# Response ID ANON-TKS9-WDUC-X

Submitted to Consultation: Improved sharing of information about medical devices | Proposed amendments relating to transparency of disruptions to supply of a medical device
Submitted on 2026-02-13 14:49:16

## Introduction

About you

What is your name?:
[redacted]

What is your email address?:
[redacted]

Are you responding as an individual or on behalf of an organisation?

I am responding on behalf of an organisation. This means I am authorised by the organisation to convey its views, and I am only providing those views in the response.

If you are responding on behalf of an organisation, what is the name of the organisation that you represent?

Please enter your organisation name:
National Aboriginal and Torres Strait Islander Ageing and Aged Care Council (NATSIAACC)

Select one (or more if applicable) of the stakeholder groups that best describes you or your organisation:

Health professional or practitioner or peak body

Specify 'Other' in the box below:

Privacy and Personal Information

I CONSENT: I am okay for my response and organisation's name to be published, but not my name.

Have you provided consent but there are particular questions you don't want us to publish?:

The TGA is aware that Artificial Intelligence (AI) may be used to assist in preparing responses to this consultation. It is a respondent's responsibility to ensure the accuracy of their response.

I acknowledge that I am responsible for reviewing and confirming the accuracy and completeness of my submission, accepting full responsibility for its content. I may have used AI in preparing my response; where AI has been used, I confirm that the content has been reviewed and confirmed by me.

## Questions 1 and 2

1 Do you agree that the TGA should release information about medical devices for the purpose of managing shortages or disruptions to supply?

Yes

a. Please explain your answer (optional):

NATSIAACC supports the release of information by the TGA about medical device shortages and supply disruptions. We acknowledge that the TGA already publishes such information and undertakes related communication activities. However, from the perspective of older people, carers, and aged care services, particularly Aboriginal and Torres Strait Islander Elders and Older People and providers, the current approach does not consistently meet the needs of those most affected by shortages and disruptions.

For Aboriginal and Torres Strait Islander Elders and Older People, access to timely, clear and culturally safe information about medical device shortages and supply disruptions is critical to maintaining health, dignity and connection to Country/Island Home, family and community. Elders and Older People often rely on medical devices and assistive technologies to remain living at home and on Country/Island Home, where wellbeing is closely tied to cultural, social and spiritual connection. When information about device availability is unclear, highly technical or difficult to access, Elders and Older People are placed at greater risk of unplanned care disruptions, avoidable hospitalisation, and inappropriate substitution of devices that may not be culturally or clinically suitable.

Information is often technically complex, difficult to navigate, and not clearly tailored to aged care contexts. Existing communication channels, including web-based notices, social media, and the information enquiries service, do not reliably reach or support Elders, Older People, carers, families, or aged care providers, especially those operating in regional, rural and remote areas. As a result, critical information intended to support continuity of care, safety, and preparedness may not translate into meaningful, timely action on the ground.

We therefore strongly encourage the TGA to move beyond the question of whether information is released, and instead focus on how information is structured, communicated, targeted, and co-designed, so that it is genuinely accessible, culturally safe, and fit for purpose for Elders, Older People, communities and Aged Care settings.

2 Should the information be released publicly or be limited to specific stakeholders only?

Yes

a. Please explain your answer (optional):

NATSIAACC supports a tiered transparency approach, underpinned by the principle that information relevant to care delivery must be accessible to older people, their carers and families, while ensuring appropriate safeguards are in place to protect privacy, dignity and community context.

Consistent with the Statement of Rights under the Aged Care Act 2024, information relating to medical devices included in the Assistive Technology and Home Modifications (AT-HM) list should be publicly available in clear, culturally appropriate and easily understandable formats. Public access to this information will support Aboriginal and Torres Strait Islander Elders, families and communities to make informed decisions about assistive technology and home modifications that directly affect safety, independence, and quality of life, particularly in rural, remote and thin market settings where access to independent advice may be limited.

At the same time, NATSIAACC recommends that the broader disclosure framework operate through a tiered transparency model, whereby high-level product, safety, performance and eligibility information is publicly accessible, while more granular, commercially sensitive, or community-identifiable data is appropriately restricted to authorised stakeholders, including ACCOs and relevant government partners. This approach ensures accountability and informed consumer choice, while also preventing misuse, misinterpretation, or deficit-framing of data relating to Aboriginal and Torres Strait Islander communities.

Overall, NATSIAACC strongly recommends a tiered model that maximises public accessibility of consumer-relevant information while maintaining necessary protections for privacy, cultural context, and community integrity.

## Questions 3 and 4

3 If we do not make information about disruptions to supply of a medical device publicly available, do you agree that information about supply disruptions should be released to the stakeholders outlined above?

Yes

a. Please explain your answer (optional) :

NATSIAACC agrees that, where information about medical device supply disruptions is not made publicly available, it must at a minimum be proactively and simultaneously released to all relevant health system stakeholders, including Aboriginal Community Controlled Health Organisations (ACCHOs) and their national and jurisdictional peak bodies.

ACCHOs are primary providers of culturally safe health and aged care services for many Aboriginal and Torres Strait Islander Elders, Older People and communities, particularly in regional, rural and remote communities. Excluding the community-controlled sector from early notification processes would create significant risks to continuity of care, timely clinical decision-making, and the ability of services to plan for suitable alternatives that are operationally viable within local workforce, infrastructure and geographic constraints.

NATSIAACC therefore recommends that notification frameworks for supply disruptions explicitly recognise ACCHOs, Aboriginal and Torres Strait Islander aged care providers, and their peak organisations as priority stakeholders, ensuring they receive the same timely alerts as state and territory health departments, hospitals, and professional bodies. This approach will support coordinated service planning, maintain trust with Elders, Older People and communities, and ensure that any substitute devices or solutions are clinically appropriate, culturally safe, and practical for use across diverse service delivery settings.

4 Do you have any concerns regarding the proposal for releasing information about disruptions to supply for a medical device?

Yes

a. Please explain your answer (optional):

Yes. NATSIAACC has several concerns regarding the current proposal for releasing information about medical device supply disruptions, particularly where the notification framework does not explicitly include the Aboriginal Community Controlled sector and Aboriginal and Torres Strait Islander aged care providers as priority recipients of early alerts.

Without formal inclusion of Aboriginal Community Controlled Health Organisations (ACCHOs), Aboriginal and Torres Strait Islander aged care providers, and their peak bodies (national and state/jurisdictional) in the initial notification process, there is a significant risk that services supporting Aboriginal and Torres Strait Islander People, particularly in regional, remote and very remote communities, may experience delays in receiving critical information. These delays could reduce the ability of providers to secure alternative devices before local stocks are exhausted, potentially disrupting continuity of care and increasing clinical and operational risk.

NATSIAACC is also concerned that, in the absence of early engagement with Aboriginal and Torres Strait Islander providers, alternative devices identified

through mainstream channels may not always be operationally suitable for remote infrastructure environments, workforce availability, or culturally safe service delivery contexts. Ensuring that community-controlled providers are notified early and involved in response planning supports locally informed transition strategies, maintains trust with Elders, Older People and communities, and aligns with the intent of Priority Reform 4 of the National Agreement on Closing the Gap, which emphasises shared access to data and information to enable informed decision-making.

NATSIAACC therefore recommends that the proposal be strengthened to explicitly recognise ACCHOs, Aboriginal and Torres Strait Islander aged care providers, and their peak organisations as core stakeholders within the early notification and response framework, ensuring equitable, timely, and coordinated management of supply disruptions across all service settings.

## Questions 5, 6 and 7

### 5 Do you agree it is appropriate for the TGA to release the information identified above in the event of a disruption to supply of a medical device?

No

a. Please explain your answer (optional):

NATSIAACC agrees that information regarding disruptions to the supply of medical devices should be released by the TGA to support timely management of clinical and service delivery risks; however, an "as needed" disclosure model must be clearly defined and applied in a way that ensures Aboriginal and Torres Strait Islander service providers are not inadvertently excluded from critical information flows.

Applying identical disclosure provisions for all stakeholder groups may not be appropriate, as stakeholders engage with end-users and communities in different ways and require different levels of operational detail. For Aboriginal and Torres Strait Islander Elders, Older People, families, carers and communities, the elements identified as publicly available information, when communicated in culturally safe, accessible and easy-to-understand formats, are generally sufficient to support informed decision-making and consumer awareness.

However, Aboriginal Community Controlled Organisations (ACCOs), Aboriginal and Torres Strait Islander aged care providers, and national and state/territory peak bodies, including NATSIAACC, should consistently receive the additional information identified as not publicly available, such as anticipated duration of shortages, known stock levels, and the reasons for supply disruptions. Access to this information is essential to enable proactive service planning, procurement adjustments, clinical risk management, and coordination of suitable alternatives, particularly in regional, remote and thin market settings.

NATSIAACC therefore supports the release of disruption-related information under the proposal, provided that the framework explicitly recognises community-controlled organisations, aged care providers, and sector peak bodies as priority operational stakeholders who routinely receive both public and restricted operational information necessary to manage the impact of supply disruptions effectively, while maintaining appropriate safeguards for privacy and commercial sensitivities.

### 6 Should sponsors of medical devices impacted by disruption to supply be provided with a notice of intent and offered an opportunity to comment on the release of the information?

No

a. Please explain your answer (optional):

Yes. NATSIAACC supports sponsors of medical devices being provided with a notice of intent and an opportunity to comment on the release of information regarding supply disruptions, provided that the process is clearly time-limited, risk-based, and does not delay disclosure where patient safety, continuity of care, or service delivery risks are present.

Providing sponsors with an opportunity to verify factual details, such as the scope of the disruption, anticipated duration, affected product lines, and available alternatives, can improve the accuracy and usefulness of information released to providers, aged care services, and consumers. This approach should operate within a defined verification timeframe to ensure that engagement with sponsors strengthens transparency without unintentionally slowing the release of critical information needed by clinicians, providers, and communities to plan appropriate responses.

NATSIAACC recommends that the Therapeutic Goods Administration adopt a risk-proportionate consultation model, whereby sponsors are notified of the intent to publish disruption information and invited to provide clarification within a short, clearly specified period. In circumstances where a medical device is critical to continuity of care, particularly for services supporting Aboriginal and Torres Strait Islander Elders and Older People, people in remote communities, or thin market settings, verification processes should occur rapidly and in parallel with early stakeholder notifications to ensure providers, including Aboriginal Community Controlled Organisations and aged care services, receive timely alerts.

This approach balances regulatory accuracy with the imperative for timely transparency, ensuring that information released is both reliable and available early enough to support service continuity, procurement planning, and culturally safe care delivery.

### 7 Please provide any further feedback or comments you have regarding proposals to collect and share information about disruption to supply of a medical device.

Please provide any further feedback in this field.:

NATSIAACC supports proposals to strengthen the collection and sharing of information relating to medical device supply disruptions and encourages the Therapeutic Goods Administration to adopt an approach that embeds health equity, early notification, and coordinated system response across all

jurisdictions and service settings.

In particular, NATSIAACC recommends that the information-sharing framework formally recognise Aboriginal Community Controlled Organisations (ACCOs), Aboriginal and Torres Strait Islander aged care providers, and relevant sector peak bodies (national and state/jurisdictional) as core operational stakeholders within notification and response arrangements. Ensuring these providers receive timely, actionable information alongside hospitals, state and territory health departments, and professional bodies will support continuity of care for Aboriginal and Torres Strait Islander People, especially in regional, remote and thin-market environments where alternative supply pathways may be limited.

NATSIAACC also encourages the development of clear, standardised notification protocols, including defined timeframes for alerts, consistent information fields (such as anticipated duration, stock availability, and recommended alternatives), and ongoing update mechanisms throughout the duration of a disruption. Providing accessible public-facing summaries, alongside more detailed operational information for providers, will further support informed decision-making by Elders, Older People, families, carers, and service providers while maintaining appropriate safeguards for commercially sensitive or privacy-protected data.

Overall, strengthening supply disruption notification systems through an equity-informed, coordinated and transparent approach will help ensure that all providers, particularly those serving Aboriginal and Torres Strait Islander communities, are equipped to respond early, maintain service continuity, and support safe, culturally appropriate care outcomes.

NATSIAACC calls for the TGA to move from a "mainstream-centric" notification model to a "Health Equity" model. This model should ensure that the Community Controlled sector is treated as an equal partner in managing supply disruptions, ensuring no Aboriginal or Torres Strait Islander Person is left at the end of a broken supply chain without a culturally safe alternative.