WESTERN SYDNEY UNIVERSITY

NICM Health Research Institute

SECURING THE FUTURE OF

COMPLEMENTARY MEDICINES MANUFACTURING IN AUSTRALIA

A STRATEGIC BUSINESS CASE

16 October 2023

ACKNOWLEDGEMENT OF COUNTRY

With respect for Aboriginal cultural protocol and out of recognition that its campuses occupy their traditional lands, Western Sydney University acknowledges the Darug, Eora, Dharawal (also referred to as Tharawal) and Wiradjuri peoples and thanks them for their support of its work in their lands (Western Sydney and beyond).

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ABBREVIATIONS AND ACRONYMS

ACRONYM	DEFINITION
CBA	Cost-Benefit Analysis
CPI	Consumer Price Index
DBC	Detailed Business Case
ERA	Excellence in Research for Australia
GMP	Good Manufacturing Practice
ILM	Investment Logic Mapping
MCA	Multi Criteria Analysis
NICM	NICM Health Research Institute, formerly the National Institute of Complementary Medicine
NPV	Net Present Value
NSW	New South Wales
OCM	Office of Complementary Medicine, TGA
OTC	Over-the-counter medicines
PC2	Physical Containment Level 2 space
PV	Present Value
SBC	Strategic Business Case
SME	Subject Matter Expert
TGA	Therapeutic Goods Administration
VIC	Victoria
WSU	Western Sydney University

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EXECUTIVE SUMMARY

PROJECT CONTEXT

The $6 billion per annum complementary medicines manufacturing industry stands at a crucial crossroads: maintain the status quo or invest in catalysing industry growth by capturing greater market share of the rapidly expanding global market. This is a pivotal moment for the sector and prompted the NICM Health Research Institute (also known as the National Institute of Complementary Medicine) at Western Sydney University to take the lead in commissioning this report.

Extensive analysis, research, and consultation identified various opportunities and challenges facing the industry and contributed to the development of an evidence-based set of recommendations and associated business case. This report presents recommendations to government, proposing a co-investment model that has the potential to support Australian manufacturers to triple industry revenues by 2032 by providing opportunities to capture a greater proportion of the global complementary medicine market and foster a skilled manufacturing workforce, protect sovereignty of supply and manufacture, and fuel job growth across Australia.

The proposed solutions are designed to facilitate the industry's growth in Australia and in overseas markets, aiming for a potential target of $15.5 billion in industry revenue by 2032. Building upon NICM Health Research Institute's Vision 2028 paper, this report emphasises collaborative efforts between the complementary medicines industry, government, and academia. By co-investing alongside industry, government can drive sector wide innovation and strengthen domestic skills and manufacturing capabilities, that will see the industry thrive in both the domestic and fast-growing export markets.

THE CASE FOR CHANGE

The Australian complementary medicines industry has demonstrated significant growth in recent years, with a compound annual growth rate (CAGR) of 3.8% from 2018 to 2022, resulting in $5.9 billion AUD revenue in 2022.[1] Forecasts indicate a continued upward trajectory with an expected 4.1% CAGR from 2023 to 2027.[2] This includes the significant strides industry has made in export revenues, exceeding AUD $1 billion annually,[3] with a strong presence in Chinese and Indian markets.

Despite this success, the industry now faces pressing challenges in defending and expanding its export market share, developing a skilled workforce, driving greater research collaboration and accessing raw materials while maintaining domestic manufacturing capabilities. To seize the opportunity for global market expansion, the Australian industry must position itself to match the projected global industry CAGR of between 19-26.5% from 2021 to 2030.[4]

INDUSTRY CHALLENGES AND OPPORTUNITIES

This report identifies several barriers hindering industry growth and has explored challenges and opportunities through six themes and proposed solutions for government to co-invest with industry. A suite of solutions and initiatives is proposed across these six themes. It is expected that these solutions will benefit the industry and contribute to realisation of the collective vision and ambition, as well as leading to flow-on economic benefits for government and community. The themes and associated solutions are outlined below:

1. **Research and innovation:** Insufficient grant funding for research and development deter manufacturers from investing in innovation that validate efficacy claims and has the potential to increase market potential. Limited funding pathways through medical grant bodies further hinder progress. Solutions explore how to accelerate research and innovation activities by providing a clear funding pathway and further incentivising industry investment in research and innovation.
2. **Supply chain risks:** The industry relies heavily on imported raw materials, exposing it to supply chain vulnerabilities. The complex approval process for raw materials hampers innovation and the development of local capabilities. Solutions in this area explore the potential to seed local industries, partner with the agricultural technology sector, use ingredients native to Australia, and explore opportunities for local manufacturing.
3. **Workforce:** The industry is facing acute skills shortages and faces challenges in addressing workforce issues. These acute shortages span research, product development, laboratory skills, GMP compliance and manufacturing equipment operation which escalate operating costs and impacts the industry's competitive edge. Solutions to workforce challenges include mapping and understanding workforce dynamics, establishing partnerships for relevant training and to address specific skills shortages in product development and commercialisation.
4. **Manufacturing costs:** Overseas competition puts Australian manufacturing under pressure, primarily due to high establishment costs and limited government support. This situation may lead to the relocation of manufacturing facilities abroad, jeopardising Australian sovereignty in manufacturing. To increase the competitiveness of Australian manufacturing, solutions explore how to acquire specific funding support, reform regulatory practice that currently favours overseas manufacturers and develop an industry-wide manufacturing roadmap.

1 Complementary Medicines Australia. (September 2022). *CMA 2022 Industry Audit Report.*
2 Complementary Medicines Australia. (September 2022). *CMA 2022 Industry Audit Report;* Euromonitor Consumer Health in Australia 2022.
3 ABS (2022) Including Green tea extract, Provitamins, Vitamins and Derivatives, sugar/maltodextrin for sports nutrition and medicaments containing vitamins or other products
4 Prudence, Grandview, FactsandFactors, Allied Market, Research and Markets, Data Bridge Market Research

5. **Growing export markets:** Trade operations face challenges due to low awareness of Australian brands, varying standards across markets and inconsistencies in regulations within the domestic market. There is more work to be done to establish the Australian complementary medicine brand globally to boost trade and facilitate Australian product entry in export destinations, solutions are explored to drive and promote awareness, improve participation in trade delegations and engage with overseas regulators.
6. **Regulatory challenges:** Stringent and costly regulations governing the complementary medicine industry in Australia aim to ensure product safety and efficacy and enable a strong reputation globally. However, they have created financial imbalances for local businesses, delaying time to market and reducing the industry's competitiveness. Solutions are explored which focus on supporting appropriate regulation of complementary medicines and re-establishing the Office of Complementary Medicine with essential skills within the TGA.

Addressing these barriers is essential for the Australian complementary medicines industry to unlock its full potential and capitalise on global market growth. Strategic measures and support from the government, including incentives for innovation, skill development, and supply chain resilience, can bolster the industry's competitiveness and strengthen its position in both domestic and international markets. By fostering collaboration and proactive solutions, the industry can overcome challenges and realise its ambitions for sustainable growth and continued success.

RECOMMENDATIONS

The strategic business case outlined in this report seeks a government co-commitment of $25 million dispersed over five years. This investment will be complemented by a co-investment of $35 million from the industry, including the tertiary sector and philanthropy, over the same period. Advancing this $60 million co-investment model could potentially capture an additional $497 million in new industry revenue over a ten year period up to 2032, while industry innovation and support may increase the proportion of international market share from 0.3% to 1.2% potentially tripling industry revenues by 2032.

These proposed solutions are intended to facilitate the industry's growth in Australia, aiming for a target of $15.5 billion in industry revenue by 2032. Building upon NICM Health Research Institute's Vision 2028 paper, this project emphasises collaborative efforts between the industry, government, and the tertiary sector. By co-investing alongside industry, government has the opportunity to drive sector wide innovation and strengthen domestic skills and manufacturing capabilities, that will see the industry thrive in both the domestic and fast-growing export markets.

The proposed solutions for industry growth are organised into different implementation options, catering to short-, medium-, and long-term goals. These options include prioritised deliverability in the short term, high-impact solutions in the medium term, and longer-term implementation requiring regulatory reform. The solutions seek to address the vision and objectives for the manufacturing industry, and de-risk threats to the industry.

The key recommendations to government and proposed funding allocations are:

1. **Prioritise support and funding for R&D incentives for industry to boost economic activity and address supply chain challenges (Themes 1 & 2)** – government investment of $4 million per annum over five years.
   - → Government to establish a funding incentive and pathway for research and development in complementary medicines.
   - → Government seeks and industry commits to a 'co-investment approach' for any funding grants – with industry providing a minimum of matching investment.
   - → Government to fund and support specific initiatives in addition to the funding and incentive pathway to bolster raw ingredient supply chain and foster innovation and exploration of new production channels.

2. **Provide targeted support for workforce initiatives (Theme 3).**
   - → Government to support the development of a complementary medicines workforce report that will map and model the current and future workforce and skills needs across industry.
   - → Government to support the establishment and design of micro-credentials for complementary medicine manufacturing skills and qualifications across all industry levels, considering links to advanced manufacturing and pharmaceuticals industry.
   - → Government to support the establishment of formal partnerships between industry and education sector to implement micro-credentialling through training providers to address critical skills shortages.

3. **Deliver funding support for complementary medicines industry through manufacturing uplift and trade promotion (Themes 4 & 5)** – government investment of $1 million per annum over five years
   - → Government to co-fund strengthening of manufacturing capability across complementary medicines industry through direct grants, leveraging existing programs, addressing unfair manufacturing competition and development of an investment roadmap to better market the attractiveness of the industry for foreign investment.
   - → Government to support initiatives that facilitate international trade and market access for Australian complementary medicines products through trade promotion.

EXECUTIVE SUMMARY CONTINUED

4. Optimise the regulatory approach to complementary medicines (Theme 6)

- → Government acknowledge and seek to rectify current complementary medicines regulatory capability gaps within the TGA, through dialogue and conversation with industry. One approach to ensure appropriate skills would be to reinstate the Office of Complementary Medicines.
- → Government to support appropriate regulation of complementary medicines and provide direct funding to the TGA to cover work outside of the direct cost recovered framework.
- → Government reviews data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence.
- → Government to support regulatory-related reforms in the trade and raw ingredients space to streamline exports, raw ingredient approvals, and other economically stimulating activities.
- → Government and TGA review of GMP licensing of overseas manufacturing facilities to examine regulatory practice that may favour overseas manufacturers.

These recommendations aim to boost manufacturing capabilities by strengthening research and innovation, developing a skilled workforce, promoting exports and simplifying regulation. With this strategic funding approach, the industry could realise its growth potential, de-risk the challenges ahead and capitalise on the opportunities in the complementary medicines sector.

ECONOMIC BENEFIT ASSESSMENT

Indicative economic analysis was undertaken to highlight the potential impacts to the Australian complementary medicine manufacturing industry resulting from:

- → Implementing the proposed solutions across the six themes identified in the section on the CASE FOR CHANGE: and
- → A potential industry growth response resulting from an assumed industry investment scenario in which:
  - Government provides an annual funding contribution of $5 million over a 5-year period (or a total of $25 million).
  - Key complementary medicines industry players match the government funding as an annual co-contribution of $7 million over the same period (or a total of $35 million).

It is assumed the abovementioned government and industry funding will be spread over targeted solutions under the six identified themes (i.e., research & innovation, raw ingredients, workforce, manufacturing, trade and regulation).

The analysis included in this business case represents a high-level benefits estimation to reflect the uplift potential in comparison to the current expected growth trajectory (presented in the section on the CURRENT STATE ASSESSMENT). The quantitative assessment of the potential benefits undertaken is based on a high-level economic benefit analysis approach. Accordingly, the net outcomes presented are illustrative only and show a potential pathway for the Australian complementary medicines industry. Specifically, the analysis highlights the market potential for the Australian industry both domestically and in overseas markets. The additional growth (incremental to the current trajectory) is driven by a range of factors including (1) Government and industry funding support); (2) an emerging global market for complementary medicines products (including China, India, Indonesia and the broader Southeast Asian region); (3) catalytic growth stemming from investment in research and innovation; and (4) Australian exports global market share increasing from 0.3% to 1.2% by Year 10. The high-level assessment of the impact of this growth scenario on industry revenue is presented in Figure *8*1.

If both the government and industry invest a combined $12 million per year for five years, it could lead to an additional $497 million in innovation driven revenue over the ten year period from 2022 to 2032 and could also assist Australian manufacturers to grow and increase their share of the global market. For example, an increase in market share to 1.2% would see the Australian industry revenue reaching $15.5 billion by 2032 (as illustrated in Figure 1 below).

The analysis undertaken was supported by a literature review of a range of investment initiatives in manufacturing, trade and research and innovation in Australia and estimated returns of government investment in manufacturing, research and development, and similar initiatives (refer Appendix 6).

This business case details how the Australian complementary medicines manufacturing industry, with targeted support from government can capture a greater proportion of a fast-growing global market, de-risk the industry, and deliver Australian led innovation and manufacturing capability to secure long term economic outcomes.

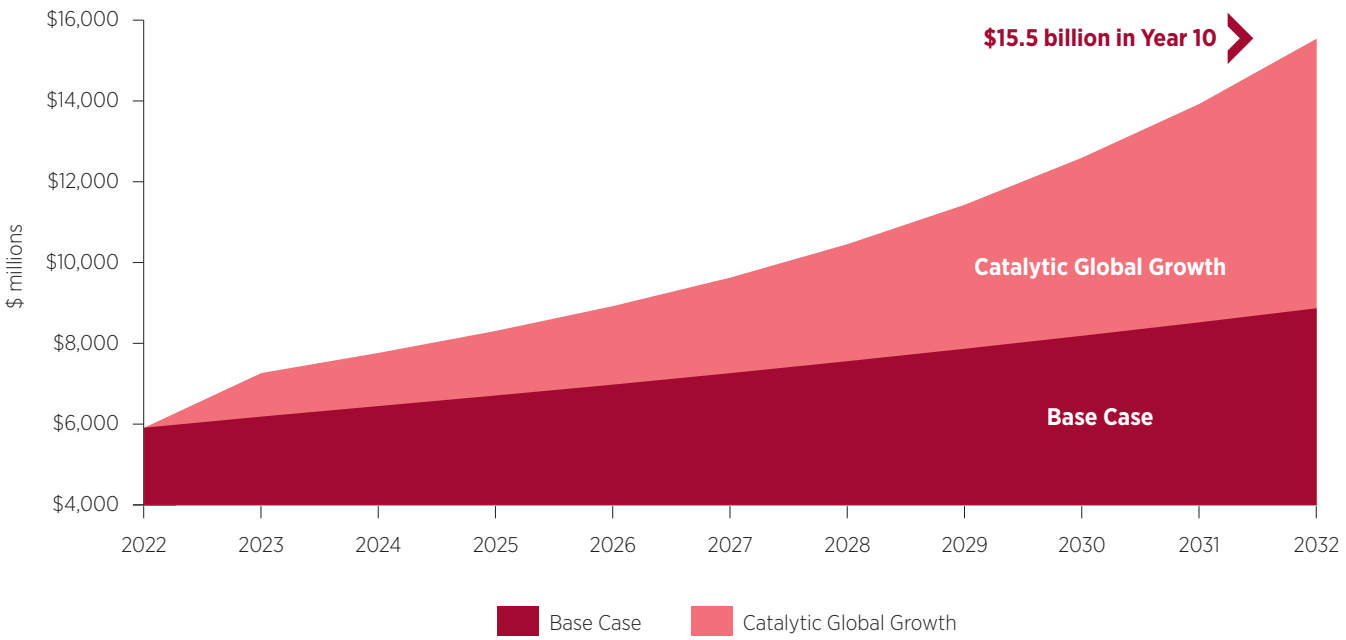


Figure 1 Australian complementary medicine industry revenue potential

PROGRAM ADMINISTRATION

As a vehicle for administration, NICM's industry collaboration model could support the establishment of this program and serve as a model for other medical research institutes in supporting manufacturing and innovation[5]. NICM is a global leader in CM research with unique capabilities supporting industry relevant research and development, including TGA certified herbal analysis facilities, GMP pharmaceutical manufacturing, GCP clinical trial capabilities and other laboratories.

NICM is involved strongly in education and training and is a leading agency in supporting government to develop relevant policy, reflected in three decades of involvement in State and Commonwealth Ministerial advisory committees, TGA advisory committees (including as Chair), Australia's National Medicines Policy Committee and numerous WHO consultancy roles. Located at the Westmead Precinct, one of the Australia's largest health, education, research, and training precincts, NICM is able to leverage the robust ecosystem of research and innovation to support progression of the solutions within this business case.

5 NICM was established with bi-partisan support in 2007 through joint seed funding from the Australian Commonwealth Government and the New South Wales Government. NICM has been ranked under the Commonwealth Government's Excellence in Research in Australia scheme as ERA 5 ('Well above world standard') over each of the last three trienniums.

INTRODUCTION

INTRODUCTION

BACKGROUND

Complementary medicines (CM) include nutraceuticals, herbal medicines, vitamins, minerals, probiotics, traditional medicines, and therapeutic dietary supplements – all of which are regulated in Australia by the Therapeutic Goods Administration (TGA). They have become increasingly popular medicines as consumers seek to improve their health and wellbeing, with approximately 75 per cent of Australians consuming complementary medicines on a regular basis.[6] The complementary medicines industry in Australian has grown largely self-sufficiently, supporting manufacturing jobs and providing valued products for customers domestically and overseas.

The Commonwealth, State and Territory governments' desire to boost manufacturing capability in key industry segments (for example, through the National Reconstruction Fund (NRF)[7]), a growing global export market, and the existing strengths of Australia's complementary medicine industry represent a clear opportunity to align ambition with policy conditions to grow the complementary medicines manufacturing industry in Australia. By capitalising on this opportunity, Australia can establish itself as an international leader in this field, providing quality products to consumers both domestically and internationally while promoting economic growth, job creation and the expansion of domestic manufacturing.

The domestic complementary medicines industry in Australia is estimated to be worth between $4.6 to $4.9 billion AUD.[8] [9] The industry value chain is comprised of raw materials suppliers, manufacturers, wholesalers, distributors, retailers as well as other ancillary parties including but not limited to regulators and academia. In addition, the Australian complementary medicines industry has a substantial export market that has reached $1.03 billion AUD in 2022[10], primarily to countries in Asia Pacific as well as other countries globally.[11]

Australia's complementary medicine products have a strong reputation globally as a premium brand, built on strict manufacturing standards, high product quality, and trust in the rigour of our regulatory approach.[12] Conversely, the same strict manufacturing standards and comparatively high wages in Australia has driven an increase in operational cost in the complementary medicines industry in Australia.

Through development of this business case the risks and opportunities for the broader industry have been examined and signalled focused approaches to de-risking the industry and ensuring Australia maintains a strong, sovereign and innovative medicines manufacturing industry whilst growing profits and high skilled jobs in Australia.

PURPOSE

NICM Health Research Institute at Western Sydney University is Australia's global leader in integrative and complementary research and policy. Established with bi-partisan support in 2007 through joint seed funding from the Australian Commonwealth Government and the New South Wales (NSW) Government, NICM plays a key national role in ensuring Australians have access to reliable evidence on complementary medicines and treatments in wide use. NICM's vision is "leading innovation and impact in health and wellbeing through evidence-based integrative medicine".

NICM released *Vision 2028: Strengthening Medicine Manufacturing in Australia* in 2022. The vision establishes an ambition for the industry that will create jobs, support development of innovative new products, double industry projected revenue, advance skills in manufacturing, help address supply chain issues in partnership with Agritech, increase manufacturing capability, and grow exports.

This business case builds on NICM's *Vision 2028* and articulates the case for the growth of Australia's complementary medicine industry – including the economic benefits and value opportunities through growth in manufacturing capacity, skilled workforce, and exports. The development of the business case has identified core challenges faced by the Australian complementary medicines industry based on analysis of available data and extensive consultation.

In summary, the business case contains the following components:

- → A detailed and in-depth assessment of the current state of Australia's complementary medicines industry, including a detailed needs analysis.
- → Clear articulation and prioritisation of the challenges facing the industry, including core risks to sovereign capabilities and to growth trajectories in international markets.

Based on this detailed analysis:

- → A suite of potential interventions will be analysed to realise investment objectives for Australia's complementary medicines industry, including consideration of opportunities to enhance innovation and collaboration between academia, industry, and government; and
- → High level economic analysis of priority interventions will be undertaken describing the potential economic benefit to be realised as an outcome of implementation.
- → A clear and compelling case for change if needed, will be developed, including the need for Government and partner investment, presented through key priority areas.

6 Complementary Medicines Australia (CMA). (2022). Consumer Sentiment Study Survey

7 The NRF is a $15 billion dollar fund established by the Australian Government to provide finance for projects that diversify and transform Australia's industry and economy.

8 CMA (2022) Industry Audit Report

9 IBISWorld. (February 2023). *Online Vitamin and Supplement Sales in Australia*

10 Australian Bureau of Statistics (ABS). (2022).

11 CMA (2022) Industry Audit Report

12 CMA, Pre-Budget Submission 2022-23

INTRODUCTION CONTINUED

A summary of the business case development process, and the purpose of each stage is provided in *Appendix 1*. This business case represents a first major step in the investment decision process, and provides a pathway forward for further analysis, investigation, and investment.

SCOPE AND LIMITATIONS

The scope of this business case includes complementary medicine products that are intended to complement conventional medicine, including vitamins, minerals, supplements, herbal, Chinese and other forms of natural medicine, that are included on the Australia Register of Therapeutic Goods as AUSTL, AUSTL (A) or AUST R, but not sold as over the counter (OTC) medicines.

The scope of this business case excludes complementary services that are often included in the wider definition of complementary medicine, such as naturopathy, acupuncture, meditation therapy, therapeutic massage, chiropractic services, aromatherapy, osteopathy, reflexology, and hydropathic service.

The scope also excludes prescription medicines such as vaccines and antibiotics, complementary medicines solely supplied and regulated at a State level which may include some First Nations medicines, and newly authorised medicinal cannabis and psychedelics.

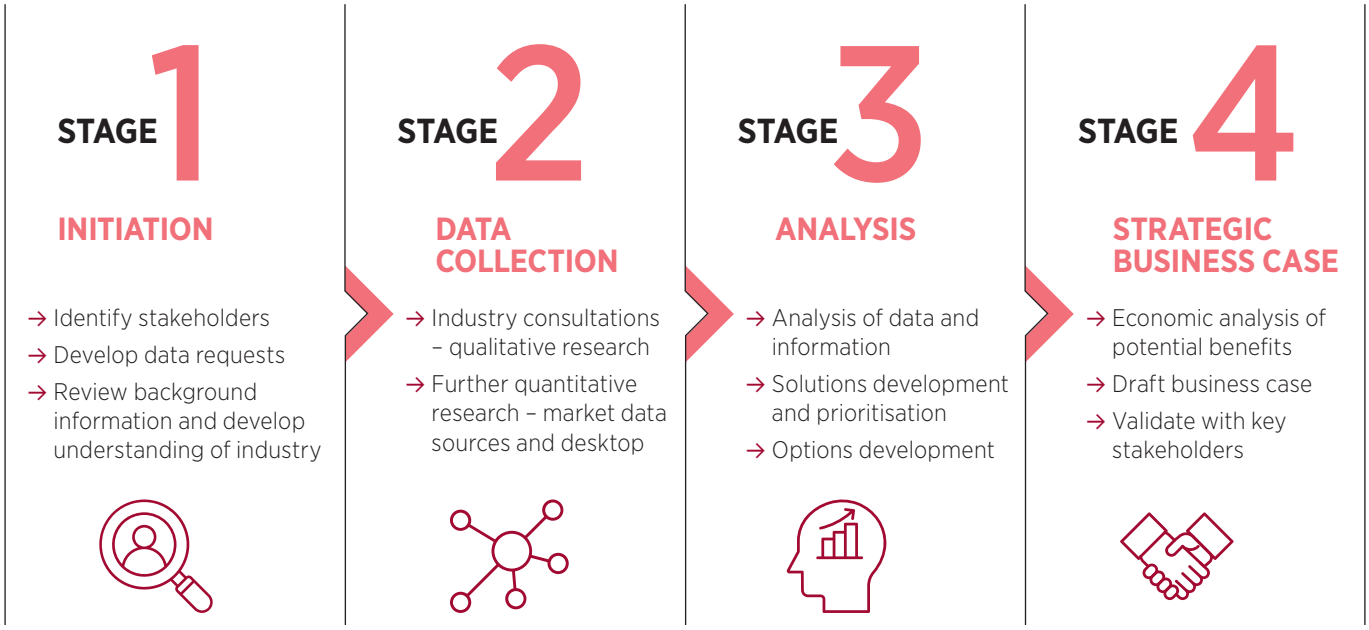
Limitations of this approach are described throughout the following sections describing our approach.

BUSINESS CASE DEVELOPMENT APPROACH

OVERARCHING APPROACH

This business case was developed with reference to government best practice, including the NSW Treasury strategic business case template and business case guidelines,[13] to provide a robust assessment of the relevant challenges the complementary medicine industry is facing, including the potential options to address them. The overarching approach is set out in Figure 2 below, and detail on methods is provided in the remainder of the section.

Figure 2 Overarching approach



13 NSW Treasury. (6 August 2018). *Strategic Business Case Template*; NSW Treasury. (6 August 2018). *NSW Government Business Case Guidelines TPP 18-06*.

QUALITATIVE AND QUANTITATIVE RESEARCH

Qualitative research

The qualitative insights in the business case have been developed via industry consultation including interviews and surveys with complementary medicines manufacturer industry leaders, extensive literature review, as well as desktop research of publicly available information:

- Interviews and surveys with industry leaders: Group and individual consultation sessions were conducted with representatives from organisations covering industry peak body, WSU departments, complementary medicines manufacturers, as well as other industry/professional services providers. The consultations have provided insights on the challenges and opportunities, regarding the current and future business within Australia and overseas. All organisations were provided with a questionnaire in advance to the virtual session and six organisations have provided written response to the questionnaire comprising quantitative data.
- **Literature review:** Reports published by government bodies, industry bodies, universities and third-party research service providers were reviewed. Such reports provided industry and segmental research and data (e.g., at categories-level such as "Vitamins").
- **Public information research:** Public disclosure and media coverage on topics, such as regulatory updates, market data, public register, companies' disclosure and reporting, were reviewed. Such information has provided examples and evidence on latest development in the industry within Australia and overseas.

Quantitative research

The focus of quantitative research was informed by qualitative insights through interviews and desktop research, and included:

- **Base case assessment:** Existing market data sourced from a range of government publication sources, industry research providers, economic data from global financial agencies and other data/insights stemming from consultation sessions are used to establish the base case of the Australian complementary medicines market. The base case assessment covers the current and forecasted demand, consumer demographics and channel preferences as well as other information such as product categories growth, providing the insight on the latest market trend and the implied area of future focus of development.
- **Economic analysis:** Due to the foundational nature of identified project initiatives and the early phase of a strategic business case, the economic assessment has been developed based on a benefits framework aligned to key theme areas identified through analysis and investigation.

In addition, due to the benefits mapping process largely identifying impacts in the regulatory sphere, the methodology developed for this assessment has relied on identifying a range of potential and likely scenarios of industry sector and workforce growth. The development of the identified scenarios has also partially relied on insights from consultation with key industry-related stakeholders.

The identification, quantification and qualification of project related impacts was undertaken on the benefits arising from addressing the industry-wide problems identified during the investment logic mapping process. While this assessment is relying on a holistic approach (i.e., national industry-wide) to assessing the impacts where possible, it is important to highlight the economic assessment methodology developed for this analysis has included steps to avoid double counting of benefits, particularly those which are linked to overlapping impacts associated with key manufacturers, supply chain and private-label manufacturers.

The analysis presented in this business case is reliant on available data and information obtained through the identified sources, for example, government published data and industry research reports.

STAKEHOLDER ENGAGEMENT

This strategic business case has been developed in consultation with a variety of stakeholders across the complementary medicines industry in Australia. Stakeholders who were consulted include the peak industry bodies in Australia, complementary medicine suppliers, local manufacturers, academics, and advisory services. A detailed list of stakeholders can be found in **Appendix 2**.

Stakeholders were engaged in the initial phases of business case development to provide insights into the complementary medicines industry in Australia. Stakeholders were engaged over four weeks from March to April in 2023. They were engaged in one-to-one or group interviews to describe the current state of the complementary medicines industry and market in Australia, as well as to provide insight into the challenges and opportunities the industry faces. These insights have been used to supplement desktop research findings in the base case and shape the development of the case for change. A detailed stakeholder engagement plan can be found in **Appendix 3**. Stakeholders were also involved in the development and validation of a long list of proposed solution options, as well as refinement into a short list for further economic analysis. The focus of stakeholder engagement activities has been on the private sector. However, it should be acknowledged that government departments and agencies, including the Commonwealth Government, State governments, and Therapeutic Goods Australia (TGA), will likely need to be engaged beyond this strategic business case.

INTRODUCTION CONTINUED

DOCUMENT STRUCTURE

The remainder of this document is structured as follows:

- → **CURRENT STATE ASSESSMENT: AUSTRALIA'S COMPLEMENTARY MEDICINE MANUFACTURING INDUSTRY** – provides a high-level understanding of the current state of the complementary medicines industry; it contextualises the environment in which the shortlisted options will operate.
- → **CASE FOR CHANGE** – outlines the core challenges being faced by the Australian complementary medicines industry, explains the opportunities and support required (the case for change), and specifies the benefits being sought (benefits).
- → **OPTIONS** – identifies a range of potential solutions and options to address the challenges and to realise the benefits identified previously. Multi-criteria analysis is used to refine the long list of identified options to a viable short list of options. Decision makers can then consider these options and make an informed choice that aligns with the strategic objectives of the broader industry.
- → **POTENTIAL BENEFITS** – a high level economic analysis on potential benefits in key theme areas.
- → **PROPOSED ACTIONS AND RECOMMENDATIONS** – outlines the recommended course of action based on the analysis and evaluation of the previous sections.

CURRENT STATE ASSESSMENT

CURRENT STATE ASSESSMENT: AUSTRALIA'S COMPLEMENTARY MEDICINES INDUSTRY

This section presents an overview of Australia's complementary medicines industry including:

- → the scope and definition of the industry;
- → the current landscape, including ecosystem overview, market size and projected growth potential and dynamics;
- → key trends in relation to products, consumers, and sales channels; and
- → an overview of the existing policy and regulatory environment in Australia.

DEFINING AUSTRALIA'S COMPLEMENTARY MEDICINE INDUSTRY

Complementary medicines, also referred to as traditional medicines, dietary supplements or natural health products, are an important part of healthcare for many Australians. Complementary medicines are regulated as medicine by the Therapeutic Goods Administration (TGA) and are off the shelf non-prescription medicines available for consumers to select, unlike prescription medicines (prescribed by a doctor) and some OTC medicines and S2 and S3 medicines (selected by a pharmacist).[14] These products are intended to enhance health, to be used in self-limiting conditions, and to complement or support conventional medical treatments, rather than replace them.

Examples of complementary medicines include most vitamin and mineral and micronutrient supplements, probiotics and postbiotics, modern herbal or plant medicines, traditional herbal or plant or fungi-based medicines including Western/European, Chinese and Ayurvedic, essential fatty acid supplements such as fish oil or algal DHA, animal-based supplements such as glucosamine and therapeutic bee products, therapeutic essential oils and certain enzymes and amino acids.

The complementary medicine industry, for the purpose of this business case, is defined as the group of companies or organisations operating in Australia that are involved in the research, testing, manufacture, packing, distribution, supply, retail and/or export of complementary medicines for domestic and international use. This definition includes, but is not limited to, large pharmaceutical companies, research and academic institutions and small and medium enterprises (SME).

AUSTRALIA'S COMPLEMENTARY MEDICINES LANDSCAPE

This section describes the complementary medicines landscape in Australia, including an overview of the ecosystem, key stakeholders, and competitive dynamics.

COMPLEMENTARY MEDICINES ECOSYSTEM

A number of stakeholders interact within Australia's complementary medicines ecosystem – including the industry itself, but also various regulators, policymakers, universities and research institutes, consumers, and export partners. These stakeholders work together to provide Australians with access to quality, safe and effective complementary medicines products and therapies. See Figure 3 *Australia's complementary medicines ecosystem.*

Key stakeholders in the ecosystem are:

- → **Commonwealth and State Governments** – The Australian commonwealth and state governments, including the treasury, and portfolio ministers are responsible for setting priorities, policies and guidelines, promoting public health and funding research supporting the advancement of the complementary medicines industry.
- → **Therapeutic Goods Administration (TGA)** – Part of the Department of Health and Aged Care, Health Products Regulation Group, a government regulatory authority responsible for regulating the supply, import, export, manufacturing, and advertising of therapeutic goods including medicines, medical devices, and biologicals in Australia.
- → **Universities/Research Institutions** – Universities and research institutions, including research companies, conduct vital research and publications to support the advancement of the industry. They may also provide formal skills and training to the industry.
- → **Australian Bureau of Statistics (ABS)** – The ABS is the independent statutory agency of the Australian Government, responsible for statistical collection and analysis and for giving evidence-based advice to federal, state and territory governments
- → **Australian Trade and Investment Commission (Austrade)** – Austrade is the Australian government's trade and investment agency. Its role is to help Australian businesses to succeed in international markets, including providing market intelligence, trade promotion, export grants and other forms of support.
- → **Complementary Medicines Australia (CMA)** – The peak industry body for the complementary medicines sector. It represents members across the supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors, and retailers.
- → **Consumer Healthcare Product Association (CHPA)** – Leading industry voice representing the manufacturers and distributors of consumer healthcare products including non-prescription medicines, as well as businesses that support the consumer healthcare product industry.

14 Therapeutic Goods Administration. (20 June 2019) *Complementary Medicines Overview*

- **Registered Health Practitioners/Practitioner Associations** – Registered health practitioners directly or indirectly related to the provision of advice, guidance, prescription, or delivery of complementary medicines. This includes doctors, herbalists, acupuncturists and so on. There are various practitioner associations representing these professions, including, but not limited to, the Australian Traditional Medicine Society, Australian Acupuncture and Chinese Medicine Association, and the Royal Australian College of General Practitioners.
- **Medicine sponsor** – A person or company who exports/imports or manufacturers therapeutic goods for supply in Australia or elsewhere. The sponsor is responsible for applying to the TGA to have their therapeutic good included on the Australian Register of Therapeutic Goods (ARTG).
- **International stakeholders** – Foreign entities at overseas designation markets including international partners, regulators in the relevant fields.
- **Suppliers** – Provide raw materials and other ingredients needed to manufacture complementary medicines.
- **Manufacturers** – Responsible for producing and packaging complementary medicines, in compliance with TGA GMP requirements.
- **Wholesalers/Distributors** – Act as intermediaries between manufacturers and retailers, ensuring the efficient inventory management and distribution of complementary medicines.
- **Retailers** – Various online and/or physical retailers responsible for the distribution and sale of complementary medicines to consumers, this includes pharmacies.
- **Health insurers** – Various commercial companies responsible for covering some of the eligible costs of treatment in hospital as a private patient in addition to paying for health care costs that Medicare doesn't cover, such as physiotherapy.
- **Workforce** – The industry relies on a range of skilled professionals, including clinicians, operators and management, to both produce complementary medicines products and ensure their safety, quality, and effectiveness.
- **Consumers** – Individuals or organisations that purchase complementary medicines for personal or business use.

MARKET SIZE AND GROWTH

This section describes the size of the complementary medicines market in Australia in the context of the global market size, as well as projected growth potential and key trends impacting these factors.

Australia's complementary medicines industry

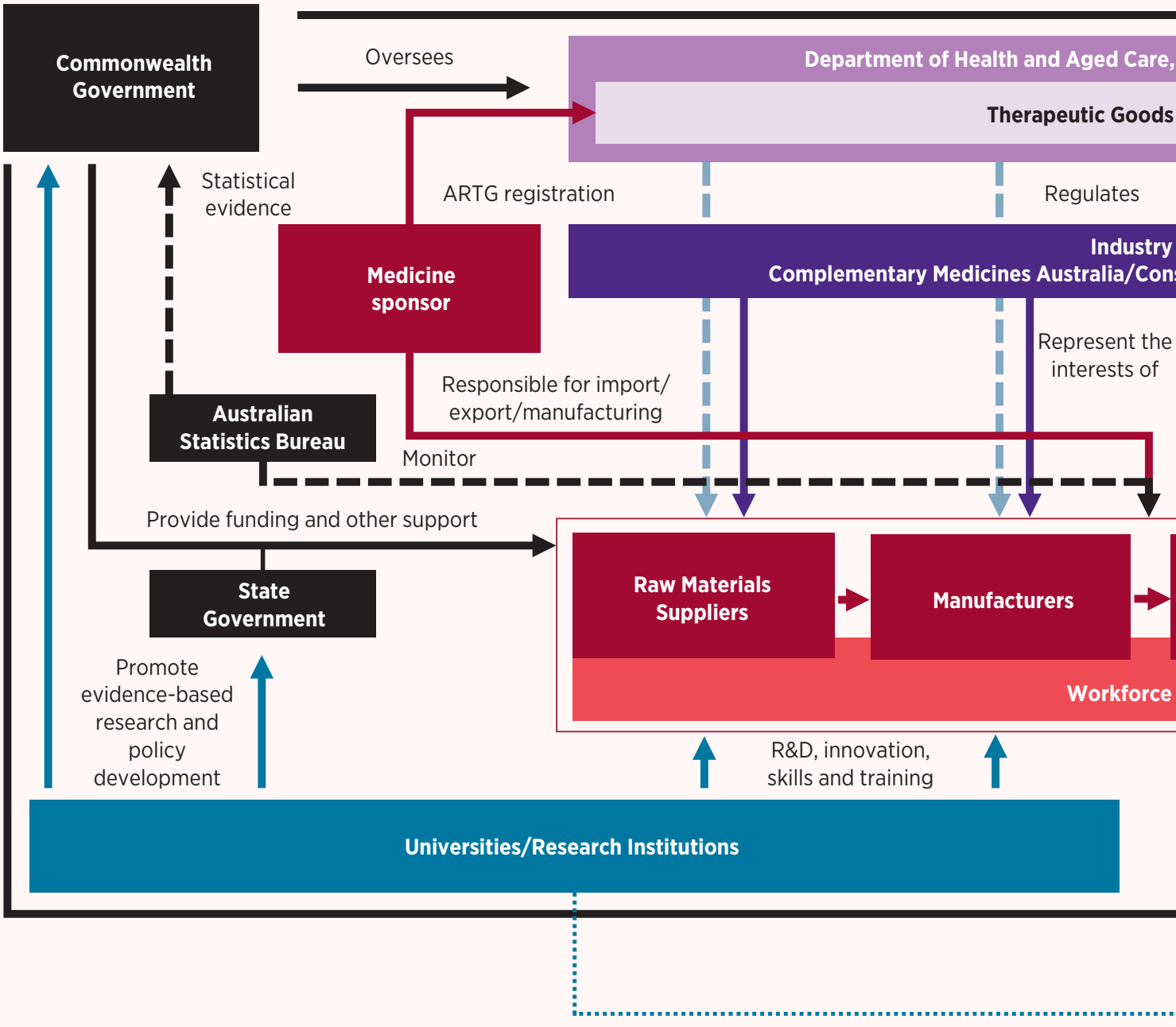
Australia's domestic complementary medicines industry has grown at a 3.8 per cent compound annual growth rate (CAGR) over the last four years, from $4.2 billion AUD revenue in 2018 to $4.9 billion AUD revenue in 2022.[15] [16] The industry is currently expected to grow at 4.1 per cent CAGR over 2023 to 2027.[17] [18] This forecast growth is lower than the indication from industry consultation, where most Australian complementary medicines manufacturers stated they expect double digit growth over a similar period.

As a comparison, global market will grow at a rate of 19 per cent to 26.5 per cent CAGR from 2021 to 2030.[19] Stakeholder consultation also echoed incremental growth of the complementary medicines industry over the past decade which has been largely driven by exports to Asia. Stakeholders reported that during the COVID-19 pandemic, the market continued to maintain growth (as shown in Figure 2) despite some experiences of supply chain issues. Growth projections are likely to be impacted by a range of factors, including continuing recovery from the COVID-19 pandemic, global supply chain disruptions, shortage of skilled workers, increasing international competition as a result of geopolitical tensions, and other international trade and regulatory barriers.[20] [21] [22]

15 Complementary Medicines Australia. (June 2017). *CMA 2017 Industry Audit Report*.
16 Complementary Medicines Australia. (September 2022). *CMA 2022 Industry Audit Report.*
17 Euromonitor Consumer Health in Australia 2022.
18 Euromonitor Vitamins and Supplements in Australia 2023.
19 Prudence, Grandview, FactsandFactors, Allied Market, Research and Markets, Data Bridge Market Research
20 IBISWorld. (January 2023). *Vitamin and Supplement Manufacturing in Australia*
21 IBISWorld. (February 2023). *Vitamin and Supplement Stores in Australia*
22 IBISWorld. (February 2023). *Online Vitamin and Supplement Sales in Australia*

AUSTRALIA'S COMPLEMENTARY MEDICINES ECOSYSTEM

Figure 3 Australia's complementary medicines ecosystem



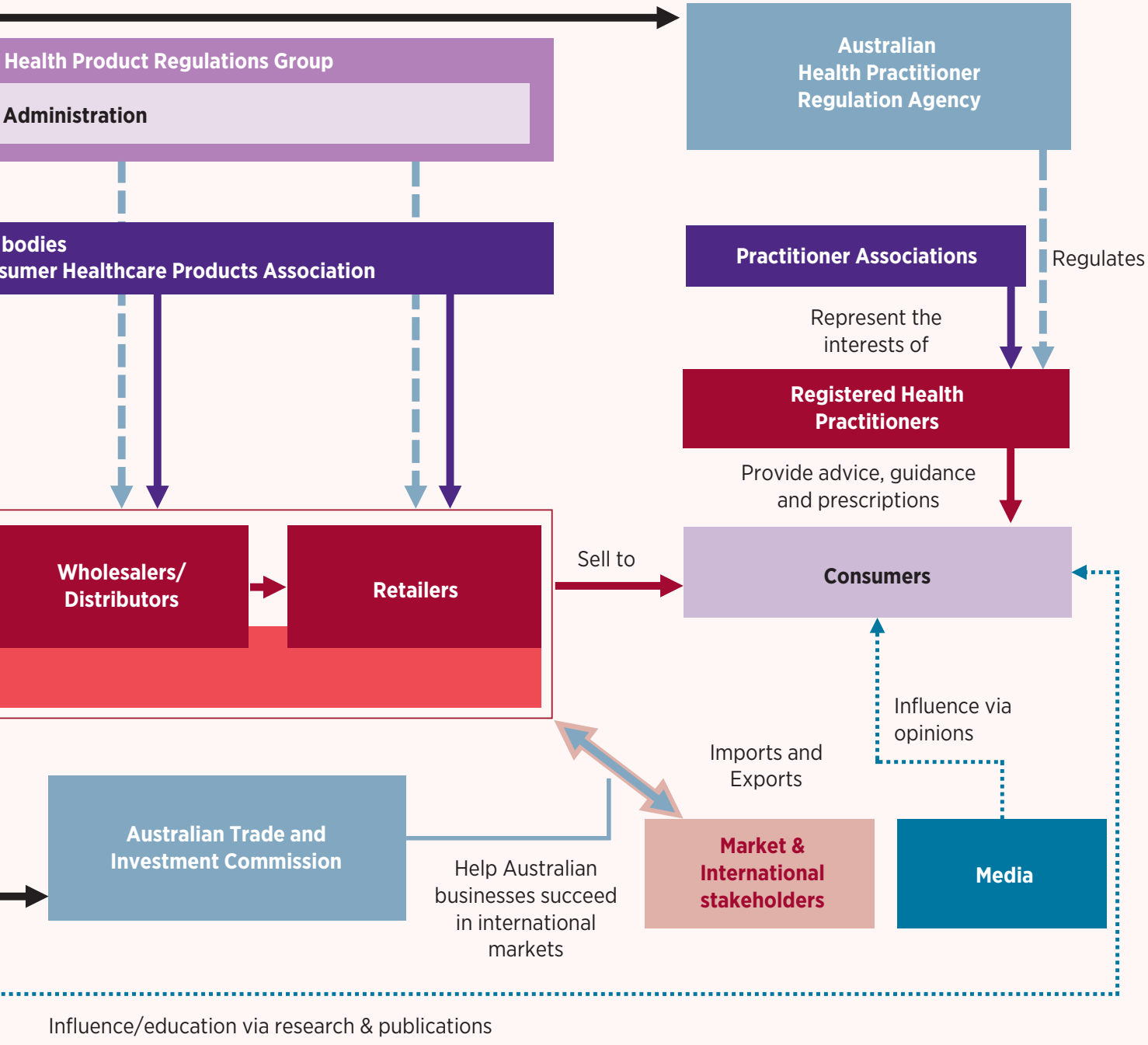

Health Product Regulations Group
Administration
bodies
sumer Healthcare Products Association
Australian
Health Practitioner
Regulation Agency
Practitioner Associations
Regulates
Represent the
interests of
Registered Health
Practitioners
Provide advice, guidance
and prescriptions
Wholesalers/
Distributors
Retailers
Sell to
Consumers
Influence via
opinions
Imports and
Exports
Australian Trade and
Investment Commission
Help Australian
businesses succeed
in international
markets
Market &
International
stakeholders
Media
Influence/education via research & publications

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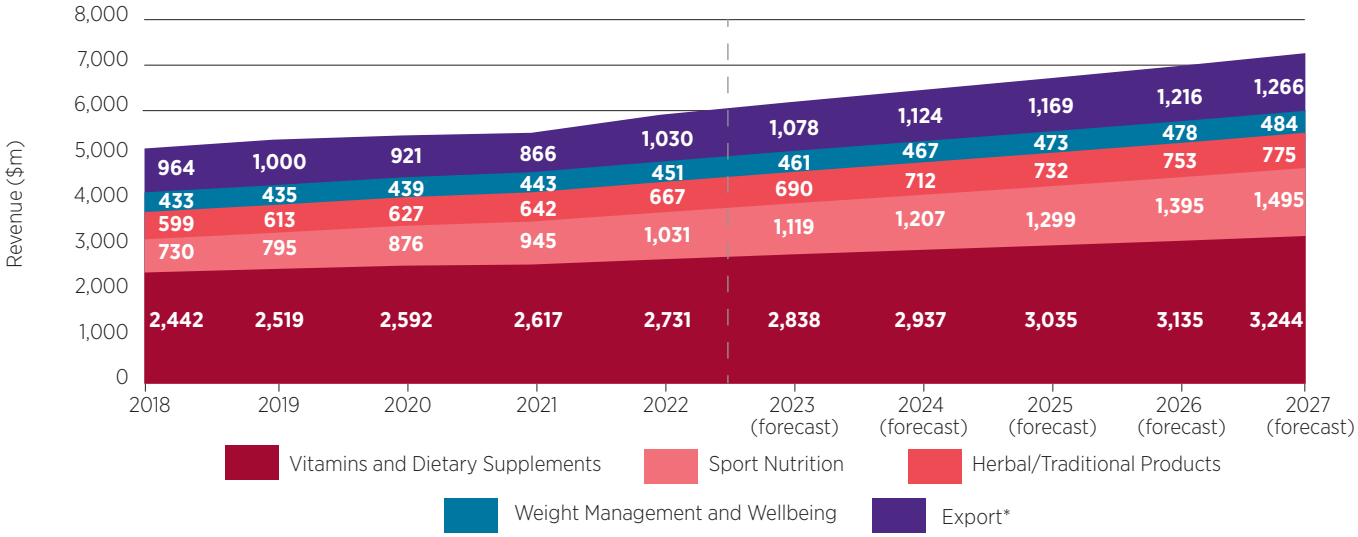
Figure 4: Australia's Complementary Medicines Industry – Revenue and Projected Growth[23]



Note for export data: published data for 2018 and forecast for 2023 onwards are not available in the public domain, current data represents high level estimation under the current study. However, these projections are also vulnerable to a complex array of factors that will be addressed below, including supply chain issues, availability of skilled workers, international trade and regulatory barriers.

The CMA Industry Audit Report 2022 puts the complementary medicines industry revenue at $4.6 billion[24] (not including exports of $1.03 billion).[25]

DEMAND DRIVING A NEED FOR EXPANDED MANUFACTURING CAPACITY. Consultation with industry has indicated that increased demand for complementary medicines products increases the need for manufacturers to expand manufacturing capacity. However, high costs associated with operations and equipment, investment lead time, and land expansion approval wait periods creates risks for manufacturers expanding onshore capacity, leading some to consider expansion offshore. Stakeholders indicated these costs and wait periods are driven by a range of factors by high establishment costs and lack of government support. If these issues are not resolved, local manufacturers could transfer their services to overseas facilities, weakening the Australian complementary medicines manufacturing sector. Stakeholders indicated that the Australian complementary medicines industry faces challenges with a risk averse attitude to growth and investment in onshore contract manufacturing capability. Stakeholders suggested that supporting the growth of local manufacturing and improving local employment and training capabilities will encourage growth of sovereign manufacturing capability.

Australia's complementary medicines workforce

In Australia, complementary medicines manufacturing sites are required to be licensed and regularly inspected under a strict code of Good Manufacturing Practice (GMP) by the TGA. In 2022, there were 77 TGA licensed product manufacturing sites for complementary medicines with various estimation on the total number of direct employees in the complementary medicine manufacturing sector (i.e., including production and non-production related employees). The various estimates are listed as below:

1. Analysis through development of this business case estimates approximately 5,500 to 6,800 direct employees (production only) in 2022 based on data reported by nine key manufacturers obtained via industry consultation.
2. REMPLAN estimated the complementary medicines industry directly employed 12,701 staff in 2016, (based on ABS direct gross revenue figure of $3.18 billion),[26] with corresponding wages and salaries of $960 million.[27]
3. Further to the estimation of current production workforce obtained through analysis of data obtained during development of the business case, based on growth rate in-line with the Australian complementary medicines industry, we have estimated the current total workforce in 2022 to be 15,900.

23 Euromonitor International. (Accessed April 2023). *Australia Market Size: Historical and Forecast Data.*
24 CMA Industry Audit Report 2022
25 ABS (2022) Including Green tea extract, Provitamins, Vitamins and Derivatives, sugar/maltodextrin for sports nutrition and medicaments containing vitamins or other products
26 REMPLAN. (2016). *Economic Impact Analysis Nutraceutical Science and Innovation Program*
27 REMPLAN. (2016). *Economic Impact Analysis Nutraceutical Science and Innovation Program*

WORKFORCE AS A KEY BARRIER FOR GROWTH. The complementary medicines industry recognises a key barrier to manufacturing growth is the lack of an appropriately skilled workforce to support all stages of complementary medicines manufacturing. Industry consultation has indicated that the availability of tailored training for the complementary medicines industry (e.g., GMP compliant training) is limited outside of on-the-job training provided by the complementary medicines manufacturers to employees, with no training programs or first-hand training facilities operating. This lack of training across various skillset such as product development, manufacturing and production, and quality control has been a driver of acute workforce shortages in response to growing demand. This issue is more prominent for rural based manufacturing facilities.

Global market size and growth

There are a range of available data sources that estimate the size of the global complementary medicines market. In the year 2022, estimates of global market size reached $325 billion AUD and the market will grow to $418 billion AUD in 2027 (i.e., excluding Eastern Europe).[28]

Estimated global growth rates are higher than Australia – the largest contributor to this strong growth is the Asia-Pacific region, especially China. With both a large ageing population and a rapidly growing middle class that has a history and comfort with using traditional herbal remedies, the Chinese complementary medicines market has grown from $61 billion AUD in 2018, to $72.6 billion AUD in 2022, and is forecast to reach $94.8 billion AUD in 2027.[29]

Table 1. Key complementary medicines market and regions ($ billion AUD)[30]

				CAGR (%)	
	2018	2022	2027	18-22	22-27
Asia Pacific	**133,300**	**156,614**	**211,780**	**4.1%**	**6.2%**
Australia	4,204	4,880	5,997	3.8%	4.2%
China	60,954	72,565	94,842	4.5%	5.5%
India	3,958	5,323	8,978	7.7%	11.0%
Indonesia	3,785	5,199	6,964	8.3%	6.0%
Vietnam	2,286	3,612	6,131	12.1%	11.2%
North America	**79,309**	**101,163**	**108,556**	**6.3%**	**1.4%**
US	75,347	95,186	101,629	6.0%	1.3%
Canada	3,962	5,977	6,927	10.8%	3.0%
Western EU	**36,339**	**41,789**	**59,347**	**3.6%**	**7.3%**
UK	4,768	7,379	10,242	11.5%	6.8%
Latin America	**15,401**	**17,783**	**25,792**	**3.7%**	**7.7%**
Middle East & Africa	**5,632**	**7,666**	**12,296**	**8.0%**	**9.9%**
Total	**269,981**	**325,015**	**417,772**	**4.7%**	**5.1%**

Vitamins and dietary supplements in Western Europe have seen steady growth in recent years, with above-average annual growth in 2020 and 2021 due to the Covid-19 pandemic – products such as vitamin C and D and mineral supplements were out of stock for much of March and April 2020.[31]

Stakeholders indicated that the global growth potential of the complementary medicines category is a key opportunity area for Australian industries, especially considering the reputation for quality, product safety and strong brand of locally produced goods. This is especially relevant in markets where the Australian reputation for manufacturing quality is a competitive differentiator compared to locally produced or other imported products.

The COVID-19 pandemic has acted as a catalyst to rising consumers health consciousness. This has driven, and is expected to continue to drive, strong global demand for health products, including complementary medicines. For example, complementary medicines products with immunity-boosting properties, such as Vitamin C, zinc, and probiotics, have performed particularly strongly in the last few years.[32]

MARKET AND COMPETITIVE DYNAMICS

Australia's complementary medicines industry is well-established and regulated with numerous brands whose products are sought locally and internationally. The industry is modestly concentrated, it is estimated the top 12 largest businesses account for over 40 per cent of the total market

28 Euromonitor. (2022, 2023). Consumer Health in Australia, China, India, Vietnam, Indonesia, UK, US, Canada, Western EU, Latin America, Middle East and Africa.
29 Euromonitor. (2023). Consumer Health in China
30 Euromonitor. (2022, 2023). Consumer Health in Australia, China, India, Vietnam, Indonesia, UK, US, Canada, Western EU, Latin America, Middle East and Africa.
31 Euromonitor. (2022). *Vitamins and Dietary Supplements in Western Europe*
32 Euromonitor International. (October 2021). *Vitamins and Dietary Supplements in Asia Pacific.*

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value, contributing approximately 1 to 8 per cent of total market value each.[33] [34] The remaining 60 per cent of market value consists of a large number of smaller enterprises who each contribute less than 1 per cent of the total market value.[35] Exports contributed substantially to the total revenue of the Australian complementary medicines industry (the export value of complementary medicines amounted to $1.03 billion AUD[36] in 2022, in addition to the $4.6 billion AUD of domestics revenue[37] in 2022). Several larger companies have become multinational brands with expansion into the Asia-Pacific region.

Complementary medicine businesses in Australia are typically not vertically integrated, and virtually all raw ingredients and materials are imported from overseas, creating considerable industry vulnerability. Some larger Australian businesses operate in-house manufacturing and product-packing sites, while others use local contract manufacturers. Where approved, some businesses also use overseas GMP-certified facilities to manufacture. Distribution and retail occur primarily through supermarkets, pharmacies, health food stores and, increasingly, e-commerce platforms. Consumers aged 35-64 are the industry's primary e-commerce market, though it suspected affluent baby boomers will increasingly shop online for age-related health supplements.[38]

Australia's competitive advantage in the complementary medicines industry for local and international consumers is due to Australia's reputation for premium products, as well as its clean and well-regulated production environment for food and medicines.[39] The complementary medicines industry in Australia operates within a regulatory regime recognised as one of the strongest in the world as products must be manufactured to the same standards as pharmaceutical products under the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP), in facilities licensed and inspected by the TGA.[40]

Global competitive landscape

In 2019, Australia temporarily overtook the US and became the number one importer of complementary medicines into China.[41] A number of drivers have been identified as responsible for Australia's competitive performance on the global stage including Australia's "clean and green" reputation, high regulatory standards and quality assurance.[42] [43] [44] In addition, Australia is geographically positioned to penetrate growing consumer demand in Asia.[45]

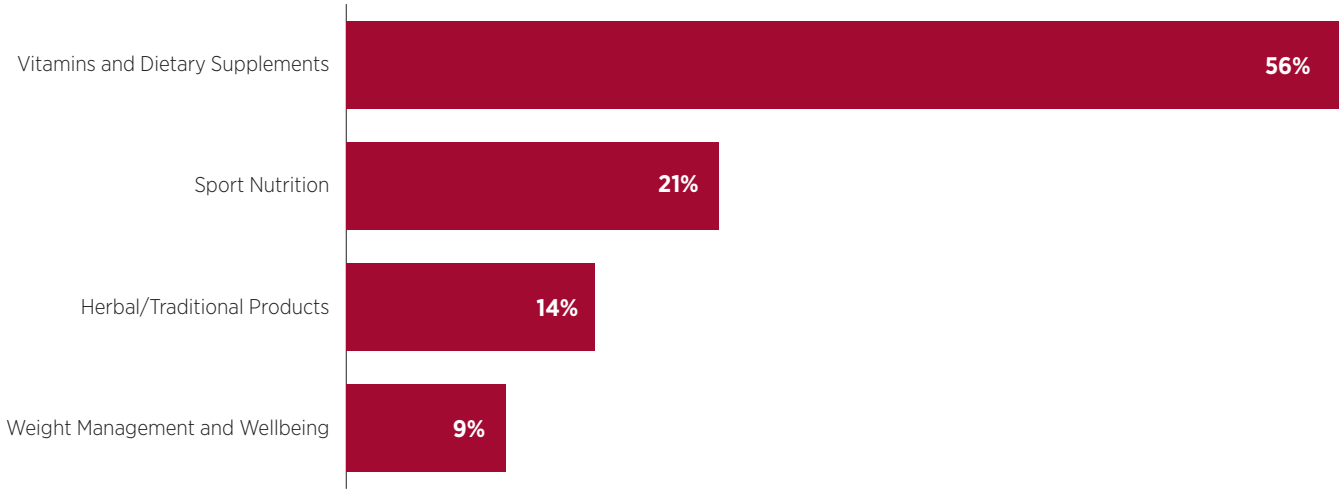
Largely due to the comprehensive TGA regulatory framework, Australian complementary medicines products are considered a trusted brand, especially in China; however, the cost of compliance in response to the regulation is impacting Australia's competitive advantage. Apart from China, India is another attractive potential export market for Australia due to the large population size and rapidly growing, incentivised middle class.

In addition to regulating the Australian domestic market, the TGA regulates the overseas manufacturers by delivering inspections for GMP certification.[46]. Industry consultation suggested that on one hand, controls for receiving overseas raw materials under Australian regulations is seen as assurance of quality, which benefits Australian complementary medicines manufacturers. On the other hand, certifying the standard of finished goods manufactured overseas (through TGA overseas GMP inspections and approvals) creates increased competition from lower labour cost markets and an additional challenge to maintain the competitive advantage of the Australian-made brand.

The Australian complementary medicines manufacturing industry has a significant export advantage afforded to it by the robust regulation scheme in Australia, in contrast with the US and other neighbouring jurisdictions, but has an export disadvantage due to ever-increasing costs of regulation which can make our Australian exports cost-prohibitive to some consumers. The advantage needs to be maintained whilst also reducing regulatory costs and inefficiencies, minimising potential negative impacts of low cost overseas competitors entering the Australian market, and avoiding unnecessary red tape that may delay or hinder regulatory approval for exported products through strong Government engagement with overseas trade bodies and regulators.

33 Euromonitor International. (November 2022). *Herbal/Traditional Products in Australia*
34 IBISWorld. (2023). *Vitamin and Supplement Manufacturing in Australia*
35 Euromonitor International. (November 2022). *Herbal/Traditional Products in Australia*
36 ABS (2022) Including Green tea extract, Provitamins, Vitamins and Derivatives, sugar/maltodextrin for sports nutrition and medicaments containing vitamins or other products
37 CMA Industry Audit Report 2022
38 IBISWorld. (2023). *Online Vitamin and Supplement Sales in Australia*
39 Austrade. (2017). *Complementary Medicine*
40 Austrade. (2017). *Complementary Medicine*
41 Therapeutic Goods Administration. (Accessed April 2023). *About the Australian therapeutic goods legislation*.
42 Austrade. (2017). *Complementary Medicines*
43 Stakeholder consultations
44 IBISWorld. (2023). *Online Vitamin and Supplement Sales in Australia*
45 Austrade. (2017). *Complementary Medicines*
46 Therapeutic Goods Administration (2021). *Australian manufacturing licences and overseas GMP certification*

Figure 5. Australian Complementary Medicine Retail Sales by Product Segment (2022)[57]



MARKET TRENDS

This section describes current complementary medicine products, consumers and sell channels, including current trends impacting each of these categories.

PRODUCTS

Complementary medicines can be broadly split into one of four product segments: Vitamins and dietary supplements (VDS); sports nutrition; herbal/traditional products; and weight management and wellbeing.

In 2022, the VDS segment reported total revenue of $2.73 billion, representing 56 per cent of total complementary medicines retail sales in Australia.[47] This was followed by sports nutrition ($1.03 billion), herbal/traditional products ($667 million), and weight management and wellbeing ($451 million); see Figure 3.[48]

Product innovation

Complementary medicines are a mature product in the Australian market, and so leading players have turned to innovation including new delivery formats, flavours, packaging and formulation to drive sales.[49] Consultation with industry stakeholders has also suggested that consumers prefer innovative edibles or snack-like VDS products which deliver the same dietary value without the stigma of taking pills. (e.g., gummy and jelly products which discretely integrate active ingredients, such as melatonin, collagen, enzymes).[50]

Stakeholder consultation indicated that there are certain product categories experiencing increased demand. These products relate to older person's health, beauty, stress and anxiety, immunity products, energy products and gut health products, as well as multivitamins, magnesium and zinc.

While consumers look for new formulations and formats of products, stakeholder interviews highlighted that there are barriers for complementary medicines businesses to invest in product innovation and product validation for complementary medicines in Australia.

HIGH PRODUCT DEVELOPMENT COST HINDERS COMPLEMENTARY MEDICINES MANUFACTURERS APPETITE TO INVEST IN INNOVATION. Stakeholder interviews highlighted that there are barriers for complementary medicines businesses to invest in product innovation for complementary medicines in Australia. For example, Australian contract manufacturers lack risk appetite for the high upfront costs of developing new products and investing in modern technology or equipment. This is particularly the case when overseas manufacturing facilities already have the capability and products on the market. An example given was the manufacturing of multivitamin gummies where formulation and manufacturing capability are more superior overseas including Israel and Taiwan.

47 Euromonitor International. (Accessed April 2023). *Australia Market Size: Historical and Forecast Data*.
48 Euromonitor International. (Accessed April 2023). *Australia Market Size: Historical and Forecast Data*.
49 Euromonitor International. (October 2019). *Consumer Health in Australia*
50 Australian Trade and Investment Commission. (August 2022). *China: Complementary Medicine Report*.

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There are also regulatory barriers to innovation. Stakeholders described that it is difficult and costly to obtain approval by TGA on the use of new ingredients, which is leading to delayed product innovation. Innovation also relies on intellectual innovation for new product ideas and formulations in complementary medicines manufacturing. Stakeholders described how innovation requires the support of research organisations including universities to provide research into new manufacturing processes, ingredients, and product formulations so that Australia is a point of genesis and leader in product innovation, product validation and manufacturing globally.

Currently, there are relatively new protection mechanisms to drive innovation with new ingredients and product development:

1. After the approval of a new ingredient by the TGA, the successful applicant will have market exclusivity for using and licensing that ingredient for a 2-year period, which prohibits unauthorised sponsors from using the ingredient in a medicine listed in the ARTG.[51]
2. The TGA Data Protection Scheme for AUST L(A) medicines provides successful applicants (sponsors) with a 5-year protection period for the clinical trial efficacy information supporting their AUSTL(A) medicine starting from the date the medicine appeared in the ARTG provided that information has not been published prior to the application being made.[52]

According to stakeholders, in addition to cost challenges and regulation challenges, factors such as low return of investment (ROI) due to limitations in use of claims for marketing purpose, sub-optimal data protection mechanism to protect novelty and secrecy might be additional reasons that hinder intellectual innovation in the Australian industry. There is also a lack of dedicated Commonwealth or State funding pathways or incentives for research and development in complementary medicines which could otherwise encourage industry to overcome barriers to innovation.

Stakeholder interviews highlighted that there are opportunities to support product innovation with the ingredients used and that could be supplied as raw materials by the First Nations communities. Several challenges to be overcome in formalising the use of such ingredients in the complementary medicines industry, including the lack of written documented evidence of efficacy, the lack of specific toxicology data, the lack of a clear mechanism for protecting the interest of First Nation suppliers, and the lack of incentives for collaboration between the First Nation community and the wider complementary medicines industry. In particular, a vagary of the Therapeutic Goods Act means that the TGA requires the licensing of most raw material suppliers and extract producers in Australia, which is not required of overseas suppliers and producers, creating a distinct disadvantage and a practically insurmountable barrier to First Nations peoples wishing to participate in the broader complementary medicines industry in Australia.

CHALLENGES REMAIN DESPITE NEW PROTECTION MECHANISMS IN PLACE: Stakeholder interviews highlighted that complex approval process remains to be a challenge for innovating with new ingredients. Anecdotal example from a manufacturer suggested that a 4-year process with non-scientific enquiry was conducted to obtain approval for a new ingredient. Other challenges include the difficulties in accessing relevant knowledge in a form that the regulator would accept from the indigenous community and the lack of incentives to collaborate with the business community.

RAW INGREDIENTS

For the manufacture of vitamin and mineral supplements and herbal medicines, it is estimated that Australia relies on up to $1 billion worth of imported ingredients annually.[53] Stakeholder consultation echoed this sentiment, indicating a large degree of dependence on imported raw materials for complementary medicines product manufacturing in Australia, estimating that 99% of raw ingredients needed in the Australian manufacturing of complementary medicines were imported from overseas. One manufacturer reported a need to import approximately 1,600 different ingredients to meet their manufacturing needs.

Overseas producers benefit from greater economies of scale leading to the availability of lower-cost raw materials compared to Australian producers; however, this reliance has introduced supply chain vulnerability. Some stakeholders from industry consultation reported that being out of stock has been a high-cost impact on local manufacturers due to loss of sales.

There are opportunities to boost local production of key ingredients – for example, looking to established producers of algae within Australia and examining its viability as a source of sustainable ingredients such as omega-3, polyunsaturated fatty acids, beta-carotene, antioxidants, iodine, zinc, calcium, and magnesium.[54] In this example, there is a wealth of Australian experience and infrastructure already available due to previous investment in biofuels which can be adapted and repositioned for use in algae farming for the health industry.[55]

The Australian agricultural sector is an opportunity area for complementary medicines raw ingredients. Focussing on Australian agritech, though better use of waste products, is one way to alleviate supply chain risk. There are numerous opportunities for the complementary medicines industry that

51 TGA. (Feb 2023). Application requirements for new substances in listed medicines.
52 TGA. (Sep 2021). Data Protection Scheme for Assessed Listed medicines.
53 AgriFutures. (2021). *Sourcing omega-3 and other active ingredients from algae*
54 Ibid
55 Ibid, p. 10

could be better leveraged. One example is the antioxidant lycopene, primarily found in tomatoes, which is used in a number of complementary medicines products. Blemished or marked tomato fruit, unsuitable for sale, is estimated at around 10% of total yield.[56] Leveraging the waste product, unsuitable for sale but entirely suitable for lycopene extraction and medicines manufacture, is one example of how the complementary medicines and agricultural sectors can collaborate within the circular economy framework, reduce waste and improve supply chain resilience. Opportunities would also exist in medicinal herb farming more broadly.

INNOVATION IN SECURING AUSTRALIAN INGREDIENT SUPPLY CHAIN NEEDS AND PROMOTING A CIRCULAR ECONOMY – TURNING WINE INDUSTRY WASTE INTO PREMIUM PRODUCTS. In 2022 the Australian wine industry crushed 1.7 million tonnes of grapes, with 22% resulting as winery waste or grape marc (leftover seeds and skin). Grape marc has a small value as low-grade animal roughage and fertiliser but is slow to break down and much of it becomes landfill. However, standardized grape seed extract made from grape marc is highly concentrated in vitamin E, flavonoids, linoleic acid and oligomeric proanthocyanidins, which are powerful antioxidants used to help reduce blood pressure, inflammation and some bacterial infections. An Australian complementary medicines manufacturer has already put this to the test: the Australian grape seed extract is three times more concentrated than current imports of grape seed extract.

The required TGA licensing of certain raw material manufacturers in Australia is a significant cost and competitive barrier for the local production of ingredients compared to importing ingredients. Regulatory allowances for these ingredient manufacturers in Australia should be aligned to the existing allowances for overseas raw material suppliers, as the TGA licensing of Australian finished product manufacturers ensures that all required ingredient checks are suitably performed before production occurs whether the ingredient is Australian or imported. Further, it is easier for a finished product manufacturer to audit local raw material producers rather than overseas ones. Aligning the allowances for Australian producers will further strengthen the supply and quality of Australian goods.

Support for Agritech, including farmers and extraction facilities, should be combined with a policy environment that fosters the collaboration amongst all relevant stakeholders, this might entail mechanism that protects the interest of the custodian of native Australian ingredients or incentives to drive business's investment into this area.

RELIANCE ON LOW-COST OVERSEAS RAW MATERIALS. Most stakeholders in the industry consultation acknowledged the under-established raw materials manufacturing sector in Australia, and lack of economies of scale have led to the over-reliance on overseas raw materials by the complementary medicines manufacturers. The use of local raw materials is likely to lead to product cost increases unless there is better use of waste products through applying circularity principles.

DOMESTICS SUPPLY OF RAW MATERIALS IS UNDER DEVELOPMENT. Industry consultation suggested that one Australian complementary medicines manufacturer has started to build local raw materials manufacturing capability that supports over 1,600 ingredients. Upon completion of that manufacturing capability, the company targets to reduce the reliance on overseas raw materials from circa 99 to 60 per cent. Despite industry's effort in establishing local supply chain, import is likely to remain as major source of raw material supply.

CONSUMERS

Consumers of all ages use complementary medicines for a variety of reasons, a consumer survey on 2,019 consumers showed that 63 per cent of those surveyed have used complementary medicines. Women are more likely to be the users of complementary medicines (69 per cent) than men (57 per cent), age group between 30 to 59 showed the highest adoption of complementary medicines (~65 per cent of respondents in this age group), where the adoption of 18-29 age group and 60+ age group are 62% and 60% respectively.[57] The importance of scientific evidence and validation cannot be understated in supporting consumers make informed choices about their health and wellbeing.

Historically, Australians have preferred to purchase their vitamins and dietary supplements from physical stores. However, the COVID-19 pandemic and changing consumer preferences has increased the proportion of purchase from online.

There are constant shifts in consumer demographics, expectations, and drivers for complementary medicines use. Millennials and Generation Z in particular are driving complementary medicines innovations. Products promoting immunity enhancement, sleep improvement, bone health, and anti-fatigue are the most popular among this age cohort.[58]

56 University Of Florida. "Lycopene-Extraction Method Could Find Use for Tons of Discarded Tomatoes." ScienceDaily. ScienceDaily, 5 May 2004.
57 Scientific Reports. (2018). Complementary medicine use in the Australian population: Results of a nationally representative cross-sectional survey.
58 Australian Trade and Investment Commission. (August 2022). *China: Complementary Medicine Report.*

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THE AUSTRALIAN CONSUMER HAS A STRONG DESIRE FOR NATURAL AUSTRALIA-MADE HEALTH PRODUCTS. Haleon, the consumer health brand for GSK, has already launched PanaNatra, an herbal alternative to paracetamol for pain (https://www.panadol.com/en-au/naturally-derived-pain-relief/naturally-derived-pain-relief-options/) PanaNatra is a unique blend of boswellia extract, curcumin and piperine used to relieve muscle and joint pain. This clinical and commercial opportunity has been recognised as by the pharmaceutical industry – consumers seek natural alternatives to reduce the intensity of reliance on conventional pharmaceuticals. This may include taking supplements to moderate the dosage of paracetamol or other commonly used drugs.

An increase in the prevalence of various chronic diseases, such as cancer, cardiovascular disease and respiratory diseases is one key driver of complementary medicines utilisation. The National Centre for Biotechnology Information (NCBI) estimates that chronic diseases currently account for about 60 per cent of deaths and 43 per cent of the global disease burden.[59] As a result, many consumers are increasingly seeking complementary medicines, not necessarily to fight disease or address specific symptoms, but to improve wellbeing and, in chronic disease prevention.[60]

A growing middle-class population globally is a potential driver of increased demand for complementary medicines. Global middle income or above population has grown from 31 per cent (2.2 billion) of total global population in 2011 to approximately 40 per cent (3.05 billion) in 2019.[61]

The global ageing population is also rapidly increasing, the United Nations projects that the number of people aged 65 years or older will reach 1.5 billion by 2050.[62] This demographic shift is leading to an increased focus on preventative and proactive approaches to health, including the use of complementary medicines.[63]

FURTHER INITIATIVES ARE REQUIRED TO PROVIDE SUPPORT IN CONSUMER UPTAKE DOMESTICALLY AND INTERNATIONALLY. Industry consultation has highlighted the need to support consumers to adopt complementary medicines by providing them with appropriate scientific evidence and information to make informed decisions for the health condition.

CHANNELS

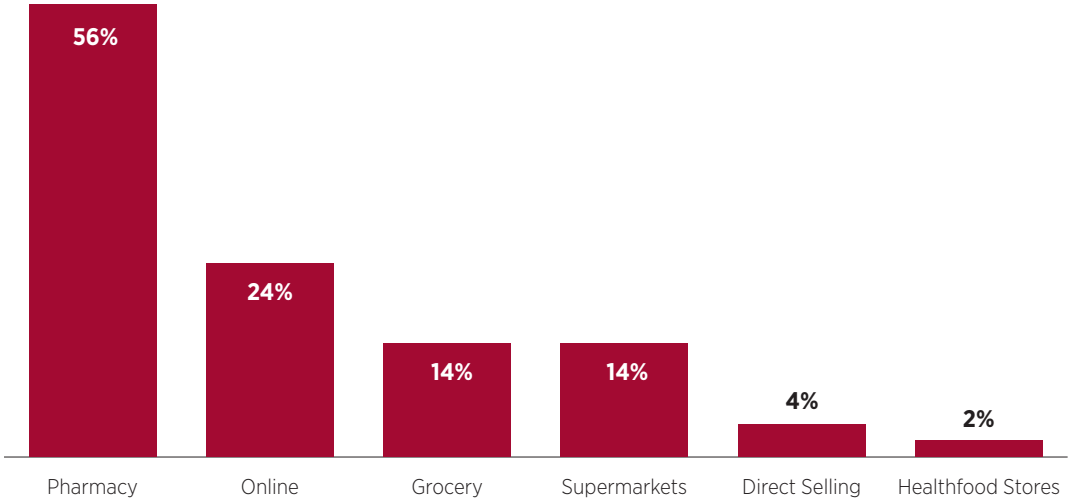
There are three main types of customer distribution channels for complementary medicines in Australia: (1) domestic sales for domestic consumption; (2) domestic sales for overseas consumption; and (3) exports.

Domestic sales for domestic consumptions

Stakeholders have validated that domestic sales of complementary medicines are dominated by pharmaceutical retailers. Chemist Warehouse was cited as a major and important channel for the complementary medicines manufacturers in the sale of vitamins and supplements in Australia. Stakeholders also described how there is a consumer shift towards purchasing products online from retailers such as iHerb.com for cheaper products which may be unavailable in domestic retail stores. This channel is typically less regulated as consumers can access overseas products which have not been subjected to the same TGA product approval processes as Australian products. The online sales channel places pressure on Australian products to remain price competitive. Online platforms also allow access to innovative products which may not be available domestically and adds to the pressure of Australian manufacturers needing to be both cost-efficient and innovative.

59 Australian Trade and Investment Commission. (August 2022). *China: Complementary Medicine Report*.
60 K. Wode, R. Henriksson, L Sharp. A Stoltenberg, J H Nordberg. (March 2019). *Cancer patients' use of complementary and alternative medicine in Sweden: a cross-sectional study*.
61 Pew Research Center. (2021). *The Pandemic Stalls Growth in the Global Middle Class, Pushes Poverty Up Sharply*.
62 Digital Jungle. (March 2022). *Daigou Innovation and Social e-commerce developments*.
63 United Nations. (October 2019). *World Population Ageing 2019*.

Figure 6. Retail Distribution of Vitamins and Dietary Supplements in Australia (2022)[64]



Domestic sales for overseas consumption

Industry stakeholders estimate the 40 per cent of Australia's complementary medicines domestic sales are purchased for overseas consumption. This occurs particularly in China with "Daigou" purchases.

Daigou refers a form of cross-border exporting in which a network of individuals purchases products in Australia then post them to China and/or other countries. In 2019, the total Daigou market in Australia (not only complementary medicines but also including other types of products, such as medicine, skincare, footwear, apparel, and luxury brands) was estimated to be worth $2.5 billion AUD. This was driven by over 1,600 gift stores, between 10,000 to 15,000 full time traders, and an additional 60,000 to 80,000 part-time shoppers.[65] Stakeholders have reported that the Daigou shoppers were responsible for doubling complementary medicines exports over a decade ago to approximately $2 billion AUD.

Over the last few years, this business model was decimated due to COVID-19, geopolitics, and other trade barriers, such as a significant decline in international students in Australia, lack of inbound tourists from overseas, nationwide lockdowns, limits on product sales by retailers (e.g., baby formula) and changed perceptions within the China market.[66]

A 2021 survey of Daigou businesses indicated the 80 per cent of businesses experienced lower sales than pre-COVID-19, including 22 per cent indicating business was 'more than 50 per cent lower' compared to pre-COVID-19.[67]

Exports

In 2022, exports represented approximately 16 per cent of total revenue in the Australian complementary medicines industry.[68] According to the Australia Bureau of Statistics (ABS), Australia's exports of vitamins, minerals and supplements totalled approximately $1.03 billion AUD in the 2022 calendar year, with the largest export destinations being China, Hong Kong, New Zealand, Vietnam, and other countries in the Asia-Pacific Figure 6 Australian Vitamins, Minerals and Supplements Exports by Destination (2022) Although China remains the largest export market for Australia's complementary medicines industry, Australian business are actively exploring opportunities in new and emerging markets, such as India, Vietnam, Indonesia, and the Middle East.[69] In south-east Asia, Australia has free-trade agreements with India, Singapore, Thailand, Malaysia, Korea, Japan, China and Hong Kong.[70] The recent free-trade agreement with India signed in December 2022 will see elimination of a 7.5 per cent tariff on vitamins and 10 per cent on pharmaceutical products.[71]

There are challenges in unlocking these new markets for Australian complementary medicines products, including a lack of Australian brand awareness, the need for greater product validation (R &D), and various trade barriers. A study conducted by the Department of Foreign Affairs and Trade identified the need for greater marketing efforts to build complementary medicines brand awareness and credibility in Southeast Asia region. However, consumers in the region are more familiar with traditional forms of medicine, which can make it difficult for foreign companies and alternative products from Australia to gain traction.

64 IBISWorld. (2023). Online Vitamin and Supplement Sales in Australia
65 Digital Jungle. (March 2022). *Daigou Innovation and Social e-commerce developments*.
66 National Institutes of Health – Office of Dietary Supplements (Accessed April 2023). *Dietary Supplement Health and Education Act of 1994. Public Law 103-417*.
67 Digital Jungle. (March 2022). *Daigou Innovation and Social e-commerce developments*.
68 Complementary Medicines Australia. (September 2022). *CMA 2022 Industry Audit Report*.
69 Australian Trade and Investment Commission. (December 2017). *Natural and Organic Products in India: Trends and Opportunities.*
70 DFAT *Free trade agreements in force.*
71 DFAT *Australia-India ECTA benefits for Australian manufacturing*


NICM

AUSTRALIAN COMPLEMENTARY MEDICINES MANUFACTURERS NEED EXPORT SUPPORT. Industry consultation has reported that several challenges faced during exporting. i) Understanding of local consumers, ii) Growing regulatory burden, iii) inconsistency in regulations (e.g., tariff) at designation market, iv) Differences in labelling requirement as well as v) Gap of regulations between Australia and designation market. Collaborative efforts between regulators, export promotion agencies, and the industry is required to enhance the competitiveness of Australian brands in overseas markets.

Figure 7. Australian Vitamins, Minerals and Supplements Exports by Destination (2022)[72]

SHIFT TOWARDS ONLINE SALES CHANNELS. Changing consumer preferences, reinforced by the COVID-19 pandemic and associated lockdowns, has increased the proportion of online/e-commerce purchases. In Australia, 24 per cent of all retail sales of vitamins and dietary supplements in 2022 was conducted online.[73] Similarly in China, since the pandemic, e-commerce (41 per cent of sales) has now overtaken direct selling (30 per cent) as the main sales channel in the country.[74]

POLICY AND REGULATORY ENVIRONMENT

This section summarises the policy and regulatory environment for the complementary medicines industry in Australia, including domestic regulation and categorisation. It highlights comparator jurisdictions and the implications of different approaches.

POLICY ENVIRONMENT

The complementary medicines policy environment is complex and influenced by a range of stakeholders and decision-makers at all levels of government. Complementary medicines are the subject of a diverse range of policy areas including health, industry, research manufacturing, trade, technology, skills / training and regional.

Federal policy environment

Federally, the complementary medicines industry must consider the policies, strategies and plans of a range of departments and agencies.

The National Health and Medical Research Council and the Medical Research Future Fund are the key funding bodies for medical and health research. The TGA is the therapeutic and medicine regulatory agency (discussed further in 3.4.2 below) within the Federal Department of Health and Aged Care.

The Federal Government has signalled a strong desire to invest in manufacturing and specifically sovereign capability – including through the establishment of a National Reconstruction Fund (NRF) – a financing vehicle to drive investment in projects that will broaden Australia's industrial base and diversify the economy. In the consultation paper published in November 2022, the Fund has a focus on medical research and advanced medical manufacturing through the $1.5 billion AUD Medical Manufacturing Plan. It has specifically highlighted medical devices, personal protective equipment, medicines, and vaccines to be the key areas.[75]

72 Australian Trade and Investment Commission. (December 2017). *Natural and Organic Products in India: Trends and Opportunities.*
73 Complementary Medicines Australia. (September 2022). *CMA 2022 Industry Audit Report*.
74 Euromonitor International. (October 2021). *Vitamins and Dietary Supplements in Asia Pacific*.
75 Department of Industry, Science and Resources. (November 2022), National Reconstruction Fund Consultation paper.

CURRENT STATE ASSESSMENT: AUSTRALIA'S COMPLEMENTARY MEDICINES INDUSTRY CONTINUED

State policy environment

Manufacturing is a critical part of the complementary medicines value chain. State governments in Australia are also actively supporting manufacturing industry development in their jurisdictions, with initiatives ranging from financial incentives, workforce development, research and targeted investment in priority segments. Through cross-industry collaborations, potential opportunities for the complementary medicines industry can be captured along the wider manufacturing value chain.

1. The *NSW advanced manufacturing industry development strategy* aims to strengthen the industry by fostering a supportive business environment and implementing targeted initiatives. The strategy focuses on increasing collaboration and research, driving the adoption of advanced processes, supporting the implementation of advanced service-oriented business models, and growing export and investment. By pursuing these opportunities, the manufacturing industry can remain a source of economic strength, job creation, and innovation in NSW. The strategy identifies medical technologies as an emerging sector with advanced manufacturing capability.[76] Industry stakeholders identified investment in advanced manufacturing as an opportunity for the complementary medicines industry, potentially in alignment with pharmaceutical and other industry partners.
2. Manufacturing is a crucial part of Victoria's economy, generating $30 billion AUD p.a. to Victoria's Gross State Product (GSP), and contributing to job growth and exports. The Victorian Government has committed to supporting the local industry with its skilled workforce, established supply chains, design and engineering expertise, and education and R&D capability. The Victorian Government's *Manufacturing Statement, "Made in Victoria"*, identifies health technologies as an area for investment, and specifically mentions the Commonwealth's medical manufacturing priority as being in alignment with state manufacturing goals.[77] Government investment in health technology presents an opportunity for the complementary medicines industry to develop manufacturing capability with demonstrated alignment of objectives.
3. Queensland has identified Townsville, Cairns, and Rockhampton as regional manufacturing hubs, investing $30 million AUD over three years to foster productivity and innovation in the economy. Advanced food manufacturing has been specifically identified as an initial focus area of the Townsville Hub, intended to enable the Townsville region to take advantage of reducing food waste in the vegetable supply chain by converting food waste into snacks and powders for health supplements and nutraceuticals.[78] Better utilisation of food waste is a key opportunity area for the complementary medicines industry, in order to develop new ingredient supply chains and reduce reliance on imports.

THERE IS ALIGNMENT BETWEEN COMMONWEALTH AND STATE GOVERNMENTS IN SUPPORT OF SOVEREIGN MANUFACTURING. The Federal Government's establishment of the NRF and the range of state-based manufacturing investment priorities (including NSW's *"Advanced manufacturing industry development strategy"*, Victoria's *"Manufacturing Statement, Made in Victoria"*, Queensland's *"Advanced Manufacturing Roadmap and Manufacturing Delivery Hub Model"*) signals strong alignment of federal and state priorities in terms of manufacturing. There are clear opportunities for the complementary medicines industry to collaborate to identify priority areas for investment and support with co-investment from Government.[79]

A COLLECTIVE APPROACH TO ADVOCATING FOR THE COMPLEMENTARY MEDICINES INDUSTRY IS REQUIRED. Stakeholders from industry consultation suggested that the current advocacy for the industry is often siloed, with individual companies pursuing own specific objectives. Compared to the medical industry at large, the complementary medicines industry could better coordinate and collectively advocate across identified priority areas.

76 Department of Industry. (2018). *NSW advanced manufacturing industry development strategy*.
77 Victorian Government. (2022). *Made in Victoria 2030: Manufacturing Statement*.
78 Queensland Government. (2018). *Manufacturing Hub Delivery Model: Cairns, Townsville, Rockhampton*
79 Department of Industry, Science and Resources. (Feb 2023). National Reconstruction Fund: Consultation Paper

REGULATORY ENVIRONMENT

Domestic regulation of complementary medicines

TGA is a division of the Australian Commonwealth Government's Department of Health. The TGA is a regulatory authority responsible for regulating the supply, import, export, manufacturing, and advertising of therapeutic goods including medicines, medical devices, and biologicals. This includes (but not limited to) approving ingredients, registering products, monitoring compliance, certifying GMP facilities, developing guidelines and policies, providing educational resources, and promoting international cooperation.[80] The TGA is regulated by the Therapeutic Goods Act 1989 (Cth). This act provides a uniform national system of controls over therapeutic goods, facilitating trade between the states and territories and benefiting both consumers and industry.[81]

Previously the TGA regulated complementary medicines through a dedicated Office of Complementary Medicine. In 2016, this office was merged with the Listed Medicines Branch to form the "Complementary and Over-the-Counter Medicines Branch". The merger was part of TGA's broader regulatory reform program aimed at streamlining regulatory processes and improving access to therapeutic goods for consumers. Industry consultation has reflected that the input from the complementary medicines industry, including opposition to the merger, is not always incorporated into TGA's regulations development process, and that might lead to suboptimal regulations for the growth of complementary medicines industry.

UNFAVOURABLE SENTIMENT TOWARDS INCREASES IN REGULATORY REFORM. Alongside public scrutiny of the efficacy and safety of complementary medicines, tighter regulatory controls have been introduced. This includes new labelling changes that came into effect 6 March 2021 (i.e., vitamins and supplements must only use indications included in the TGA's pre-approved permitted indications list); and new 2021 Advertising Code that came into effect on 1 January 2022.[82]

Participants in industry consultations also provided many anecdotes of unnecessary, duplicative, or ineffective regulation that could be streamlined.[83] Stakeholders have also reflected the sentiment that TGA's regulatory approach can be a barrier to the industry, as regulations are sometimes set in motion with minimal direct or thorough consultative processes with industry participants and which frequently undervalue industry concerns including the high cost of regulation and regulatory changes. There are challenges that have been acknowledged by the TGA in attracting and retaining appropriate expertise within the Administration to regulate the $6 billion pa industry effectively and fairly.

Complementary medicines must be included on the Australian Register of Therapeutic Goods (ARTG) before they can be sold in Australia. There are three types of complementary medicines, though all complementary medicines are listed (i.e., listed or assessed listed).[84] As of 8 May 2023, there are 11,407 complementary medicines in the ARTG's record.[85]

1. **Listed complementary medicines – AUST L – 11,289**
   Came into effect in 1991, listed complementary medicines contain only pre-approved low risk ingredients and make only pre-approved low risk health claims and are not assessed for efficacy before being sold in Australia. Such medicines have an AUST L number on the label.[86]

2. **Assessed listed complementary medicines – AUST L(A) – 2**
   A new assessed listed medicines pathway was introduced in March 2018.[87] Assessed listed complementary medicines have an AUST L(A) number on the label. These medicines must contain only pre-approved low risk ingredients but may make more scientifically elaborate and intermediate risk health claims. For example, referring to reference conditions such as rheumatoid arthritis. Assessed complementary medicines must undergo an efficacy assessment through human clinical trials prior to market authorisation. .

3. **Registered complementary medicines – AUST R – 116**
   Registered complementary medicines have an AUST R number on the label. These are higher risk medicines that are required to undergo a full individual safety, quality and efficacy assessment before market authorisation. They may contain ingredients or dosages that are not permitted for listed and assessed listed medicines and may contain higher risk health claims, including referring to treatment and prevention of certain conditions. While some can be chosen by the consumer, some are only available through a health professional. Many of these medicines however have been grandfathered as AUST R since 1989, rather than having been processed through the full regulatory assessment.

80 DFAT *Free trade agreements in force.*
81 DFAT Australia-India ECTA benefits for Australian manufacturing
82 TGA. (Last update in Mar 2023). Guidance on applying the Advertising Code rules.
83 NICM. (March and April 2023). *Industry Consultations.*
84 Therapeutic Goods Administration. (Accessed April 2023). *Complementary medicines overview.*
85 ARTG Search. (Accessed on 8 May 2023). *Medicines only, excluding approval area of Drug Safety Evaluation Branch, Non-prescriptive medicines.*
86 NPS Medicinewise (2004). *What does TGA approval of medicines mean?*
87 Euromonitor International. (October 2021). *Vitamins and Dietary Supplements in Asia Pacific."*

CURRENT STATE ASSESSMENT: AUSTRALIA'S COMPLEMENTARY MEDICINES INDUSTRY CONTINUED

RECOMMENDATION FOR REFINEMENT OF AUST L(A) CATEGORY. AUST L(A) was intended to provide a faster and more efficient way of identifying safe and effective medicines for higher therapeutic indications (claims) than permissible under the AUST L scheme. Contrary to its intentions the implementation of this scheme has resulted in watering down of and significant uncertainty about intermediate claims that would be accepted by the TGA whilst being meaningful to consumers, making it less attractive to industry particularly due to the high risk cost of clinical trials.

High cost of compliance and pharmacovigilance

Industry consultation has suggested the cost of regulations to be a challenge for complementary medicines manufacturers. High cost of regulations at multiple steps are required on the end-to-end process (e.g., pre-vetting & qualifying suppliers, validation of production processes, auditing, and testing in relation to GMP requirements etc). This includes but not limited to acquiring raw materials, sponsor listing fees, testing, manufacturing, and product registration. An additional high cost burden is that the TGA requires medicine sponsors to meet the pharmacovigilance reporting responsibilities for all medicines registered or listed on the ARTG by the sponsors, this includes but not limited to detecting, assessing, understanding, and preventing adverse effects and other medicine-related problems, which is a highly duplicative process for listed medicine sponsors to perform.[88] While the current compliance requirement other than pharmacovigilance literature monitoring is considered acceptable by some stakeholders, the constant changes in regulations by the TGA to be remains a significant challenge. The Therapeutic Goods Advertising Code underwent several changes in the last five years due to a final major version requiring significant fixes to an earlier significant rewrite of the Code. Some examples suggested that the regulation cost could reach 4.4 per cent of total revenue or approximately 9 per cent of product cost.

Approval of ingredients

Australia has a stricter and more rigorous approval process for ingredients used in the manufacturing process compared to other markets. The TGA has a formal process for assessing the safety and efficacy of ingredients before they can be used in a complementary medicine's product. In some countries, pre-market approvals of ingredients are not required.[89]

TGA approval processes for raw ingredients can be complex, involving high costs and long waits. For example, the industry consultation example suggests that raw material approvals are circa of 12 months; however, in extreme cases it could take as long as 2 to 4 years. This approval process should be refined to be commensurate with the risks involved with the product. Other markets do not have the same process for approval of ingredients. For example, in the United States, dietary supplements are regulated as food products under the Dietary Supplement Health and Education Act (DSHEA) 1994. Therefore, they do not require pre-market approval of ingredients or products by the FDA, and manufacturers are responsible for ensuring the safety and labelling of their products.[90]

Global regulation of complementary medicines

Developed countries have regulatory authorities responsible for varying levels of oversight of products which are regulated as dietary supplements or health foods, however they are not comparable to TGA regulation for listed complementary medicines, as they do not regulate them as medicinal products and do not require pharmaceutical level GMP. Some examples of authorities responsible for some level of oversight of dietary supplements include the European Food Safety Authority, the United States Food and Drug Administration (FDA), Health Canada, Health Sciences Authority (Singapore). and the China Food and Drug Administration (CFDA).

In some rare cases, international products are registered through assessment schemes as medicinal products (rather than foods or dietary supplements), and have comparable safety, quality and efficacy requirements to Australian higher risk registered complementary medicines. Comparable high risk medicinal authorities include the FDA, the European Medicines Agency (EMA), the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, Pharmaceuticals and Medical Devices Agency (PMDA) in Japan,

Some of the main differences between how complementary medicines is regulated in Australia compared to overseas jurisdictions is summarised below:

88 TGA. (2021). Pharmacovigilance responsibilities of medicine sponsors.

89 Therapeutic Goods Administration. (February 2018). *Australian regulatory guidelines for complementary medicines.*

90 National Institutes of Health – Office of Dietary Supplements (Accessed April 2023). *Dietary Supplement Health and Education Act of 1994. Public Law 103-417.*

STRINGENT APPROVAL PROCESS AND LACK OF R&D INCENTIVE LIMITS USE OF LOCAL INGREDIENTS AND TRADITIONAL INDIGENOUS MEDICINES: Limited documented evidence on local ingredient efficacy, as well as the absence of toxicology on Indigenous ingredients, delays TGA approval of such ingredients. Compounding this issue is that there are currently no government schemes or incentives in place to support the research and development to accelerate utilisation of local ingredients in medicine manufacture. Were these challenges addressed, utilisation of local and Indigenous ingredients in medicine manufacturer could represent a key opportunity area for the local communities, Indigenous business and the complementary medicines industry at large, through an innovation and competitive advantage driven by unique products.

Product approval

Complementary medicines are regulated as medicines in Australia with a formal electronic listing process onto a central TGA register, requiring numerous legal declarations from a business before complementary medicines can be sold. In contrast, it is considered as functional foods under food type regulations in other countries. For example, the United States have less stringent requirements as the FDA does not require pre-market approval for most dietary supplements, but manufacturers must notify the agency about the ingredients in their products and the claims they make.[91]

Increased local regulatory requirements at designation markets

Australian complementary medicines manufacturers need to adhere to the tightened local regulations at designation markets. For example, China has recently tightened up rules and some products on e-commerce platform will no longer be allowed to be marketed or use their claims.[92]

SYSTEMIC SUPPORT REQUIRED FOR AUSTRALIAN EXPORTERS TO GROW IN OVERSEAS MARKETS. Australian exporters need to constantly adjust to fulfil the regulatory requirements in destination markets. Despite Austrade and the Department of Foreign Affairs and Trade providing support in overseas growth markets such as China, there is room greater engagement across the industry, including greater participation in Austrade delegations and negotiations. Industry consultation has also demonstrated support required to understand discrepancies in regulations standards for Australian-made complementary medicines products to increase the competitiveness of Australian exports.

Increased protection to Australian domestic consumers and industry

In July 2022, TGA has published new priority areas for compliance activities relating the import, advertising, and supply requirements, including e-commerce supply of unapproved goods in Australia. CMA has stated that they actively support monitoring and deterrence activities of the TGA in removing supply of illegal and unauthorised therapeutic goods in Australia.[93] Consistent regulatory reduction of unauthorised overseas products on Australian e-commerce platforms would improve the safety, innovation, and strength of the Australian complementary medicines industry. Consequently, the competitiveness of the Australian complementary medicines industry would increase.

91 National Institutes of Health – Office of Dietary Supplements (Accessed April 2023). *Dietary Supplement Health and Education Act of 1994. Public Law 103-417*.

92 Euromonitor International Herbal/Traditional Products in Australia, November 2022

93 CMA. (July 2022). Tech Alert: TGA advertising and supply compliance priorities 2022-23.

THE CASE FOR CHANGE

THE CASE FOR CHANGE

The following section describes the case for investment and support to realise the following collective ambition and objectives for Australia's complementary medicines manufacturing industry:

- → grow Australia's complementary medicines manufacturing industry;
- → de-risk the industry from uncompetitive manufacturing and supply chain issues;
- → grow a skilled workforce to enable the industry and contribute to economic growth and prosperity; and
- → capture a greater share of the international export market for Australian companies.

The challenges identified by industry have been organised and presented as a case for change through six thematic areas, each with proposed solutions able to be progressed over the short-, medium- or long-term. The potential benefit of each solution is described.

The themes each contain solutions that can be progressed by various stakeholders, including government, industry, the tertiary sector, peak industry bodies and the regulator. Potential owners of each of the solutions are identified throughout. NICM together with Australia's broader complementary medicine industry, has identified the need for more strategic and coordinated action by government, together with academia and the private sector, to accelerate the growth of Australia's complementary medicines manufacturing industry and to protect its global leadership position. This collaborative effort across the complementary medicines ecosystem is required to move forward and achieve the future vision for the industry.

THEME 1: RESEARCH & INNOVATION

THE CHALLENGE – LACK OF INCENTIVES AND LIMITED EXISTING PATHWAYS

There are insufficient incentives for complementary medicines manufacturers to invest in research and innovation and lack of available pathways for funding through medical grant bodies.

Research and innovation within the complementary medicines industry has been underdeveloped due to lack of incentives. Under TGA regulations, complementary medicines that have not undergone proven efficacy clinical trials are not able to be marketed using the claim of efficacy. However, due to complicated trial processes, financial constraints and lack of strong intellectual protections, complementary medicines manufacturers are disinclined to advance research and innovation in the area. Well-intentioned efforts to address this disincentive, such as the AUST L(A) scheme, have not realised intended benefits due to perceived deviation from original intent of the scheme through implementation. As a result, the cost-benefit advantage for industry is weakened and Australia's complementary medicines industry struggles to maintain competitiveness through evidence-based recognition of benefits.

Clinical trials are necessary for complementary medicines to use claims of efficacy. However, the trial process is arduous, requiring significant time and resources to complete. Post-development commercial success is not a guarantee – the investment required and the commercial uncertainty, is a barrier for companies considering research and innovation. As it stands, industry has limited capacity to fund and undertake clinical trials, and while there exist opportunities to partner with NICM and other appropriate universities to accelerate this process, lack of any incentives from government restricts this pathway.

Industry consultation highlighted that only a limited number of local complementary medicines manufacturing organisations are investing in research and innovation. Stakeholders reported that investment tends to be limited to the larger companies that can afford the capital outlay to keep innovating. As consumers seek new complementary medicine formats, such as 'easier to swallow' pills or higher-efficacy products, local suppliers struggle to respond to this demand. Consequently, consumers turn to e-commerce platforms that source from overseas manufacturers that are not constrained to a comparable level of regulation. Reliance on overseas manufacturers draws away potential revenue from the Australian market.

Complementary medicines research and innovation are not effectively encouraged in the Australian complementary medicines industry, and continued stagnation in this area is detrimental to the industry. Failure to effectively leverage research, anticipate market demands and employ innovative approaches risks significantly decreasing the reputation of the Australian complementary medicines industry. Reforms in this area are not only possible but sensible, with the potential to spur business development, boost revenue, and attract investment. Furthermore, the reputation of the Australian complementary medicines industry will be critically strengthened through efficacy studies, helping to address negative publicity stemming from products being taken to market with unsubstantiated claims of efficacy. Moreover, greater intellectual protection would give researchers the reassurance needed to propel innovation.

THE CASE FOR CHANGE CONTINUED

THE OPPORTUNITY – CLARITY OF INNOVATION PATHWAYS FOR INDUSTRY TO DRIVE INVESTMENT AND GROWTH

Drive research and innovation activities by direct funding support and enhancing data/intellectual property protection mechanism to incentivise investment into innovating the Australian complementary medicines manufacturing industry.

PROPOSED SOLUTIONS:

R&I1. Establish a substantial and clear complementary medicines research and development funding incentive and pathway to accelerate health innovation, industry collaboration and co-creation of new products for a 5–10-year period.

→ Government seeks and industry commits to a 'co-investment approach' for any funding grants – with industry providing a minimum of matching investment.

Potential owner(s): Government (program design and funding), Industry (commitment and execution), Universities/research institutions

The establishment of a clear funding incentive pathway would address the risk of Australia's CM industry losing position to other markets with greater rates of innovation. It will also support growth and upskilling of the industry workforce through expanded business activity alongside manufacturing capacity and capability growth.

Funding and clear incentives would allow industry greater ability to overcome impediments to investment in innovative technology, such as cost, lead-time, supply chain challenges, global material prioritisation and intellectual property protection. Where possible, capitalising on existing government sources of funding for manufacturing and advanced technologies and implement across CM ecosystem (i.e., basic equipment, AI, pastillation and other dose format technologies) should be explored.

NICM can play an important role supporting the implementation of the solutions identified above. For example, industry can partner with and leverage NICM's research capabilities and facilities to support collaborative R&D. NICM does and will continue to work with the industry to enhance the competitiveness of Australian products through research and innovation. This could in the future entail collaborative development between NICM, brands and manufacturers along the end-to-end capability, including but not limited to clinical trials, new product development, evidence package and compliance to suit domestic and international requirements, GMP training, training in pharmaceutical manufacturing, stability and other commercial services.

THEME 2: RAW INGREDIENTS

THE CHALLENGE – OVER RELIANCE ON IMPORTS AND SUPPLY CHAIN VULNERABILITY

The Australian complementary medicines manufacturing industry has an over-reliance on overseas raw materials, leading to supply chain vulnerability. Current complex approval process on new ingredients impedes innovation and build-up of sovereign capability.

A central issue for the Australian complementary medicines industry are the origin of the raw ingredients used in the complementary medicines. Industry consultation revealed that for some manufacturers most raw materials used are sourced from overseas. There are several reasons for the utilisation of overseas sources, including difficult domestic approval processes, the strength of overseas economies and producers, and under-developed local industries for raw ingredients. The over-reliance on overseas sources introduces risk to the complementary medicines supply chain.

Due to their regulation as medicines in Australia, new or changed ingredients used in complementary medicines must undergo a formal application process with the TGA before they can go to market. However, this process is long, costly and difficult compared to other jurisdictions and requires large amounts of data that can be difficult to generate, and industry consultations have revealed that it can take as long as two to four years on occasion for raw ingredients to gain TGA approval due to the "stop clock" nature of the TGA process. The strict and expensive approval processes involved in maintaining a presence in the complementary medicines industry discourages investment.

Overseas producers can produce and supply raw materials quicker and at lower costs. Australian manufacturers have utilised the availability of low-cost ingredients available for importation from countries which are able to produce ingredients at lower prices. While cost-effective, the widespread nature of this practice exposes the Australian complementary medicines industry to increased risk of supply chain shortages and delays. In addition, the cost-effective nature of overseas supply discourages investment in and development of local raw ingredient supply, and a potential source of economic activity, supply chain resilience and home-grown product. The inequality of the application of PIC/S to Australian raw material manufacturers further compounds the inability of Australian producers to supply ingredients.

There is also a wealth of ingredients used by First Nations people which are not utilised by the Australian complementary medicines industry. Due to the limited documented evidence on the efficacy of Indigenous Australian ingredients, the TGA has not approved their use in complementary medicines in Australia and most importantly, does not have approval frameworks tailored to the unique circumstances of First Nations systems which are not compatible with the usual assessment considerations. This barrier leads to missed opportunities for First Nations businesses and the Australian complementary medicines industry to innovate and scale the development of unique products.

Addressing issues in the availability and utilisation of raw ingredients in Australia would significantly advance the reputation and strength of the domestic complementary medicines industry.

THE OPPORTUNITY – DOMESTIC SUPPLY AND LOCAL OPPORTUNITY

Establish and bolster an Australian domestic supply chain for the complementary medicine's raw ingredients and boost opportunities for local businesses including Agritech.

PROPOSED SOLUTIONS:

RI1. Seek support from government to address supply chain issues experienced across the complementary medicines industry by funding partnerships between the agricultural sector and complementary medicines raw ingredient industry to initiate the extraction and manufacturing of local raw materials.

→ The funding should complement existing investment by industry in such measures and can support development of new channels for the raw ingredient industry locally and be a launching off point for partnerships to accelerate industry development.

Potential owner(s): Government (funding and execution), Agricultural sector, Farmers, Raw ingredient industry

RI2. Advocate for government funding to conduct a risk assessment of Australia's complementary medicines ingredient supply chain, to better protect and enhance Australian raw ingredient supply through integrated and enhanced supply chains.

→ A comprehensive and clear risk assessment would identify areas to invest in and support, and potentially develop local raw ingredient industries (including investment in utilisation of Agritech waste) and explore opportunities for circularity and re-use.

→ It is expected that this activity would benefit other industries which also make use of similar ingredients, for example the pharmaceutical industry.

Potential owner(s): Government (funding), Industry

RI3. Engage with Federal (NIAA) and State government agencies to explore opportunities for Indigenous business development in the CM industry.

→ Collaborate with First Nation representatives, NACCHO, the National Health Leadership Forum, Australian Government under the 'Implementation Plan for the National Aboriginal and Torres Strait Islander Health Plan' to explore opportunities for traditional Indigenous ingredients to be used in complementary medicine integrated as part of the Implementation Plan. *This process would require extensive consultation to initiate.*

Potential owner(s): Regulator, Industry peak body, Local producers

NICM can play an important role in the implementation of the solutions above. In partnership with industry NICM could support the research required to develop and test Australian raw ingredients for domestically made products, as well potentially as the integration of the use of Australian ingredients into product development. This may entail an end-to-end process including literature reviews, clinical trials on efficacy and the practical use of the products through integrative healthcare centre. NICM could also provide expertise and research capacity tackling supply chain for the industry via working with sister institute, HIE, to resolve supply chain issues with the latest know-how in agriculture and horticulture.

THE CASE FOR CHANGE CONTINUED

THEME 3: WORKFORCE

THE CHALLENGE – ACUTE SKILLS SHORTAGES, POOR COORDINATION, AND AVAILABILITY OF SKILLS

The complementary medicines industry is facing acute skills shortages across the high-skilled workforce ranging from research, product development, laboratory skills, GMP and manufacturing equipment operators. This is contributing to additional operating costs impacting the Australian complementary medicines manufacturing industry's competitive advantage.

Manufacturing organisations are facing a significant challenge in recruiting and retaining skilled workers to meet the demand of the market. From tablet press operators to lab technicians and quality control specialists, the required skillset is diverse, and organisations are having to offer higher salaries to attract the right individuals as well as train on-site at significant cost. Challenges mean business must often rely on an increasingly casual workforce to meet a range of skills demands.

The use of an increasingly casualised workforce leads to other challenges, such as high turnover rates, poor knowledge transfer, insufficient continued professional development opportunities and low production outcomes. The costs associated with recruitment and salary increases to attract employees can be expensive, which is why overseas manufacturing is becoming more appealing due to the availability of more reliable labour at a lower cost.

GMP regulations necessitate that only trained personnel be employed in the production of medicines. To earn certification, GMP training must be completed that meets industry standards and specific proficiencies are required for each level of manufacturing. Unfortunately, training is limited, and it mainly consists of studying standard operating procedures and observing experienced operators, which does not give an adequate balance between theory and practice. As a result, it is difficult for new recruits to gain the requisite aptitudes for their job.

Formal degree qualifications and diplomas are relevant pathways for other skillsets in demand across the industry, though few institutions offer formal qualifications in complementary medicines. Lack of options for further study also reduces the authority of complementary medicines within Australia, especially when considering the popularity of medicine degrees. Therefore, limited courses within the education sector impacts the ability of the complementary medicines industry to grow within the country.

The Australian complementary medicines industry would benefit from the standardisation of training standards and methodology. A workforce lacking in necessary skills and knowledge can lead to missed opportunities for product investment and industry growth. If knowledge is not adequately transferred at a rate that keeps pace with the global complementary medicines industry, Australia will fall behind international competition. The complementary medicines industry could benefit from leveraging the GMP training initiatives and programs developed in the bioprocessing sector and led by MTP Connect. Partnering with MTP Connect to access existing and develop additional programs for the complementary medicines industry could ensure an efficient and effective way to bridge the gap in GMP skills.

THE OPPORTUNITY: SUPPORT AND ENABLE GROWTH OF THE COMPLEMENTARY MEDICINE'S WORKFORCE

Develop professional training and development system that build a growth-enabling workforce with globally recognised qualification across end-to-end value chain of the complementary medicines industry.

PROPOSED SOLUTIONS:

WF1. Government to fund the development of a complementary medicines workforce report that will map and model the current and future workforce and skills needs across industry.

Potential owner(s): Universities/research institutions, Industry peak body, Government (funding)

WF2. Government to fund the establishment and design of micro-credentials for complementary medicine manufacturing skills and qualifications across all industry levels, considering links to advanced manufacturing and pharmaceuticals industry.

Potential owner(s): Industry peak body, Universities/research institutions, Government (funding)

WF3. Government should support the establishment of formal partnerships between industry and education sector to implement micro-credentialling through training providers to address critical skills shortages.

Potential owner(s): Government, Industry peak body, Universities/research institutions, industry, training providers

NICM can support the development of Australia's complementary medicines workforce and implementation of the above solutions in a range of ways. NICM can support increasing access to standardised education and training for students/existing and prospective professionals in the complementary medicines manufacturing industry. NICM can leverage academic resources to drive the development of micro credentials and other education and training material to address the needs of the industry. As a world-renowned tertiary education institution, NICM could facilitate engagement between Federal and State education bodies to integrate various training programs into formal programs at the higher education level.

THEME 4: MANUFACTURING

THE CHALLENGE – UNCOMPETITIVE MANUFACTURING, PROHIBITIVE COSTS, AND RISK OF OVERSEAS COMPETITION

Australian manufacturing is under competitive pressure from overseas jurisdictions. This is driven in large part due to high establishment costs and limited government support, which could result in transfer of local manufacturing to overseas facilities and the weakening of Australian sovereign manufacturing.

The Australian complementary medicines industry has already experienced significant growth and is expected to continue growing alongside the global market. Given this projected market growth, it is necessary to consider the multiple, often competing, factors that are expected, such as operating costs, equipment costs, investment lead time and infrastructure, and land expansion approvals. These factors increase risks for the already risk-averse manufacturers, thus enticing them to move production overseas.

Many overseas jurisdictions have implemented policies aimed at promoting manufacturing by providing substantial funding and support for the development of these industries. Consequently, it is crucial to address the need for leveling the playing field for manufacturers and creating favourable conditions to ensure the establishment and growth of robust sovereign manufacturing capabilities.

Moving production to locations overseas is attractive to manufacturers who seek cheaper production methods. This temptation is compounded when considering the stringent regulatory processes that are currently in place. In a fast-paced and competitive industry, the economic costs, complex proceedings, and long wait periods deter manufacturers and investors. The barriers to accessible production processes and attractive overseas alternatives will lead to the outsourcing of local production and the removal of Australia as a serious competition in complementary medicines industry.

Furthermore, the stringent regulatory processes for domestic complementary medicines lead some to outsource their products from overseas companies. Overseas producers are often situated within larger economies and have lower raw material costs. As more product is outsourced from overseas companies, the reputations of these companies will gradually overshadow the reputation of Australian complementary medicines manufacturers, and local manufacturers will cease to be a serious competitor in the complementary medicines industry. This will lead to a missed opportunity to support sovereign manufacturing capability and strengthen local production.

As the demand for complementary medicines increases, Australia must find sustainable ways to keep pace with international competitors. Failing to reform manufacturing capabilities would lead to Australia falling behind in the industry and losing significant financial investment in the industry. Addressing issues within the manufacturing of Australian complementary medicines can increase production and investments within the industry, thus growing adjacent industries.

THE CASE FOR CHANGE CONTINUED

THE OPPORTUNITY – BOOSTING COMPETITIVENESS AND MANUFACTURING CAPACITY

Increase the competitiveness of Australian complementary medicines manufacturing capability through direct funding support, regulatory reform, and an industry-wide investment roadmap.

PROPOSED SOLUTIONS:

M1. Directly support local manufacturing growth and innovation through infrastructure grants, targeted funding, and capital.

→ Industry engages with existing government manufacturing policies and programs at Federal and State level (for example, state manufacturing development policies) to identify eligibility and demonstrate alignment of existing opportunities for investment support (noting Federal and State government manufacturing priorities), to provide access to capital support and expand manufacturing opportunities.

Potential owner(s): Government (funding), Industry (alignment and engagement), Industry peak body (coordination and support)

M2. Align overseas regulatory requirements through modification of the TGA approval system for GMP.

→ Advocate to the TGA to include a requirement for overseas manufacturers to have an established relationship with an Australian manufacturer to be able to seek Australian GMP certification.

Potential owner(s): Industry peak body, Regulator

M3. Develop a complementary medicine industry-wide manufacturing investment roadmap to better market and boost attractiveness of the complementary medicines industry for foreign investment and encourage suppliers to maintain and expand their business in Australia.

→ Additional actions considered through this roadmap could include tax and land incentives, boosting the availability of skilled and expert talent, and accessibility of local supply chains. The manufacturing investment roadmap should also consider measures of sustainability noting the increasing importance of those criteria in investment decision making.

Potential owner(s): Government (industry development), Universities/research institutions (advice), Industry peak body (coordination and support), Industry (engagement)

NICM can play an important role supporting the implementation of the manufacturing solutions identified above, which is strongly aligned with the support NICM can provide in the research and innovation theme, set out in the section on the CASE FOR CHANGE.

THEME 5: TRADE

THE CHALLENGE – LACK OF BRAND PROMOTION AND EXPORT BARRIERS

Strong Australian brand advocacy has yet to be established to grow Australian-made products' reputation and credibility, as well as challenges with foreign treatment of Australian goods at export destinations.

The Australian complementary medicines industry faces several issues with its trade operations, including the lack of strong awareness on Australian brands, discrepancy in standards across markets, regulations that unintentionally preference overseas competitors, and inconsistent regulations across sales channels within the Australian domestic market.

There is currently a lack of awareness of the advantages offered by the Australian complementary medicines industry. According to the Department of Foreign Affairs and Trade, there is a need for greater marketing efforts to build the Australian's brand and credibility in the Southeast Asia region. The lack of awareness of the benefits of Australia's complementary medicines industry slows international investments and expansions.

Discrepancies in approval standards and processes between Australian domestic certification standards and local requirements at export destinations have contributed to longer wait times and higher approval costs upon overseas expansion. Stakeholders from industry consultation have reported that delays in approvals and increased costs have been caused by a failure to bridge standards between the Australian and overseas market.

The TGA's approach to regulate the complementary medicines manufacturers overseas may have also created competition for the domestic industry. While the costly and stringent regulatory framework has earned a strong reputation for Australian products due to high quality and safety standards, this has also provided the same boost for overseas manufacturers via the provision of Australian GMP certification. Through this action, the TGA has enabled overseas manufacturers to benefit from the strong reputation of Australian complementary medicines, instead of utilising and supporting existing local manufacturers. Furthermore, the Australian TGA GMP approval of foreign operators reduces the distinction between them and their Australian counterparts, thus removing the competitive advantage of Australian product. Enhancing the international reputation and brand awareness of the Australian complementary medicines industry will support a strong presence in the international industry and build meaningful relationships. Without addressing current challenges in trade operations, the potential of the Australian complementary medicines industry may go unexplored by investors. As the industry's reputation is strengthened and international relationships are forged, overseas sales should be expected to increase, driving production levels and elevating profits.

THE OPPORTUNITY: DRIVING EXPORT GROWTH THROUGH BRAND PROMOTION AND TRADE FACILITATION

Boost exports by facilitating the entry of Australian complementary medicines products at overseas markets, including driving coordinated industry-wide effort to promote the Australian brands, enhance trade agreements and easing the regulatory burden upon market entry.

PROPOSED SOLUTIONS:

T1. Government drive and promote awareness of the 'Australian brand' for CM through support for industry partnerships:

- → Cross-industry partnership across government, industry body, CM manufacturers, academia, Austrade/state government trade and investment agencies to drive initiatives that uplift Australian brands' competitiveness
- → Funding to establish a CM export program (through Austrade and state government trade and investment agencies) to reduce the time, cost, and risks of export (e.g., for initiatives that uplift Australian's brands)
- → Promotion of investment opportunities in existing research and development ecosystem within Australia for CM (i.e., NICM, existing manufacturers) to attract funding for additional capacity and growth of industry

Potential owner(s): Industry peak body, Universities/research institutions, trade facilitation agencies

T2. Drive greater CM industry participation in relevant trade delegations and negotiations.

- → The CM industry is growing and is a strong brand in key export markets for Australia, such as China and other Asia Pacific countries. Greater engagement and participation in trade initiatives could help support the growth of the CM export market and benefit Australian export growth more broadly.

Potential owner(s): Industry peak body, Trade facilitation agencies (Federal, State)

T3. Engage with overseas regulators to identify ways to streamline CM product approval processes at export destination countries.

- → Engaging with foreign regulators (with TGA/government support) to overcome regulatory hurdles for exports will help reduce the cost of export.
- → To support this effort, industry and the TGA should also identify and document any discrepancies between regulatory standards for CM products manufactured here and overseas.

Potential owner(s): Regulator, Industry peak body

THEME 6: REGULATION

THE CHALLENGE – STRICTNESS, COST, AND REGULATORY CAPABILITY

The regulations on complementary medicine in Australia are strict and costly. While they aim to ensure the safety and efficacy of the products, they have created an unbalanced financial situation for local businesses. The financial burden has impacted the time to market and decreased the competitiveness of the local industry.

The regulatory framework for complementary medicines in Australia is one of the industry's greatest strengths. Strict quality standards and rigorous requirements placed on manufacturers have created a reputation for Australian complementary products of high quality and safety. The same regulatory framework also creates several challenges for investment in and growth of the complementary medicines industry within Australia due to cost of compliance. Several other challenges arise from the TGA's reduced awareness and capacity to support a targeted and tailored regulatory approach for complementary medicine following changes to their approach in recent years. One such impact is that approval processes that are not commensurate to the risk they are intended to mitigate – for example, approvals for new raw ingredients were reported to take a minimum of 12 months, but on occasion between two and four years.

A lack of collaboration and proactive engagement with the industry on regulatory matters further exacerbates this challenge. Industry input and feedback on specific issues is not always incorporated into updates to the regulatory framework. This absence of stakeholder input when making regulatory decisions has created a situation where stakeholders lack loyalty to Australian markets, resulting in businesses seeking opportunities overseas.

The already high cost of compliance with the domestic regulatory framework impacts the competitive advantage of Australian products, issues include tight regulatory controls, complex regulatory processes, high financial costs involved in compliance and the arduous process required to navigate the regulatory framework. These tighter regulatory controls, such as stricter labelling and advertising, impede sales and add to administrative workloads. In addition, a requirement for ongoing monitoring and reporting of adverse events and the introduction of pharmacovigilance requirements adds administrative burden and further increases to cost of regulatory compliance.

A new challenge for regulators is the growth of the online sales channel. The growth of e-commerce platforms has seen a concurrent rise in online sales of complementary medicines products, presenting a range of benefits for organisations in terms of flexibility and relative cost efficiencies. However, the public domain nature of these platforms, combined with their

THE CASE FOR CHANGE CONTINUED

often difficult-to-regulate environment and weak intellectual property protections, can discourage risk-averse businesses from engaging with the Australian complementary medicines industry online.

There are challenges for research and innovation efforts due to the absence of strong intellectual protection for complementary medicines. Despite the intellectual property protection regulations are in place (i.e., the 2-year exclusivity rights of use of approved raw ingredients, and the 5-year data protection mechanism for clinical trials), there is limited evidence showing manufacturers have begun to take advantage of such regulations. As such, innovators are more likely to base in jurisdictions that can offer the necessary intellectual protections, contributing to a 'brain drain' in the Australian complementary medicines industry.

There is a clear opportunity to address the current challenges with regulation through the solutions identified above, providing for a more balanced regulatory approach and optimising the ability of the regulator to shape a performant market for complementary medicines in Australia. In doing so, the benefits of the existing regulatory approach, in maintaining high quality and reputation, are maintained while balancing regulatory burden for the industry.

THE OPPORTUNITY – OPTIMISING THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES AND UPLIFTING TGA CAPACITY AND CAPABILITY

Optimise the complementary medicines regulatory framework and funding approach and enhance the TGA's capacity and capability to oversee and implement practical updates, while preserving benefits of existing regulatory framework.

PROPOSED SOLUTIONS:

R1. Re-establish the separate Office of Complementary Medicines within the TGA to provide greater focus on regulatory matters relevant to the $6Bpa complementary medicines industry, including specific focus on:

- → Ensuring an appropriate and expected level of internal skills commensurate with the requirement to regulate complementary medicines efficiently and in an informed manner.
- → Pharmacovigilance, risk and compliance;
- → Improving community understanding of the safety and quality of CM Australian products;
- → Align State and TGA legislation to allow for a simplification of TGA feed and charges; and
- → Standardised regulatory assessment process for products sold across domestic and overseas channels.

Potential owner(s): Regulator

R2. Support appropriate regulation of complementary medicines and provide funding to the TGA to cover work outside of the direct cost recovered framework.

- → Provide specific funding to the TGA to undertake services that are currently unfunded public good activities mandated through legislation/policy but that cannot be attributed to ARTG sponsors and should not be cost-recovered
- → Provide TGA with specific funding to undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods

Potential owner(s): Government (funding), Regulator, Industry peak body

R3. Review data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence.

- → Expand the AUST LA intermediate indications and create more flexible policy to balance the description of claims messages on product efficacy that is commensurate with the risk of the products, to incentivise CM's companies' investment.
- → Advocate for enhanced IP protection mechanisms to encourage R&D effort and incentivise financial investment in R&D.

Potential owner(s): Regulator, Industry peak body, NICM

NICM can play a key role supporting and driving advocacy to implement the above solutions: NICM can provide input and assist in the development of government policies and guidelines to ensure a balance of guidance or direction that is relevant, practical, and supportive of the industry and the Australian community at large, while also rigorous and continues to protect consumers and promote safety. From regulatory issues to consumer perception on complementary medicines, NICM will continue to support advocacy with independent research and evaluation to provide evidence-based information through various channels, including but not limited to submission to government and regulators, academic publications as well as other media releases.

BENEFITS AND SOLUTIONS

There are a range of economic benefits able to be realised by deploying the solutions to address the opportunities and challenges outlined above. Table 2 below summarises the key benefits across each of the theme areas and the summary of solutions proposed to realise the benefits.

Table 2: Problem statement, response, and benefits

THEME	PROBLEM STATEMENTS	RESPONSE AND SOLUTIONS	BENEFITS
 **RESEARCH AND INNOVATION**	*There are insufficient incentives for complementary medicines manufacturers to invest in research and innovation and lack of available pathways for funding through medical grant bodies*	Establish a substantial and clear complementary medicines research and development funding incentive and pathway to accelerate health innovation, industry collaboration and co-creation of new products for a 5–10-year period.	Increased business activity due to increased investment and innovation. Quantified in this report as producer surplus and labour surplus Increased attractiveness of Australian products, improved business activity and revenue as a result of producing new product formulations Enhanced protection of CM companies' investment in innovation and IP
 **RAW INGREDIENTS**	*The Australian complementary medicines manufacturing industry has an over-reliance on overseas raw materials, leading to supply chain vulnerability. Current complex approval process on raw materials have impeded innovation and build-up of sovereign capability*	Seek support from government to address supply chain issues experienced across the complementary medicines manufacturing industry by funding partnerships between the agricultural sector and complementary medicines raw ingredient industry to initiate the extraction and manufacturing of local raw materials. Advocate for government funding to conduct a risk assessment of Australia's CM ingredient supply chain, to better protect and enhance Australian raw ingredient supply through integrated and enhanced supply chains Engage with Federal (NIAA) and State government agencies to explore opportunities for Indigenous business development in the CM industry	Increased economic activity (supply chain) Better use of Agritech waste products Increased use of ingredients native to Australia
 **WORKFORCE**	*The complementary medicines industry is facing acute skills shortages across the high-skilled workforce ranging from research, product development, laboratory skills, GMP and manufacturing equipment operators. This is contributing to additional operating costs impacting the Australian complementary medicines industry's competitive advantage*	Develop a detailed CM industry workforce report, mapping and modelling current and future workforce and skills needs across the industry Support the establishment and design of micro-credentials for CM manufacturing skills and qualifications across all industry levels – considering links to training on advanced manufacturing and pharmaceuticals more broadly Establish a formal partnership between business, industry and tertiary education institutions to identify ways to address lack of product development and commercialisation expertise across the CM industry	Increased employment opportunities, research activities and output Increased productivity and skills proficiency

THE CASE FOR CHANGE CONTINUED

THEME	PROBLEM STATEMENTS	RESPONSE AND SOLUTIONS	BENEFITS
MANUFACTURING	*Australian manufacturing capability is not competitive due to high establishment costs and limited government support, which could result in transfer of local manufacturing to overseas facilities and the weakening of Australian sovereign manufacturing*	Directly support local manufacturing growth through infrastructure grants, targeted funding, and capital Reduce unfair overseas manufacturing competition through modification of the TGA approval system for GMP Develop a CM industry-wide manufacturing investment roadmap to better market and boost attractiveness of the CM industry for foreign investment and encourage suppliers to maintain and expand their business in Australia	Increased economic activity. Quantified in this report as producer surplus and labour surplus
TRADE	*Strong Australian brand advocacy has yet to be established to grow Australian-made products' reputation and credibility, as well as a challenges with foreign treatment of Australian goods at export destinations*	Drive and promote awareness of the 'Australian brand' for CM through industry partnership Drive greater CM industry participation in relevant trade delegations and negotiations Engage with overseas regulators to identify ways to streamline CM product approval processes at export destination countries.	Increased economic activity (exports) due to stronger Australian Brand, increased competitiveness and streamlined approval processes. Quantified in this report as producer surplus (i.e., corporate profits) and labour surplus (new employment opportunities).
REGULATION	*The regulations on complementary medicine in Australia are strict and costly. While they aim to ensure the safety and efficacy of the products, they have created an unbalanced financial situation for local businesses. The financial burden has impacted the time to market and decreased the competitiveness of the local industry*	Re-establish the separate Office of Complementary Medicines within the TGA to provide greater focus on regulatory matters relevant to the $6Bpa complementary medicines industry. Support appropriate regulation of complementary medicines and provide direct funding to the TGA to cover work outside of the direct cost recovered framework. Review data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence	Increased business activity due to increased competitiveness of Australian complementary medicines products. Quantified in this report as producer surplus[94] (i.e., corporate profits) and labour surplus[95] Improved speed-to-market for new complementary medicines products Improved community/public awareness regarding the safety, innovation, and strength of the Australian CM industry

To illustrate potential impact, high-level economic analysis has been conducted to determine the potential benefit for stakeholders. Refer to the section on the POTENTIAL BENEFITS for the economic analysis.

The confirmation and detailed analysis of potential benefits requires further consideration, in particular consideration of costs and available investment. The effectiveness of solutions in achieving the benefits intended should be monitored and tracked as they are executed. Please refer to Appendix 4 for the list of key performance indicator proposed to be monitored during implementation.

94 Producer surplus is defined as profit flowing to producers and/or capital owners.
95 Labour surplus is theoretically generated by an initiative causing either increases in wages or increases in employment.

ALIGNMENT TO GOVERNMENT PRIORITIES

Several strategies and plans of the Commonwealth, NSW and Victorian Governments align with responding to the current challenges identified in the Australian complementary medicine industry, key aligned strategy as outlined below.

Policy alignment (Appendix 8) contains the full list of relevant policies and strategies with mapping to relevant themes.

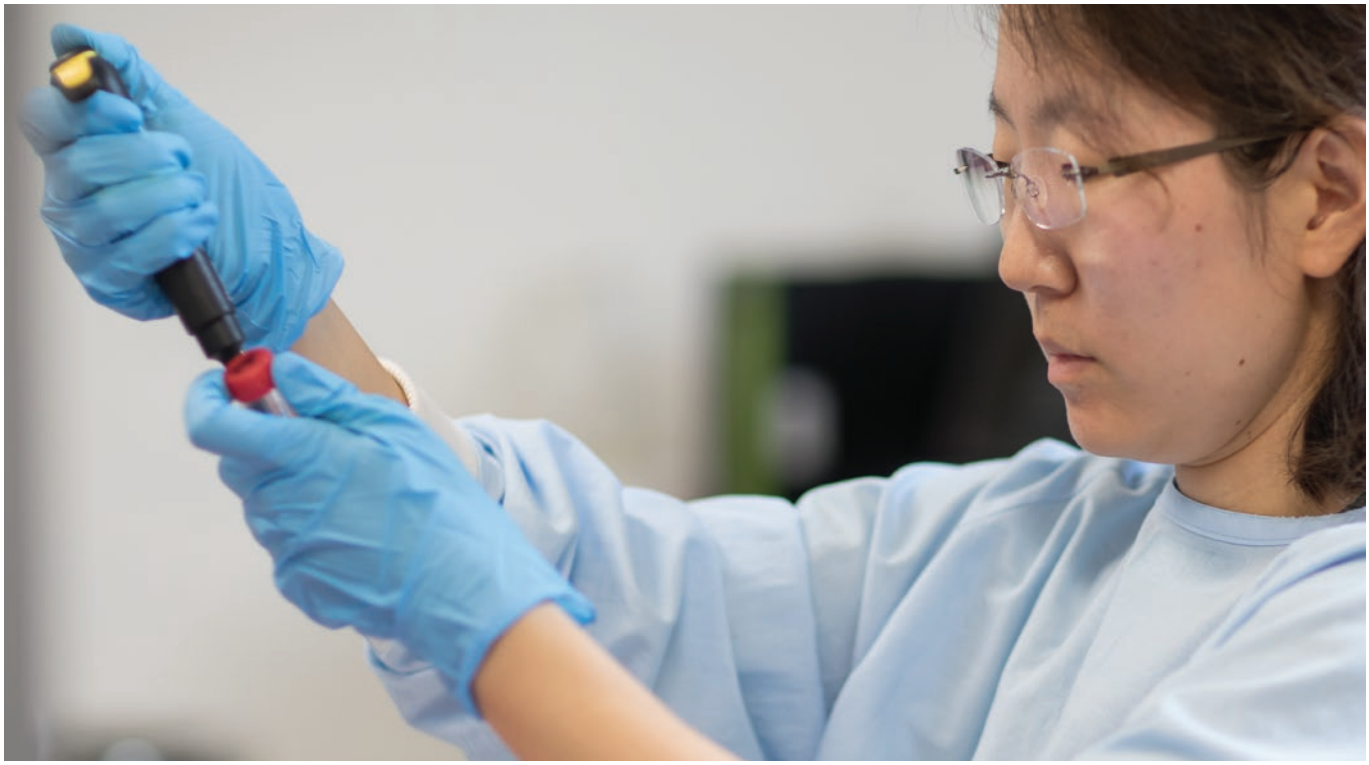
Key ones include

- The Commonwealth Governments' $15 billion National Reconstruction Fund
- State-based manufacturing support schemes such as:
  - NSW Future Economy Fund
  - NSW Regional Investment Attraction Fund
  - Breakthrough Victoria
  - Queensland's Advanced Queensland suite of programs and funds

In addition to aligning with Commonwealth and NSW government strategic plans and policies, the proposed solutions will adhere to all relevant pieces of legislation and Codes of Practice, including:

Therapeutic Goods Act 1989 (Cth);

- Therapeutic Goods Regulations 1990 (Cth);
- Therapeutic Goods Regulation 2008 (NSW);
- NSW Code of Good Manufacturing Practice for Therapeutic Goods;
- NSW Guidelines for the Labelling of Therapeutic Goods.



OPTIONS

OPTIONS

This section describes the **options** to address the vision and objectives for the manufacturing industry, de-risk any threats to the industry and realise the opportunities described in the previous section.

Solutions described in the CASE FOR CHANGE represent activities that should be implemented to affect positive change to support medicines manufacturing in Australia. They are high level interventions that describe a sensible response to challenges in specific theme areas.

Options on the other hand represent the 'packaging up' of the solutions informed by the **prioritisation process** undertaken. The options escalate in scale and complexity. Options are presented separately to the benefits of solutions – a high-level economic analysis has been undertaken to estimate the potential impact of solutions in each of the theme areas. Note that a longer list of solutions had been assessed and prioritised based on a set of criteria designed to evaluate the strategic fit and viability of each solution. This is explored further in the following section section entitled POTENTIAL BENEFITS.

This remainder of this section outlines the development and prioritisation approach, explains the assessment and prioritisation of solutions, and defines options.

DEVELOPMENT AND PRIORITISATION

An iterative approach was taken to developing solutions, beginning with investment logic mapping. Industry consultation was undertaken to input into and validate a long list of potential solutions, which then informed the details of solutions and how they were positioned within each theme areas. This process of input and consultation provided valuable insight into how to best develop and implement solutions that are tailored to the needs of the industry. This approach has enabled the creation of a long list of solutions tailored to the industry's specific needs and has the potential to deliver tangible outcomes. The steps below set out at an elevated level the process worked through and captured in this business case. Evaluation of the options has not been undertaken at this stage; however, solutions are assessed and prioritised (and described in the next section).

Table 3 Overview of Investment logic mapping (ILM) approach

→ **Challenges** – current challenges present in the Australian complementary medicine industry.

→ **Problem statement** – a specific need or gap in the industry that the strategic business case wishes to highlight and ultimately address.

→ **Benefits** – identifies the overarching benefits the strategic business case aspires to deliver by addressing the service need.

→ **Responses** –outlines potential strategic responses to realise the benefits identified; they should be realistic, achievable, and informed by evidence.

→ **Solutions** – represents activities to address components of the service needs; they provide the detail of how the strategic responses will be put into effect.

→ **Options** – represent the 'packaging up' of the solutions and strategic responses to combine multiple activities/strategies to respond to the service need. Typically options escalate in scale and complexity and consider the best holistic approaches for addressing the service need and realising benefits. Options represent the potential government intervention that are evaluated in detail in the detailed business case (post completion of the strategic business case.

CHALLENGES	PROBLEM STATEMENT	BENEFITS	RESPONSES	SOLUTIONS	OPTIONS
STEP 1: Develop list of challenges identified for the Australian complementary medicine industry based on a combination of desktop research and industry consultations.	**STEP 2:** Review the long list of challenges and group similar ones together, looking for common themes and patterns. Clearly articulate all the discrete problems that underpin the problem statement.	**STEP 3:** Identify the benefits sought if each of the aforementioned problems are addressed.	**STEP 4:** Identify potential strategic responses/ interventions. Potential responses are evaluated against the extent to which they are able to deliver the aforementioned benefits sought.	**STEP 5:** Identify the specific tasks and activities required to implement the strategic response, including identifying resources, assigning responsibility and developing a time frame for implementation.	**STEP 6:** Review and collate the list of solutions and strategic responses into a list of potential options. Evaluate options using a pre-agreed options assessment criteria.

OPTIONS CONTINUED

ASSESSMENT AND PRIORITISATION OF SOLUTIONS

A prioritisation matrix was developed as a framework to evaluate the long list of solutions and form a view on those which had the highest potential to deliver positive outcomes for the complementary medicines manufacturing industry. This matrix enabled the assessment of each solution on criteria including policy alignment, economic potential, legal/ regulatory implications, commercial viability, and deliverability. The assessment was conducted in consultation with industry experts and has been validated with key stakeholders.

The prioritisation activity allowed identification of those solutions that had the greatest potential to deliver meaningful outcomes and to focus our resources on those solutions with the highest priority. The prioritisation matrix also allowed identification of any areas that needed further research or development to make sure solutions were viable and effective.

A set of weighting to each criterion is applied to each solution to establish the priorities amongst the set of potential solutions (See Options that follow).

Table 4 Solutions prioritisation criteria and assessment mechanism

GROUPING	CRITERIA	WEIGHTING (%)	RATIONALE FOR PRIORITISATION	ASSESSMENT		
				LOW (1 SCORE)	LIMITED/ PARTIAL (3 SCORE)	HIGH (5 SCORE)
Political (15%)	Government policy alignment	15%	Comply with commonwealth and state government policies, priorities and strategies	No/limited compliance	Either state/ commonwealth	Both state/ commonwealth
Economic (65%)	Job creation potential	15%	Create a large number of new jobs in the medium term (i.e. next 5 years)	Limited impact	Moderate impact	High impact
	Manufacturing potential	15%	Enable manufacturing capacity and capability growth (i.e. new sites/new technology)	Limited impact	Moderate impact	High impact
	R&D potential	10%	Enable innovation within the current boundaries for with potential new technology/product format/raw material	Limited impact	Moderate impact	High impact
	Export potential	10%	Enable export growth to existing and new markets	Limited impact	Impact existing markets	Impact new and existing markets
	Australia brand	5%	Strengthen the perception of Australian brands domestically and overseas	Limited impact	Indirect impact	Direct impact
	Australia's sovereign capability	10%	Create and enable growth of local supply chain for raw materials	Limited impact	Moderate impact	High impact
Legal (5%)	Regulatory reform	5%	Drive regulatory reform for CM industry and build industry partnership with TGA	No effect	Indirect impact/ influence	Direct impact/ influence
Practicality (15%)	Meets service need	5%	Address the needs of industry (manufacturers, retailers, consumer, industry partners etc)	No direct response	Respond to some needs	Respond to important needs
	Commercial viability	5%	Provide commercial viability and is financially sustainable	Minimal	Realistically moderate	High ROI
	Deliverability	5%	Deliver at low cost of investment and low complexity in stakeholder engagement requirements	High cost and complexity	Modest cost and complexity	Low cost and complexity

OPTIONS

The Options have been developed following the solutions development and prioritisation activities described above. Using the criteria above, the options have been developed to include a 'menu' of different solutions, described below.

OPTION 1: do nothing

→ The 'base case'

→ No solutions included in this option

OPTION 2: deliverability prioritised

→ Includes solutions which scored highly against the 'deliverability' criteria and show strong alignment with policy or strategic agendas of government

→ Little or limited difficulty or cost anticipated in implementation.

OPTION 3: high impact

→ *Includes solutions from Option 2*

→ Includes solutions which scored highly in economic potential

→ Excludes solutions which prescribe regulatory or legislative reform

OPTION 4: longer term reform

→ *Includes solutions from Options 2 and 3*

→ Includes solutions which require longer term planning and preparation in order to achieve outcomes, including regulatory reform

→ Includes solutions which propose creation of new organisations or bodies to support industry-wide goals

Options are described for the purpose of illustrating potential implementation pathways, and benefits are not quantified for specific options. As described in the case for change, each of the solutions have a variety of potential owners and relevant stakeholders and are likely to be progressed independently of each other, making the calculation of benefits for specific solutions and therefore options difficult.

The options serve to illustrate how focus can be applied in different theme areas to achieve short-, medium- and long-term outcomes. Key to success and achieving investment objectives will be a coordinated approach across industry, government, and academia, as well as clear ownership and accountability for initiatives in specific areas.

The full suite of solutions in each option is set out in the table below. Solution scoring can be found in **Appendix 10**.

OPTIONS CONTINUED

Table 5 Options

OPTION	OPTION DESCRIPTION
OPTION 1 (Do nothing)	Base case
OPTION 2 (Deliverability prioritised)	Deliver initiatives that will provide targeted benefit to the industry while prioritising ease of implementation. **Solutions:** **Trade:** **#2:** Drive greater CM industry participation in relevant trade delegations and negotiations. **Workforce:** **#1:** Develop a **complementary medicines industry workforce report that will map and model the current and future workforce and skills needs across industry.** **Raw ingredients:** **#2:** Secure government funding to conduct a risk assessment of Australia's CM ingredient supply chain, to better protect and enhance Australian raw ingredient supply through integrated and enhanced supply chains.
OPTION 3 (High impact)	Deliver initiatives with high potential to spur growth of the industry, exports, and workforce. **Solutions** *(in addition to Option 2)***:** **Regulations:** **#2:** Support appropriate regulation of the $6 billion pa complementary medicines manufacturing industry and provide funding to the TGA to cover work outside of the direct cost recovered framework. **Workforce:** **#3:** Establish a formal partnership between business, industry, and tertiary education institutions to identify ways to address lack of product development and commercialisation expertise across the CM industry. **Research and innovation:** **#1:** Establish a substantial and clear complementary medicines research and development funding incentive and pathway to accelerate health innovation, industry collaboration and co-creation of new products for a 5–10-year period. **Manufacturing:** **#1:** Directly support local manufacturing growth through infrastructure grants, targeted funding, and capital. **#3:** Develop a CM industry-wide manufacturing investment roadmap to better market and boost attractiveness of the CM industry for productive foreign investment and encourage suppliers to maintain and expand their business in Australia. **Raw ingredients:** **#1:** Seek support from government to address supply chain issues experienced across the complementary medicines manufacturing industry by funding partnerships between the agricultural sector and complementary medicines raw ingredient industry to initiate the extraction and manufacturing of local raw materials.
OPTION 4 (Long term reform)	Orchestrated whole-of-industry reform campaign including regulatory reform and cross-industry initiatives within and beyond Australia **Solutions** *(in addition to Option 2 and 3)*: **Regulations:** **#1:** Re-establish the separate Office of Complementary Medicines within the TGA to provide greater focus on regulatory matters relevant to the $6Bpa complementary medicines industry. **#3.** Review TGA data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence. **Trade:** **#3:** Engage with overseas regulators to identify ways to streamline CM product approval processes at export destination countries. **Workforce:** **#2:** Government to fund the establishment and design of micro-credentials for complementary medicine manufacturing skills and qualifications across all industry levels, considering links to advanced manufacturing and pharmaceuticals industry. **Manufacturing:** **#2:** Reduce unfair overseas manufacturing competition through modification of the TGA approval system for GMP. **Raw ingredients:** **#3:** Engage with Federal (NIAA) and State government agencies to explore opportunities for Indigenous business development in the CM industry.

POTENTIAL BENEFITS

POTENTIAL BENEFITS

Even in early stages of investment decision making, measuring potential benefits is an essential component of the process. Establishing a reasonable and robust baseline (base case), verified with industry input, is integral to ensuring reliable and accurate measurements, along with conservative estimates of growth based on available evidence and information.

At this stage, due to the foundational nature of the solutions proposed, only the costs related to potential government funding (and industry co-contributions) have been considered in the economic analysis. This will be an important next step as the detail of initiatives is developed to ensure a robust assessment of costs and benefits.

The identified benefits are primarily driven by a range of drivers which include:

- → Investment targeting areas such as research and innovation, manufacturing and export promotion will catalyse domestic and international growth for the Australian complimentary medicines industry; and
- → Emerging global industry for complementary medicines in developing markets such and China, India and the broader Southeast Asia region.

APPROACH FOR THE ECONOMIC BENEFITS ANALYSIS

OVERALL APPROACH

Indicative economic analysis was undertaken to present the potential impacts to the Australian complementary medicine manufacturing industry resulting from:

- → Implementing the proposed solutions across the six themes identified in in the section on the CASE FOR CHANGE; and
- → An assumed industry growth response resulting from an assumed industry investment scenario in which:
  - The Commonwealth Government provides an annual funding contribution of $5 million over a 5-year period (or a total of $25 million).
  - Key complementary medicines industry players match the Commonwealth funding as an annual co-contribution of $7 million over the same period (or a total of $35 million).

It is assumed the abovementioned Commonwealth and industry funding is targeted at solutions under the two key themes of research and innovation and manufacturing. The proposed actions for government associated with the remaining themes of raw ingredients/supply chin, workforce, trade and regulation are cost neutral and no new funding has been allocated against them.

This analysis represents a high-level benefits estimation to reflect the uplift potential in comparison to the current growth trajectory (business as usual) as presented in the section on the CURRENT STATE ASSESSMENT. It is important to highlight that the underlying approach does not constitute a detailed impact assessment directly driven by specific business activities, but it captures the indicative potential benefit pathways from a whole-of industry level.

KEY PARAMETERS AND ASSUMPTIONS

The key parameters and assumptions for this economic benefits assessment are outlined in Table 7.

BENEFITS ASSESSMENT APPROACH

Due to the foundational nature of solutions within the business case, the benefits associated with the identified solutions have been quantified (where possible) at a **Theme Level** as opposed to at a solution level. As such, this economic analysis has only focused on the key quantifiable themes as opposed to the options presented in Section 5. This approach has been undertaken to provide an overview of indicative benefits at a high level, noting the variety of potential implementation pathways for the solutions focussed on different themes within the Australian complementary medicine manufacturing industry. The six themes which have been quantitatively assessed are illustrated below. It should be noted that the assumed funding (from Government and industry) will be distributed to sectors which are most likely to provide catalytic industry growth such as research and innovation, workforce, manufacturing and trade (export promotion).

RESEARCH AND INNOVATION

RAW INGREDIENTS

WORKFORCE

MANUFACTURING

TRADE

REGULATION

Section 4 on the CASE FOR CHANGE provides a detailed overview of the six identified themes.

Table 6 Key parameters and assumptions

ITEM	ASSUMPTION	SOURCE
Community of interest	Australia	Base assumption
Base date for PV	2023 (calendar year)	Base assumption
Consumer Price Index (CPI)	2.5 per cent per annum	In line with Commonwealth Government's target for long-term inflation.
Period of analysis	10 years from year of project decision (2023). Due to the nature of the project, a time horizon of 10 years is necessary to allow the complementary medicines industry to implement the solutions and realise benefits. For example, some proposed solutions will only see benefits realised after 5 years of the investment decision.	Core assumption.
Base case projections	Projected growth for the Australian complementary medicine industry (20-year forecast horizon).	Euromonitor, Ibis World and industry consultation
Forecast project growth	Projected Australian complementary medicine industry growth as a result of implementing the identified project solutions.	Literature review, desktop research, and industry consultation. Growth assumptions benchmarked against global case studies relating to public spending on manufacturing initiatives and R&D funding.
Corporate profit margins	Annual profit margins resulting economic activities relating to the complementary medicine industry.	Ibis World/Euromonitor.
Timing of benefit realisation	The year in which benefits associated with the identified solutions are anticipated to commence. **Theme 1 Research & Innovation:** 2027 **Theme 2 Raw Ingredients:** 2025 **Theme 3 Workforce:** 2024 **Theme 4 Manufacturing:** 2025 **Theme 5 Trade:** 2024 **Theme 6 Regulation:** 2025	Industry consultation. Literature review, case studies, previous experience and desktop analysis.
Funding allocation (Per year over 5 years)	**Total assumed annual funding from Government:** $5 million **Total assumed annual funding from industry:** $7 million **Research & Innovation:** $4 million (government) and $5.6 million (industry co-contribution) **Manufacturing and supply chain:** $1 million (government) and $1.4 (industry co-contribution) **Workforce:** zero **Trade (export promotion) and regulation:** zero	Based on an assumed: Total Government funding of $25 million distributed over 5 years; and Total industry funding of $35 million distributed over 5 years.
Australian CM exports market share (in comparison to global CM industry market)	**Current Australian export global market share (2023):** 0.3% **Target market share in Year 10:** 1.2%	The target market share of 1.2% in Year 10 is presented as a conservative potential growth path for the Australian complementary medicines industry.
Value of global CM industry market	**Global complementary medicines market value (2023):** AUD$350.7 billion **Forecast growth rate:** 5.1% (2022-2027)	Various Euromonitor Consumer Health Industry Reports for individual countries (2022)

POTENTIAL BENEFITS CONTINUED

ITEM	ASSUMPTION	SOURCE
Proxies for Return on grant/funding investment	**Initial Project Fund:** funding to industry-led projects to improve companies' productivity, competitiveness and innovative capacity: **$21.6 for every $1** in funding from government and industry. **Early-Stage Research Fund:** funding to support small-scale and pilot research projects to benefit firms and early-stage research, allowing the projects to then move quickly to larger-scale research or commercialisation. **$19.8 for every $1** in funding from government and industry. **Advanced Manufacturing Ecosystem Fund:** funding to support am advanced manufacturing ecosystem. The fund aims to grow advanced manufacturing capabilities and increase investment in and output of advanced manufacturing activity. **$18.2 for every $1** in funding from government and industry.	Sourced from desktop research and returns on returns on funding investment related to the **Advanced Manufacturing Growth Centre** (refer Appendix 6 for more details).

BENEFIT ANALYSIS

This analysis has also incorporated a range of other assumptions and logic which have supported the projected Australia complementary medicine manufacturing industry growth. These include:

- **Australian industry market share and growth projections** have been estimated for the Australian domestic industry and the export markets for the complementary medicines industry. These forecasts have been estimated based on the following assumptions and market characteristics:
  - The Australian complementary medicines industry faces a range of international market opportunities ripe for unlocking. This industry currently presents a very low global market share and presents a range of growth opportunities particularly in markets such as China and future target markets including India and Indonesia.

    It has been estimated that Australian exports represented only 0.3% of the global market value (in 2023). Highlighting this, while an estimated 66% of Australian exports are destined for China, the total value of these exports equates to only 0.9% of the Chinese complementary medicines market.
  - Due to the early stage and high-level nature of this strategic assessment, this analysis is based on a core scenario in which the solutions, initiatives and options identified in Sections 4 and 5 unlock a range of global growth and investment attraction opportunities.

    As a result of investments in research and innovation (and manufacturing), workforce initiatives and the promotion of Australian exports, this industry growth scenario proposes that the Australia's complementary medicines exports increase from 0.3% of total global value to 1.2% in Year 10.

    The abovementioned industry growth scenario is formed around indicative revenue targets attainable from growing Australia's global market share. This will only be achievable with critical government support in the form of funding and grants particularly in areas such as research and innovation, manufacturing and export promotion, please a variety of external factors included but not limited to the continued increased demand for Australian manufactured complementary medicines in key markets such as China, India, Indonesia and broader South East Asian markets.
- **Grant funding** – As noted previously, to unlock Australia's global potential in the complementary medicines markets, NICM is seeking Government support of $5 million per annum over 5 years (totalling $25 million). It is intended for this funding value to be matched by industry, commitments from WSU and philanthropic donations to the value of $35 million over the same five-year period.

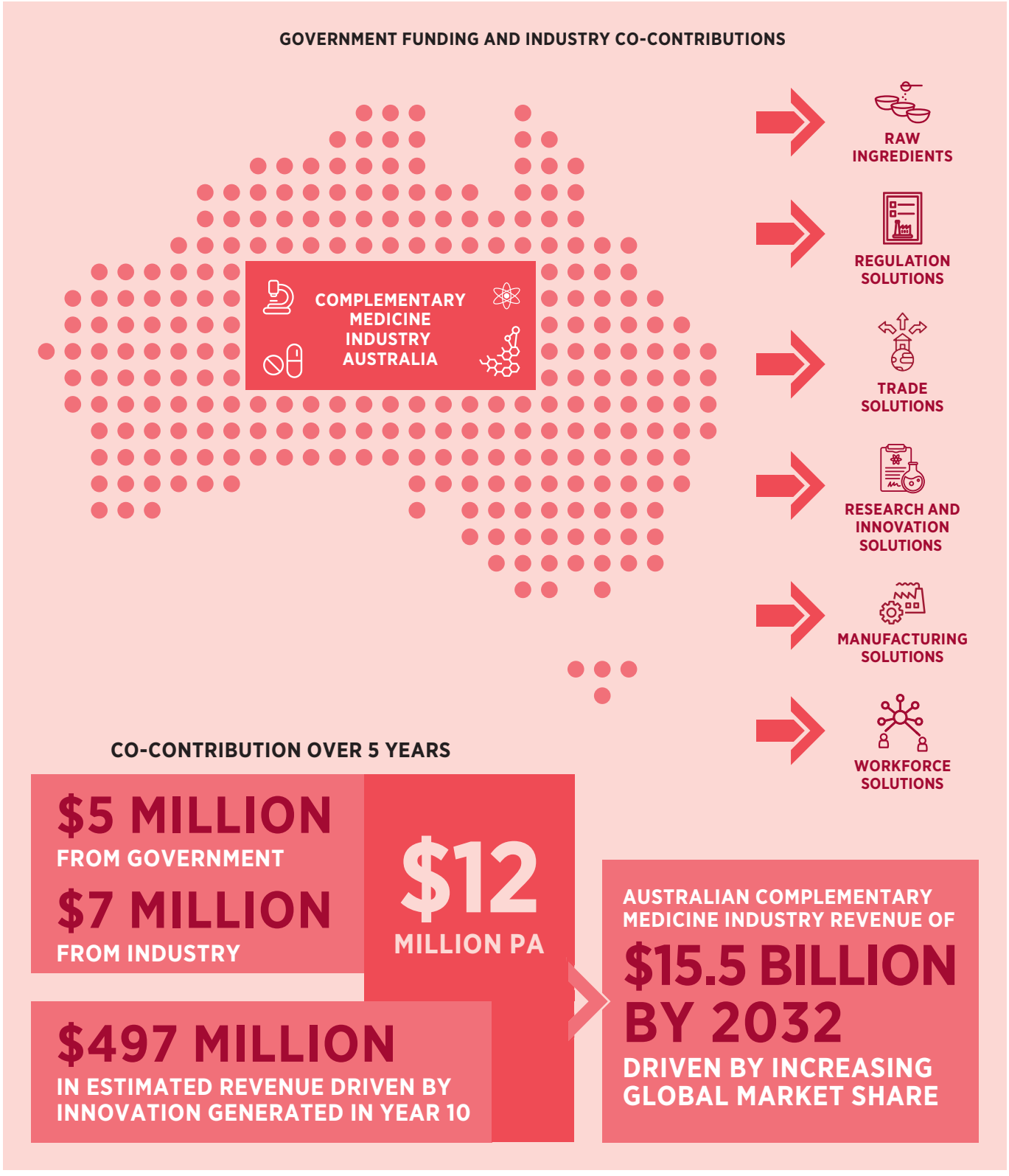
  The return on investment from Government funding and industry co-contributions has been supported by appropriate case studies which reflect whole-of-industry initiatives, investment in research & innovation, investment in manufacturing eco-systems, etc.

  In particular, this analysis has focused on the Advanced Manufacturing Growth Centre (AMGC) which was established in 2015 as a key element of the Australian Government's Industry Growth Centre initiative. Its key goal is to drive innovation, productivity and competitiveness across Australia's manufacturing industry. While the AMGC is not strictly focused on the health industry, the initiative has strong alignments to NICM's vision for the complementary medicines industry.

  An overview of AMGC and returns on funding received across a range of programs are presented in Appendix 6.

  Based on research on returns on investment in manufacturing, research and innovation and supporting case studies, the returns on Government funding of $5 million per year over 5 years and an evenly matched co-contribution from industry are presented in Figure 7.

Figure 8 *Return on Government and industry funding and grants*



POTENTIAL BENEFITS CONTINUED

BASE CASE

The definition of the base case is important for the economic appraisal as it represents a comparator against which the economic impacts (benefits) of the proposed solution will be assessed. The increment between the base case and the identified solutions represents the net benefit of the solutions on the Australian community.

The base case is a continuation of the current state of the industry. In other words, no dedicated funding allocated to the identified solutions.

LIMITATIONS

It is important to note the quantitative assessment of the potential benefits undertaken in this report has been based on a high-level economic benefit analysis approach. As such, the net outcomes presented in this report are illustrative only and show a potential pathway for the Australian complementary medicines industry.

Due to the scope of the initiates and the limitations of data relating to some of the identified benefits, only those benefits judged as being the most readily quantifiable have been included for quantification in this economic assessment. In addition, the identified solutions and initiatives presented in the CASE FOR CHANGE are preliminary in nature and associated costings for these have not yet been developed. Due to these limitations, benefits and costs will need to be investigated in further granular detail in the later phases of the Business Case process.

BENEFITS

The solutions and initiatives presented in the CASE FOR CHANGE will provide a number of benefits to a wide range of stakeholders, including corporations, educational institutions, peak industry bodies (i.e., CMA and TGA) and the broader population of Australia. The benefits aligned with the quantified themes are outlined in Table 7.

Therefore, it should be noted that the associated monetary values in this assessment do not provide a complete estimate of the benefits of the project solutions, and this Strategic Business Case should be evaluated with consideration given to the qualitative benefits discussed in the CASE FOR CHANGE. The quantitative complementary medicine industry market benefits present a snapshot (point-in-time estimate) of total domestic sales and export revenues.

It is likely that any future solution will require a partial/full combination of the six themes to catalyse industry attraction and growth.

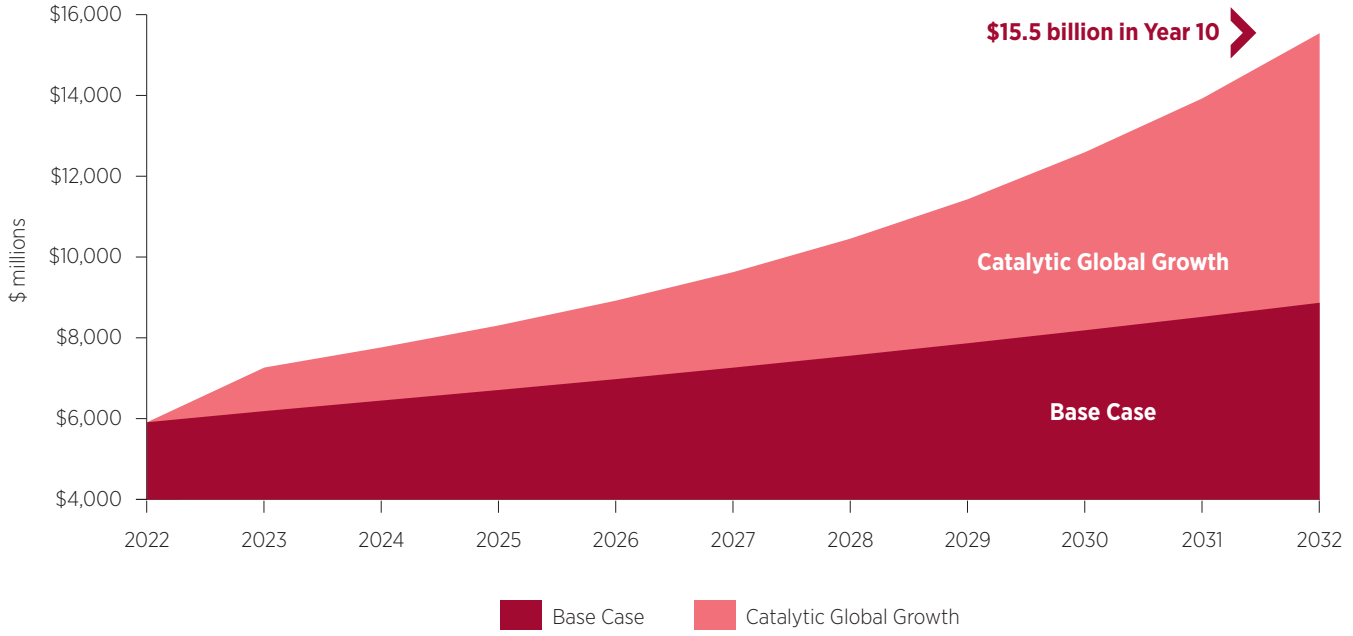
Table 7 Market related benefits (measured in revenue)

ITEM	ASSUMPTION
QUANTITATIVE MARKET BENEFITS (MEASURED IN REVENUE)	
ITEM	**DESCRIPTION**
Increase to CM industry exports	The direct impacts to the market value of Australian complementary medicine industry exports have been quantified. This benefit measures the incremental export sales (or revenue) as a result of the proposed solutions when compared to the base case (or business as usual).
Increase to CM industry domestic market sales	This benefit measures the incremental value of the Australian complementary medicines market value when compared to the base case (or business as usual).

HIGH LEVEL ECONOMIC BENEFITS ASSESSMENT

The high-level benefits assessment results are presented in Figure 8. As noted previously, the additional growth (incremental to the base case) is driven by a range of factors beyond the immediate funding proposed as part of this business case which include: (1) Government and industry funding support); (2) an emerging global market for complementary medicines products (including China, India, Indonesia and the broader Southeast Asian region); (3) catalytic growth stemming from investment in research & innovation; and (4) Australian exports global market share increasing from 0.3% to 1.2% by Year 10. It is worth highlighting the results presented below are high-level and represent the growth potential for the complementary medicines industry.

Figure 9 Australian complementary medicine industry revenue potential



This economic analysis should be considered preliminary in nature as the identified solutions and themes are still at a strategic level. The analysis undertaken in this section has been supported by a literature review of a range of investment initiatives in the manufacturing, trade and research and innovation in Australia and estimated returns of government investment in manufacturing, research and development, and similar initiatives (refer Appendix 6). The findings in this analysis reflects a range of limited strategic level inputs. As such, the following items should be considered should this project and the shortlisted options proceed to the next stage in the business case cycle. Future initiatives include, albeit not limited to:

- → Developing a detailed description and undertaking a refinement of the scope of works for each shortlisted solution.
- → Developing detailed costings related to the implementation of options and solutions.
- → Conducting further 'deep-dive' consultations with key industry players (including industry peak bodies) to assist in developing a robust understanding of identified project impacts.
- → A series of activities are planned to improve the assessment approach, refine the costs and benefits, and improve value for money during the Final Business Case phase.

PROPOSED ACTIONS

PROPOSED ACTIONS AND RECOMMENDATIONS

As per the findings outlined in the base case assessment and case for change sections of this business case, cross-industry collaborative effort is required to overcome the current challenges. There is clear and visible consensus across the complementary medicines industry on the way forward and government support, alongside industry's commitment, is required to achieve industry growth objectives.

The industry has significant potential, with an estimated growth potential of $15.5 billion by 2032. Despite this potential, the risk of inaction is real and present. The complementary medicines industry has been an independent of government success story to date, growing from infancy to an approximately $6 billion industry annually.

Australia is one of the top exporters of complementary medicines to the region, including China – with limited government support in priority areas, competitive advantage will erode. The export market for complementary medicines is large and growing and Australia risks missing the opportunities at hand.

The industry employs thousands across the country across key skills categories including manufacturing. Without support to bolster workforce capability and capacity the industry will stagnate, and jobs will be lost, along with opportunity cost if new jobs fail to be created. Lessons have been learned in recent years throughout the Covid-19 pandemic regarding the importance of local manufacturing capability and securing supply chains, and the risk of these lessons going unlearned is real without focus and attention on known issues.

The following are priority recommendations to government, and key actions, to support the sustainable growth of the complementary medicines industry and broader ecosystem – through the creation of an environment where health innovation thrives and provides solutions to the industry's challenges. These recommendations should be progressed as a priority alongside industry's ongoing efforts to progress.

RECOMMENDATION 1: PRIORITISE SUPPORT AND FUNDING FOR R&D INCENTIVES FOR INDUSTRY TO BOOST ECONOMIC ACTIVITY AND ADDRESS SUPPLY CHAIN CHALLENGES

GOVERNMENT TO ESTABLISH A COMPLEMENTARY MEDICINES MANUFACTURING INDUSTRY RESEARCH AND DEVELOPMENT FUNDING INCENTIVE PROGRAM.

Investment in research and innovation yields substantial returns, driving progress and fostering economic prosperity. By allocating resources towards innovation, governments create an ecosystem that sparks new discoveries and breakthroughs, leading to transformative advancements. These investments not only generate intellectual property and valuable patents but also stimulate job creation, attract investment, and position countries at the forefront of technological advancement, ultimately driving long-term economic growth.

This is of particular relevance for the complementary medicines industry. Growing research and development in the complementary medicines industry is of the highest priority and provides the clearest immediate pathway to growth and innovation. Research and innovation, as set out in the case for change, has been historically underdeveloped due to a lack of incentives and complicated regulatory processes, driving risk-averse behaviour from industry and a lack of investment.

Research and innovation incentives can also play a part in addressing supply chain risks for raw ingredients. These risks to the complementary medicines industry materialised during the Covid-19 pandemic as the industry is heavily reliant on imports and has limited domestic supply available for key ingredients. Some industry-led efforts are underway to address this, however government can play a key role to support sovereign raw ingredient industries by encouraging partnerships between universities, research institutions, similar sectors (including agritech) to explore potential ways to unlock raw ingredient supply and foster new industries.

The establishment of a substantial funding incentive program by government, with appropriate co-investment and delivery commitments from industry and academia, will crucially support industry to overcome investment barriers such as costs, lead-time, supply chain challenges and global material prioritisation.

NICM's industry collaboration model is trusted and effective and could support the establishment of this funding incentive program, and could also serve as a model for other medical research institutes in the commercialisation of R&D.

KEY ACTIONS:

- → Government establishes a funding incentive and pathway for research and development in complementary medicines to the value of $4 million per year over a five-year period (solution R&I1).
- → Government seeks and industry commits to a 'co-investment approach' for any funding grants – with industry providing a minimum of matching investment.
- → Government to fund and support specific initiatives in addition to the funding and incentive pathway to bolster raw ingredient supply chain and foster innovation and exploration of new production channels (solutions RI1 and RI2).

PROPOSED ACTIONS AND RECOMMENDATIONS CONTINUED

RECOMMENDATION 2: PROVIDE TARGETED SUPPORT FOR WORKFORCE INITIATIVES

GOVERNMENT TO PROVIDE SUPPORT TO COMPLEMENTARY MEDICINES INDUSTRY WORKFORCE GROWTH EFFORTS BY SUPPORTING WORKFORCE CAPABILITY BUILD AND FUNDING SKILLS INITIATIVES.

Government support for the complementary medicines industry workforce will be a vital driver of industry growth in Australia. By investing in education and training initiatives, the government can support the nurturing of a skilled workforce capable of developing innovative products and manufacturing excellence. In recognising the industry's potential significance, government can play a pivotal role in unlocking its workforce potential. By fostering an environment that empowers professionals and promotes excellence, the government can pave the way for unparalleled growth and prosperity in the complementary medicines.

To continue to develop as an industry a professional training and development system must be established to support the entire complementary medicines industry with relevant and in-demand skills across the end-to-end value chain. Domestic manufacturing capacity and capability relies on an appropriately skilled, complementary medicines manufacturing workforce.

Support for the complementary medicines industry workforce aligns seamlessly with broader manufacturing priorities at both the federal and state levels in Australia. In support the bolstering of this industry, governments can strengthen local manufacturing capabilities and contribute to economic diversification. Furthermore, investing in a skilled and innovative workforce within the complementary medicines industry aligns with Australia's focus on advancing high-value, knowledge-intensive industries that drive long-term sustainable growth. This strategic alignment positions Australia as a global leader in both manufacturing excellence and the development of leading, cutting-edge complementary medicines.

KEY ACTIONS:

- → Government to fund the development of a complementary medicines workforce report that will map and model the current and future workforce and skills needs across industry (solution WF1)
- → Government to fund the establishment and design of micro-credentials for complementary medicine manufacturing skills and qualifications across all industry levels, considering links to advanced manufacturing and pharmaceuticals industry (solution WF2).
- → Government to support the establishment of formal partnerships between industry and education sector to implement micro-credentialling through training providers to address critical skills shortages (solution WF3).

RECOMMENDATION 3: DELIVER FUNDING SUPPORT FOR COMPLEMENTARY MEDICINES INDUSTRY THROUGH MANUFACTURING UPLIFT AND TRADE PROMOTION

FUND AND SUPPORT MANUFACTURING AND TRADE INITIATIVES TO PROPEL THE COMPLEMENTARY MEDICINES INDUSTRY TOWARDS MANUFACTURING EXCELLENCE AND TRADE EXPANSION.

The complementary medicines industry in Australia has demonstrated tremendous potential for growth and export opportunities. To harness this potential fully, we recommend the government's support to fund and support a suite of priority initiatives in manufacturing, trade and raw ingredients focus areas, alongside advances made in the research and innovation, workforce and regulatory areas. By strategically investing in these areas, Australia can solidify its position as a global leader in complementary medicines.

Manufacturing growth is a key priority of federal and state governments through various strategies and policy statements. The complementary medicines industry is a largely home-grown and mostly self-sustained manufacturing industry which is seeking support to grow sovereign capability and compete more effectively in the region and globally. Support for complementary medicines manufacturing through direct funding, grants, expansion of eligibility of existing programs and other initiatives is fully aligned with government's stated priorities in manufacturing and has numerous flow-on benefits for communities, regions. Individuals and related industry.

The Australian complementary medicines industry trades on a strong brand courtesy of a stringent and well-respected regulatory approach. Expanding the industry's global reach is a crucial component of broader growth, through access to new and nascent markets, export facilitation, participation in delegations and showcasing Australian-made products in new and innovative ways. The government could potentially provide targeted financial support and market intelligence to assist businesses navigating complex regulatory environments in key markets.

KEY ACTIONS:

- → Government to co-fund strengthening of manufacturing capability across complementary medicines industry through direct grants, totalling $1 million per year over five years, leveraging existing programs (solution M1), addressing unfair manufacturing competition (solution M2), and development of an investment roadmap to better market the attractiveness of the industry for foreign investment (solution M3).
- → Government to support initiatives that facilitate international trade and market access for Australian complementary medicines products through trade promotion (solutions T1 and T2).

RECOMMENDATION 4: OPTIMISE THE REGULATORY APPROACH TO COMPLEMENTARY MEDICINES

OPTIMISE THE REGULATORY APPROACH TO COMPLEMENTARY MEDICINES IN AUSTRALIA THROUGH IMPROVED REGULATORY CAPABILITY AND FOCUS.

The regulatory framework for complementary medicines in Australia is a significant strength of the industry due to rigorous quality and safety standards. These stringent regulations instil consumer confidence and ensure that only safe and effective products reach the market. They also provide a significant boost for export potential and reputation of Australian products in the region and globally.

However, continuous improvement and small refinements to the regulatory processes can further reduce the burden on industry stakeholders, enhance efficiency, and streamline compliance, leading to cost savings and increased business activity. By maintaining a balance between rigorous standards and industry-friendly regulations, Australia can foster a thriving and globally competitive complementary medicines sector.

KEY ACTIONS:

- → Government acknowledge and seek to rectify current complementary medicines regulatory capability gaps within the TGA, through dialogue and conversation with industry. One approach to ensure appropriate skills would be to reinstate OCM (solution R1).
- → Government to support appropriate regulation of complementary medicines and provide direct funding to the TGA to cover work outside of the direct cost recovered framework (solution R2)
- → Government reviews data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence (solution R3).
- → Government to support regulatory-related reforms in the trade and raw ingredients space to streamline exports (solution T3), raw ingredient approvals (RI3), and other economically stimulating activities.
- → Review GMP licensing of overseas manufacturing facilities.

APPENDICES

APPENDICES

APPENDIX 1: KEY STAGES OF DEVELOPING A BUSINESS CASE

STAGES	STAGE 0: PROBLEM DEFINITION	STAGE 1: STRATEGIC BUSINESS CASE	STAGE 2: DETAILED BUSINESS CASE	UPDATE AND REVISIONS OF THE BUSINESS CASE
Purpose	Needs analysis and confirmation	Options analysis	Options selection	Updates and revision to the business case
Approach	→ Identify the need for government intervention and make case for change → Identify the problem, benefits, strategic response, costs, risks and stakeholders	→ Confirm the case for change → Identify and screen options that meet the intervention objectives based on a high-level analysis	→ Confirm way forward → Select the preferred option based on thorough analysis → Assess commercial and management aspects for the selected option	→ Updates and revision to the Detailed Business Case following funding decision or after procurement
Output	→ Progress with Strategic Business Case development → If necessary, seek funding approval for the next stage based on the output of this stage	→ Confirm way forward → Progress with Detailed Business Case Development → If necessary, seek funding approval for the next stage based on the output of this stage	→ Preferred option confirmed	→ Update elements of the Case for Change, Cost Benefit Analysis, Financial Appraisal, Financial Impact Statement, Commercial Analysis and Management Analysis

APPENDICES CONTINUED

APPENDIX 2: KEY STAKEHOLDERS CONSULTED DURING THE DEVELOPMENT OF THIS STRATEGIC BUSINESS CASE

#	DATE/TIME	PARTICIPANTS
1	23 March 23	→ **NICM** Dennis Chang – Director NICM Health Research Institute Alan Bensoussan – Program Lead → Joelle Metri – Program support
2	28 March 2023, 10:30am to 11:30am	→ **Vitex** Dr Aniss Chami, CEO
3	28 March 2023, 1:00pm to 2:00pm	→ **Complementary Medicine Australia** Emma Burchell, Director of Operations Lucy Lang, Regulatory Affairs → **Swisse** Nick Mann, CEO David Donnelli, Associate Director of Operations ANZ
4	29 March 2023, 1:00pm to 2:00pm	→ **Consumer Health Products Australia** Deon Schoombie, CEO
5	5 April 2023, 10:00am to 11:30am	→ **Metagenics** Michael Micallef, Global Head Regulatory Affairs → **Star Combo Pharma** Su Zhang, CEO → **TSI Pharmaceuticals** Lin Zheng, General Manager Contract Manufacturing Division → **PharmaCare** Tobey-Ann Pinder, Head of Regulatory Affairs → **Integria** Angelo Andronis, General Manager Technical
6	12 April 2023, 10:00am to 11:00am	→ **Blackmores** Alystair Symington, CEO John O'Doherty, Head of Public Affairs
7	12 April 2023, 11:00am to 12:30pm	→ **Bio Concepts** Michael Osiecki, Managing Director → **Healthcare Product Specialists** Simone Abaron, CEO → **Advanced Wellness Regulatory Solutions** Rachael Keenan, Director → **Allure Wellness Consulting** Rachel Di Leva, Director
		→ **NICM**
8	26 April 2023 4:30pm to 5:15pm	→ **Lipa Pharmaceutical** Gulhan Demirci – Chief Innovation Officer
9	28 April 2023 10:00am to 11:00am	→ **Sanofi** Gladys Peters – General Manager
10	9 May 2023 11:00 am to 12:00 pm	→ **Complementary Medicine Australia** Emma Burchell, Director of Operations → **Swisse** David Donnelli, Associate Director of Operations ANZ → **Blackmores** John O'Doherty, Head of Public Affairs
11	26 May 2023 2:30 pm to 3:00 pm	→ **Swisse** David Donnelli, Associate Director of Operations ANZ
12	30 May 2023 4:30 pm to 5:00 pm	→ **Complementary Medicine Australia** Emma Burchell, Director of Operations

APPENDIX 3: STAKEHOLDERS – CASE FOR CHANGE

STAKEHOLDERS

A summary of the key stakeholders/stakeholder groups who will be impacted and/or have an interest in the options are summarised below.

STAKEHOLDER/ STAKEHOLDER GROUP	INTEREST, INFLUENCE OR IMPACT	KEY RISKS AND CONSIDERATIONS	LEVEL OF ENGAGEMENT
NICM Health Research Institute formerly National Institute of Complementary Medicine (NICM)	→ Subject of the service need → Responsibility for presenting the options to industry and driving desired industry outcomes	Critical stakeholders to co-create value and own industry outcomes	Strong engagement and consultation (for leadership team) Inform and engage (across the organisation)
Complementary Medicines Australia (CMA)	→ Subject of the service need → Responsibility for working with NICM to drive desired industry outcomes	Potentially responsible for other projects or initiatives that may provide improved outcomes from effective integration/ synchronisation	Strong engagement and consultation
Consumers	→ Ultimate beneficiaries of improved complementary medicine industry → Consideration of value for money with taxpayer funds	No actions to be taken at present	Monitor and respond
Workforce	→ Ultimate beneficiaries of improved complementary medicine industry	No actions to be taken at present	Monitor and respond
Manufacturers	→ Subject of the service need	Critical stakeholders to co-create value and own industry outcomes	Strong engagement and consultation
Suppliers	→ Subject of the service need	Critical stakeholders to co-create value and own industry outcomes	Strong engagement and consultation
Retailers	→ Subject of the service need	Critical stakeholders to co-create value and own industry outcomes	Strong engagement and consultation
Academia/ Research Companies	→ Subject of the service need	Critical stakeholders to co-create value and own industry outcomes	Strong engagement and consultation
Industry Consultants	→ Independent expert advice on current challenges and opportunities for the complementary medicine industry	Critical stakeholders to co-create value	Strong engagement and consultation
Health Insurers	→ Subject of the service need	Level of engagement is dependent on the impacts of proposed solutions on insurance sector	Inform and engage
Health practitioners	→ Provide guidance and advice to consumers regarding the purchase and use of complementary medicines	Impacts on approach for awareness and uptake of complementary medicine	Inform and engage
Therapeutic Goods Australia	→ Subject of the service need → Regulate the complementary medicine industry, ensuring that medicines are safe, effective, and of high quality	Impacts on approach for current regulation of industry	Strong engagement and consultation

APPENDICES CONTINUED

STAKEHOLDER/ STAKEHOLDER GROUP	INTEREST, INFLUENCE OR IMPACT	KEY RISKS AND CONSIDERATIONS	LEVEL OF ENGAGEMENT
NSW Treasury/ NSW Govt Treasurer	→ Responsible for providing economic and financial advice and potential funding guidance	Level of engagement to be determined by pending decision on options' scope and funding sources.	Monitor and respond
NSW Govt Ministers[96]	→ Portfolio Minister	There is a risk that the Minister's expectations/ambitions do not align with industries. A lack of support at a Ministerial level could prevent the recommendations presented in this SBC from being progressed to a Detailed Business Case.	Maintain confidence
Commonwealth Treasury/ Commonwealth Govt Treasurer	→ Responsible for providing economic and financial advice and potential funding guidance	Level of engagement to be determined by pending decision on options' scope and funding sources.	Monitor and respond
Commonwealth Government Ministers[97]	→ Portfolio Minister	Level of engagement to be determined by pending decision on options' scope and funding sources.	Monitor and respond

96 Relevant New South Wales Government Ministers may include the Minister for Jobs and Tourism, Minister for Agriculture; Regional and Western NSW, Minister for Industry and Trade; Innovation, Science and Technology; Minister for Medical Research

97 Relevant Commonwealth Government Ministers may include the Minister for Health and Aged Care, Minister for Skills and Training, Minister for Industry and Science

APPENDIX 4:
FUTURE STAKEHOLDER ENGAGEMENT PLAN

STAKEHOLDER/ STAKEHOLDER GROUPS	INTEREST, INFLUENCE OR IMPACT	KEY RISKS AND CONSIDERATIONS	LEVEL OF INTEREST	LEVEL OF INFLUENCE	LEVEL OF ENGAGEMENT	RISK OF NOT ENGAGING	STAKEHOLDER NEEDS AND EXPECTATIONS
NICM Health Research Institute formerly the National Institute of Complementary Medicine (NICM)	→ Subject of the service need → Responsibility for presenting the options to industry and driving desired industry outcomes	→ Critical stakeholders to co-create value and own industry outcomes	High	High	Strong engagement and consultation (for leadership team)	TBC	TBC
Complementary Medicines Australia (CMA)	→ Subject of the service need → Responsibility for working with NICM to drive desired industry outcomes	→ Potentially responsible for other projects or initiatives that may provide improved outcomes from effective integration/ synchronisation	High	High	Strong engagement and consultation	TBC	TBC
Consumers	→ Ultimate beneficiaries of improved complementary medicine industry → Consideration of value for money with taxpayer funds	→ No actions to be taken at present	Low	Low	Monitor and respond	TBC	TBC
Workforce	→ Ultimate beneficiaries of improved complementary medicine industry	→ No actions to be taken at present	Low	Low	Monitor and respond	TBC	TBC
Manufacturers	→ Subject of the service need	→ Critical stakeholders to co-create value and own industry outcomes	High	High	Strong engagement and consultation	TBC	TBC
Suppliers	→ Subject of the service need	→ Critical stakeholders to co-create value and own industry outcomes	High	High	Strong engagement and consultation	TBC	TBC
Retailers	→ Subject of the service need	→ Critical stakeholders to co-create value and own industry outcomes	High	High	Strong engagement and consultation	TBC	TBC

APPENDICES CONTINUED

STAKEHOLDER/ STAKEHOLDER GROUPS	INTEREST, INFLUENCE OR IMPACT	KEY RISKS AND CONSIDERATIONS	LEVEL OF INTEREST	LEVEL OF INFLUENCE	LEVEL OF ENGAGEMENT	RISK OF NOT ENGAGING	STAKEHOLDER NEEDS AND EXPECTATIONS
Academia/ Research Companies	→ Subject of the service need	→ Critical stakeholders to co-create value and own industry outcomes	High	High	Strong engagement and consultation	TBC	TBC
Industry Consultants	→ Independent expert advice on current challenges and opportunities for the complementary medicine industry	→ Critical stakeholders to co-create value	High	High	Strong engagement and consultation	TBC	TBC
Health Practitioners	→ Provide guidance and advice to consumers regarding the purchase and use of complementary medicines	→ Impacts on approach for awareness and uptake of complementary medicine	Low	High	Inform and engage	TBC	TBC
Therapeutic Goods Australia	→ Subject of the service need → Regulate the complementary medicine industry, ensuring that medicines are safe, effective, and of high quality	→ Impacts on approach for current regulation of industry	High	High	Strong engagement and consultation	TBC	TBC
NSW Treasury/ NSW Govt Treasurer	→ Responsible for providing economic and financial advice and potential funding guidance	→ Level of engagement to be determined by pending decision on options' scope and funding sources.	Low	Low	Monitor and respond	TBC	TBC

STAKEHOLDER/ STAKEHOLDER GROUPS	INTEREST, INFLUENCE OR IMPACT	KEY RISKS AND CONSIDERATIONS	LEVEL OF INTEREST	LEVEL OF INFLUENCE	LEVEL OF ENGAGEMENT	RISK OF NOT ENGAGING	STAKEHOLDER NEEDS AND EXPECTATIONS
NSW Govt Ministers[98]	→ Portfolio Minister	→ There is a risk that the Minister's expectations/ ambitions do not align with industries. A lack of support at a Ministerial level could prevent the Recommendations presented in this SBC from being progressed to a Detailed Business Case.	Low	High	Maintain confidence	TBC	TBC
Commonwealth Treasury/ Commonwealth Govt Treasurer	→ Responsible for providing economic and financial advice and potential funding guidance	→ Level of engagement to be determined by pending decision on options' scope and funding sources.	Low	Low	Monitor and respond	TBC	TBC
Commonwealth Government Ministers[99]	→ Portfolio Minister	→ Level of engagement to be determined by pending decision on options' scope and funding sources.	Low	Low	Monitor and respond	TBC	TBC

98 Relevant New South Wales Government Ministers may include the Minister for Jobs and Tourism, Minister for Agriculture; Regional and Western NSW, Minister for Industry and Trade; Innovation, Science and Technology; Minister for Medical Research

99 Relevant Commonwealth Government Ministers may include the Minister for Health and Aged Care, Minister for Skills and Training, Minister for Industry and Science

APPENDICES CONTINUED

APPENDIX 6: ECONOMIC ANALYSIS – RETURN ON INVESTMENT GROWTH BENCHMARKS

A desktop and literature analysis were undertaken to investigate the estimated returns of government investment in manufacturing initiatives, research, and development, grant funding, etc. This includes the distribution of these returns as spill overs or direct returns to the industry investment. Industry consultation with key industry players also provided input into growth projections for the Australian complementary medicine industry over the forecast horizon. These estimates informed the development of the assumptions on the treating of industry support within the economic model.

Description	Return	Source
Quantifying Australia's return to Innovation	The most conservative estimates in CSIROS's report resulted in every $1 of research and development investment creating an average of $3.5 (2020-dollar terms) in economy-wide benefits for Australia in today's dollars, and a 10% average annual return	CSIRO
Advanced Manufacturing Growth Centre analysed the revenue return from 78 co-funded projects	Effect on revenue: A combined industry and government co-funding pool of $66.8m with a forecast of $1.2b additional revenue and 2,361 new jobs from 78 projects. The first 10 initiatives yielded a total of 136 new or upskilled roles. An additional $56.5 million in revenue was injected into the Australian economy. The revenue creation represents an averaged return on investment of 6:1, based on a co-funding investment of $8.05 million ($2.3 derived from Federal funding and the remainder industry).	CDC Group[100]
The Quantitative Effects of Trade Policy on Industrial and Labor Location – United States	Increased in support to trade initiatives (including an 8% increase in trade tariffs) resulted in a positive effect on manufacturing firms' entry and manufacturing employment. This resulted in 1.8% percent increase in the number of manufacturing firms in the United States, and a 0.06% increase in the manufacturing sector employment	Yale University, NBER, and Penn State University[101]
Stimulating the Science and Research Ecosystem Creates Jobs and Investment ()	$470m investment in research related projects resulted in estimated additional Gross State Product of between $1.1-$1.7b (between 2000 – 2008), 6,200 to 7,200 new FTE jobs between 2000 and 2014 and an increase of 1,750 additional export contracts valued at $173 million in 2020-dollar terms. Key outcome: $1 dollar investment resulted in between $2.34 to $3.62	Australian Council of Learned Academies, 2020

100 Available at: https://www.amgc.org.au/media-releases/australian-manufacturing-wins-as-amgc-forecasts-billion-dollar-return/. Last viewed on 25 May 2023.

101 Available at: https://spinup-000d1a-wp-offload-media.s3.amazonaws.com/faculty/wp-content/uploads/sites/40/2019/11/QETPILL.pdf. Last viewed on 25 May 2023.

CASE STUDY

ADVANCED MANUFACTURING GROWTH CENTRE (AMGC) (NSW, AUSTRALIA)

DESCRIPTION

AMGC is an industry-led, not-for-profit organisation established in 2015 as a key plank of the Australian Government' Industry Growth Centre Initiative. Its goal is to drive innovation, productivity and competitiveness across Australia's manufacturing industry.

AMGC operates to:

- → Deliver respected in-depth research to demonstrate how a company can take concrete steps to mitigate market volatility and become an advanced manufacturer;
- → Based on this research, engage in projects that illustrate best practices to accelerate manufacturing in Australia;
- → Present key learnings from projects to industry through face-to-face events and the newly launched digital Manufacturing Academy, paving the way for other companies and research institutions to model these practices.

FUNDING RETURNS

- → $137.2 million committed funding (AMGC, industry and in kind)
- → $1.62 billion in estimated revenue generated
- → For every $1 dollar of funding $11.8 of revenue is generated

Funding initiatives:

- → **Initial Project Fund:** The AMGC Initial Project Fund will provide co funding for industry-led projects to improve the companies productivity, competitiveness and innovative capacity. $51m funding = $1.1 billion revenue.
- → **Advanced Manufacturing Early Stage Research Fund:** supports small-scale and pilot research projects to benefit smaller firms and early stage research, allowing the projects to then move quickly to larger-scale research or commercialisation. $16.1m in funding = $319.5m.
- → **Commercialisation Fund** grants to Australian companies to commercialise new products and processes based upon already existing or new IP Investment in Australian manufacturing projects aim to transition a new product or process from the pilot/prototype stage to full commercial operations. $69.1m in funding = $195.8 million in revenue.
- → **Advanced Manufacturing Ecosystem Fund** seeks to build the advanced manufacturing ecosystem in the Northern Territory. The fund aims to grow advanced manufacturing capabilities and increase investment in and output of advanced manufacturing activity in the Northern Territory, and grow the number of advanced manufacturing jobs located in the Northern Territory. $220,000 in funding = $4m in revenue.

APPENDICES CONTINUED

APPENDIX 7: EXTENDED LIST OF POTENTIAL PERFORMANCE TRACKING

THEME	BENEFITS	HOW CAN SUCCESS BE MEASURED
Research & innovation	Increase business activity driven by investment and innovation	→ Revenue of Australian complementary medicines industry → Investment of Australian complementary medicines industry → Number of globally recognised efficacy studies → Public sentiment on the credibility of claims made by the complementary medicines
	Increase revenue driven by increasing attractiveness of Australian products (including existing and new product development)	→ Number of complementary medicines registered in the ARTG
	Enhance protection of investment in innovation and Intellectual Property (IP) of complementary industry	→ Number of IP approvals
Raw ingredients	Develop Australian domestic supply chain capability, contributing to overall uplift in economic output	→ Investment in domestics supply chain (e.g., manufacturing of raw materials)
	Increase the use of Australian indigenous ingredients, contributing to overall uplift in the Australian sovereign capability	→ Economic output (e.g., revenue) of Australian indigenous ingredients products relevant for the complementary medicines industry
	Promote the development of Australia's First Nations agricultural industry	→ Number of business establishment in the First Nations community relevant for the complementary medicines industry
Workforce	Develop standardised training addressing specific skills shortages	→ Number of qualified personnel (production related) with recognised skills and/or micro-credentials available for Australian the CM manufacturing industry → Number of students enrolled in relevant skills training programs and micro-credentials (production related) offered by Australian academic institutions in partnership with industry → Number of qualified personnel (with non-production related skillset such as regulatory affairs, R&D) with globally recognised qualifications for the CM industry in Australia
	Increase employment opportunities, research activities and output	→ Number of jobs across Australian complementary medicines industry
Manufacturing	Increase business activity in the complementary medicines industry, contributing to the wider manufacturing output of Australia	→ Production of Australian complementary medicines sector → Investment in Australian complementary medicines sector
Trade	Increase export activity driven by stronger Australian brand, increased competitiveness and streamlined approval process	→ Production of Australian complementary medicines sector → Profitability of Australian complementary medicines sector → Export activities of complementary medicines products
Regulation	Increased business activities by enhancing the competitiveness of Australian complementary medicines products	→ Production of Australian complementary medicines sector → Investment in the Australian complementary medicines sector
	Improve the speed-to-market for new complementary medicines products	→ Approval lead time (market research)
	Improve public awareness regarding the safety, innovation and strength of the Australian complementary medicine products	→ Expenditure to facilitate industry wide advocacy, communications, and information exchange → Public awareness on the sector, including regulatory updates, industry wide campaigns etc → Cross-sector collaboration activities

APPENDIX 8: POLICY ALIGNMENT

Several strategies and plans of the Commonwealth, New South Wales and Victorian Government align with responding to the current challenges identified in the Australian complementary medicine industry, key aligned strategy as outlined below.

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Therapeutic Goods Administration	The Therapeutic Goods Administration (TGA) is the therapeutic and medicine regulatory agency of the Australian Government. The TGA requires that CMs are listed on the Australian Register of Therapeutic Goods (ARTG) before they can be sold in Australia, as either listed CMs, assessed CMs, or registered CMs. The TGA regulates the provisions of CMs through the Complementary Medicines Branch.	✔				✔	✔

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Department of Health and Aged Care: National Medicines Policy (NMP) 2022	The NMP aims to ensure equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians; Medicines are used safely, optimally and judiciously, with a focus on informed choice and well-coordinated person-centred care; Support for a positive and sustainable policy environment to drive world-class innovation and research, including translational research, and the successful development of medicines and medicines-related services in Australia. Scope under the NMP context include complementary medicines.	✔			✔		

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
National Health and Medical Research Council	The National Health and Medical Research Council (NHMRC) provides funding for research in complementary medicine through its various grant schemes, including the Investigator Grants, Ideas Grants, and Partnership Projects. Since 2012, NHMRC has provided more than $28 million in funding for scientific research into complementary medicine. Currently, the NHMRC's Natural Therapies Working Committee is overseeing evaluations on the clinical efficacy of natural therapies that are currently excluded from private health insurance rebates.				✔		
Medical Research Future Fund	The Medical Research Future Fund (MRFF) is a long-term investment of $20 billion into supporting Australian health and medical research. MRFF strategies are distinct to those addressed by the NHMRC and are intended to complement other investments by state/territory governments and the private sector. Previous submissions to the MRFF have advocated for funding of research projects to facilitate informed policy decisions on the use of complementary medicines in preventative health.				✔		

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Australian Research Council	The Australian Research Council (ARC) is the primary non-medical research funding agency of the Australian Government. The ARC distributes over $800 million in funding each year and operates under a separate budget to the NHMRC. Relevant schemes to complementary medicines include the Discovery Program, which aims to improve fundamental research and expand the research capacity in Australia.				✔		
Department of Industry, Science, and Resources	The Department of Industry, Science and Resources is a federal government department. It is responsible for connecting industry, resources, and the scientific industry to consolidate the federal government's attempts to drive competitiveness, productivity, and economic growth. It was established in its current form in July 2022.				✔	✔	

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Department of Health and Aged Care	This Department of the Australian Government is concerned with achieving federal goals for primary health care and mental health, population and Indigenous health, and community participation in recreational activities that improve health and wellbeing. The NHMRC is a subsidiary of the Department of Health and Aged Care.				✔		
National Reconstruction Fund	The National Reconstruction Fund, introduced by the Albanese Labour government, provides a crucial financing vehicle to drive financial investment in projects that will broaden Australia's industrial base and diversify Australia's economy. The Fund will drive investment in key sectors including medical research and advancing medical manufacturing through the $1.5 billion Medical Manufacturing Plan.				✔	✔	
Cooperative Research Centres Program	The Cooperative Research Centres Program provides funding for medium to long-term industry-led research collaborations. There are currently no CM-related funded CRCs.				✔		

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
The Entrepreneurs' Programme	The Entrepreneurs' Programme provides business owners with expert advice and financial support through grants. Specifically, the Programme has an Innovation Connections service that provides funding for research as they may apply to the business. This may include businesses that develop or produce therapeutic, medical, or pharmaceutical products or devices, including CM.				✔		
Advanced Manufacturing Growth Centre	The Advanced Manufacturing Growth Centre (AMGC) is a key pillar of the federal Industry Growth Centre Initiative. The AMGC is an industry-led and not-for-profit organisation that aims to drive competitiveness, productivity, and innovation within Australia's manufacturing industry. Members include Complementary Medicines Group Pty Ltd and Ferngrove Pharmaceuticals Australia Pty Ltd, who manufacture high-quality Australian made CMs.					✔	
Agri-Business Expansion Initiative	The Agri-Business Expansion Initiative is part of a long-term strategy and commitment by the government to expand and diversify the export market for Australian agribusinesses.		✔				

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Austrade Corporate Plan 2022-2023 AND Priority Investment Sectors	The Austrade Corporate Plan aims to deliver quality trade and investment services to businesses and policy advice to the Australian Government. A priority of the Plan is to drive trade diversification in Australia. For instance, a key initiative of the Plan is to bolster the resilience of agribusiness exporters through a sustained surge of market entry and expansion support through the Agribusiness Expansion Initiative. Austrade has supported the complementary medicines industry in the form of trade promotion, access to regulatory assistance, and export market grants through the Export Market Development Grants scheme.		✔				✔
Boosting Business Innovation Program (NSW)	The Boosting Business Innovation Program aims to give small businesses access to research organisations to build strong local communities and stimulate economic growth across NSW. The Program is supported by an $18 million investment by NSW Government, and key collaborators include AgriTech and Western Sydney University.				✔		

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Regional Investment Attraction Fund (NSW)	The Regional Investment Activation Fund aims to facilitate new private sector investment to regional NSW and is supported by a $110 million investment from the NSW Government. Regional NSW is of interest due to their leadership in economic and export sectors including advanced manufacturing and medical technology.		✔		✔	✔	
Regional Job Creation Fund	The Regional Job Creation Fund supports existing businesses and job creation in regional NSW through a $240 million investment. This is relevant to the complementary medicines industry as regional NSW is the home of Australia's agribusiness industry and manufacturing sector.					✔	✔

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Future Economy Fund	The Future Economy Fund aims to drive productivity in emerging high-value industries including medical technology and is supported by a $703.4 million investment by the NSW Government. Specifically, $142 million of the total will be dedicated to funding research and development in advancing collaboration with universities. $219 million of this total will be dedicated to accelerating growth and investment in priority industry sectors such as medical technology.				✔		
NSW Future Industries Investment Program	This Program prioritises the productivity growth in emerging high-value technologies, including medical technology. The Program is supported by up to $30 million in grant funding. Medical and life sciences are key emerging industries identified under this framework.				✔		

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Research Attraction and Acceleration Program, Office of Chief Scientist	The NSW Government has allocated $10.2 million in funding to support innovation and investment in NSW's research and development capacity. The Physical Sciences Fund is an annual competitive technology development and commercialisation program supported by a $5 million investment through the Research Attraction and Acceleration Program. The purpose is to obtain significant economic, environmental, and social benefits by financially supporting physical sciences such as earth sciences. In the case of CM, funding may be used to support manufacturing costs or specialist equipment and infrastructure.					✔	✔
Investment NSW Corporate Strategy 2022-2023	This Strategy aims to create jobs, increase the research and develop expenditure to 2.4 per cent of GDP, and double exports. The Strategy identifies medical technology and life sciences as key target sectors that will be targeted.		ü	ü			

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Biomedical Translation Bridge	This initiative of the MRFF aims to invest in the translation of new therapies, technologies, and medical devices. Under the 10-year MRFF Investment Plan, the Biomedical Translation Bridge Initiative is now part of the Medical Research Commercialisation Initiative.				✔		
Accelerating R&D in NSW Action Plan and 20-Year R&D Roadmap	The Accelerating R&D in NSW Action Plan was founded based on the principle that investment should be better focused and coordinated to accelerate the translation of research into crucial products and services. Priority areas relevant to complementary medicines include launching a Small Business Innovation Research Program; turbocharging precincts to attract national and global technology industries and drive collaboration with universities; targeting strategic support for NSW universities; and establishing a matchmaking program to connect sellers and buyers.				✔	✔	

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Made in Victoria 2030 (VIC, 2022)	Made in Victoria 2030: Manufacturing Statement sets out the Victorian Government's priorities for enhancing sovereign advanced manufacturing, attracting and stimulating investment, increasing productivity, and creating new jobs for Victoria.			✔	✔	✔	
Yuma Yirramaboi: Victorian Aboriginal Employment and Economic Strategy (VIC, 2022)	The Strategy recognises the capabilities and assets of Aboriginal Victorians, harnesses the strength of the Victorian Government as a purchaser, service provider and investor. The government is taking a significant step towards delivering on the commitment of economic prosperity and parity for Aboriginal Victorians.			✔			✔

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Queensland Biomedical 10-Year Roadmap and Action Plan (QLD, 2017)	The QLD government aims to support the biomedical industry to increase employment and business opportunities in the state. The roadmap seeks to leverage benefits for Queensland available through Commonwealth initiatives. The Australian Government's Industry Growth Centre, MTPConnect, in its Sector Competitiveness Plan outlines a 10-year vision to maximise the Australian medical technologies, biotechnology and pharmaceutical sector's competitiveness and productivity, and to achieve more rapid and sustained growth.			✔	✔		
Advancing health 2026 (QLD, 2016)	Advancing health 2026 was developed to guide Queensland government investment into health over the longer term and to reorient our system to be flexible and innovative in taking advantage of new technologies, while improving health outcomes for the population at large.				✔		

APPENDICES CONTINUED

STRATEGY/ POLICY	ALIGNMENT TO THIS PROJECT	PROBLEM STATEMENTS					
		REGULATIONS	TRADE	WORKFORCE	RESEARCH & INNOVATION	MANUFACTURING	RAW INGREDIENTS
Queensland Advanced Manufacturing 10-Year Roadmap and Action Plan (QLD 2022)	The Advanced Manufacturing Roadmap and Action Plan 2022–2026 will support Queensland's manufacturing industries to adopt leading-edge design, technologies and processes that create sustainable jobs, contribute to the government's clean energy and decarbonisation agenda, and drive international competitiveness.			✔	✔	✔	
Queensland Trade and Investment Strategy 2022-2032	This Strategy will ensure that Trade and Investment Queensland can continue to support our exporters to reach new markets and boost sales where they are already trading, as well as to attract more overseas investment into Queensland.		✔	✔		✔	
Queensland Better Regulation Update (2021)	The policy aims to reduce the compliance burdens to support small businesses in Queensland, including Aboriginal and Torres Strait Islander owned business development.	✔					

In addition to aligning with Commonwealth and State government strategic plans and policies, the proposed options will adhere to all relevant pieces of legislation and Codes of Practice, including:

- → Therapeutic Goods Act 1989 (Cth).
- → Therapeutic Goods Regulations 1990 (Cth).
- → Therapeutic Goods Regulation 2008 (NSW);
- → NSW Code of Good Manufacturing Practice for Therapeutic Goods;
- → NSW Guidelines for the Labelling of Therapeutic Goods

APPENDIX 9: ROLE OF NICM

NICM Health Research Institute is Australia's global leader in integrative and complementary research and policy. NICM plays a key national role in ensuring Australians have access to reliable evidence on complementary medicines and treatments in wide use.

NICM was established with bi-partisan support in 2007 through joint seed funding from the Australian Commonwealth Government and the New South Wales Government. With approximately 70 staff and research students, NICM is now the largest complementary medicine research institute in the West that provides comprehensive services from pharmaceutical development and testing to clinical trials, translation into practice and policy research. NICM has been ranked under the Commonwealth Government's Excellence in Research in Australia scheme as ERA 5 ('Well above world standard') over each of the last three trienniums.

NICM has built unique capabilities and teams with a history of supporting industry relevant research and development, as well as GMP testing services. The NICM team has been undertaking internationally compliant (and auditable) clinical trials for the industry since 1995 and has developed clinical trial related Standard Operating Procedures relevant to complementary medicines. NICM is also licensed by the TGA to undertake chemical testing for the industry, develop analytical methods and validate product shelf life to ensure compliance with Australian GMP. NICM has capabilities to undertake many pre-clinical mechanistic and pharmacokinetic studies to provide additional appropriate validation for industry products.

NICM is Australia's leading agency in supporting Government to develop relevant complementary medicine policy and assist with translation into practice. This is reflected in three decades of involvement in State and Commonwealth Ministerial advisory committees, TGA advisory committees (including as Chair), Australia's National Medicines Policy Committee and numerous WHO consultancy roles. NICM works closely with the University's School of Medicine, the Westmead Hospital consultants, and physicians, and as part of the global Consortium for Integrative Medicine (including lead 'ivory tower' medical schools at Harvard, Yale, Oxford, and others). This capability provides exceptional opportunities for meaningful integrative medicine practices to be tested and validated (or rejected). Specifically, NICM continues to develop and provide evidence packages to support industry product submissions to the TGA.

In summary, the core NICM capabilities in support of industry include:

1. **Preclinical and clinical product research & development:** As an ERA 5 ranking institute, NICM is globally recognised for its world-class research and innovations in integrative and complementary medicine. NICM has some of the very few research facilities licensed by the TGA to undertake testing and provide certificates of analysis for herbal products. The clinical and laboratory research have been providing the evidence to close the gap between the general use of complementary medicines and our understanding of how they work.
2. **Provision of health information:** NICM provides relevant health information including contribution to national policy and clinical practice guidelines, as well as evidence packages for industry.
3. **GMP commercial support services:** NICM is a full-service research-intensive institute from the bench to the bedside (preclinical, clinical and translational). NICM supports the industry by way of product chemical testing and shelf-life validation, advances evidence-based analysis focusing on product quality, safety, efficacy, and effectiveness.
4. **Other industry development efforts:** NICM supports and executes other initiatives to develop the complementary medicines industry. NICM operates Australia's first university-based integrative health centre. Through the integrated healthcare services provided, it represents an opportunity to explore new ways to achieve better patient outcomes, backed up by evidence-based research. This could inform the development of traditional, complementary, and integrative medicines. NICM is also about to launch a new GMP manufacturing facility to assist industry in undertaking small batch runs for clinical trials, developing novel and innovative medicines, and provide training in pharmaceutical manufacturing

NICM has been contributing to the development of the complementary medicines industry with strong support by Western Sydney University. The university has recently supported a $28m restoration of heritage building which has provided research facilities including a GMP facility to NICM.

Located at the Westmead Precinct, one of the Australia's largest health, education, research, and training precincts, NICM is able to leverage the robust ecosystem of research and innovation to support progression of the solutions within this business case.

Beyond NICM's, other entities within Western Sydney University that NICM is closely connected with can potentially support or be engaged to support implementation of solutions. This includes Hawkesbury Institute for the Environment (HIE), which has a strong track record in horticulture and agricultural technology relevant to the solutions within the business case.

APPENDICES CONTINUED

NICM'S RECENT DEVELOPMENTS

Supported by Western Sydney University, NICM has been driving industry development activities including the below:

- → **Westmead Innovation Quarter (iQ):** This is a partnership between Western Sydney University and Charter Hall (an Australian property development and funds management company). The centre has provided NICM's new facilitates in the Innovation Quarter includes TGA certified herbal analysis facilities, GMP pharmaceutical manufacturing as well as other facilities for clinical trial and other laboratories.[102]
- → **NICM has unique capabilities and record in engaging with industry relevant opportunities:** NICM has been driving research and innovation by leading numerous industry-engaged and government funded research projects. For example, the multi-hospital vascular dementia trial, and the recently developed $660,000 medicinal cannabis endometriosis study funded by a philanthropy that represents the first study to determine the efficacy of medicinal cannabis on the symptoms of endometriosis[103].
- → **Next Practice – Western Sydney Integrative Health (WSIH):** This partnership between Western Sydney University and Next Practice care is the Australia's first university based academic integrative healthcare centre. The collaboration enables evaluation on treatments and new person-centred, multidisciplinary model of care service provision. The initiative is also in line with the World Health Organization's strategy of increasing public awareness and strengthening the role traditional, complementary, and integrative medicine plays in keeping populations healthy.[104]
- → **Continuous build out of facilities:** Recently NICM has completed the build of a GMP manufacturing facilities, a Natural Product Development Laboratory, and additional Physical Containment Level 2 (PC2) space expected to operational in the first half of 2023.
- → **Support for education and training:** NICM is involved strongly in education and training with forty higher degree research students, and is developing short courses for health practitioners and industry

Although there are 58 medical research institutes in Australia, NICM is the sole research institute focused on complementary medicine.

102 Western Sydney University (2023). First stage of world-class Innovation Quarter health and commercial precinct opens at Westmead.
103 Western Sydney University (2023). Medicinal cannabis endometriosis study funded.
104 Western Sydney University. (2023). Integrative Health Centre.

APPENDIX 10: SOLUTION PRIORITISATION

SOLUTION SCORING – 1, 3 OR 5

			Policy	Economic						Legal	Option-specific considerations		
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%
Research & innovation	R&I1	Establish a substantial and clear complementary medicines research and development funding incentive and pathway to accelerate health innovation, industry collaboration and co-creation of new products for a 5–10-year period.											
Raw ingredients	RI1	Seek support from government to address supply chain issues experienced across the complementary medicines industry by funding partnerships between the agricultural sector and complementary medicines raw ingredient industry to initiate the extraction and manufacturing of local raw materials.											

APPENDICES CONTINUED

			Policy	Economic						Legal	Option-specific considerations		
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%
Raw ingredients	RI2	Advocate for government funding to conduct a risk assessment of Australia's complementary medicines ingredient supply chain, to better protect and enhance Australian raw ingredient supply through integrated and enhanced supply chains.											
	RI3	Engage with Federal (NIAA) and State government agencies to explore opportunities for Indigenous business development in the CM industry.											
Workforce	W1	Develop a detailed CM industry workforce report, mapping and modelling current and future workforce and skills needs across the industry.											
	W2	Support the establishment and design of micro-credentials for complementary medicine-specific training and qualifications across all industry levels – considering links to training on advanced manufacturing and pharmaceuticals more broadly.											

			Policy	Economic						Legal	Option-specific considerations		
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%
Workforce	W3	Establish a formal partnership between business, industry and tertiary education institutions to identify ways to address lack of product development and commercialisation expertise across the CM industry.											
Manufacturing	M1	Directly support local manufacturing growth and innovation through infrastructure grants, targeted funding, and capital.											
	M2	Reduce unfair overseas manufacturing competition through modification of the TGA approval system for GMP.											
	M3	Develop a complementary medicine industry-wide manufacturing investment roadmap to better market and boost attractiveness of the complementary medicines industry for foreign investment and encourage suppliers to maintain and expand their business in Australia.											

APPENDICES CONTINUED

			Policy	Economic						Legal	Option-specific considerations		
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%
Trade	T1	Drive and promote awareness of the 'Australian brand' for CM through industry partnerships.											
	T2	Drive greater CM industry participation in relevant trade delegations and negotiations.											
	T3	Engage with overseas regulators to identify ways to streamline CM product approval processes at export destination countries.											
Regulations	R1	Re-establish the separate Office of Complementary Medicines within the TGA to provide greater focus on regulatory matters relevant to the $6Bpa complementary medicines industry											
	R2	Support appropriate regulation of complementary medicines and provide direct funding to the TGA to cover work outside of the direct cost recovered framework.											
	R3	Review data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence											

SOLUTION PRIORITISATION RESULTS

			Policy	Economic						Legal	Option-specific considerations			
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability	Total
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%	
Research & innovation	R&I1	Establish a substantial and clear complementary medicines research and development funding incentive and pathway to accelerate health innovation, industry collaboration and co-creation of new products for a 5–10-year period.	0.5	0.8	0.8	0.5	0.5	0.2	0.3	0.1	0.3	0.3	0.1	**4.0**
Manufacturing	M1	Directly support local manufacturing growth and innovation through infrastructure grants, targeted funding, and capital.	0.8	0.8	0.8	0.3	0.3	0.1	0.1	0.1	0.3	0.3	0.1	**3.6**
	M2	Reduce unfair overseas manufacturing competition through modification of the TGA approval system for GMP.	0.5	0.2	0.2	0.1	0.5	0.3	0.1	0.2	0.2	0.2	0.1	**2.2**
	M3	Develop a complementary medicine industry-wide manufacturing investment roadmap to better market and boost attractiveness of the complementary medicines industry for foreign investment and encourage suppliers to maintain and expand their business in Australia.	0.5	0.8	0.8	0.5	0.3	0.3	0.1	0.1	0.3	0.3	0.1	**3.7**

APPENDICES CONTINUED

			Policy	Economic						Legal	Option-specific considerations			
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability	Total
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%	
Raw ingredients	RI1	Seek support from government to address supply chain issues experienced across the complementary medicines industry by funding partnerships between the agricultural sector and complementary medicines raw ingredient industry to initiate the extraction and manufacturing of local raw materials.	0.2	0.5	0.5	0.1	0.3	0.2	0.5	0.1	0.2	0.2	0.2	**2.6**
	RI2	Advocate for government funding to conduct a risk assessment of Australia's complementary medicines ingredient supply chain, to better protect and enhance Australian raw ingredient supply through integrated and enhanced supply chains.	0.5	0.5	0.5	0.1	0.3	0.2	0.5	0.1	0.2	0.2	0.3	**3.0**
	RI3	Engage with Federal (NIAA) and State government agencies to explore opportunities for Indigenous business development in the CM industry.	0.5	0.5	0.2	0.3	0.1	0.2	0.5	0.2	0.1	0.1	0.1	**2.4**

			Policy	Economic						Legal	Option-specific considerations			
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability	Total
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%	
Workforce	W1	Develop a detailed CM industry workforce report, mapping and modelling current and future workforce and skills needs across the industry.	0.8	0.5	0.5	0.1	0.1	0.1	0.1	0.1	0.3	0.3	0.3	**2.8**
	W2	Support the establishment and design of micro-credentials for complementary medicine-specific training and qualifications across all industry levels – considering links to training on advanced manufacturing and pharmaceuticals more broadly.	0.5	0.8	0.8	0.3	0.1	0.1	0.1	0.1	0.3	0.3	0.1	**3.1**
	W3	Establish a formal partnership between business, industry and tertiary education institutions to identify ways to address lack of product development and commercialisation expertise across the CM industry.	0.5	0.8	0.5	0.3	0.1	0.1	0.1	0.1	0.2	0.3	0.2	**2.8**

APPENDICES CONTINUED

			Policy	Economic						Legal	Option-specific considerations			
Theme	#	Solutions	Government policy alignment	Job creation potential	Manufacturing potential	R&D potential	Export potential	Australia brand	Australia's sovereign capability (raw material)	Regulatory reform	Meets service need	Commercial viability & feasibility	Deliverability	Total
			15%	15%	15%	10%	10%	5%	10%	5%	5%	5%	5%	
Trade	T1	Drive and promote awareness of the 'Australian brand' for CM through industry partnerships.	0.8	0.2	0.5	0.3	0.5	0.3	0.3	0.1	0.3	0.2	0.2	**3.3**
	T2	Drive greater CM industry participation in relevant trade delegations and negotiations.	0.8	0.2	0.2	0.3	0.5	0.3	0.3	0.1	0.2	0.2	0.3	**3.0**
	T3	Engage with overseas regulators to identify ways to streamline CM product approval processes at export destination countries.	0.8	0.2	0.5	0.1	0.5	0.2	0.1	0.3	0.3	0.3	0.1	**3.0**
Regulations	R1	Re-establish the separate Office of Complementary Medicines within the TGA to provide greater focus on regulatory matters relevant to the $6Bpa complementary medicines industry	0.5	0.2	0.2	0.1	0.1	0.1	0.1	0.3	0.3	0.2	0.1	**1.8**
	R2	Support appropriate regulation of complementary medicines and provide direct funding to the TGA to cover work outside of the direct cost recovered framework.	0.5	0.2	0.2	0.1	0.1	0.1	0.1	0.3	0.3	0.2	0.2	**1.9**
	R3	Review data protection mechanisms and permissible claims and indications associated with proven clinical trial evidence.	0.5	0.2	0.2	0.1	0.5	0.2	0.1	0.2	0.2	0.2	0.2	**2.2**

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