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MEDIA RELEASE

Australia has world-class regime for safety of non-prescription analgesics

The Australian Self-Medication Industry (ASMI), the peak industry body representing non-prescription consumer healthcare products, said today that moves in the U.S. to impose further regulatory measures on acetaminophen (paracetamol) are not warranted in Australia as consumers here had already benefited from a range of safeguards to ensure the safe and quality use of these products.

Paracetamol has had a very long history of safe and effective use in Australia and the risks are minimal when used according to instructions on the label.

The comments follow a decision by an advisory committee to the U.S. Food and Drug Administration (FDA) recommending a lower maximum dose for over-the-counter acetaminophen, known in Australia as paracetamol.

ASMI Executive Director, Juliet Seifert said the situation in the U.S. is significantly different to that in Australia.

“The two regulatory environments are fundamentally different. In Australia there are pack size restrictions which do not apply in the US. Larger packs up to maximum of 100 dosage units and combination and children’s products can only be sold in pharmacies where professional advice is available when required. Only small pack sizes may be sold in other retail outlets such as supermarkets.

“In the U.S. tubs of 500 tablets can be sold in supermarkets. Given the concerns about safety, it is somewhat surprising that the advisory panel rejected a recommendation that would have seen these pack sizes reduced,” Ms Seifert said.

There have been a number of thorough examinations surrounding the use of analgesics in Australia in recent years which resulted in improved safeguards. The Therapeutic Goods Administration (TGA) undertook a comprehensive review of paracetamol in 2003.¹ That followed an earlier review issued by the TGA in 1998.² The 2003 review was followed by a public education initiative for paracetamol incorporating additional product labelling, and fact sheets for health practitioners and consumers. Label warning became mandatory in 2005.

¹ *Review of Non-prescription Analgesics*, prepared for the Medicines Evaluation Committee by David B Newgreen, April 2003.

² *Review of Non-prescription Analgesics*, prepared for the Therapeutic Goods Administration by David B Newgreen, February 1998.

Industry has also invested heavily in improving label comprehension to ensure the quality use of these products. Consumer-focused labelling assists consumers to select the most appropriate product and to use the product safely and to best effect.

ASMI has had in place an Analgesics Working Group, comprising representatives of manufacturers, which has been actively engaged in examining relevant research and evidence. It works closely with the TGA in determining whether additional consumer safeguards may be required.

“We are conscious that as an industry, we have an obligation to be proactive in ensuring that we adopt best practice in all aspects of analgesic use including issues such as labelling, packaging, dosage, and availability of public information,” Ms Seifert said.

It is important that all medicines are used strictly according to label instructions and if symptoms persist to seek advice from a healthcare professional.

About ASMI: The Australian Self-Medication Industry (ASMI) is the peak industry body for the Australian self care industry representing consumer healthcare products including over-the-counter medicines and complementary medicines. ASMI’s mission is to promote better health through responsible self-care. This means ensuring that safe and effective self-care products are readily available to all Australians at a reasonable cost. ASMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the broad national health strategy. .asmi.com.au

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