



11th April 2008

PAGB response to the use of additives in children's medicines

Sheila Kelly, PAGB Executive Director, comments: "If children are feverish or in pain parents should be able to treat them without being concerned that they are putting them at risk. The industry takes this issue seriously and manufacturers have reviewed their Adverse Drug Reaction (ADR) reports. Medicines contain smaller amounts of additives than are in foods and are only taken for a short period of time. The ADR reports have not provided any evidence to suggest that the use of additives in children's medicines causes any harm."

"Colours and preservatives in medicines perform a valid function, such as preventing the medicine going off or masking the unappealing colour of the active ingredients, and are not used unnecessarily. All the ingredients are listed on the labels and parents should check these, particularly if their children have allergies."

The European Food Standards Agency and the Food Standards Agency in the UK have been looking at the issue of additives in children's foods. This follows a study conducted by the University of Southampton.

The EFSA evaluation of additives¹ concluded 'the findings of the (Southampton) study cannot be used as a basis for altering the ADI (Acceptable Daily Intake) of the relevant food colours or sodium benzoate'. The UK Food Standards Agency has not recommended regulatory action but has asked manufacturers to consider reducing the levels of colours in children's foods as they serve no purpose other than to colour the products. They have made no request to reduce the levels of sodium benzoate which is included as a preservative.

PAGB² would like to highlight that before they are launched, all medicines are assessed for safety by the Medicines and Healthcare products Regulatory Agency (MHRA)³. To be approved, all ingredients included within all medications have to be



safe for the intended user, with the benefit of each ingredient considered to outweigh any associated risk.

-ENDS-

For further information please contact:

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¹ European Food Safety Authority (EFSA), Assessment of the results of the study by McCann et al. (2007) on the effect of some colours and sodium benzoate on children's behaviour [1] – Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC)
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178694648892.htm

² PAGB (Proprietary Association of Great Britain) is the trade association representing manufacturers of over-the-counter medicines and food supplements.

³ MHRA (Medicines and Healthcare products Regulatory Agency) is the authority that regulates medicines in the UK.