

**Labelling and Packaging of Cough and Cold Medicines  
Stakeholder and Public Consultation October - December 2009  
Submission received from the Australian Medical Association**

The AMA notes the Therapeutic Goods Administration (TGA) review of the safety and efficacy of registered over-the-counter (OTC) cough and cold medicines for children aged 2-12 years, and the overseas regulatory environment in relation to the usage of these medicines in children.

The AMA supports the recommendations proposed by the TGA and Medicines Evaluation Committee (MEC) in respect of the use of cough and cold medicines in children aged 2-12 years, to:

- 1) require labelling of over-the-counter cough and cold medicines to provide specific dosage instructions and warnings about use in young children;
- 2) market all over-the-counter cough and cold medicines in containers with child-resistant closures; and
- 3) restrict supply of cough and cold medicines to pharmacist only for use in children aged 6-12 years, and to prescription only for use in children under 6 years of age.

The reported lack of evidence of clinical efficacy of these products, combined with the potential for significant adverse reactions relating to their use in children, outweighs any benefit from their use in children under 6 years of age, and suggests a precautionary approach for children aged 6-12 years.

If a child is unwell, has a temperature and/or has trouble breathing they should see a doctor to ensure they receive appropriate medical attention. The AMA is concerned that treating what appear to be the symptoms of coughs and colds in children with OTC medicines may delay the diagnosis and treatment of more serious conditions such as asthma, pneumonia or meningococcal disease.

Where a more serious condition is ruled out, the doctor will advise on the most appropriate treatment, which may not be medication. In the event cough and cold medicines are rescheduled to prescription only for children under 6 years of age, a doctor may still choose not to prescribe them given the lack of efficacy surrounding their use.

A visit to a doctor for what appears to be a common cold in a child is not an inefficient use of health resources. Medical practices have a variety of arrangements

in place to ensure patients who require an urgent consult, particularly small children, can see a doctor.

Doctors and pharmacists play an important role in educating consumers about the appropriate use of medicines and effective treatments for coughs and colds based on the available evidence. Given the current widespread use of OTC cough and cold preparations, any rescheduling will require an education campaign to ensure medical practitioners, pharmacists, parents and care givers are well informed about the reasons for the decision and on appropriate treatment options.