



australian nursing federation

24 August 2012

Ms Rebecca Doolan
Project Manager
Labelling and Packaging Review
Therapeutic Goods Administration
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Dear Ms Doolan

Review of the Labelling and packaging of medicines

The Australian Nursing Federation (ANF) welcomes the current review of labelling and packaging of medicines being undertaken by the Therapeutic Goods Administration (TGA).

With a membership of over 220,000 the ANF is the largest professional and industrial organisation in Australia for nurses, midwives and assistants in nursing. Members of the ANF are employed in a wide range of settings in urban, rural and remote locations in both the public and private sectors.

The ANF participates in the development of policy relating to nurses and midwives on issues such as: practice, professionalism, regulation, health and aged care, community services, veterans' affairs, education, training, workforce, socio-economic welfare, occupational health and safety, industrial relations, social justice, human rights, immigration and migration, foreign affairs and law reform.

Given the vast number of ANF members across all areas of the health and aged care sectors, our organisation has a strong and vested interest in medicines and all other therapeutic products used in treatment regimes. The nursing and midwifery professions play a critical role and are proactive in quality use of medicines, optimizing patient safety. This involves not only being able to readily identify medicines information on labels and packaging for themselves in medicines administration, but also in assisting patients and consumers with product information.

As frontline health professionals across all age groups and all settings where health and aged care is delivered, nurses and midwives frequently encounter issues arising from confusing, incomplete or poorly presented information on medicines labels and/or packaging. Consequently we welcome the review of the current status of labelling and packaging, and the proposed regulatory changes to promote safer use of medicines.

The ANF is of the view that improved regulations will reduce clinical risk and support the safe management and administration of medicines by our members in the many and varied environments in which they practice, particularly the residential and community aged care sectors.

In accordance with professional practice guidelines, registered nurses and midwives, are entrusted with the responsibility for:

- administering medicines in accordance with prescribed orders
- delegating to, and supervising, administration of medicines by appropriately qualified enrolled nurses
- delegating to, and supervising, appropriately qualified assistants in nursing (however titled) when they are engaged in assisting residents/clients to self-administer medicines
- educating and advising residents/clients/patients and family members

The proposed recommendations by TGA and the Australian Commission on Safety and Quality in Health Care (ACSQHC) would provide for an improved standard in labelling of medicines, reducing confusion and resultant medicines administration errors.

On behalf of our nursing and midwifery members the ANF works closely with the ACSQHC to improve the safety and quality of health and aged care. In particular, we participate on committees and working groups for medication management safety: developing mechanisms for national consistency on medicines administration and reconciliation; and safer medicines labelling processes for user applied labels. Through this work we have been privy to the submission being prepared by the ACSQHC for this current TGA review. The ACSQHC has supported many of the changes proposed by the TGA, and have made recommendations for additional changes to strengthen the regulations on labelling and packaging of medicines.

The ANF fully supports the approach taken in the ACSQHC submission and requests the TGA act on the advice proffered by the Commission.

In relation to an expert advisory body the ANF categorically supports the establishment of such a group to act as a labels and packaging advisory committee. As mentioned previously nurses and midwives have a significant role in quality use of medicines, working across diverse population groups, geographic, health and aged care settings. The close relationship nurses and midwives have with health and aged care consumers means they are well positioned to understand the importance of labelling and packaging of medicines – what works well for safe medicines use and what increases risk of errors occurring; and, to provide feedback on these matters. As the largest professional body representing the nursing and midwifery professions, the ANF requests that nurses and midwives be members of this committee.

The ANF acknowledges the matters that are outside the scope of this review, as outlined in the consultation paper. We would like to take this opportunity, however, to highlight two issues of concern relating to dose administration aids (DAAs), based on feedback from our registered nurse members. These are:

- Insufficient or inconsistent labelling and packaging of dose administration aids (DAAs), such as Webster or calendar packs, which are prepared for consumers by a pharmacist or dispensary assistant.
- Errors in re-packaging of medicines from the original manufacturers packaging into multi and single dose DAAs. These DAA's are prepared and packaged external to the health or aged care facility where they are used. Contemporary research highlights that there is an approximate 12% error rate in the re-packaging of medicines into DAAs¹. Our members identify that in some facilities they are now being required by their employers to double check that the pharmacy has re-packaged these medicines correctly.

The Pharmaceutical Society of Australia, in conjunction with the Pharmacy Guild, has developed a set of *Professional Practice Standards* (Version 4, 2010) which includes a standard on DAAs². Given the problems outlined above are persisting despite the existence of self-regulatory standards, the ANF considers this to be a matter of extreme priority that must be addressed by the TGA. We request a review of current practices with DAAs and consequential development of regulatory standards on labelling, packaging and re-packaging from original manufacturers containers.

Should you require any additional information or wish to discuss the matters raised in this submission please contact Elizabeth Foley, Federal Professional Officer, on (03) 9602 8500 or elizabethf@anf.org.au.

Yours sincerely,



Lee Thomas

Federal Secretary

References:

1. Hussainy, S, Marriott, J, van Koeverden, P, and Gilmartin, J. 2012. How accurate are manually prepared dose administration aids in residential aged care facilities? *Australian Pharmacist*. April. p. 320-325.
2. Pharmaceutical Society of Australia. 2010. (Version 4). *Professional Practice Standards (Standard 7 Dose Administration Aids Service)*. Available at: <http://www.psa.org.au/supporting-practice/professional-practice-standards/version-4>

The industrial and professional organisation for nurses and midwives in Australia

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