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## **MEDIA RELEASE**

### **Red tape burden on over-the-counter medicines inhibiting the take-up of patient self care**

Australia's system of regulating non-prescription medicines could benefit from the experience of the UK health system, which has seen a cut in red tape, more streamlined processes for industry and more timely access to medicines for the public following a shift to a more risk-based approach, the Australian Self-Medication Industry (ASMI) Conference in Sydney heard today.

Keynote international speaker, Chris Horsey, is Head of Better Regulation in the Department of Health in England, which, working with the UK medicines regulator and the pharmaceutical industry (PAGB), has implemented an internationally acclaimed program to better regulate medicines, known as the Better Regulation of Medicines Initiative (BROMI).

Working in partnership with the industry, the regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), has taken a leading role in a risk-based approach to over-the-counter (OTC) medicines regulation.

"The outcome has been to deliver new and updated medicines to patients faster, minimise the burden on industry and free-up industry and the regulator to focus on innovation and safety," Mr Horsey said.

"The perception of risk moves over time and as medicines move through the cycle and become OTC, the risk significantly diminishes. The level of regulatory oversight should match the level of risk as far as possible, ensuring the public are protected, at all times," he said.

The Executive Director of the Australian Self-Medication, Juliet Seifert, said some of the initiatives implemented in the UK system should be examined in Australia, where light touch regulation is the exception rather than the rule.

"Regulatory compliance imposes a heavy cost on industry and is increasingly out of step with the direction of health policy with its focus on promoting self care and improved preventative health.

“Increasing access to proven and safe non-prescription medicines also has the capacity to reduce the burden on doctors who face backlogs from the treatment of patients who present with easily treatable minor ailments,” Ms Seifert said.

The ASMI conference, titled: ‘Self Care: How much is your responsibility?’ heard from other speakers including the Federal Minister for Health & Ageing, Nicola Roxon, the Minister for Small Business, Independent Contractors and the Service Economy, and Minister Assisting the Finance Minister on Deregulation, Dr Craig Emerson, and the Parliamentary Secretary for Health, Mark Butler.

Cavan Redmond, Group President, Pfizer Diversified Businesses, said it was time for a fundamental re-think of the regulation of over-the-counter medicines, so that products with lower risk and extended use were not subject to the same rigorous and costly assessment as higher risk medicines.

“In order to protect patient choice and avoid crippling an already overburdened healthcare system, we must refrain from viewing non-prescription medicines as prescription medicines and instigate a new system whereby products are evaluated according to the ‘sliding scale of risk and benefit’,” Mr Redmond said.

The US-based industry body representing the OTC sector, the Consumer Healthcare Products Association (CHPA) noted a change in risk and perception that was characterised by recent tougher controls surrounding children’s cough and cold medicines which has recently been foreshadowed in Australia.

The President of CHPA, Dr Linda Suydam said that industry and regulators were under greater scrutiny which contributed to calls for enhanced safety in some categories of medicines, and which saw the crackdown on paediatric cough and cold products spread from the US to the UK, Canada and Australia.

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**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.  
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