



Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Order No. 69D

Amendment to Therapeutic Goods Order No. 69
General requirements for labels for medicines

I, JOHN SKERRITT, National Manager of the Therapeutic Goods Administration and delegate of the Minister for Health for the purposes of the exercise of the Minister's powers under section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, hereby AMEND Therapeutic Goods Order No. 69 *General requirements for labels for medicines*, made on 27 August 2001, as amended, in the manner set out below.

1. **Under clause 2 'Interpretation',**

DELETE the current definition of '*Required Advisory Statements for Medicine Labels*'.

2. **Under clause 2 'Interpretation',**

DELETE the current definition of '*warning statements*' and

REPLACE with the following new definition:

- (a) any advisory statements that are required to be included in a medicine's label as specified in the *Medicines Advisory Statements Specification 2014*, a legislative instrument made by the Minister under subsection 3(5A) of the Act, as in force from time to time;
- (b) any warning statements specified in the standard that applies to the medicine;
- (c) a warning statement indicating that incorrect route or method of administration may be hazardous;
- (d) any warning required by the Secretary of the Department of Health to be included as a condition of registration or listing in relation to the medicine;
- (e) any warning statement specified in the Regulations that applies to the medicine;
- (f) any warning statements specified in the Poisons Standard that applies to the medicine.

This Order commences on the day after it is registered on the Federal Register of Legislative Instruments.

Dated this 23rd day of May 2014.

(Signed by)
Professor John Skerritt
Delegate of the Minister for Health