Senate Economics Committee Inquiry into Australian Manufacturing

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Economics References Committee inquiry into “The Australian manufacturing industry”
Committee Secretary Senate Standing Committees on Economics
PO Box 6100
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Canberra ACT 2600

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Introduction

Complementary Medicines Australia is the leading peak body representing a thriving medicines sector supporting Australian jobs, research, manufacturing and exports by meeting community demand for preventative and complementary healthcare. The sector in Australia is a highly capable manufacturing industry required to comply with pharmaceutical (PIC/S GMP) requirements including regular inspections, and strict mandatory pharmacopoeial and other TGA quality standards.

The COVID-19 pandemic has highlighted the limitations of global supply chains and gaps in Australia's manufacturing capability. The strategic importance of domestic manufacturing, securing production and distribution of essential medicines and vaccines, has had to be rediscovered.

During the pandemic, CMA members pivoted to meet the needs of Australians with manufacturing sites remaining operational to continue to produce and distribute needed medicines. Listed medicines manufacturers adapted to the situation in the early days of the pandemic, in which there was a significant shortage of hand sanitiser, to start producing essential supplies and other PPE for Australia.

The public health and economic challenges facing our country in the aftermath of the COVID-19 pandemic are unprecedented. While manufacturers have adapted to produce much-needed personal protective equipment during COVID-19, Australia needs a more sophisticated manufacturing plan than just responding to crises.

We know that Australia only produces two thirds of the amount of manufactured goods it consumes, while most developed nations produce excess to these requirements. Compared with other OECD countries this puts Australia at 36th, essentially last on the leader board, for manufacturing self-sufficiency measures. The report released by the Australia Institute's Centre for Future Work however, shows renewal of the sector could generate as much as $180 billion in new sales, $50 billion in additional GDP and more than 400,000 jobs.

Complementary medicines are one of the high value-add groups identified for growth opportunities. To support a globally recognised Australian medical products industry with the capability, capacity and expertise to locally manufacture advanced and high-value medical products using sophisticated processes, complementary medicines are one of the high value-add groups identified for growth opportunities in the Medical Products National Manufacturing Priority Road Map.[i]

The role that the Australian manufacturing industry has played, is playing and will play in the future can be further capitalised for economic growth, national resilience, rising living standards for all Australians and regional security.

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Australian Manufacturing Success Story - Complementary Medicines

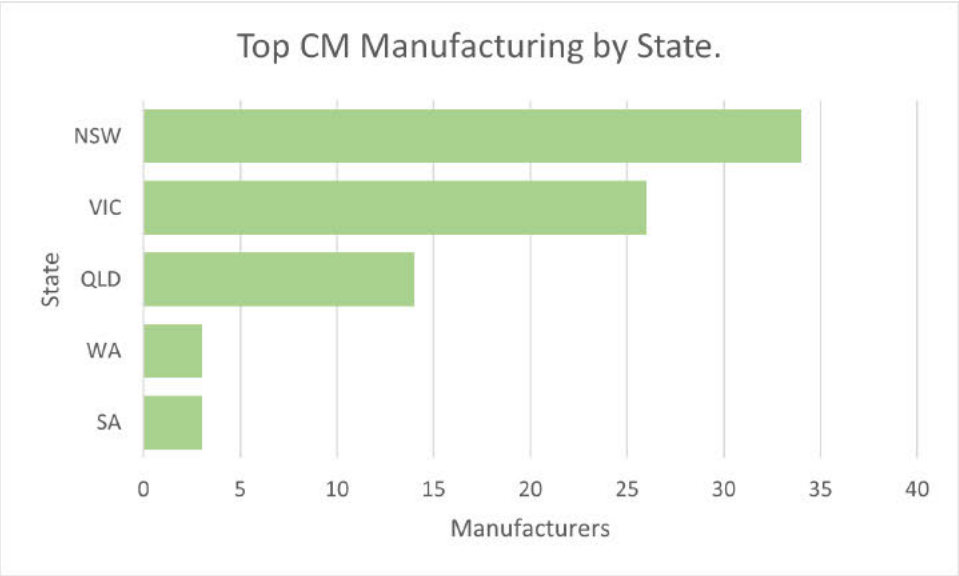
Manufacture of complementary medicines has been the only medicines manufacturing industry to retain a very strong presence in Australia compared to over-the-counter medicines such as paracetamol and prescription medicines, which are largely imported.

The Australian complementary medicine industry is now worth AUD$5.69bn, growing at a speed that outpaces the general economy. Australian exports of complementary medicines hit a record high of AUD$1bn last year, with Asia driving most growth. Australia holds the number one source of nutrition and health foods imports to China with an import volume of AUD$1.19bn.[ii]

Figure 1: Australian CM Manufacturing License by Location

Australian CM Manufacturing License by State	Count
NSW	34
VIC	26
QLD	14
WA	3
SA	3
Total	**80**

Figure 2: Top CM Manufacturing License by Location



Risk commensurate regulation and whole-of-Government policy-setting and support

Complementary medicines have large and state of the art facilities which are inspected and certified to comply with Australian TGA GMP requirements under the pharmaceutical level PIC/S convention, requirements that are higher than anywhere in the world for complementary medicines.

CMA manufacturers have developed the ability to pivot when needed to supply other kinds of goods in an emergency. However, our manufacturers remain under persistent threat of going out of business or down-scaling due to ever-increasing red tape and upregulation by the Therapeutic Goods Administration (TGA) in respect of advertising, product and manufacturing regulation, not all of which is strictly essential or commensurate with risk.

For example:

- The TGA medicines regulator are working on requirements for probiotics which risk shutting down a significant portion of the probiotic industry, if implemented.
- This has been approached for technical reasons that are not risk commensurate and that are not ready for wide scale implementation in industry for a variety of technical and commercial reasons relating to implementation of new and different technologies requiring validation of test methods and development timeframes, or alternatively, the development of data that can take many years and huge levels of investment.
- The proposals are threatening to remove a significant multi-million dollar portion of Australian manufacturing sector for reasons that are largely based on theoretical concerns where there have not been any real world problems identified for probiotics safety and quality that are not already been adequately dealt with by existing approaches and legislation.
- During this time, no risk to the community has occurred to stimulate such action. The proposals would effectively require advanced systems and methodologies that are not yet in full production.
- Suggesting an implementation timeframe of 2 years does not off-set the above barriers, without the offer of Government support in implementation. The industry has clearly indicated that this process needs to progress organically over a likely period of 5-10 years and if the Government wish to speed the process up then active Government support of the process will be needed – rather than unrealistic imposition of requirements that are not yet ready.
- As demonstrated above, a huge portion of Australian manufacturing is under threat due to the opinion or preference of several individuals whom do not have experience or insight into the probiotics industry or manufacturing and whom, as of the date of this submission, demonstrated an unwillingness to listen to the submissions provided by industry.
- Industry have provided alternate acceptable scientific propositions over the practical and reasonable and currently scientifically acceptable approach to take for lower risk probiotic organisms. Instead, the regulator is playing a rigid and inflexible approach to regulation that is not risk-based for this type of product and is a dramatic course of action that will shut down a large portion of probiotics manufacturing, effectively

removing Australia from a valuable and rapidly advancing field of therapeutics, an approach that is internationally **unsupported** by the probiotics sector.

Australian Probiotics Industry

Probiotics are a relatively young and still fast-growing but technically complex field in manufacturing and health, with a great deal of research and development still occurring. If Australia implement the above measures we will be the only nation in the world voluntarily removing ourselves from the a significant portion of the probiotics manufacturing sector. To do so for reasons that only certain individual Government officers have arrived at, without a nuanced understanding of probiotic production and associated commercial and scientific development, appears ludicrous and an own goal for Australia.

Removing Australia from the huge growth field of probiotics production (which has onflow effects to reducing investment and research) is inherently counterproductive to Australia's position as a scientifically advancing nation, which currently has an enormous growth demand for probiotics manufacturing due to the safe and effective outcomes they have for millions of consumers. Raising these issues in light of the whole of government approach to the modern manufacturing strategy with the regulators drafting the requirements has resulted in no change of approach except for a "two year transition period". This remains unrealistic given the basis of the information provided by industry, indicating that they are either not aware of or have no interest in engaging in the larger Government drives to nurture and stimulate Australian scientific development, research and on-shore manufacturing strengths.

While a "whole-of-Government" approach to national success in manufacturing is often referenced in Government policy documents, we rarely see this approach occurring at the level that is the "make or break" policy-setting level. We do not see Government departments communicating with each other about how to work together to nurture industries and help to increase technologies and capabilities in a sustainable and supported way to support both manufacturers and consumers collectively and positively. Rather the reality is a regulator who can act as an independent silo providing commercial ultimatums for industry without essential, risk-commensurate and data-based reasons, ultimatums that cannot always be met and the whose result would be an unnecessary shutdown of manufacturing and redirection of consumer purchasing decisions to products manufactured offshore available for purchase on international e-commerce websites – a situation that is significantly out of alignment with the goals of the greater Government.

To support the continuance of the Australian CM manufacturing sector, one of the few remaining local medicines manufacturing industries that does have the ability to pivot if needed to increase national resilience and security in goods production, more Government support and care in ensuring TGA regulation is risk-commensurate and essential needs to be taken. This can be done by implementing direct regulatory measures to minimise regulatory burden, find fee relief where possible and ensure whole-of-government alignment where it matters – technical regulation of complementary medicines that is strongly aligned with goals of the modern manufacturing initiative and the Government Deregulation agenda.

Recognition, Regulation and Specialist Leadership

An important driver of growth is community and Government recognition of the positive contribution complementary medicines have on health and wellbeing and most importantly, preventative impacts on chronic illnesses. Subsequently, the ability to recognise, communicate and even promote such benefits is fundamental.

An opportunity to advance a "Right Touch, Light Touch" re-regulatory program is appropriate and a call-to-action for the complementary medicines sector. Australia already has a strong manufacturing sector in complementary medicines, but our industry is under constant risk of reduction of domestic and international supply opportunities due to a regulatory system that is being driven without a strong understanding of the industry being regulated and an increasingly over-conservative interpretation of principles-based legislation.

The regulatory drive is significantly up-regulatory and increasing in red tape without strong reasons to do so, which is resource and time intensive. This subdues the ability for growth and reasonable innovation and depresses the key successful on-shore medical manufacturing sector in Australia.

The Complementary Medicines sector requires strong policy and technical leadership in its regulatory application by an experienced complementary medicines specialist, leadership capable of achieving the delicate balance of driving positive growth reforms whilst maintaining essential safety and quality regulatory controls. This will permit the greater leveraging of valuable therapeutic uses of complementary medicines, supported by a high-quality, risk appropriate medicines system integrating to stimulate manufacturing.

Growing raw materials in Australia – untapped opportunity

The COVID-19 pandemic and the large increases in freight have highlighted the costs and risks of continuing to largely rely on overseas suppliers. While we will never be able to compete on some ingredients due to the scale of production and wages/infrastructure, the Australian community and industry would be better served if we can scale up material manufacturing locally on ingredients that we do or could develop a strength in, such as herbal or biological raw materials.

Australia has an opportunity to establish new ground as a global supplier of medicinally potent herbal raw materials and herbal medicine extracts if approached with positive support by Government. Further, Australia has specialist expertise and facilities in herbal medicine identification and therapeutic use that are potentially poised, with Government policy support, to launch Australia as a global leader in supplier of herbal medicines in both complementary and prescription medicines.

Currently, Australia obtains a vast majority of herbal extracts for commercial use from India, China, and Europe. Yet, medicinal herbs are a high-value add product that can be used as the base ingredient in both complementary medicines, and in some cases, prescription medicines (crops include opium poppies grown in regional NSW as opposed to traditional sourcing from Afghanistan - the Australian trials of which has been successful and could be expanded for herbal based medicines of all kinds.)

Medicinal herbs can thus be an important crop where Australia has a significant advantage of abundant natural resources with a wide variety of climactic suitability for different herb types and many small farms and family farms that would want to accommodate a small but high-value crop that

can be built upon to increase our strategic participation in medical product development and innovation.

Removing significant barriers to manufacturing raw materials in Australia

Overseas manufacturers of the raw materials do not have the requirement to obtain a TGA GMP license, whereas most Australian raw materials manufacturers do, despite the fact that the same materials are supplied to GMP-licensed Australian finished product manufacturers whom have to conduct the same range of quality testing before acceptance. This discrepancy in the law causes a significant un-level playing field between Australian and overseas material manufacturers. Such costs are often added to higher local wage and ancillary costs, and the problem is compounded by a lack of available staff whom are familiar with TGA GMP. It is a highly significant disincentive to local Australian processors and manufacturers to open and operate in Australia.

Considering that the finished product manufacturer in Australia must perform the equivalent qualification and testing requirements as for overseas materials and suppliers, it does not add value from a safety or quality perspective. As long as the raw material supplier has a basic standard of HACCP/GMP (similar to processed food product regulation in Australia), this should be adequate without requiring a TGA GMP license for raw materials, as it relies on the validation of the TGA GMP-licensed finished product manufacturer – it is easier and more accessible for them to validate an Australian raw material manufacturer than it is an overseas one.

The regulatory barrier, inability to access trained staff easily, and cost burdens means that prospective raw material companies in this space are unable to compete on price with overseas suppliers and therefore unable to find a good business case to begin or to continue local operations in Australia. Industry and Government must proactively grasp the opportunity to change rules – specifically the removal of TGA GMP licensing requirements for Australian raw material manufacturers – that aren't adding value and prevent Australia from increasing its capability as a manufacturing nation.

The role that government can play in Assisting our domestic manufacturing industry

Research and development & attracting investment

As the research base, recognition and commercialisation of complementary medicines grow, investment will be attracted for further private and commercial funding of more research for more clinical possibilities. Australia has had some regulatory reforms to help better recognise research, but more is needed to get it off the ground. We have already shifted from first gear to second gear. The sector needs Government support both fiscally and from a policy leadership perspective to help boost into third gear until the momentum can become more self-sustaining.

Government can play a role in funding pragmatic interventionalist clinical trials for complementary medicines specifically. Such an approach would gain local and international recognition for the preventative effects of complementary medicines in averting long term chronic illnesses and would help gain regulatory approval provided the right regulatory environment and leadership is in place to capitalise and make use of the research.

A primary issue experienced by the sector when it comes to attracting and retaining manufacturing is the ability for Australia to engage and connect relevant stakeholders across jurisdictions and expertise. Further Government support is needed to encourage growth in domestic manufacturing initiatives

such as MTPConnect, a not-for-profit organisation that seeks to accelerate the rate of growth of the medical technology, biotechnology and pharmaceutical (MTP) sector in Australia.

Formed in 2015 as part of the Federal Government's Industry Growth Centres Initiative, which encompasses the six National Manufacturing Priorities, with complementary medicines being earmarked as one of them, MTPConnect seeks to provide an ecosystem where scientific discoveries are developed from the proof-of-concept stage to successful translation and commercialisation. MTPConnect has a mandate to collaborate and commercialise across the sector, CMA believes that this could be further strengthened with engagement of specialist institutes included in the below.

Greater Government involvement is needed to be able to commercially leverage upon the unique and valuable capacities of the below institutes and infrastructure:

1. Western Sydney University's **NICM Health Research Institute** is Australia's global leader in integrative and complementary medicine research and policy. As an Excellence in Research for Australia (ERA) 5 ranking institute, they are globally recognised for our world-class research and innovation.
2. The **National Centre for Naturopathic Medicine (NCNM)** at Southern Cross University is an internationally recognised centre of excellence and innovation in naturopathic medicine and health education, research and practice. As evidence-based natural medicine and multi-disciplined care plays an increasingly critical role in healthcare, NCNM will be at the forefront of solutions. The Centre was founded in 2020 through a $10 million donation from the Blackmore Foundation.
3. The **National Institute of Integrative Medicine** (NIIM) in collaboration with universities and other medical bodies, conducts research into the safety and efficacy of integrative medicine and complementary therapies for the prevention, detection and treatment of disease. The Institute conducts research in many areas including heart health, cognition, chronic diseases to support the growing scientific evidence base showing that the integrative medical approach supports the treatment of complex illnesses.
4. Herbal quality can be a significant issue globally, with adulteration of turmeric products in India attracting negative attention. We are fortunate in Australia to have one of the world leading laboratories in herbal identification in **Southern Cross Plant Science** that is used by many in the Australian herbal industry to identify and test herbal medicines.
5. NICM has established state-of-the-art **Herbal Analysis and Pharmacology Laboratories** for the investigation of the pharmacology and chemistry of herbal medicines. It is one of the few university laboratories to be licensed by the Therapeutic Goods Administration to undertake testing and provide certificates of analysis for herbal products.

Research, recognition and commercialisation allows more specific therapeutic claims to be made and recognised for complementary medicines and will showcase Australia as a world leader in this field that has ever increasing consumer demand.

Potential research pathways include:

- **Probiotics**: Further discovery of the ever-growing field in gut health, women's health, and specific immune benefits.
- **Low-THC cannabis extracts** for low-risk applications.
- **Herbal medicines**: Translating traditional herbal medicine uses into proven modern-day indications.

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- **Omega-3 and biological compounds**: Australia has access to natural resources, including the potential to increase research into krill oil or vegan algal-DHA oil to support indications relating to neural growth and development and anti-inflammatory pathways.
- **Vitamin, minerals and other nutrients** to support more evidence-based recommendations for specific therapeutic uses.
- **New or emerging natural compounds or extractives** including native medicinal herbs.
- **Consumer-medical research into suitability of preventative indications for more serious health conditions.**

Supply chain support

Import duties of manufacturing materials and machinery is also an important factor - zero import duty on manufacturing capital & spares for complementary medicine manufacturing is recommended; most of it is currently zero but occasionally there is a 5% import tax.

Australian Government's Biosecurity import conditions database - BICON

The BICON import system is becoming increasingly difficult to navigate and the consequences of not gaining the correct permit at the correct time can be severe and catastrophic.

Over the last two years, CMA have been receiving increasing reports from our members of shipments of raw materials, or finished goods being refused entry. This includes situations where the same materials and products have not been refused previously. The Bicon requirements are constantly changing with little or no notice to affected parties, putting consignments at risk. An allegation of a lack of a required permit causes the containers to be returned to its source country or to be destroyed at the cost of tens or even hundreds of thousands of dollars, risking businesses that cannot afford this expense. It is unacceptable that the Bicon system can operate with so many administrative problems with such severe consequences for business. Smaller businesses have struggled to negotiate positive outcomes after a negative assessment, placing them at disadvantage. Finally, all members report that BICON officers can be inconsistent in their decisions, with some requesting a permit and some not, and in most cases where problems arise the inspectors have not been assessing the level of risk contextually, for example, a consignment of highly processed fish oil capsules has a low biosecurity risk.

Overall, the BICON system does not provide business confidence and is a significant risk to manufacturers. It is an administrative mine-field of decision-making and with a difficult to use system. This must be resolved through positive and streamlined reforms that prevents severe impacts on importing manufacturers if errors are inadvertently incurred. Government can assist manufacturers by conducting a complete overhaul of the usability of the BICON system, suggested improvements include:

- Digital Transformation to make the system clearer, more user-friendly, and to ensure that there is far less possibility for misunderstandings by industry or inconsistent interpretations by BICON inspectors.
- Ability to apply for permits retrospectively if there is a misunderstanding, especially for consignment of goods that are inherently lower risk. This prevents high costly return or destruction of goods that damages businesses and manufacturers trying to operate efficiently

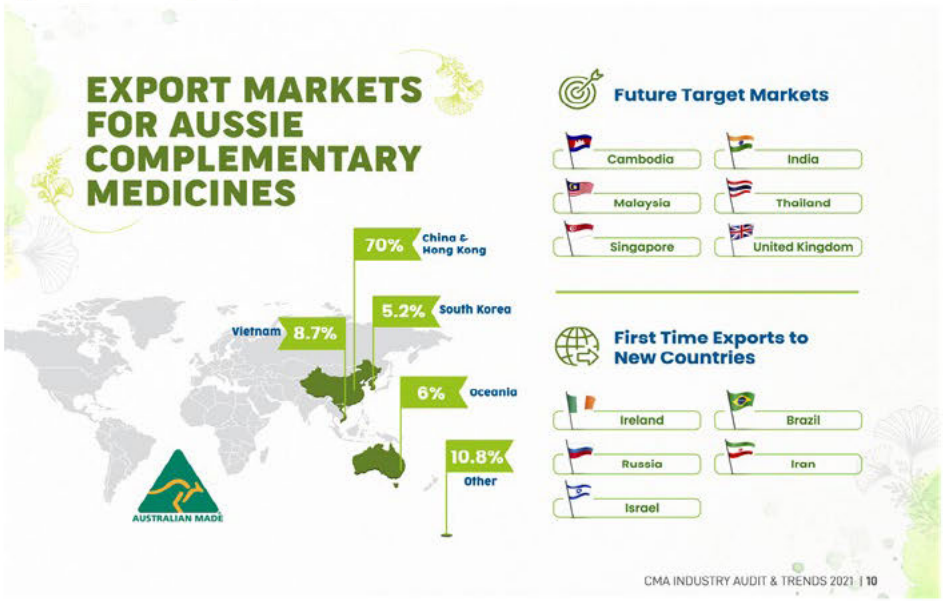
in Australia which is already a high cost environment for manufacturing without administrative bungles and inconsistencies by BICON system and inspectors.

- Isolation of the ingredient of concern in a container of ingredients. A supplier may send a container load of ingredients for use in manufacturing of complementary medicines. If one ingredient is found to have the incorrect permit, the entire container is confiscated rather than the controversial items in question. This leads to expensive losses, administrative difficulties in having to rearrange manufacturing schedules, and unnecessary delays in manufacturing numerous products.
- Exemptions from Bicon permit requirements for small samples for TGA licensed GMP manufacturing facilities. The manufacturers are *required* to test samples to evaluate a material before it can be approved for use and a contract entered into for a larger purchase of the material. It is unnecessary for GMP manufacturers to apply for a permit for a small amount of a sample, for example, up to 100g for testing purposes. The rejection and destruction of the samples prevents the testing from proceeding which creates a manufacturing delay of a new product. There needs to be exemptions for permit requirements on materials which are samples for assessment and not an actual delivery of a consignment material. The exemption could specifically apply to TGA-licensed GMP manufacturers as necessary.

Government procurement and trade policy

Currently, CMA is exploring new export opportunities for the sector to countries in Southeast Asia, as well as diversifying export opportunities in the Asia-Pacific regions, UK, India, US and Canada. Key growth opportunities to enter the dietary supplement market more harmoniously into Indonesia, Vietnam, Malaysia, and other countries exist and could be furthered by supportive measures at a Government level.

Figure 3: CMs Top Export Markets 2020[iii]



[redacted]

Australia could further strengthen its position as a global leader in the manufacture of complementary medicines by tapping into its reputation as a producer of "clean, green and safe" raw materials and finished products for domestic use and export. As mentioned earlier in this submission, there is an opportunity for Australian agriculture to expand operations to include new crops to supply more of the raw ingredients needed for complementary medicine production within Australia, which in turn is supported by funding of Australian research to verify and discover efficacious therapeutic uses, combined with courageous, visionary leadership of the regulation of the complementary medicines sector to permit medicines approval for suitable therapeutic conditions particularly in preventative health.

Skills and training

Manufacturers are having issues obtaining sufficient skilled and unskilled labour in general. There is a skilled and unskilled workforce crisis. There is not enough lab analysts, technicians and engineers. These are compounded by issues where staff need to be isolated due to COVID-19 restrictions or get tested or due to post-vaccination effects. Trained resources with the skills to backfill those positions whilst our workforce is following the mandated requirements and necessary health orders are difficult to find.

It would be valuable to utilise a program to access highly-skilled and low-skilled workers through migration and to utilise more student involvement that in turns helps with their knowledge and training.

Reliable, cheap, renewable energy to keep Australia's manufactured exports competitive in A carbon-constrained global economy

Complementary medicines manufacturers are among those organisations committed to achieving net zero carbon emissions by 2050, a goal aligned to the Paris Climate Agreement to which Australia is a signatory. To meet these targets, organisations need to act to not only improve energy efficiency and increase renewable energy, but also reduce emissions through their value chain. CMA would encourage greater investment into organisations that assist individual business in developing their own clean energy and net zero emissions pathways.

The opportunity for reliable, cheap, renewable energy to keep Australia's manufactured exports competitive in a carbon-constrained global economy and the role that our manufacturing industry can play in delivering the reliable, cheap, renewable energy that is needed. Specifically, Government initiatives or support of commercial or start-up initiatives to access cheaper/subsidised renewable energy programs.

For example: co-contribution on energy savings capex. In the past the government had a 33% co-contribution scheme on capital investment projects. This helps bring capital paybacks from 5 years to about 3.3 years. It was scrapped mid-way leaving businesses that made commitments in limbo.

The government must prioritise catalysing and facilitating excellence in corporate sustainability. Assisting organisations to become sustainability leaders, initiatives like the NSW Government, translates this by:

- supporting organisations to embed sustainability into everyday practices

[redacted]

- helping organisations to be more efficient and save money by reducing resource and energy use, water use and waste
- encouraging organisations to set ambitious targets to reduce carbon emissions
- cultivating networks and collaborations to solve sustainability challenges and achieve the United Nations Sustainable Development Goals.

Conclusion

CMA commends the Senate Economics Committee for convening this inquiry into Australian manufacturing. We are willing to contribute to further discussions on this topic to ensure any reforms in this area have the greatest likelihood of achieving the desired outcomes in driving investment in domestic manufacturing and contributing to the national economy.

Summary of Key Recommendations

1. Retain and attract highly skilled Australian jobs in the sector by maintaining complementary medicines as one of the high value-add groups identified for growth opportunities in the Medical Products National Manufacturing Priority Road Map.
2. Continue funding and support for the implementation of the Modern Manufacturing Strategy and its programs - to achieve a globally recognised Australian medical products industry with the capability, capacity, and expertise to locally manufacture advanced and high-value medical products using sophisticated processes.
3. Offer manufacturing grant opportunities for MMI projects of various sizes such that SMEs are not excluded by virtue of size of co-contribution.
4. Future proof the complementary medicine probiotics industry in Australia by overcoming bureaucratic roadblocks.
5. Harness strategic partnerships by connecting relevant stakeholders across jurisdictions and expertise and leverage for innovative opportunities in Australia.
6. Increase business confidence in the BICON Imports system by conducting a review as to its accessibility and digital application to current import permit issues.
7. In conjunction with AgriFutures Australia, leverage Australia as the clean, green and safe destination for raw materials and finished products for domestic use and export by expanding operations to include new crops to supply more of the raw ingredients needed for complementary medicine production within Australia.
8. Encourage greater investment into organisations that assist individual business in developing their own clean energy and net zero emissions pathways.

[redacted]

Attachment 1.Specific examples of BICON problems:

1. BICON asked for a permit for an import consignment of a batch of products that were listed on the Australian Register of Therapeutic Goods and thus manufactured in an approved manufacturing facility. The tabletted and manufactured product contained a small quantity of a microalgae substance that is approved for use in the Therapeutic Goods (Permissible Ingredients) Determination for listed medicines. BICON destroyed around 950 units at a loss of $60,000 due to a lack of a permit. The destruction of the consignment was not risk commensurate to the import product. The business should have at least been given the opportunity to apply for a permit retrospectively. The company reported that when this product came by air they asked for a permit, when the same product came by sea, they didn't ask for a permit. Inconsistency caused part of the confusion. Destruction of highly processed manufactured product in an TGA approved manufacturing facility is an extremely low biosecurity risk and the destruction of the consignment was not risk-commensurate. This kind of administrative bungle is absolutely something that must be addressed at a management level for BICON.

2. A large manufacturer who regularly imports bulk pre-manufactured fish oil capsules, suddenly had multiple containers stopped by AQIS for not having an import permit. This had never been required previously. Several days later, containers with the exact same product were allowed through without question. The containers that had been refused were threatened with destruction of the product worth tens of thousands of dollars, and it took a great deal of resources and emergency appeal by the company to address this situation.

3. Recently a manufacturer from China was trying to send a "sample for laboratory evaluation" of hydrolysed collagen to an Australian manufacturer customer for their evaluation for a proposed new product to be manufactured in Australia. The sample was supplied in a sealed plastic bottle, properly labelled, with shipping declaration of what it contained, and sent by standard international express courier.

   The sample arrived in Australia in 4 days, then was held in customs for about 3 days. A Biological Declaration was requested by the courier company and we provided this, stating it was a single sample for lab evaluation, with a declaration of its origin (fish). This was finally lodged with customs on about day 12 (after to and fro with courier). Day 16, another request for a letter of authority for customs clearance. On day 25 there was finally a ruling from customs – Import permit required. The Australian manufacturer agreed that the sample could be destroyed as it would take up to 4 weeks to get an import permit. And even if a permit was given, they may have needed to get another different permit for commercial quantities if the material name or product name changed. They organised through a local supplier to get a similar sample couriered. This took another week or so. In all about 3-4 weeks was lost, and the manufacturing and product launch had to be put back approx. 1 month.

   The manufacturer was aware that for commercial batches, an import permit would be required, but not for a testing sample in a licensed GMP facility.

   The manufacturer found that the courier company was of little help, customs were no help in the initial stages, and so they had to guess how to proceed to try to get resolution. They could not talk directly to customs as it had to go through the courier company. It seems that since the most recent round of import updates, it has become much more difficult for the courier companies.

[redacted]

References

[i] DISER Medical Products National Manufacturing Priority road map https://www.industry.gov.au/data-and-publications/medical-products-national-manufacturing-priority-road-map

[ii] Centre for Future Work (2018), OECD 'Statistics on Trade in Value Added. Reference < https://www.oecd.org/sti/ind/measuring-trade-in-value-added.htm>

[iii] Austrade, 2021. Australian Complementary Medicines Export Statistics 2018-2020, Canberra: s.n.

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