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SUBMISSION

Tuesday, 16 July 2024

AMA submission to the TGA on updates to medicine labelling rules

Closes 18 Jul 2024

TGA.Scientific@health.gov.au

Public consultation on proposed changes to TGO 91 and TGO 92 to support medicine safety

The AMA continues to support ongoing improvements to Australia's medicine labelling regulations and is pleased to acknowledge the positive changes already affected. Clearly labelled active ingredients with appropriate, standardised terminology facilitates clarity for practitioners in prescribing medicines and promotes greater safety for patients using medicines.

This submission does not directly respond to all questions put forward to stakeholders. However, the AMA agrees with the principles and ongoing refinement to regulations to ensure clear and consistent standards. The AMA supports the scope of the proposed changes, particularly the important safety measures to be addressed ahead of the broader sunsetting review process, and acknowledging the ongoing consultation that contributes to the robustness of review.

1. Make sure that quantities of active ingredients in injectable medicines intended for electrolyte replacement are clearly expressed in units important to health professionals.

The AMA supports the recommendation to require the quantity of potassium chloride to be expressed in mmol, as the most relevant clinical unit. This is an important safety measure given the high-risk nature of this medication if incorrect doses are administered.

The AMA supports the recommendation to continue the current requirements for all other active ingredients for the reasons outlined in the paper. The addition of mmol equivalence where space permits will be helpful to clinicians.

These updates are appropriate to provide clarity to sponsors of affected medicines for injection to support medicine safety.

The AMA endorses the proposed amendments to guidance in Appendix A and Appendix C, aimed at supporting the safe and quality use of medicines. A transition period of two years is reasonable to accommodate suppliers with the implementation of these changes.

2. Make sure that clear instructions on how to prepare and store certain injectable medicines administered by healthcare professionals is available in the appropriate format. This is to support recent changes to the Product Information (PI) as a package insert for injectable products. (The TGA) are particularly seeking feedback from health professionals on a proposal to allow a QR code to link to electronic information instead of a separate package insert where instructions for preparation cannot fit on the label, for certain medicines.

The TGA's proposed changes regarding instructions for the preparation of injectable products administered by healthcare professionals highlights specific criticism of hard copy information inserts raised during the public consultation. Hard copies carry a larger environmental footprint and risk becoming out of date or omitting important safety information. The use of digital documentation in medicine labelling may mitigate against these risks to the benefit of all consumers.

However, the AMA holds some concerns, specifically regarding the preparation of injectable medicines. Access to the internet at the time of administration may be limited due to network issues (data coverage inside healthcare facilities is often problematic) or in rural/remote areas. There is a risk that without a hardcopy insert, clinicians may be unfamiliar with how to prepare and administer medications.

The AMA is supportive of a QR code for communicating PI information. However, we recommend continuing with package inserts outlining instructions for preparation as per appendix D. Broader consultation could then be undertaken to ascertain the usefulness of the insert and any unindented consequences of moving to a digital-only option.

The AMA does not see this as a clinically urgent recommendation and so review could be delayed until the sunsetting review period if multiple changes are to be minimised.

The AMA is supportive of a QR code to access PI. This ensures information can be updated swiftly as well as minimising the environmental impact of printing lengthy PI documents.

3. Improve information on listed medicine labels about large solid oral dosage forms intended to be swallowed whole.

The AMA is supportive of regulatory changes requiring listed medicines in the form of large dosage units intended for swallowing to be labelled with a warning to provide greater practitioner and patient awareness of potential choking hazards.

Further regulatory changes regarding limits on the size of dosage forms may be appropriate in future to reduce adverse events, particularly considering choking-related adverse events are more likely among aged cohorts, a vulnerable demographic that may benefit from greater regulatory safeguards.

The AMA approves of the suggestion to limit proposed labelling requirements to only listed medicines at this time and considers the suggested guidance regarding specifics raised under this point in Appendix G to be appropriate. In particular, we support the recommendation to include the word

“warning” on the label, and to include medicines where the width only is >9mm. Consideration could be given to a standardised 22m length cutoff (rather than 22mm for tablets and 23.3mm for capsules) to aid in regulatory simplicity and sponsor compliance. However, the AMA leaves direct feedback on that point to sponsors.

If these changes are implemented, a transition period of two years is again reasonable for suppliers to implement the changes.

The AMA has no additional comments to add. The AMA is supportive of this review process, and we look forward to contributing to further consultations on proposed reforms.

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