ANZCA
FPM

Monday 4 September 2023

Scientific Operation Management Section
Scientific Evaluation Branch
Medicines Regulation Division/Health Products Regulation Group
Australian Government, Department of Health and Aged Care
PO Box 100, Woden ACT 2606

Via email: TGA.Scientifc@health.gov.au

Dear Sir/Madam

Re: Australian medicine labelling rules – TGO 91 and TGO 92 – consultation

The Australian and New Zealand College of Anaesthetists (ANZCA) commends the work of the Therapeutic Goods Administration (TGA). We welcome the opportunity to provide feedback on Australian medicine labelling requirements to optimise the safe and correct use of medicines.

ANZCA, including the Faculty of Pain Medicine, is committed to setting the highest standards of clinical practice in the fields of anaesthesia, perioperative medicine, and pain medicine. As one of the largest medical colleges in Australia, ANZCA is responsible for the postgraduate training programs of anaesthetists and specialist pain medicine physicians, in addition to promoting best practice and ongoing continuous improvement that contributes to a high-quality health system.

Our submission is confined to improvements for the labelling of high-risk medications, especially neuromuscular blocking agents (NMB). ANZCA is extremely appreciative of the work to date on this matter. We have contributed to previous reviews and are familiar with the national user-applied labels and standards and packaging standards for these labels with red being the internationally accepted label colour for NMBs. Many health care organisations in Australia also observe the convention of using red 5ml syringes exclusively for NMBs.

Despite these regulations, they do not eliminate the risks associated with 'lookalike' vessels insofar as the shape and colour of the ampoule or vial, and the colour of the label, of different high-risk medications oftentimes 'look alike'. This heightens the risk of inadvertently misidentifying ampoules and vials, thereby causing patient harm.

The risks associated with 'lookalike' vessels and labels of high-risk medications are heightened by the very nature of the work of anaesthetists, which:

- Routinely involves separating drugs from their vessels and labels into syringes to administer the contents to their patient.
- Occasionally requires that they work in relatively low lighting environments, e.g., radiology/hybrid operating theatres.

Reports to ANZCA show that the risk of inadvertent administration of NMBs due to misidentification of ampoules and vials remains significant and ongoing. As per data from ANZCA's online Australian and New Zealand Anaesthetic Incident Reporting System, webAIRS, the most commonly reported incidents involved the administration of a non-depolarising NMB instead of a depolarising NMB or a Benzodiazepine.

Recommendations

ANZCA is of the view that more precise regulations for the packaging and labelling of high-risk medications is needed to reduce the risk and incidence of inadvertent swapping or misidentification of lookalike ampoules or vials. Accordingly, we recommend that the following aspects of packaging and labelling of high-risk medications become regulated:

- Colour to differentiate NMBs from other high-risk medications. Specifically, red to *always* and e*xclusively* be the colour for these agents and includes the:
    - Colour of the plastic cap overseal and the metal ferrule
    - Colour of the text on plastic ampoules
    - Background colour of labels for ampoules and vials.
- Provision, within the packaging of high-risk medications, of transferable or peel-off labels, which can be attached directly to a syringe at the point of preparation to offset the separation of the drug with its label. The colour coding of such labels should be consistent with the above recommendations.

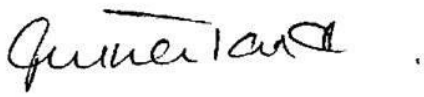
Please find attached two international publications, which consider the above issues:

- Institute for Safe Medication Practices Canada: *Neuromuscular Blocking Agents: Sustaining Packaging Improvements over Time (2014)* **(Attachment A).**
- U.S. Food and Drug Administration: *Safety Considerations for Container Labels and Carton Labelling Design to Minimize Medication Errors – Guidance for Industry (2022*) **(Attachment B).**

The risk of patient harm due to inadvertent swapping of high-risk ampoules or vials is of high concern for anaesthetists. ANZCA looks forward to being informed about the outcomes of the consultation and to the implementation of precise regulations that will improve the safe use of medications.

If you would like more information about the above issues raised, please contact the ANZCA Safety and Quality Committee @SQ@anzca.edu.au.

Yours sincerely



Associate Professor Joanna Sutherland
Chair, ANZCA Safety and Quality Committee