

Submission by the Australian Nursing and Midwifery Federation

Consultation on proposed changes to labelling of medicines supplied in Australia

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**Australian
Nursing &
Midwifery
Federation**



Australian Nursing and Midwifery Federation / Consultation on proposed changes to labelling of medicines supplied in Australia.

Annie Butler
Federal Secretary

Australian Nursing and Midwifery Federation
Level 1, 365 Queen Street, Melbourne VIC 3000
E: anmffederal@anmf.org.au
W: www.anmf.org.au



Introduction

1. The Australian Nursing and Midwifery Federation (ANMF) is Australia's largest national union and professional nursing and midwifery organisation. In collaboration with the ANMF's eight state and territory branches, we represent the professional, industrial and political interests of more than 356,000 nurses, midwives and care-workers across the country.
2. Our members work in the public and private health, aged care and disability sectors across a wide variety of urban, rural and remote locations. We work with them to improve their ability to deliver safe and best practice care in each and every one of these settings, fulfil their professional goals and achieve a healthy work/life balance.
3. Our strong and growing membership and integrated role as both a trade union and professional organisation provides us with a complete understanding of all aspects of the nursing and midwifery professions and see us uniquely placed to defend and advance our professions.
4. Through our work with members, we aim to strengthen the contribution of nursing and midwifery to improving Australia's health and aged care systems, and the health of our national and global communities.
5. The ANMF thanks the Therapeutic Goods Association (TGA) for the opportunity to provide feedback on the consultation on *Proposed changes to labelling of medicines supplied in Australia and Proposed changes to rules for the new standards replacing TGO 91 and TGO 92.*



Overview

6. The ANMF agrees with the view that the new standards set out in TGO 91 and TGO 92 must support and facilitate the safe and quality use of medicines, by ensuring appropriate labelling.
7. The ANMF and its members support the standardised and consistent presentation of medicine-related information on medicine labels.
8. This submission has reviewed the content of the paper prepared by the TGA. Given the breadth of the proposed reforms, this submission does not address every question raised, our comments are limited to questions involving key issues of direct relevance to the ANMF's operations and expertise.

9. Declaring Allergens And Other Substances

10. **Q1, Do you agree with proposed change to require wheat to be declared on medicine labels**
11. **Q2, Do you agree with the proposed change to require mollusc to be declared on medicine labels**
12. **Q3, Do you agree with the proposed change to require tree nuts to be declared as the specific tree nut on medicine labels**
13. **Q4, Do you agree with the proposed change to require injectable medicines and medicines inhaled into the lungs to state "contains milk" products if they contain lactose from milk origin**

Questions 1 - 4

14. The ANMF recommends that, in the interests of public safety, common allergens should be clearly listed on medicine labels. Aligning pharmaceutical labelling requirements with existing food labelling standards would provide greater consistency and transparency for consumers.
15. People living with allergies and sensitivities rely on accurate, accessible information to avoid exposure to substances that could trigger serious allergic reactions. Extending clear allergen disclosure to medicines would help ensure they can make informed decisions and use pharmaceutical products with greater confidence and safety. The above statements are relevant to Questions 1 - 4.



16. Q5, Do you agree with the proposed change to when sulfites must be declared on medicine labels

17. The ANMF supports the listing of sulfites in accordance with international standards and Australian food labelling standards. This approach would promote consistency across food and pharmaceutical products. Aligning these standards is particularly important for people living with sulfite intolerance, as it enables them to identify potential risks more easily and avoid products that may trigger adverse reactions.

18. Q6 Do you agree with the proposed change to when gluten must be declared on medicine labels

19. Q7 Do you agree with the proposed change for the source of gluten be declared

Questions 6 -7

20. The ANMF supports the proposed change requiring gluten to be declared on medicine labels, with the specific source clearly identified. This measure would enhance transparency and align with best-practice allergen disclosure standards.

21. People living with coeliac disease or gluten intolerance must adhere to a strict gluten-free diet, as even small amounts of gluten can cause significant health consequences, including gastrointestinal damage and other serious complications. Clear and consistent gluten labelling on medications is therefore essential to prevent inadvertent exposure and enable individuals to manage their condition safely. The above statements apply to Questions 6 -7.

22. Q8, Do you agree with the proposed change to require pollen, propolis and royal jelly to be declared for all routes of administration, rather than only when the medicine is for oral administration

23. The ANMF supports the sharing of information that promotes safe, consistent, and well-informed medication administration by nurses, midwives, and carers at every point of care. Access to clear, accurate, and standardised information enables health professionals to make sound clinical decisions, reduce the risk of medication errors, and safeguard patient safety. Consistent communication and transparent labelling practices are fundamental to delivering high-quality care and protecting public health.



24. Q9, Do you agree that pollen with the approved guidance that to clarify that pollen should be declared irrespective of its source

Partially. It does seem very onerous to include the exact source on all relevant labels, where it is already declared as present.

25. Q10, Do you agree with the proposed change to require declaration statements for prescription medicines to be included on the label (unless there is not enough space), instead of also allowing the label to direct the consumer to the Consumer Medicine Information (CMI)

The ANMF agree as long as there is clear direction for the consumer to review the CMI prior to consumption, due to the presence of a declared substance.

26. Q11 Do you agree with the proposed change to declare aspartame as ‘contains aspartame (phenylalanine) ’ on medicine labels instead of contains aspartame

27. Q12, Do you agree with the proposal to clarify the requirements for declaring phenylalanine

28. Q13 ,Do you agree with the proposed change to declare hydroxybenzoic acid esters as ‘contains hydroxybenzoic (parabens) ’ on medicine labels instead of contains hydroxybenzoates

29. Q14, Do you agree with the proposed change to labelling requirements for declaring antimicrobial preservatives

30. Q15, Do you agree with the planned guidance to recommend that preservatives are declared on labels as ‘ Contains [name of preservative] as preservative

31. Q16, Do you agree with the clarifying the intent of Column 4 in Schedule 1 and clarifying the requirements for lecithin

32. Q17, Do you agree with the plan to give more guidance about declaring substances without a cut off

33. Q18, Do you think that any more substances should be added to Schedule 1 or more changes made to requirements for declaring substances that are critical to support medicine safety



Questions 11 – 18

34. The ANMF supports clear, consistent and unambiguous labelling to promote safe medication administration by nurses, midwives and carers. This statement applies to Questions 11 –18.

Active Ingredients

35. **Q21, Do you agree with the proposed changes to labelling requirements for displaying vaccine active ingredients and vaccine descriptors**
36. Comprehensive consideration must be given to the possible implications that omitting all active ingredients from the vaccine label may have on vaccine hesitancy. While we acknowledge that it is proposed that a full list of active ingredients is available in the Product Information (PI), it is important to consider this risk and the broader implications on perceived transparency and public confidence. Mistrust is a known driver of vaccine hesitancy, and this approach risks exacerbating this issue.
37. **Q22, Do you agree with the proposed guidance on font size for active ingredients in relation to the name of the medicine on registered medicine labels**
38. **Q23, Do you agree with the proposed changes where active ingredients can be shown on the main label**
39. **Q24, Do you agree with the guidance plan for registered non-prescription medicines about what active ingredients do not need to be repeated below the name of the medicine**
40. **Q25, Do you agree with the proposed guidance about displaying insulin concentration on medicine labels**
41. **Q26, Do you agree with the proposed change to require single use injectable solutions with a total stated volume of 1ml to show the volume of fill in numbers**
42. **Q27, Do you agree with the proposed guidance on how to express quantity of active ingredients in single use injectable medicines**

Questions 22 – 27

43. The ANMF supports clear, consistent, and unambiguous labelling to promote safe medication administration and overall safe medication practices by nurses, midwives, and carers.



44. Clear labelling is essential to reduce the risk of error, support informed clinical decision-making, and enhance patient safety across all care settings. These statements apply to Questions 22 – 27.
45. **Q28, Do you agree with the proposed change to require microgram to be shown in full, unless it does not fit on the label of a small or very small container**
46. The ANMF supports the proposed change requiring the term “microgram” to be written in full on medicine labels. Abbreviating microgram increases the risk of misinterpretation and medication error, particularly in high-risk clinical environments where clarity is critical to patient safety.
47. However, the ANMF does not support the second statement unless there is a clear and demonstrated limitation due to the size of a small or very small container. In such cases, alternative risk-mitigation strategies should be considered to ensure clarity is not compromised.
48. The ANMF urges the Therapeutic Goods Administration (TGA) to reconsider this decision to ensure labelling standards prioritise patient safety and minimise the potential for medication errors.
49. **Q34, Do you agree with the planned guidance to recommend that active ingredients such as cholecalciferol (vitamin D3) are labelled using both micrograms and international units**
50. The ANMF supports the dual presentation of units on medicine labels. This approach enhances clarity and supports safe medication practices. Displaying units in dual format enables nurses and midwives administering medications to more readily confirm the correct dosage, regardless of whether the unit documented by the prescriber differs from that shown on the packaging. Consistent and transparent labelling reduces the risk of misinterpretation and medication error, thereby strengthening patient safety.
51. **Q35, Do you agree with the proposed change to require red font for certain information when potassium is the principle active ingredient in an injectable medicine.**



52. The ANMF supports the use of red lettering for potassium on medicine labels. Potassium is widely recognised as a high-risk medication, and red lettering is frequently used on packaging as a visual safety cue.
53. Mandating this colour would promote consistency for nurses and midwives, particularly those working across multiple health care organisations where labelling practices may vary. Standardised red lettering would act as an immediate alert trigger for all health professionals administering this high-risk medication, thereby strengthening medication safety practices and enhancing public safety.
54. **Q37, Do you agree with the planned updates to guidance on expressing active ingredients, including more example labels, advice for liposomal medicines and reminders to avoid trailing zeros.**
55. The ANMF supports the TGA providing additional example labels to guide best practice and promote consistency in medication labelling. The ANMF considers that advice regarding trailing zeros should be explicit and include a clear recommendation to avoid their use in prescribing. The inclusion of a trailing zero in a medication order (for example, writing 1.0 mg instead of 1 mg) is widely recognised as unsafe practice. There are well-documented instances of patients receiving incorrect dosages due to misinterpretation of trailing zeros. To minimise the risk of medication error and protect patient safety, the avoidance of trailing zeros should be clearly stated and reinforced within labelling and prescribing guidance.
56. **Q41, Do you agree with requiring a statement ‘Swallow whole. Do not crush or chew ‘ on labels of medicines that are modified release or enteric coated formulations for oral administration**
57. The ANMF supports the inclusion of clear statements explaining how medicines should be administered, particularly for modified-release or enteric-coated formulations. These products require specific handling and administration practices to ensure their safety and effectiveness, and inappropriate administration may result in harm.
58. Clear, accessible advice should be provided for any medication where additional information improves public safety. The ANMF considers that this information should also be printed on the outside of packaging to promote public awareness and support safe administration practices.



This is particularly important for individuals who administer medications as part of their employment, but who are not registered health professionals, ensuring they have clear guidance to minimise risk and protect patient safety.

59. Q42 Do you agree with the planned guidance updates about warning statements on labels of prescription and related medicines

60. The ANMF supports mandating cytotoxic warnings on generic medicines to enhance safety for clinicians administering these medications. Clear, prominent warnings help nurses, midwives, and carers understand the precautions necessary to protect themselves during handling.
61. The ANMF recommends that such warnings be applied to any medication that is mutagenic, teratogenic, or reprotoxic. Consistent and explicit labelling ensures that all healthcare workers, regardless of their role, are aware of the risks and can implement appropriate safety measures, thereby reducing occupational exposure and safeguarding both health professionals and patients.
62. The ANMF firmly believes that changes to current labelling protocols must only be implemented if they can be demonstrably proven, through current research, to maintain or enhance patient safety and outcomes. The inclusion of any new information on medication labels must never compromise the clarity, prominence, and legibility of the strength and dosage information.
63. Human factors are the most common cause of medication errors. These errors often involve misreading labels, miscalculating drug strengths, and misinterpreting dosages. Clinicians who misunderstand the strengths and dosages of injectable medicines risk making life-threatening errors. Medication errors due to misinterpretations of labelling are a serious concern, with the potential to cause significant harm to patients. This highlights the critical importance of presenting strength information in a clear, unambiguous manner, regardless of the packaging format.
64. Medication label information must therefore be legible, understandable, and succinct. This is especially critical in emergency situations, where immediate access to clear and accurate



information is essential for ensuring patient safety. Clinicians facing time-sensitive decisions require labelling that is easy to read, comprehend, and act upon. Anything less than this can lead to delays and potentially compromise patient outcomes. The ANMF urges that all decisions regarding medication labelling are based on robust scientific evidence and a commitment to patient safety as well as acknowledgement of practitioner requirements.

65. **Q43, Do you agree with the proposed requirements for non-prescription medicines that are large solid oral dosage forms**
66. The ANMF is supportive of large dosage warning statements. This will help improve consumer safety. The direction to swallow with water must be clear but should offer a safe alternative for people who cannot perform this task safely.
67. **QR codes, Machine Readable Codes and Instructions for Preparation**
68. **Q44, Do you agree with the proposed changes to displaying warning statements on labels of listed medicines.**
69. **Q45, Do you agree with the proposed requirements for using QR codes on medicine labels**
70. **Q46, Do you agree with the planned guidance for using machine readable codes on machine labels**
71. **Q47, Do you agree with the proposed changes to requirements to allow some injectable medicines administered by healthcare professionals to use a QR code instead of providing printed instructions for preparation**
72. **Q48, If the proposed changes to requirements for instructions for preparation for instructions for injectable medicines administered by healthcare professionals were implemented, which medicines do you think should or should not be allowed to use a QR code instead of printed preparation instructions. For example, should anaesthetic agents have printed instructions**
73. **Questions 44 – 48**
74. The ANMF is supportive of the inclusion of QR codes in healthcare; this use of technology allows for the sharing of relevant information quickly and efficiently. The potential drawbacks to the use of these codes as an alternative to printed information will be for areas that have



limited or inconsistent access to the internet and supportive technology. Our members advise that accessing working computers, and handheld devices varies greatly across areas.

75. Each employer would need to provide devices that are readily accessible and or available for this purpose which could be problematic. This could also be problematic for consumers who have limited access to technology and or devices that would allow this information to be viewed in their homes. There would need to be alternative methods available to access this type of information for each medication that has a QR code. We strongly object to the removal of the printed package insert in instances where the instructions for preparation cannot fit on the label for the following reasons:

76. Digital literacy of staff

77. While some healthcare settings utilise smartphones for communication, research by de Jong et al. (2020) highlights limited insight into smartphone use by nurses across diverse healthcare environments (primary care, community care, aged care and disability care, etc.). Furthermore, Kuek & Hakkennes (2020) report that up to 20% of healthcare staff experience anxiety using information systems. The Queensland Nursing Midwifery Union's (QNMU) own research (2019) indicates that digital technologies are often perceived as time-consuming and burdensome by nurses and midwives, which can potentially compromise patient care (Kuek & Hakkennes, 2020). Implementing QR codes without addressing these concerns could exacerbate existing anxieties and inefficiencies.

78. Use of Personal Devices for work purposes

79. Smartphone use for work purposes is not universally permitted across healthcare facilities. Even when allowed, local policies may restrict access to specific professions (e.g., medical officers). Additionally, while some facilities may provide work phones, this is not the norm for most nurses and midwives. We strongly oppose the expectation that nurses and midwives use personal devices for work tasks, and we argue that information critical to patient care should not be contingent on personal resources.



80. *Unreliable Internet Connectivity*

81. Major hospitals experience internet "black spots" hindering mobile device access. The QNMU's Digital Technology and Information Systems survey (2019) revealed that 40% of respondents faced challenges accessing the internet, with only half satisfied with support services. Furthermore, in the instance of a technology failure, IT helpdesk services cannot guarantee response times that ensure emergency patient care will not be compromised.

82. These issues are even more pronounced in rural and remote areas, where some locations lack phone coverage altogether. For community nurses reliant on home visits, this presents a significant risk if they cannot access vital medication instructions. Furthermore, retrofitting public hospitals for digitalisation can be challenging due to infrastructure limitations. These issues highlight the potential for QR codes to exacerbate existing disparities in access to information for nurses and midwives working in diverse geographic locations.

83. *System Outages and Redundancy*

84. Telecommunication network outages can significantly disrupt healthcare services, impacting both critical and general care (ABC News, 2023; Ritchie & Epstein, 2024). QR code functionality relies on a stable internet connection (Wi-Fi or 4G) and a dependable electricity supply. Clinicians without QR scanners, or facing disruptions, will inevitably resort to printing information. Nurses and midwives often rely on printed information due to cumbersome or malfunctioning digital systems. A system reliant on QR codes creates a single point of failure, potentially jeopardising patient safety.

85. *Maintaining a Physical Copy for Emergencies*

86. The current system with printed package inserts offers a reliable and readily accessible solution, especially in emergencies or situations with limited digital access. A physical copy can be easily referenced without relying on technology or internet connectivity. This is particularly crucial in time-sensitive situations or when dealing with critically ill patients.



87. *Information accuracy concerns*

88. This may also lead to clinicians resorting to workarounds such as printing or relying on external sources (e.g., Australian Injectable Drugs Handbook) potentially leading to outdated information. The printed insert should remain the primary source of truth to avoid this gap. While proponents claim QR codes link to the most up-to-date information, medication information typically doesn't change as frequently as medications are manufactured.

89. *The Potential for Human Error*

90. The introduction of QR codes could inadvertently increase the risk of human error. Scanning a QR code requires additional steps compared to simply referencing a printed insert. This additional step could lead to confusion or delays, particularly for nurses and midwives unfamiliar with the technology or working in high-pressure environments. The above statements apply to Questions 44 - 48.

91. **Q49, Do you agree with the proposed changes to stop allowing embossing or debossing batch numbers and expiry dates on the primary pack unless they are also printed or clearly contrast with a dark background**

92. The ANMF supports any changes that enhance medication labelling to improve safety and clarity. In particular, the ANMF endorses solutions that ensure batch numbers and expiry dates are printed clearly and presented in strong contrast against a dark background. Clear visibility of this information is essential for nurses, midwives, carers, and patients to accurately identify medications, verify their validity, and reduce the risk of errors or the use of expired products.

93. **Q53, Do you think more guidance is needed on displaying diluents in injectable medicines**

94. The ANMF is supportive of displaying diluents on injectable medicine labels. Poor label clarity, such as omission of diluents, make it difficult to quickly and accurately identify potential drug interactions, especially in fast-paced or urgent clinical environments. The ANMF endorses any labelling practices that help prevent medication errors by providing nurses, midwives, and carers with accurate, accessible information at the point of administration. Clear identification of



diluents reduces the risk of incorrect preparation or administration, thereby enhancing patient safety and supporting safe medication practices.

95. Q60 Do you agree with the planned guidance for labelling blister packs

96. The ANMF supports the provision of more detailed guidance on labelling blister packs to promote the safe use of medicines. ANMF members have extensive experience with medicines dispensed in blister packs that are subsequently administered by nurses or midwives, where the medication is not readily identifiable by appearance alone.

97. Blister packs are frequently used by older patients and by carers who assist with medication administration. Clear, consistent, and easy-to-read labelling on these packs helps prevent errors, ensures medicines are administered correctly, and supports both patients and carers in maintaining safe medication practices. Improved guidance would enhance safety, particularly for populations at higher risk of misadministration.

98. Q62, Do you agree that more guidance is needed on showing the route of administration on injectable medicine labels

99. The ANMF supports the development of clearer guidance on displaying the route of administration on injectable medicine labels. A straightforward statement, such as “to be given intravenously,” is a low-cost intervention that can significantly reduce the risk of patient harm. Similar to the use of coloured stickers on intravenous pumps, syringes, and IV lines in healthcare settings, clearly indicating the administration route on the medicine label provides an additional safety layer, helping nurses, midwives, administer medications correctly and safely.

100. Q63, Do you agree with the proposal to require a label statement for listed medicines with a vaginal route of administration.

101. The ANMF agrees with the inclusion of a clear label statement for all medicines administered via the vaginal route. This is particularly important because certain medications administered this way may pose risks to people who are pregnant or could become pregnant. Clear labelling ensures that health professionals, carers, and others who provide medication support are aware of these risks and can take appropriate precautions. It also informs the



general population, promoting safe and informed use of these medicines and helping to prevent potential harm.

102. **Q64, Do you agree with the planned guidance updates about colour contrast**

103. The ANMF supports the TGA providing guidance on the use of contrasting colours in medication packaging. Readability of packaging is extremely important for nurses, midwives, and carers, as it reduces risk of misreading labels and helps prevent medication errors. Clear, high contrast labelling enables health professionals and patients to accurately identify medicines, supporting safe and efficient clinical practice.

104. **Q65, Do you agree with the planned guidance updates about graphics on prescription medicines**

105. The ANMF supports the TGA providing guidance about graphics on medicine packaging. A significant part of nurses' and midwives' roles involves reading packaging and labels to verify that they have the correct medication for administration. The consistent use of graphics across all medicines would improve readability, reduce the risk of errors, and support safe and efficient medication practices for both health professionals and carers.

106. **Q66, Do you agree with the planned guidance updates about differentiating medicines**

107. The ANMF supports the planned guidance from the TGA regarding differentiation of medicines. The ANMF supports mandating the use of certain colours for specific medicines, such as potassium being consistently labelled in red. We also support the consideration of both clinical and environmental contexts when designing labels, ensuring that medicines are easily identifiable, safe to use, and appropriate for the settings in which they are administered. This approach enhances medication safety for nurses, midwives, carers, and patients.



108. **General Requirements Including Application, Exemptions, Definitions and Transition Periods**

109. **Q70 Do you agree with the planned changes to correct the text size requirements for listed medicines**

110. The ANMF agrees with the planned changes to correct the text size requirements for listed medicines. Small text on labels can make it challenging for nurses, midwives, and carers to read and verify medications accurately. This often leads to multiple checks and clarifications between staff, increasing the risk of delays or errors. Ensuring text is a legible size is essential so that readability is not a barrier to safe medication practice, supporting efficiency, accuracy, and patient safety.

111. **Q72, Do you agree with the proposed transition periods for the new labelling standards**

112. Yes, the ANMF considers this review period of three years appropriate for the introduction of new labelling standards. The ANMF expects that the TGA will provide supporting information and education to assist healthcare professionals with these changes. Transition periods in healthcare can be challenging, even when intended outcomes are positive, so clear guidance and educational resources are essential to ensure smooth adoption and to maintain patient safety throughout the implementation process.

113. **Q73, Do you agree with the plan to update the structure of the guidance to reflect different types of medicines and different orders**

114. Yes, the ANMF supports the plan to update the structure of the guidance for different types of medicines and orders. An integrated approach with clear visibility for our members would be best.

115. **Q74, Do you think that any more changes should be made to medicine labelling requirements in the new standards replacing TGO91 and TGO 92 that are critical to support medicine safety**

116. The ANMF supports the proposed changes and does not have any further recommendations or changes that are critical to support medicine safety.



Q75, If you have any other comments or general feedback about medicine labelling requirements, please include them here

117. The ANMF would like to thank the TGA for the opportunity to provide feedback on the planned labelling of medicines under TGO 91 and TGO 92. Safe medication practice is a core aspect of the work of nurses, midwives, and carers. How our members read and interpret medicine labels is critical to preventing errors and can directly save lives.

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