GBMA Generic and Biosimilar Medicines Association

No Patient Left Waiting: A Reform Roadmap for Medicine Supply Resilience

GBMA Summit White Paper

August 2026

www.gbma.com.au

Stakeholders Who Shared Their Insights to Inform this Paper

ACKNOWLEDGEMENT

GBMA is grateful for the valuable insights shared by Summit participants and external stakeholders which helped shape this white paper. Their participation does not necessarily signal endorsement of the paper or its recommendations, which reflect the views of GBMA.

We also acknowledge the significant work undertaken by the Therapeutic Goods Administration (TGA) and other stakeholders to strengthen Australia's medicine shortages framework, including the establishment of reporting requirements, public shortages notifications, enhanced communication processes and coordination mechanisms that support patient access.

GBMA Summit and stakeholder input

This paper reflects the key themes that emerged from the GBMA Summit and subsequent stakeholder discussions with industry, patient, clinical, pharmacy and policy participants. Stakeholders consistently identified the same system pressure points: low price settings that can undermine sustainable supply, shortage management processes that are often too reactive, public information that does not always show the real patient-level impact, and regulatory pathways that can be too slow or administratively complex during supply stress. The reform package therefore focuses on three practical areas where government and industry can work together by strengthening PBS sustainability settings, improving coordination, and streamlining regulation so Australia can respond faster without compromising quality or safety.

GBMA position

This paper draws on Summit participant expertise, stakeholder workshops and the supply chain experience of the generic and biosimilar sector to set out a reform package that is practical, proportionate and ready for partnership discussions across industry and Government.

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Executive Summary

Australia's medicines system is under increasing pressure from global supply volatility, rising input costs, concentrated manufacturing, and domestic policy settings that can make low-cost essential medicines difficult to sustain. These pressures are now being felt by patients, pharmacists, clinicians and suppliers through more frequent and more complex shortages.

As we approach the next strategic agreement in the face of increasing geopolitical challenges, this is a critical opportunity to move from a reactive shortage-management model to a more resilient supply framework that protects patient access before disruption occurs. This paper sets out the practical reforms the GBMA believes are needed now to strengthen PBS sustainability, improve early coordination and communication, and streamline regulation without lowering safety or quality standards.

Australia is not unique when it comes to medicine shortages – so we need to manage what we can control locally. More than 90 per cent of prescription medicines used in Australia[1] are imported, increasing Australia's exposure to global manufacturing, logistics and allocation pressures.

Australian patients are already bearing the consequences of medicine supply disruption.
Delayed or interrupted treatment, heightened anxiety, additional appointments, and higher out-of-pocket costs when usual subsidised medicines are unavailable.
The GBMA Summit clearly articulated that Australia needs a medicines policy framework which prevents avoidable shortages before they reach patients and manages unavoidable disruptions through earlier, more coordinated and clinically useful action..

Medicine shortages are not isolated incidents or short-term logistics failures. They are a visible symptom of deeper structural pressures arising from aspects of the current policy environment: concentrated global manufacturing, rising input and freight costs, small-market allocation decisions, declining prices for older medicines, and regulatory processes that can be too slow or fragmented during supply stress.

Reliable access to medicines is a cornerstone of Australia's health system. Without reform, Australia risks becoming a less attractive and less viable market for essential medicines, increasing reliance on fewer suppliers and leaving patients, clinicians and pharmacists exposed when global disruptions occur. These pressures fall most heavily on the generic and biosimilar sector, which supplies the majority of PBS medicines.

1. https://doi.org/10.1016/j.sapharm.2020.12.001

GBMA is seeking three linked commitments:

1. Strengthen long-term PBS sustainability settings;
2. Improve shortage identification, coordination and communication; and,
3. Streamline regulation so Australia can respond faster without lowering standards.

ACTION	THEME	FOCUS
ADDRESS ROOT CAUSES	Strengthen long-term PBS sustainability settings	• Review floor price settings and indexation mechanisms to ensure sustainability of supply of essential medicines. • Reform minimum stockholding requirements so they are risk-based and outcome-focused.
MANAGE SYSTEMS (BACK-END)	Improve shortage management, coordination and communication	• Co-design with Government and the TGA a targeted shortage management partnership that enables earlier coordinated action before shortages affect patients, building on existing mechanisms and using peak bodies as a neutral coordination point where appropriate. • Update the TGA Medicine Shortages Database to group shortages by molecule/active ingredient and audience-specific views • Develop escalation pathways for shortage signals, and clearer clinical guidance on substitution options where appropriate.
INCREASE PRODUCTIVITY	Streamlining regulations to boost efficiency and resilience, without lowering standards	• Increase the use of reliance and recognition pathways to accelerate access to medicines and regulatory approvals • Reform the section 19A pathway to ensure it operates as a predictable and proportionate emergency mechanism, during a shortage.

The Need for Reform

Australia is in need of practical reforms. The GBMA believes now is the time to strengthen PBS sustainability, improve early coordination and communication, and streamline regulation without lowering safety or quality standards. Medicine shortages are an increasing global challenge, but Australia's exposure is shaped by domestic policy choices. Supply disruptions have become more frequent and complex because of manufacturing concentration, rising input costs, international competition for limited stock, and sudden demand changes.

The scale of the issue is already visible: the TGA Medicines Shortage Database was reporting hundreds of current and anticipated shortages in 2026 with stakeholders consistently noting, for a small and geographically distant market such as Australia, these pressures can translate quickly into patient access problems when local settings do not make supply commercially viable.

Australia has invested significant effort in mechanisms that help manage shortages once they are visible, including mandatory reporting, shortage databases, substitution instruments and emergency import pathways. These tools are important, but they are reactive and do not address the root causes. A system that relies too heavily on emergency importation, stockpiling, local workarounds and repeated case-by-case communications will remain costly and reactive, leaving Australia and patients vulnerable.

Why the current system cannot keep pace with supply pressures

CURRENT STATE	FUTURE STATE Building a more resilient medicines system
Manage shortages after they are formally visible.	Prevent avoidable shortages earlier by addressing market, pricing, stockholding and regulatory settings.
Focus on lowest price and static compliance measures.	Recognise value, supply continuity, competition and redundancy as core PBS sustainability outcomes.
One-way data requests and siloed sponsor-by-sponsor engagement.	Targeted two-way dialogue using existing processes and peak body coordination where useful and legally appropriate.
Public shortage reporting that can underestimate patient-level impact.	Molecule-level, severity-based and audience-specific communication that helps patients and clinicians understand what action is required.
Section 19A and emergency imports as routine pressure valves.	Section 19A retained as a safety valve, with fewer avoidable escalations because the system is more viable and more agile.

Medicine supply resilience – through a patient lens

Luke Escombe: Musician, comedian and Crohn's and Colitis Australia Ambassador

For patients living with chronic and complex conditions, reliable access to medicines is not simply a matter of convenience. At the GBMA Summit, Luke Escombe shared his experience of living with Crohn's disease and relying on a medicine for his health.

"Patients cannot simply 'wait' when a medicine is unavailable. They may not have a substitute. They may not have time to navigate repeated appointments, pharmacy calls, special supply arrangements or emergency workarounds before their condition deteriorates".

Luke's story demonstrates why medicine supply resilience must be viewed through a patient lens. A shortage, delay or disruption is not merely a logistical problem. For patients, it can mean pain, relapse, deterioration, hospitalisation, loss of independence, loss of work and major life-altering treatment decisions.

His message to the GBMA Summit was clear: patients relying on vital medicines are walking a tightrope. The role of policy, regulation and industry coordination is to build the strongest possible safety net beneath them.

Australia is exposed to global supply pressures

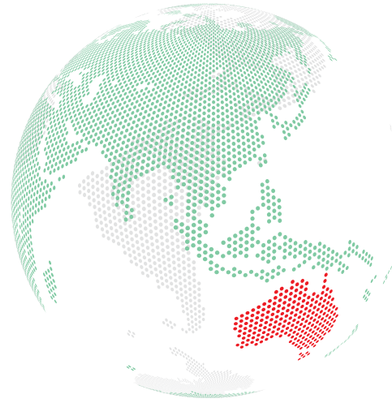
Australia relies heavily on global medicines supply chains. As a small, geographically distant island nation and relatively low-volume market, Australia competes for finite manufacturing capacity, active pharmaceutical ingredients, packaging inputs, logistics capacity and finished product supply. Summit participants emphasised when global shocks occur, suppliers must make allocation decisions across markets, and Australia's lack of commercial attractiveness can affect where limited stock is prioritised.

External shocks, such as sudden increases in freight, fuel, insurance, manufacturing or logistics costs, do not create the underlying sustainability problem. They expose it. Where PBS prices remain fixed or continue to decline while input costs increase, suppliers have less flexibility to maintain supply, absorb disruption, or compete for limited global stock.

Domestic policy settings cannot eliminate global volatility, but they can either increase or reduce Australia's resilience.

Australia in the Global Context

- A small player in a highly competitive global market
- 0.33% of the global population
- Global manufacturing is dominated by large-scale markets
- In global markets, scale and commercial attractiveness drive prioritisation
- Australia is a price-taker and a demand-taker in global markets
- Real world challenges are constantly evolving, requiring adaptability



Locating Australia in the Global Health Context

Global demand is rising

- Healthcare demand and expenditure are increasing globally, driven by ageing populations, chronic disease and innovation
- Competition for medicines, manufacturing capacity and supply is intensifying across all markets

Australia in context

- Australia represents ~2% of global pharmaceutical demand[2]
- In global markets, scale and commercial attractiveness drive prioritisation

Australia's health expenditure

- Australia's total health expenditure continues to grow in line with global trends
- However, this is driven primarily by hospital and service costs, expenditure on medicines is declining

Pricing reality

- Australia sits in the bottom 25% of international medicine pricing
- Australia is a low-price, small-volume market operating in a rapidly expanding global system.

2. https://doi.org/10.1016/j.sapharm.2020.12.001

Generic and biosimilars account for over 70 per cent of medicines supplied through the Pharmaceutical Benefits Scheme, while representing less than 30 per cent of the cost to taxpayers.

Cost of inaction

The cost of inaction is not theoretical. Stakeholders consistently noted if current settings remain unchanged, Australia will continue to pay for shortages through poorer patient outcomes, avoidable workforce burden, inefficient emergency responses and a progressively less attractive market for essential medicines.

COST AREA	IMPACT OF INACTION
Patient outcomes	Delayed or interrupted treatment; uncertainty and anxiety; higher out-of-pocket costs in some shortage scenarios; potential clinical deterioration; and avoidable hospital, specialist or GP demand.
Healthcare workforce burden	Pharmacists, GPs, specialists and hospital teams spend time sourcing stock, identifying alternatives, adjusting treatment plans, explaining different delivery systems and dosage requirements, reassuring patients and managing local workarounds.
System inefficiency	Siloed queries, duplicated hospital responses, fragmented communication, inefficient stock movements, and emergency action once the shortage is already visible.
Emergency supply costs	Expedited freight, emergency importation, destruction of emergency stock, substitutions and non-standard products can cost more than earlier investment in sustainable supply settings.
Market sustainability	Ongoing price compression, rising supply costs and uncertainty about future policy settings can make it less attractive for suppliers to enter or remain in Australia. This can increase reliance on a single supplier, reduce competitive redundancy, and leave fewer options when global disruptions occur.
Wastage and opportunity cost	Poorly targeted stockholding obligations can create short-dated stock, expiry, storage pressure and capital tied up in inventory that may never be needed.

Generic and biosimilar medicines contribution

Generic and biosimilar medicines are the backbone of everyday essential medicine supply in Australia. By volume, they account for more than 70 per cent of medicines supplied through the Pharmaceutical Benefits Scheme, while representing less than 30 per cent of the cost to taxpayers[3]. Because this sector supplies most PBS medicines, its strength and resilience are critical to maintaining reliable and affordable access for Australian patients.

The health of the generic and biosimilar medicines sector is therefore a key measure of the resilience of Australia's medicines system. When market conditions make it difficult for suppliers to enter or remain in Australia, the consequences can extend across the health system, increasing reliance on fewer suppliers and reducing the availability of backup supply when disruptions occur.

Sponsors have deep expertise in supply chain management

Sponsors undertake extensive work to anticipate risks, manage inventory, and respond to supply disruptions. It is essential PBS and regulatory settings focus on addressing root causes of supply disruptions and do not undermine the commercial viability of maintaining a reliable supply in the first place.

3. Data on file

Action Plan and Indicative Timeframes

Translating these opportunities into meaningful change will require coordinated action across the medicines ecosystem. GBMA is committed to working collaboratively with Government, the Department of Health, Disability and Ageing, the TGA, industry partners and broader supply-chain stakeholders to deliver practical solutions, agree priorities and establish clear implementation pathways.

The following Action Plan outlines the proposed areas of focus, key activities and indicative timeframes to progress these recommendations and strengthen Australia's medicine supply resilience.

ADDRESS ROOT CAUSES

Strengthen long-term PBS sustainability settings

In the Strategic Agreements

What Government, Department and Industry Should Do Now

1. **Review and update PBS floor price settings**
Ensure they recognise value, supply continuity and competition and move away from price only considerations.

2. **Introduce targeted Indexation**
Prevent erosion of floor price value and reduce emergency interventions.

3. **Reassess Minimum Stockholding Requirement (MSR) scope and design**
Focus MSR on medicines with genuine vulnerability and avoid unnecessary expansion.

4. **Recognise wholesaler stock in MSR compliance**
Provide a more accurate picture of national supply.

5. **Partner with industry to quantify stockholding costs**
Use real world data to inform MSR design and avoid unintended consequences.

MANAGE SYSTEMS (BACK-END)

Improve shortage management, coordination and communication

In the short-term

What Government, Department and Industry Should Do Now

1. **Establish a targeted shortage management partnership**
Enable structured, early coordination between industry, peak bodies and Government.

2. **Enhance the TGA Medicine Shortages Database**
Group by molecule and provide audience specific views.

3. **Support two way dialogue during emerging risks**
Enable safe, aggregated coordination without compromising commercial confidentiality

4. **Provide practical clinical guidance within the database**
Include substitution pathways and alternative options where appropriate.

INCREASE PRODUCTIVITY

Streamlining regulations to boost efficiency and resilience, without lowering standards

With mid/long-term system changes

What Government, Department and Industry Should Do Now

1. **Expand reliance and recognition pathways**
Use trusted overseas regulatory decisions to accelerate access to safe, high quality medicines.

2. **Modernise the Section 19A pathway**
Clarify criteria, improve timelines, and ensure it remains an emergency mechanism.

3. **Streamline administrative processes during shortages**
Reduce friction, simplify documentation, and improve escalation pathways.

4. **Provide clear, consistent regulatory guidance to sponsors**
Ensure expectations are consistently understood, especially during supply stress.

5. **Enable faster approval of variations that support supply continuity**
Prioritise pack size changes, manufacturing site changes, and other supply critical variations.

What This Reform Package Delivers

For Patients
- Fewer shortages
- Clearer information
- Faster access to alternatives
- Reduced anxiety and disruption

For Clinicians & Pharmacists
- Better visibility of real world supply
- Practical substitution guidance
- Less time spent sourcing stock

For Government
- A more resilient PBS
- Lower emergency response costs
- Stronger market participation
- Better alignment between affordability and availability

For Industry
- Predictable, sustainable settings
- Clearer regulatory pathways
- More effective and efficient coordination

Affordability, availability and resilience must be connected. This reform package strengthens all three, ensuring Australian patients can rely on the medicines they need, when they need them.

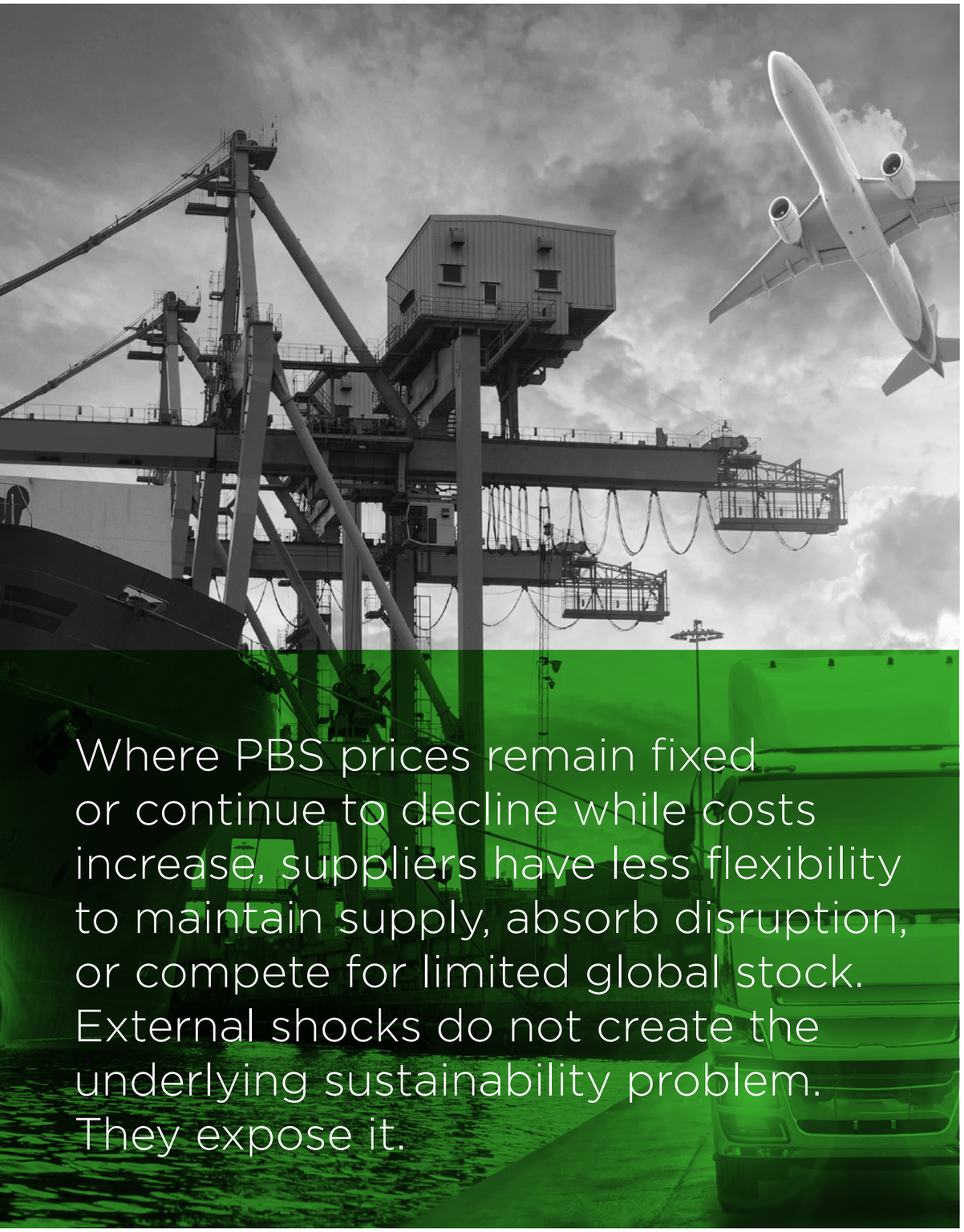
Australia needs a medicines supply system that is affordable, reliable and resilient.

Conclusion

Australia needs a medicines supply system that is affordable, reliable and resilient. At present, those objectives are not sufficiently connected. Policies that achieve low prices but weaken market participation can ultimately reduce patient access and increase whole-of-system costs.

COVID-19, global conflict, geopolitical tensions, energy shocks and inflation have all reinforced the same lesson: Australia cannot control global supply volatility, but it can choose whether domestic settings make the country more or less resilient when volatility occurs.

The reform package in this paper is practical and proportionate. It recognises the importance of PBS affordability, but affordability cannot be separated from continuity of supply. It recognises the role of minimum stockholding, but stockholding must be risk-based, evidence-led and assessed against its full cost. It recognises the importance of communication and emergency pathways, but more information and more section 19A activity are not substitutes for a sustainable medicines market.



Where PBS prices remain fixed or continue to decline while costs increase, suppliers have less flexibility to maintain supply, absorb disruption, or compete for limited global stock. External shocks do not create the underlying sustainability problem. They expose it.

Appendix One

THEME ONE: STRENGTHEN LONG-TERM PBS SUSTAINABILITY SETTINGS AND SUPPLY CONTINUITY

Why this matters

Affordable medicines are a core strength of Australias PBS. However, affordability only matters if medicines remain available. For many essential, high volume, low cost medicines, cumulative price reductions and rising global supply costs have created a widening gap between policy intent and commercial reality.

The Problem

PBS prices for essential medicines have eroded over time

Floor prices were introduced to prevent medicines falling below a viable level, but they have not been reviewed or indexed. As manufacturing, freight, API, energy and stockholding costs rise, the real value of the floor price falls.

Suppliers cannot absorb rising global costs indefinitely

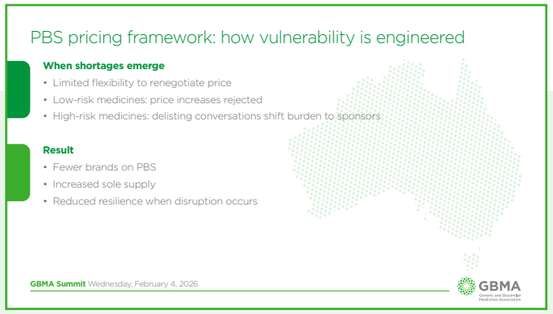
Summit stakeholders highlighted that during global shocks, Australian sponsors must compete for limited stock while facing rising upstream costs. Current PBS settings give them no flexibility to respond.

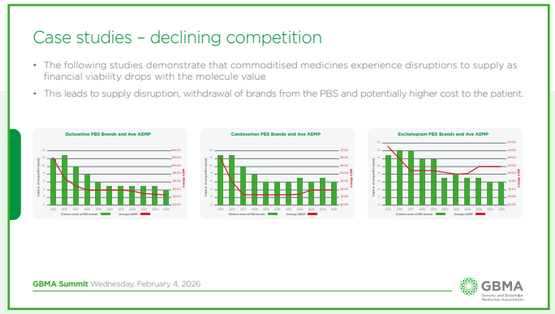
Minimum Stockholding Requirements (MSR) are not targeted

MSR do not address the root causes of shortages. If applied too broadly, MSR can:

- create short dated stock
- increase wastage
- tie up capital
- push suppliers out of the market

Stockholding is not a substitute for a sustainable medicine market. The result is a growing mismatch between the policy objective of maintaining low prices and the practical requirements of maintaining supply.





Policy Objective
To ensure essential medicines remain viable to supply in Australia by aligning PBS pricing and stockholding settings with real world supply costs and risks.

A medicine is only affordable if it remains available to patients when needed.

Practical Policy Settings

Reform 1: Review floor price settings and introduce targeted indexation

Action
- Conduct a targeted review of PBS floor price settings for low cost essential medicines.
- Introduce a transparent indexation mechanism so floor prices maintain real value over time.

Purpose
- Prevent erosion of viability for essential medicines.
- Reduce reliance on ad hoc price increases or emergency interventions.
- Support multi supplier competition and supply continuity.

Outcome
- A predictable, sustainable pricing environment that preserves supply before shortages occur.

Reform 2: Review Minimum Stockholding Requirements (MSR) to ensure proportionality

Action
- Reassess the list of medicines subject to MSR to ensure it targets products with genuine supply vulnerability.
- Recognise wholesaler stock in MSR compliance to reflect real world supply.
- Work with industry to quantify stockholding costs, wastage, storage pressure and capital impacts.
- Avoid broad expansion of MSR without evidence of benefit.

Purpose
- Ensure MSR delivers genuine resilience rather than unnecessary cost and waste.
- Reduce unintended consequences such as product withdrawal or reduced competition.

Outcome
- A risk based, evidence led MSR that strengthens, rather than distorts, supply resilience.

What Government, Department and Industry Should Do Now

1. **Review and update PBS floor price settings**
   Ensure they reflect current supply costs and remain viable over time.
2. **Introduce targeted indexation**
   Prevent erosion of floor price value and reduce emergency interventions.
3. **Reassess MSR scope and design**
   Focus MSR on medicines with genuine vulnerability and avoid unnecessary expansion.
4. **Recognise wholesaler stock in MSR compliance**
   Provide a more accurate picture of national supply.
5. **Partner with industry to quantify stockholding costs**
   Use real world data to inform MSR design and avoid unintended consequences.
6. **Maintain multi supplier competition as a core PBS sustainability outcome**
   A viable market is the strongest protection against shortages.

Real-Life Policy Impacts

CASE STUDY ONE: Nicotine Patches - When PBS Pricing Threatens Supply

In 2023, access to subsidised nicotine replacement therapy (NRT) was threatened following the withdrawal of nicotine gum and lozenges from the Pharmaceutical Benefits Scheme (PBS) and a scheduled 26% statutory price reduction for nicotine patches.

These changes placed nicotine patches at high risk of delisting, raising significant public health and equity concerns.

Aboriginal, Torres Strait Islander peoples and other priority populations disproportionately rely on PBS subsidies to access first line smoking cessation therapy. Nicotine patches are a World Health Organization Essential Medicine and are often the only recommended pharmacotherapy for people who are pregnant or unable to use alternative treatments.

National Aboriginal Community Controlled Health Organisation (NACCHO) led a coordinated advocacy response, engaging clinical, public health and consumer stakeholders. The Minister for Health and Aged Care, the Hon Mark Butler MP, used his Ministerial discretion to exempt nicotine patches from the statutory price reduction. NACCHO emphasised that fair and appropriate PBS pricing is essential to retain multiple generic brands, protecting supply continuity, consumer choice and resilience against medicine shortages.

Policy Significance
PBS pricing settings can unintentionally destabilise supply of essential medicines. When prices fall below viability, medicines can disappear from the market, even when clinically critical.

CASE STUDY TWO: Pain medicines - Global Market Contraction Meets Local Vulnerability[4,5]

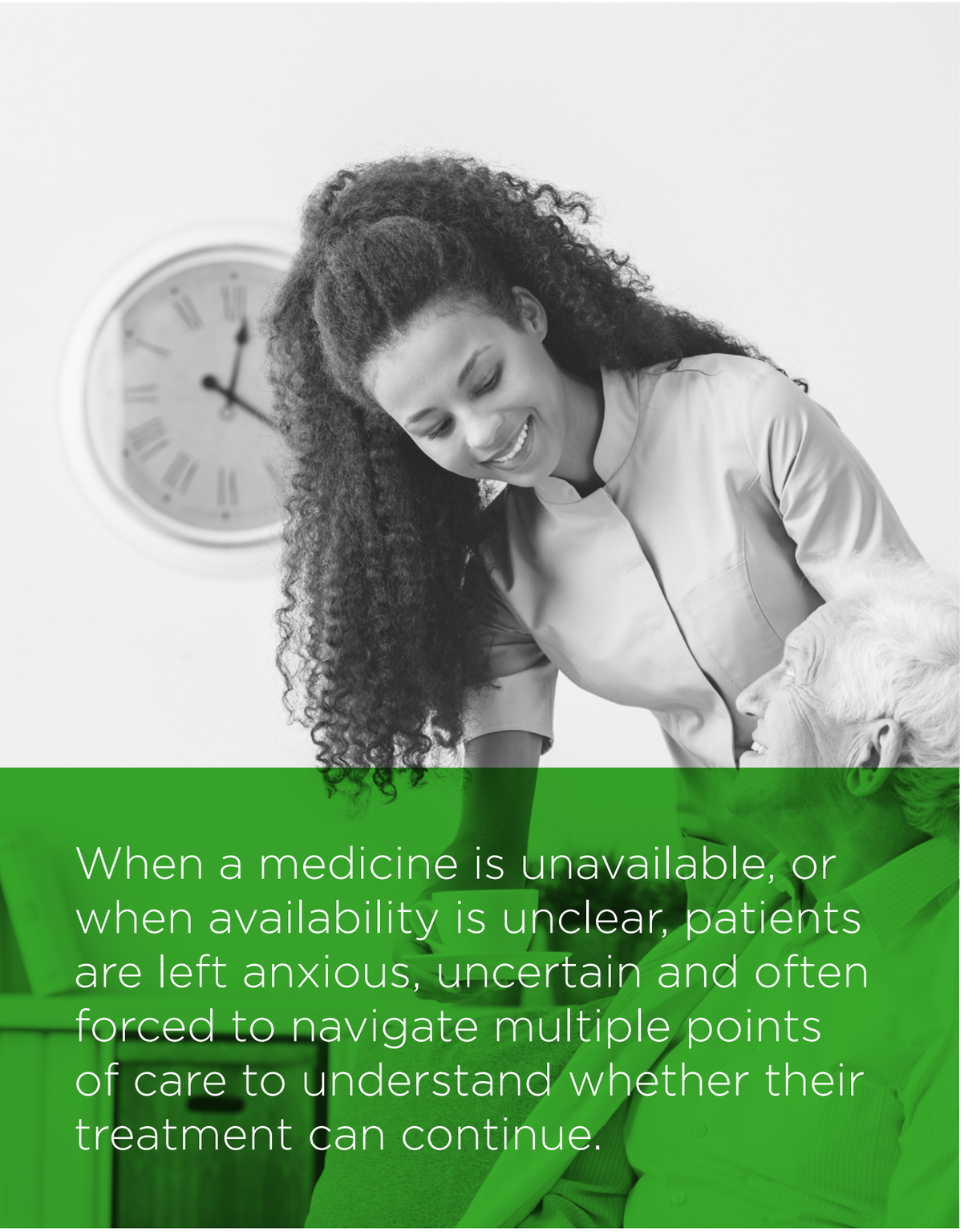
In early 2023, oral liquid morphine was removed from the Australian market, followed by discontinuations of multiple morphine and oxycodone products used in palliative care and chronic pain management.

"The global market has shrunk, impacting pricing and availability of these critical medicines."

Australia's low prices make it harder to retain supply when global markets contract. These shortages threaten patients quality of life due to side effects, substandard treatment and increased costs.

Policy significance
When global supply tightens, Australia must be commercially competitive or risk losing access to critical medicines.

4. Ongoing pain medicine shortages risks quality of life for all Australians - Palliative Care Australia
5. Palliative care patients face added stress and extra costs amid pain medicine shortages - ABC News



When a medicine is unavailable, or when availability is unclear, patients are left anxious, uncertain and often forced to navigate multiple points of care to understand whether their treatment can continue.

Appendix Two

THEME TWO: IMPROVE SHORTAGE IDENTIFICATION, COORDINATION AND COMMUNICATION

Why this matters

Medicine shortages are ultimately experienced by patients first. When a medicine is unavailable, or when availability is unclear, patients face anxiety, delays, additional appointments, and uncertainty about whether their treatment can continue. This uncertainty flows through the health system: specialists must consider alternatives, pharmacists spend significant time sourcing stock, and hospitals develop local workarounds.

Australia has strong mechanisms for managing shortages once they are visible, but these tools are reactive. By the time a shortage appears on the TGA database, the opportunity to prevent disruption has often passed.

Stakeholders at the GBMA Summit were clear: Australia needs clearer communication, and more coordinated action.

The Problem

Current communication tools are not user friendly

The TGA Medicine Shortages Database provides transparency, but it is not designed for:

- patients
- clinicians
- pharmacists needing practical guidance.

Current limitations of medicine shortages database

- Potential to cause undue concern.
  - As of 10 April 2026, the database reports 389 current shortages.
  - However, 232 (60%) of these have alternate ARTG registered brands available.
  - Without this context, the headline figure may appear alarmingly high and does not accurately reflect real-world medicines supply.
- Limited patient-relevant visibility – the database does not present information in a way that is easily understood or meaningful, and in fact can be misleading.
- Reporting is at the sponsor level and does not reflect pharmacy-level stock or local availability.

The database does not present information in a way that is easily understood or meaningful, and in fact can be misleading.

Lack of coordination increases system wide burden

Without structured two way dialogue, individually rational decisions, such as increasing local stock “just in case”, can worsen national shortages.

Policy Objective

To coordinate responses more effectively, and provide clear, clinically useful information to patients and healthcare professionals.

Practical Policy Settings

Reform 1: Co-design a targeted shortage management partnership with Government and the TGA

Action

- Establish a structured, lawful mechanism for coordination between sponsors, peak bodies, the TGA and Government.
- Work with GBMA and other peak bodies as neutral coordination points where appropriate.
- Build on existing mechanisms such as TGA shortage risk assessments and medicine action groups.
- Enable two-way dialogue so sponsors can understand broader market context and respond proportionately.

Purpose

- Earlier coordination, before they escalate into patient level disruption.
- Reduce siloed responses and improve national coordination.
- Ensure commercially sensitive information is shared safely and appropriately.

Outcome

- A more agile system that coordinates responses more effectively.

Reform 2: Update the TGA Medicine Shortages Database to improve clarity and usability

Action

- Group shortages by molecule/active ingredient first, with brand level detail underneath.
- Create audience specific views for patients, pharmacists, prescribers and sponsors.
- Include practical information on alternatives and substitution pathways where clinically appropriate.

Purpose

- Provide a clearer picture of whether a shortage affects patients, not just individual brands.
- Reduce unnecessary anxiety and prevent over ordering.
- Support clinicians and pharmacists with actionable information.
- Poor visibility drives defensive behaviours such as stockpiling and duplicated sourcing efforts, increasing system-wide costs.

Outcome

- A database that functions as a clinical and operational tool, not just a list of unavailable products.

REAL LIFE COORDINATION EXAMPLE

COVID 19: Medicines Shortages Working Party (MSWP)

During the pandemic, the Medicines Shortages Working Party — run by GBMA and Medicines Australia under an ACCC determination

This group demonstrated that temporary, authorised information sharing can improve coordination when designed with clear safeguards.

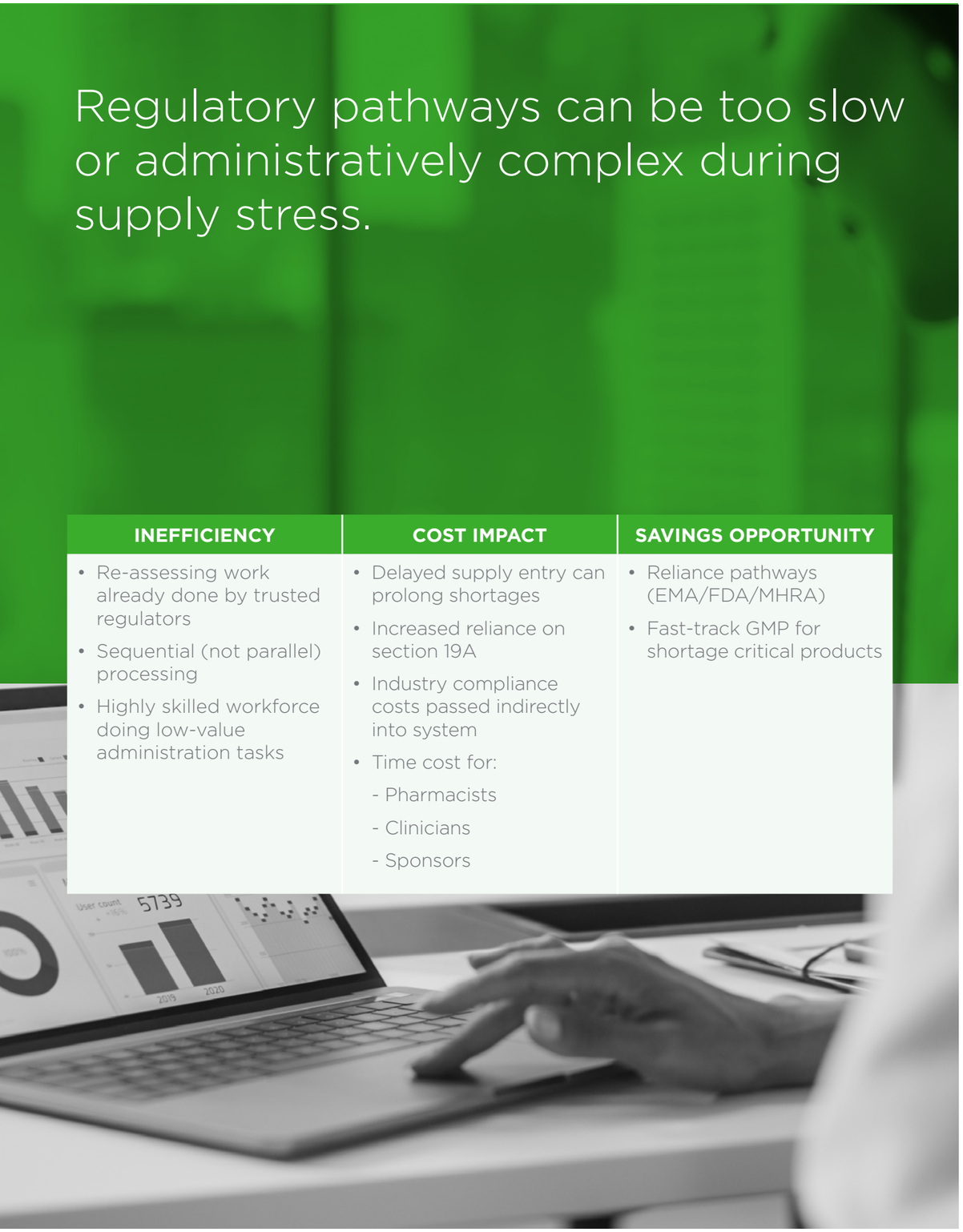
This model shows that structured, lawful collaboration works and can be adapted for ongoing shortages management.

View an example process flow of how this was managed

PROPOSED IMPROVEMENT	RATIONALE
Group shortage reporting by molecule/ active ingredient first, with brand-level detail underneath.	Helps users distinguish between a brand shortage and a patient-level access problem for the medicine as a whole.
Create audience-specific views or guidance for patients, pharmacists, prescribers and sponsors.	Different users need different information. A patient-facing view should reduce anxiety; a sponsor view may require more operational detail.
Include practical information on alternatives and substitution pathways where clinically appropriate.	Moves the database from a list of what is unavailable to a tool that supports action.

What Government, Department and Industry Should Do Now

1. **Establish a targeted shortage management partnership**
   Enable structured coordination between industry, peak bodies and Government.
2. **Enhance the TGA Medicine Shortages Database**
   Group by molecule, and provide audience specific views.
3. **Support two way dialogue during emerging risks**
   Allow sponsors to understand broader market context and respond proportionately.
4. **Use peak bodies to reduce competition law**
   Enable safe, aggregated coordination without compromising commercial confidentiality.
5. **Provide practical clinical guidance within the database**
   Include substitution pathways and alternative options where appropriate.
6. **Shift from reactive to proactive shortages management**
   Identify risks earlier and act before patients are affected.



INEFFICIENCY	COST IMPACT	SAVINGS OPPORTUNITY
• Re-assessing work already done by trusted regulators • Sequential (not parallel) processing • Highly skilled workforce doing low-value administration tasks	• Delayed supply entry can prolong shortages • Increased reliance on section 19A • Industry compliance costs passed indirectly into system • Time cost for: - Pharmacists - Clinicians - Sponsors	• Reliance pathways (EMA/FDA/MHRA) • Fast-track GMP for shortage critical products

Appendix Three

THEME THREE: STREAMLINING REGULATIONS TO BOOST EFFICIENCY AND RESILIENCE, WITHOUT LOWERING STANDARDS

Why this matters

Australia's regulatory system is internationally respected for its rigour and safety. However, during periods of supply stress, regulatory processes can be too slow, too complex, or too administratively burdensome to support timely responses. This can delay access to alternative products, prolong shortages, and increase pressure on patients, clinicians and suppliers.

Streamlining regulation does not mean lowering standards. It means ensuring that safe, high quality alternatives can reach patients faster, and that sponsors can respond more efficiently when global disruptions occur.

Stakeholders at the GBMA Summit consistently emphasised that regulatory agility is essential to supply resilience. Australia has strengthened its capacity to manage shortages, but not the capacity to prevent them. Stakeholder feedback reinforced that regulatory settings must be capable of operating differently during supply stress.

The Problem

Reliance and recognition pathways are under-utilised

Australia has access to high quality regulatory decisions from trusted overseas regulators. However, reliance and recognition pathways are not used to their full potential, leading to:

- slower approvals
- duplicated assessment effort
- delayed access to alternative products during shortages

Section 19A is being used as a routine pressure valve

Section 19A is intended as an emergency mechanism to allow temporary importation when no registered product is available. But because other regulatory pathways are slow, Section 19A is increasingly used as a default workaround, creating:

- administrative burden
- unpredictable timelines
- reliance on non standard products
- repeated emergency responses

The steep increase in section 19A approvals between 2021 and 2024 (26 vs. 130 approvals, respectively) reflects growing systemic strain.

YEAR	NUMBER OF S19A APPROVALS
2021	26
2022	49
2023	26
2022	49
2021	26

By the time a section 19A is triggered, therapeutic alternatives, continuity of care and affordability are already significantly compromised.

Administrative complexity slows down supply responses

Regulatory processes that are clear, remove duplication, have clear escalation pathways and have consistent expectations will support agility and response time-frames that help to mitigate against shortages eventuating.

Policy Objective

To ensure Australia can respond faster and more efficiently to supply disruptions by modernising regulatory pathways, reducing unnecessary administrative burden, and preserving high safety and quality standards.

Practical Policy Settings

Reform 1: Increase the use of reliance and recognition pathways

Action

- Expand and formalise reliance on trusted overseas regulators for assessments, variations and approvals.
- Prioritise reliance pathways during shortages or when alternative products are urgently needed.
- Provide clear guidance to sponsors on when
- and how reliance pathways can be used.

Purpose

- Reduce duplication of regulatory effort.
- Accelerate access to safe, high quality medicines.
- Improve Australia's competitiveness for global supply allocation.

Outcome

- Faster approvals, reduced administrative burden, and more timely access to alternatives during shortages.

Reform 2: Reform the Section 19A pathway to ensure it is predictable, proportionate and used appropriately

Action

- Clarify the criteria, timelines and documentation requirements for Section 19A approvals.
- Introduce service standards or indicative timeframes for urgent cases.
- Ensure Section 19A remains an emergency mechanism, not a routine substitute for viable regulatory pathways.
- Improve coordination between TGA, sponsors and peak bodies during 19A applications.

Purpose

- Reduce uncertainty and administrative burden for sponsors.
- Ensure emergency imports are used only when necessary.
- Improve patient access to temporary alternatives during genuine shortages.

Outcome

- A more predictable, proportionate and efficient emergency import pathway.

Reform 3: Streamline regulatory processes to reduce friction during supply stress

Action

- Review and simplify administrative requirements that slow down responses during shortages.
- Improve escalation pathways within the TGA for emerging supply risks.
- Provide clearer, more consistent guidance to sponsors on regulatory expectations during shortages.
- Enable faster approval of pack size changes, manufacturing site changes, and other variations that support continuity of supply.

Purpose

- Reduce avoidable delays.
- Ensure regulatory processes support, rather than hinder, supply resilience.
- Allow sponsors to respond more quickly to global disruptions.

Outcome

- A more agile regulatory system that maintains safety while enabling faster, more coordinated action.

REAL WORLD IMPLICATIONS

A more agile regulatory system protects patients

When regulatory processes are slow or unclear, patients experience:

- delayed access to alternatives
- prolonged shortages
- increased anxiety and uncertainty
- additional appointments and clinical burden

Streamlined regulation ensures tha**t safe, effective alternatives reach patients faster,** reducing the real world impact of shortages.

A more predictable system supports market participation

Sponsors are more likely to maintain supply in Australia when regulatory processes are:

- clear
- timely
- proportionate
- predictable

This strengthens market viability — a core driver of supply resilience.

What Government, Department and Industry Should Do Now

1. **Expand reliance and recognition pathways**
   Use trusted overseas regulatory decisions to accelerate access to safe, high quality medicines.
2. **Modernise the Section 19A pathway**
   Clarify criteria, improve timelines, and ensure it remains an emergency mechanism.
3. **Streamline administrative processes during shortages**
   Reduce friction, simplify documentation, and improve escalation pathways.
4. **Provide clear, consistent regulatory guidance to sponsors**
   Ensure expectations are consistently understood, especially during supply stress.
5. **Enable faster approval of variations that support supply continuity**
   Prioritise pack size changes, manufacturing site changes, and other supply critical variations.

About GBMA

The GBMA is the national association representing companies that manufacture, supply and export generic and biosimilar medicines. Members of GBMA ensure all Australians are offered high quality generic and biosimilar medicines, which provide affordable health outcomes that benefit all Australians.

The generic and biosimilar medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public. GBMA members have invested over $500 million of additional inventory and supply infrastructure for PBS medicines, improving access and health security for Australia.

Contact Details

Generic and Biosimilar Medicines Association
Level 17, 1 Denison St, North Sydney NSW 2060
admin@gbma.com.au

GBMA