

Submission to the
Productivity Commission

SEPTEMBER 2025

Creating a More Dynamic and Resilient Economy Interim Report

Response to Draft
Recommendations on
Regulating to Promote
Business Dynamism

About Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the \$6.2 billion complementary medicines sector in Australia, representing businesses throughout the supply chain. Complementary medicines encompass vitamin and mineral supplements, probiotics, targeted nutritional and herbal therapeutics based on modern scientific trials, as well as traditional medicines that are based on generations of cultural use across the globe. The World Health Organization recognises the fundamental importance of integrating complementary and traditional medicines into health systems worldwide.

CMA collaborates with the Therapeutic Goods Administration (TGA) and other government agencies to develop and uphold effective, balanced regulatory standards for these products. CMA advocates for improved consumer access to complementary medicines and seeks opportunities to foster industry growth, innovation and Australia's competitive advantage in global markets.

About the Complementary Medicines Industry

The complementary medicines industry makes a significant contribution to the Australian economy, generating approximately \$6.2 billion in annual revenue and directly employing nearly 16,000 people. Unlike other medicines and other manufacturing industries, we have been able to protect and grow our manufacturing industry on Australian soil, with 82 TGA-licensed manufacturing facilities across Australia. With annual exports reaching \$1.2 billion, the industry represents an Australian manufacturing and export success story.

Over 75% of Australian households use complementary medicines, reflecting a growing emphasis on preventive health and wellbeing. Our industry plays an important role in supporting informed healthcare choices and reducing pressure on the broader healthcare system.

The industry is arguably the most highly regulated in the world for this sector, with stringent requirements to protect product safety, quality, and efficacy, highly developed manufacturing processes are employed to conform to Good Manufacturing Practice (GMP) requirements under the international Pharmaceutical Inspection Co-operation Scheme (PICS).

Our international reputation for excellence has established high demand in many markets, particularly in key export destinations like China, where "Made in Australia" carries premium value.

Executive Summary

CMA welcomes the Productivity Commission's interim report on *"Creating a More Dynamic and Resilient Economy"* and particularly supports the focus on regulating to promote business dynamism. The report's recognition that excessive or inappropriate regulation can disproportionately inhibit economic dynamism directly aligns with our industry's concerns about increasing regulatory overreach with inadequate checks and balances, creating risks to future growth and productivity.

Regulation is a pillar of the success of the complementary medicines sector. It also remains its greatest threat, with unique regulatory challenges that exemplify many of the issues identified in the PC's report. Our experience reflects the impacts of overly prescriptive regulation, inadequate consultation, regulatory tunnel vision, and creeping regulatory burdens. These challenges are particularly acute for an industry that faces intense international price competition in the export market.

While we strongly support robust regulation to ensure product safety and quality, we have observed an increasing burden that is not always commensurate with risk. Cumulative and increasing burden that is

often dismissed as minor or inconsequential by the regulator can directly affect business dynamism and growth.

The current senior TGA leadership are generally supportive of industry but can be hampered by a lack of resourcing to focus on positive change to support business, a lack of insight by decision-makers into how regulatory decisions impact short and long term business operations, and a structural framework that does not require regulators to focus on broader objectives when making regulatory decisions.

Industry remains concerned that cumulative regulatory burden remains a serious ongoing risk to an otherwise successful Australian manufacturing industry. CMA supports that the PC's recommendations, if properly implemented and with sector-specific measures, can address the systemic regulatory issues that inhibit business dynamism while maintaining high standards that underpin Australia's international reputation.

International competitiveness and regulatory benchmarking

Australia's complementary medicines industry competes globally based on quality and regulatory standards. However, if there are ongoing increases to regulatory burden without external review for proportionality, our competitive advantage may be undermined. The delicate regulatory balance under which industry operates already has a high level of cumulative regulatory burden.

A lack of structured checks and balances on regulation means there is a constant risk of industry damage, particularly when new staff in influential regulatory positions lack understanding, hold an unfavourable attitude to industry or a careless attitude to regulatory burdens, or have the propensity to drive ever-stricter regulatory controls.

While high standards can justify premium pricing, there are limits to what markets will bear, particularly as international regulatory frameworks improve. To quote a former CEO of a major local manufacturer:

"Australia can afford to be twice as expensive as our competitors, not three times."

Like other Australian manufacturing industries that have been lost, cumulative regulatory burden can cause businesses to look at moving manufacturing overseas. Australia should be focusing on strategic ways to maintain essential safeguards while reducing cumulative and excessive regulatory burdens.

Economic benefits of regulatory reform

Industry growth potential

Appropriate regulatory reform could stimulate significant industry expansion through:

- **Manufacturing investment:** Reduced regulatory burden could attract additional investment, supporting the government's objective of strengthening Australian manufacturing capability. Lower compliance costs would improve the competitiveness of Australian operations, encouraging companies to maintain and expand local production.
- **Innovation boost:** Streamlined regulatory processes would encourage greater investment in research and development, supporting the development of new products and technologies. This would strengthen Australia's position as an innovation hub and support the transition to higher value-added manufacturing.
- **Export growth:** More efficient regulatory processes could accelerate time-to-market for export products, improving competitiveness in international markets. Regulatory harmonisation with key export destinations could reduce duplication and compliance costs, making Australian products more globally competitive.

- **Employment benefits:** Industry growth would create additional employment opportunities across the supply chain, including high-skilled positions in manufacturing, research and development, quality assurance, and regulatory affairs.

Consumer benefits

Risk-appropriate regulation would benefit consumers through:

- **Continued safety assurance:** Maintaining high safety standards while reducing unnecessary restrictions that don't contribute to improved safety outcomes. This would ensure consumers continue to have access to safe, high-quality products while benefiting from innovation and competition.
- **Product innovation:** Encouraging the development of new and improved products that better meet consumer needs. Streamlined regulatory processes would enable faster introduction of innovative formulations and delivery systems.
- **Competitive pricing:** Reducing regulatory costs that are ultimately passed on to consumers through higher product prices. More efficient regulatory processes would help keep Australian products competitively priced.
- **Choice and access:** Ensuring regulatory requirements do not unnecessarily restrict the range of products available to consumers or create barriers that limit access to beneficial products.

Broader economic impact

The complementary medicines industry's success contributes to broader economic objectives through:

- **Advanced manufacturing:** Supporting Australia's transition to high-value, knowledge-intensive manufacturing that can compete globally on quality. The industry demonstrates how regulatory excellence can support manufacturing competitiveness.
- **Export revenue:** Contributing to Australia's trade balance and international competitiveness through high-value exports that leverage Australia's regulatory reputation and technical expertise.
- **Innovation ecosystem:** Supporting research institutions, technical service providers, and other knowledge-intensive services that contribute to Australia's innovation capacity.
- **Regional development:** Supporting employment and investment in regional areas where many manufacturing facilities are located, contributing to economic development outside major metropolitan areas.

Response to Productivity Commission's Draft Recommendations

Draft Recommendation 2.1: Set a clear agenda for regulatory reform

Requirement to consider net regulatory effectiveness

The current regulatory environment lacks clear principles requiring consideration of economic impact and international competitiveness. Agencies like the TGA often default to risk aversion, prioritising avoidance of theoretical risk over enabling business growth and innovation. This narrow focus ignores economic costs, innovation impacts, or international competitiveness.

This has created regulatory creep resulting in increasing costs on compliant businesses, with minimal or questionable consumer benefit. It has also resulted in a regulatory framework so complex that it is easier for the regulator to pursue compliant actors for lower risk safety, quality and efficacy issues than pursue major infringements by non-compliant actors operating outside the main regulatory system.

Refer: Case Study A, B, C, J, L, O.

CMA Recommendation 1:

The whole-of-government statement should require, instead of only recommend, that regulators consider the following when making new decisions, and review decisions if requested by industry.

- **Net societal impact:** Assessment of net regulatory effects on consumers and society, not just narrow regulatory objectives.
- **Economic impact assessment:** Systematic analysis of costs and benefits, including impacts on employment, investment, and exports.
- **Freedom of choice:** Preservation of consumer access by applying proportionate safeguards rather than restrictions.
- **Innovation incentives:** Greater regulatory flexibility to encourage research, development, and market entry.
- **Risk proportionality:** Ensure regulatory approach reflects actual – not theoretical – risks, and regulation should not be the default option.
- **Simplicity and clarity:** Regulations should be clear, easy to follow, and applied in a consistent and proportionate way.
- **Enforcement ability:** Regulations must be enforceable on the majority or significant breaches undermine the integrity of the framework.

Improved consultation requirements

The statement should establish clear standards for meaningful consultation that go beyond current practice. Consultation often occurs too late in the policy cycle, after fundamental thought processes have already occurred, resulting in inflexible approaches to outcomes and feedback being dismissed. Even when early consultation with industry occurs, there is often a lack of full transparency about influencing factors, preventing stakeholders from effectively challenging or negotiating best regulatory outcomes. Regulatory changes imposed with inadequate consultation and no checks and balances on impact result in substantial compliance costs and market disruption for reasons that are not always well supported.

Refer Case Study B, C, D, E, G, H, I, L, N, P, Q, R.

CMA Recommendation 2: The whole-of-government statement should require regulators to demonstrate that consultation is meaningful, including requirements to:

- Engage with industry throughout the policy development stage, including prior to public consultation, with full transparency on underlying drivers and reasoning.
- Reflect a balanced assessment that considers multiple perspectives, rather than being influenced by the author's personal views or preferred outcomes.
- Offer 3-4 regulatory options in public consultation, rather than a single option. This practice is recommended by the Department of PM&C but is rarely implemented.
- Provide proportionate time for responses, such as 10-12 weeks on complex issues.
- Share draft policy outcomes post-consultation; explain how feedback has shaped draft outcomes and seek final comments before decision-making.

Implementation and accountability

The statement should establish clear accountability mechanisms requiring regulators to demonstrate how competing objectives are weighed. Criteria for balancing safety, quality and economic impact must be legislated and reviewable.

Structural reform is required to support improved transition timelines for implementation. Cumulative regulatory burdens arise when different TGA divisions impose overlapping timelines for changes to labels or product formulations—each costing tens of thousands of dollars and hundreds of staff hours. It is a significant impost on business that hampers the ability to produce and innovate. Despite a sympathetic posture from regulators, in practice little is done to harmonise or extend transition periods often because it is inconvenient to manage in legislation. Minor administrative inconvenience to government officials should not outweigh major impost on business.

Refer: Case Study D, E, F, G, H.

CMA Recommendation 3: The statement should require regulators to provide explanations of decisions made, including:

- How safety and quality considerations were weighed against economic impacts.
- Assessment of cumulative regulatory burden.
- Why regulatory action is justified and what regulatory offsets are provided.
- How international regulatory approaches were considered.
- Whether decisions made in the interests of consumers align with consumer preferences.

Tangible reductions in regulatory burden

CMA supports survey-based measures to gauge compliance burden, reductions in the dollar value of compliance burdens of regulation, and improved measures based on analysis of primary and secondary legislation. The statement should also encourage consideration of innovative or previously unexplored mechanisms to reduce cumulative compliance burden.

Refer: Case Study A, D, E, F, G, H, K, L, M, N, Q.

CMA Recommendation 4: The statement should expect regulators to:

- Consult industry on reversing or halting existing regulations that increase burden without tangible safety and quality gains. For example:
 - not implementing new versions of manufacturing requirements intended for other medicine categories (e.g. prescription medicines) for listed complementary medicines unless they are deemed critical; and
 - not implementing new international technical and scientific guidelines for listed complementary medicines as the default mechanism.
- Conduct a review of standards, including for labelling and manufacturing, to remove excessive burden that reduces flexibility for no major consumer benefit.
- Review and simplify guidance that creates complex and difficult regulatory burdens without need or legislative underpinnings, for example, the Listed Medicines Evidence Guidelines.

Draft Recommendation 2.2: Bolster high-level scrutiny of regulations

Increased Office of Impact Analysis engagement

The Office of Impact Analysis (OIA) guidelines are appropriate, but there are distinct challenges in applying them meaningfully in real world regulatory contexts, as core principles of the document are not always applied by regulators, and there is no appeal mechanism for external review.

Industry expertise on manufacturing processes, international regulatory approaches, market dynamics, and consumer needs is critical to informed regulatory decision-making. Yet, it is often excluded until late in the decision-making process, when fundamental approaches have already been determined.

Further, decisions to not conduct a regulatory impact assessment can be made by the OIA if the regulator states it is a safety problem, with no industry visibility or right of reply. The extent of the safety problem and the regulatory response can be far overstated relative to the evidence, which has an exaggerated regulatory impact on businesses and consumers—precisely why an impact analysis is needed.

In some cases, the OIA have given an exemption to the TGA to consult on regulatory decisions that could have serious safety outcomes. This exemption has been used to introduce additional new requirements which are unrelated to serious safety outcomes, and outside of the intended scope of the exemption. There has been no review of the decisions or ability to appeal either the TGA or the OIA.

Refer: Case Study B, D, H, L, Q.

CMA Recommendation 5: Industry associations should have direct access to the OIA when regulatory decisions impact their sector. This should include:

- Early notification of proposed regulatory changes affecting the industry, and ability to provide advice at this stage.
- Greater opportunity to advise on broad impacts during policy development.
- Access to draft impact analyses for review and comment.
- Ongoing dialogue on regulatory trends and cumulative impacts.
- Involvement in post-implementation reviews of regulatory effectiveness.

Increased Parliamentary scrutiny

CMA supports greater parliamentary scrutiny of regulatory impacts on Australian industry, both domestically and internationally. Parliamentary committees provide important oversight of legislation but lack the technical expertise necessary to assess complex regulatory decisions in specialised sectors.

A great deal of consequential legislation for complementary medicines now sits in delegated instruments, where decisions can be made quickly and easily by regulators, but mechanisms to seek disallowance of delegated instruments are burdensome and difficult to access.

Refer Case Study O, B, F.

CMA Recommendation 6: Parliamentary scrutiny should be enhanced through:

- Access to independent technical expertise.
- Scrutiny of impact to industry, on both domestic and international competitiveness.
- Power to require regulators to justify controversial decisions.
- Systematic review of cumulative regulatory impacts.
- Easier mechanisms for industry associations to seek disallowance of legislative instruments if productivity or market access impacts are anticipated.

Draft Recommendation 2.3: Enhance regulatory practice to deliver growth**Improved negotiation and flexible options for decisions affecting businesses**

Industry perceives a higher-than-expected rejection rate of applications for innovative new claims, new ingredients or new products with higher level health claims. Sometimes application rejections occur without meaningful communication or attempt to resolve concerns with the applicant. In some cases, applications are refused without discussion, even when issues are minor and unrelated to safety, quality or efficacy.

The current regulatory system lacks adequate mechanisms to challenge inappropriate or inadequately considered regulatory decisions. Formal legal appeals are costly, time-consuming, and often impractical for most businesses, creating an imbalance where regulators can impose significant costs on businesses with limited accountability or recourse. The main appeal mechanism, the “Section 60 review” has, in the last 5-10 years, become an avenue where the TGA typically re-confirms its decisions without genuine reconsideration of the validity of the decision, meaning industry stakeholders have lost faith in the integrity of the appeal mechanism.

Many of these issues could be resolved through better negotiation, transparency and problem-solving in the initial decision-making process. For Section 60 reviews, a fairer and more balanced approach to consideration of the issues should be implemented to ensure critical decision-making.

Refer Case Study J, K.

CMA Recommendation 7: Before applications are rejected, regulators should be required to:

- Meet with industry over application concerns.
- Consider objections to application refusals.
- Explore alternative pathways to resolution.
- Assess whether approval could be justified based on assessment of comparable approvals from the TGA and comparable regulatory bodies.

Strengthen Consultation and Impact Assessment

Regulatory processes often focus on rare or theoretical risks while neglecting broader impacts such as consumer demand, economic costs, innovation, and export potential. The complementary medicines industry has faced numerous regulatory changes where insufficient consultation has led to disproportionate decisions on ingredient restrictions, manufacturing changes, and ingredient scheduling, often without proper assessment of alternatives. These decisions can significantly reduce consumer access to products, drive purchases overseas, and undermine Australian industry viability.

New and historic regulatory decisions restrict consumer access to products without adequate impact assessment. These decisions may be made without considering proportionate alternatives that would mitigate risk while preserving access.

This imbalance leads to regulatory decisions that may reduce theoretical risks by small amounts while imposing disproportionate economic costs and failing to meet consumer preferences locally. When regulatory decisions lack consultation or fail to consider business impacts, there is limited recourse.

Evidence showing which products Australian consumers are regularly purchase from overseas e-commerce sites due to lack of market access in Australia should trigger reconsideration of past regulatory decisions. When consumers purchase from offshore e-commerce websites for a single product, they often add additional products to reach free shipping, fostering loyalty to foreign brands and impacting Australian business dynamism and long term manufacturing viability.

Refer Case Study D, E, F, G, I, L, N, P, Q, R.

CMA Recommendation 8: To improve regulatory balance and accountability:

- Require early industry and consumer engagement at the policy development stage, particularly for market access issues.
- Mandate comprehensive impact assessments incorporating cost-benefit analysis, competitiveness, consumer demand, and global regulatory context.
- Provide adequate consultation periods for complex industry responses, such as 10-12 weeks for complex or technical issues.
- Ensure regulators demonstrate how consultation feedback has shaped the final decision.
- Establish adequate transition periods to allow adaptation to new requirements.

Independent adjudicator for unresolved regulatory disputes

Occasionally there are new, ongoing or historic regulatory issues that pose enduring issues for industry, yet industry is unable to secure regulatory attention to resolve them.

These concerns can arise from inadequate consultation at the time the decision was made or can be due to impacts that were not considered at the time.

Refer Case Study B, D, F, H, I, L, M, Q, R.

The adjudicator should have power to:

- **Require reconsideration:** Direct regulators to reconsider decisions with proper consultation and impact assessment
- **Recommend alternatives:** Suggest alternative approaches that achieve regulatory objectives with lower compliance costs
- **Set timelines:** Establish binding timelines for regulatory decision-making
- **Monitor compliance:** Ensure regulatory agencies implement recommendations and improve processes

CMA Recommendation 9: An independent adjudicator mechanism should be established for regulatory disputes, allowing industry to seek review when:

- Major stakeholders (consumers, industry) dispute scheduling decisions.
- Regulatory processes did not follow established procedures or fair principle.
- Reduced market access significantly decreases consumer access or increases consumer costs.
- Regulatory decisions are made without adequate industry consultation or impose significant compliance costs on businesses without impact assessment.
- The regulator makes decisions that appear to hold an element of bias towards a preferred opinion or use justifications that are unreasonable.
- Economic or business impacts were not properly assessed.
- Regulatory requirements appear excessive relative to identified risks.

Risk based regulation

At the same time as ever-increasing regulatory burden on compliant businesses, the complementary medicines industry also faces risks from under-regulation of businesses that are not compliant with the most basic aspects of regulation. This illustrates an overly complex and bureaucratic regulatory framework – it is often easier for more insignificant issues to be pursued with cooperative businesses, while serious noncompliance goes unaddressed.

While compliance for all products is important, it remains true that significant noncompliance of bad actors with evasive techniques is being economically rewarded through a lack of, or difficulty with, enforcement. This poses economic risks to the compliant manufacturing economy and undermines trust in the regulator, leaving business fearful of regulation or unfairly targeted, rather than confidence that the regulator is protecting against the most egregious offenders.

Refer Case Study A, L, M, R.

These risks can only be mitigated by the kind of structural change that this Interim Report suggests. Industry welcomes a simpler and more balanced approach to reduce regulatory burden while subjecting the most fundamental non-compliances to reliable enforcement for a fair and level playing field.

CMA Recommendation 10: The regulator should implement genuine risk-based regulation that:

- **Apportions resources according to risk:** A whole of industry risk matrix should be developed and all issues should be triaged according to risk.
- **Considers broad risks:** Assessment should not only consider direct impacts to safety, quality and efficacy but net risks to the integrity of the marketplace and the Australian manufacturing industry.
- **Focuses resources:** Concentrates regulatory attention on genuinely high-risk issues or major breaches of law.
- **Regular review:** Periodic reassessment in consultation with industry.

Conclusion

Our industry's experience demonstrates that Australia can maintain world-leading regulatory standards while creating an environment that supports business productivity, innovation, and international competitiveness. CMA strongly endorses the Productivity Commission's recognition that excessive and inappropriate regulation can inhibit economic dynamism and resilience.

A fundamental shift in regulatory culture from risk aversion toward balanced consideration of safety and economic objectives is required. Implementation must be accompanied by sector-specific measures that address the unique challenges facing highly regulated industries. Regulatory checks and balances must be structurally built-in as a part of regulatory operations, with the opportunity for industry to appeal to an external body if there are major concerns.

The complementary medicines sector should be prioritised for regulatory review given its economic significance, manufacturing presence in Australia, export potential, and regulatory complexity.

Economic imperative

Australia faces increasing international competition for investment and market share in high-value manufacturing industries. Regulatory frameworks that impose unnecessary costs or delays put Australian businesses at a competitive disadvantage and discourage investment in local operations. Conversely, regulatory systems that maintain high standards while supporting business efficiency can provide competitive advantages that support industry growth and development.

The complementary medicines industry already contributes \$6.2 billion annually to the Australian economy and employs nearly 16,000 people. With appropriate regulatory reform, the industry has potential to significantly expand its contribution through increased manufacturing investment, export growth, and innovation development.

Implementation commitment

The opportunity exists to create regulatory systems that serve as international models for balancing safety and economic objectives. With appropriate leadership, commitment and implementation, Australia can maintain its reputation for regulatory excellence while creating an environment that supports business dynamism, innovation and economic growth.

CMA is committed to working constructively with government, regulators and other stakeholders to implement regulatory reforms that benefit consumers, businesses, and the broader Australian economy. Our industry holds extensive technical expertise and international experience that can contribute to developing more effective regulatory approaches.

Successful implementation of regulatory reform will require:

- **Political leadership:** Clear commitment from government leaders to prioritise economic dynamism alongside safety and quality objectives
- **Cultural change:** Fundamental shift in regulatory agency culture toward balanced decision-making and support of personnel involved in implementing consultations and decision making
- **Stakeholder partnership:** Meaningful collaboration between regulatory agencies and industry
- **Continuous improvement:** Regular review and refinement of regulatory approaches based on evidence and experience

We look forward to the PC's final report and government implementation of reforms that will improve Australia's competitiveness while maintaining standards that underpin consumer confidence and international reputation.



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