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MEDIA STATEMENT

ASMI welcomes progress on updating of OTC medicine requirements

The Australian Self-Medication Industry (ASMI) has been lobbying for progress on the Australian Regulatory Guidelines for OTC Medicines (ARGOM) Review Project, and today welcomed the commencement of stakeholder consultation by the TGA on key sections of the guidelines.

ARGOM sets out the information to be supplied to the TGA with applications for registration or variation of OTC medicines, and thus forms a critical element in the registration of products prior to commercialisation for the consumer healthcare sector in Australia. The current ARGOM was published in 2003 and has only had minimal change since that time.

The Executive Director of ASMI, Dr Deon Schoombie said that ASMI has been active in supporting the progress of the ARGOM review with the TGA, and commencement of the consultation marks a milestone in the updating and reform of OTC Medicines regulation in Australia.

As part of the ARGOM Review Project, the TGA and industry have been working collaboratively, with the TGA drafting the revised sections and small industry project teams providing feedback on these sections. The updated sections released for broad consultation today describe the data required to support a successful new registration or variation application for an OTC Medicine.

In the meantime, the Business Process Reform (BPR) Project for OTC medicines, which is just commencing, will deliver the new processes by which these applications will be evaluated. Those sections of the ARGOM 2003 which describe the current evaluation process will remain unchanged until then.

Clarity of the TGA's current requirements for OTC Medicine applications will help industry to design products and prepare medicine applications to meet those updated expectations, which will be of benefit to both TGA and industry. The availability of up-to-date guidelines will be fundamental to the success of the BPR Project for OTC medicines.

"The TGA's BPR project for OTC medicines is expected to deliver predictability of evaluation timeframes based on the submission of OTC medicine applications which comply with published requirements. It is therefore vital that these updates to the ARGOM proceed in a timely manner to allow OTC medicine sponsors time to factor the revised guidelines into their development programs," Dr Schoombie said.

"The outcomes of the Labelling and Packaging Review will also be fundamental to the success of this reform initiative. Clarity on labelling and "umbrella branding" requirements will also be a determinant of better quality OTC medicine applications and must be achieved before a revised business process can deliver the results of predictable processing timeframes," Dr Schoombie said

ASMI will be consolidating member comments to the ARGOM consultation.

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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