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MEDIA STATEMENT

New study affirms current labelling appropriate for NSAIDs

An updated study which provides some new information on the cardiovascular risks of non-steroidal anti-inflammatory drugs (NSAIDs) reaffirms the industry's view that the current labeling of various NSAID products is appropriate, the Australian Self-Medication Industry (ASMI) said today.

The study, published in *PLoS Medicine*, pooled observational studies to assess the risk of cardiovascular events in patients using a number of different NSAIDs.ⁱ

ASMI Regulatory and Scientific Affairs Director, Steven Scarff, said the study provides some useful information around cardiovascular risk related to NSAIDs, in particular to the relative risk between over-the-counter (OTC) and prescription doses.

"While there are some limitations to the study, including its reliance on observational studies, it does shine a light on some risks associated with these products, and in particular the relationship between higher doses and increased risk."

"It is important to note that over the counter (OTC) use of NSAIDs involves taking low doses for short periods of time. Under these conditions, the authors of the study concluded that both ibuprofen and naproxen did not increase cardiovascular risk.

While prescription doses of Diclofenac were associated with an increased cardiovascular risk, the authors of the study were left to speculate on the risks posed by OTC use.

"Diclofenac is a common anti-inflammatory medicine and has been in use for many years. Anyone who is in a high risk category such as people with heart problems should, as with any medication, consult their GP or pharmacist before using any medicines.

Mr Scarff said it was worth remembering that NSAIDs are available without a prescription at low doses for short-term use in self-limiting conditions, and already contain warnings on the label for high risk conditions.

"It is important that consumers take note of the label warnings and only use the products as directed. Based on all the information available, we believe that these label warnings remain appropriate.

"Among other things, these warnings advise consumers with certain existing health problems or who are taking other medications to first seek the advice of their healthcare professional.

"NSAIDs are safe when used as directed, but like any medicine they pose a safety risk if used incorrectly or by people who should not be using them," Mr Scarff said.

“It is important to read labels carefully, and to strictly follow all the directions and, if the pain or other symptoms persist, to consult a doctor or pharmacist,” Mr Scarff said.

¹ McGettigan P, Henry D (2011) Cardiovascular Risk with Non-Steroidal Anti-Inflammatory Drugs: Systematic Review of Population-Based Controlled Observational Studies. PLoS Med 8(9): e1001098. doi:10.1371/journal.pmed.1001098

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. www.asmi.com.au

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