



Department of

**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/10/09
Date: 31 March 2009

DRUG ALERT

MEDICINES RECALL

Action within 48 hours

Dear Healthcare Professional

AstraZeneca UK Ltd

NebuChamber Device (Inhalation Aid)
(Recall of all stock - no batch number is quoted on the device)

AstraZeneca and the MHRA Devices division have requested distribution of the enclosed information concerning a defective medical device which is widely prescribed and distributed through community pharmacies, clinics and hospitals. **All stock of the NebuChamber is being recalled from pharmacies, hospitals and distributors.**

This product is an inhalation aid intended to be used with Pulmicort® pressurised metered dose inhaler manufactured by AstraZeneca. It consists of a metal spacer and mouthpiece and a facemask can be used in some patients.

NebuChamber contains a one-way valve and it is essential that the mouthpiece is attached to the spacer in the correct direction. The product is normally manufactured to achieve this. AstraZeneca has received reports that the mouthpiece can sometimes be attached in the incorrect direction which is clinically significant.

AstraZeneca is also requesting Pharmacists and/or Doctors to contact known patients who have received a NebuChamber device and arrange for a device other than NebuChamber to be provided or switch the patient to an alternative medication.

If an alternative device or treatment is not available or suitable, healthcare professionals are asked to emphasise the importance of correct assembly. **The frosted end of the mouthpiece must be attached to the spacer.**

No new patients should be offered NebuChamber at present. AstraZeneca is unable to supply acceptable replacement devices for the immediate future. Replacement stocks will be made available as quickly as possible. We note that this device does not bear batch numbers. When acceptable stock is distributed in the future we envisage there will be advertisements in the trade press to inform users and explain how to identify the new acceptable devices.

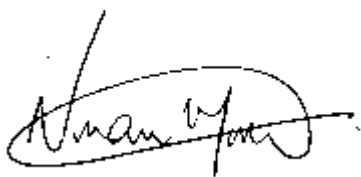
Please return all NebuChamber stocks to the original supplier (either AAH or Unichem).

For medical information enquiries, please telephone AstraZeneca Medical Information on 01582 836836.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:
CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPPET