

Attachment A: Proposed additions to the Reportable Medicines Determination

Table 1 lists the 23 registered, non-prescription medicines which are proposed to be included within the [Reportable Medicines Determination](#). The clinical use of each medicine is provided, as well as the TGA's reason(s) for proposed inclusion:

- *Medicines Watch List* – a medicine considered to be of 'critical impact' in shortage situations through its current inclusion in the Medicines Watch List.
- *PBS* – a non-reportable medicine listed on the Pharmaceutical Benefits Scheme (PBS) and considered to pose a high risk to impacting the health of Australians if a shortage or discontinuation occurs in the future.
- *Previous shortage* – a non-reportable medicine involved in a previous shortage that raised a significant public health concern, where the TGA temporarily approved overseas alternative products in place of the unavailable registered medicine to support continuity of patient care in Australia.

Table 1: Registered non-prescription medicines proposed for inclusion in the Reportable Medicines Determination.

Medicines	Clinical use	Reason
Activated charcoal (with or without sorbitol) formulations for oral administration	Treatment of poisoning and drug overdose by oral ingestion	Medicines Watch List
Adrenaline (epinephrine) injection	Treatment of anaphylaxis or cardiac arrest	PBS Medicines Watch List
Barium sulfate	Oral radiographic contrast agent, used to assist diagnosis of gastrointestinal tract conditions	Previous shortage
Calcium gluconate injection	Critical care situations including cardiac resuscitation, severe hyperkalaemia (high blood potassium levels) and acute hypocalcaemia (low blood calcium levels)	Medicines Watch List
Calcium gluconate topical preparations	Treatment of tissue destruction, bone decalcification and accompanying severe pain from hydrofluoric acid burns	Medicines Watch List
Cyproheptadine	Antihistamine, also used in treatment of serotonergic toxidromes (e.g. poisoning from antidepressant medicines)	Medicines Watch List
Ethanol injection	Treatment of acute methanol and ethylene glycol poisoning	Medicines Watch List
Folinic acid (calcium folinate) oral dosage forms (containing 500 micrograms or more of folinic acid per recommended daily dose)	Treatment of anaemias from folic acid deficiency; treatment of methotrexate toxicity	PBS

Medicines	Clinical use	Reason
Hydroxocobalamin injection	Prevention and treatment of anaemias from vitamin B ₁₂ deficiency	PBS
Isosorbide dinitrate oral or sublingual dosage forms	Treatment of acute angina/chest pain; prevention of angina; treatment of heart failure	PBS
Magnesium sulfate injection and infusion	Prevention and treatment of life-threatening seizures in toxaeemias of pregnancy (pre-eclampsia and eclampsia); emergency treatment of some heart arrhythmias and acute hypomagnesaemia (low blood magnesium levels)	Medicines Watch List
Mannitol powder for inhalation	Chronic treatment of cystic fibrosis	PBS
Pancreatic enzymes (preparations containing 20,000 BP units or less of lipase activity per dosage unit)	Pancreatic enzyme replacement for patients with pancreatic exocrine insufficiency (e.g. cystic fibrosis)	PBS
Permethrin topical preparations	First line treatment for sarcoptes scabiei (scabies)	PBS Previous shortage
Phosphate salts for injection (including any of the following actives: dibasic sodium phosphate dodecahydrate, monobasic potassium phosphate, dibasic potassium phosphate)	Severe hypophosphataemia (low blood phosphate levels)	Medicines Watch List
Phytomenadione (Vitamin K) injection	Treatment of haemorrhage, severe hypo-prothrombinaemia (deficiency of blood clotting factors) and warfarin overdose. Prevention and treatment of vitamin K deficiency bleeding in newborns	Medicines Watch List
Sodium bicarbonate oral dosage forms (e.g. capsule)	Management of kidney failure associated with renal tubular acidosis in which bicarbonate replacement becomes necessary	PBS
Sodium bicarbonate injection	Treatment of metabolic acidosis (too much acid in the blood which can be life-threatening)	Medicines Watch List
Sodium chloride 0.9% (normal saline) solution for injection	Intravenous fluid therapy to restore or maintain hydration and salt levels, or as a vehicle for the administration of injectable medicines	Current shortage
Sodium nitrite injection	Antidote for cyanide poisoning (in conjunction with sodium thiosulfate)	Medicines Watch List
Sodium thiosulfate injection	Antidote for cyanide poisoning (often with sodium nitrite) and prevents sodium nitroprusside induced cyanide poisoning	Medicines Watch List
Theophylline oral liquid	Maintenance treatment of severe asthma	PBS
Thiamine hydrochloride injection	Treatment of vitamin B1 deficiency, including Wernicke encephalopathy	Medicines Watch List