

Dear Colleague,

**Reintroduction of the Volumatic Spacer Device**  
**Important New Information**

In August I wrote to you regarding the decision of GlaxoSmithKline to discontinue the supply of the Volumatic spacer device for use with pressurised metered dose inhalers and replace it with the AeroChamber Plus spacer device. Following concerns raised by the Committee on Safety of Medicines regarding possible changes in drug delivery to the lung when switching from the Volumatic spacer device to the AeroChamber Plus (particularly important for corticosteroids and long-acting  $\beta_2$  agonists), GSK has committed to reintroduce the Volumatic device. National product information for the GSK (trading as Allen & Hanburys) metered dose inhaler product range has been amended to state that only the Volumatic spacer device should be used with GSK products.

**Reintroduction of Volumatic**

GSK expects to supply newly manufactured stock in the UK from mid-February 2006. In the meantime a limited interim supply of Volumatic spacer devices from other countries will be made available from 3 January 2006. GSK will separately provide UK Volumatic Patient Information Leaflets to pharmacies so that these can be dispensed with overseas product in January/February 2006, where appropriate.

**Advice for Prescribers**

The Commission on Human Medicines advises the following, in relation to patients using spacer devices with GSK pressurised metered dose inhalers:

*If you are prescribing any spacer device to a patient for the first time, these patients should be monitored frequently in the normal way for the emergence of or worsening of symptoms of disease or adverse effects. Any patients who are switched to a different device should be regarded in the same way as new patients, and the same careful monitoring is required.*

- **Patients who require a spacer device for the first time** with Allen & Hanbury inhalers, from 3 January 2006 should be prescribed a Volumatic spacer device (making best use of the limited interim stocks). New patients should only be dispensed an AeroChamber Plus spacer device if interim stocks of the Volumatic are insufficient or not available.
- **Patients who are currently using a Volumatic** spacer device should retain the device, and continue to use it in accordance with the manufacturer's instructions. These devices can be replaced with newly manufactured stock from mid-February 2006, as necessary.
- **Patients who have switched to the AeroChamber Plus spacer device** have no urgent need to switch back to the Volumatic unless they are experiencing difficulties with the device or their asthma control or the emergence of adverse effects gives cause for concern, therefore:
  - Patients should continue to use the AeroChamber Plus until the new Volumatic becomes available (mid February 2006).
  - These patients should be monitored for the emergence of or worsening of symptoms of disease or adverse effects both before and after switching back to the Volumatic.
  - **Priority** for switching back to the Volumatic from February 2006 should be given to **children** and those taking **high dose corticosteroids** and long-acting  $\beta_2$  agonists.
  - Patients taking short-acting bronchodilators only (as required) are a low priority for switching back.

For inhaled  $\beta_2$  agonist bronchodilators the most frequent signs of toxicity are headache, tremor and palpitations; for inhaled corticosteroids the most serious concern from over exposure is adrenal suppression and particularly when high doses are administered to children and adolescents.

A questions and answers document will be placed on the website of the Medicines and Healthcare products Regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk) For further information please telephone 02070842000.

Yours sincerely,

Professor Gordon W Duff  
Chairman of the Commission on Human Medicines