From the Chief Medical Officer:
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Department of
Health, Social Services and Public Safety
An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí
www.dhsspsni.gov.uk

URGENT COMMUNICATION

HSS(MD)27-2005

All General Practitioners for cascade to:
- Practice Staff including Practice Nurses and Sessional Doctors

Community Pharmacists
Directors of Public Health in HSS Boards
Directors of Pharmaceutical Services in HSS Boards and Trusts
Directors of Nursing in HSS Boards
Directors of Nursing in HSS Trusts for cascade to:-
- Respiratory Nurse Specialists
- Community Nurses, Health Visitors and School Nurses

Directors of Primary Care for cascade to:-
- Out of Hours Services; and
- Prescribing Advisers in Primary Care

Medical Directors of HSS Trusts for cascade to:
- All doctors in HSS Trusts

Regional Medicines and Poisons Information Service

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Your Ref:
Our Ref:
Date: 16 August 2005

Dear Colleague

RE: DISCONTINUATION OF THE VOLUMATIC SPACER DEVICE – IMPORTANT NEW INFORMATION

The supply of the Volumatic spacer device is being discontinued. Attached to this letter are:

1. Advice from Professor Gordon Duff, Chairman of the Committee on Safety of Medicines (CSM); and
2. A questions and answers document for patients and carers.

HPSS organisations and Family Practitioner Services are asked to distribute this new information widely and to follow the advice outlined in the CSM letter. Patients currently using a Volumatic should retain this device and continue to use it in accordance with the manufacturer's instructions. Those who require a new Aerochamber Plus spacer device or a switch from a Volumatic to this device should be monitored closely to see if the response to their medicines changes in any way.

Yours sincerely

HENRIETTA CAMPBELL (DR)
CHIEF MEDICAL OFFICER

FRANCIS RICE (MR)
ACTING CHIEF NURSING OFFICER

NORMAN MORROW (DR)
CHIEF PHARMACEUTICAL OFFICER

This letter is available at www.dhsspsni.gov.uk and also on the DHSSPS Extranet which can be accessed directly at http://extranet.dhsspsni.gov.uk or by going through the HPSS Web at http://www.n-i.nhs.uk and clicking on DHSSPS.

Dear Colleague

Discontinuation of the Volumatic Spacer Device
Important New Information

GlaxoSmithKline will discontinue the supply of the Volumatic spacer device and manufacture of the Volumatic has ceased. The Volumatic spacer device is unlikely to be readily available on prescription from the end of this month. GlaxoSmithKline will distribute the AeroChamber Plus spacer device (a valved holding chamber) as a replacement for the Volumatic.

A spacer device may be used by patients who find it difficult to synchronise aerosol actuation with inspiration of breath. However the use of a spacer device with a pressurised metered dose inhaler may increase drug delivery to the lungs. Therefore for those drugs where systemic absorption occurs primarily in the lung the use of a spacer device could potentially lead to an increased risk of systemic adverse events.

Data are available that support the use of the Volumatic spacer device. However as only limited data are available at this time to support the AeroChamber Plus spacer device it is not clear what effect the AeroChamber Plus has on drug delivery to the lungs. The pharmacokinetic data that are available suggest that the AeroChamber Plus spacer device may change systemic exposure to inhaled medicines compared with systemic exposure seen with the Volumatic spacer device. In some patients this may result in an increase in systemic exposure and therefore it is important that patients are monitored frequently.

Currently a clinical study is ongoing which may provide further information regarding the effect of spacer devices on drug delivery to the lung. As soon as results from this study are available they will be fully evaluated by an expert working group of the Committee on Safety of Medicines.

In the meantime **if your patients use a Volumatic spacer device it is recommended that they should retain this device and continue using it according to the manufacturer's instructions.**

If you are prescribing a spacer device to a patient for the first time and you are prescribing an AeroChamber Plus spacer device, **these patients should be monitored frequently in the normal way for the emergence or worsening of symptoms of disease or adverse effects.**

If you are changing a patient's spacer device from a Volumatic to the AeroChamber Plus such patients should be regarded in the same way as NEW patients receiving a spacer device for the first time and should be monitored frequently for the emergence or worsening of symptoms of disease or adverse effects.

For inhaled $ß_2$ 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 particularly with high doses administered to children and adolescents.

When prescribing a new spacer device the patient's response to their inhaled medicines should be carefully evaluated and the dose may need to be titrated against signs and symptoms. Alternative treatments may need to be considered.

A questions and answers document will be placed on the website of the Medicines and Healthcare products Regulatory Agency www.mhra.gov.uk. For further information please call 02070842000.

I will write to you again when further information is available.

Yours sincerely,

Professor Gordon W Duff
Chairman of the Committee on Safety of Medicines

VOLUMATIC QUESTIONS AND ANSWERS

1. What is the issue relating to Volumatic?

The supply of the Volumatic, a particular type of spacer device which is used with asthma inhalers, is being discontinued. The manufacture of the Volumatic spacer has now ceased and the device will be unlikely to be readily available after the end of August 2005. Another spacer will be available to replace the Volumatic (the AeroChamber Plus spacer).

2. What is a spacer?

A spacer is a large plastic or metal tube that can be attached to a pressurised metered dose inhaler (*asthma inhaler*). At one end there is a mouthpiece and at the other end there is a hole for the inhaler to fit into. Using a spacer device can help those who have difficulty co-ordinating the use of their inhaler with breathing in, particularly young patients or those who have difficulty with breathing in and 'pressing' their inhaler at the same time. Spacers are also recommended for all children and adolescents on inhaled corticosteroids and for adults taking high doses of some inhaled corticosteroids.

3. What medicines are used with a spacer?

There are three main types of inhaled drugs where spacers may be used, *relievers*, *preventers* and *controllers*. *Relievers* are short acting $beta_2$ agonists or bronchodilators and relieve asthma symptoms. Salbutamol (eg Ventolin) and terbutaline (eg Bricanyl) are two examples. Ipratropium bromide (eg Atrovent) is a different type of bronchodilator but also relieves symptoms. Inhaled corticosteroids are *preventers*, they are used to prevent asthma attacks or reduce their frequency. There are several different inhaled steroids but they all work in the same way. For example beclometasone dipropionate (eg Becotide), budesonide (eg Pulmicort) and fluticasone propionate (eg Flixotide). The long acting $beta_2$ agonists also known as *controllers* help to control asthma and chronic obstructive pulmonary disease (COPD) and are used in combination with inhaled corticosteroids. Salmeterol xinafoate (eg Serevent) is an example of a long-acting $beta_2$ agonist. Some inhalers contain a combination of two drugs, Seretide inhaler is an example of a single inhaler containing both salmeterol xinafoate and fluticasone proprionate.

4. Which inhalers are used with the Volumatic spacer device?

The following asthma treatments may be used with the Volumatic spacer: Ventolin Evohaler, Serevent Inhaler, Flixotide Evohaler, Seretide Evohaler, Becotide Inhaler and Becloforte Inhaler and Salamol CFC-free inhaler. The Volumatic spacer also fits a number of other inhalers.

5. Can patients just switch from using one spacer device to another?

Changing spacer devices affects the amount of medicine reaching the lungs. It is possible that changing from the Volumatic Spacer to the Aerochamber Plus spacer will affect the amount of medicine inhaled into your lungs. An expert working group of the Committee on Safety of Medicines (CSM) is meeting in September to consider the results of a new study looking at the effect of spacer devices on drug delivery to the lung. Until further recommendations are available, the advice of the CSM is that

patients who have to switch to using the Aerochamber Plus should be closely monitored in case their response to their medicine changes in any way.

6. What could be the consequences of switching spacer devices?

Because a different spacer may change how much medicine is inhaled, switching spacers may affect the control of your asthma or COPD or may increase the risk of you experiencing side effects from your medicine.

Most people do not experience side effects with their inhaled medicines. Signs of too much of a short-acting inhaled beta$_2$ agonist (reliever) or long-acting beta$_2$ agonist (controller) may include headache, tremor and palpitations (rapid heart rate). Inhaling corticosteroid (preventer) may affect the normal production of steroids in the body. Signs and symptoms may include loss of appetite, abdominal pain, weight loss, tiredness, nausea, vomiting, faintness or sweating and rarely convulsions.

7. What are patients and parents being advised to do?

If you or your child are currently using the Volumatic spacer device you are advised to keep it carefully and continue using it according to the manufacturer's instructions. It should last for between 6 and 12 months.

If you need to change from a Volumatic to the Aerochamber Plus for any reason you will be closely monitored by your doctor for the appearance of symptoms of asthma or any worsening of symptoms of asthma or emergence of side effects.

8. Why is the Volumatic spacer being discontinued?

This is due to the closure of the factory that manufacture the Volumatic spacer. The Volumatic spacer is larger and more cumbersome than newer spacers such as the Aerochamber Plus.

9. How are health professionals and patients being informed about the discontinuation of the Volumatic?

All doctors, nurses and pharmacists are being informed in a letter from the Chairman of the Committee on Safety of Medicines. Spacer devices are only available on prescription and therefore doctors will discuss with their patients the need to switch from the Volumatic to the Aerochamber Plus when their spacer needs replacing. An information sheet will be available for patients to help them use their new spacer.

10. Will people have to do without a spacer?

No – there are other spacers available. Patients who cannot get a Volumatic spacer will be given the Aerochamber Plus spacer. Patients using the Aerochamber Plus for the first time will be closely monitored by their doctor for the appearance of symptoms of asthma or any worsening of symptoms of their disease or emergence of side effects.