Improvements to the Therapeutic Goods Advertising Code
TGA Consultation Survey: ANDHealth Response

September 2026

1. About the consultation

The Australian Therapeutic Goods Administration (TGA) within the Department of Health, Disability and Ageing sought feedback on options and proposed changes to improve the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 through a public consultation survey that ran between 9 July 2026 and 3 September 2026. This consultation focused on targeted issues where improvements may be needed, it was not a full review of the Code. The below responses were provided by ANDHealth to the TGA.

ANDHealth's submission focused on the consultation questions directly relevant to its core business of supporting software-based and software-enabled digital and connected health technologies and its expertise regarding Software as a Medical Device Regulation (SaMD).

2. About ANDHealth

ANDHealth is Australia's leading national digital and connected health commercialisation organisation – powering the transformation of health and care through trust, evidence and growth. Our purpose is to accelerate the commercialisation and uptake of evidence-based digital and connected health technologies, products, platforms and services.

ANDHealth accelerates innovation into impact by building capability and equipping innovators to scale investable businesses to drive better health and economic outcomes for Australia. Through non-dilutive investment, world-class expertise and dedicated accelerator and incubator programs, ANDHealth supports companies to take their technologies from idea to global adoption and exit.

ANDHealth has partnered with the Therapeutic Goods Administration (TGA) as its core industry outreach, training and education partner for Australian Software as a Medical Device (SaMD) regulation since August 2021. Since the partnership began, ANDHealth has supported over 2,300 Australian innovators in navigating Australia's Software as a Medical Device (SaMD) regulatory frameworks, through individual "Office Hours" sessions and sold-out webinars.

3. Our response

Issue 1A: Mandatory statements for advertisements about therapeutic goods that are not available for purchase by the public

1. Do you agree with the implementation of a mandatory statement to the effect of '[This product] or [Treatment with this product] is only available through a [Health Professional*]' for advertisements in the public domain about therapeutic goods that are only available for supply through a health professional?

* With this statement, advertisers can specify the type of health professional consumers must consult to access the good or treatment with the good.

Response: **Yes**

ANDHealth supports introducing a mandatory statement for advertisements about SaMD that is only available for supply through a health professional. Some SaMD, particularly clinically directed tools

such as diagnostic or decision-support software, is only accessed through a treating health professional rather than sold directly to consumers. A consumer viewing this advertising could otherwise assume direct purchase is possible. A mandatory statement specifying that the product is only available through a health professional would prevent this confusion. It would also let advertisers specify the type of health professional a consumer needs to consult, giving a clear next step. Applying the same mandatory statement to SaMD keeps advertising requirements consistent across all ARTG-listed products, regardless of format.

2. Do you agree with the implementation of a mandatory statement to the effect of 'This product is not available for purchase by the general public' for advertisements in the public domain about therapeutic goods that are not available for supply to consumers?

Response: **Yes**

ANDHealth also supports applying the equivalent mandatory statement to SaMD that is never supplied to consumers under any circumstances. Some SaMD, such as software embedded in hospital systems or used only for internal clinical or laboratory purposes, is never accessed by consumers directly, in the same way laboratory diagnostic equipment is not. Advertising for these products should carry the same statement already proposed for other therapeutic goods in this category. This keeps SaMD advertising consistent with the broader Code, rather than creating an unexplained gap for software specifically.

Issue 1B: Advertising requirements for software-based medical devices

3. Do you support mandatory inclusion of the ARTG number in advertising about SaMD products?

Response: **Yes**

Please provide a brief explanation about your response:

ANDHealth supports mandatory inclusion of the ARTG number in advertising for software as a medical device (SaMD).

Software-based medical devices can be distributed quickly and at scale through digital channels, including websites and app stores. These channels can also shorten the path from advertising to purchase.

At the point of sale, consumers may be presented with SaMD products alongside products that are not included in the ARTG. To an untrained eye, these products can appear similar. Clear information from advertising through to purchase is therefore important.

Requiring a visible and verifiable ARTG number would be a practical transparency measure. It would allow consumers, health professionals and procuring organisations to confirm a product's ARTG status without needing to interpret medical device classification rules.

ANDHealth regularly sees confusion about whether a software product meets the definition of a medical device and requires regulation. Through our TGA webinar program and office hours, "Does our product meet the definition of a medical device?" is consistently the most common question raised. If SaMD product developers experience this level of uncertainty, consumers are likely to experience even greater confusion.

Including the ARTG number in advertising would help purchasers identify regulated products and provide greater confidence that the product has met applicable regulatory requirements. Where

practical, ANDHealth recommends that SaMD advertising be subject to the same requirements that apply to other medical devices.

4. Do you support the introduction of any of the following measures in advertisements for SaMD products to improve transparency about the ARTG inclusion and compliance with Australian regulatory requirements?

The implementation of a 'tick' or other recognisable symbol to indicate the SaMD is included in the ARTG.

Response: **Yes**

Please provide a brief explanation about your response:

ANDHealth supports the introduction of a recognisable "registered" symbol for software as a medical device (SaMD).

A symbol would provide consumers with a faster and lower-effort indication that a product is included in the ARTG than a registration number alone. This is particularly important in direct-to-consumer mobile and app-based advertising, where space is limited and consumers may not have the time or opportunity to look up a registration number.

The symbol should supplement, rather than replace, mandatory display of the ARTG number. The symbol would provide an immediate indication of registration. The ARTG number would allow consumers, health professionals and procuring organisations to verify the product's registration status and seek further information where needed. This may support product selection and a more informed assessment of the product's suitability.

An ARTG "tick" could also provide a clear focal point for future consumer education. If the TGA chooses to run public education activities, the symbol could help consumers recognise the difference between regulated medical devices and products that have not been included in the ARTG.

For the symbol to be effective, it should be a single, recognisable mark controlled by the TGA and supported by clear rules for its use. This would reduce the risk of the symbol being used by unregistered products or confused with app-store badges and other certifications commonly displayed in digital marketplaces.

Together, the symbol and ARTG number would give consumers an immediate indication of registration, a pathway to verify that status in more detail, and a simple concept that could be reinforced through TGA consumer education.

The inclusion of a link to the instructions for use (IFU) for the SaMD when an advertisement facilitates directly the supply of the good.

Response: **Yes**

Please provide a brief explanation about your response:

ANDHealth supports requiring advertisements that facilitate the direct supply of SaMD to include a direct link to the relevant IFU.

Software-based medical devices can be distributed quickly and at scale through digital channels. Digital advertising can allow consumers to move directly from an advertisement to downloading or purchasing a product in only a few steps. This makes advertising and point of sale important decision points for consumers.

Consumers should be able to easily access clear information about a product's intended purpose, appropriate use, limitations and warnings before downloading, purchasing or using it. The IFU is the appropriate location for this information, rather than attempting to compress detailed safety and use information into advertising copy.

A direct link would enable consumers to access this information without needing to search for it independently. This is important because consumers may not know that an IFU exists, understand its relevance, or know where to find it. Easy access to the IFU would also help consumers compare products and make a more informed assessment of whether a product is suitable for their needs.

Where practical, SaMD advertising requirements should align as closely as possible with requirements applying to other ARTG-listed medical devices.

The inclusion of the name, address and contact details of the sponsor

Response: **Yes**

Software-based medical devices can be distributed quickly and at scale through digital channels, including websites and app stores. In these settings, the platform, product name or consumer-facing brand may be the only information visible to a consumer. The relationship between the brand and the legal sponsor may not be clear, whether by design or simply because of the way digital products are marketed and distributed.

The digital nature of SaMD also means products can be updated frequently. Product names, branding, advertising content and visual design may change more regularly than for physical therapeutic goods. This can make it difficult for consumers to identify the entity responsible for the product they are considering, downloading or purchasing.

Requiring sponsor details in advertising would provide a clear and practical transparency measure. It would allow consumers, health professionals and procuring organisations to identify the party responsible for the product, ask questions and confirm that the product has an accountable Australian sponsor. This is particularly important given the global reach of digital platforms and the ease with which overseas products can be promoted to Australian consumers.

Sponsor identification should be readily available when consumers are provided with advertising material and when they are making decisions about downloading, purchasing or using a product. This is especially important where digital advertising enables consumers to move from an advertisement to access or purchase in only a few steps.

Including sponsor details in SaMD advertising would align requirements more closely with those applying to other ARTG-listed therapeutic goods. It would create a consistent expectation across the broader Therapeutic Goods Advertising Code, rather than introducing an unusual or disproportionate requirement for SaMD.

The inclusion of the Unique Device Identification (UDI) number

Response: **Yes**

Please provide a brief explanation about your response:

ANDHealth supports including the Unique Device Identification (UDI) in SaMD advertising, where applicable.

Software-based medical devices can be updated frequently. A single ARTG inclusion may therefore cover multiple versions of a product over time. Displaying the applicable UDI at the point of advertising would provide greater transparency and help health professionals, procuring organisations and technically informed consumers make more informed decisions.

The UDI would enable these audiences to identify the particular product or version being promoted. It would also provide a reference they can use to seek further information through the Australian UDI Database or other relevant sources before downloading, purchasing or using the product.

This is particularly relevant for digital SaMD advertising. Consumers can move quickly from an advertisement to downloading, purchasing or accessing a product. Advertising may also promote a specific version, feature, update or intended use. Displaying the UDI in that advertisement would help ensure the information being considered relates to the particular version being promoted.

The UDI should complement, rather than replace, the ARTG number and any recognisable ARTG registration symbol. Together, these measures would provide an immediate indication that a product is regulated, a means to verify ARTG inclusion, and more detailed version-level identification at the point of advertising.

Applying the requirement only where a UDI is applicable would be proportionate. It would also align SaMD advertising requirements with the broader UDI framework for other ARTG-listed medical devices.

5. Do you agree with the introduction of a specific mandatory statement or selection of statements for advertising about SaMD?

Response: **Yes**

If yes, please provide your preferred option:

ANDHealth supports introducing software-specific mandatory statements for SaMD advertising.

Existing mandatory statements were developed primarily for physical therapeutic goods, rather than software as a medical device (SaMD). They may not translate clearly to software-based medical devices, particularly where consumers access a product advertising through an app store or website and there is no physical label to inspect.

For SaMD, the key consumer risk is often misunderstanding a product's intended purpose, limitations, warnings or appropriate role in care. A clear, software-specific mandatory statement at the point of advertising would prompt consumers to consider this information before downloading, purchasing or accessing a product.

This aligns with ANDHealth's experience through its TGA webinar program and office hours. "Does our product meet the definition of a medical device?" is consistently the most common question raised. This indicates that intended use, regulatory scope, and the distinction between regulated and non-regulated software are already areas of confusion for product developers. Consumers are likely to experience similar, or greater, uncertainty.

ANDHealth recommends that the TGA provide a small selection of approved mandatory statements, rather than prescribe a single fixed statement for all SaMD. SaMD includes a broad range of products, from consumer-facing self-management tools to clinically directed products used by health professionals. A limited set of approved options would allow sponsors to use wording that is relevant and meaningful to the particular product and advertising context, while maintaining a clear and consistent regulatory standard.

Where practical, SaMD advertising requirements should align with the broader Therapeutic Goods Advertising Code. However, software-specific wording is needed to ensure mandatory statements remain clear, relevant and effective in digital advertising environments.

6. Do you agree with the proposal to require all relevant health warnings to always be included in advertising for SaMD products that facilitate directly the purchase or supply?

Response: **Yes**

7. Do you support the inclusion of a mandatory statement to inform users when a SaMD product is, or operates using, an AI model or system?

Response: **Yes**

If yes, please explain which mandatory statement(s) you think should be considered, in terms of disclosing whether a SaMD product uses AI.

ANDHealth supports a mandatory statement disclosing the use of AI in SaMD advertising.

Consumers should be able to identify, at the point of advertising, when a product uses AI before deciding whether to access, download or purchase it. This is particularly important in digital settings, where consumers can move quickly from an advertisement to accessing a product through an app store or website.

A simple, factual disclosure would provide useful context about how the product operates. It would help consumers, health professionals and procuring organisations understand that the product's outputs, recommendations or interactions may be informed by AI, rather than solely by conventional software logic. ANDHealth agrees that end-user transparency regarding AI-enabled decisions, interactions and AI-generated content is an important issue for AI-enabled medical device software.

This disclosure should be distinct from any additional warnings that apply to SaMD using generative AI. A general AI disclosure would indicate that AI is used in the product. Separate, targeted warnings for generative AI would address the additional risks that can arise where outputs may be variable, inaccurate or inappropriately relied upon without suitable human oversight.

ANDHealth recommends that the disclosure remain generic and technology-neutral. AI methods and terminology are evolving quickly. A generic disclosure would remain relevant as technologies develop, without requiring sponsors to repeatedly revise advertising to reflect technical changes that may not be meaningful to consumers.

The purpose of the disclosure should be to provide transparency and context through a short, neutral statement. It should inform consumers without acting as a blanket warning or implying that all AI-enabled SaMD presents the same level of risk. This would support informed decisions at the point of advertising while remaining proportionate for lower-risk uses of AI.

Requiring disclosure of AI use would align with the TGA's broader work to improve transparency for SaMD and AI-based medical devices in digital and online environments.

8. Should advertisements about SaMD products that are, or operates using, a generative AI model or system include additional warnings?

Response: **Yes**

If yes, please explain which warning statement(s) you think should be included in advertising about SaMD that are, or operates using, a generative AI model or system.

ANDHealth supports additional mandatory warnings for SaMD that uses generative AI.

Consumers and health professionals should be clearly informed, at the point of advertising, when a SaMD uses generative AI. This is particularly important in digital settings, where consumers may move quickly from an advertisement to accessing, downloading or purchasing a product.

Generative AI can produce outputs that vary between uses and may be inaccurate, incomplete or inappropriate for an individual's circumstances. Where the product is intended to support health-related decisions, there is also a risk that users may place undue reliance on outputs without appropriate clinical oversight.

ANDHealth supports mandatory warnings that address these specific risks. The warnings should clearly communicate that:

- The product uses generative AI and its outputs may vary or contain inaccuracies.
- Outputs should be reviewed by an appropriately qualified health professional before being relied on for clinical decision-making, where the product's intended use or advertising indicates that outputs may inform clinical decisions.

These warnings should be distinct from the general disclosure that a product uses AI. A general AI disclosure provides basic transparency about the technology used. Additional warnings for generative AI address the particular risks associated with generative outputs and the potential for inappropriate reliance.

AI and machine learning are consistently the most frequently raised topics in ANDHealth's TGA webinar program, including through live questions and post-webinar surveys. This indicates that developers and the broader market recognise that AI-enabled health products require particular care. Clear, targeted warnings would help ensure that consumers and health professionals receive practical information at the point of advertising, before deciding whether to access or use the product.

Where practical, warning requirements for generative AI-enabled SaMD should align with the broader Therapeutic Goods Advertising Code. However, the distinct risks associated with generative AI support additional, targeted warnings in advertising.

9. Is there further information you would like to be included in online advertising about AI-enabled SaMD products?

Response: **Yes**

If yes, please explain what other information should be included in advertising about AI-enabled SaMD products to support informed decision making by consumers and health professionals.

ANDHealth supports including a direct link to the relevant ARTG record in advertising for AI-enabled SaMD.

Consumers, health professionals and procuring organisations should be able to verify a product's ARTG status at the point of advertising. This is particularly important for SaMD, where users can move quickly from an online advertisement to downloading, purchasing or accessing a product.

The public ARTG is the appropriate and authoritative source for this information. It can be searched by product name, sponsor or ARTG number. A direct link to the relevant ARTG record, or to a pre-populated ARTG search, would make verification easier without creating a separate register or duplicating TGA processes.

The link would provide a practical pathway to further information about the product, its sponsor and its ARTG status. Where relevant, it could also be supported by improved ARTG search and filtering functionality for SaMD and AI-enabled medical devices. The TGA already publishes an AI-enabled-device list based on ARTG information, which demonstrates the potential to make these products more visible within the existing system.

This measure should complement the other proposed transparency requirements. An ARTG registration symbol could provide an immediate indication that a product is regulated. The ARTG number would support direct verification. A link would allow users to access authoritative information before deciding whether to access, purchase or use the product.

This approach would improve transparency while keeping the requirement proportionate and avoiding unnecessary duplication of TGA systems.

Issue 2A: Clarity regarding the definition of 'prominently displayed or communicated'

13. Do you agree with the proposed change to the definition of 'prominently displayed or communicated'?

Response: **Yes**

Please explain your answer and tell us how these changes may affect you.

Please tell us your suggestions or comments for updated Code guidance about this topic.

ANDHealth supports the proposed change to the definition of "prominently displayed or communicated." The current definition does not explicitly require a visual statement to stand out, only to be easily read from a reasonable distance. This gap has allowed some advertisers to use very small or low-contrast text for required disclaimers, while making the promotional claims themselves far more prominent. ANDHealth has seen this pattern occur in real software advertising. Adding an explicit "standing out" requirement would close this gap and give advertisers a clearer, more objective standard to apply. Retaining the current wording would let this kind of disclaimer practice continue.

Guidance suggestion: updated guidance could usefully include concrete examples of font size, contrast and placement that would, and would not, meet the "standing out" requirement, to help advertisers self-assess compliance.

Issue 4B – The requirement for citations to scientific and clinical research in advertising

23. Would illustrative examples in guidance showing express vs implied references to research (and the resulting citation obligations) address current pain points?

Response: **Yes**

ANDHealth supports the use of illustrative examples to clarify express and implied references to research. Advertisers and reviewers often disagree about whether a claim is an implied reference to a specific study or a general statement about a product's effect. Clear examples showing the difference, alongside the citation obligations each one triggers, would give advertisers a practical way to check their own content before publishing. This kind of guidance is more useful than a further amendment to the Code, since the underlying rule is reasonable but its application in practice is unclear.

24. What additional guidance, in relation to Section 11 of the Code, is needed?

Please provide your response below.

Response: **Yes**

ANDHealth has no further changes to propose to the guidance on Section 11 itself, other than a suggestion to add an SaMD-specific examples to Attachment 1. This could be something along the lines of "clinically-validated algorithm" or "94% accuracy", so advertisers can apply the same standard to software claims as to other therapeutic goods claims.

ENDS