MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Dexamethasone injection – 20 September 2022	
Details of affected product(s)	Dexamethasone Mylan 4 mg/mL solution for injection vial – ARTG 163200 Dexamethasone Mylan 8 mg/2 mL solution for injection vial – ARTG 163199
Reason for communication	Disruption to supply due to manufacturing constraints
Date issue made apparent	August 2022
Supply impact dates	1 June 2022 – 30 April 2023

Main therapeutic applications

Dexamethasone is a corticosteroid indicated for replacement therapy and as a treatment in corticosteroid responsive conditions including rheumatic diseases, neoplastic states and shock.

Alternative agents

An alternative 4 mg/mL product has been approved for supply under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989. Dexamethasone 4 mg/mL injection (Mylan brand from the US) are available in packs of 25 through Alphapharm Pty Ltd (trading as Viatris) until **30 April 2023**. The sponsor has confirmed that sufficient supply of the S19A alternative will be available to meet normal demand.

Further supply of Dexamethasone Mylan 8 mg/2 mL solution for injection vials has been arranged under an approval granted by the Therapeutic Goods Administration under section 14 and 14A of the Therapeutic Goods Act 1989 until **28 February 2023**. Supply may be intermittent. It is encouraged that backorders are in place with wholesalers to ensure stock is released when available.

Remaining supply of the Australian registered stock should be reserved for indications where these alternative agents are not appropriate.

Precautions, safety issues and other considerations associated with alternatives

Dexamethasone 4 mg/mL injection

The section 19A alternative (Mylan brand from the US):

- should be used according to the TGA approved Product Information for the Australian registered product.
- is presented in a pack size of 25, compared to the Australian registered pack size of 5 units.
- contains additional inactive ingredients and preservatives (including methylparaben and propylparaben) not present in the Australian registered product.
    - **This is to be considered if the medicine is being administered via any route other than those approved in the Product Information for the Australian registered product (including, but not limited to, intrathecal, epidural, intravitreal and oral administration).**

The Australasian Neonatal Medicines Formulary steering group has recommended that **preservative-free injectable dexamethasone preparations** be used in neonates. Methylparaben and propylparaben have the potential to cause kernicterus in neonates < 2 months old.

Dexamethasone 8 mg/2 mL injection

The alternative supply available under section 14 and section 14A is non-compliant with the British Pharmacopeia monograph in that it does not meet the pH acceptance requirements. The product supplied will not have a pH greater than or equal to 9.0.

Impacts of this communication on clinical practice

Actions to address the disruption to supply of dexamethasone injection should be coordinated and implemented by the local Drug and Therapeutics Committee.

Associated regulatory or policy references

PD2022_032 Medication Handling

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au

HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au