PROTECTING PATIENTS AND THE PUBLIC FROM HARM THROUGH STRONGER REGULATION OF THE NATUROPATHY PROFESSION

Submission to government seeking inclusion of the naturopathy profession in the National Registration and Accreditation Scheme for the health professions

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DRAFT FOR CONSULTATION

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EXECUTIVE SUMMARY

The purpose of this submission is to present an assessment of the profession of naturopathy against the AHMAC criteria for statutory registration[1] and to seek the support of state, territory and Commonwealth Health Ministers for the urgent and critical addition of naturopathy as a regulated profession under the National Registration and Accreditation Scheme (NRAS).

Naturopathic practice is complex and multi-modal, incorporating core naturopathic therapies and practices that may include applied nutrition, clinical nutrition, herbal medicine, and lifestyle modification among other therapies (Lloyd et al., 2021: viii). Naturopathic practice is underpinned by a strong philosophy and principles – at its core is a focus on health promotion and disease, patient centred care and promotion of wellness and wellbeing. There are an estimated 15,000 naturopaths and Western herbalists in Australia providing primary care to 6-8% Australians with acute and chronic conditions through approximately four million visits each year. This often occurs in parallel with other conventional medical and health services, including pharmaceutical medical use.

This submission details the evidence and rationale for the statutory registration of naturopathic practitioners in Australia – the objective is to protect the health, safety and well-being of the millions of Australians who consult naturopaths each year.

We detail the scale and scope of naturopathic practice in Australia. We present a profile of patients who consult naturopaths and a profile of the naturopathic workforce. We present evidence of the scope and seriousness of the risks associated with naturopathic practice and naturopathic products. We detail the many, ultimately ineffective, attempts made over the decades to mitigate these risks, through profession-led voluntary certification schemes.

While most naturopaths practise in a safe, competent and ethical manner, we detail many cases of egregious harm caused to patients by naturopaths, or more often, those professing to be a naturopath with minimal or no naturopathic qualifications.

For several decades there have been calls from most naturopathy professional bodies for governments to intervene to strengthen regulation of the profession. This is because:

- → without statutory registration, there is no effective means to prevent untrained or undertrained persons from assuming the title ‘naturopath’ and holding themselves out to the public as qualified to practise the profession.
- → without statutory registration, there is no effective means to enforce the standards of practice that set the minimum expectations of naturopathic diagnosis and treatment to ensure safe and competent patient care.

1. See Australian Health Ministers’ Advisory Council. (2018). AHMAC Information on regulatory assessment criteria and process for adding new professions to the National Registration and Accreditation Scheme for the health professions. https://agedcare.royalcommission.gov.au/system/files/2020-10/AHP.0002.0001.0001.pdf

Without government leadership and support, the profession has been unable to enforce across the entire profession minimum entry to practice qualifications, probity checks and practice standards, professional indemnity insurance or ongoing professional development – all the requirements needed to assure the safety and quality of naturopathic services.

In highlighting the significant risk of harm to the public from the unregulated practice of naturopathy, this submission assesses the suitability of various alternative models for regulation of the profession, including why continuing the status quo (no change in regulation) is not a satisfactory option for protecting the public.

This submission is informed by a solid evidence base. It encourages governments to take a systems approach – to understand the institutional context within which naturopathic services are delivered, to better understand the risk profile of the profession – why the unregulated practice of naturopathy carries greater risks to the public than other regulated and unregulated health professions, and why these risks have proven to be so resistant to mitigation efforts on the part of the profession.

The submission concludes with a recommendation directed at AHMAC and all Australian state, territory and Commonwealth Health Ministers – that statutory registration of the naturopathy profession under the NRAS is urgent and necessary, to assure the Australian community of the quality and safety of naturopathic practice and practitioners, and to prevent harm to patients.

This recommendation accords with policy recommendations from the World Health Organization (WHO) concerning the need to regulate traditional and complementary medicine (T&CM) practitioners, products and practice to achieve better integration of the health system (WHO, 2013: 7; WHO, 2019). The preferred model is a Naturopathy Board of Australia, structured and operating according to the same legislative template as the other National Boards under the NRAS.

ASSESSMENT against the AHMAC Criteria

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

Conclusion: **It is appropriate** for Health Ministers to exercise responsibility for regulating naturopathic practitioners and naturopathic practice. Naturopathy is a health profession and clearly within the scope of the health portfolio. It does not 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?*

Conclusion: The treatment modalities, scope of practice, and practice context of naturopaths all contribute to a **risk profile for an unregulated naturopathy profession** that is **unacceptably high** and on par with or greater than many of the health professions that are subject to statutory registration. These risks are not just theoretical – there is a pattern of harm evident, with repeated cases over three decades.

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

Conclusion: The **risk profile of the naturopathy profession is substantial** and there is a pattern of harm to consumers that is not being adequately addressed under current regulations. The existing mix of self-regulatory, co-regulatory, negative licensing and other mechanisms are failing to adequately address the risks of harm associated with unregulated naturopathic practice. Without enforceable controls over entry to practise in the profession, there are no effective mechanisms to enforce minimum practise standards and no effective methods of preventing unqualified individuals from continuing to practice. Without enforceable qualification and probity requirements, people who have no qualifications whatsoever, those who been expelled from associations for misconduct and those deregistered from other regulated professions, cannot be prevented from continuing to offer naturopathy services to the public or shifting from one association to another. Without enforceable qualification and probity requirements and an effective mechanism to monitor practitioners for compliance with practice standards, the profession is targeted by those who are disposed to exploit the vulnerabilities of their patients for personal gain. **Existing regulatory mechanisms are failing** to deal with this fundamental problem.

***CRITERION 4**: Is regulation possible to implement for the occupation in question?*

Conclusion: **Regulation is possible to implement** for the **naturopathy** profession – it **is a well-defined and well-established health profession in Australia**. It has an established body of knowledge, modalities, principles and philosophies and established education and practice standards. The profession is supportive of registration and able to support a self-funded National Board. It is possible to implement regulation.

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

Conclusion: **Regulation is practical to implement** for the naturopathy profession. Introduction of statutory registration is not without some practical challenges. However, experiences in other jurisdictions and with the implementation of registration of the Chinese medicine profession shows that these **challenges are solvable**. This experience can be drawn upon in implementing appropriate arrangements for the naturopathy profession.

***CRITERION 6**: Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?*

Conclusion: This assessment provides prima facie evidence of the need for statutory registration of the naturopathy profession and that **the benefits of regulation are expected to outweigh the costs**. This assessment demonstrates that existing mechanisms for protecting the public are inadequate and that statutory registration is the only option that will provide sufficient protection from harm, given the risk profile of the profession. Governments are urged to allocate the resources required to undertake a RIS.

1. INTRODUCTION

Purpose of this submission

The purpose of this submission is to present an assessment of the profession of naturopathy against the AHMAC criteria for statutory registration[2] and to seek the support of state, territory and Commonwealth Health Ministers for the urgent and critical addition of naturopathy as a regulated profession under the National Registration and Accreditation Scheme (NRAS).

This submission details the evidence and rationale for the statutory registration of naturopathic practitioners in Australia – the objective is to protect the health, safety and well-being of the millions of Australians consulting with naturopaths each year.

We detail the scale and scope of naturopathic practice in Australia. We present a profile of patients who consult naturopaths and a profile of the naturopathic workforce. We present evidence of the scope and seriousness of the risks associated with naturopathic practice and naturopathic products. We detail the many, ultimately ineffective, attempts made over the decades to mitigate these risks, through profession-led voluntary certification schemes.

While most naturopaths practise in a safe, competent and ethical manner, we detail many cases of egregious harm caused to patients by naturopaths, or more often, those professing to be a naturopath with minimal or no naturopathic qualifications.

Without government leadership and support, the profession has been unable to enforce minimum entry-to-practice qualifications, probity checks and practice standards, professional indemnity insurance or ongoing professional development – all the requirements needed to assure the safety and quality of naturopathic services.

About the Australian Naturopathic Council (ANC)

In 2019, the ANC was established with a platform to provide broad-based representation for the naturopathy profession, and with the intention to press for an expansion of the NRAS to provide national registration for the naturopathy profession[3].

2. See Australian Health Ministers' Advisory Council. (2018). AHMAC Information on regulatory assessment criteria and process for adding new professions to the National Registration and Accreditation Scheme for the health professions. https://agedcare.royalcommission.gov.au/system/files/2020-10/AHP.0002.0001.0001.pdf

3 The objectives of the ANC are to; foster understanding and communication, and where appropriate, the sharing of information amongst the naturopathic stakeholders in Australia regarding successes, challenges and new initiatives within each organisation; identify areas of common interest and, where appropriate, opportunities for cooperative and/or complementary action; facilitate communication amongst Australian naturopathic stakeholders in support of the quality, viability and sustainability of the naturopathic profession in Australia; improve efficiencies amongst Australian naturopathic stakeholders by communicating openly and sharing resources where appropriate to decrease workload and duplication. See https://www.naturopathiccouncil.org.au/

The ANC is the only peak body in Australia that represents organisations that are recognised by the World Naturopathic Federation (WNF) as a naturopathic professional association, educational institution or registration body. Founding members of the ANC are:

- → Australian Register of Naturopaths and Herbalists (ARONAH)
- → Complementary Medicine Association (CMA)
- → Endeavour College of Natural Health (ECNH)
- → Naturopaths and Herbalists Association of Australia (NHAA)
- → Torrens University (incorporating the former Southern School of Natural Therapies).

In 2020, the ANC commissioned research to investigate the risks of naturopathic care in Australia and the options for strengthening regulation of the naturopathic profession (ANC, 2020). The report of this research is scheduled for public release in the new year and is drawn upon throughout this submission (Carlton et al., forthcoming).

What consumers expect

When making health care decisions, Australians are entitled to reasonable assurance that the naturopath they choose to consult is appropriately trained and regulated to the same standard generally expected of any primary care practitioner with a similarly broad scope of practice.[4] Unlike the USA and Canada, where naturopathic medicine is a licensed profession in more than half the States and Provinces,[5] there is no such assurance for the Australian public.

While the vast majority of naturopaths are well trained and practise safely and competently, the health and safety of Australians is at risk because of an unknown number who flout professional norms and breach professional codes of conduct.

Without effective controls over entry-to-practice, anyone is at liberty to set up a practice and offer their services as a naturopath, with little or no naturopathic training. And they do. We know that some individuals who have been practising as a naturopath with no qualifications whatsoever, some having been deregistered from NRAS, have eventually come to the attention of regulators, but often only after multiple patients have suffered serious harm (Wardle, 2014: 354; Carlton et al., forthcoming).

World Health Organization policy

The World Health Organization (WHO) has long called for Member States to better regulate traditional and complementary medicine (T&CM) practitioners and practice. The WHO Global Traditional Medicine Strategy titled *WHO Traditional Medicine Strategy 2014-2023* identifies a range of challenges facing Member States in regulating the T&CM workforce (WHO 2014: 40); the Strategy encourages Member States to strengthen quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners (WHO 2013: 45).

4. The scope of practice of naturopaths includes the use of ingestive therapies or treatments, including oral medications such as herbal medicines, or nutritional supplements such as vitamins (CMA, 2021).
5. Naturopathic medicine is a licensed profession in at least 25 US States and 5 Canadian provinces (Lloyd et al., 2021: 37-39).

The WHO Global Report on Traditional and Complementary Medicine 2019 states:

> *T&CM is used by at least 80% of the Member States across all WHO regions, with more than 90% of Member States in the Eastern Mediterranean, South-East Asia and Western Pacific regions reporting use of T&CM. This uniformly high use of T&CM across all regions reinforces the need for policy development, appropriate laws and regulations, safety and monitoring systems, and integration of T&CM products, practices and practitioners into health systems (WHO, 2019: 45).*

Calls from the profession for governments to strengthen regulation

For several decades there have been calls from sections of the naturopathy profession for governments to intervene to strengthen regulation of the profession (Lin et al., 2005; NHAA, 2006; Naturopaths for Registration, 2008; Wardle, 2008a; Wardle et al., 2012; 2013; Weir, 2016).

While the representative arrangements for the naturopathy profession are relatively fragmented, with multiple peak professional associations, each with its own policy on the question of registration for naturopaths, some associations see statutory registration as a vehicle to lift standards and better protect the public. The arguments run along the following lines:

- → without statutory registration, there is no effective means to control entry to practise, to prevent untrained or undertrained persons from assuming the title 'naturopath' and holding themselves out to the public as qualified to practise the profession
- → without statutory registration, there is no effective means to enforce the standards of practice that set the minimum expectations of naturopathic diagnosis and treatment that ensure safe and competent patient care
- → naturopaths are primary care practitioners with a very broad scope of practice – other primary care health professions with a similar risk profile (and similarly broad scope of practice that includes the use of ingestive therapies) are already regulated under the NRAS[6]
- → this lack of effective regulation is contrary to what patients generally expect – they expect practitioners to be properly trained and regulated (Lin et al., 2005: 247).

Over the last two decades, news coverage and media releases have highlighted cases of harm to the public and called for stronger regulation of unqualified persons who assume the title and trappings of the profession – see Table 1 for a selection of media releases and news coverage.

6. Regulated health professions with the authority to prescribe medicines are: medical practitioners, nurses and midwives, optometrists, paramedics, podiatrists and Chinese medicine practitioners.

TABLE 1: Selection of media releases and news coverage of cases of harm and calls for stronger regulation of the naturopathy profession

Date	Source/type	Description
Sept 2022	ARONAH Media Release	Calls for registration of naturopaths highlighted on SBS Insight Program
Jun 2022	ABC News	Perth naturopath Rodrigo Bascunan Cabrera jailed for abusing women after bogus diagnoses
Apr 2022	ABC News	Perth naturopath Mauricio Bascunan Cabrera handed a six-year jail term for abusing 18 patients
Nov 2021	ARONAH Media Release	Registering naturopaths is urgently needed to protect the public as a purported "naturopath" is found guilty of sexually assaulting 18 women
Aug 2021	Nine News	Adelaide Hills naturopath suspended from providing COVID-19 advice after publishing anti-vax piece
Aug 2021	ARONAH Media Release	Naturopath comes under investigation for advice on COVID-19 vaccinations
Dec 2020	ARONAH Media Release	Urgent call for Government registration of naturopaths to protect the public
Jun 2020	ARONAH Media Release	Why do we need Registration/Regulation of the Naturopathic profession in Australia? Guest post from the ANC
Apr 2018	ABC News	Naturopath jailed for at least seven months for role in starving infant
Apr 2018	ARONAH Media Release	Government delaying registration of naturopaths exposes public to ongoing risk
Aug 2017	ARONAH Media Release	Delays in statutory registration of naturopaths exposes public to ongoing risk
Jun 2016	ARONAH Media Release	Naturopathy can be safe and effective but registration is the key
May 2016	Sydney Morning Herald	Herbalist declared risk to public after claiming his remedies would cure cancer
Jul 2015	The Guardian	Sydney naturopath arrested after baby comes close to death on treatment plan
Feb 2015	ARONAH Media Release	Dodgy naturopathy courses putting public at risk
Oct 2010	ARONAH Media Release	National register of naturopaths and herbalists to improve public safety
Oct 2010	ABC News	Unregulated naturopaths putting lives at risk.
Jul 2010	ABC News	Incompetent care led to Dingle's death
Oct 2008	Sydney Morning Herald	Sex assault naturopath jailed
April 2008	Sydney Morning Herald	Naturopath banned for life
Apr 2005	ANC News	Naturopath's qualifications unverifiable, inquest told
Sept 2002	The Age	Call for control on alternative medicine

What has happened to date

Naturopaths were previously registered by statute for seven years in the Northern Territory under the *Health Practitioners and Allied Health Professions Registration Act 1985* (NT). However this legislation was repealed in 1992 following national agreement on which professions should be subject to statutory registration in every Australian state and territory and implementation of the associated *Mutual Recognition (NT) Act 1992*.

Attachment 1 sets out key events in the history of regulatory policy making with respect to the profession of naturopathy.

An important milestone in 2004 saw the Victorian Government Department of Human Services commission a consortium of researchers led by La Trobe University to conduct independent research on the risks, benefits and regulatory requirements for the profession of naturopathy and Western herbal medicine. The resulting report (the Lin Report) was published in 2005 and included an assessment of the naturopathy profession against the AHMAC Criteria for statutory registration. The report, and its principal recommendation – that governments legislate to provide a statutory registration scheme for the profession – was brought forward by Victoria to AHMAC for consideration soon after.

However, by the end of 2005, following publication of the Productivity Commission's report *Australia's Health Workforce*, the national reform process to establish the NRAS was underway and the prime focus of governments and Health Ministers during the subsequent decade was on dismantling the multiple state-based registration schemes and setting up (and then bedding down) the NRAS.

During this period, representations were made to government from time to time concerning the need for statutory registration of naturopaths, however associations were informed they must wait until work to update the AHMAC criteria and processes for regulatory assessment was completed and new guidelines issued. This took governments 10 years from the date the Intergovernmental Agreement to proceed with the NRAS was signed (COAG, 2008; AHMAC, 2018).

In 2016 the Australian Natural Therapists Association (ANTA) made a formal submission to the Health Workforce Principal Committee of AHMAC seeking statutory registration for naturopaths (Weir, 2016).[7] However, it is not clear whether the submission was progressed to AHMAC or the Ministerial Council for consideration and it seems no formal response was ever received.

In 2018, AHMAC finally published an updated regulatory policy (the AHMAC Guidance), providing greater clarity concerning the criteria and process for regulatory assessment of professions for inclusion in the NRAS.

7. The ANTA submission encompassed nutritionists as well as naturopaths and Western herbal medicine practitioners.

Our approach to preparing this submission

This submission updates and extends the regulatory assessment undertaken in 2005 as part of the study commissioned by the Victorian Department of Human Services (the Lin Report). It also draws on recent evidence reported in several commissioned research studies including from the WNF health technology assessment (Lloyd et al., 2021) and the forthcoming research report commissioned by the ANC (Carlton et al., forthcoming). Key data sources are set out in Table 2.

TABLE 2: Key data sources drawn upon to prepare this submission

Organisation	Authors	Title of report	Year
State of Victoria, Department of Human Services Victoria	Lin, V., Bensoussan, A., Myers, S.P., McCabe, P., Cohen, M., Hill, S., & Howse, G.	*The practice and regulatory requirements of naturopathy and Western herbal medicine.* (the Lin Report)	2005
Australian Natural Therapists Association (ANTA)	Weir, M.	*Submission to Chair, Health Workforce Principal Committee, Registration of Naturopathy, Western Herbal Medicine and Nutritional Medicine.*	2016
World Naturopathic Federation (WNF)	Lloyd, I., Steel, A., & Wardle, J. (Eds).	*Naturopathy practice, effectiveness, economics & safety* (the WNF Health Technology Assessment)	2021
World Health Organization (WHO)	Lin, V.K., Carlton, A.L., Short, S., Balasubramanian, M., Leslie, K., & Bourgeault, I.L.	*WHO Global Guidance on Health Practitioner Regulation: A large scale rapid review of the design, operation and strengthening of health practitioner regulation systems.*	2022
Australian Naturopathic Council (ANC)	Carlton, A.L., Carè, J., Steel, A., Myers, S., & Wardle, J.	*A review of the risks, the benefits and the regulatory requirements for the profession of naturopathy. A study funded by member organisations of the Australian Naturopathic Council and members of the naturopathy profession.*	2023

The submission highlights the significant risk of harm to the public from the unregulated practice of naturopathy. It assesses the suitability of various alternative models for regulation of the profession, including whether continuing the status quo (no change in regulation) is a satisfactory option.

This submission is informed by a solid evidence base. It encourages governments to take a systems approach – to understand the institutional context within which naturopathic services are delivered, to better understand the risk profile of the profession – why the unregulated practice of naturopathy carries greater risks to the public than other regulated and unregulated health professions, and why these risks have proven to be so resistant to mitigation efforts on the part of the profession.

Section 2 of this submission provides an overview of the naturopathic profession, its practice and its patients.

Section 3 provides a summary of the AHMAC Guidance and the criteria and process for regulatory assessment.

Sections 4-10 set out the assessment of the naturopathy profession against each of the threshold criteria for statutory registration set out in the AHMAC Guidance.

The submission concludes with a recommendation directed at AHMAC and all Australian state, territory and Commonwealth Health Ministers – t**hat statutory registration of the naturopathy profession under the NRAS is urgent and necessary,** to assure the Australian community of the quality and safety of naturopathic practice and practitioners, and to prevent harm to patients.

This recommendation accords with policy recommendations from the WHO concerning the need to regulate the T&CM professions to achieve better health system integration (WHO, 2013: 7; WHO, 2019).

Our preferred model is a Naturopathy Board of Australia, structured and operating according to the same legislative template as the other National Boards under the NRAS.

2. DEFINING NATUROPATHY: ITS PRACTITIONERS, ITS PATIENTS & ITS PRACTICE

What is naturopathy

Every culture has its own traditional system of medicine, with most traditions dating back many centuries. Naturopathy is the traditional system of medicine that originated in Europe, was formalised as a distinct system of medicine during the 19th century and is now practised around the world (Lloyd et al., 2021: viii).

The WNF describes naturopathic practice as complex and multi-modal, incorporating core naturopathic therapies and practices that may include applied nutrition, clinical nutrition, herbal medicine, lifestyle modification, mind-body medicine, counselling, naturopathic physical medicine, hypnotherapy and other practices (Lloyd et al., 2021: viii). Naturopathic practitioners, products and practices are generally included under the World Health Organization (WHO) definition of traditional and complementary medicine (T&CM) (WHO, 2019: 8).[8]

Naturopathic practice is underpinned by a strong philosophy and principles – at its core is a focus on health promotion and disease prevention, patient-centred care and promotion of wellness and wellbeing. Attachment 2 provides further details on definitions and the scope of naturopathic practice.

The earliest records of the practice of naturopathy and Western herbal medicine (WHM) in Australia date back to the early 20th century (Jacka, 1998: 12). Today, Australian naturopaths are autonomous primary care practitioners who treat patients with a broad range of acute and chronic conditions throughout the lifespan. The core therapeutic modalities practised by Australian naturopaths are:

→ dietary advice
→ lifestyle prescription
→ nutritional medicine, and
→ herbal medicine (McIntyre et al., 2019).

A common component of naturopathic practice is the extemporaneous compounding of herbs, generally in aqueous alcohol extracts, to individual patients for therapeutic purposes (Lin et al., 2005: 2). For the purposes of this submission, the terms ‘naturopath’ and ‘naturopathy’ include those who practise all four therapeutic modalities, as well as those who identify as a ‘herbalist’ and practise the single therapeutic modality of Western herbal medicine.

8. The WHO Global Report on Traditional and Complementary Medicine 2019 includes the following definitions: Traditional medicine Traditional medicine has a long history. It is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness; Complementary medicine The terms “complementary medicine” and “alternative medicine” refer to a broad set of health care practices that are not part of that country’s own traditional or conventional medicine and are not fully integrated into the dominant health care system. They are used interchangeably with traditional medicine in some countries; Traditional and complementary medicine T&CM merges the terms TM and CM, encompassing products, practices and practitioners (WHO, 2019: 8).

The naturopathic workforce

We cannot be certain how many naturopaths are practising in Australia since, unlike the registered health professions, there is no routine collection of annual workforce data. However, we do know that naturopathy is the largest and most widely practised of the registered and non-registered T&CM professions in Australia.

Attachment 3 provides a summary of the findings from a systematic review of studies of the naturopathic workforce (Steel et al., 2022). Extrapolating from data published by Leach (2013) and data available from the Practitioner Research and Collaboration Initiative (PRACI)[9] operating out of the Australian Research Centre in Complementary and Integrative Medicine at the University of Technology Sydney, we estimate the size of the naturopathy workforce to be around 15,000 practitioners, of whom approximately 14,000 identify as naturopaths (9,000 of these as a naturopath only) and 6,000 as herbalists (1,000 of these as a herbalist only). Approximately one-third (5,000) of the total naturopathy workforce identifies as both a naturopath and a herbalist.

Most naturopaths are in independent private practice (Steel et al., 2020). Naturopaths are found in city and country areas, in large and small towns, in rural and remote locations (Steel et al. 2017; Wardle et al., 2011), practising in solo, group and integrative medicine practices (Steel et al., 2020).

Naturopathic patients and their health conditions

Naturopaths treat patients with a wide range of health conditions both as primary care practitioners and in collaboration with other healthcare providers (Lloyd et al., 2021: 89). Attachment 4 provides a summary of key findings from a systematic review of studies of the patients who use the services of naturopaths (Steel et al., 2022).

While over 70% of naturopathic patients present with chronic conditions, naturopaths also treat patients with acute conditions and provide preventive and palliative care – see Table 3 for the proportion of patients with a nationally-significant health condition who consult a naturopath for that condition (Steel et al., 2022).

A typical naturopathic consultation will generally involve the prescription, recommendation or use of an average of four different categories of naturopathic treatments, therapies, or practices (Lloyd et al., 2021: 386).

9. Launched in 2015, PRACI is the largest known practice-based research network for complementary healthcare in the world. It is a multi-modality practice-based research network of more than 1000 members representing fourteen complementary medicine professions across Australia, over one-quarter of whom identify as naturopaths and Western herbalists (Steel et al. 2017; Steel at al., 2020).

TABLE 3: Proportion of patients who consulted a naturopath or herbalist for management of a specific health condition, by health condition (n=2488)

Health condition	Proportion of patients who consulted a naturopath or herbalist seeking treatment or care for the specified health condition		
	Naturopath (%)	*Herbalist (n, %)*	*Either naturopath or herbalist (n, %)*
Non-insulin dependant diabetes mellitus	7.7%	7.1%	10.0%
Malignant cancer	15.8%	13.0%	19.2%
Heart disease	21.4%	6.7%	23.5%
High blood pressure	11.8%	5.6%	8.7%
High cholesterol	10.0%	15.4%	20.0%
Autommune condition	12.5%	20.%	22.2%
Osteoarthritis	33.3%	0.0%	25.0%
Asthma	5.9%	5.3%	8.3%
Endometriosis	14.3%	28.6%	33.3%
Polycystic ovarian syndrome	33.3%	14.3%	25.0%
Anxiety	17.9%	7.7%	18.9%
Mood disorder	16.7%	9.5%	13.6%
Sleep disorder	19.1%	8.7%	20.0%

Number and cost of naturopathic consultations

Various studies have estimated the number and cost of naturopathic consultations each year. More recent research indicates that there are **4 million** visits to naturopaths annually (ANC 2021: 6; McIntyre et al., 2019). In 2007 it was estimated that Australians made around five million visits to naturopaths and three million visits to WHM practitioners every year (Xue et al., 2007). It was also estimated that around 11 per cent of 45-50 year old Australian women consult with a naturopath or herbalist (Adams, Sibbritt & Young, 2007), with this rising to around 16% for those with complex conditions such as cancer (Adams, Sibbritt & Young, 2005). A strong focus of naturopathic treatment is on prevention of disease, promoting health and wellbeing through maintenance of a healthy lifestyle (Lloyd et al., 2021: viii) as well as active treatment prescriptions such as herbal medicine.

More recent survey data suggests that the demand for naturopathy services has remained steady in recent decades (McIntyre et al., 2019; MacLennan et al., 2006; MacLennan et al., 2002). Each year, it is estimated that **6-8% of Australians** make the choice to use the services of a naturopath to help manage their health (McIntyre et al., 2019), often in parallel with other conventional medical and health services (Adams et al., 2003; Lin et al., 2005: 236; Carlton et al., forthcoming).

Out-of-pocket expenses reportedly average between $50 and $100 per patient per annum (McIntyre et al., 2019). With a conservatively estimated 4 million naturopathic consultations annually (ANC 2021: 6; McIntyre et al., 2019), the out-of-pocket expenses for Australians may be as high as $400 million.

3. BACKGROUND TO THE AHMAC REGULATORY ASSESSMENT CRITERIA AND PROCESS

The regulatory assessment policy framework

The policy framework governing government assessments of the need for statutory registration of the non-registered health professions is set out in three key documents.

First, the *Intergovernmental Agreement for a National Registration and Accreditation Scheme for the health professions* (the NRAS IGA), signed in 2008 by Australian state, territory and Commonwealth Governments committed all governments to the establishment of NRAS. The NRAS was established for 14 professions in 2010-12 and the scheme was expanded in 2016 to include the profession of paramedicine and regulate midwifery as a separate profession (making 16 regulated health professions encompassing 24 health occupations, regulated by 15 National Boards).

Attachment B of the NRAS IGA sets out the arrangements for inclusion of other health professions in the National Scheme and adopts the AHMAC criteria for regulatory assessment that were first agreed upon in 1995 – see Textbox 1.

TEXTBOX 1: The AHMAC criteria

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?
2. Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
3. Do existing regulatory or other mechanisms fail to address health and safety issues?
4. Is regulation possible to implement for the occupation in question?
5. Is regulation practical to implement for the occupation in question?
6. Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

Sources: AHMAC, 1995; COAG, 2008; AHMAC, 2018

The NRAS IGA references two 'guiding principles in developing these criteria':

> (a) the sole purpose of registration is to protect the public interest; and
> (b) the purpose of registration is not to protect the interests of health occupations.

Second, in 2018 AHMAC published a document titled *AHMAC information on regulatory assessment criteria and process for adding new professions to the National Registration and Accreditation Scheme for the health professions* (the AHMAC Guidance).

The AHMAC Guidance outlines the process to be followed by the NRAS Ministerial Council (comprising all state, territory and Commonwealth Health Ministers) when deciding whether to extend the scope of the NRAS to include a non-registered health profession. The document sets out:

- → how the NRAS Ministerial Council (formerly known as the COAG Health Council or CHC) considers submissions
- → details of the six 'threshold criteria' from the NRAS IGA that a profession must meet in order to be considered for regulation under the NRAS, and
- → a two-stage assessment process which includes assessment against the six AHMAC criteria as well as a regulatory impact assessment (RIA).

The AHMAC Guidance notes that statutory registration is one of a number of types of regulation governing health workers in Australia and can be restrictive and costly compared with other forms of regulation that may provide similar benefits at lower cost to the community (AHMAC, 2018: 5). These other forms of regulation include:

- → self-regulation
- → negative licensing
- → protection of title
- → credentialing
- → various forms of co-regulation (AHMAC, 2018: 5)

Attachment 5 provides a description of these types of occupational regulation.

Third, in 2021, an updated guidance on the Regulatory Impact Assessment (RIA) process was published on the website of the Australian Government Department of Prime Minister and Cabinet's Office of Best Practice Regulation (OBPR) in a document titled *Regulatory impact analysis guide for Ministers' meetings and national standard setting bodies* (2021).

The regulatory assessment process

The AHMAC criteria have not changed since they were first agreed upon in 1995 (AHMAC, 1995; COAG, 2008; AHMAC, 2018). The key change is in the assessment process, which has been revised to include a further hurdle – that an RIA be done that complies with the requirements set out in the OBPR publication outlined above (OBPR, 2021).

We understand that while decisions to extend statutory registration to a non-registered health profession are subject to national agreement, there are circumstances where a state or territory government may choose to 'go it alone' and regulate a health profession outside of the NRAS, with or without securing the prior agreement or blessing of the NRAS Ministerial Council. An example has occurred recently with the passage through the South Australian Parliament of legislation to establish a registration scheme in that state for the profession of Social Work[10].

10. See the Social Workers Registration Act 2021 (SA) at: https://www.legislation.sa.gov.au/__legislation/lz/v/a/2021/social%20workers%20registration%20act%202021_56/2021.56.un.pdf

4. COMMON MYTHS ABOUT NATUROPATHS AND NATUROPATHIC PRACTICE

Before presenting this assessment of the naturopathic profession against the AHMAC criteria, we consider it important to articulate and challenge some of the myths that surround naturopathy and shape the experiences of the profession in its dealings with government, health service providers and the wider community. These myths are often reflected in deeply held beliefs of decision-makers, bureaucrats and many of our health service colleagues.

We are firmly of the view that these myths must be dispelled, to provide the best opportunity for regulatory policy decisions to be fair and evidence-informed.

Myth No.1: Naturopathy is a fringe health care practice that is not widely used by Australian consumers

Naturopathy is not a fringe health care practice. It has a long history of practice in Australia (Jacka, 1998) and is widely used by a sizeable segment of the Australian population.

We estimate that approximately **6-8% of the Australian population use naturopathy annually** (MacLennan et al., 2002; Lin et al., 2005; MacLennan et al., 2006; McIntyre et al., 2019). This means in any year, there are an estimated **4 million consultations** with naturopaths and herbalists.

As outlined earlier, we estimate the size of the naturopathic profession to be approximately **15,000 practitioners**. This is larger than six of the 16 NRAS regulated health professions.[11] It is more than twice the size of the optometry and podiatry professions and larger than the professions of Chinese medicine, chiropractic and osteopathy combined.

Naturopaths are found practising across Australia, in **urban and rural areas**, and in solo, group and integrative practices (Steel et al., 2017; Steel et al. 2020; Wardle et al., 2011; Carlton et al., forthcoming)

Myth No.2: Naturopathic practice is low risk – naturopathic medicines are natural and therefore safe

Any healthcare discipline that uses ingestive therapies carries a heightened risk for patients. Herbal medicines and nutritional supplements are pharmacologically active agents that have the capacity to change physiological function and therefore, can have adverse effects (Lin et al., 2005: 37). Like pharmaceutical drugs, herbal medicines can have both predictable and idiosyncratic adverse reactions. The potential for herb/herb, herb/pharmaceutical drug and herb/food interactions heighten these risks.

Some herbal medicines are considered to be sufficiently toxic to justify restricting their use only to suitably qualified practitioners. This is achieved when herbs are 'scheduled', that is, they are included in *The Poisons Standard* (the Standard for the Uniform Scheduling of Medicines and Poisons – the SUSMP), sometimes because of a substance the herb contains.

11. The Ahpra/National Boards Annual Report 2020-21 reported the following number of registrants Australia-wide: 829 ATSI health practitioners; 4,863 registered Chinese medicine practitioners; 5,968 registered chiropractors; 6,288 registered optometrists; 2,951 registered osteopaths and 5,783 registered podiatrists.

Some naturopathic medicines have been scheduled (see Attachment 6), an indicator of the risks associated with their use or misuse.

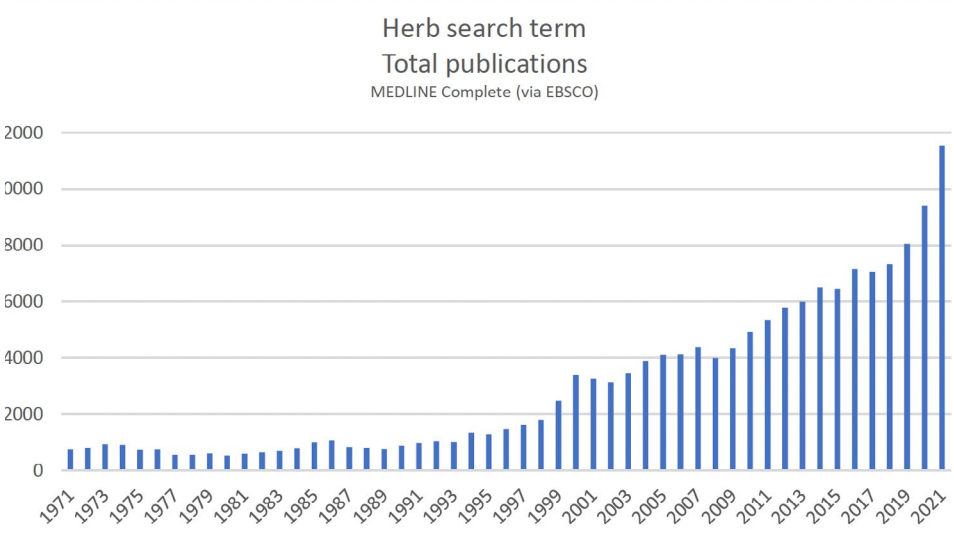
To maximise the therapeutic benefits and mitigate the risks, medicines should be prescribed, compounded and dispensed to patients by properly qualified practitioners. This is the same for herbal and nutritional medicines. Currently, Chinese herbalists are regulated by the Chinese Medicine Board of Australia under the NRAS, due to the potential harm associated with Chinese herbal medicine. Chinese herbal medicine generally relies on the preparation of herbs under aqueous extraction, with many boiled in water. Western herbal medicine generally relies on ethanolic extraction of herbal medicines which have significantly greater toxicity than aqueous extraction (Gafner et al., 2004; Parekh et al., 2005; Zdanowski et al., 2014), thereby increasing the risk profile of the naturopathic profession.

Myth No. 3: Naturopathic practice is not evidence based – there is no scientific evidence that naturopathy is effective, and any reported benefits of naturopathic medicine are most likely due to the placebo effect

In recent decades, there has been an exponential growth in research into naturopathic practices and products and the research base for naturopathic practice is extensive in scope and scale (Lloyd et al., 2021; Myers & Vigar, 2019; Lin et al., 2005; Carlton et al., forthcoming).

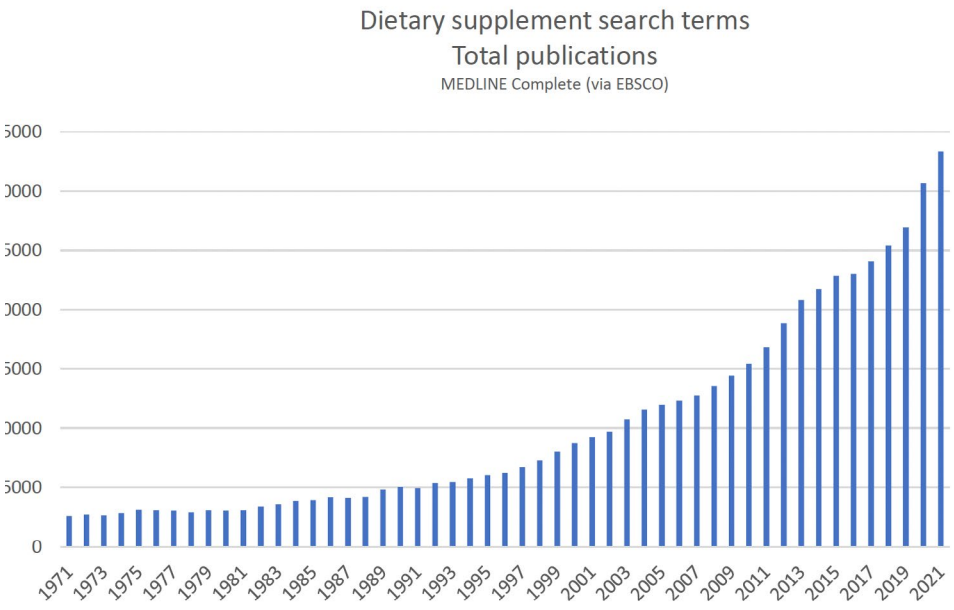
To illustrate, the ANC research report includes a bibliometric analysis of research publications published over a 50-year period between 1971 and 2021. We found that citations for 'herbal medicine' as a subject from a single database (Ovid MEDLINE) increased by more than 15 times – from 738 citations in 1971 to 11,535 in 2021 (see Figure 1).

FIGURE 1: Results of bibliometric analysis of 'herbal medicine' search term



During the same period, citations for dietary supplements increased nearly 13 times – from 2,624 citations in 1971 to 33,387 in 2021. This published research covered a range of subject areas including anti-bacterial agents, anti-coagulants, antioxidants, anti-inflammatories, bone density, COVID-19, gastrointestinal microbiome, osteoporosis, and vitamin and mineral deficiencies (Carlton et al., forthcoming) (see Figure 2).

FIGURE 2: Results of bibliometric analysis of 'dietary supplement' search term



Not only have we witnessed exponential growth in the volume of research conducted on naturopathic practices and products, but the quality of research has also changed in line with the maturing of the profession and the growth of its research capability. For example, we found not a single systematic review or meta-analysis citation related to 'herbal medicine' as a subject in PubMed prior to 1991. However, since 1991, this type of research has steadily grown, with 496 systematic reviews published in the year 2021. Similar growth rates are also seen for randomised controlled trials for 'herbal medicine' and 'dietary supplement' and systematic reviews for 'dietary supplement' (Carlton et al., forthcoming) (see Figures 3 and 4).

FIGURE 3: Results of bibliometric analysis of systematic reviews and randomised controls trials using 'herbal medicine' search term.

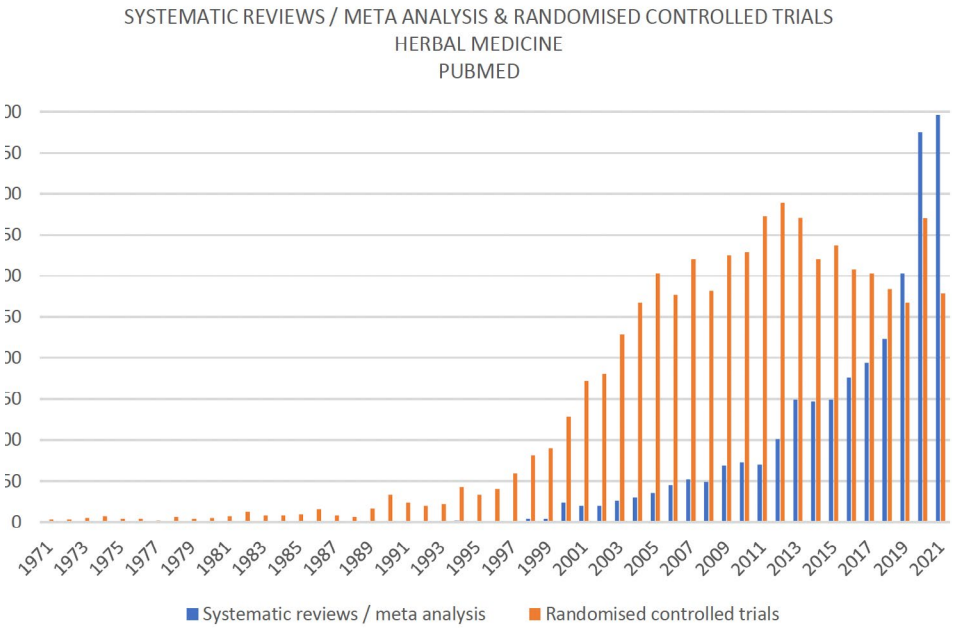
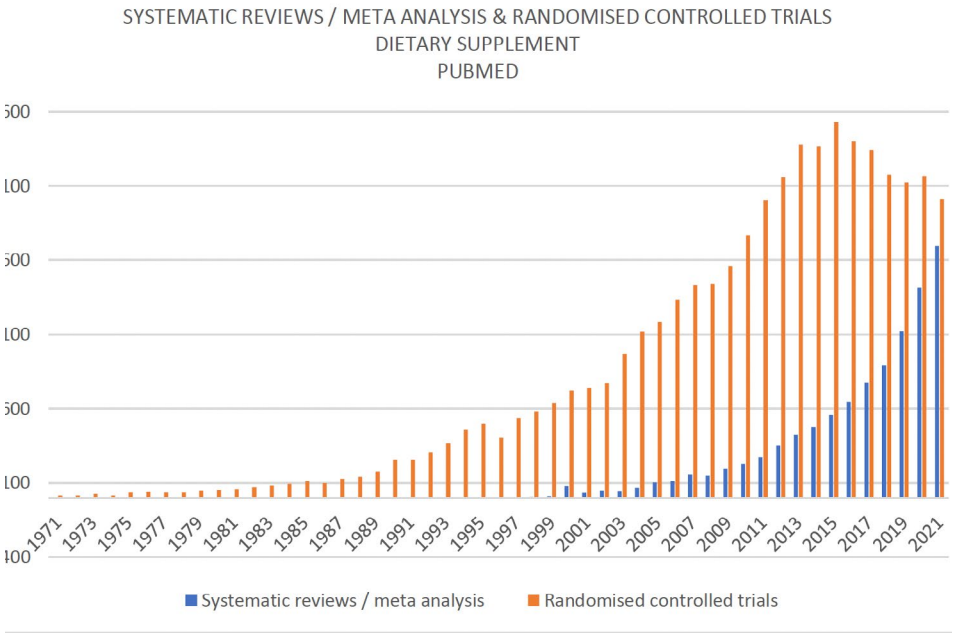


FIGURE 4: Results of bibliometric analysis of systematic reviews and randomised controls trials using 'dietary supplement' search term.



The WNF health technology assessment found that:

- → since 1987, naturopathic researchers have published over 2,200 peer-reviewed articles, 81% of these published since 2008 (Lloyd et al., 2021: 131)
- → many of these articles were published in highly ranked journals (Lloyd et al., 2021: 135-6)
- → naturopathic researchers conducted clinical research in over 80 different illness populations and overall showed a positive outcome in 81% of studies (Lloyd et al., 2021: 140)
- → Australian naturopathic researchers punched well above their weight internationally, producing almost 30% of this research output (Lloyd et al., 2021: 132).

Only one in ten publications explicitly mentioned the term 'naturopathy' and the researchers concluded that this may be contributing to the misbelief that naturopathic practice is not evidence-based (Lloyd et al., 2021: 137).

Clinical naturopaths also have demonstrated a strong commitment to evidence-based clinical practice, with more than 80% of surveyed naturopaths reporting they use research from scientific journals to guide practice 'always', 'most of the time' or 'about half the time' (Steel et al., 2021).

Myth No.4: Those who choose to see a naturopath or use naturopathic medicine are either ill-informed, misled or lacking in suitable alternatives

This is a common charge levelled at those who choose T&CM and underestimates the agency and health literacy of Australian health consumers. Successive research studies have found that consumers choose these therapies for a range of reasons, often because they have a chronic health condition that has failed to respond to conventional medicine (Foley et al., 2020a; Foley et al., 2020b; Carlton et al., forthcoming).

Earlier studies found that the most common demographic using T&CM including naturopathy were middle class, well-educated women (Bensoussan & Myers, 1995; Lin et al., 2005; MacLennan et al., 2006).

More recently, Foley and colleagues found that the most prevalent users were those between 18 and 29 years of age (39.3%), in a relationship (51%), employed (70%), and held a bachelor's degree or higher (40.5%) (2020a). Similarly, McIntyre & colleagues found that individuals who consult naturopaths are generally 18 to 29 years, more highly educated and are more likely to be employed than the general population (McIntyre et al., 2019). Studies also suggest that patients are often more satisfied with the services they received from their naturopath than they are with services from their GP (Foley et al, 2020b).

It is not surprising that the naturopathic patient profile is skewed towards those from higher socio-economic groups – naturopathic services are currently not reimbursable under either public or private health insurance which disadvantages those on lower incomes.

Myth No. 5: Most naturopaths have little interaction with conventional healthcare professionals and there is little cross-referral of patients

While there is little recent research that quantifies the extent of cross-referral between naturopaths and other medical and allied health practitioners, data collected as part of the ANC study suggests cross-referral is occurring on a routine basis, both to and from naturopaths (Carlton et al., forthcoming).

A practitioner survey of naturopaths and Western herbalists (Casey et al., 2008) found almost all respondents (99%) referred patients to other health care professionals, 93% reporting that they regularly referred patients to medical practitioners. Common reasons for referral were for pathology testing, treatment or prescription, medical diagnosis and confirmation of medical diagnosis, and treatment of acute infectious diseases. Approximately half the 649 respondents reported receiving referrals from medical practitioners and almost 97% of practitioners indicated that they would like to see closer collaboration and cooperation with the medical community.

As naturopathy is not a regulated profession, referral from members of the medical community places an onus on the referring doctor to satisfy themselves that the naturopathic practitioner practises in a safe, competent, and ethical manner. This is perceived as a limiting factor on the extent of inter-professional communication. Researchers have found that GPs and other conventional health practitioners express reluctance to refer to naturopaths and other complementary therapy practitioners because of fear of liability if something goes wrong (Cohen et al., 2005). However, GPs are more likely to refer patients to a naturopath if they believe in the efficacy of or have seen positive results from naturopathy (Wardle, Sibbritt & Adams, 2014).

Anecdotally, we know of repeated efforts by naturopaths to engage collegially with their medical and allied health colleagues and the frustration they experience when they are declined entry or not invited to participate in service provider networks, association forums and other collegiate inter-disciplinary networks (Carlton et al., forthcoming).

Myth No.6: Naturopathic services are safe because naturopaths are regulated in the same way as other health professionals

Many consumers believe complementary medicines are safe and do not interfere with conventional treatment (Foley et al., 2019). However, extensive studies of adverse events associated with the use of naturopathic medicines contradict this view (Myers & Cheras 2004; WNF, 2021: 71-8).

Naturopaths also report that patients often express surprise when they learn that naturopathy is not a registered profession and naturopaths are not subject to the same quality controls and regulations as other regulated health professions (Carlton et al., forthcoming). This is consistent with the findings from a consumer survey of T&CM practices which found that respondents believed such practices, including naturopathy, should be regulated like pharmaceutical drugs, where a consultation with a qualified practitioner is required before medicines are purchased (Evans et al., 2008).

Naturopaths are not regulated in the same way as other health professions that use ingestive therapies. One of the consequences is they are denied access to some important tools of their trade that are restricted under the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) (The Poisons List). It is a perverse outcome of our regulatory system that medical practitioners, who have no training in the safe and competent use of herbal medicines, are legally authorised and able to prescribe scheduled herbal medicines while naturopaths who are properly trained in the safe use and contraindications of these herbal medicines are not.

Myth No.7: Registration of naturopaths will afford undue recognition and status to practices that are unscientific and unproven

This type of objection was raised (and dismissed as immaterial) during the policy deliberations that preceded the decision of the Victorian Government to introduce statutory registration for the Chinese medicine profession in that state (Department of Human Services, 1998: 18).

The two guiding principles agreed by AHMAC in 1995 and reiterated by COAG in 2008 provide clear guidance for policy decision-making – *that the sole purpose of registration is to protect the public interest and that the purpose of registration is not to protect the interests of health occupations* (AHMAC, 1995: 1). Under the NRAS, the main guiding principle is that protection of the public and public confidence in the safety of services is paramount.[12]

Of central concern is not whether registration will or will not improve the status of the profession but rather, whether the risks (and costs) of unregulated practice are of such magnitude that statutory registration is warranted. The RIA process reinforces this policy principle – it requires careful problem definition, specification of government objectives, risk assessment, stakeholder mapping and engagement, framing of feasible options and weighing of the costs and benefits of each option (including no change) and on whom these costs and benefits fall (OBPR, 2021).

There is nothing in the AHMAC criteria to suggest that the differential impacts of one or other type of occupational regulation, whether real or speculative (such as increasing the legitimacy or status of a profession) is or should be a determinative factor in decision-making. Rather, the key concern appears to be finding the best, most cost-effective way to safeguard members of the public who choose to use a particular type of practitioner or treatment modality.

12. See recent amendments to the Health Practitioner Regulation National Law at https://documents.parliament.qld.gov.au/com/HEC-B5E1/HPRNLOLAB2-5F6C/submissions/00000037.pdf

Myth No. 8: The naturopathy profession will not be 'ready' for registration until it has achieved national consensus on entry-to-practice qualifications and practice standards

The Australian Register of Naturopaths and Herbalists (ARONAH) has developed course accreditation, practice and continuing competency standards but has no effective means to enforce these (ARONAH, 2021). However, several forces combine to make it virtually impossible for the naturopathy profession to reach a consensus on and then implement degree level training for entry-to-practise as a naturopath.

These forces include: a deregulated education market with multiple private providers; fragmented representative arrangements with multiple professional associations that compete for members, with some prepared to accept qualifications at less than degree level to attract members; and insufficient incentives for education providers to upgrade their courses.

A similar dynamic was evident when the Victorian Government took the decision to introduce statutory registration for the Chinese medicine profession (Department of Human Services, 1998: 10, 20):

> *Despite over 20 years of efforts, the TCM profession has been unable to establish a self-regulatory system that has the wide support of the majority of groups within the profession. There is no reason to believe that efforts at self-regulation will be any more successful in the future (Department of Human Services, 1998: 20).*

This issue has a long and complex history.

In 2003 the Expert Committee on Complementary Medicines recommended strengthening of practitioner education and training and independent accreditation of courses (2003: 24).

In 2013, government education authorities took the decision to remove naturopathic and WHM diploma and advanced diploma qualifications from the Health Training Package and cease delivery of these programs within the Vocational Education and Training (VET) sector (Australian Government, 2013).[13] Teachout of non-degree level programs was expected to be completed by 2018. The policy rationale for this decision was that degree level was the appropriate standard for entry-to-practise in the naturopathy profession, given its scope of practice. However, in a deregulated education market, and with the withdrawal of naturopathy from the Private Health Insurance Rules, there are few incentives to enforce this policy position.

As a consequence, not only is there no pressure on providers to upgrade their offerings to degree level, there is evidence that providers are entering or re-entering the market to offer diploma-level and short courses in naturopathy and WHM. Competing for members, some professional associations have responded by continuing to recognise qualifications at less than degree level for membership purposes, qualifications that should have been phased out by 2018. Without the capacity to enforce degree level as the minimum qualification for entry-to-practice, we are now seeing further dilution of education standards (Carlton et al., forthcoming).

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13 See https://training.gov.au/training/details/hlt07 for notice of naturopathy and WHM advanced diploma qualification deletion from the Health Training Package.

Statutory registration guarantees uniform and enforceable minimum levels of entry-to-practice training (Bensoussan et al. 2004: 26; Baxter 2009: 27; Grace et al. 2007: 23; McCabe 2008: 174), something that has eluded the naturopathic profession for decades (Breakspear 2013: 170, 171; McCabe 2008: 174; Wardle et al. 2012: 369).

Myth No. 9: Most naturopaths don't see the benefits of registration and don't want naturopathy to be a nationally registered health profession.

Successive surveys of the profession have found consistent results – that a majority of the naturopathy profession is supportive of statutory registration for the profession. For instance, member and practitioner surveys conducted in Australia over the past ten years indicate that between 61.7% and 85.0% of respondents are in favour of statutory registration, and between 3.3% and 22.6% are not (Barnes 2021; Braun et al., 2013; Steel et al., 2020). This suggests solid support from the profession for statutory registration of naturopaths.

Myth No.10: Naturopathy and homeopathy are just different names for what is essentially the same practice.

Homoeopathy is a therapy that has its own history, philosophies, principles of practice and body of knowledge that are distinct from naturopathic practice. While there is some crossover, with some naturopaths also practising homoeopathy, this is not unique to the naturopathic profession. For instance, a 2022 study of health service use in Australia found that 3.9% of Australians use homeopathy, and of those more than half (51.2%) report being prescribed or recommended a homeopathic remedy by a medical doctor (i.e., general practitioner, specialist doctor or hospital doctor) (Steel et al., 2022).

Myth No.11: Naturopaths are operating on a level playing field.

There are significant structural, institutional, funding and attitudinal barriers to the full participation of naturopaths in the Australian healthcare system.

A systematic review of the global literature on health practitioner regulation undertaken in 2021-22 points to continuing interest in and use of T&CM by consumers around the world, including in Australia (Lin et al., 2022). However, studies suggest that government policy in many countries is lagging.

Researchers found that T&CM practitioners from established occupations such as naturopathy continue to struggle for institutional recognition of their practice and to engage collaboratively with other primary care practitioners (Lin et al., 2022). Much of the literature highlights the underlying power relations and epistemic tensions between professional groups that adversely impact the position and role of T&CM practitioners in the health system (Lin et al., 2022). Despite approximately 4 million consultations annually, naturopaths are not considered part of the Australian healthcare workforce and their contribution to health of the Australian community health goes largely unrecognised – for instance there is no mention of naturopaths in Australian Health 2018 (Australian Institute of Health and Welfare, 2018).

In some jurisdictions, registration laws are used to restrict T&CM practitioner scopes of practice and prevent access to their tools of trade (herbal medicines) (Lin et al., 2022). However, many jurisdictions, licensing/registration schemes have been enacted and in a few jurisdictions, legislators have enacted provisions to protect registered practitioners from disciplinary action where they practise a therapy that departs from prevailing medical practice[14].

Researchers point to the benefits of statutory registration for these established T&CM professions, to prevent the untrained and unqualified from entering practice (Lin & Gillick, 2011; Lin et al., 2022).

14. See for example, section 25.4 of British Columbia's Health Professions Act which states “The college must not act against a registrant or an applicant for registration solely on the basis that the person practises a therapy that departs from prevailing medical practice unless it can be demonstrated that the therapy poses a greater risk to patient health or safety than does prevailing medical practice.”

5. ASSESSMENT AGAINST THE AHMAC CRITERIA

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

Naturopathy is a health profession – the services provided by naturopaths fall within the statutory definitions of a 'health service' that are contained in health complaints legislation in each state and territory; consumer complaints about naturopaths are handled by health complaints commissioners in each state and territory.

Responsibility for policy decisions concerning occupational regulation of the profession of naturopathy properly sits under the health portfolio, with state, territory and Commonwealth Health Ministers. There are no other ministerial portfolios at either state/territory or Commonwealth level that have greater responsibility for regulation of naturopaths:

- → Naturopaths deliver health care services to the Australian public. Consumers seek the services of naturopaths as primary contact practitioners, for health advice, both for therapeutic purposes and for the maintenance of health and well-being.
- → Consumer use of naturopathic services in parallel with conventional medicine is well established in all age groups. This dual usage can continue over a prolonged time because many users are treated for chronic illnesses or are using naturopathy products to deal with the effects of other medical treatments for serious health conditions (Lin et al., 2005: 290).
- → Naturopathic medicines and other products are governed by a suite of laws that sit within the portfolios of state, territory and Commonwealth Health Ministers. These include therapeutic goods and medicines laws, health complaints laws and infection control standards under public health legislation.
- → Although the advertising and sale of naturopathic medicines and products are covered under fair trading and trade practices legislation, this is the same for the products and services provided by other regulated health practitioners.

Conclusion regarding Criterion 1:

It is **appropriate for Health Ministers to exercise responsibility** for regulating naturopathic practitioners and naturopathic practice. Naturopathy is a health profession and falls clearly within the scope of the health portfolio. It does not 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?

Naturopaths are primary care practitioners who work autonomously, principally in solo or group private practices (Steel et al., 2020). The practise of naturopathy is broad in scope and presents a range of risks of varying significance. These risks can be categorised as follows:

- → risks associated with the treatments used by naturopaths
- → risks associated with the scope of practice of naturopaths
- → risks associated with the practice context.

2.1 High-risk activities of naturopaths compared with NRAS regulated professions

There are various frameworks for assessing risk, including some developed specifically to assess the occupational regulation requirements for health professions (Professional Standards Authority 2016; AHMAC 2013; COAG Health Council 2015) One such framework has been applied in several AHMAC and COAG Health Council reports (AHMAC, 2013; COAG Health Council, 2015).

These reports include a risk assessment tool – a list of 13 'high-risk activities' against which regulated and unregulated health professions are rated and compared. The tool identifies whether or not these high-risk activities are part of the usual scope of practice of each profession. Table 4 presents this risk assessment tool, modifying it to include a 14th 'high risk activity' (frequent treatment or care of patients from vulnerable groups). The profession of naturopathy is rated and compared with the 16 health professions that are already regulated under the NRAS.

Of the 14 high-risk activities listed in Table 4, the scope of practice for naturopaths typically includes at least nine (9) of these activities. This is a high number, compared with most regulated health professions, which range between three (optometrists, pharmacists and psychologists) and 14 (medical practitioners). Only five regulated professions have a higher risk rating than naturopaths. They are medical practice (14), nursing and midwifery (11), paramedicine (10) and Chinese medicine (10).

Below is a description of the nine high-risk activities that are part of the usual scope of practice of the naturopathy profession.

High-risk activity No. 1: Putting an instrument, hand or finger into a body cavity

Naturopaths are trained to use an otoscope and tongue depressor to assist in physical examination of a patient and diagnosis of conditions involving infections, abscesses etc.

High-risk activity No. 4: Procedures below the dermis, mucous membrane, in or below surface of cornea or teeth

Naturopaths often employ diagnostic tests that require drawing blood from the patient using sub-dermal lancets (i.e. 'skin pricks'). These are commonly undertaken on site during the clinical encounter. They require the naturopath to have a sound and up to date understanding of infection prevention and control procedures to minimise the risk of spreading infectious diseases.

High-risk activity No. 5: Prescribing a scheduled drug, supplying a scheduled drug (includes compounding), supervising that part of a pharmacy that dispenses scheduled drugs

Under Australian drugs and poisons laws, naturopaths are not currently authorised to prescribe scheduled medicines, even when these are in herbal form, appear in pharmacopoeias around the world and are part of the usual scope of practice of naturopaths in other countries.

However, naturopaths routinely prescribe orally administered herbs and nutrients (Casey et al., 2007). There are a wide range of products that are considered the 'tools of the trade' for the typical scope of practice of naturopaths. A good proportion of these are extemporaneously dispensed for an individual patient; that is, they are compounded onsite at the naturopathic clinic, for example herbal tinctures or powdered products that are mixed into a unique formula to address the health needs of an individual patient.

Also, many products prescribed by naturopaths are classed as 'practitioner only products', that is, products that are listed or registered on the Australian Register of Therapeutic Goods. Labelling and supplying products as 'practitioner only' allows the product company to make stronger claims of health effects than those products supplied solely for retail purchase. Naturopaths supplying practitioner only products to patients can apply to certain professional associations that have been approved by the Australian Government Department of Health and Aged Care's Therapeutic Goods Administration (TGA) for a TGA Advertising Certification of Exemption. This certificate is recognised by herbal medicine wholesalers and enables the naturopath to access to practitioner only products under the assumption that the clinician is appropriately qualified to make sense of the material and draw on their more advanced training to determine safe and appropriate application of the product. It is important to note, however, that 'practitioner only' products do not exist as a category under the Therapeutic Goods Act 1989 as amended and has no legal basis (Expert Committee on Complementary Medicines in the Health System, 2003).

High-risk activity No. 7: Supplying substances for ingestion

Naturopaths typically operate a dispensary from their clinic, supplying herbal medicines and nutritional medicines to patients. Between 69% and 79% of naturopaths report often prescribing liquid herbal medicines (usually aqueous ethanolic extracts), nutritional supplements and/or herbal tablets in clinical practice (Steel et al., 2020). Researchers report that over 97% of naturopathy and Western herbal medicine practitioners operate a dispensary and over 96% of these practitioners compound individual and multi-herbal formulae for patients (Casey et al., 2007).

High-risk activity No. 8: Managing labour or delivering a baby

While management of labour is not part of the usual naturopathy scope of practice, naturopaths, particularly those who practise WHM frequently consult with women who are seeking advice pre-conception, during pregnancy and to induce labour. There is also evidence that Australian pregnant women who report preparing for labour are twice as likely to consult a naturopath compared with women who do not prepare for labour (Steel et al., 2014). Towards the end of pregnancy, naturopaths prescribe treatments to facilitate labour and childbirth and help prevent unnecessary interventions (Steel & Martin, 2019: 722). These treatments are typically administered as teas to prepare the woman for delivery and to facilitate labour, by modulating the frequency of uterine contractions.

High-risk activity No. 11: Primary care practitioners who see patients with or without a referral from a registered practitioner

Naturopaths provide primary care consultations, with or without a referral from a medical practitioner or other registered health practitioner. They provide naturopathic care to around 6-8% of the Australian population (McIntyre et al., 2019; Steel et al., 2018), representing around four million consultations each year (McIntyre et al., 2019). An estimated 2 million Australians see a naturopath at least annually, of whom 60% consider their naturopath to be their primary health provider, and 22% consult a naturopath as their sole health care provider (Wardle et al., 2019).

The rate of use of naturopathic services in the Australian community appears to have remained relatively stable for the past 25 years (MacLennan et al., 2002; MacLennan et al., 2006; Steel et al., 2018). These findings confirm the enduring presence of naturopathy and naturopaths in the Australian healthcare system as primary care clinicians.

High-risk activity No. 12: Treatment commonly occurs without others present.

Naturopaths mainly operate from a private practice and most practise autonomously. A survey of practitioners found that 72.5% of 280 naturopaths reportedly worked in solo clinical practice (Steel et al., 2020). For practitioners who share a clinic location with other health practitioners, the vast majority would still conduct private consultations with patients.

High-risk activity No. 13: Patients commonly required to disrobe.

Naturopathy is an eclectic therapeutic practice that incorporates many different treatment modalities. Some naturopaths include manual therapies such as massage, dry needling, Bowen Therapy, myotherapy, Tui Na and moxibustion in their range of offerings. When offering these treatment modalities, patients are required to disrobe to enable physical examination and the application of manual therapy techniques.

High-risk activity No. 14: Frequently treat or care for patients from vulnerable groups

Naturopaths frequently treat patients from vulnerable groups, including pregnant and breastfeeding women, children, people with disabilities and chronic pain conditions, women with a history of sexual assault and or domestic violence, First Nations people, people from NESB, LBTQI+, elderly, frail and terminally ill patients (Steel et al., 2020).

	REGULATED															UNREGULATED	
	ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH	CHINESE MEDICINE	CHIROPRACTORS	DENTAL PRACTITIONERS	MEDICAL PRACTITIONERS	MEDICAL RADIATION	NURSES AND MIDWIVES	OPTOMETRISTS	OCCUPATIONAL THERAPISTS	OSTEOPATHS	PARAMEDICS	PHARMACISTS [v]	PHYSIOTHERAPISTS	PODIATRISTS	PSYCHOLOGISTS		NATUROPATHS
1. Putting an instrument, hand or finger into a body cavity [i]	X	X		X	X		X				X		X				X
2. Manipulation of the spine [ii]		X	X		X					X			X				
3. Application of a hazardous form of energy [iii] radiation				X	X	X	X		X				X				
4. Procedures below dermis, mucous membrane, in or below surface of cornea or teeth	X	X		X	X	X	X				X			X			X
5. Prescribing a scheduled drug (incl. compounding), supervising that part of a pharmacy that dispenses scheduled drugs	X	X		X	X		X	X			X	X		X			X
6. Administering a scheduled drug or substance by injection	X	X		X	X	X	X				X			X			
7. Supplying substances for ingestion	X	X			X		X				X	X					X
8. Managing labour or delivering a baby		X			X		X				X						X
9. Undertaking psychological interventions to treat serious disorders or with potential for harm					X		X				X				X		
10. Setting or casting a fracture of a bone or reducing dislocation of a joint					X												
11. Primary care practitioners who see patients with or without a referral from a registered practitioner	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
12. Treatment commonly occurs without others present [iv]	X	X	X		X	X	X	X	X	X	X		X	X	X		X
13. Patients commonly required to disrobe	X	X	X		X	X	X		X	X	X		X				X
14. Frequently treat or care for patients from highly vulnerable groups	X				X												X
TOTAL risk factors per profession	**9**	**10**	**4**	**6**	**14**	**6**	**11**	**3**	**4**	**4**	**10**	**3**	**6**	**5**	**3**		**9**

TABLE 4: Assessment of the NRAS professions and the naturopathy profession against 14 high risk activities or procedures

Notes on Table 4

i. Beyond the external ear canal, beyond the point in the nasal passages where they normally narrow, beyond the larynx, beyond the opening of the urethra, beyond the labia majora, beyond the anal verge, or into an artificial opening in the body.

ii. Moving the joints of the cervical spine beyond the individual's usual physiological range of motion using a high velocity, low amplitude thrust.

iii. Electricity for aversive conditioning, cardiac pacemaker therapy, cardioversion, defibrillation, electrocoagulation, electroconvulsive shock therapy, electromyography, fulguration, nerve conduction studies or transcutaneous cardiac pacing, low frequency electromagnetic waves/fields for magnetic resonance imaging and high frequency soundwaves for diagnostic ultrasound or lithotripsy.

iv. Includes practitioners who practise solo or treat with no others present, such as medical specialists and practitioners who may be solely responsible for clinical care overnight or in a remote community.

v. Paramedics included as per indicative assessment made in Final report: Options for regulation of paramedics (2016).

Source: Modified from AHMAC, 2015: 110-1.

This list of high-risk activities are part of the usual scope of practice of the naturopathic profession in Australia – with one exception. While prescribing a scheduled medicine is included here, there is currently no mechanism in Australian State or Territory drugs and poisons laws for naturopaths to be authorised to prescribe herbal medicines that have been scheduled in *The Poisons Standard* either as a whole herb or because of a substance the herb contains. Attachment 6 provides a list of herbs that are restricted and may only be prescribed by medical practitioners (Lin et al., 2005: 109). These herbs are listed in the British and US herbal pharmacopoeias and are typically used by naturopaths in countries where naturopathy is widely practised.

The literature provides extensive references on the risks associated with naturopathic practice (Lloyd et al., 2021; Weir, 2016; Lin et al., 2005; Carlton et al., forthcoming). An overview of these risks is set out in Table 5.

These are not just theoretical risks. Attachment 7 provides case examples of where these risks have been realised in practice in Australia.

TABLE 5: Overview of the main risks to public health and safety associated with naturopathic practice

RISKS ARISING FROM CONSUMPTION OF HERBAL AND NUTRITIONAL MEDICINES	
TYPE OF RISK	**DESCRIPTION**
Adverse reactions / interactions	Poor prescribing of treatments for the patient's condition. Failure to observe contraindications and consider known interactions between herbal medicines and pharmaceutical medicines. Failure to correctly investigate concurrent medication use of patients, consider the potential for interactions with medications or other naturopathic treatments e.g. use of *Glycyrrhizin* species in patients with hypertension. Lack of awareness/ attention to potential contraindications and appropriate dosage Failure to adequately monitor patient use of treatments for reactions (Wardle, 2008b; Wardle & Adams, 2014). Effects range from minor to severe. Mild adverse effects include allergic reactions, pain, burning sensation, constipation, dermatitis, diarrhoea, dizziness, drowsiness, fatigue, gastrointestinal upset, headache, sleep disorders nausea, and vomiting. More severe effects include blurred vision, confusion, dysphagia, severe nausea, EEG changes, loss of consciousness, acute lung injury renal failure, coagulation abnormalities, hepatitis, stroke, acute myocardial infarction, haemorrhage, circulatory failure, congestive heart failure, perforation of the gastrointestinal tract, seizures and epilepsy, and death (Posadzki et al., 2013).
Incorrect prescribing, incorrect treatment duration, or unnecessary testing	Prescribing insufficient doses/products or greater than necessary doses/products, inappropriate duration of treatment, or the unnecessary utilisation of diagnostic tests (Wardle & Adams 2014). Failure to adhere to prescribing guidelines for appropriate dosing for children, teenagers, and smaller / larger adults. Inadequate monitoring of liver/kidney function with prolonged use of some herbs. Inefficacy of treatment, overdosing or toxicity of treatment, inadequacy of treatment, testing with no/little patient benefit, financial harm. Statutory practice guidelines for testing, and scalable dosage prescriptions.

RISKS ASSOCIATED WITH THE CLINICAL JUDGEMENT OF THE PRACTITIONER	
TYPE OF RISK	**DESCRIPTION**
Missed or misdiagnosis	Failure to appropriately diagnose patient condition requiring referral to other health practitioner (Wardle, 2008). Poor case taking, inadequate knowledge of pathology or acknowledgement of limitations of practice, leading to inappropriate treatment rather referring to another practitioner. May lead to serious and potentially untreatable conditions or death that may have been cured or result in a better prognosis with earlier intervention.
False diagnosis	Diagnosing patients with non-existent pathologies (Wardle & Adams 2014). Taking advantage of information asymmetries to 'diagnose' and 'treat' fictitious or non-existent pathologies. Exposes patients to unnecessary treatment, stress and expense.
Advice to cease or delay conventional treatments	Informing patients to forego conventional treatment when commencing naturopathic treatment (Wardle, 2014: 357). Prescribing a herbal formula for conditions e.g. hypertension, and advising the patient to cease taking medically prescribed pharmaceuticals. Immediate withdrawal of pharmaceutical medications can be dangerous and can lead to rebound hypertension. Recommendation to avoid chemotherapy or other cancer treatments.
Delayed diagnosis	Failure to diagnose serious medical conditions or to recognise limitations of own practice skills and knowledge, and when to refer to other health practitioner (Wardle, 2008b; Wardle & Adams 2014). Condition incorrectly diagnosed and practitioner assumes treatment will be effective. Condition correctly diagnosed and practitioner assumes treatment will be effective. May lead to serious and potentially untreatable conditions or death that may have been cured or result in a better prognosis with earlier intervention.
Failure to refer on in a timely manner	Failure to know when to refer to other health practitioners, e.g. atypical myocardial infarction or cancer not detected or referred to medical practitioner. May lead to serious and potentially untreatable conditions or death that may have been prevented, cured or result in a better prognosis with earlier intervention.
Monopolisation of patient	Practitioners abusing their position of authority to monopolise patient care for financial gain. Informing patients that all their health needs can be satisfied by the practitioner and discouraging them from seeing their GP or other relevant health professional. Financial exploitation, risks of delayed diagnosis and treatment of serious conditions.
False consultations (by unqualified person purporting to be a naturopath)	Consumer mistakenly believes they received advice from a qualified naturopath (Wardle, 2008b). Consumer attends a private practice, a multidisciplinary clinic, pharmacy, or health food store seeking advice from an untrained or inadequately trained person. Consumers may be inappropriately advised to commence or cease treatment, take products that may interact with medication due to not taking an adequate history of the patient, may be prescribed products that are dangerous, or lack quality control in their manufacture, or be prescribed products that are contraindicated in pregnancy Serious herb-drug interactions may occur including concurrent use of anti-depressant medications and commonly used herbal products, potentially leading to serotonin syndrome leading to severe reactions and even death.

	Patients have become gravely ill or died from ceasing lifesaving medications, such as insulin or ceasing lifesaving medical therapies, such as kidney dialysis as advised by unqualified practitioners.
Undermining public health messaging	Failure of practitioner to follow public health guidelines in their assessment and treatment of patients. Giving patients contrary advice to that provided by health officials. Discouraging patients from vaccinating themselves, their children and families.
Creating an unreasonable expectation of beneficial treatment	Persisting with the use of naturopathic treatments for serious injuries or conditions despite lack of improvement and for which immediate conventional treatment is required (Makinnon, 2008).
Overservicing	Prescribing treatments for financial gain rather than patient need. Lack of separation between treatment prescription and product sale, as exists in conventional GP consultations, incentivises unscrupulous practitioners to overservice patients (Wardle, 2014).
Lack of informed consent	Failure of practitioner to adequately inform patients of the potential risks of or precautions associated with treatment (Lin et al., 2005: 33-34) (Wardle & Adams 2014). Failure of practitioner to fully inform patients of the risks of naturopathic prescriptions during chemotherapy to deal with adverse effects of conventional treatment. Inefficacy of conventional treatment where there may have been a reasonable expectation of remission.
Holding out as qualified practitioner	Use of the title doctor without appropriate qualifications (Wardle & Adams 2014) Professing to be a naturopath without adequate training. Inappropriate use of the title of doctor lends false legitimacy. Patient believes they are consulting with a qualified practitioner when they are not. Patient is of the mistaken belief that the practitioner is more qualified than they actually are and entrusts their health to a someone who is inadequately trained for the task potentially leading to adverse health outcomes.
Sexual misconduct, inappropriate relationship with patient	Sexual misconduct was the most common category of misconduct established against unregistered health practitioners. (Wardle, 2014: 361). This category includes inappropriate consensual relationships with patients as well as inappropriate, non-consensual sexual contact or harassment of a patient. Inappropriate questioning, touching or relationships with patients of a sexual nature with children or adults. Short and long term physical and psychological harm.
Inappropriate relationship with patient	Poor understanding of professional boundaries can lead to emotional, physical and fiscal harm through exploitation and manipulating power dynamics between clinician and patient.
Financial exploitation of patient	Consumers taken advantage of financially by unscrupulous practitioners (Wardle, 2008b; Wardle & Adams, 2014). Consumer is sold an inferior product/s with dubious efficacy, safety, or reliability. Consumer is overcharged for product/s and/or consultation or sold products/ services for financial gain rather than patient need. Financial harm, particularly in diagnoses such as cancer where patients may cling to false hopes of cure.

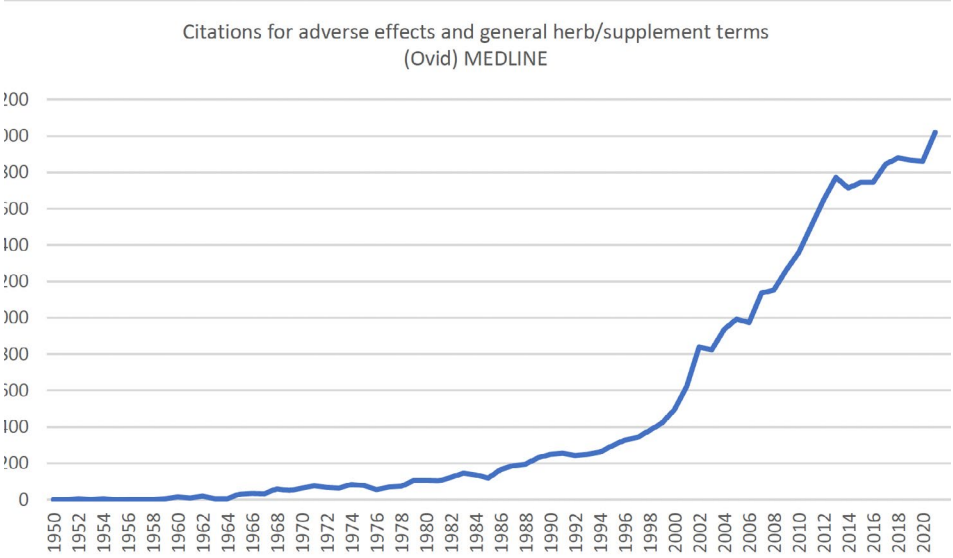
2.2 Risks associated with treatment modalities used by naturopaths

Risks associated with the treatment modalities used by naturopaths fall into two categories:

- → risks associated with the exercise of clinical judgement by the naturopath
- → risks that arise from the consumption of nutritional and herbal medicines.

Within the broader research community there is increasing focus on the adverse effects associated with herbal and nutritional products. The chart below shows the exponential growth in published research from a single database (Ovid MEDLINE) on adverse effects using general herb and supplement terms (see Figure 5) (Carlton et al., forthcoming).

FIGURE 5: Results of bibliometric analysis of adverse effects & 'herb'/'supplement' terms



Source: Carlton et al., forthcoming.

The findings of the Lin Report (2005: 30-34) are confirmed with updated data from key sources (Lloyd et al., 2021: 71-78; Carlton et al., forthcoming):

- → Cases of adverse events related to acts of commission (such as recommending cessation of medical treatment or failure to avoid known interactions with pharmaceuticals) and acts of omission (such as misdiagnosis and failure to refer on to an appropriate practitioner) have been reported in the literature and in the media. Although these events do not appear to be widespread, the COVID-19 pandemic has highlighted cases and the potentially serious consequences.
- → Like conventional pharmaceutical medicines, herbal medicines can produce predictable and unpredictable effects. Examples of both have been identified in the literature. Predictable effects include direct toxicity, toxicity related to overdose of a preparation, and interaction with pharmaceutical medicines. Unpredictable effects include allergic and anaphylactic reactions to herbal medicines, and idiosyncratic reactions (Colalto, 2012; WHO, 2004).
- → A number of herbs and supplements are known to cause toxic reactions and while severely toxic substances are restricted by current drugs and poisons legislation, several potentially toxic substances continue to be available to naturopaths for use in prescriptions (Asif, 2012; Brown, 2017; Brown, 2018; Posadzki et al., 2013).
- → Herbal medicines have potential to interact with pharmaceutical drugs (Gurley et al., 2012), and numerous cases of such herb-drug interactions have been reported (Myers & Cheras 2004; Izzo & Ernst, 2009).

The level of risk identified is likely to be an underestimate because:

- → there appears to be significant under-reporting to government agencies of adverse events associated with nutritional and herbal medicines, due in part to the lack of awareness of the appropriate avenues for such reporting
- → some practitioners are likely to be fearful that reporting adverse events may result in withdrawal of access to medicines
- → the ADRS database administered by the TGA is limited in its usefulness with respect to complementary medicines
- → complaints data held by professional associations are largely about professional issues rather than adverse reactions to medicines (Lin et al., 2005: 292).

Also, there is concern that the risk profile for naturopathy is increasing due to various factors such as:

- → the loss of government incentives, for naturopaths to participate in voluntary certification (loss of private health insurance rebates or naturopathic treatments; removal of naturopathic education programs from the Health Training Package)
- → concurrent use of pharmaceutical medicines along with herbal medicines and nutritional supplements (Morgan et al., 2012)
- → the development of manufacturing techniques that alter the potency of products
- → the application of naturopathic and herbal medicines to a wider range of illnesses.

→ the accessibility of products from overseas suppliers with unknown manufacturing standards and product authentication processes (Lin et al., 2005: 46-7, 292; Carlton et al., forthcoming).

There is some evidence to suggest that practitioners occasionally use scheduled herbs which they are not authorised to use. This suggests either a lack of awareness of the legal restrictions that apply to herbal medicines or wilful lawbreaking (Lin et al., 2005: 108; Carlton et al., forthcoming).

Researchers have found GPs report that patients presenting with adverse events associated with complementary medicine practices in 1 out of every 125 consultations and have estimated the proportions due to specific practices such as naturopathy and herbal medicine. Extrapolated over the 38,388 GPs in 2020-21 there are an estimated 394,000 adverse events every year that may be attributed to naturopathic practices and of these over 100,000 are considered serious by GPs. This may be greater than the adverse events attributed by GPs to Chinese herbal medicine and chiropractic – see Table 6.

TABLE 6: Adverse events reported to GPs extrapolated to annualised data and to total GP population in Australia

	GP reported adverse events over 4 weeks (%)[15]			Estimated Total AEs over 48 wks (n)[16]	Estimated serious AEs over 48 wks (n) [14]
	Mild	Serious	Total		
Adverse events attributed to:					
Naturopathy	9.6	3.6	13.2	180,576	49,248
Herbal medicine	11.5	4.1	15.6	213,408	56,088
Naturopathy/herbal medicine				**393,984**	**105,336**
Chinese herbal medicine	5.6	1.8	7.4	101,232	24,624
Chiropractic	13.1	4.7	17.8	243,504	64,296
Source:					

2.3 Risks associated with scope of practice

Naturopaths are primary care practitioners who provide diagnostic and treatment services under a paradigm that differs from that of conventional biomedicine.

Naturopaths have a very broad scope of practice – they see patients from every demographic and treat a wide range of health conditions, including patients with potentially life-threatening illnesses (Carlton et al., forthcoming). They do this without the need for a referral from a medical practitioner.

Every naturopath has a professional obligation to recognise the limits of their practice and to refer on to other practitioners, including medical practitioners, when the needs of the patient dictate. This is an important part of the ethical and clinical training of naturopaths.

15 Source: Cohen et al., 2005.
16 Assumptions:
• 38,388 GPs in Australia in 2020-21 (Australian Government Department of Health and Aged Care, https://hwd.health.gov.au/resources/data/gp-primarycare.html
• 171 million GP consultations in 2020-21 (AIHW, https://www.aihw.gov.au/reports/health-care-quality-performance/general-practice-allied-health-and-other-primary-c)

Harm can occur when a naturopath fails in their exercise of clinical judgement, either through acts of commission or omission. These risks relate to incorrect, inadequate, or delayed diagnosis, or failure to make timely referrals to practitioners who are best placed to treat the patient. These risks increase when the naturopath has received insufficient clinical and ethical training to recognise the limits of their practice and make appropriate referrals.

The Lin Report presented data from a survey of GPs which suggested that while GPs expressed concerns about specific herbal products and interactions, they were more concerned about the scope of practice of naturopaths than the specific risks of the therapies used (2005: 226, 227). Since that survey, there is an increasing body of evidence of serious harm and deaths that have been linked to naturopaths who have failed in their professional duty – to make appropriate and timely referrals.

Attachment 7 includes a selection of high-profile cases where naturopaths have been prosecuted for offences ranging from sexual assault to making dubious treatment claims and misrepresenting their qualifications to advising their patients to cease conventional medical treatments. Many of these individuals have had insufficient training and would not be eligible to practise naturopathy if minimum entry level qualification and probity standards were enforced.

2.4 Risks associated with the practice context

When compared with other regulated health professions, there are four main contextual factors that increase the comparative risks associated with naturopathic practice:

- → the absence of effective controls over entry to practise as a naturopath
- → the difficulties for patients in identifying who is properly qualified and in good standing as a naturopath
- → the challenges for patients of navigating two systems of medicine, particularly for those who use naturopathy in conjunction with conventional biomedicine
- → the absence of quality controls exercised through employers, public sector work settings and third-party payment systems (health insurers).

First, as outlined earlier, with the lack of effective controls over entry-to-practise as a naturopath, any person can set up practice without qualifications or probity checking. There is no enforced minimum entry level qualification, no minimum standard of education necessary for clinical practise as a naturopath and no checking to ensure the person is of good character prior to their commencing practice.

This heightens the risk to service users because, as outlined above, naturopaths have a very broad scope of practice, treating patients with a wide range of health conditions, using treatment modalities that carry inherent risks. Also:

- → naturopaths do not have access to the range of diagnostic tools that are available to practitioners of conventional medicine
- → untrained or undertrained persons are less likely to recognise the limits of their skills and knowledge and to refer on appropriately
- → misdiagnosis is more likely if clinical training hours are inadequate or there is inadequate exposure during training to a range of patients and health conditions
- → training and guidelines on the clinical management of patients who use naturopathic medicines in conjunction with pharmaceutical drugs

This data shows a pattern of harm associated with those who seize the opportunity to 'make a quick buck', choosing to flout professional norms by establishing themselves in practice without industry recognised qualifications. Anecdotal evidence suggests such practitioners are predisposed to disregard other ethical norms and standards of professional practice. Recent cases demonstrate this problem – unqualified persons who pretend to be qualified have used the opportunities presented by their practise a naturopath to breach the trust of their patients by committing sexual assault (see Attachment 7).

The media coverage of these cases reports these people as 'naturopaths', because that is the title they have assumed for themselves. However, the reality is that most are not qualified naturopaths – they may have done short courses, may have no qualifications at all, or have been deregistered from a health profession regulated under the NRAS. They have traded on the reputation of and trust in the naturopathic profession to exploit vulnerable patients.

Second, compounding these problems, there is no single trusted source of information for prospective patients about who is qualified as a naturopath and in good standing in the profession. Instead, there are multiple and competing professional associations, all of which claim to represent qualified naturopaths but set different qualification standards for membership and provide different levels of service to members and to the public. This adds to the confusion for prospective patients.

This multitude of professional bodies with their varying standards exacerbates the information asymmetry so that the average consumer is likely to struggle to know who is properly qualified as a naturopath and who is not.

Third, since most naturopaths work autonomously, in independent private practice rather than as an employee or in a public or funded sector agency, the quality controls that usually apply in such settings (employment contracts, clinical governance systems, risk audit, performance appraisal etc) are absent.

With the removal of naturopathic services from the eligibility for rebates under the Commonwealth *Private Health Insurance Rules*, there are no institutional quality control measures applied by third party payers to naturopaths, that is, no public and private health insurers who scrutinize claims data and may alert regulators to professional practice or clinical governance failures.

Fourth, for those who use both naturopathy and conventional medical practitioners, there are heightened risks associated with herb/drug interactions. These risks are exacerbated by a general lack of communication among the various providers and the lack of training and guidance for practitioners on the clinical management of patients who use naturopathic medicines in conjunction with pharmaceutical drugs. As more people with chronic health conditions choose naturopathic treatment, the potential for herb/drug interactions increases. Compounding this problem, there is evidence that many patients do not tell their treating medical practitioners of their use of naturopathic medicines:

> *Participants in the focus group reported that they didn't not do so because the doctor might reject the therapy or because they felt that they should be in charge of their health (Lin et al., 2005: 295).*

One study of consumers of naturopathy services found:

- → the majority of patients self-refer following recommendation from another person
- → treatment is sought for a wide range of physical and psychological problems, and management is multifaceted (including lifestyle advice, nutritional supplements, herbal medicines and exercise)
- → those seeking naturopathic care frequently do so for chronic conditions, which means they are likely to be frequent and routine users
- → approximately half of the profiled patients had previously consulted a medical practitioner (general or specialist) for their complaints before visiting a naturopath, but communication between practitioners occurred in only a minority of cases
- → among the profiled patients receiving naturopathic treatment, over one third were also taking pharmaceutical drugs
- → poor communication between medical and complementary medicine practitioners can have dangerous consequences in terms of drug interactions and delayed diagnosis (2005: 294).

More recent data suggests these risks remain and are being compounded by the variability in education and training of naturopaths (Carlton et al., forthcoming). Those who enter practice with inadequate or no qualifications and clinical training are less likely to have the capacity or motivation to keep up-to-date with the exponential growth in naturopathic research, they are less likely to be engaged with their peers in scholarly collaboration or to adopt evidence based naturopathic practice.

Conclusion regarding Criterion 2:

The treatment modalities, scope of practice, and practice context of naturopaths all contribute to **a risk profile for an unregulated naturopathy profession** that is **unacceptably high** and on par with or greater than many of the health professions that are subject to statutory registration. These risks are not just theoretical – the data shows there is a pattern of harm, with repeated cases over three decades.

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

Successive attempts at profession-led self-regulation, over almost three decades, have largely been ineffective. Efforts have been hampered by the fragmented representative arrangements, the ongoing disagreements amongst professional associations about the entry level qualifications required for safe and competent practice and lack of government leadership and support.

The naturopathic profession is subject to a range of laws and regulations at federal, state and local government levels (See Attachment 8). Taken together, these laws present a complex and confusing array of mechanisms for assuring the quality of naturopathic services and protecting public health and safety. While responsibilities are shared across a range of regulators, there are significant gaps and deficiencies. Unlike the NRAS for the registered health professions, there is no single regulator that has sufficient powers to effectively mitigate these risks. The failures are in four areas:

→ Failures of self-regulation
→ Failures of co-regulation
→ Limitations of code regulation (negative licensing)
→ Lack of access for naturopaths to some of their tools of trade.

Failures of self-regulation

Self-regulation of a health profession (also referred to as 'voluntary certification') generally comprises the following elements:

→ a professional association with a constitution and/or bylaws that set out the rules of the association
→ a board of directors constituted with persons elected by members of the association
→ published membership requirements that include:
  ↳ a recognized minimum qualification for practising membership
  ↳ agreement to comply with a Code of Conduct and standards of practice set by the association
→ a process for assessing and approving qualifying education programs for membership eligibility purposes
→ operation of a publicly accessible web-based searchable register enabling the public to locate qualified practising members who are in good standing with the association
→ policies and processes for receiving and investigating complaints about members and dealing with any misconduct
→ by-laws that enable removal of membership from those who breach the Code of Conduct.

Given the risk profile of naturopathic profession (see Criterion 2), relying on self-regulation to protect the public from harm have proved to be woefully inadequate (Carlton et al., forthcoming).

International evidence

The WNF health technology assessment investigated occupational regulation regimes across 108 countries. Researchers make the point that reliance on voluntary certification is problematic when the practices of a health profession present potentially serious risks to public health and safety:

- → Where there are no statutory powers to restrict entry to a profession, those with minimal or no qualifications can set up practice and use the titles of the profession without meeting acceptable minimum standards of training and practice. This has led to widely varying standards of practice and levels of qualifications, substantial fragmentation of these professions, and no widely recognised and accepted peak bodies (Lloyd et al., 2021: 50).
- → Most professional associations rely on volunteers drawn from the profession and may lack access to the necessary skills, resources and capacity to handle the complexity associated with effective regulation (Lloyd et al., 2021: 50).
- → There are conflicts of interest in the operation of voluntary certification which can compromise public protection, for example where the professional association is responsible for representing its members interests and at the same time accrediting programs that are tied to membership and dealing with complaints about members.
- → Schemes that operate at arms-length from professional associations (such as the model adopted in Australia by ARONAH) are often constrained by poor resourcing and policy capacity and as with all voluntary certification, the standards apply only to those practitioners who choose to opt in (Lloyd et al., 2021: 50).

Without strong and consistent institutional support from professional associations, education institutions, employer bodies, insurers and governments, voluntary certification schemes generally lack sufficient incentives for practitioners to comply with qualification and practice standards and efforts to deal with non-compliance are generally ineffective (Lloyd et al., 2022: 50). Successive studies of complaints management systems of Australian naturopathic professional associations further support the WNF findings:

- → Unlike complaints and disciplinary systems operated by statutory bodies, there is little transparency or accountability and little published information about the procedures followed or the outcomes achieved (Carlton et al., forthcoming).
- → In many cases, those managing the disciplinary processes lack experience in matters of procedural fairness (Lin et al., 2005).
- → Most complaints management systems have limited or no avenues of appeal and, most importantly lack teeth - naturopaths who are the subject of investigation have been known to let their membership lapse to avoid disciplinary action (Carlton et al., forthcoming).

Why is self-regulation failing?

Many of the most egregious cases described in Attachment 7 appear as isolated individual failures. However, they reflect a broader institutional failure that has been confronting the naturopathic profession for some time.

In response, the profession has made every effort to get its house in order. Some of the better resourced professional associations have made considerable efforts to develop a uniform and effective model of regulation, however these efforts have been largely unsuccessful (Lin et al., 2005: 296; Carlton et al., forthcoming).

It is fair to say that for almost three decades, successive efforts to unite and better regulate the profession have largely failed.

Textbox 2 lists some of these initiatives – each initiative has come from the profession, with little or no support from government. While there has been a significant reduction in the number of professional associations that represent naturopaths since 2005, this consolidation has failed so far to achieve the unified voice on professional standards, education and practice that is needed for effective profession-led self-regulation (Carlton et al., forthcoming).

A significant contributing factor in the failure of these initiatives is the lack of consensus that degree level (rather than diploma or advanced diploma) should be the minimum standard of training accepted for entry to practice as a naturopath and eligibility for association membership (Carlton et al., forthcoming). This lack of agreement on entry to practice qualifications underpins and contributes to the fragmentation of representative arrangements within the profession.

TEXTBOX 2: Profession-led self-regulation initiatives – 1991-2022

- → 1991 – the Federation of Natural and Traditional Therapists (FNTT) is established as an umbrella body comprising multiple professional associations.
- → 2003 – the NHAA proposes the establishment of a single national Complementary Medicine Registration Board to advise each state and territory government and implement harmonised legislation across Australia for naturopaths and Western herbalists (NHAA, 2003).
- → 2003 – the Complementary Medicine Practitioner Associations Council (CMPAC) was established by ANTA and ATMS) in response to an ATO requirement for practitioner membership of a national "register" to qualify for GST exemption for naturopathic consultations.
- → In 2010 the Australian Register of Naturopaths and Herbalists (ARONAH) was established as an independent voluntary regulatory body to ensure minimum standards for naturopathy and Western herbal medicine in Australia that mirrors government requirements for the regulation of health practitioners.
- → In 2019 the Australian Naturopathic Council (ANC) was established as a coordinating council representing naturopathic organisations with a shared vision for the advancement of naturopathy in Australia. The ANC is one united body that represents Australian naturopathic practitioners with relation to lobbying, statutory registration, and policy formation and interpretation.

If it were simply a matter of the profession redoubling its efforts, then it would be reasonable for governments to expect more from the profession. However, it is wrong to assume that these failures result from of lack of capability or effort on the part of the profession. Instead, they reflect broader institutional failures associated with the power dynamics at play within and beyond the profession – a lack of authoritative guidance, support and recognition from governments and other institutions such as insurers and employers.

Effective certification schemes are operating for many unregistered allied health professions – see for example Speech Pathology Australia, the Dietitians Australia and the Australian Association of Social Workers (AASW)). However, the politics at play mean the naturopathy profession is ultimately incapable of achieving the unified institutional representation that is needed to achieve effective self-regulation, to the detriment of patients. See Textbox 3 on the ARONAH experience.

TEXTBOX 3: The Australian Register of Naturopaths and Herbalists – efforts to establish a self-regulatory scheme and voluntary register for naturopaths and herbalists

- → In July 2013, the Australian Register of Naturopaths and Herbalists was officially opened for registration.
- → Since then practitioners have been encouraged to join the voluntary register through articles published in practitioner journals and social media.
- → ARONAH has struggled to build a solid registrant base over the last 10 years and while there have been new registrants each year, just as many do not re-register.
- → Reasons given by practitioners not re-registering include:
    - ↳ Unwilling to increase insurance cover to levels required for registration
    - ↳ Change in views regarding registration since COVID-19 pandemic
    - ↳ No perceived benefit from registration
    - ↳ Not happy with ARONAH
    - ↳ Non-payment
    - ↳ Financial reasons
    - ↳ Retired from practice or no longer practising

Source: ARONAH, 2022

Similar challenges were faced by the Chinese medicine profession in the 1990s – an increasing risk profile, fragmented professional representation, inability to achieve broad consensus within the profession on minimum standards of training for entry to practise (despite successive efforts), and lack of broader institutional reinforcement of self-regulation (Victorian Government, Department of Human Services, 1998). In that case the Victorian Government recognised the need to intervene in the public interest, legislating to establish the first registration scheme for the Chinese medicine profession in Australia (Carlton, 2017: 186-202).

Failures of co-regulation

Governments play an important role in reinforcing and supporting professional association led practitioner certification schemes – principally by providing incentives that encourage practitioners to participate in and comply with certification requirements.

For instance, by tying access to recognised provider status under various government health insurance schemes (Medicare, Veterans Health, traffic accident and workers compensation) with participation in a professional association led certification scheme, governments have established powerful incentives for allied health practitioners to join such certification schemes and comply with the standards set. Other examples of co-regulation include:

→ the Federal Government's Private Health Insurance Rules[17] which determine what types of health services are eligible for patient rebates paid by private health insurers
→ the Commonwealth Department of Immigration's recognition of some allied health professional associations as assessing authorities for the purpose of assessing the qualifications of applicants for skilled migration (SPA, undated).

However, unlike in the UK[18] where a strong co-regulatory scheme operates for the unregulated health professions, the Australian governments have missed several important opportunities to use the levers of co-regulation to require or reinforce unified national qualification and practice standards for the naturopathy profession.

Australian governments provide few incentives for naturopaths to submit to voluntary certification with a peak professional association and when they do, the standards of multiple associations are recognised, thereby undermining any efforts to achieve uniform national standards. It is important to distinguish the contextual factors that shape naturopathic practice:

→ Unlike many allied health professions, most naturopaths are self-employed and work in independent private practice rather than for large employers (Steel et al., 2020).
→ Unlike many allied health professions, naturopaths are not generally employed in the publicly funded health services where governments have a role in setting standards, via funding arrangements and/or policy directions.
→ Unlike many allied health professions, the services provided by naturopaths are not reimbursable under Australia's universal health insurance scheme or other third-party payers such as for veterans health services, workers compensation, traffic accident schemes.
→ Unlike many allied health professions, the services provided by naturopaths have not been reimbursable by private health insurance funds since this entitlement was removed in 2019.[19]

Since publication of the Lin Report, several important opportunities have been missed for government to implement a common minimum qualification standard for entry to practise. In fact, standards have deteriorated with the Federal Government's withdrawal of two important mechanisms previously relied upon to set minimum standards for naturopathic practice:

→ the removal in 2019 of eligibility of naturopaths for provider rebate status with private health funds (see Textbox 4), and
→ the withdrawal in 2016 of the VET sector accreditation of naturopathic qualifications and training providers[20] (see Textbox 5).

17. See https://www.health.gov.au/health-topics/private-health-insurance/about-private-health-insurance/private-health-insurance-laws
18. The United Kingdom Government operates a co-regulatory scheme in the form of its Voluntary Registers Program – see (https://www.professionalstandards.org.uk/what-we-do/accredited-registers).
19. See https://www.health.gov.au/health-topics/private-health-insurance/private-health-insurance-reforms/natural-therapies-review-2019-20
20 Withdrawn after December 2015 with teach out till the end of 2018. See https://ianbreakspear.com.au/2014/11/24/confirmed-advanced-diplomas-to-be-deleted-december-2015/

TEXTBOX 4: Changes to the Commonwealth Private Health Insurance Rules affecting the naturopathic profession

In 2018, the Commonwealth Government decided to change the *Private Health Insurance Rules* to prevent private health insurers from providing rebates for consultations provided by recognised providers of naturopathic medicine. From 1 April 2019, 16 natural therapies were excluded from private health insurance cover, including the profession of naturopathy.

This decision by the Australian Government means that private health funds cannot currently offer cover for any services provided by a naturopath. The decision was made following a 2015 review of the Australian Government Rebate on Private Health Insurance. On 7 April 2019, a further review was announced by the Federal Minister for Health (the 2019-20 Review) and is still underway.

The effect of this decision has been to remove the most significant incentive that encouraged those entering practise as a naturopath to put the effort into obtain an acceptable education qualification. It also removed the incentive for practitioners to join a professional association, thereby reducing the effectiveness of the voluntary certification schemes operated by these associations and the degree of accountability and oversight exercised by the associations for maintaining professional standards, such as enforcing mandatory continuing professional development and professional indemnity insurance.

TEXTBOX 5: Changes to remove naturopathic qualifications from the Health Training Package

July 2014 Update: Advanced Diplomas of Homeopathy, Naturopathy, Nutritional Medicine and Western Herbal Medicine to be aligned at Bachelor degree level.

All Complementary & Alternative Health (CAH) qualifications in the Health Training Package (HLT07) are currently under review. As part of the review, content is being updated and improved, both to better meet industry needs and to comply with the new national Standards for Training Packages. An Industry Reference Group (IRG) comprising representatives from all CAH modalities oversees this work, and there is also a smaller Subject Matter Expert Group (SMEG) for each modality.

In March 2014, Subject Matter Expert Groups recommended that the Advanced Diplomas of Homeopathy, Naturopathy, Nutritional Medicine and Western Herbal Medicine should be aligned at Bachelor degree level, and therefore be removed from the Training Package. The Complementary & Alternative Health Industry Reference Group agreed to accept these recommendations in May 2014. It also confirmed and agreed to the historical and future process surrounding this re-alignment of qualifications. See the two process diagrams below. The current timeframe for removal of the qualifications from the Training Package is December 2015, and students enrolled before that time will not be affected by the change. CS&HISC is not involved in professional association recognition of qualifications, and those associations would manage any transition arrangements.

Source:https://anpa.asn.au/files/CSHISC_COMMUNICATION_CAH_ADVANCED_DIPLOMAS_July_2014.pdf

The Lin Report was critical of the ATO for recognising, for GST purposes, multiple sets of standards for multiple professional associations. Recognition of multiple professional associations means that a practitioner found to have breached the standards of one association can join another association that has national standards and maintain their GST-free status as a 'recognised professional' (2005: 257). The effect of these changes has been to undermine efforts by professional associations to set and enforce minimum qualification and practice standards. See Textbox 6 (GST Tax arrangements)

TEXTBOX 6: Goods and Services Tax (GST) law

Under the Commonwealth's GST legislation, *A New Tax System (Goods and Services Tax) Act 1999* (Cth) (the GST Act), a person may obtain GST-free status for the provision of naturopathy and herbal medicine services.
Under section 38.10(1) of the GST Act, the supply of a health service is GST-free if:

- → the service is of a kind specified in the Table in that section
- → the supplier is a 'recognised professional' in relation to the supply of that service, and
- → the supply would be generally accepted, in the profession associated with supplying services of that kind, as being necessary for the appropriate treatment of the recipient of the service.

Naturopathy and herbal medicine are specified as health services in the table in section 38.10(1). Under section 38.10(4), the supply of goods (such as herbal medicines) is also GST-free if it is made to a person by the naturopath in the course of supplying the GST-free service and it is supplied, used or consumed at the premises at which the service is supplied.

Because no Australian state or territory currently requires naturopaths to be registered (or approved or have permission) to provide their professional services, a naturopath who wishes to be classed as a 'recognised professional' for the purpose of providing GST-free services must be a member of a professional association that has 'uniform national registration requirements' for naturopaths.

The website of the Australian Taxation Office (ATO) states that a professional association that has uniform national registration requirements is not defined in the GST Act and that if a particular association wants confirmation of its status, a specific ruling may be sought from the ATO. A number of national associations with naturopath members have done this.[21]

The marginalised position of naturopaths in the healthcare system

These institutional failures (the absence or removal of government incentives for naturopaths to participate in profession-led voluntary certification) reflect the broader power relations embedded within the Australian healthcare system – the marginalised position of the naturopathy profession, its exclusion from many mainstream healthcare settings and the difficulties faced by the profession in influencing or shaping healthcare and regulatory policy (Carlton et al., forthcoming).

21. Four professional associations – ANTA, ATMS, CMA and NHAA – indicate on their websites that members are eligible to provide GST-free services.

It is not surprising this lack of institutional recognition compromises the efforts of the profession to effectively self-regulate. The end result of the removal of government incentives is that consumers are even more exposed and vulnerable to fly-by-night opportunists who lack proper naturopathic qualifications and are predisposed to flout professional norms to exploit the trust of their patients for their own gain.

The limitations of code regulation (negative licensing)

There is evidence that increasing numbers of consumers are lodging complaints with state and territory health complaints commissioners and that in some instances, Commissioners have taken action against so-called 'naturopaths', including by issuing prohibition orders (Carlton et al., forthcoming).

A negative licensing or 'code regulation' scheme is in operation in four Australian states (New South Wales, Queensland, South Australia and Victoria). A national agreement signed by all state, territory and Commonwealth governments in 2015 committed every state and territory to implement the scheme in accordance with a nationally agreed policy framework.[22]

Tasmania legislated amendments to its health complaints legislation, but the powers are yet to be commenced.[23] In Western Australia, legislation has been introduced to the Parliament but not yet enacted or commenced.[24] There is no publicly available information to indicate whether the ACT and Northern Territory have progressed the development of legislative amendments to give effect to the Ministerial Council agreement of 2015.[25]

In 2020 amendments to the NSW scheme extended the powers of the NSW Health Care Complaints Commission to cover health organisations, as well as individual practitioners,[26] and in September 2022, the NSW Public Health Regulation 2022 was amended to introduce a *Code of Conduct for health organisations*.[27]

Apart from these extended powers in NSW, the four schemes operate in broadly the same way – see Textbox 7.

22. Victorian Department of Health on behalf of the Australian Health Ministers' Advisory Council, Final Report A National Code of Conduct for health care workers. 2015.
23.Tasmania has enacted legislation but it has not yet commenced. See the Health Complaints Amendment (Code of Conduct) Act 2018 (Tas): https://www.healthcomplaints.tas.gov.au/national-code-of-conduct#:~:text=The%20Code%20of%20Conduct%20outlines,to%20protect%20you%20from%20infection
24. See the Health and Disability Services (Complaints) Amendment Bill 2021: https://www.hadsco.wa.gov.au/News/2022/09/20/National-Code---update-September-2022
25. In 2017, the NT Department of Health published an Information Paper on proposed changes to give effect to the National Code of Conduct and prohibition order powers, but there is no indication of any progress in framing the necessary legislative changes. See: http://www.hcscc.nt.gov.au/wp-content/uploads/2017/11/National_Code_of_Conduct_NT_Information_Paper.pdf
In the ACT, no information was identified on the public record to indicate progress with legislative changes.
26. See Health Legislation (Miscellaneous Amendments) Act 2020 (NSW)
27. See https://www.hccc.nsw.gov.au/about-us/about-the-commission/legislation

TEXTBOX 7: Key features of code regulation (negative licensing) schemes in four states

- → A health complaints law is enacted (or amended) that contains definitions of 'health service' and 'health care worker' (or equivalent term such as 'non-registered health practitioner'). These definitions determine the scope of the negative licensing powers and to whom these powers apply.
- → A statutory code of conduct is made by regulation. The Code of Conduct sets minimum standards of practice for all non-registered health care workers who provide a health service, regardless of their discipline or occupation, the nature of their practice, the titles they use, or how they badge, describe or advertise the services they provide. See for example, the regime in Queensland, Australia.[28]
- → The regulator (a complaints commissioner supported by an administrative office) has statutory powers to receive and investigate complaints from health service users or other interested parties and has the power, if warranted, to issue a 'prohibition order', to attach conditions to a worker that limit their scope of practice, or to ban them from practice altogether.
- → If a health care worker who is subject to a prohibition order breaches the order, they may be prosecuted through the courts. Offenses are punishable by fines or up to two years imprisonment.
- → Health complaints commissioner websites provide online searchable public registers of prohibition orders provide information to the public on the prohibition orders issued and other warning statements and press releases. There are links to and mutual recognition of the orders published in other states, to prevent those subject to a prohibition order from skipping across the border to continue practising.

Under these schemes, while there is no legal barrier to entry to an unregistered profession – anyone can set out their shingle and practise, no matter what their level of training or skill – the law provides a mechanism for a regulator (usually a health complaints commissioner or health ombudsman) to receive and investigate complaints about a practitioner. The regulator may then issue a prohibition or banning order to remove a practitioner from practice if it finds that the practitioner has committed a serious offence or a breach of minimum standards of practice AND their continued practice presents a serious risk to the public.

An online register of prohibition orders informs the public of the identity of prohibited or banned workers and provides details of the misconduct. See for example the register of prohibition orders published by the NSW Health Care Complaints Commissioner in Australia.[29]

There are, however, some deficiencies in these arrangements which, when considered in light of the risk profile of the naturopathy profession, raise concerns about the adequacy of the protections afforded consumers and the effectiveness of this mechanism in the absence of other controls over professional practice.

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28. Queensland Health. The National Code of Conduct for Health Care Workers (Queensland). 2015; Available from: https://www.health.qld.gov.au/system-governance/policies-standards/national-code-of-conduct.
29. NSW Health Care Complaints Commission. Prohibition Orders. 2021; Available from: https://www.hccc.nsw.gov.au/Decisions-Orders/Register-of-Prohibition-Orders-in-Force

First, the National Code of Conduct has been implemented in only four out of eight states and territories (NSW, South Australia, Queensland and Victoria), and Western Australia recently pass legislation for implementation of the code. The Health Complaints Commissioners in four jurisdictions (ACT, Northern Territory, Tasmania and Western Australia) have no Code of Conduct, no strengthened complaints investigation powers, and no powers to issue prohibition orders even in the most egregious cases such as the Cabrera brothers – See Attachment 7).

Second, given the harms that have been reported, complaints mechanisms appear to be underutilized, in some cases lacking in transparency and are not standardized across jurisdictions. The level of information available to the public concerning prohibition orders issued under the four schemes is highly variable. For example, in Victoria, virtually no information is published on the website of the Health Complaints Commissioner when a prohibition order or interim prohibition order is published. We question how members of the public are supposed to know and understand the seriousness of the matters dealt with by the Commissioner and take necessary steps to protect themselves from practitioners who are unfit to practise if the most basic information about the nature of the misconduct that led to the prohibition order remains confidential.

A recent study of the operation of these negative licensing schemes has found a range of other anomalies, inconsistencies and gaps in the way the schemes operate:

- → In NSW prohibition orders may be removed once they have expired whereas in Queensland ('Qld') prohibition orders may be removed if the Health Ombudsman ('HO') or the Queensland Civil and Administrative Tribunal ('QCAT') revokes the prohibition order. This means the numbers of prohibition orders reported in the NSW Health Care Complaints Commission ('HCCC') and Qld Office of the HO (OHO) *Annual Reports* do not accord with those available on their websites.
- → Unlike the NRAS, there is no link or permanent record of disciplinary decisions provided to the public for unregistered health practitioners.
- → Unlike at the NRAS, there is no national register of prohibition orders available for the public to easily search to check unregistered practitioner qualifications or details.
- → Information available on the type of practitioner issued with prohibition orders is variable, with lack of adequate description on the Queensland and Victorian websites and some of the details or reasons for issuing a prohibition order are not provided.
- → Many of the prohibition orders in Queensland provide no detail or reasons for why a prohibition order was made.
- → There is no standardisation in the reporting of complaints data across the jurisdictions so it is difficult to compare the schemes against the most basic of performance indicators. For example, while NSW provides an annual breakdown of complaints against types of unregistered health practitioners, Queensland does not. (Doolan, forthcoming).

Third, the threshold for regulatory action by a complaints commissioner is generally 'serious risk to public health or safety' or commission of a serious criminal offence, that is, an offence punishable by imprisonment. This is a very high threshold for regulatory action. As a consequence, only the most egregious cases result in regulatory action and a prohibition order (Lloyd et al., 2021: 51). Presumably if the complaints are not suitable for conciliation, they are closed without further action.

Fourth, the use of the prohibition order powers is largely reactive, with regulatory action triggered usually once harm has already occurred (Lloyd et al., 2021: 51). Such schemes do not provide the infrastructure to enable proactive and non-punitive quality assurance measures to be applied. Minimum levels of practitioner training and probity checks are not enforceable, nor are education programs to assist practitioners to identify and prevent inappropriate practice behaviours – measures that would be expected to prevent recidivism and reduce the risk of breaches by other practitioners (Lloyd et al., 2021: 51).

At least one Health Complaints Commissioner has reported on some of the deficiencies:

> *In the absence of the ability to identify all classes of unregistered practitioners or to know how many are in each class, communicating clearly to consumers and providers about who is regulated and who is not is difficult. Planning and effective regulation is also a significant challenge… defined and consistent treatment standards or protocols are often not in place… evidence gathering throughout investigations may be more difficult and resource intensive (NSW HCCC 2019, 33).*

Finally, a recent study found the proportion of complaints that result in a prohibition order removing the practitioner from practice appears to be higher for unregistered practitioners under code regulation in NSW compared with removals (cancellation or suspension of registration) for practitioners under the NRAS (Doolan, forthcoming). The NSW HCCC statement on unregistered practitioners states 'these investigations tend to raise serious concerns of public health and safety and generate intensive and complex investigations.' (NSW HCCC 2020, 55). This finding suggest that while the prohibition order powers may be serving an important public protection function, the data shows that stronger regulation with a preventive focus is warranted.

Lack of access for naturopaths to their tools of the trade

As outlined earlier, the current system of limiting access to toxic herbs via the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) means competent naturopaths are denied access to some important herbs used in naturopathic treatment. The effect of these scheduling arrangements places a range of herbal medicine products out of reach of those practitioners who are trained to use them. It is a perverse outcome of the scheduling arrangements that only registered medical practitioners (for schedule 4 medicines) and pharmacists (for schedule 2 and 3 medicines) are authorised to prescribe these herbal medicines, but without the necessary training to do so safely and competently.

Conclusion regarding Criterion 3:

The **risk profile of the naturopathy profession is substantial** and there is a pattern of harm to consumers that is not being adequately addressed under current regulations.

The existing mix of self-regulatory, co-regulatory, negative licensing and other mechanisms are failing to adequately address the risks of harm associated with unregulated naturopathic practice. Without enforceable controls over entry to practise in the profession, there are no effective mechanisms to enforce minimum practise standards and no effective methods of preventing unqualified individuals from continuing to practice.

Without enforceable qualification and probity requirements, people who have no qualifications whatsoever, those who been expelled from associations for misconduct and those deregistered from other regulated professions, cannot be prevented from continuing to offer naturopathy services to the public.

Without enforceable qualification and probity requirements and an effective mechanism to monitor practitioners for compliance with practice standards, the profession is targeted by those who are disposed to exploit the vulnerabilities of their patients for personal gain. **Existing regulatory mechanisms are failing** to deal with this fundamental problem.

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

The Australian and New Zealand Classification of Occupations (ANZCO) designates naturopathy as occupational Skill level 1, Bachelor's degree or higher.[30] This is equivalent to other health occupations such as dentists, general practitioners, nurses, optometrists, pharmacists,

> *"252213 NATUROPATH*
> *Treats internal health problems, metabolic disorders and imbalances through treatment of the whole person using natural therapies. Registration or licensing may be required.*
> *Skill Level: 1"*

Naturopathy has an established body of knowledge and, up until 2018, the boundaries of its practice were defined via the VET sector Health Training Package. In 2022, ARONAH issued *Competency Standards for Naturopathic Practitioners* following an extended consultation with the profession and key stakeholders.[31]

The WHO has issued benchmarks for training in naturopathy to ensure practice meet minimum levels of adequate knowledge, skills and awareness of indications and contraindications (WHO, 2010: viii). The WHO Western Pacific Region has issued guidance on how Member States may strengthen occupational regulation of the health workforce, including the T&CM professions (WHO WPR, 2016; 2019).

The WNF has issued a Naturopathic Educational Program Guide to promote accreditation of naturopathic educational programs and the highest educational standards for the naturopathic profession globally (WNF, 2022). Education for naturopaths has been offered at tertiary level for over five decades in Australia. When training of naturopaths was included in the Health Training Package and courses were accredited in the VET sector, there was broad agreement on core competencies and curriculum requirements. Naturopathy curriculum have been developed at bachelor's degree level and offered by several universities.

It is therefore possible to define the profession and its body of knowledge sufficiently for the purposes of regulation.

Conclusion regarding Criterion 4:

Regulation is possible to implement for the **naturopathy** profession – it **is a well-defined and well-established health profession in Australia**. It has an established body of knowledge, modalities, principles and philosophies and established education and practice standards. The profession is supportive of registration and able to support a self-funded National Board. It is possible to implement regulation.

30. See https://www.abs.gov.au/ausstats/abs@.nsf/Product+Lookup/61E502FFBABDD327CA2575DF-002DA5B2?opendocument
31. See http://www.aronah.org/course-accreditation/

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

Practitioners of naturopathy are recognised and regulated in many other jurisdictions, including the USA and Canada. The WNF report documents numerous examples of occupational licensing regimes, particularly in the USA and Canada.

There is a clear precedent for regulation of T&CM professions in Australia. Chinese medicine has been successfully regulated under a protection of title model, first in Victoria from 2000 and then nationally since 2012. The Lin Report documented some of the practical challenges faced by the Chinese Medicine Registration Board of Victoria when establishing the registration scheme, including with respect to the following:

- → setting the registration fee – given the actual number of practitioners and the number likely to be granted registration were unknown
- → conducting the 'grandparenting' process – particularly assessing the competence of existing practitioners who had low level qualifications but who had undertaken multiple additional short courses and whose clinical training was limited
- → setting appropriate standards for education – by defining learning outcomes (rather than specifying curricula design) and by allowing institutions time to upgrade their courses
- → educating the profession, private health funds and the public about the role of the regulator and distinguishing this from the role of professional associations
- → aligning standards for practice with other registration boards (Lin et al., 2005: 300).

While similar practical issues are likely with registration of naturopaths, the problems are not insurmountable and the number of potential registrants would be expected to be considerably higher than for Chinese medicine (Lin et al., 2005: 300).

These examples demonstrate the practicality of implementing occupational regulation for the naturopathy profession.

Conclusion regarding Criterion 5:

Regulation is practical to implement for the naturopathy profession. Introduction of statutory registration is not without some practical challenges. However, experiences in other jurisdictions and with the implementation of registration of the Chinese medicine profession shows that these **challenges are solvable** and this experience can be drawn upon in implementing appropriate arrangements for the naturopathy profession.

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

The range of feasible options that may be assessed under a Regulation Impact Statement (RIS) process are the same range of options assessed in the RIS on the National Code of Conduct for health care workers and the COAG Health Council RIS on paramedics. They are:

- → The status quo (no change)
- → Strengthened self-regulation – a quality assured voluntary registers scheme
- → Code regulation (negative licensing)
- → Statutory registration

Table 7 compares each main type of occupational regulation against a list of key features and capabilities.

TABLE 7: Types of occupational regulation and key features/capabilities

Key feature/capability	Type of occupational regulation			
	Voluntary Certification	Co-regulation	Negative licensing	Occupational licensing/ statutory registration
Statutory basis	No	Maybe	Yes	Yes
Enforceable minimum qualifications for entry to practice	No	No	No	Yes
Probity checking of persons prior to entry to practice	No	No	No	Yes
Accreditation of qualifying programs for entry to practice	Yes	Maybe	No	Yes
Enforceable minimum standards of practice	No	No	Yes	Yes
Mandatory continuing professional development (CPD)	Yes (for members)	Maybe	No	Yes
Obligation to report professional misconduct by fellow practitioners	No	No	Yes	Yes
Powers to monitor practitioner compliance with practice standards	No	No	No	Yes
Powers to impose conditions or limitations on a practitioner's practice	No	No	Yes	Yes
Power to issue practice guidelines/codes	Yes	No	No	Yes
Complaints and disciplinary powers	Yes (for members only)	Maybe	Yes	Yes
Powers to remove unfit practitioners from practice	No	No	Yes	Yes
Offences and penalties for unauthorised use of professional titles	No	No	No	Yes
A publicly accessible register of qualified practitioners	Maybe	Maybe	No	Yes
A publicly accessible register of disqualified or barred practitioners	No	No	Yes	Yes
Publication of disciplinary decisions	No	No	Yes	Yes
Protection from civil liability for board members discharging regulatory functions	No	No	Yes	Yes

FOLLOWING COMPLETION OF CONSULTATIONS, INSERT HERE TABLE WITH NARRATIVE ASSESSMENT OF THE COSTS AND BENEFITS OF EACH OPTION AS IT WOULD APPLY TO THE PROFESSION OF NATUROPATHY

The preferred option - statutory registration of the naturopathy profession under the NRAS

Some naturopathy practices pose a significant risk of harm, and these risks are compounded by the primary healthcare context and the broad scope of practice of naturopaths. Existing regulatory mechanisms are inadequate for safeguarding and protecting consumers. There are definable modalities within naturopathy for which it is possible to implement regulation. There are some practical challenges, but implementation lessons can be drawn from the experience of introducing statutory registration for the Chinese medicine profession in 2012 and more recently the paramedicine profession in 2018. The benefits of protecting public health and safety through statutory registration are considered to outweigh the potential adverse effects.

Cost of registration

Registration fees vary with the size of the profession – smaller professions have higher fees because there are less economies of scale.

Assuming a registrant base of approximately 15,000 naturopaths, we estimate that the fee for general registration would be in the order of $300-$350 per annum per registrant, although this figure would be expected to reduce after the first few years, once the financial reserves of the new National Board were established.

This figure has been arrived at based on the following assumptions:

- → naturopathy is a medium sized profession, much larger than the registered professions of chiropractic, osteopathy and Chinese medicine but smaller than medical radiation and paramedics.
- → The fee charged for general registration in 2022 for other similar sized professions:[32]

Profession	Registrant base (2020-21)	General registration fee (2022)
Medical radiation practice	21,844	$203
Paramedicine	21,492	$240
Chiropractic	5,968	$530
Chinese medicine	4,863	$579 (one division)

Source: Ahpra/National Boards Annual Report 2020/21 and Ahpra website

32. For general registration fees for 2022-23 for each regulated health profession see: https://www.ahpra.gov.au/About-Ahpra/What-We-Do/Who-we-work-with/Cost-Allocation-Implementation-Statement-NSW.aspx
For registrant numbers see the Ahpra/National Boards Annual Report for 2020-21 at: https://www.ahpra.gov.au/Publications/Annual-reports/Annual-Report-2021.aspx

→ While there are some complexities with regulating the naturopathy profession due principally to the use of ingestive medicines, it is expected the profession would be less costly to regulate than the Chinese medicine profession or Chiropractic. This is because of the greater economies of scale (naturopathy is approximately three times the size of these two professions), most naturopaths are trained in Australia and there would unlikely be the translation costs that are faced by the Chinese Medicine Board.

Benefits of statutory registration

Statutory registration is warranted given the risk profile of the naturopathy profession and the range of harms to the public from uncontrolled entry to the profession and the scope of practice of naturopaths. There are risks associated with use of ingestive medicines which are exacerbated if practitioners are not properly trained about indications, contraindications, and the interactions between naturopathic medicines and pharmaceutical drugs. Existing regulatory arrangements are insufficient to protect the public from unqualified or under-qualified practitioners.

The code of conduct and prohibition order powers of health complaints commissioners in four states (negative licensing) provide insufficient public protection because commissioners are generally alerted only after a patient has been harmed. These powers do not prevent unethical persons from setting up practice where they see an opportunity to make money by exploiting vulnerable patients. The cases presented in this submission show a pattern of harm that will only continue without stronger controls over entry to the profession.

Under statutory registration, the regulation and representative functions of professional associations would be separated, thereby reducing the possibility of conflicts of interest. Professional associations would be able to focus their resources on support of their members and professional development. Statutory registration would provide more robust and effective complaints and disciplinary processes.

Conclusion regarding Criterion 6:

This assessment provides prima facie evidence of the need for statutory registration of the naturopathy profession and that the substantial benefits of regulation are expected to outweigh the costs. This assessment demonstrates that existing mechanisms for protecting the public are inadequate and that statutory registration is the only option that will provide sufficient protection from harm, given the risk profile of the profession. **Governments are urged to allocate the resources required to undertake a RIS.**

6. CONCLUSIONS

Insert this section following completion of the consultations.

ATTACHMENT 1: KEY EVENTS AND ACTIONS IN THE HISTORY OF AUSTRALIAN REGULATORY POLICY ON REGULATION OF THE NATUROPATHIC PROFESSION

Date	Event
1985	Northern Territory introduces registration of the naturopathic profession with enactment of the *Allied Health Professions Registration Act 1985* (NT).
1992	Northern Territory repeals the *Allied Health Professions Registration Act* and abolishes registration of the naturopathic profession.
July 1998	Report of Victorian Ministerial Advisory Committee on Traditional Chinese Medicine recommends 'That further work be done to establish whether there is a need for statutory registration of practitioners of Western herbal medicine and that this include examination of mechanisms to allow prescribing and dispensing of scheduled Western herbal medicines by suitably qualified practitioners' (Victorian Government Department of Human Services, 1998: 50).
December 1998	Report of the Committee on the Health Care Complaints Commission 'recommends that the Minister for Health examine the feasibility of establishing umbrella legislation to cover unregistered health care practitioners which establishes a generic form of registration, generic complaint and disciplinary mechanisms, a uniform code of ethical conduct, entry criteria agreed amongst the relevant professions…' (NSW Parliament Legislative Assembly, Committee on the Health Care Complaints Commission 1998: 60).
September 2003	Report of Commonwealth Expert Committee on Complementary Medicines in the Health System released – recommends Health Ministers review the findings of the current New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners and move quickly to implement statutory regulation where appropriate.' (Commonwealth of Australia Department of Health, 2003: 129).
November 2005	Research Report commissioned by Victorian Government Department of Human Services finds statutory regulation of naturopaths and Western herbal medicine practitioners is warranted (Lin et al., 2005).
November 2005	Report of the Committee on the Health Care Complaints Commission released – Chairman's Foreword 'Only formal registration ensures uniformity of professional standards and effective disciplinary processes. Health care complaint handling and registration go hand in hand. This is true for all complementary medicine providers who are currently unregistered… In light of recent concerns that have been highlighted during the course of this inquiry about other areas of unregistered complementary medicine, the Committee intends to revisit its previous report *Unregistered Health Practitioners*…' (NSW Parliament, Committee on the HCCC November 2005: xi, xii).
December 2005	Report of Productivity Commission *Australia's Health Workforce* recommends establishment of a National Registration and Accreditation scheme for the health professions (Productivity Commission 2005: 127).
September 2006	Report of the Health Care Complaints Committee 'recommends the progress of Victoria in relation to the regulation of practitioners of naturopathy and

	Western herbal medicine be monitored, with the view to further exploring the possible registration of these practitioners in NSW.' (Report, September 2006, 82).
March 2008	Intergovernmental Agreement signed by the Council of Australian Governments, setting out the criteria that are to be applied to assess submissions for expansion of the NRAS to include additional health professions (COAG, 2008, 22).
June 2009	Inquiry Into Bogus, Unregistered and Deregistered Practitioners (SA) recommends negative licensing in SA, but identified counsellors and naturopaths which required greater regulatory oversight (30th Report of the Social Development Committee, June 2009).
July 2010	NRAS commences with national registration for 10 health professions, including chiropractic and osteopathy.
July 2012	Registration commences under the NRAS for four additional professions, one of which is the Chinese medicine profession which includes Chinese herbal medicine practitioners.
April 2013	*Final Report on Options for the Regulation of Unregistered Health Practitioners* released, concludes 'a single National Code of Conduct with enforcement powers for breach of the Code is considered likely to deliver the greatest net public benefit to the community.' (AHMAC, 2013: 7).
April 2015	COAG Health Council 'agreed to the terms of the first National Code of Conduct for health care workers … and to a policy framework to underpin nationally consistent implementation of the Code…' (COAG Health Council, *Communique* 17 April 2015, 1).
November 2015	COAG Health Council agrees to amend the National Law to include the profession of paramedicine in the NRAS (COAG Health Council, 2015)
September 2016	Australian Natural Therapists Association (ANTA) lodges a submission to the Health Workforce Principal Committee of AHMAC seeking statutory registration for the naturopathy, Western herbal medicine and nutritional medicine professions (Weir, 2016).
September 2018	AHMAC publishes guidance on the regulatory assessment criteria and process for adding new professions to the NRAS. (AHMAC, 2018).
October 2020	The ANC commissions research and preparation of a submission to build upon and update the 2005 Lin Report (ANC, 2020).
November 2020	The ANC releases a draft AHMAC submission for public consultation with the naturopathy profession (ANC, 2020).

ATTACHMENT 2: DEFINITIONS AND THE SCOPE OF NATUROPATHIC PRACTICE

Naturopathy is a distinct traditional and complementary system of medicine practiced around the world with strong historical and cultural roots in Europe. Naturopathy is defined by two core philosophies and seven principles, guided by distinct naturopathic theories.

The core philosophies of naturopathy are vitalism (the innate intelligence of living organisms) and holism (the body as a complex adaptive system that exists as a unified whole).

These philosophies are underpinned by seven naturopathic principles that guide practice:

I. First, Do No Harm (primum non nocere)
II. Healing Power of Nature (vis medicatrix naturae)
III. Treat the Cause (tolle causam)
IV. Treat the Whole Person (tolle totum)
V. Doctor as Teacher (docere)
VI. Health Promotion and Disease Prevention
VII. Wellness and Wellbeing.

Naturopathic practice embodies theoretical and conceptual frameworks that inform practitioner clinical reasoning and decision making. These concepts include:

→ The Naturopathic Therapeutic Order - a systematic approach to treatment that moves from minimally invasive to more forceful treatments as necessary
→ The Theory of Complex Systems reflected in naturopathic practice - that the body is a complex and self-sustaining dynamic and evolving system functioning within an environment of multiple nested systems which are interconnected.

Naturopathic clinical assessment is person-centred with the goal of determining the factors contributing to a patient's state of health and their symptoms and conditions. It involves investigation into lifestyle, social, environmental, external and genetic factors. Practitioners employ a range of assessment tools including a thorough case history, standard conventional physical examinations and laboratory testing along with traditional naturopathic assessment techniques such as nail, tongue and pulse diagnosis. The three main goals of a naturopathic assessment and diagnosis are to:

(1) determine the factors contributing to a patient's state of health, their symptoms and/or diseases, and identify the underlying causes of the disease state
(2) collect the proper information to inform a naturopathic diagnosis to accurately categorize the symptoms, condition and/or disease-state using biomedical terminology and diagnostic criteria along with traditional naturopathic diagnostic concepts
(3) assess the patient's vitality and state of wellbeing to guide treatment and healing ability. (Lloyd et al., 2021: 1-2)

ATTACHMENT 3: SUMMARY OF FINDINGS FROM A SYSTEMATIC REVIEW OF THE LITERATURE ON THE CHARACTERISTICS OF THE NATUROPATHY WORKFORCE

A 2020 systematic review was conducted to identify the characteristics and experiences of the Australian naturopathic workforce. The review identified fifteen relevant studies conducted at national and regional levels and employed survey research, secondary analyses, semi-structured interview and focus groups.

Overall, the review found that the research published since the Lin Report (2005) indicates some features of the naturopathic workforce and naturopathy practice have changed while others have remained consistent. The key areas covered by the research were practitioner and practice characteristics and behaviours, patient profiles and professional and interprofessional issues.

The review confirmed that Australian naturopaths operate as primary care clinicians, providing care to diverse populations with varied health conditions, including vulnerable or marginalised communities. In some rural areas, the evidence suggests naturopaths may represent up to one third of primary care practitioners, with a similar number of naturopaths as general practitioners. Naturopaths engage with patients on a range of important health issues including diet and nutrition, mental health, substance use and, in some instances, vaccination. This important role in primary care means that provision of inaccurate or misleading information can undermine important public health messaging and present significant risks to the community.

Although bachelor's degree qualifications in naturopathy and Western herbal medicine have been available in Australia for more than 20 years and is considered the minimum qualification required for safe and competent practice of the profession, the review data suggests that between 2011 and 2020, the proportion of naturopaths with Advanced Diploma qualifications increased from one third to almost half of the profession.

The review confirmed that while naturopathy is a multi-modality practice employing an eclectic range of practices, Western herbal medicine is a core part of naturopathic practice with almost all naturopaths prescribing herbal medicine products 'sometimes' or 'often', naturopaths spending a greater proportion of their clinic prescribing time on herbal medicine that another other type of therapy surveyed, and over one third of naturopaths holding separate herbal medicine qualifications. The review also confirmed that naturopaths frequently employ ingestive medicines in their practice, most commonly herbal medicines and nutritional supplements, increasing the risk profile of the profession.

The principal operating model adopted by naturopaths is solo practice with implications for the risk profile of the profession and public safety, where quality assurance mechanisms, such as clinical governance systems and credentialling are likely to be limited or absent.

Naturopaths access and use published research literature to inform their clinical practice and are well-represented among the allied health professions undertaking federal government funded research in Australia. Internationally, the naturopathic research community has produced more than 2000 research articles across a broad range of health condition and treatment topics. The challenges naturopaths face in applying research evidence to clinical decisions, as reported in this review, are shared by other health professions, and has led to extensive research attention being directed towards improving the translation and implementation of new research into clinical practice more generally. Naturopaths also use other information sources, but there are differences in where they seek knowledge from, and limitations they perceive for, each type of information source. This suggests that the naturopathic profession requires support in accessing and applying knowledge from various sources, but this support should be relevant to the specifics of naturopathic professional culture and practice rather than simply employing mechanisms used for other health professions.

Division and fragmentation of the naturopathic profession along with commercialisation and co-option of the naturopathic title by unqualified persons were considered current professional challenges by naturopaths, who also believed regulation was the core solution to these challenges (Wardle et al, 2013). This supports the review finding that the profession continues to be largely supportive of registration. Despite this support, the voluntary independent register that was established for naturopaths and Western herbalists in Australia remains under-subscribed and the profession continues to fact the effects of unregulated entry to practice for naturopathy.

ATTACHMENT 4: FINDINGS FROM STUDIES ON THE PROFILES OF PATIENTS WHO USE NATUROPATHIC SERVICES

- → In 2005 the Lin report found that women consulted with naturopathy and herbal medicine practitioners at almost three times the rate of men (Lin et al, 2005: 236, 239), with 68% of naturopathy and WHM patients being women (p. 239). The age range of women consulting with practitioners ranged from infants to 86 years of age , with women aged 45-50 years (28% of users) (2005: 236), and 41-60 years (43.1%) (2005: 239) making up the greatest proportion.
- → In 2020 three studies presented data on the profiles of patients and populations treated by naturopaths (Malhotra et al, 2020; Steel et al, 2020b; Wardle et al, 2010) [7, 10, 11]. Malhotra & colleagues (2010) addressed patient drivers for seeking naturopathic care for sleep disorders [10], Steel & colleagues (2020a) reported on populations and conditions treated by naturopaths [7] and Wardle & colleagues (2010) examined naturopathy in rural health [11].
- → Malhotra & colleagues (2020) found that patients have an inherent belief in the benefits of complementary treatment approaches and often use conventional medicines concurrently [10].
- → Steel & colleagues (2020b) identified the populations most frequently reported as “often” treated by naturopaths included middle age (88.5%), adolescents (45.2%) and older people (34.4%) [7]. Naturopaths also report treating children “sometimes” (52.6%) and pregnant women “sometimes” (45.9%) or “often” (24.2%) [7].
- → Steel & colleagues (2020b) found the conditions most frequently reported as “often” treated by naturopaths included fatigue (95%), digestive disorders (83.7%), anxiety and depression (77.4%), irritable bowel syndrome (IBS) (66.9%), menstrual disorders (61%) and sleep disorders (60.5%) [7]. Other conditions reported to be treated “often” by naturopaths included thyroid complaints (46.7%), chronic pain (38.8.%), headache/migraine (38.7%), recurrent infections (37.5%) and arthritis (31.2%) [7].
- → Wardle & colleagues (2010) found rural patients and populations have an affinity with naturopathy – they prefer a preventative approach to health, favouring self-care, and they appreciate the time commitment and support provided by naturopaths [11].

ATTACHMENT 5: TYPES OF OCCUPATIONAL REGULATION

Four main types of occupational regulation are outlined below. These have been adapted from various sources (AHMAC 2018; Carlton 2017; WHO WPR 2016). They are:

→ Voluntary certification
→ Co-regulation
→ Negative licensing
→ Occupational licensing or statutory registration

Voluntary certification (also known as self-regulation)

Under voluntary certification there is no underpinning statute enacted by government that confers powers on a regulator to license members of the profession or occupation. Rather, professionals join and establish an association with a constitution, Bylaws and rules for its members. The association may be registered as a body corporate under the relevant law of a country.

On joining the association, professional members agree to abide by the rules of the association and its code of ethics. The association may operate a consumer complaints mechanism and the rules may provide for members to be expelled for serious breaches of the code of ethics. However, the system is entirely voluntary – practitioners can choose not to join an association and still practise and can continue to practise if expelled from an association for misconduct.

A variation on this type of occupational regulation is where a legal entity is established specifically to carry out regulatory functions on behalf of a profession separately from the professional association/s. While there is organizational separation of the regulatory functions from the membership representation and advocacy functions, the system continues to be entirely voluntary. While consumers, insurers and health service providers may rely on the professional association for trusted advice about who is qualified to practise the profession, there is no direct involvement or recognition from government.

Co-regulation

Co-regulation is similar to voluntary certification. The key difference is that some of the functions of the self-regulating professional association may be either delegated from or recognized by government. This government recognition or delegation may be conditional on the certification body meeting specified standards in relation to governance and its certification standards and processes. This recognition process establishes, in effect, a partnership between government and the certifying body, and the benefits that flow to practitioners from certification create incentives for practitioners to comply with the professional association's standards.

Code regulation (also known as negative licensing)

Under a negative licensing system, there is no legal barrier to entry to an unregistered profession – anyone can set out their shingle and practice, no matter what their level of training or skill. However, a law is enacted that provides a mechanism for a statutory regulator to receive and investigate complaints about a practitioner. The regulator may issue a prohibition or banning order to remove a practitioner from practice when the regulator finds that a practitioner have committed an offence or a breach of minimum standards of practice and their continued practice presents a serious risk to the public. There may be offences for breach of a prohibition order and an online searchable public register of prohibition orders.

Occupational licensing (also known as statutory registration)

Under an occupational licensing system, the purpose and functions of the system are not determined by the profession alone (as in the case of voluntary certification) but are generally set out in legislation or other instrument of authority and are subject to public scrutiny (through the responsible parliament and minister). The legislation establishes a regulatory body with powers to register/license and regulate practitioners. Entry to a regulated profession is limited only to those the regulatory body considers to be properly qualified and of good character. This gate-keeping role is underpinned by statute, with powers for the regulatory body to prosecute unregistered persons who 'hold themselves out' as qualified to practice the profession when they are not. The statute provides an effective mechanism for restricting entry to the profession, and disciplinary powers to deal with practitioners whose practice falls below an acceptable standard.

There are two distinct models of occupational licensing: reservation of title and reservation of practice. While registration/licensing laws generally prohibit unregistered/unlicensed persons from using restricted professional titles or pretending to be qualified and registered when they are not (reservation of title), some laws go further, prohibiting unregistered persons from providing certain types of clinical services (reservation of practice). Such laws create an exclusive scope of practice, in effect a monopoly, for the profession or occupation concerned.

ATTACHMENT 6: SELECTED SCHEDULED (RESTRICTED) HERBS THAT NATUROPATHS IN AUSTRALIA ARE UNABLE TO USE DUE TO MEDICINES SCHEDULING ARRANGEMENTS

Aconitum spp (Aconite, Monkshood, Wolfsbane)
Acorus calamus (Sweet flag or Sweet sedge)
Aristolochia spp (Chinese fairy vine)
Atropa belladonna (Deadly nightshade)
Borago officinalis (Borage)
Colchicum autumnale (Autumn crocus or Meadow saffron)
Convallaria spp (Lily of the valley)
Datura spp (Jimson weed or Thorn apple)
Digitalis (Foxglove)
Ephedra spp (Ma huang)
Gelsemium spp (Yellow jasmine)
Hyoscyamus niger (Henbane)
Piper methysticum (Kava)
Lobelia inflata (Indian tobacco)
Mandragora officinalis (Mandrake)
Melilotus officinalis (Sweet clover)
Pulmonaria spp (includes Lungwort)
Rauwolfia spp (Indian snake root)
Sanguinaria canadensis (Bloodroot)[33]
Senecio spp
Symphytum spp (Comfrey)
Tanacetum vulgare (Tansy)
Tussilago farfara (Coltsfoot)

Source: Lin et al., 2005: 109.

33 Effective 1 Feb 2020. Sch 10 Bloodroot. https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decisions-amend-or-not-amend-current-poisons-standard-november-2019/13-final-decision-relation-sanguinarine

Practitioner	Nature of conduct	Selection of media coverage
Mauricio Bascunan Cabrera AND Rodrigo Cabrera	Convicted of sexually assaulting eighteen women between 2010 and 2017 Convicted of sexually assaulting five women after giving them false diagnoses	http://www.aronah.org/registering-naturopaths-is-urgently-needed-to-protect-the-public-as-a-purported-naturopath-is-found-guilty-of-sexually-assaulting-18-women/ https://www.abc.net.au/news/2022-04-14/perth-naturopath-mauricio-bascunan-cabrera-jailed-for-abuse/100695040 https://www.abc.net.au/news/2021-11-18/naturopath-mauricio-bascunan-cabrera-guilty-assaulting-patients/100609284 https://www.abc.net.au/news/2022-06-16/perth-naturopath-rodrigo-cabrera-jailed-for-abusing-patients/101157838#:~:text=Perth%20naturopath%20Rodrigo%20Bascunan%20Cabrera%20jailed%20for%20abusing%20women%20after%20bogus%20diagnoses,-By%20Joanna%20Menagh&text=A%20Perth%20naturopath%2C%20whose%20brother,after%20giving%20them%20bogus%20diagnoses.
Marilyn Bodnar	Acquitted of manslaughter of a 42 year old woman who died after Bodnar had placed her on a 63 day water only fast in 1986.	https://www.abc.net.au/news/2018-04-05/naturopath-sentenced-to-seven-months-in-jail/9622276

	In 2018 Bodnar entered a plea of guilty and was convicted for failing to provide for a child causing danger or death. This was due to her advising a breastfeeding mother to undertake a raw food only diet to treat her infant's eczema. When the child was admitted to hospital he was in a critical condition, within days of death and suffered significant developmental delay. Although permanently prohibited from providing any health services, Bodnar was convicted in 2022 for breaching this lifetime ban.	https://www.smh.com.au/national/nsw/dodgy-nsw-naturopath-jailed-after-baby-nearly-starved-to-death-20180405-p4z7we.html https://reasonablehank.com/2018/08/02/convicted-naturopath-marilyn-bodnar-issued-permanent-prohibition-order-by-nsw-hccc/ https://www.dailytelegraph.com.au/subscribe/news/1/?sourceCode=DTWEB_WRE170_a_GGL&dest=https%3A%2F%2Fwww.dailytelegraph.com.au%2Fnewslocal%2Fbanned-naturopath-convicted-over-a-babys-near-death-appears-in-manly-court-for-giving-illegal-health-advice%2Fnews-story%2Fb98ddc6886911a95f5842a25e0bb1cd4&memtype=anonymous&mode=premium&v21=dynamic-high-control-score&V21spcbehaviour=append
Robert Jarvis	PO issued against Jarvis for three years for asking inappropriate questions regarding a female client's sexuality, touching the patient's breasts and failing to have appropriate professional indemnity in place. Jarvis breached this PO and was issued with a permanent prohibition order after he inappropriately touched and spoke to a young woman in a meditation class.	https://www.hccc.nsw.gov.au/Hearings---decisions/Public-statements-and-warnings/Mr-Robert-Jarvis---Permanently-prohibited-from-providing-any-health-services
Sean Kirsten	PO issued against Kirsten for two years for claiming to be an expert in nutrition and treating people with complex medical and mental health conditions with a $2000 12-week program. He advised one client to stop taking antidepressant medication she had been taking	https://www.dailytelegraph.com.au/newslocal/central-sydney/liar-sean-kirsten-sanctioned-by-hccc-after-masquerading-as-doctor-

	for three years without consulting her treating doctor. He held himself out as willing or able to cure cancer.	dietitian-and-nutritionist/news-story/bfc5d3a0bc793400a76ff29f97573257
Aleksander Strande	PPO issued against Strande as had wilfully misrepresented and overstated the level of his qualifications. He made claims about the efficacy of treatments which could not be substantiated. He lacked knowledge to determine whether the products he prescribes may have adverse reactions with their prescribed medications. He failed to provide information to clients regarding the herbal medicines and pressured his clients to continue treatment with him despite complaints of adverse side effects. He was not willing to seriously reflect on his practice and has no insight into the limitations of his training and qualifications and his competence to treat serious illnesses.	https://www.hccc.nsw.gov.au/decisions-orders/media-releases/2019/mr-aleksander-strande-breaches-of-code-of-conduct-permanent-prohibition-order https://www.hccc.nsw.gov.au/decisions-orders/public-statements-and-warnings/public-statement-and-statement-of-decision-in-relation-to-mr-aleksander-strande
Barbara O'Neill	PPO issued against O'Neill for making dubious and dangerous health claims regarding infant nutrition, causes and treatment of cancer, antibiotics and vaccinations that are not evidence based or supported by mainstream medicine.	https://www.hccc.nsw.gov.au/decisions-orders/public-statements-and-warnings/public-statement-and-statement-of-decision-in-relation-to-in-relation-to-mrs-barbara-o-neill
Wayne Leibelt	A PO was issued against Liebelt and he was indefinitely prohibited from providing health education or information related to COVID vaccinations or advice in relation to COVID vaccinations. This was due to an article that he wrote and was published in an Adelaide newspaper which contained claims that were false and misleading. He was not trained or qualified to provide information about COVID 19 vaccines and had based his claims on non-peer reviewed opinion and speculation.	https://www.hcscc.sa.gov.au/wp-content/uploads/2021/12/21_12_08-Liebelt.pdf http://www.aronah.org/naturopath-comes-under-investigation-for-advice-on-covid-19-vaccinations/
Ian Pile	A PO was issued against Pile for advising a client with metastatic bowel cancer and a colostomy bag that by taking his prescribed herbs her cancer would be 'cured in a couple of weeks.' He provided the client with herbs with emetic properties that caused her to	https://www.hccc.nsw.gov.au/Hearings---decisions/Public-statements-and-warnings/Public-Statement-and-Statement-of-Decision-in-the-matter-of-Ian-Pile

	vomit soon after taking them. He used the herb Bloodroot in a capsule when it is restricted to topical use in Australia. He gave liver detoxifying herbs to a client with liver metastases and failed to monitor or request tests of liver enzymes. He failed to confer with the patient's orthodox treating practitioner. He failed to demonstrate a sound understanding of any adverse interactions. He held himself out as qualified, able or willing to cure cancer and failed to maintain accurate and contemporaneous clinical records. He also failed to ensure that appropriate indemnity insurance arrangements were in place. Despite the PO issued in NSW, Pile relocated to SA and was issued with another indefinite prohibition order for offering health services in the Mt Gambier area and distributing bitter sweet almond capsules (containing a dangerous chemical – prussic acid that can cause cyanide poisoning) and asserting its efficacy in fighting cancer.	https://www.smh.com.au/national/nsw/herbalist-declared-risk-to-public-after-claiming-his-remedies-would-cure-cancer-20160501-gojac3.html https://www.hcscc.sa.gov.au/2020/03/12/public-statement-prohibition-order-mr-ian-pile/ https://www.adelaidenow.com.au/subscribe/news/1/?sourceCode=AAWEB_WRE170_a_GGL&dest=https%3A%2F%2Fwww.adelaidenow.com.au%2Fnews%2Flaw-order%2Fherbalist-ian-pile-banned-from-practising-after-promising-to-cure-cancer-with-herbs-only-to-cause-cyanide-poisoning%2Fnews-story%2Fe7da02ce004fd77bb1d81e7f28330d8b&memtype=anonymous&mode=premium&v21=dynamic-high-control-score&V21spcbehaviour=append
Daisley		Daisley:https://www.news.com.au/national/nsw-act/courts-law/glamorous-influencer-savannah-daisleys-court-battle-over-child-sex-allegations/news-story/9a032bec17894a87060267516b4bbf05
George Zaphir	Issued an IPO for leading patients to believe that he could cure cancer with black salve and Vitamin C injections. He failed to appropriately refer on patients to other health practitioners when their condition did not improve. He plead guilty to 56 counts of	https://www.9news.com.au/national/a-current-affair-george-zaphir-chiropractor-ban-practicing-guilty-court/5db9d5ab-a24e-4f27-8532-0c1f3127adfa

	breaching the prohibition order and was convicted and fined $30,000 in 2019.	
Diedre Brophy	An IPO was issued against Brophy which prohibited her from providing any health services including thermal imaging, diagnosing illness, and the manufacture advice or supply of black salve or any naturopathy service. She recently contested 5 counts of contravention of the order and was found guilty on 3 counts and ordered to pay a fine of $5,000	https://www.oho.qld.gov.au/protective-orders/ms-deidre-brophy https://www.cairnspost.com.au/subscribe/news/1/?sourceCode=CPWEB_WRE170_a_GGL&dest=https%3A%2F%2Fwww.cairnspost.com.au%2Ftruecrimeaustralia%2Fpolice-courts-cairns%2Ftablelands-woman-deidre-karen-brophy-who-invented-and-sold-cancer-treatment-online-dealt-with-by-court%2Fnews-story%2Ff5c98687c4f4c817ce1794874cf12f9a&memtype=anonymous&mode=premium&offerset=cp_truecrime_premium
Jeffrey Dummett aka Jeremiah Hunter	Acquitted of manslaughter of a patient. A 39 year old man with chronic kidney disease died after undergoing a 10 day detoxification program. He had ceased prescribed kidney dialysis four times a day and other medication to undergo the program. A post mortem examination found the man had died from a heart attack and an undiagnosed heart condition.	https://www.abc.net.au/news/2005-04-26/naturopaths-qualifications-unverifiable-inquest/1558370 https://www.smh.com.au/national/naturopath-found-not-guilty-of-patients-death-20070922-gdr63i.html https://www.smh.com.au/national/naturopath-not-guilty-of-manslaughter-20070921-1062.html
Francine Scrayen	Convinced a woman with a rectal tumour that homeopathic treatment could provide a cure for her cancer. The State Coroner found that the woman had died as a result of complications of metastatic rectal cancer.	https://www.abc.net.au/news/2010-07-30/incompetent-care-led-to-dingles-death/925976

Wilson 2008		https://www.smh.com.au/national/sex-assault-naturopath-jailed-20081028-5a6a.html
Reginald Fenn	Convicted of the manslaughter of an 18 day old baby boy with a critical aortic stenosis which could only be treated by surgery. The infant died of heart failure before an operation was carried out. Fenn advised that his herbal drops had cured the baby and on this advice, the parents cancelled his operation.	https://quackwatch.org/naturopathy/legal/fenn/ https://www.smh.com.au/national/naturopath-guilty-of-manslaughter-20040213-gdicpd.html
Thomas Sam	Convicted of manslaughter by criminal negligence for repeatedly failing to accept conventional medical treatment and continuing homeopathic treatment of his nine month old daughter's eczema condition. The infant died three days after being admitted to hospital.	https://www.abc.net.au/news/2009-09-28/parents-jailed-over-babys-death/1445256 https://www.dailytelegraph.com.au/baby-gloria-thomass-parents-thomas-and-manju-sam-jailed-for-not-getting-proper-medical-help/news-story/f5f2c684a45b482ce589dde9744b9a82
Melbourne naturopath	Professor David Ashley, director of Haematology and Oncology at the Royal Children's Hospital, Melbourne, said he had been contacted by many doctors after he revealed in The Age on Saturday that a boy with a 60 per cent chance of cancer survival died last year following his parents' decision to stop chemotherapy. A Melbourne naturopath had advised the parents that an unconventional treatment might offer a cure. But the boy died six months later, three days after his parents returned him to hospital requesting chemotherapy be restarted. Professor Ashley said he had been surprised by the number of similar anecdotes from other physicians at the Royal Children's and Royal Melbourne hospitals.	https://www.theage.com.au/national/call-for-control-on-alternative-medicine-20020925-gdumlc.htm

	The baby, a boy under the age of one, was epileptic and under the care of the Royal Children's Hospital Neurology Department. The hospital's Director of Neurology, Associate Professor Andrew Kornberg, said the family did not want to give the baby conventional medicine because they were also seeing a natural therapist. Dr Kornberg said the infant was having tens of seizures a day while off medication. National Herbalists Association of Australia president Susan Dean supported registration of alternative practitioners, full disclosure of ingredients in herbal remedies and greater medical training for alternative practitioners.	

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