National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of salbutamol 2.5mg/2.5ml and 5mg/2.5ml nebuliser liquid unit dose vials

Date of issue:	26-Feb-24	Reference no:	NatPSA/2024/003/DHSC_MVA

This alert is for action by: All organisations involved in prescribing, dispensing, and administering salbutamol 2.5mg/2.5ml and 5mg/2.5ml nebuliser liquids.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in acute medicine, ambulance services, GP practices, pharmacy services in all sectors, private healthcare providers and those working in the Health and Justice sector.

Explanation of identified safety issue:

A Medicines Supply Notification (MSN) issued on 14 February 2024, detailed a shortage of salbutamol 2.5mg/2.5ml and 5mg/2.5ml nebuliser liquid. The resolution date is to be confirmed.

The supply issues have been caused by a combination of manufacturing issues resulting in increased demand on other suppliers.

Terbutaline, salbutamol with ipratropium, and ipratropium nebuliser liquids remain available, however, they cannot support an increase in demand.

Ventolin® (salbutamol) 5mg/ml nebuliser liquid (20ml) is out of stock until mid-April 2024 and cannot support an increased demand after this date.

Unlicensed imports of salbutamol nebuliser liquid can be sourced. Lead times vary. Information relating to imports was outlined in the MSN and is available on the SPS Medicines Supply Tool which also details any changes to resupply dates, updates to this communication and an up-to-date supply overview.

NOTE: Supplies of licensed salbutamol nebuliser liquid have been allocated for those ambulance services which cannot administer unlicensed medicines via PGDs.

Actions required

Actions to be completed as soon as possible and not later than 8 March 2024.

All providers MUST:

1. Liaise with local pharmacy teams and place urgent orders for unlicensed imports of salbutamol nebuliser liquid - do not wait for supplies to be exhausted before placing orders for imports.
2. Wean all patients off nebulisers as soon as their condition has stabilised.
3. Consider use of high-dose salbutamol pressurised metered-dose inhaler (pMDI) via a large volume spacer in patients with mild to moderate asthma attacks or COPD (see clinical information) ensuring the patient is issued with a new inhaler to avoid risk of using a near empty device and can administer it effectively if not being administered by a healthcare professional. NOTE A

Secondary care providers should:

4. Where a pMDI is not appropriate, prescribe salbutamol nebuliser liquids when required (PRN) rather than regularly (QDS), as early as possible during admission, if appropriate.
5. Prioritise supplies of salbutamol nebuliser liquids for the following indications:
   a. acute, severe exacerbations of COPD and asthma
   b. bronchospasm secondary to refractory anaphylaxis
   c. in patients who cannot use a pMDI
   d. other conditions where the use of high-dose salbutamol pMDI via a spacer is inappropriate e.g. moderate to severe hyperkalaemia

Primary care prescribers should:

6. Review need for home nebuliser use, and if deemed necessary, determine if the patient has sufficient supplies of nebuliser liquid at home before issuing repeat prescriptions. NOTE B

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Clinical information

Salbutamol is a selective beta$_2$-agonist providing short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction. The nebuliser liquids are licensed for use in the management of chronic bronchospasm unresponsive to conventional therapy, and in the treatment of acute severe asthma.

BTS/SIGN guidance recommends that in patients with mild to moderate asthma attacks beta$_2$-agonists can be administered by repeated activations of a pMDI via an appropriate large volume spacer (one puff administered at a time; according to response, another puff administered every 60 seconds up to maximum of 10 puffs). In acute-severe or life-threatening asthma, beta$_2$-agonists should be administered by an oxygen-driven nebuliser (2.5mg-5mg salbutamol). If there is an initial poor response, subsequent doses should be given in combination with nebulised ipratropium. Once improving on 2-4 hourly salbutamol, patients should be switched to a pMDI and spacer treatment as tolerated.

NOTE A: It is well known that it can be difficult to recognise when a pMDI inhaler without a dose counter is empty. Even when there is no active drug left the pMDI will continue to actuate, expelling propellant gas but no therapeutic agent. This may lead to inadvertent use of 'empty' inhalers but a perception that the patient is receiving a therapeutic dose. The consequences of this are potential exacerbation and destabilisation of asthma.

NOTE B: The MHRA issued a Drug Safety Update[6] in August 2022 that included advice on nebulised asthma rescue therapy in children and adolescents. It advised that the use of nebuliser devices at home to deliver asthma rescue medication to this age group, without specialist medical supervision, can mask a deterioration in the underlying disease, which could result in delays in seeking medical attention and have fatal or serious consequences. Nebulised asthma rescue medication should not be prescribed to children and young people for use at home unless under specialist medical supervision.

References:

1. BTS/SIGN guidance on the management of asthma
2. NICE guideline [NG115]: Managing exacerbations of COPD
3. SmPC: salbutamol nebuliser solution
4. BNF: salbutamol
5. BNFC: salbutamol
6. MHRA Drug Safety Update (August 2022)
7. Resuscitation Council UK: Emergency treatment of Anaphylaxis
8. UK Kidney Association Guidelines: Treatment of Acute Hyperkalaemia in Adults

Stakeholder engagement:

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service Medicine Advice, Medicine Shortage Response Group, NHS England, National Clinical Director for Respiratory and national patient safety team, British Thoracic Society, Medicine and Healthcare products Regulatory Agency and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and straightforward National Patient Safety Alert. In response to CHT/2019/001 and CHT/2023/002 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.