

From the Chief Executive Officer of Medicines and Healthcare products Regulatory Agency

8th August 2006

Dear Colleague,

BECLOMETASONE DIPROPIONATE PRESSURISED METERED DOSE INHALER

IMPORTANT INFORMATION

Under the terms of the Montreal Protocol, production and supply of chlorofluorocarbons (CFCs) is being phased out worldwide. As a result pressurised metered dose inhalers (pMDIs) for use in asthma and chronic obstructive pulmonary disease (COPD) previously formulated with CFCs are now being formulated with hydrofluoroalkane (HFA) propellants and are CFC-free. These reformulated CFC-free pMDIs have been gradually introduced onto the UK market over the last ten years.

There are two beclometasone dipropionate CFC-free pMDIs available on the market in the UK: Qvar marketed by Ivax Pharmaceuticals Limited has been available for a number of years and Clenil Modulite marketed by Trinity-Chiesi Pharmaceuticals Limited has been introduced to the market recently. **These two CFC-free products, both containing the active substance beclometasone dipropionate are NOT equipotent and this could have safety implications.** The purpose of this letter is to alert healthcare professionals to this and help ensure the intended product is prescribed and dispensed.

PRESCRIBING AND DISPENSING INFORMATION

- **Prescribers** should be aware:
 - that prescriptions written using the generic name *beclometasone dipropionate* do not distinguish between CFC-containing and CFC-free formulations of beclometasone dipropionate, and pharmacists can dispense either. When prescriptions are written using the generic term *beclometasone dipropionate CFC-free inhaler*, there are two products that can be dispensed, Qvar and Clenil Modulite, **and these two products are not equipotent;**

therefore

 - when the prescriber wishes a patient to have a CFC-free formulation of beclometasone dipropionate that intention should be made clear by **prescribing the product by brand name.**

- **Pharmacists** receiving a generic prescription for a beclometasone dipropionate pMDI **must establish** whether a CFC-free product is required, and if so, which of the two available branded products should be dispensed.

NEW PATIENTS OR PATIENTS BEING SWITCHED

For new patients or patients being switched from one beclometasone dipropionate inhaler to another, advice on dosing is as follows:



1. **Clenil Modulite (Trinity-Chiesi Pharmaceuticals Limited) should be prescribed at the same dose as the currently available CFC-containing beclometasone dipropionate pMDIs.**
2. **Qvar (Ivax Pharmaceuticals Limited) has a 2 to 2.5 fold greater potency than the currently available CFC-containing beclometasone dipropionate pMDIs and therefore should be prescribed at a lower dose than the currently available CFC-containing beclometasone dipropionate pMDIs. Further information is available in the Summary of Product Characteristics.**
3. **Clenil Modulite is authorised for use in children; Qvar is not authorised for use in children (12 years of age and younger).**
4. **For all inhaled corticosteroids and in line with accepted clinical practice, when control of asthma is achieved the dose of the inhaled corticosteroid should be titrated to the lowest dose at which effective control of asthma is maintained.**

When a prescriber transfers a patient to a beclometasone dipropionate pMDI which is not equipotent with the patient's existing therapy, the importance of this should be discussed with the patient and titration of the dose of the inhaled steroid managed carefully in order to avoid confusion and loss of disease control.

Conversion table for dosing with CFC-containing beclometasone dipropionate (CFC-BDP), Clenil Modulite or Qvar

Total Daily Dose (micrograms/day)				
CFC-BDP	200-250	300	400 - 500	600-750
Clenil Modulite	200-250	300	400 - 500	600-750
Qvar	100	150	200	300

Total Daily Dose (micrograms/day)				
CFC-BDP	800 - 1000	1100	1200 - 1500	1600 - 2000
Clenil Modulite	800 - 1000	1100	1200 - 1500	1600 - 2000
Qvar	400	500	600	800

A questions and answers document will be placed on the website of the Medicines and Healthcare products Regulatory Agency www.mhra.gov.uk and on the website of the Department of Health www.dh.gov.uk.

For further information please call the MHRA on 0207 084 2000 or Isabelle Izzard (Dept of Health) on 0207 972 2913.

Yours sincerely,

Professor Kent Woods CEO/MHRA