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22 February 2011

MEDIA STATEMENT

Proton Pump Inhibitors (PPIs) and Fracture Risk

The Australian Self-Medication Industry (ASMI) is aware of a newly published observational cohort study conducted in Denmark¹ which identifies a potential association between the long-term use of high-dose PPIs and reduced efficacy of alendronate (oral bisphosphonate) in preventing hip fractures amongst elderly patients.

This was an observational cohort study and therefore had some limitations as well as a number of strengths. One of the important limitations was that it could not determine whether the change in hip fracture risk was causally related to PPI use or whether it was due to other factors such as comorbidities or medication compliance. In assessing their findings, the authors stated that:

"In our study, PPI users benefited less from alendronate in terms of hip fracture risk than did nonusers. We included both comorbidity and comedication terms in the base models, but because the 2 groups may differ in other, unmeasured confounders it remains possible that the difference in alendronate response is driven not by PPIs themselves but by differences in nonskeletal risk factors for osteoporosis that would not respond to bisphosphonates."

ASMI Regulatory and Scientific Affairs Director, Steven Scarff noted the following important findings from the study:

- For Defined Daily Doses of PPI below 360 there was no impact on fracture risk.
- For persons younger than 70 years of age there was no impact on fracture risk.

This study reveals a loss of protection against hip fracture with alendronate in elderly patients taking high doses of PPIs for long periods of time. Of relevance to over-the-counter (OTC) users of PPIs, this study also shows that:

- Short term PPI use was not associated with a higher fracture risk compared to no PPI use.
- The fracture risk for persons under 70 years of age is unchanged whether the person uses a PPI or not.

PPIs that are available OTC in Australia are for short-term use (a maximum of 14 days) at half the Defined Daily Doses used in the Abrahamsen study and are Pharmacist Only Medicines. No medicine is without risk and this study will assist pharmacists in determining the suitability of PPIs for each individual.

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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ⁱ Abrahamsen B et al. Proton Pump Inhibitor Use and the Antifracture Efficacy of Alendronate. *Arch Intern Med*, 2011, Feb 14. [Epub ahead of print]