

4<sup>th</sup> October 2010

Dear Colleague,

**New CHM Advice: Codeine containing linctus not suitable for cough in children under 18 years**

**Issue**

I am writing to inform you that, in completing its review of cough and cold medicines for children, the Commission for Human Medicines (CHM) has advised that over-the-counter (OTC) liquid medicines containing codeine should no longer be used in children under 18 years.

**Manufacturers** will update the packaging and leaflets for their products and new stock is expected to start to appear in pharmacies from April 2011. CHM has also advised that all OTC liquid codeine medicines should be packaged in Child Resistant Containers (CRCs) by June 2012.

**Products affected** include preparations of Codeine Linctus BP that have an indication for children, as well as branded products, including Pulmo Bailly, Galcodine Linctus and Galcodine Paediatric Linctus.

**Existing stock** does not need to be removed from shelves but pharmacists are asked to consider the new advice when recommending cough medicines. Pharmacists should continue to manage adult sales and we expect that pharmacists will consider alternative treatments or only supply the up-to-date labelled product where there are children under 18 years in the family.

**Background**

Codeine has traditionally been used in the treatment of dry, unproductive cough.

Coughs occur frequently in children but they are considered airway-protective and a self-limiting symptom, and are rarely harmful if left untreated.

The MHRA review examined both the safety and efficacy of OTC liquid cough medicines containing codeine for the treatment of children and concluded that:

- There is a lack of evidence of efficacy for codeine in the symptomatic treatment of cough in children of any age group
- There are safety concerns regarding the use of codeine for the treatment of cough in children due to its central mode of action and the significant variability in its metabolism to morphine
- overall, the risks of OTC cough medicines for children containing codeine outweigh the possible benefits

There are also safety concerns regarding the accidental ingestion of OTC liquid codeine medicines: the use of CRCs would help to reduce the risk of accidental ingestion by young children.

### **Codeine warning for breast feeding mothers**

CHM has also advised that all codeine containing medicines should carry a breast feeding warning. Information about the side effects in breast fed babies from maternal use of codeine-containing medicines was published in 'Drug Safety Update' in November 2007:

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON2032916>.

The CHM advised that this risk should be outlined in the SmPC and Patient Information Leaflet of every codeine-containing medicine. Pharmacists are asked to consider the advice if supplying a codeine containing product to breastfeeding mothers.

An updated Drug Safety Update item will appear in the October 2010 bulletin. A full Public Assessment Report will be published on the MHRA website.

### **Further Information**

For further information on this advice please refer to our website (<http://mhra.gov.uk>) or contact the MHRA Information Centre by email ([info@mhra.gsi.gov.uk](mailto:info@mhra.gsi.gov.uk)) or by telephone (020 7084 2000).

Yours faithfully

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