Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018

I, LARRY KELLY, a delegate of the Minister for Health, make this order under section 10 of the *Therapeutic Goods Act 1989*.

Dated 15 June 2018

(*signed by*)

LARRY KELLY
Delegate of the Minister for Health

Contents

1 Name

This instrument is the *Therapeutic Goods Order No. 91B - Therapeutic Goods Order No. 91 (Standard for labels of prescription and related medicines) Amendment Order 2018*.

2 Commencement

This instrument commences on 2 July 2018.

3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines

1 Section 6 Interpretation

Insert:

neuromuscular blocking agent means, for the purposes of this Order, any of the ingredients (or salts thereof) specified in Schedule 3 to this Order;

2 After subsection 9(3)

Insert:

(3A) Where medicines are supplied as part of a composite pack, the names of each active ingredient, together with its quantity or proportion, must be provided separately in relation to each medicine's formulation**,** on the main label of the composite pack.

3 Subsection 9(8)

Repeal the subsection, substitute:

(8) For subsection 9(6), where medicines are supplied as part of a composite pack:
   (a) the total number of active ingredients in all of the medicines in the composite pack are to be counted; and
   (b) if the same active ingredient is contained in two or more medicines in the composite pack, each of those active ingredients is to be counted separately;

   for the purposes of determining if subsection 9(6) applies to the composite pack; and

   (c) the required information under subsection 9(6) must be provided separately in relation to the formulation of each medicine in the composite pack.

4 Before subsection 10(9)

Insert:

(8A) Neuromuscular blocking agent-containing medicines

In addition to the requirements of sections 8 and 9, and the requirements in subsections 10(3), (4), (5) and (15) as applicable, if a medicine contains a neuromuscular blocking agent, then:

(a) the label on the primary pack must include the warning statement 'Warning: Paralysing agent' in black text on a fluorescent red or warm red background; and

(b) the label on the container must include the warning statement 'Warning: Paralysing agent' in black text on a fluorescent red or warm red background, except:

(i) where subsection 10(5) applies, in which case this warning statement may be shortened to 'Warning: Paralyser' or 'Paralyser'; or

(ii) where subsection 10(15) applies, in which case this warning statement must be on the label of each ampoule, and may be shortened to 'Warning: Paralyser' or 'Paralyser', and may be in any colour text with no background colour.

5 Title of Section 11(6)

Omit "**inclusion**", substitute "**Inclusion**".

6 After Schedule 2

Insert:

Schedule 3 – Specified neuromuscular blocking agents (or salts thereof)

alcuronium
atracurium
cisatracurium
dimethyltubocurarine
doxacurium
fazadinium
gallamine
hexafluronium
mivacurium
pancuronium
pipecuronium
rocuronium
suxamethonium
tubocurarine
vecuronium