

TASMANIA

THERAPEUTIC GOODS REGULATIONS 2022
STATUTORY RULES 2022, No. 46

CONTENTS

1. Short title
2. Commencement
3. Wholesaler of therapeutic goods to comply with Code
4. Labelling of certain therapeutic substances

THERAPEUTIC GOODS REGULATIONS 2022

I, the Governor in and over the State of Tasmania and its Dependencies in the Commonwealth of Australia, acting with the advice of the Executive Council, make the following regulations under the *Therapeutic Goods Act 2001*.

Dated 5 July 2022.

B. BAKER
Governor

By Her Excellency's Command,

JEREMY ROCKLIFF
Minister for Health

1. Short title

These regulations may be cited as the
Therapeutic Goods Regulations 2022.

2. Commencement

These regulations take effect on 1 August 2022.

3. Wholesaler of therapeutic goods to comply with Code

(1) In this regulation –

Therapeutic Goods Regulations 2022
Statutory Rules 2022, No. 46

r. 4

Code means the "*Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*", first published by the former entity of the Commonwealth known as the National Coordinating Committee on Therapeutic Goods on 1 April 2011, and as republished from time to time by the Therapeutic Goods Administration of the Commonwealth.

- (2) A person who supplies therapeutic goods by wholesale must comply with the Code.

Penalty: Fine not exceeding 20 penalty units.

4. Labelling of certain therapeutic substances

- (1) In this regulation –

container, when used in relation to any therapeutic substance, means any vessel, bottle, tube, capsule, tin, box, case, wrapper, cover or other like receptacle or envelope that immediately contains the substance;

Poisons List has the same meaning as in the *Poisons Act 1971*;

therapeutic substance means a substance supplied for therapeutic use;

therapeutic use has the same meaning as in the Commonwealth Act;

unscheduled therapeutic substance means a therapeutic substance that is not specified

in any of the Schedules to the Poisons List.

- (2) A person specified in item 1, 2 or 4 of Schedule 8 to the *Therapeutic Goods Regulations 1990* of the Commonwealth must not supply an unscheduled therapeutic substance for therapeutic use unless the person complies with the standards constituted by the following orders made under section 10 of the *Therapeutic Goods Act 1989* of the Commonwealth:
- (a) *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines;*
 - (b) *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.*

Penalty: Fine not exceeding 20 penalty units.

- (3) The label on a container containing a therapeutic substance must show the following details:
- (a) the words “KEEP OUT OF REACH OF CHILDREN” in red on a white background;
 - (b) if the substance is intended for external use only, the word “POISON”, or the words “FOR EXTERNAL USE ONLY”, in red on a white background;
 - (c) if the substance is intended for the treatment of a person, the name of the person;

Therapeutic Goods Regulations 2022
Statutory Rules 2022, No. 46

r. 4

- (d) if the substance is intended for the treatment of an animal, the species of animal and the name of the animal's owner.
- (4) In addition to the requirements of subregulation (3), the label on a container containing a therapeutic substance that is supplied on prescription must show the following details:
 - (a) the directions for use;
 - (b) the prescription reference number;
 - (c) the date on which the prescription was supplied, unless that date is clear from the prescription reference number.
- (5) The provisions of subregulations (3) and (4) are complied with if the information referred to in those subregulations is shown by tags, brands or marks, or statements printed or in clear writing on the container.

Therapeutic Goods Regulations 2022
Statutory Rules 2022, No. 46

Printed and numbered in accordance with the *Rules Publication Act 1953*.

Notified in the *Gazette* on 13 July 2022.

These regulations are administered in the Department of Health.

EXPLANATORY NOTE

(This note is not part of the regulations)

These regulations –

- (a) require wholesalers of therapeutic goods to comply with the "*Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*"; and
- (b) contain labelling requirements for certain therapeutic substances; and
- (c) are made consequentially on the repeal of the *Therapeutic Goods Regulations 2012* under section 11 of the *Subordinate Legislation Act 1992*.