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MEDIA STATEMENT

New restrictions on availability of codeine based pain relievers not warranted

The Australian Self-Medication Industry (ASMI), the industry body representing non-prescription consumer healthcare products said today that foreshadowed moves to make it more difficult for consumers to purchase over-the-counter (OTC) medicines containing codeine were extreme and premature.

The National Drugs and Poisons Schedule Committee (NDPSC) has foreshadowed consideration, at a meeting in June, of whether to reschedule pain relievers containing ibuprofen and codeine to Schedule 8, a category reserved for drugs at high risk of being abused.

The Scientific Director for ASMI, Deon Schoombie said that OTC analgesics combined with codeine have a long history of safe use when used according to label instructions.

Many thousands of Australians have benefited from them for many years and should continue to do so.

These medicines play an important role in relieving mild to moderate pain and any move to restrict their availability would be an enormous inconvenience to thousands of responsible users. In particular, older people who suffer chronic pain, perhaps from arthritis, would be enormously inconvenienced

The NDPSC is considering two elements associated with these medicines: how readily codeine can be extracted from products for the manufacture of illicit drugs, and the more general issue of abuse of these products.

In relation to the issue of separation, there is no substantive evidence of codeine being diverted, so any further inquiry into this aspect would therefore seem to be of academic interest only.

In regard to alleged abuse of codeine-based products, there appear to have been a very small number of anecdotal reports of increased misuse. Two cases of perforated gastric ulcers associated with gross misuse of the product were reported in the *Medical Journal of Australia*. It was noted that '72 tablets per day and 'a packet a day for the last year' had been used in these cases.

Aside from the MJA report, the supporting ‘evidence’ is apparently anecdotal and insufficient to justify further restriction on access. Industry has, as yet, had no opportunity to see, let alone assess, the quality of this information.

It is important when considering this issue that a balance is achieved between the activities of a small minority who abuse the product, and the thousands of consumers who use it responsibly and safely. In fact, the NDPSC has a statutory responsibility to consider not only the risks, but also the benefits associated with the use of a medicine.

ASMI agrees that healthcare professionals should maintain a high level of vigilance - adverse reactions need to be reported to the Adverse Drug Reactions Advisory Committee (ADRAC) and pharmacists need to maintain a high degree of awareness about people buying large quantities.

There is already a level of regulation appropriate to the product’s efficacy and safety profile. The medicine can only be sold in a pharmacy, and the sale of larger packs (containing 72 tablets or capsules) generally also requires personal intervention by a pharmacist.

At the moment there is no hard evidence of widespread abuse that would warrant prescription only status for these products.

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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