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SUBMISSION

Wednesday, 18 March 2026

AMA submission – Proposed changes to labelling of medicines supplied in Australia

Consultation closes 23 March 2026

By email: TGA.Scientific@health.gov.au

The Australian Medical Association (AMA) supports the Therapeutic Goods Association's (TGA's) proposal to replace Therapeutic Goods Order No. 91 (TGO 91) and Therapeutic Goods Order No. 92 (TGO 92) with new labelling standards as part of the October 2026 sunsetting process, and we welcome the opportunity to comment on targeted improvements that strengthen patient safety, clinical usability, and consumer understanding.

Medicine labelling functions as a frontline consumer protection mechanism: it is often the only consistently available safety communication at the point of selection, dispensing, and administration, and it materially influences whether medicines are used safely and correctly. The TGA itself has noted labels which are hard to read or understand make medication errors more likely — so improvements to labelling standards operate as practical risk controls, not administrative niceties.

The AMA has supported and encouraged this reform trajectory for several years, including through our 2023 targeted submission on priorities for improving TGO 91 and TGO 92 and our 2024 submission supporting targeted safety updates (including clearer, clinically meaningful presentation of key information and stronger consumer-facing warnings).

This submission continues our consistent advocacy.

The AMA's overarching position is straightforward: clear, consistent, and clinically meaningful labels reduce medication harm, support quality use of medicines (QUM), and strengthen health literacy. Our key statements, expanded in the body of this submission, are as follows:

- The AMA supports the replacement standards and the TGA's direction of travel, especially where changes reduce avoidable harm and improve label comprehension.
- Updating mandatory substances and warnings — including changes better aligning with food allergen labelling and the circumstances in which sulphites must be declared — will improve safety and informed choice, provided requirements remain clear and consistently applied.
- Improving consumer information about large oral dosage forms is a sensible, patient-safety reform that warrants strong support, given reported serious choking-related adverse events.

- The AMA supports clearer identification of medicines by making the active ingredient (generic) name the primary name on labels, with brand names secondary, to reduce confusion from brand substitution and support safer prescribing and telehealth care.
- Digital modernisation (including QR-codes) can add value, but labels must not assume reliable internet access at the point of care; critical preparation and safety information must remain accessible when connectivity fails.
- The new standards should reduce reliance on exemptions without weakening safety requirements and should provide sponsors with clarity while maintaining label integrity and patient protection.
- The standards should support transparency for non-prescription, listed and complementary products, acknowledging consumers often lack awareness of evidence limitations and potential risks (including interactions), and need clearer, more honest information to make informed decisions.

The AMA believe input from clinicians is important to ensure the final framework remains clinically meaningful, safety-centred, and genuinely comprehensible for consumers.

Clear labelling as a patient safety measure

The AMA supports reform which improves the safe and quality use of medicines by making labels easier to read, interpret, and act upon. This includes clear identification of active ingredients, consistent terminology, and unambiguous presentation of clinically meaningful information.

In consultation with our members, medical practitioners reported patients often identify medicines by brand name and packaging appearance, yet pharmacy substitution and generic packaging may mean the same active ingredient may appear under different brand names and colours. This can create confusion for patients and clinicians, particularly during telehealth where visual confirmation is limited. The AMA therefore supports requirements that make the active ingredient (generic) name clearly prominent and readily findable, with brand names presented in a secondary manner, to improve medicine identification, continuity of care, and safety.

The AMA notes the consultation proposes several changes to how active ingredients are displayed, including requirements relating to hydrates/solvates/salts, active ingredient prominence and location on labels (including different approaches for prescription and non-prescription medicines), and updates relevant to specific medicine groups such as vaccines. These changes are directly relevant to preventing selection and administration errors. The AMA supports reforms to standardise presentation in a clinically meaningful way and reduce avoidable variation across labels, consistent with our longstanding support for clearer, standardised active ingredient information to promote safer prescribing and use.

We also note proposed changes to active ingredient quantity expression, including matters relevant to insulin, injections, and the units used to express quantities. Quantity expression should reflect the way clinicians prescribe and administer medicines in real-world settings, particularly for high-risk products. Consistent with our prior labelling advice, the AMA encourages the TGA to prioritise approaches which will reduce ambiguity, support safe dosing decisions, and minimise the likelihood of error where time pressures and imperfect conditions can otherwise amplify risk.

From a health system perspective, the rationale is compelling: medication errors impose substantial harm and cost, and improvements to reduce avoidable confusion support better outcomes and

efficiency. The AMA has previously highlighted the scale of preventable medication harm and the importance of systems — rather than individual vigilance alone — in supporting QUM.

The replacement standards should continue to prioritise label clarity that supports safe use in real-world settings (clinical environments and consumer self-selection) and should avoid reforms which will inadvertently shift risk back onto patients or frontline clinicians.

Updating substances and warnings

The consultation proposes updating "the substances and warnings that must be declared on medicine labels," including changes intended to better align with food labelling rules such as requiring wheat declarations, and changes to when sulphites must be declared.

Clear and consistent disclosure of relevant substances improves safety for patients with allergies and sensitivities and supports informed decision-making. This is especially important for non-prescription and self-selected medicines, where the label often serves as the primary safety document at the point of purchase.

In addition to wheat and sulphites, the AMA notes the proposed replacement standards would expand and refine declarations for a broader set of substances relevant to consumer safety and informed choice, including marine mollusc, tree nuts, lactose and milk products, gluten, and substances such as pollen, propolis and royal jelly, as well as clarifications on how substances are declared (including matters such as aspartame/phenylalanine, hydroxybenzoates (parabens), and antimicrobial preservatives).

The AMA supports these reforms where they improve clarity and consistency for consumers and clinicians, particularly at the point of self-selection for non-prescription and listed medicines. We encourage the TGA to ensure these declarations remain prominent, consistently phrased, and practical to interpret, so the requirements meaningfully reduce avoidable harm rather than simply adding more text to the label.

Improving consumer information to support informed choices

The consultation proposes improving label information to help consumers make informed choices, including providing more information about large oral dosage forms following reports of serious choking-related adverse events.

The AMA has consistently supported stronger warnings and practical information on labels for large solid oral dosage forms for non-prescription medicines. In the AMA's 2023 targeted submission, we supported including warnings, images and/or advice to limit choking risks for non-prescription medicines as a "simple, sensible reform." The AMA reiterated support for improved information about large solid oral dosage forms in our 2024 submission on updates to labelling rules.

Beyond large, solid oral dosage forms, the AMA notes the consultation proposes changes to warning statements and advisory information, including warnings for modified-release and enteric-coated medicines and measures to improve warning statement visibility for listed medicines. We have consistently called for reforms that increase the visibility and usability of warnings where they materially reduce foreseeable harm or misuse, particularly for products consumers self-select. We encourage the TGA to ensure warning statements are presented in a way that is noticeable at the

point of purchase and use. Such an approach should support informed choice without overwhelming consumers with dense or poorly prioritised information.

The AMA supports the proposed reforms to improve consumer-facing labelling for large oral dosage forms, including prominent warnings and practical information to reduce choking risks. We recommend the TGA ensure their final approach makes the risk information noticeable and usable at the point of purchase and first use, recognising heightened risk among older people and other vulnerable groups.

Safety must not be dependent upon digital connectivity

The consultation proposes to modernise the standards, including updating rules to support increased use of technologies such as QR codes.

The AMA supports digital access to up-to-date product information in principle. However, we have previously raised practical safety concerns where digital-only access replaces information needed at the point of care. In our 2024 submission, the AMA supported QR codes for communicating Product Information (PI) but cautioned internet access at the time of administration may be limited (including in healthcare facilities and rural/remote areas) and recommended maintaining hard-copy preparation instructions where clinically relevant.

This position reflects a broader QUM reality: safety-critical processes must work when systems are under strain and conditions are imperfect. A label reform that performs brilliantly in a metropolitan office with strong Wi-Fi but fails in a hospital “black spot” or a remote clinic misses the point of safety reform. The AMA supports modernisation measures, including QR codes, where they provide additional access to current information — but critical safety and preparation information must remain available without requiring reliable internet access.

Clarifying rules and exemptions without diluting safety

The consultation aims to clarify rules for medicine sponsors and reduce exemption applications by aligning requirements with accepted labelling practices.

The AMA consistently calls for efforts improving regulatory clarity and reducing administrative burden — where this can occur without compromising safety or consumer understanding. The AMA has previously contributed to the refinement of labelling regulations to ensure clear and consistent standards. We support reforms that clarify sponsor obligations and reduce unnecessary exemptions, provided the final standards maintain safety-critical requirements and do not create ambiguity, which would undermine consistent labelling outcomes.

The AMA supports requirements and guidance protecting readability and reducing avoidable confusion, particularly where branding elements risk obscuring safety-critical information. We encourage the TGA to ensure the final standards protect minimum legibility in small packs and preserve clear placement of key information so safety does not become optional when label real estate is tight.

However, changes must be proportionate and consider the benefits to medicine supply through retaining consistency with international packaging requirements. The AMA is aware Australia’s small market size, combined with Australia-specific packaging requirements, can contribute to supply vulnerability by reducing flexibility for sponsors to redirect stock intended for other markets. The AMA

supports the TGA's intent to reduce exemption applications by aligning requirements with accepted labelling practices, and encourages the TGA to consider supply-resilience impacts when finalising the replacement standards. Any Australia-specific requirements must be demonstrably necessary for safety and reviewed to ensure they do not inadvertently prolong lead times or reduce opportunities for safe substitution.

Listed medicines and complementary products: transparency, evidence and safer consumer understanding

The consultation's aim to improve label information so consumers can make informed choices is particularly relevant to non-prescription products.

The AMA's position statement on complementary and alternative treatments notes their use in Australia is considerable and increasing, and consumers are often insufficiently aware that many complementary and alternative treatments lack adequate scientific evidence for effectiveness. It also notes potential risk when consumers access these products without professional medical guidance, including risks of interactions and harm to vulnerable groups.

The AMA has also previously raised systemic concerns about listed medicines; Specifically, that listed medicines are not evaluated for compliance or efficacy before being included on the Australian Register of Therapeutic Goods (ARTG) and post-market monitoring identifies high levels of non-compliance, reinforcing the need for strong regulatory settings which will protect consumers and support informed decision-making.

Notably, general practitioners have emphasised clearer labelling for listed and complementary products should assist consumers to understand both evidence limitations and dose-related risk. Crucially, this should include where patients inadvertently take cumulative high doses across multiple supplements. The AMA urges the TGA to consider label formats which prioritise making dose magnitude immediately intelligible to consumers (for example, expressing relevant vitamin content in a way that clearly indicates the proportion of recommended daily intake), alongside prominent, standardised interaction warnings for recognised higher-risk ingredients (for example, St John's wort and other products known to interact with prescription medicines). These practical measures would support safer self-selection, reduce avoidable harm, and improve the quality of information available to patients and clinicians.

The AMA notes improved labelling requirements will only deliver patient benefit where expectations are clear, enforceable, and supported by appropriate compliance action when sponsors mislabel products or fail to communicate material risk.

We also emphasise the replacement standards should support stronger transparency for non-prescription and listed products, including clear presentation of ingredients and safety warnings, to reduce confusion and support informed consumer choices.

While some aspects of claims and advertising controls may sit outside the immediate scope of these replacement labelling standards, the AMA encourages the TGA to ensure labelling rules do not permit the presentation of vague, non-specific symptom claims in a way that misleads consumers about likely benefit. Labelling should support informed choice by distinguishing clearly between evidence-supported therapeutic claims and claims where scientific validation is limited or uncertain.

The AMA encourages the TGA to ensure the final standards and associated guidance strengthen consumer understanding of evidence limitations and interaction risks for complementary and alternative products, consistent with the AMA's position statement for complementary treatments.

Transition and implementation considerations

In prior labelling consultations, the AMA has highlighted the importance of incorporating reasonable transition periods within the requirements for suppliers to implement changes. For example, in the 2024 consultation on targeted safety measures, we supported a two-year transition period as reasonable for suppliers implementing those changes. Transition arrangements must be practically implementable to ensure reforms addressing clear and material safety risks are not unnecessarily delayed.

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