## SHPA submission to Australian medicine labelling rules: targeted consultation on priorities for future improvement to TGO 91 and TGO 92 requirements, September 2023

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

To provide feedback to this consultation, SHPA has sought expertise from over 160 specialist members belonging to SHPA's speciality practice groups of Dispensing and Distribution, Electronic Medication Management and Medication Safety. These groups comprise of expert members managing the dispensing and distribution of medicines across hospitals, automated dispensing systems and working in dedicated medication safety roles across Australian health services.

In these high-risk, fast-paced acute settings, where nurses administer medicines to patients, any errors or ambiguity in labelling and packaging of medications can have detrimental downstream effects on patient safety. Hospital pharmacists, particularly medication safety pharmacists, have an important role in educating nurses how to read and interpret medicines labelling to safely administer medicines. Often, this education is in spite of medicine labelling which has been a factor in medication administration errors in hospital and other care settings. SHPA therefore welcomes the opportunity to provide feedback to the consultation questions below.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

### Consultation Questions

**1. Do you have any comments about the TGA's intention to address the risk from large sized oral dosage forms by updating labelling rules included in TGO 92 for listed medicines as a priority?**

SHPA does not believe that updating labelling rules to address the potential choking risks from large sized oral dosage forms is a priority area. However, we have several comments that should be considered if this is to be updated.

Firstly, clarity is required on what constitutes as a 'large sized oral dosage form'. Sizing and shape particulars of oral dosages would need to define these parameters in order for labelling to be consistent. The TGA's Guidance for *TGO 101: Standard for tablets, capsules and pills*[1], does not set out maximum recommended size of oral dosage forms. However, the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) recommends appropriate dosage size and shape of tablets and capsules.[2] If sizing of oral dosage forms were to be defined, specialist consultation should be sought to determine what constitutes as large enough to pose choking risk as well as considering differing consumer views on what is deemed large or not. This may differ based on the shape and formulation of the oral dose, e.g. soft, elliptical gel capsules of a large size may be easier to swallow than large, round standard tablets.

Given that predominantly, the choking related adverse events were associated with listed medicines available for self-selection, clear imaging on packaging would need to be used to convey sizing to consumers. Consumers may not be aware of the actual size of the oral dosage until they visibly view the product after having purchased it. Alternatively, it may be more useful to state on the packaging to '*if you have swallowing difficulties*, *seek advice from a pharmacist prior to purchasing this product'.*

In a hospital setting, a pharmacist, doctor, speech pathologist or nurse would determine if a patient were unable to swallow a large oral dosage form and therefore this labelling would not be necessary. Swallowing difficulties would be assessed prior to prescribing, with more appropriate formulations or strategies being selected to aid in administration.

Hospital pharmacists play a vital role in advising and educating other healthcare professionals on medicines administration in patients with swallowing difficulties or people with enteral feeding tubes. SHPA is committed to safe swallowing practices, and produces a key resource, Don't Rush to Crush[3], Australia's essential guide utilised by healthcare professionals to safely administer oral medicines to this cohort of patients. This vital resource provides safe strategies that may or may not necessarily involve crushing oral dosage forms and facilitates the choice of the safest and most effective available treatment options. To reduce adverse events related to choking on large oral dosage forms, SHPA believes that greater education is required around swallowing awareness through health promotion activities for consumers and further healthcare professional education on available formulations.

2. **Do you have any comments about the TGA's intention to update TGO 91 before the broader sunsetting review to clarify requirements for expressing quantities of active ingredients in units important to health professionals, including the concentration of electrolytes for injection in millimoles?**

SHPA supports the expression of quantities of active ingredients in units and millimoles where appropriate. This is of particular importance for electrolytes (e.g. magnesium, potassium calcium) to be expressed in millimoles. Medicines such as insulin, oxytocin and heparin should be expressed in units. Enoxaparin is currently an exception to this where milligrams are expressed with anti-Xa units provided alongside (40 mg enoxaparin = 4,000 units of anti-Xa).

It is important to reiterate that dispensing software should reflect the usual prescribing units and those provided on the packaging and not vice versa.

3. **What are the highest priorities for improving medicine labels and the requirements of TGO 91 and TGO 92 and guidance to support the safe and quality use of medicines? Why? If you have more information, examples, or comments about the areas of improvement you consider high priority, please give them. If you list more than 3 high priority items, please also tell us which you think are the top 3 priorities for improvement.**

### Clarity of expiry dates

SHPA believes that expiry dates are currently challenging to determine on packaging such as foil strips or on glass ampoules. Sizing of text and clarity of the embossing or text can be difficult to ascertain. In addition, clarity and guidance is required on the expiry date modifications to reflect when medicines are removed from secondary packaging or when they are taken out of specific storage conditions. For example, risperidone (Risperdal Consta) long-acting injection has varying expiry dates if it is removed from the cold chain. In addition, when a product is opened or removed from packaging, the subsequent effect on expiry dates must be determined (e.g., salbutamol nebules).

### Unit-dose barcoding

Unit dose is a system of packaging where each dose unit is separately packed in a protectively sealed unit and labelled with the name of the medicine, strength, dose contained within the pack, batch number and expiry date. To facilitate closed-loop medicines management, SHPA recommends that unit dose packaged medicines should also have a barcode. Unit dose packaging has numerous advantages:

- each dose unit is identifiable to the point of administration
- dose integrity minimises wastage as unused doses maybe re-issued

- barcoded unit dose medicines support verification at the bedside

This ensures that the right patient is being administered the right medicine, at the right dose, at the right time and in the right form, as prescribed. In some hospitals it is not feasible or practical to prepare unit doses locally. Other hospitals may choose to pack medicines into unit doses locally or collaboratively. Currently, there are no requirements for manufacturers of medicines to provide hospital medicines in a format that complies with unit-dose packaging requirements.

SHPA believes that unit-dose barcoding should be a priority area to ensure closed-loop medication management. The importance of this is reiterated in SHPA's Position Statement: Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging.[4] Barcode scanning of medications at the unit dose level would most probably start with unambiguous identification of the product using the Global Trade Item Number (GTIN) allocated to identify this level of the product contained within the 2D barcode (GS1 DataMatrix).

For future considerations, a single barcode for the primary packaging is recommended. Currently many medicines have both a 2D and 1D barcode with differing purposes, but these could be unified into a single 2D barcode. The barcodes may also include data related to the batch number and expiry date, which will assist in the management of medication alerts and recalls due to improved tracking and tracing of doses within hospitals. The introduction of identification and barcoding including batch number and expiry date information should start at least with secondary packaging to ensure that the end-to-end supply can better be managed across all processes and be introduced as part of a planned transition program. As it is a requirement for nurses to check the expiry date of the medication prior to administration, it is desirable for barcodes on unit dose packaging to include expiry date to enable digital checking of this. If the information is not able to be contained in the barcode, then it must be available visually.

As further outlined in the Australian Commission on Safety and Quality in Health Care's (ACSQHC) *Barcoding and other scanning technologies to improve medication safety in hospitals report*[5], to achieve optimal patient safety, workflow strategies and cost benefits, organisations should consider unit-dose barcoding on packaging. Without a nationally supported change to mandate that barcodes are available at the medicinal product unit of use there is no feasible way to systematically enable this safety and quality improvement.

### Minimum spacing for labelling

SHPA recommends that the minimum available space allocated on packaging for a standard size dispensing label and associated warning labels should be mandated to ensure best medication safety practices.

According to the current TGO 91, and as outlined in ACSQHC's *National standard for labelling dispensed medicines*[6], medicines packaging must dedicate a space of at least width 70 mm × height 30 mm for the dispensing label - however, the dispensed medicine label size used by many pharmacy dispensing systems is currently width 80 mm × height 40 mm. Consideration should be given to extending the mandated labelling space to ensure all of the necessary information can be provided to patients without obstructing other important information on the packaging.

4. **We have identified 2 safety related matters to address before we conduct the sunsetting fitness for purpose review. Do you think any more of the high priority matters need updates to medicine labelling rules and guidance in the short term to support medicine safety before a broader 'sunsetting' review? If so, please tell us which matters you think we need to address soon and why.**

Not applicable.

5. **What are the priorities for providing more clarity to medicine sponsors to support clear and consistent medicine labels when we conduct the fitness for purpose review before the sunsetting of TGO 91 and TGO 92? Why? If you have more information or examples, please provide them. If**

**you list more than 3 items, please also tell us which you think are the top 3 priorities for improvement.**

Medicine sponsors should be encouraged to consider clear labelling, in particular, to high-risk medicines, to minimise selection errors by pharmacists and dispensary staff whilst not causing undue alarm to consumers who receive the packaged medicines.

6. **Do you have any further comments to help us plan and prepare for review of labelling requirements before TGO 91 and TGO 92 sunset? We would especially appreciate your thoughts about the extra questions and consideration points we have raised about some of the individual matters in this paper.**
   - The TGO 91 and TGO 92 should endeavour to drive consistency in labelling through the standardisation requirements of font size, placement of warning statements, and presentation of trade names.
   - Labelling rules for all listed medicines should prioritise patient safety and improve patient health literacy, and not contribute to confusion.

**References**


[1] Therapeutic Goods Association. (2020). Guidance for TGO 101 Standard for tablets, capsules and pills. Available at: https://www.tga.gov.au/sites/default/files/guidance-tgo-101.pdf

[2] U.S. Department of Health and Human Services. Food and Drug Administration. (2013). Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules Guidance for Industry. Available at: https://www.federalregister.gov/documents/2013/12/10/2013-29395/draft-guidance-for-industry-on-size-shape-and-other-physical-attributes-of-generic-tablets-and#:~:text=The%20Food%20and%20Drug%20Administration%20%28FDA%29%20is%20announcing,of%20generic%20tablets%20intended%20to%20be%20swallowed%20intact.

[3] The Society of Hospital Pharmacists of Australia. (2023). Don't Rush to Crush. 4th Edition

[4] The Society of Hospital Pharmacists of Australia. (2019). Position Statement: Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging. Available at: https://shpa.org.au/publicassets/baa132c4-de53-ec11-80dd-005056be03d0/position_statement_-_unit_dose_packaging.pdf

[5] Bainbridge M, Askew D. Australian Commission on Safety and Quality in Health Care. (2017). Barcoding and other scanning technologies to improve medication safety in hospitals. Sydney: ACSQHC; 2017

[6] Australian Commission on Safety and Quality in Health Care. (2021). National standard for labelling dispensed medicines. Sydney: ACSQHC; 2021