From the Chief Medical Officer
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HSS(MD) 09/2024

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FOR ACTION

Chief Executives, Public Health Agency/HSC Trusts/NIAS
Deputy Secretary SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward distribution to practice staff) and Community Pharmacies
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

NATIONAL PATIENT SAFETY ALERT – SHORTAGE OF SALBUTAMOL 2.5MG/2.5ML AND 5MG/2.5ML NEBULISER LIQUID UNIT DOSE VIALS

Actions for all healthcare professionals involved in prescribing and dispensing:
All providers MUST:

1. Liaise with local pharmacy teams (both primary and secondary care) 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.

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

Summary 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 should be preserved and allocated for those ambulance services which cannot administer unlicensed medicines via PGDs.

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.

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.

The MHRA issued a Drug Safety Update 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

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

Yours sincerely

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Chief Medical Officer

PROFESSOR CATHY HARRISON
Chief Pharmaceutical Officer

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