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13 November 2011

MEDIA STATEMENT

ASMI applauds global push for new approach to regulatory decision-making for over-the-counter medicines

The Australian Self-Medication Industry (ASMI) today welcomed the release of a proposed new model designed to better evaluate and measure the benefits of over-the-counter (OTC) medicines, and thus aid regulatory decision-making.

The model is based around a tailored benefit/risk framework that applies a broader definition of “benefits”, beyond clinical trial data, and includes elements such as consumer satisfaction, dependency on healthcare systems, and time-off work.

It was developed through a grant from the World Self Medication Industry to independent researchers and has been published in the journal, *Clinical Pharmacology and Therapeutics*, under the title ‘*Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit-Risk Assessment*’.ⁱ

The Executive Director of ASMI, Dr Deon Schoombie said the model was developed as tool to assist sponsors in determining the benefit/risk profile of non-prescription medicines, and to assist with the assessment of these factors in regulatory decision-making.

“In an environment where there is an increasing demand for sound evidence and evidence-based decision-making, it is important for the medicines industry to collaborate with regulators to develop a practical benefit/risk framework to apply to the OTC sector,” he said.

The proposed model is based on a value-tree method that seeks to define specific benefit/risk outcomes across a number of key areas relevant to non-prescription medicines. It was previewed to Australian industry representatives in October by one of the lead authors, Professor Eric Brass, of the David Geffen School of Medicine at UCLA.

Dr Schoombie said the presentation was timely, in light of the business process improvement program set to commence for OTC medicines at the Therapeutic Goods Administration (TGA), since the new model has the capacity to help maintain a strong non-prescription regulatory culture.

“Our view is that there has often been a narrow definition of benefits in regard to OTC medicines, which has overlooked the role that they play in public and individual health outcomes by helping consumers to stay well, keep active and remain productive.

“More recently, we have seen a progressive imbalance, where risk has been afforded greater weight, in the absence of sound arguments around likely benefits, Dr Schoombie said.

The proposed new model is designed to assist both regulators and manufacturers to better assess risks and benefits, to improve risk management, and to enhance communication to consumers. It is anticipated that as the model evolves over time, it will serve as a guide to industry and regulators on the approach for future submission and product applications

“Our hope is that this will help to start discussions between regulators and industry on the way that product submission and applications can be assessed with greater consistency and certainty in the future,” Dr Schoombie said.

¹ Brass E P, Lofstedt R, & Renn O; Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit–Risk Assessment, *Clinical Pharmacology & Therapeutics*, November 2011
www.nature.com/clpt/journal/vaop/ncurrent/index.html

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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