



Therapeutic Goods Order No. 80A Amendments to Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines

Therapeutic Goods Act 1989

I, JOHN SKERRITT, a 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* (the Act) and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the Act, hereby AMEND Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines*, made on 27 August 2008, in the manner set out in Schedules 1, 2 and 3.

Dated September 17 2012

(signed by)

JOHN SKERRITT

Delegate of the Minister for Health

1 Name of Order

This Order is the Therapeutic Goods Order No. 80A *Amendments to Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines*.

2 Commencement

This Order commences on and from 1 October 2013.

Schedule 1 Amendments to Part 1 of Schedule 1 of TGO 80

This Schedule sets out the following amendments to Part 1 of Schedule 1 of *Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines* (TGO 80):

1. **ADD** a new class of substances to the table in Part 1: ‘ANGIOTENSIN II ANTAGONISTS’; and

ADD the following examples for this class of substances in that table: ‘Candesartan’, ‘Eprosartan’, ‘Irbesartan’, ‘Losartan’, ‘Olmesartan’, ‘Telmisartan’ and ‘Valsartan’.

2. **ADD** the following examples under the following existing classes of substances in the table in Part 1:

Existing Class of Substance	Additional examples
ANTICHOLINERGICS	Solifenacin
ANTIDEPRESSANTS	Desvenlafaxine Duloxetine
ANTIEPILEPTICS	Lacosamide Zonisamide
ANTI-HISTAMINES	Levocetirizine
ANTINEOPLASTIC AGENTS	Dasatinib Erlotinib Lapatinib Nilotinib Sorafenib Sunitinib
ANTI-PARKINSON DRUGS	Rotigotine
ANTIPSYCHOTICS	Paliperidone
ANTITHROMBOTIC AGENTS	Dabigatran Prasugrel Rivaroxaban
BETA BLOCKING AGENTS	Nebivolol
ORAL BLOOD GLUCOSE LOWERING AGENTS	Sitagliptin

3. **AMEND** the reference in the table in Part 1 to ‘BENZODIAZEPINE DERIVATIVES’ to refer instead to ‘BENZODIAZEPINE DERIVATIVES and BENZODIAZEPINE RELATED DRUGS’; and

ADD the following additional examples for this class of substance: ‘Zolpidem’, ‘Zopiclone’ and ‘Zaleplon’.

4. **AMEND** the reference in the table in Part 1 to ‘OPIOIDS, excluding pholcodine’ to refer instead to ‘OPIOIDS’.

Schedule 2 Amendments to Part 2 of Schedule 1 of TGO 80

This Schedule sets out the following amendments to Part 2 of Schedule 1 of TGO 80:

1. **ADD** the following entries:

ALISKIREN.

AMBRISENTAN.

AZADIRACHTA INDICA (NEEM), in a preparation for human dermal use containing more than 1 per cent of cold pressed neem seed oil.

BOSENTAN.

BROMHEXINE.

CARAPICHEA IPECACUANHA (IPECACUANHA).

CHLORAL HYDRATE.

CILOSTAZOL.

DEFERASIROX.

DEXTROMETHORPHAN.

GUAIPHENESIN; GUAIFENESIN.

IVABRADINE.

LANTHANUM.

LENALIDOMIDE.

OXYMETAZOLINE.

PENTOOXYVERINE.

PHOLCODINE.

POLYGALA SENEGA (SENEGA).

VARENICLINE.

XYLOMETAZOLINE.

2. **REPLACE** the entry ‘METHYL SALICYLATE, in a liquid preparation containing 25 per cent or more of methyl salicylate’ with:

‘METHYL SALICYLATE, in a liquid preparation containing 5 per cent or more of methyl salicylate’.

Schedule 3 Amendments to Part 3 of Schedule 1 of TGO 80

This Schedule sets out the following amendments to Part 3 of Schedule 1 of TGO 80:

1. **ADD** the following entries:

Aliskiren.

Ambrisentan.

ANGIOTENSIN II ANTAGONISTS

Azadirachta indica (Neem), in a preparation for human dermal use containing more than 1 per cent of cold pressed neem seed oil.

BENZODIAZEPINE RELATED DRUGS

Bosentan.

Bromhexine.

Candesartan (*Angiotensin II Antagonists*).

Carapichea ipecacuanha (Ipecacuanha).

Chloral hydrate.

Cilostazol.

Dabigatran (*Antithrombotic Agents*).

Dasatinib (*Antineoplastic Agents*).

Deferasirox.

Desvenlafaxine (*Antidepressants*).

Dextromethorphan.

Duloxetine (*Antidepressants*).

Eprosartan (*Angiotensin II Antagonists*).

Erlotinib (*Antineoplastic Agents*).

Guaiphenesin; Guaifenesin.

Irbesartan (*Angiotensin II Antagonists*).

Ivabradine.

Lacosamide (*Antiepileptics*).

Lanthanum.

Lapatinib (*Antineoplastic Agents*).

Lenalidomide.

Levocetirazine (*Antihistamines*).

Losartan (*Angiotensin II Antagonists*).

Nebivolol (*Beta Blocking Agents*).

Nilotinib (*Antineoplastic Agents*).

Olmesartan (*Angiotensin II Antagonists*).

Oxymetazoline.

Paliperidone (*Antipsychotics*).
Pentoxifyverine.
Pholcodine.
Polygala senega (Senega).
Prasugrel (*Antithrombotic Agents*).
Rivaroxaban (*Antithrombotic Agents*).
Rotigotine (*Anti-Parkinson Drugs*).
Sitagliptin (*Oral Blood Glucose Lowering Agents*).
Solifenacin (*Anticholinergics*).
Sorafenib (*Antineoplastic Agents*).
Sunitinib (*Antineoplastic Agents*).
Telmisartan (*Angiotensin II Antagonists*).
Valsartan (*Angiotensin II Antagonists*).
Varenicline.
Xylometazoline.
Zaleplon (*Benzodiazepine Derivatives and Benzodiazepine Related Drugs*).
Zolpidem (*Benzodiazepine Derivatives and Benzodiazepine Related Drugs*).
Zonisamide (*Antiepileptics*).
Zopiclone (*Benzodiazepine Derivatives and Benzodiazepine Related Drugs*).

2. **REPLACE** the reference to ‘METHYL SALICYLATE, in a liquid preparation containing 25 per cent or more of methyl salicylate’ with:

‘METHYL SALICYLATE, in a liquid preparation containing 5 per cent or more of methyl salicylate’.

3. **AMEND** the reference to ‘OPIOIDS, excluding pholcodine’ to refer instead to ‘OPIOIDS’.