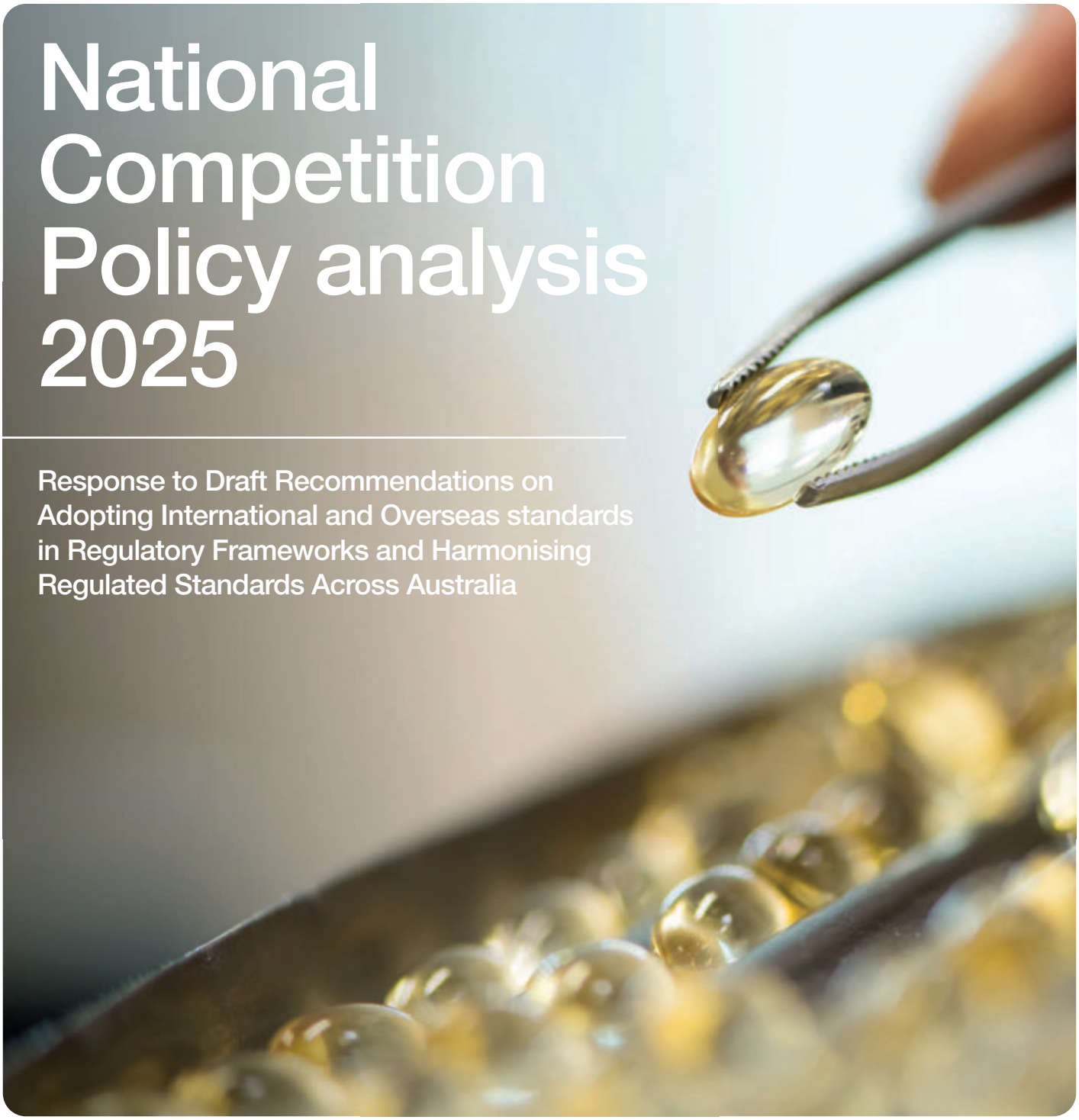
Complementary Medicines Australia

Submission to the Productivity Commission

SEPTEMBER 2025

National Competition Policy analysis 2025

Response to Draft Recommendations on Adopting International and Overseas standards in Regulatory Frameworks and Harmonising Regulated Standards Across Australia



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 high-quality 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. This trend is particularly pronounced among higher education and income demographics, demonstrating the industry's 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 driven high demand in many markets, particularly in key export destinations like China, where "Made in Australia" carries premium value.

Response to Draft Recommendations

Standards

CMA welcomes the opportunity to comment on the Productivity Commission's National Competition Policy Analysis 2025. This submission addresses the standards reform stream, concerning the adoption of international and overseas standards in regulatory frameworks and the harmonisation of regulated standards across Australia, as set out in the Interim Report.

CMA notes the Commission's conclusion that wider recognition of international and overseas standards, together with interstate harmonisation, can deliver substantial economy-wide benefits in the order of $1.9–$3.8 billion per year, or about 0.1–0.2 per cent of GDP, subject to case-by-case assessment. The purpose of alignment to international standards should be to achieve safety outcomes at lower cost and with greater timeliness, but it cannot be assumed that this will be the case unless there is a sector-by-sector analysis. For listed and complementary medicines[1], such gains will

[1]Listed medicines are low-risk medicines included in the Australian Register of Therapeutic Goods (ARTG) with an AUST L or AUST L(A) number. They may only contain permitted ingredients and make low-level indications (TGA). Over 99% of complementary medicines on the ARTG are listed medicines.

only be realised if alignment to international standards is proportionate and outcomes focused within Australia's therapeutic goods regulatory framework and if legislative and process changes are amended to ensure the application of international standards remains appropriate and sector-specific in the domestic context.

In the case of listed complementary medicines, international standards are already legislated as mandatory but also interact with Australian standards. While there are benefits to utilising international standards, there are also drawbacks that have not been sufficiently addressed in the therapeutic goods regulatory framework, which we outline in this submission. These drawbacks may undermine the integrity of the framework and create risks to business dynamism and productivity, unless appropriate solutions can be found. We raise our concerns in this report as it not only needs to be addressed for the complementary medicines sector within the therapeutic goods framework but may also act as a warning for other sectors on how challenges need to be anticipated and effectively managed if international standards are to be adopted into Australian legislation.

The complementary medicines sector faces a unique challenge: therapeutic goods must comply with one of the three "default" standards, which are all international pharmacopoeias: the British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.) or the United States Pharmacopoeia - National Formulary (USP-NF). Because the BP and Ph. Eur. provide relatively few standards relevant to complementary medicines, the USP-NF standards are the ones most applicable to a considerable proportion of raw materials and finished products in this category. However, because USP–NF standards are not mandatory in their home jurisdiction, relying on them as mandatory in Australia can create significant challenges. In particular, ingredient specifications and test methods are often unsuitable, or technologically impracticable in the Australian context.

In the USA, compliance to USP-NF monograph is voluntary, but manufacturers often declare compliance with the USP on their label as a marketing advantage This creates a commercial incentive for business to draft and amend monographs in ways that can exclude competitors rather than serving as a true "minimum acceptable" standard for all industry. For example, a monograph may specify a unique reference standard produced by a single organisation or mandate a proprietary analytical method that only a handful of laboratories can perform.

In the US, competitors without access to these tools are only prevented from making a USP label claim; they can still lawfully sell their products. However, in Australia, USP–NF is a mandatory default standard under the Therapeutic Goods Act. This means that provisions originally intended to be voluntary marketing differentiators in the US can create legal and commercial barriers for Australian manufacturers to actually produce goods.

Where there are not ongoing commercial or other incentives in the USA to update monographs, they can become out of date or irrelevant.

Some monographs include testing methods that are not available in Australian TGA licensed laboratories, meaning that some tests cannot be performed and compliance not fully determined. As a result, some manufacturers continue to rely on the previous USP methodology, as they are unable to meet the revised testing requirements.

Under the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act), section 14 and 14A makes it an offence to import, export or supply therapeutic goods that do not comply with an applicable standard, unless the Secretary grants written consent. The TGA refers to this as "Section14/14A consent" which is sought via an application with an assessment fee applicable for every affected complementary medicine. From a productivity standpoint, this process is highly problematic, and industry considers it to be almost entirely dysfunctional for the purposes of default standards relating to quality and manufacturing for the following reasons:

- Within the TGA, there are limited personnel with the relevant technical and manufacturing expertise to assess applications relating to complex or non-standard manufacturing methods used in complementary medicines. These officers have other resource-intensive duties, and the assessment of section 14 applications is on top of their existing workload. This creates significant delays in the assessment of applications. It also creates the risk that applications are instead given to officers without the full relevant technical expertise to assess, which increases the likelihood of rejection for the application.

- The application is designed for finished products (the final medicine) so if a challenge with a monograph for a single raw material ingredient —used in tens or hundreds of medicines— is detected, it requires a separate application for each medicine that contains that ingredient by every affected sponsor: an extremely expensive, inefficient, high red tape exercise.

- Assessment of applications for section 14/14A consents can take many months, if not years, with no legislated timeframes for completion. Manufacturing of the affected products are expected to grind to a halt during assessment, impacting manufacturers, product sponsors, retailers, and consumers. If manufacturers cannot operate efficiently, this significantly impacts business' ability to function effectively, risking business dynamism, innovation, and employment stability.

- The TGA treats section 14 consents as a discretionary pathway of last resort, available only in exceptional circumstances. The TGA is also currently extraordinarily risk-averse in approving any deviation from a quality standard, apparently due to concerns of liability and reputational risks for the regulator. Industry widely perceives there is extremely high likelihood of denial of consent if an application is made even if the application has reasonable grounds and there is no appreciable concern for safety, quality or efficacy. Businesses who seek section 14 consents also consider they are highly likely to lose business to competitors who are not making equivalent applications for the same challenges but remain undetected.

- The TGA treats the Section 14 consent pathway as a temporary solution, and any approvals are granted for a defined period or for specific batches. Businesses must often nominate a period or particular batches for the consent, and the TGA generally impose limits or conditions—including time restrictions—when granting consent. The TGA website states that consent is generally not granted for a period longer than 2 years[2]. However, the challenges with specifications and analytical methods present in some monographs are generally not temporary issues, they are ongoing ones, creating a mismatch between a potential consent and the reality.

These structural problems in the regulatory framework are significant. The complementary medicines sector fully support the maintenance of standards that create and uphold appropriate safety and quality standards for complementary medicines, and the industry rigorously upholds Australian specific Ministerial standards set by the TGA, in addition to relevant international default standards. However, the process for addressing issues where default standards are out-of-date, inappropriate in the Australian setting, or not possible to conform to if there are methodological and laboratory issues, is not fit-for-purpose. Industry must be able to operate without temporary or permanent interruptions to production if there are challenges with standards that are not reasonably expected to impact the safety, quality or efficacy of the finished product.

The Interim Report's recognition of the World Trade Organisation (WTO) Code of Good Practice makes clear[3] that voluntary standards should draw on international references, except where this would be ineffective or inappropriate, for example, due to fundamental technological limitations, and that duplicative conformity assessments should be avoided. Industry should not be locked into a single prescriptive method, where that method does not impact the outcome. Alternative pathways are

[2] TGA guidance: Consent to import, supply or export therapeutic goods that do not comply with standards - information for industry
[3] World Trade Organization (WTO), Agreement on Technical Barriers to Trade (TBT Agreement), Annex 3: Code of Good Practice for the Preparation, Adoption and Application of Standards

particularly important where testing methods in international standards assume analytical platforms that are not commercially available to, or proportionate for, listed medicines. This can particularly occur for probiotics and other highly complex ingredients.

Alignment with international standards should be configured using alternative pathways to allow sponsors to demonstrate equivalence to the safety and quality outcomes of those standards, or a justification that quality, safety and efficacy of the finished product is not impacted, where compliance is not possible.

CMA recommends the Commission endorse improvements to regulatory framework with a range of alternative regulatory pathways for compliance with international default standards, particularly any that are voluntary in their country of origin. Implementation of alternative pathways would ensure alignment faithful to the Interim Report's performance-based drafting and "deemed-to-comply" concepts.

1. Review of the hierarchy of standards in the *Therapeutic Goods Act 1989*

Recommendations to specifically provide alternative regulatory pathways for listed complementary medicines where materials or products that cannot conform with a particular specification or test methodology in an international standard are provided below. These recommendations may also be relevant to other industries facing similar hurdles and complexities.

There are numerous standards applicable to medicines, both Australian Ministerial standards and numerous international 'default' standards. To ensure the foundational system of applying domestic and international standards to medicines is functioning as intended, a review of section 10 of the Therapeutic Goods Act is recommended. The current hierarchy set out in section 10 may not have fully anticipated how Ministerial standards for finished products interact with default standards for raw material ingredients. This creates duplication and unnecessary red tape or loss of commerce in raw materials by requiring more than one form of compliance to equivalent requirements. CMA recommends a review of section 10 of the Therapeutic Goods Act to ensure the framework operates efficiently and as it is intended, which is to prevent unnecessary duplication. A case example is included in Case Study 1.

2. Consultation to review the adoption of new monographs in default standards

New monographs and updates to monographs in default standards are automatically adopted in Australia, even where they do not align with the existing regulatory framework for listed medicines as described in Case Study 2. "Auto-adoption" is feasible and practical for prescription medicines, where there are equivalent regulatory frameworks across the world. It is not always feasible for complementary medicines, where globally many different regulatory frameworks are in place, often with different regulatory categorisations of the affected products.

Although auto-adoption of updates to the default standards is built into the Therapeutic Goods Act, section 3C the Therapeutic Goods Act allows the Minister to determine if all or part of a default standard does not apply to specified therapeutic goods. This provision was intended to provide flexibility where international standards are inappropriate or disproportionate in the Australian context. However, in practice, section 3C is rarely exercised, and new or updated pharmacopoeial monographs become immediately effective on Australian products without any structured review. For complementary medicines, section 3C has only been utilised once, in 2025, to provide an exemption to a labelling requirement present in an international default standard that is not normally expected in Australia.

Section 3C provides an opportunity for an ongoing exemption to all or part of a standard and is an effective alternative to Section 14 consents for industry, if willing to be exercised by the regulator.

We note that the TGA has previously suggested that industry make a submission to the publisher of the default standard during a consultation period for a monograph. This is sometimes a useful pathway but only if industry can both successfully anticipate and prevent any changes that would impact Australia during the initial consultation period for the monograph. Such submissions are not always practical or successful, as these monographs are usually developed for other regulatory frameworks and jurisdictions, and sometimes may also be influenced by other considerations.

CMA recommends regulators undertake consultation on the adoption of new monographs relevant to complementary medicines when they are added to the international default standards to ensure that they are fit-for-purpose, and that section 3C is exercised more regularly where a manufacturing specification or method is not appropriate or available in Australia instead of reliance on Section 14 applications only. In this way, adoption of new standards should only be accepted where a review demonstrates that the new standard addresses a risk not already controlled in Australia and is risk-commensurate to listed medicines.

3. Legislated provision to use risk assessments as an alternative to Section 14 consents

Where an international test specification or method is technologically inappropriate or impractical in Australia, including where the required laboratory equipment is not reasonably available— we submit that is onerous, inefficient and commercially unproductive for regulators to intervene in every variation identified via a Section 14 consent.

Risk assessments without explicit section 14 consents should be permitted as an alternative pathway to:

- Allow minor deviations to specifications that have no consequential impact on safety and quality of the finished product.
- Permit a validated and fit for purpose alternative method if the same outcome in terms of safety, quality and compliance can be achieved.
- Omit certain tests if the test methods are commercially unavailable in Australia and there is no significant impact on safety, quality or efficacy.

For example, evidence generated by NATA/ISO/IEC 17025 accredited laboratories[4], whether domestic or overseas, should be recognised to avoid repeated testing that does not alter the safety outcome[5]. Under this pathway, a sponsor could demonstrate the same outcome using equivalent specifications or methods recognised in Australia, including those validated in accredited laboratories and finished product controls, already established in the domestic regulatory framework.

4. Overhaul of the Section 14 consent mechanism

CMA recommends a comprehensive overhaul of the section 14 process due to the concerns outlined earlier.

Section 14 applications should be limited to situations where a risk assessment alone is not considered appropriate, and the direct assessment and approval by the regulator is required. This needs to take into consideration that the regulatory body has time and resource constraints.

[4] ISO/IEC 17025 accreditation (by NATA in Australia) evidence laboratory technical competence and supports mutual acceptance of test results

[5] Mutual acceptance of validated results from accredited labs (ISO/IEC 17025) reduces duplicative testing without changing safety outcomes.

Appropriate situations for Section 14 consents are likely to be where there is a moderate or higher risk that the safety, quality, efficacy or performance of the goods could be impacted.

Applications must only be assessed by staff with relevant technical expertise, including relevant laboratory and manufacturing knowledge.

Decisions should be issued within commercially viable timeframes, which is in the order of weeks, not months. The Section 14 consent outcome needs to be decided within a legislated timeframe so that businesses have predictable outcomes and can plan accordingly.

In contrast to the current risk-averse culture of the TGA, regulators should assume a positive stance towards granting approvals unless there are insurmountable safety or quality risks, so that businesses have confidence that they are supported by the regulatory system under reasonable circumstances.

5. Other pathways to creating legislated alternatives to default monographs

For finished products, Australian Ministerial standards, also known as Therapeutic Goods Orders, are an existing legislative mechanism that creates viable Australian-specific alternatives to international default standards. They may increase or decrease the requirements as appropriate to the Australian context and will override an equivalent requirement in a default standard. For finished dosage forms, currently there is only a Ministerial standard that applies to tablet, capsules and pills, not other dosage forms such as powders, liquids, gels and gummies.

An equivalent mechanism to provide a legal Australian alternative for raw materials (ingredients) is not currently in place. We propose that this is necessary to introduce as an additional alternative regulatory pathway, particularly in recognition that specifications in the USP-NF can be driven by commercial interests for USA marketing purposes and may aim to exclude competitors rather than create a minimum acceptable safety, quality, or efficacy expectation for all manufacturers.

In cases where analytical procedures are unavailable in Australia, mechanisms like section 3C should primarily be explored. Section 3C should also be explored if specifications in monographs for default standards are unrealistic or unsuitable. Where it is not possible for the TGA to determine that certain specifications in a monograph should be exempt under section 3C, there should remain additional permanent pathways to compliance where the temporary Section 14 consents cannot provide an ongoing resolution.

Therefore, in circumstances where the specifications of the raw materials are suitable from a safety, quality and efficacy perspective but cannot comply with an applicable monograph in the USP-NF or other default standard on an ongoing basis and section 3C is deemed unsuitable, companies should be able to apply to the TGA to request the development of an Australian alternative specification or specifications for the monograph in the default standard.

A cost-recovered ingredient assessment pathway already exists: The TGA can assess ingredient specifications for quality, safety, and relevance to the Australian regulatory framework via paid applications to vary the Permissible Ingredients Determination under section 26BD (1) of the Therapeutic Goods Act. Upon the request of an applicant, the Permissible Ingredients Determination could permit an alternative monograph or an alternative specification to the monograph in the default standards. We acknowledge this may require a corresponding exemption under section 3C from the applicable default standard monographs to permit the alternative specification or monograph to apply if the product does not comply to the default standard. However, together, these provisions offer a potentially viable mechanism to creating Australian-specific standards for ingredients used in listed complementary medicines to create Australian-specific requirements where necessary for businesses while ensuring regulatory oversight of safety, quality and efficacy.

Government funded access to standards in legislation

Because sponsors and manufacturers of listed complementary medicines must comply with relevant default standards—the BP, Ph. Eur. and USP–NF—this means, in practice, businesses must maintain active subscriptions to multiple pharmacopoeias to understand and apply mandatory regulatory requirements. If there is no applicable monograph in one pharmacopoeia, then an applicable monograph in one of the other default standards applies. This means businesses cannot subscribe to only one pharmacopoeia, they must subscribe to all three.

These subscriptions are costly—particularly for small and medium-sized enterprises (SMEs) that make up majority of the listed complementary medicines sector—costing thousands for each subscription as the minimum payment option. For large multinational pharmaceutical companies, subscription costs may be absorbed as part of global operations. For smaller complementary medicine manufacturers and sponsors, the impost is disproportionate: many must purchase multiple pharmacopoeias even though only a handful of their products may be covered by monographs in those texts.

Providing funded free or low-cost access, as recommended by the Interim Report, would ensure that compliance obligations under the Therapeutic Goods Act are transparent, accessible and affordable for all sponsors, particularly SMEs. This reform would directly reduce regulatory burden, simplify access, and create a more level playing field between SMEs and larger global players.

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