328 Special leave refused – *R v Wilson* [2012] HCASL 82 Naturopath – sexual assault – character issue Massage part of naturopathy Act of commission – inappropriate actions

International

Date	Facts	Type of medicine	Location	Links and citations
2014	Robert Young, a naturopath, was arrested and later convicted of two charges of treating people without a licence, on the basis that his treatment (discussed on Oprah Winfrey's show, where he and a woman named Kim Tinkham appeared and claimed he had cured Kim's breast cancer) involved intravenous administration of medicine rather than purely dietary recommendations. Tinkham died of cancer two years after appearing on Oprah's show	Naturopathy, Nutritional Medicine	California, USA	http://www.mbc.ca.gov/About_Us/Media_Room/2014/news_releases_20140124_young.pdf http://www.digitaljournal.com/article/301197 Unregistered naturopath provided cancer treatment Act of omission – failure to refer Act of commission – inappropriate therapy
2012	Kathleen Helms, a "naturopathic doctor", ran two clinics. She was arrested for practicing medicine without a licence after she diagnosed a woman with Lyme disease and gave her an infusion of dimethyl sulfoxide, as well as injections of animal cells and a regimen of vitamins. On the evening after the last infusion, the patient became seriously ill at home and was rushed to hospital where she was told she had hours to live as her organs were shutting down. The woman survived but now must live in an assisted living facility. Investigators believe there may be other victims.	Naturopathy	California, USA	https://www.fbi.gov/sandiego/press-releases/2012/encinitas-woman-arrested-on-charges-of-practicing-medicine-without-a-license Naturopath misconduct Act of omission – failure to refer
2011	Lori G Kimata, a naturopath, was sued for negligence for the home birth of an infant who suffered brain damage. Kimata allegedly failed to adequately monitor the labour and realise that the baby was showing signs of distress that warranted immediate transfer to a hospital for an emergency caesarean delivery.	Naturopathy	Hawaii, USA	http://www.casewatch.org/civil/kimata/complaint.shtml Naturopath misconduct Act of omission – failure to refer

Date	Facts	Type of medicine	Location	Links and citations
2008	Robert Martens, an 84 year old man, died after Mitra Javanmardi, a naturopath, injected him with magnesium. Javanmardi was charged but was acquitted, because the naturopath had followed precautions but the dose had apparently been contaminated.	Naturopathy	Montreal, Canada	http://www.cbc.ca/news/canada/montreal/mitra-javanmardi-quebec-naturopath-in-fatal-injection-case-found-not-guilty-1.3024678 Act of omission – failure to refer Act of commission – inappropriate therapy
2008	The courts removed a 13 year old girl (suffering from a rare condition) from her mother's care after the mother withheld medication and fed her only wheatgrass juice and raw food on the advice of a "natural treatment centre" in Florida. By the time the girl was taken to hospital, her stomach was full of liquid as a result of the untreated disease.	Naturopathy, Nutritional Medicine	Quebec, Canada	http://www.cbc.ca/news/canada/montreal/sick-teen-taken-from-mom-who-treated-her-with-natural-remedies-1.708224 Naturopath misconduct Act of omission – failure to refer Act of commission – inappropriate therapy
2006	A naturopath prescribed an adult female who was two months pregnant (and told the practitioner so) four different supplements, one of which contained juniper berries. The patient took the supplements for 12 days, and during her next OB/Gyn appointment, no foetal heartbeat could be detected and an ultrasound showed the foetus to be lifeless. According to at least one on-line source, juniper berries should be avoided during pregnancy, and among the documented adverse effects of this supplement are anti-implantation, abortifacient and emmenagogue effects.	Naturopathy	Colorado, USA	http://hermes.cde.state.co.us/drupal/islandora/object/co%3A4902 at page 30 Naturopath misconduct Act of commission – failure to observe contraindications
2005	Parents were convicted of starving their three children with a 'vegan' diet (but not a healthy one) on the advice of a naturopath named Windy Skeete. Skeete never saw the children, but told their parents they had 'malabsorption syndrome'. Along with the 'nutritional' diet, she prescribed slippery elm and bilberry. After one of the children suffered several seizures, Skeete finally recommended the parents seek medical assistance.	Naturopathy, Herbal Medicine, Nutritional Medicine	Arizona, USA	http://www.phoenixnewtimes.com/news/diet-from-hell-6403704 Act of commission – inappropriate therapy
2005	Jo Ann Burggraf, 58 year old woman, had pain in her joints and legs. She sought treatment from Sidney Myers, a "naturopathic doctor". Myers treated her with EPFX (low frequency energy	Naturopathy	Oklahoma, USA	http://www.seattletimes.com/seattle-news/how-one-mans-invention-is-part-of-a-growing-worldwide-scam-that-snares-the-desperately-ill/

Date	Facts	Type of medicine	Location	Links and citations
	machine). Burggraf's pain grew worse to the point where she often blacked out. She was taken to hospital by helicopter and died hours after admission of undiagnosed leukaemia. Myers says the reason the treatment didn't work on Burggraf is Myer's had 'just a few days of training' and 'really didn't know what I was doing'.			Naturopath misconduct Act of commission – inappropriate therapy Act of omission – failure to detect significant underlying pathology
2005	The FDA and IRS raided a clinic run by a naturopath twice in 2005 and seized equipment and dietary supplements. He continued to practice until the Health Department suspended the clinic a few months later on the basis that he was an immediate danger to the public. In May 2006, the practitioner was found guilty of 18 counts of wire fraud and three counts of money laundering for frightening healthy people into thinking they were ill, performing incorrect and unnecessary medical tests and selling patients $1.3 million worth of treatment and products after providing incorrect diagnoses.	Naturopathy	Rhode Island, USA	http://hermes.cde.state.co.us/drupal/islandora/object/co%3A4902 at page 28 Naturopath misconduct Act of commission – inappropriate therapy and misdiagnosis
2004	Cat Bresina, a 17 year old girl, went into cardiac arrest and was rushed to hospital after being treated by a naturopath (Brian O'Connell) using photoluminescence or ultraviolet blood irradiation. Doctors suspected the cause of the heart attack was an embolism, anaphylactic shock or a contaminated product.	Naturopathy	Colorado, USA	http://www.westword.com/news/do-no-harm-5085877 http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 22 Act of commission – inappropriate therapy
2004	Adult female was being treated for breast cancer by a naturopath, who told her she was improving when in fact she was deteriorating. The cancer destroyed her right breast and developed in the muscle and bone.	Naturopathy	Seattle, USA	http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 23 Act of omission – failure to refer
2004	A 54 year old male went into convulsions and died after being injected with vitamins and an anti-inflammatory drug by a naturopathic faith healer. He was being treated for a persistent skin disorder.	Naturopathy	Los Angeles, USA	http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 24 Act of commission – inappropriate therapy
2004	David Pontius, a Canadian naturopath, was charged for the death of Diane Shepherd, a woman in Utah, after treating her there. The naturopath allegedly treated her for breast cancer after claiming	Naturopathy	Utah, USA	http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 24

Date	Facts	Type of medicine	Location	Links and citations
	the cancer was caused by gangrene and mercury poisoning in her teeth. The naturopath gave her a muscle test and a body scan, and advised her to eat apricots and remove her fillings.			Act of commission – inappropriate therapy
2004	A 47 year old woman with a 'persistent feeling of malaise' sought treatment from a naturopath. The woman had a thyroid condition. The naturopath allegedly advised her that he could cure her thyroid condition and there would be no need for her to take her hormone medication anymore. She was given a detailed schedule to wean her off the medication. The patient suffered increasing fatigue and other symptoms, but was told the treatment was working. She saw an endocrinologist who evaluated her condition as between dangerous and critical.	Naturopathy	Colorado, USA	http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 25 Act of commission – inappropriate therapy Act of omission – failure to refer
2004	A woman in Colorado with a thyroid condition sought treatment from a naturopath. She was given alternative thyroid medication. Within a month, she suffered from hot flashes, hair loss, fluid retention, weight gain and fatigue. A blood test indicated that her thyroid levels were very low and that continued failure to take her medication could have long term consequences.	Naturopathy	Colorado, USA	http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 26 Act of omission – failure to refer Act of commission – inappropriate therapy
2002 to 2004	"Herbalist" Barbara Tarwater was charged with practising medicine without a licence in a clinic, by engaging in iridology, live-cell analyses, and applied kinesiology muscle tests, and prescribed and/or administered essential oils, herbal products, raindrop therapy, colonic irrigation, and intravenous vitamin treatment. One case involved person with cancer. The matter was dropped when Tarwater indicated she had left practice and would never again diagnose or prescribe.	Western Herbal Medicine	Washington, USA	http://www.casewatch.org/ag/ut/tarwater/conclusions.shtml Unregistered naturopath misconduct Act of omission – failure to refer
2001	Megan Wilson, a 16 year old girl, died of asthma attack after Lucinda Messer, a naturopath, treated her respiratory distress with vitamin B12 injection and herbal 'tincture' (although there is some dispute of facts in that the naturopath also says she told the family	Naturopathy	Seattle, USA	http://www.seattleweekly.com/2005-06-08/news/death-by-natural-causes/ and http://www.pereylaw.com/verdicts-settlements/naturopathic-negligence-asthma-wrongful-death/

Date	Facts	Type of medicine	Location	Links and citations
	to take the girl to the hospital, and the family says she never said that). Wrongful death case settled out of court.			Act of omission – failure to refer Act of commission – inappropriate therapy
1999	Laurence Perry, a naturopath, recommended an 8 year old girl (Helen Rose Kolitwenzew) with insulin dependent diabetes stop taking insulin. The child died of high blood sugar levels caused by insulin deprivation. The naturopath was found guilty of involuntary manslaughter.	Naturopathy	North Carolina, USA	http://web.archive.org/web/20020422082931/http://cgi.citizen-times.com/cgi-bin/story/news/11095 http://www.naturowatch.org/licensure/coloradosunrise05.pdf at page 23 Act of commission – inappropriate therapy Act of omission – failure to refer

Schedule B
Higher Education Thresholds – Learning Outcomes and Assessment

1. The expected learning outcomes for each course of study are specified, consistent with the level and field of education of the qualification awarded, and informed by national and international comparators.
2. The specified learning outcomes for each course of study encompass discipline-related and generic outcomes, including:
    a. specific knowledge and skills and their application that characterise the field(s) of education or disciplines involved
    b. generic skills and their application in the context of the field(s) of education or disciplines involved
    c. knowledge and skills required for employment and further study related to the course of study, including those required to be eligible to seek registration to practise where applicable, and
    d. skills in independent and critical thinking suitable for life-long learning.
3. Methods of assessment are consistent with the learning outcomes being assessed, are capable of confirming that all specified learning outcomes are achieved and that grades awarded reflect the level of student attainment.
4. On completion of a course of study, students have demonstrated the learning outcomes specified for the course of study, whether assessed at unit level, course level, or in combination.
5. On completion of research training, students have demonstrated specific and generic learning outcomes related to research, including:
    a. a detailed understanding of the specific topic of their research, within a broad understanding of the field of research
    b. capacity to scope, design and conduct research projects independently
    c. technical research skills and competence in the application of research methods, and
    d. skills in analysis, critical evaluation and reporting of research, and in presentation, publication and dissemination of their research.
6. Assessment of major assessable research outputs for higher degrees by research, such as theses, dissertations, exegeses, creative works or other major works arising from a candidate's research incorporates assessment by at least two assessors with international standing in the field of research, who are independent of the conduct of the research, competent to undertake the assessment and do not have a conflict of interest, and:
    a. for doctoral degrees, are external to the higher education provider, and
    b. for masters degrees by research, at least one of whom is external to the higher education provider.
7. The outputs arising from research training contribute to the development of the field of research, practice or creative field and, in the case of doctoral degrees, demonstrate a significant original contribution.

Schedule C

Profile of the

Australian Natural Therapists Association Ltd

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The Australian Natural Therapists Association Limited (ANTA) is the largest national democratic association of *'recognised professional' traditional* medicine and natural therapy [Complementary Medicine] practitioners who work in the areas of health care and preventive medicine.

ANTA was founded in 1955 and represents the multi-disciplinary interests of approximately 10,000 accredited practitioners Australia-wide. ANTA is one of the original *Schedule 1* bodies as defined in the regulations of the Therapeutic Goods Act 1989.

ANTA was recognised by the Australian Taxation Office, in November 2002, under a private ruling as *'…a professional association that has uniform national registration requirements for practitioners of traditional medicine and natural therapies…'* thereby allowing ANTA practitioners of Acupuncture, Chinese Herbal Medicine, Naturopathy and Western Herbal Medicine to practise GST- free.

ANTA:

- provides an egalitarian representation of all disciplines accredited by the association
- possesses infrastructure, systems, policies and procedures which enables the Association to encompass all aspects of the profession
- represents the interests of individual disciplines
- acts as advocate for practitioners of all disciplines accredited by the Association
- promotes the health and safety of consumers of traditional medicine and natural therapy health services

The disciplines recognised by ANTA and accredited by the Australian Natural Therapists Accreditation Board (ANTAB) are:

Acupuncture	**Aromatherapy**
Ayurvedic Medicine	**Chinese Herbal Medicine**
Chiropractic/Osteopathy	**Homoeopathy**
Naturopathy	**Nutritional Medicine**
Oriental Remedial Therapy	**Remedial Massage Therapy**
Traditional Chinese Medicine	**Myotherapy**
Counselling	**Musculoskeletal Therapy**
Western Herbal Medicine	**Shiatsu**

ANTA supports Statutory Registration of Natural Therapists

ANTA is committed to continuous quality improvement and providing the Australian public with the highest possible standards for the conduct and safety of traditional medicine and natural therapy practitioners, and addresses standards for conduct and safety through:

- The high standard of entry requirements for potential members
- Yearly review of entry standards to maintain currency and ensure relevance
- Active participation in setting standards at national and state levels via industry reference group and working committee participation
- Free student membership to the Association
- Yearly review of the courses on offer within the profession, and courses currently accredited by ANTAB
- Compulsory yearly proof of minimum continuing professional education requirements of members
- Provision of “free” continuing professional education seminars in all states of Australia
- Provision of online continuing professional education services for members
- Provision of free continuing professional education webinars for members
- Compulsory up-to-date first aid certificates
- Compulsory specialised professional indemnity insurance
- The Association enforces a strict Code of Professional Ethics
- The Association maintains effective public complaints handling and resolution mechanisms outlined in the Constitution
- The Association maintains a National Administration Office, which is open five days a week and staffed by an Executive Officer and fully trained support staff
- The Association maintains fully computerised membership, accreditation and course recognition databases and systems
- Provision of communication via the members' page on the ANTA website of the most up to date information related to the profession
- Provision of regular newsletters and ANTA e-News detailing information of current interest to the profession
- Provision of a professional publication ‘The Natural Therapist’, four times a year offering the latest information available on topics of interest to the profession
- Provision of an ANTA website to allow interested persons and consumers to obtain information about the Association, natural therapies and traditional medicine and the location of accredited practitioners of the Association
- Provision of a free Natural Therapies App to allow interested persons and consumers to obtain information about natural therapies and details of ANTA practitioners in their area
- Provision of free access by members to the latest scientific publications and health resources published by eMIMS
- Provision of free access by members to the latest scientific publications and health resources published by EBSCO Host including:
  - 2800+ full text medical journals
  - Access to the world’s most reputable bibliographic indexes for medicine, allied health and complementary/alternative medicine (CINAHL, MEDLINE & AMED)
  - 700+ evidence based articles for consumer health researchers
  - 300+ full text books and monographs
  - Hundreds of special reports and booklets and much more.

- Provision of free access by members to the latest up to date scientific information and health resources published by IM Gateway including:
  - 300 Herbs
  - 350 Diseases and Conditions
  - 250 Supplements
  - Herb – Drug Interaction Guide
  - Supplement – Drug Interaction Guide
  - Treatment Options
  - Organ and Body Systems
  - Drug Induced Depletions
  - Evidenced Based & Peer Reviewed Information
- Provision of funding grants for research into traditional medicine and natural therapies
- Provision of online resources and latest research for members
- Provision of annual ANTA Student Bursary Awards totalling $12,000 p.a. to encourage excellence in the study of traditional medicine and natural therapies
- Setting of standards for clinics, hygiene and infection control
- Setting of standards for skin penetration
- Setting of standards for keeping and maintaining patient records
- Making public the requirements for recognition of traditional medicine and natural therapy courses by ANTA for membership purposes
- Making public details of traditional medicine and natural therapy courses recognised by ANTA for membership purposes
- Only recognising government accredited courses that meet ANTA's stringent requirements (note - ANTA does not recognise courses delivered totally by distance education)
- Making public details of ANTA membership criteria and qualifications
- Consultation with members on matters of importance. The Association uses the Members' web page, consultation meetings, newsletters, ANTA e-News, social media and the magazine to consult with members
- A '1800' free-call number promoted to consumers and practitioners, facilitating a direct path of communication with the Association's national administration office staff
- A '1800' free-call number and web page promoted to consumers and practitioners, to identify appropriately qualified practitioners in the consumer's geographical area
- Undertaking ongoing internal audits of its policies and processes of operation and all matters to do with professional practice
- External audits of procedures, policies and processes to ensure compliance with the principles of best practice
- Publishing an annual report on the activities and performance of the Association
- Undertaking a yearly audit of its Constitution which includes the Association's Complaints, Ethics and Disciplinary Panels
- Undertaking a yearly audit of its Code of Professional Ethics
- Ongoing consultation and collaboration with other professional associations
- Ongoing dialogue and correspondence with ministers, government departments and regulatory bodies
- Ongoing research of policies in overseas professional associations and policies of overseas governments
- Maintaining a Natural Therapy Adverse Events Register
- On line polling of members and the public on relevant professional and health issues
- Democratic voting system for the election of directors by members

ANTA is a public company limited by guarantee, and is governed by a National Council [Board of Directors] which is elected by the members of the Association for a term of three years. The Council in turn elects all office bearing positions within the Association, which are for a term of one year.

National Council is supported by the services of a full time Executive Officer, full time Company Secretary and full time National Administration Office staff.

ANTA practises a policy of consultation with representatives of all stakeholders of traditional medicine and natural therapies, as well as being available to all government and regulatory bodies associated with the professions.

Persons wishing to discuss with ANTA any matters relevant to the professions of traditional medicine and natural therapies should contact:

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