Labelling and Packaging of Cough and Cold Medicines
Stakeholder and Public Consultation October - December 2009
Submission received from The Royal College of Physicians (RACP)

Thank you for inviting The Royal Australasian College of Physicians (RACP) to provide comment on the proposed changes to the labeling and packaging of these Over the Counter (OTC) products in Australia.

The consultation documents on the TGA website have been closely reviewed by Fellows within the Paediatrics & Child Health Division who are leading experts in Paediatric Chest Medicine and Paediatric Therapeutics. We have also invited broader input from all Paediatricians within the Division. As per the request in your letter of 26 October 2009, we have prepared a consolidated response from the RACP, which is as follows:

1) We support the proposed TGA recommendations, as listed in sections 2(a)-2(d) of the Consultation document (22 October 2009) and subheading 6 on pages 12-13 of the TGA Internal Panel Report (May 2009). Indeed, we are delighted that the TGA has responded to the concerns that many Fellows have expressed for some time about these OTC cough and cold medicines. Specifically, that there is no evidence of benefit, but evidence of potential harm, particularly in very young children. In view of the unfavourable risk: benefit profile of these medicines, we strongly support the TGA's proposal to bring their labeling in line with the currently available evidence and similar changes recently initiated in the UK and Canada.

2) We also support the TGA's specific proposals with regard to the labeling changes. We agree that the label should include a clear warning statement that OTC cough and cold medicines should not be given to children under the age of 6 years and suggest further that it: a) be accompanied by a clear explanation that these medicines do not provide benefit and may cause harm in this age group; and b) not include a dosage for children under the age of 6 years.

3) We agree strongly that these measures **must** be effectively supported by widespread education of parents and caregivers, medical practitioners, pharmacists and relevant other health professionals (e.g. early childhood nurses) to ensure that the rationale for the changes and the nature of the concerns about unfavourable risk: benefit profile are well understood by all. This education should address broader Quality Use of Medicines (QUM) issues in the symptomatic management of young children with coughs and colds rather than being limited to the labeling changes for OTC cough and cold medicines alone (e.g. place of non-medicine treatment options; and issues associated with complementary medicines as possible alternatives parents/carers might choose).

   We recognise that the proposed labeling changes may have potential unintended negative consequences. For example, if parents have these medicines in the house for use in an older child, they may be tempted to also give them to a younger sibling with cough. In view of the lack of a recommended dose for younger children, parents may guess a dose, with potential for overdosing and associated harm.

   In order to avoid such possibilities, it is therefore crucial that timely and effective educational campaigns accompany these labeling changes to ensure caregivers have a very clear understanding of the reasons for the changes (i.e. that they are in the best interests of young children) and modify their use of these medicines (and other potential alternatives) in line with basic QUM principles.

In summary, we congratulate the TGA for their action on OTC cough and cold medicines and are in full agreement with their specific recommendations. We hope you find our additional suggestions also helpful to your deliberations.