Response ID ANON-TKS9-WDUR-D

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 2026-02-20 14:32:07

Introduction

About you

What is your name?:
Kingston Wong

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:
Harrison-AI Medical Pty Ltd

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

Manufacturer (Australian), Australian Sponsor, Regulatory Affairs Consultant

Specify 'Other' in the box below:

Privacy and Personal Information

I CONSENT: I am okay for my response, name and organisation's name to be published.

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):

Harrison.ai supports the objective of improving transparency and coordination in relation to significant disruptions to the supply of higher□risk medical devices, where this is necessary to protect public health and to support continuity of care. However, it is not clear if the scope of these proposals include Software as a Medical Device (SaMD). Currently the proposals, as currently described, are primarily framed around physical medical devices and traditional supply chains, and may have unintended consequences if applied without adaptation to SaMD.

In other jurisdictions, medical device shortage is typically defined as a situation where supply is unable to meet demand for a given period. While this construct is well suited to physical devices and consumables, SaMD does not generally rely on traditional manufacturing, warehousing and logistics supply chains. For many SaMD products, supply is effectively continuous through digital deployment, with risk instead arising from other factors such as:
•cybersecurity incidents or infrastructure outages affecting availability or performance;
•planned deprecations of legacy versions;
•withdrawal from the market due to safety or performance concerns; and
•interoperability or integration dependencies (e.g. hospital IT infrastructure, third□party platforms).

If these disruption to supply proposals are extended to SaMD, then we would welcome further TGA guidance and consultation specifically addressing how the disruption to supply concept should be interpreted and applied for different kinds of devices such as SaMD, including examples of reportable and non□reportable scenarios, and how this would interact with existing incident, recall and cybersecurity reporting channels.

We therefore strongly recommend that:

1. The scope of the proposed mechanism be clearly defined. The consultation paper does not currently specify which kinds of devices or classes of devices are intended to be captured, nor what constitutes a “shortage” or “disruption to supply” in the context of different device categories, including SaMD. Clear definitions are critical so that obligations are predictable, proportionate, and consistently interpreted by sponsors and other stakeholders.

2. The framework be limited, at least initially, to physical medical devices where traditional supply constraints apply (e.g. implantables, critical life‑support equipment, essential consumables). For SaMD, the concept of shortage needs careful consideration and should be addressed using a risk‑based approach that reflects the actual modes of unavailability (e.g. system outages, planned decommissioning, dependence on external IT ecosystems), rather than physical stock levels.

3. The scope be focused on higher‑risk devices and situations where unavailability could reasonably be expected to lead to death, serious injury, or serious public health impact (e.g. critical life‑support systems, diagnostic technologies essential to acute care, or devices of declared public interest such as ventilators or respiratory support equipment during a pandemic). This aligns with the patient‑centred intent of the TGA’s medical devices action plan and avoids diluting the signal with large volumes of low‑impact notifications.

4. Not all disruptions be required to be published, especially where the manufacturer can provide suitable alternatives or work‑arounds that adequately mitigate risk. For many SaMD products, one‑to‑one alternatives do not exist due to deep integration into local infrastructure, clinical workflows, user acceptance testing, training, and organisation‑specific configuration. Substituting software in a clinical environment is non‑trivial, often requiring months of validation, change management and training to ensure safe and effective use. Imposing an expectation of “use an alternative software device” without acknowledging these practical constraints may inadvertently increase risk rather than mitigate it.

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

Yes

a. Please explain your answer (optional):

Harrison.ai agrees information should primarily be released to specific stakeholders for high‑risk physical devices.

For higher‑risk physical devices, we support targeted notification to stakeholders who are directly responsible for patient care and for managing operational impacts of disruptions (e.g. health services, state and territory health departments, relevant clinical professional bodies). These stakeholders are best placed to interpret the information, assess local risk, implement mitigation strategies, and communicate appropriately to patients and consumers.

We recommend caution regarding broad public dissemination of shortage or disruption information for high‑risk devices, particularly where the devices are not available to the general public as consumer products but are instead “prescribed” or deployed through clinical pathways. In such cases:
•Public release may create undue fear, distress or urgency among patients, especially where clinical teams already have plans in place to manage the disruption or where impact is limited to specific settings.
•There is a material risk that high‑level shortage or disruption information will be misinterpreted or amplified in ways that do not reflect the actual clinical risk or availability of alternative care pathways.
•For SaMD, where technical nuances (e.g. redundancy, cloud failover, partial functionality, local configuration) significantly influence impact, brief public statements may not accurately represent the real‑world situation.

We therefore support a model where:
•Shortage/disruption information for higher‑risk devices is primarily supplied to a defined list of stakeholders directly involved in clinical and operational decision‑making.
•Public communication is reserved for clearly defined circumstances (e.g. major public health emergencies, or situations where patients need to take direct actions) and is carefully coordinated with sponsors and health services to ensure clarity and avoid unnecessary alarm.

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) :

Harrison.ai supports the release of information about disruption to supply for higher risk physical devices to the stakeholder groups directly involved in clinical and operational decision‑making as these are appropriate actors to plan and manage responses to shortages.

However, we do not support the inclusion of “sponsors of medical devices that may be a suitable alternative to the affected medical device” as a stakeholder category. In practice, it is very difficult, and often impossible, for either the TGA or sponsors to reliably identify suitable alternatives based solely on publicly available ARTG information. Product equivalence in a clinical setting depends on many factors that are not apparent from the ARTG entry, including:
•specific indications, patient sub‑groups and clinical workflows;
•interoperability, integration and IT architecture (especially for SaMD);
•hospital contractual frameworks and procurement constraints; and

•training, user acceptance and implementation maturity.

We therefore recommend that:
•Suitable alternatives for the purpose of regulatory communication be limited to devices (hardware or SaMD) from the same manufacturer/sponsor, where the sponsor can appropriately attest to equivalence or suitability and support implementation.
•Identification of alternative products from other sponsors remain a matter for clinical and procurement decision‑making within health services, guided by clinical evidence and local circumstances, rather than a regulatory matching exercise.

For SaMD in particular, apparently similar products may differ substantially in functionality, data models, integration requirements, user interface and training needs, such that suggesting cross‑sponsor alternatives without detailed clinical and technical evaluation could inadvertently increase patient risk.

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):

Harrison.ai notes that most sponsors already maintain established communication pathways with their customers to notify them of product supply disruptions, planned decommissioning, and business continuity arrangements, including estimated timeframes for resolution. For SaMD, these arrangements often form part of contractual service‑level agreements and incident management processes. There is a risk of conflicting or duplicative messaging if TGA's communications do not align in timing or content with sponsor–customer obligations.

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?

Yes

a. Please explain your answer (optional):

As mentioned, Harrison.ai notes that most sponsors already maintain established communication pathways with their customers to notify them of product supply disruptions, planned decommissioning, and business continuity arrangements, including estimated timeframes for resolution.

Harrison.ai recommends the scope of this framework be focused on higher‑risk devices and situations where unavailability could reasonably be expected to lead to death, serious injury, or serious public health impact. For these devices, Harrison.ai agrees TGA should be able to release the types of information listed giving consideration to the concerns raised in the previous responses. Information about any alternative medical device and the availability of that device should be limited to alternatives from the same manufacturer/sponsor.

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?

Yes

a. Please explain your answer (optional):

Harrison.ai agrees that sponsors should be provided with a notice of intent and an opportunity to review and comment before information is released as is important for ensuring accuracy, protecting commercially sensitive information where appropriate, and avoiding unintended misinterpretation. This is particularly important for SaMD, where technical and operational details can be complex and context‑dependent.

We recommend that TGA:
•Clearly define the standard timeframe within which sponsors should respond to a notice of intent (e.g. a defined number of business days), including expectations for urgent versus routine situations.
•Outline the circumstances under which TGA may proceed to publish or share information without sponsor input (e.g. urgent public health threats or situations where sponsor is uncontactable), and how this will be communicated to the sponsor.
•Provide clarity on how disagreements will be handled, for example where the sponsor and TGA have differing views about the scope, level of detail or interpretation of the information to be released. A structured process for resolving such disagreements, including the possibility of including both perspectives where appropriate, would support transparency and fairness.

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.:

Harrison.ai maintains that any proposed amendments relating to transparency of disruptions to supply of a medical device should be explicitly limited in scope to higher‑risk physical medical devices, and to circumstances where unavailability could reasonably lead to serious patient harm or significant public health impact. Applying the same approach to SaMD without substantial adaptation risks conceptual confusion, regulatory overlap with existing post‑market and cybersecurity frameworks, and unintended consequences for digital health innovation and continuity of care.

For higher‑risk physical devices (such as implantables, life‑support equipment, and critical consumables), we recognise the clear public health rationale

for structured, regulator□led transparency where genuine shortages or material disruptions to supply arise. In these cases, if carefully scoped and implemented, can support early planning, coordinated response, and maintenance of essential clinical services.

However, we do not consider it appropriate at this stage to extend this framework broadly to SaMD and other digital solutions, where:
•Supply is not constrained by physical manufacturing or stock, but by technical availability, performance and integration;
•Existing regulatory tools for safety, performance, recalls, and cybersecurity already apply; and
•Substitution or migration to alternative software is complex, lengthy, and highly context□specific, making a shortage/disruption framework poorly suited to the characteristics of SaMD and other digital solutions.

We therefore recommend that:
•The legislative and policy changes made under this reform are clearly described and implemented as applying only to higher□risk physical devices (and any devices explicitly designated by TGA as being of special public interest in defined emergency contexts).
•Any future extension of a disruption□to□supply transparency model to SaMD be subject to a separate, targeted consultation that considers the specific characteristics of software, integration into health IT infrastructure, and overlap with existing post□market and cybersecurity arrangements.
•Guidance materials, external communications and stakeholder engagement clearly distinguish between the physical□device shortage framework and other mechanisms used to manage issues with software, connectivity or performance.

Within this narrower, risk□based scope focused on high□risk physical devices, Harrison.ai supports the intent of the reforms and encourages TGA to continue working closely with sponsors, health services and professional bodies to ensure messaging is consistent, actionable, and aligned with existing clinical and contractual communication channels.