Management of medication shortages in NSW

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Clinical Excellence Commission, NSW

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Acknowledgement of Country

I acknowledge the Traditional Custodians of the various lands on which we all work today and the Aboriginal and Torres Strait Islander people participating in this meeting.

I pay my respects to Elders past, present and emerging and celebrate the diversity of Aboriginal peoples and their ongoing cultures and connections to the lands and waters of NSW.

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Recognition of living experience

The Clinical Excellence Commission recognises and values consumers, patients, carers, loved ones and staff as partners in healthcare.

The voices of people with living experience are powerful. Their contribution is vital to the work of continuously improving safety and quality in our health system.

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The Clinical Excellence Commission

Specialists in safety: partners in improvement

We are:

- Committed to continuous improvement in patient safety.
- In partnership with hospitals, we work to enhance and develop a strong and reliable safety culture, ensuring patients and their families and carers have a positive experience of care.
- We strive for safer care, for every patient, every time.

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CEC statutory functions

The CEC is the lead agency for system level **medicine and medical device issues**. Guided by *Coordination of responses to urgent system-level medicine or medical device issues* PD2019_019. These issues may result from, but are not limited to:

- Product defect/contamination
- Manufacturing disruptions (e.g. raw ingredient shortage or plant shutdown)
- Supply chain disruptions
- Increased product demand
- Regulatory issues and recalls
- Business decision to no longer manufacture or stock an item
- Increasing global reliance on single manufacturers

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news.com.au

Lifestyle > Health > Health Problems

Medicine shortage leaves Aussies struggling to fill scripts

A well-known doctor is calling for urgent changes to secure hundreds of basic medications which are now in short supply.

Aisling Brennan

@AislingBrennan9

less than 2 min read April 23, 2023 - 4:24PM

ABC NEWS SHARE

Medicine shortages an ongoing issue despite stockhold rules, advocates say

7.30 / By the Specialist Reporting Team's Alison Branley

Posted Wed 6 Sep 2023 at 6:59pm, updated Thu 7 Sep 2023 at 2:22am

The Sydney Morning Herald

Children bearing brunt of antibiotics shortage as pharmacists resort to making their own

By Melissa Cunningham and Aisha Dow

January 9, 2023 — 7.00pm

Daily Telegraph

News > National

More than 50 antibiotics still in shortage in Australia, according to TGA database

More than 400 medicines are in short supply across the nation, including more than 50 antibiotics. See why and if your medicine is on the list.

Amanda Sheppeard

2 min read July 3, 2023 - 7:39PM

News Corp Australia Network

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TGA says Australia is experiencing a shortage in over 400 medicines

July 04, 2023 - 6:59AM sky news .com.au

Impact on our patients

- Potential for increase in medication errors, patient harm and mortality, resulting from:
  - improper or inadequate drug substitutions, suboptimal care
  - delays in care
  - adverse events related to alternatives (sometimes inferior)
  - confusion by patients, family and carers.
- Potential for increased patient out-of-pocket expenses.
- Frustration and resulting increase in complaints.

What the shortages have highlighted

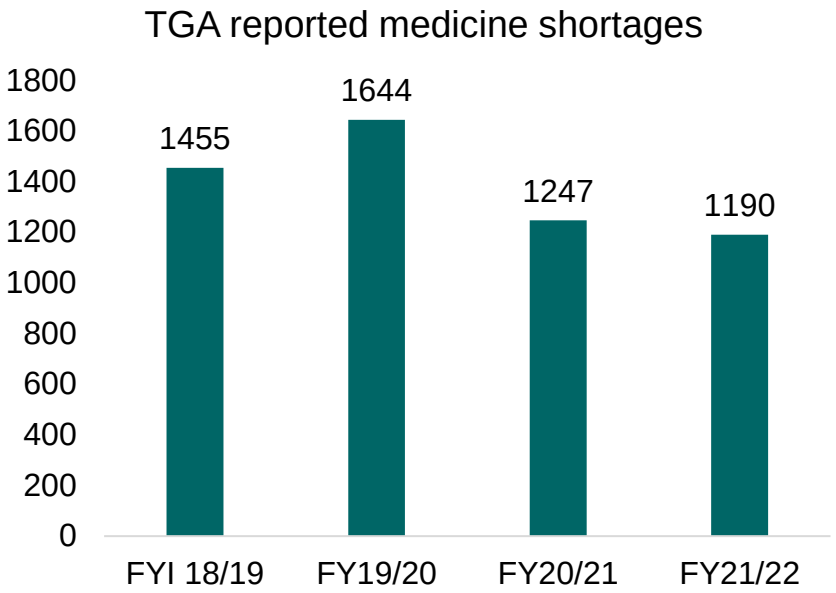
- Australia is **heavily reliant** on international supply chains for medications – over 90% of medicines are imported.
- Need to reduce **duplication of effort** when dealing with shortages and discontinuations.
- Care must be taken to **prevent medication safety risks** associated with introduction of alternatives during shortages.

Our NSW vision

The model for the management of medication shortages, discontinuations and recalls:

- Ensure **equity** of **access**
- Promote **consistency** in the approach taken
- Ensure an **appropriate and timely response**
- **Reduce duplication of effort** within the NSW public health system

Significant shortages



Currently:

- **431** shortages listed on TGA website
- **44** deemed critical

In 2023 the CEC has:

- Reviewed **211** supply issues
- Reported **69** to the front line

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Management of medication shortages/discontinuations in NSW

Notification of shortage

Notifications received from numerous sources:

- TGA
- HealthShare NSW
- Local facilities
- Drug companies

Information gathering

- Analyse usage and current stock on hand using available data
- Determine if suitable alternatives are available
- Seek expert advice from relevant clinical groups

Risk assessment

- Assess impact on patient safety based on information gathering in accordance with PD2019_019
- Develop risk mitigation strategies

Management of medication shortages/discontinuations in NSW (II)

Interagency communication

- Risk assessment and proposed strategies presented to multi-agency medicine shortage assessment and management (MSAM) team
- Team consists of representation from the CEC, HealthShare NSW, State Preparedness and Response Branch, Chief Pharmacist Unit and relevant clinical leads

Communication to public health facilities

- Dependent upon risk category agreed by MSAM team
- Communication method varies based on risk category

Communication methods

Low risk – short term affecting a small number of patients and/or an alternative medicine is available that is directly interchangeable	Managed locally.
Medium risk – short term shortages affecting a significant number of patients or where safety issues relating to available alternatives have been identified	Entry on Medication Safety Updates (MSU) webpage on CEC website and distribute **Medication Safety Communication** or **Safety Notice**.
High risk – involves essential medicines where an alternative is available but not directly interchangeable or broader system impacts are anticipated	Entry on MSU webpage and distribute **Safety Notice** or **Safety Alert**.
Extreme risk – involves essential medicines where no suitable alternative is available and/or will significantly limit capability to deliver health services	Entry on MSU webpage, distribute **Safety Alert** and escalate to Secretary.

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Medication Safety updates webpage

Medication Safety Communications

Search for: Show All

Sort: Date Updated | Descending | Sort

Be notified of updates on this page

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Date last updated: 18 Sep 2023

The information provided on this page is intended for use by NSW health clinicians. It may not be relevant to clinicians from other states or territories and is not the complete list of medicine shortages reported to the Therapeutic Goods Administration – refer to the TGA Medication Shortages Information Initiative and Medicines Safety Update.

Medicine Affected	Issued	Updated	Update	Status
Methylprednisolone sodium succinate injection	11-Jul-23	18-Sep-23	There is a current disruption to the supply of methylprednisolone sodium succinate (Solu-Medrol Act-O-Vial) 40 mg and 125 mg powder for injection due to manufacturing issues. Supply is expected to return from January 2024. Link Healthcare have received approval under Section 19A of the Therapeutic Goods Act to import supply of methylprednisolone sodium succinate (Solu-Medrone) 40 mg and 125 mg for injection from the United Kingdom until 29 February 2024. Refer to the Medication Safety Communication for further information on this disruption to supply, available alternatives, and associated safety considerations (by clicking on the medication name on the left).	Current
Vigabatrin	11-Jul-23	18-Sep-23	There is a current disruption to the supply of vigabatrin (Sabril) 500mg tablets due to manufacturing issues until at least 30 October 2023. The Therapeutics Goods Administration (TGA) has made a Serious Scarcity Substitution Instrument (SSSI) which allows community pharmacists to dispense a vigabatrin oral sachets when the prescribed tablets are unavailable without prior approval from the prescriber. The instrument will be in effect until 31 January 2024, unless ended earlier if the scarcity is resolved. Further information regarding the shortage and SSSI is available on the TGA webpage (accessible by clicking the medicine name to the left). Additionally, Sanofi have received approval under Section 19A (S19A) of the Therapeutics Goods Act to import supply of alternative 500 mg tablets from the UK until 31 January 2024, however supply of the stock is limited. The alternative is identical in active ingredient and strength. It should be noted that the blister packaging of the S19A alternative is blue (compared to the Australian registered stock which is clear).	Current
Entecavir	21-Aug-23	18-Sep-23	There is a current disruption to the supply of multiple brands of entecavir 0.5 mg tablets due to manufacturing issues and unexpected increases in consumer demand. Limited stock remains available. NSW Health facilities can contact HealthShare NSW for further information on obtaining supply. It is recommended that facilities closely monitor their stock levels and consider the need to dispense smaller quantities for PBS patients (i.e. 1 month) until the supply returns to normal.	Current

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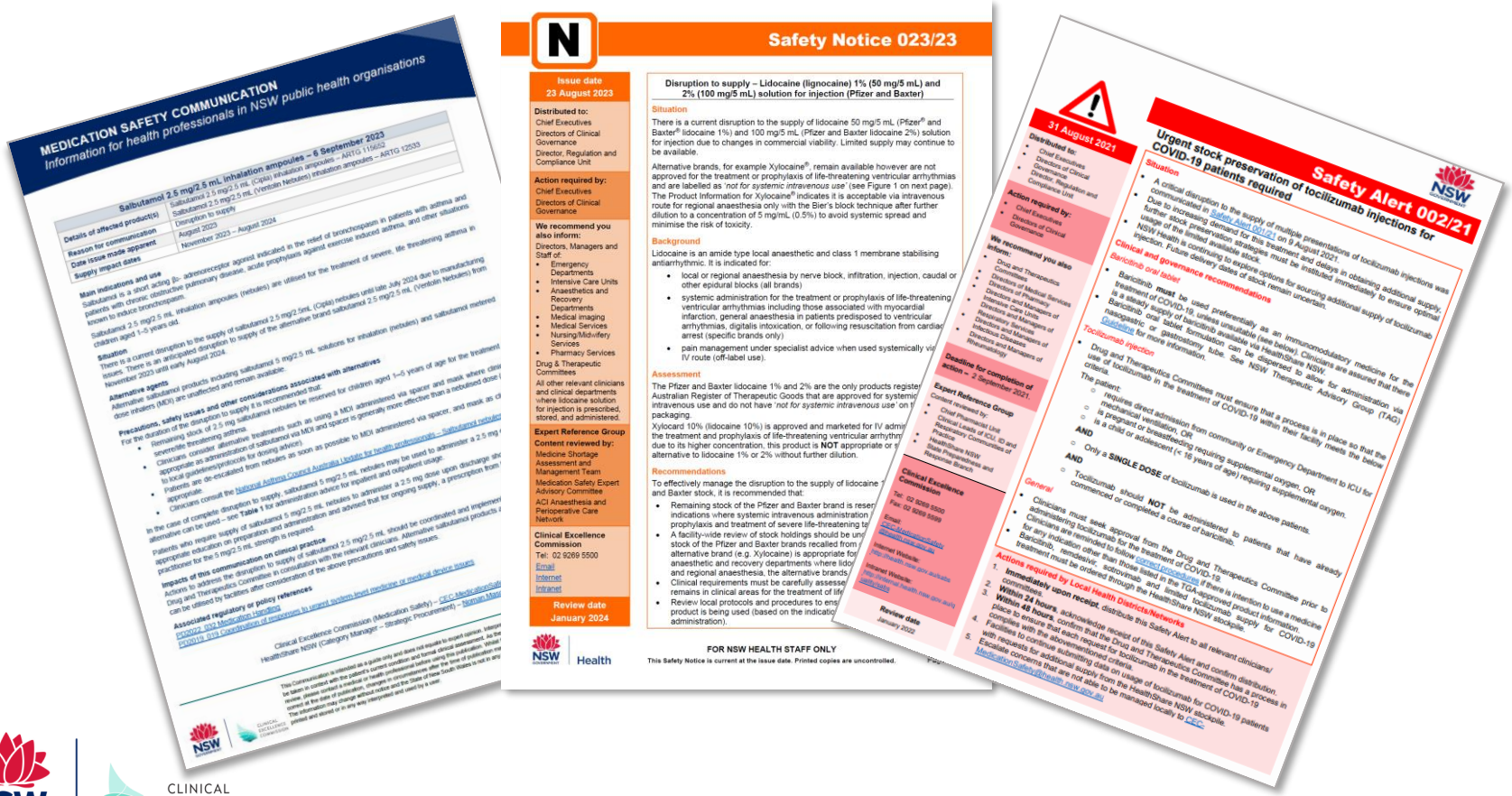
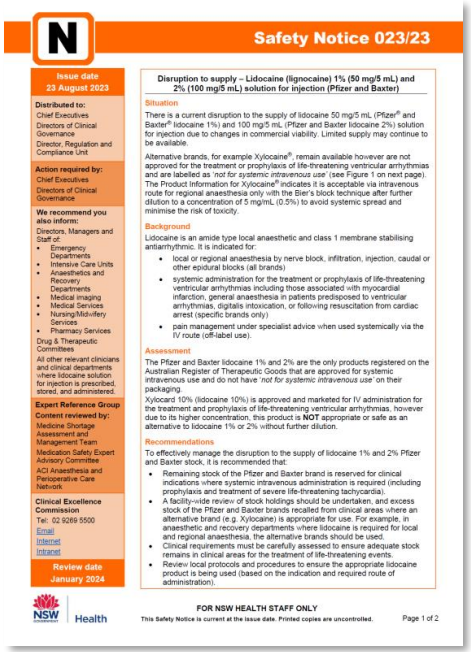

MEDICATION SAFETY COMMUNICATION
Information for health professionals in NSW public health organisations
Salbutamol 2.5 mg/2.5 mL inhalation ampoules – 6 September 2023
Safety Notice 023/23
Disruption to supply – Lidocaine (lignocaine) 1% (50 mg/5 mL) and 2% (100 mg/5 mL) solution for injection (Pfizer and Baxter)
31 August 2021
Urgent stock preservation of tocilizumab injections for COVID-19 patients required
Safety Alert 002/21

Lidocaine (lignocaine) 1% (50 mg/5 mL) and 2% (100 mg/5 mL) solution for injection (Pfizer and Baxter)



Safety Notice 023/23

Issue date
23 August 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Emergency Departments
- Intensive Care Units
- Anaesthetics and Recovery Departments
- Medical Imaging
- Medical Services
- Nursing/Midwifery Services
- Pharmacy Services

Drug & Therapeutic Committees
All other relevant clinicians and clinical departments where lidocaine solution for injection is prescribed, stored, and administered.

Expert Reference Group Content reviewed by:
Medicine Shortage Assessment and Management Team
Medication Safety Expert Advisory Committee
ACI Anaesthesia and Perioperative Care Network

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet
Intranet

Review date
January 2024

Disruption to supply – Lidocaine (lignocaine) 1% (50 mg/5 mL) and 2% (100 mg/5 mL) solution for injection (Pfizer and Baxter)

Situation

There is a current disruption to the supply of lidocaine 50 mg/5 mL (Pfizer® and Baxter® lidocaine 1%) and 100 mg/5 mL (Pfizer and Baxter lidocaine 2%) solution for injection due to changes in commercial viability. Limited supply may continue to be available.

Alternative brands, for example Xylocaine®, remain available however are not approved for the treatment or prophylaxis of life-threatening ventricular arrhythmias and are labelled as '*not for systemic intravenous use*' (see Figure 1 on next page). The Product Information for Xylocaine® indicates it is acceptable via intravenous route for regional anaesthesia only with the Bier's block technique after further dilution to a concentration of 5 mg/mL (0.5%) to avoid systemic spread and minimise the risk of toxicity.

Background

Lidocaine is an amide type local anaesthetic and class 1 membrane stabilising antiarrhythmic. It is indicated for:
- local or regional anaesthesia by nerve block, infiltration, injection, caudal or other epidural blocks (all brands)
- systemic administration for the treatment or prophylaxis of life-threatening ventricular arrhythmias including those associated with myocardial infarction, general anaesthesia in patients predisposed to ventricular arrhythmias, digitalis intoxication, or following resuscitation from cardiac arrest (specific brands only)
- pain management under specialist advice when used systemically via the IV route (off-label use).

Assessment

The Pfizer and Baxter lidocaine 1% and 2% are the only products registered on the Australian Register of Therapeutic Goods that are approved for systemic intravenous use and do not have '*not for systemic intravenous use*' on their packaging.
Xylocard 10% (lidocaine 10%) is approved and marketed for IV administration for the treatment and prophylaxis of life-threatening ventricular arrhythmias, however due to its higher concentration, this product is **NOT** appropriate or safe as an alternative to lidocaine 1% or 2% without further dilution.

Recommendations

To effectively manage the disruption to the supply of lidocaine 1% and 2% Pfizer and Baxter stock, it is recommended that:
- Remaining stock of the Pfizer and Baxter brand is reserved for clinical indications where systemic intravenous administration is required (including prophylaxis and treatment of severe life-threatening tachycardia).
- A facility-wide review of stock holdings should be undertaken, and excess stock of the Pfizer and Baxter brands recalled from clinical areas where an alternative brand (e.g. Xylocaine) is appropriate for use. For example, in anaesthetic and recovery departments where lidocaine is required for local and regional anaesthesia, the alternative brands should be used.
- Clinical requirements must be carefully assessed to ensure adequate stock remains in clinical areas for the treatment of life-threatening events.
- Review local protocols and procedures to ensure the appropriate lidocaine product is being used (based on the indication and required route of administration).

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FOR NSW HEALTH STAFF ONLY
This Safety Notice is current at the issue date. Printed copies are uncontrolled.
Page 1 of 2

Appeared on Bridgewest out of stock report on **2 August 2023** as an *"anticipated"* disruption to supply.

Liaison with HealthShare NSW to determine availability of alternative brands.

Liaison with product sponsors/TGA to determine reasons why **"not for systemic IV administration"** included on packaging of alternative brands.

Information from clinical networks regarding the suitability of alternative brand(s).

Safety Notice produced in collaboration with MSAM and MSEAC and released on **23 August 2023** to assist sites running critically low.

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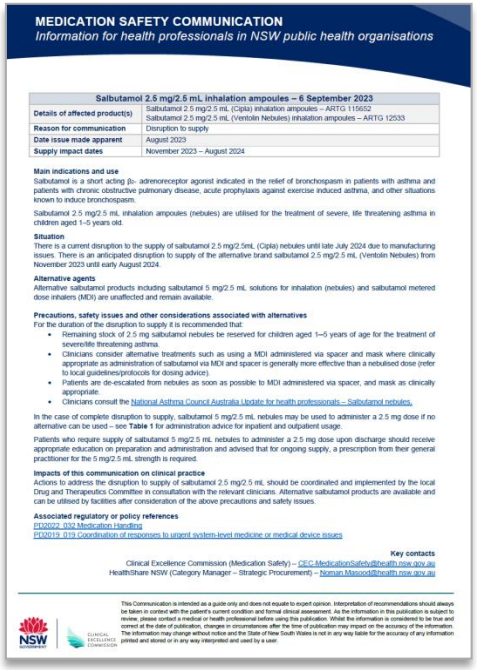
Salbutamol 2.5 mg/2.5 mL nebules



MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Salbutamol 2.5 mg/2.5 mL inhalation ampoules – 6 September 2023

Details of affected product(s)	Salbutamol 2.5 mg/2.5 mL (Cipla) inhalation ampoules – ARTG 115652 Salbutamol 2.5 mg/2.5 mL (Ventolin Nebules) inhalation ampoules – ARTG 12533
Reason for communication	Disruption to supply
Date issue made apparent	August 2023
Supply impact dates	November 2023 – August 2024

Main indications and use

Salbutamol is a short acting β2- adrenoreceptor agonist indicated in the relief of bronchospasm in patients with asthma and patients with chronic obstructive pulmonary disease, acute prophylaxis against exercise induced asthma, and other situations known to induce bronchospasm.

Salbutamol 2.5 mg/2.5 mL inhalation ampoules (nebules) are utilised for the treatment of severe, life threatening asthma in children aged 1–5 years old.

Situation

There is a current disruption to the supply of salbutamol 2.5 mg/2.5mL (Cipla) nebules until late July 2024 due to manufacturing issues. There is an anticipated disruption to supply of the alternative brand salbutamol 2.5 mg/2.5 mL (Ventolin Nebules) from November 2023 until early August 2024.

Alternative agents

Alternative salbutamol products including salbutamol 5 mg/2.5 mL solutions for inhalation (nebules) and salbutamol metered dose inhalers (MDI) are unaffected and remain available.

Precautions, safety issues and other considerations associated with alternatives

For the duration of the disruption to supply it is recommended that:

- Remaining stock of 2.5 mg salbutamol nebules be reserved for children aged 1–5 years of age for the treatment of severe/life threatening asthma.
- Clinicians consider alternative treatments such as using a MDI administered via spacer and mask where clinically appropriate as administration of salbutamol via MDI and spacer is generally more effective than a nebulised dose (refer to local guidelines/protocols for dosing advice).
- Patients are de-escalated from nebules as soon as possible to MDI administered via spacer, and mask as clinically appropriate.
- Clinicians consult the National Asthma Council Australia Update for health professionals – Salbutamol nebules.

In the case of complete disruption to supply, salbutamol 5 mg/2.5 mL nebules may be used to administer a 2.5 mg dose if no alternative can be used – see **Table 1** for administration advice for inpatient and outpatient usage.

Patients who require supply of salbutamol 5 mg/2.5 mL nebules to administer a 2.5 mg dose upon discharge should receive appropriate education on preparation and administration and advised that for ongoing supply, a prescription from their general practitioner for the 5 mg/2.5 mL strength is required.

Impacts of this communication on clinical practice

Actions to address the disruption to supply of salbutamol 2.5 mg/2.5 mL should be coordinated and implemented by the local Drug and Therapeutics Committee in consultation with the relevant clinicians. Alternative salbutamol products are available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy references

PD2022_032 Medication Handling

PD2019_019 Coordination of responses to urgent system-level medicine or medical device issues

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

Disruption to supply communicated to HealthShare NSW by drug sponsors by **late July 2023**. Liaison between HealthShare NSW and CEC to consider implications.

Assessment of historical usage and stock on hand to determine impact of disruption to supply.

Advice sought from manufacturer and clinical experts regarding inpatient and outpatient use of alternative strengths/forms.

Medication Safety Communication developed in consultation with MSAM and MSEAC due to safety issues relating to available alternatives have been identified. Released **6 September 2023.**

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