



Safety Alert 005/12

Date 24/12/2012

Recall Ventolin & Asmol Inhalers – 10 batches

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance

For response by:

- Directors of Clinical Governance

We recommend you also inform: (eg's)

- Directors of Emergency Medicine
- Directors of Pharmacy
- Directors of Medical Services
- Medical staff
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Deadline for completion of action

27/12/2012

Expert Reference Group

- Advice from GSK
-

Clinical Excellence Commission

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Internet Website:
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Background

GlaxoSmithKline (GSK) has issued a voluntary recall of 10 batches of Ventolin and Asmol Inhalers due to a *“fault in the delivery mechanism leading to an inconsistent dose”*.

GSK advise:

“In devices that are affected, the dose of salbutamol may not be delivered in full. In some cases, approximately one third of the normal dose may be delivered per actuation or ‘puff’ of the inhaler. Despite the wide therapeutic margin of salbutamol, it is possible that this could reduce the efficacy of the medicine.”

A TGA recall notice will also be issued shortly.

Specific Incident

GSK advise the batch number of the affected products are:

- **VENTOLIN batch numbers: KN7170, KN7173, KN7178, KN7179**
- **ASMOL batch numbers: KL6790, KL6795, KL6796, KL6797, KL6798, KL6799**

GSK advise that their other products are not affected.

GSK advise that *“supply to Australian patients has not been impacted”* and that *“GSK will be replenishing the wholesaler channel over the Christmas period with sufficient stock”*.

Mandatory actions for Local Health Districts/Networks

- Inform pharmacies, emergency departments and wards of this safety notice.
- Remove affected stock from clinical areas and replace stock.
- Advise Emergency Departments that additional asthma patients may attend due to the lack of efficacy of Ventolin and Asmol Inhalers

References

- GSK advice attached.

Action required by Local Health Districts /Networks

1. Ensure pharmacies, emergency departments and wards are aware of this safety notice.
2. Report to CEC by 27/12/2012 when action complete.