



Therapeutic Goods (Medicines Watch List) Determination 2018

I, Jane Cook, as delegate of the Minister for Health, make the following determination.

Dated Fifth of December 2018

(signed by)

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Medicines Watch List) Determination 2018*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 January 2019.	1 January 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 30EJ(1) of the Act.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) medicine;
- (b) reportable medicine.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

IV or intravenous, in relation to a medicine, means the route of administration that is delivered within or into a vein.

ml means millilitre.

mmol means millimole.

PO or per oral, in relation to a medicine, means the route of administration that is taken through the mouth into the gastrointestinal system or administered to the oral cavity to obtain a local or systemic effect.

5 Medicines Watch List

The medicines set out in Schedule 1, being reportable medicines, are determined for the purposes of subsections 30EF(2) and 30EG(2) of the Act.

Schedule 1—Medicines Watch List

(section 5)

Column 1 Item	Column 2 Medicine
1	medicines that contain any of the following antimicrobial agents: <ul style="list-style-type: none">(a) aciclovir IV(b) amikacin(c) amphotericin B IV (liposomal)(d) ampicillin(e) benzylpenicillin(f) cefepime(g) chloramphenicol IV(h) ciprofloxacin IV(i) colistin(j) ethambutol(k) ganciclovir(l) gentamicin IV(m) isoniazid(n) metronidazole IV(o) phenoxymethylpenicillin(p) piperacillin and tazobactam(q) rifampicin PO or IV(r) sodium fusidate PO or IV(s) trimethoprim and sulfamethoxazole IV(t) vancomycin(u) voriconazole IV
2	medicines that are, or contain, any of the following antidotes or treatments for poisonings: <ul style="list-style-type: none">(a) activated charcoal(b) desferrioxamine injection(c) digoxin specific antibodies(d) edetate calcium disodium injection(e) ethanol injection(f) folinic acid (calcium folinate) injection(g) fomepizole(h) methylene blue IV(i) n-acetylcysteine IV

Column 1 Item	Column 2 Medicine
	(j) pralidoxime
	(k) sodium nitrite IV
	(l) sodium thiosulfate IV
3	medicines for emergency or critical care that contain any of the following:
	(a) adrenaline IV
	(b) alteplase
	(c) amiodarone IV
	(d) argipressin (vasopressin)
	(e) calcium gluconate gel
	(f) calcium gluconate injection
	(g) cyproheptadine
	(h) danaparoid
	(i) dantrolene injection
	(j) desmopressin IV
	(k) dexamethasone IV
	(l) diazepam IV
	(m) glucagon injection
	(n) glyceryl trinitrate IV
	(o) hydralazine IV
	(p) hydrocortisone IV
	(q) isoprenaline
	(r) mesna
	(s) morphine IV
	(t) methoxyflurane
	(u) metoprolol IV
	(v) neostigmine
	(w) nimodipine PO or IV
	(x) noradrenaline
	(y) phenytoin IV
	(z) phosphate IV
	(za) prednisolone PO
	(zb) protamine
	(zc) pyridostigmine
	(zd) quinine injection
	(ze) rasburicase
	(zf) salbutamol IV
	(zg) sodium bicarbonate 100mmol per 100ml injection

Column 1	Column 2
Item	Medicine
	(zh) sodium polystyrene sulfonate (zi) suxamethonium (zj) terlipressin (zk) tenecteplase (zl) thiamine IV (zm) vitamin K (phytomenadione) IV
4	medicines that contain any of the following anticoagulants: (a) enoxaparin (b) heparin (c) warfarin
5	medicines that are any of the following vaccines: (a) a vaccine included in the National Immunisation Program Schedule, as in force or existing at 1 July 2018 (b) absorbed diphtheria tetanus vaccine (c) bacillus calmette-guerin vaccine
6	medicines for use in obstetrics that contain any of the following: (a) ergometrine (b) magnesium sulfate IV (c) misoprostol
7	medicines that are any of the following antivenoms: (a) black snake antivenom (b) box jellyfish antivenom (c) brown snake antivenom (d) death adder antivenom (e) funnel web spider antivenom (f) polyvalent snake antivenom (g) red back spider antivenom (h) sea snake antivenom (i) stone fish antivenom (j) taipan antivenom (k) tiger snake antivenom
8	medicines that are any of the following: (a) adrenaline autoinjector (b) glyceryl trinitrate sublingual (c) naloxone injection

Column 1	Column 2
Item	Medicine
	(d) naloxone nasal spray
	(e) salbutamol inhaler
