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MEDIA RELEASE

OTC medicines sector to get less regulation but more scrutiny, regulator tells ASMI Conference

The over-the-counter (OTC) medicines sector will benefit from greater certainty and predictability from regulators, but should expect to come under increased community scrutiny, the Australian Self Medication Industry (ASMI) national conference in Sydney heard today.

Dr Rohan Hammett, the National Manager of the Therapeutic Goods Administration (TGA) told the conference that the business reform process underway for the OTC sector will bring significant benefits in medicine approvals and timelines.

“You are going to see greater clarity from the TGA on what you are required to do. You will see greater predictability, faster approvals, and we will be working much more closely with our international counterparts, adopting similar approaches to regulation of over-the-counter medicines.

“What I hope we will see from you is actually improved dossiers. The information that we evaluate is much better evaluated if the information you provide is accurate, correct and complete.

“Ultimately what we have found when doing this with other sectors is that there is a loss of flexibility in processes that have arisen over decades within the TGA. But the trade-off in loss of flexibility is more than outweighed by the predictability, clarity and efficiency of the regulatory environment.

“I think the other thing you need to prepare yourselves for is greater scrutiny. I have no doubt that the community will continue to look at what we as the regulator do very closely, but also at what you, as the responsible and viable industry do, particularly as it pertains to marketing approaches to consumer literacy which may not always provide the accurate information that is required.”

Dr Hammett also warned of a “fragility of trust” arising from marketing approaches that lack a thorough evidence base.

“One very bad marketing idea can do a lot of damage to trust that has been built up in our attempts to improve health literacy,” he said.

In response to a question, he said that in the prescriptions medicine sector, approval times at the TGA have been reduced from approximately 500 days to as little as 270 days. He said that the business improvement process for OTC medicines should lead to “similar efficiencies with predictable timelines”.

He conceded that for some OTC medicines, the level of regulation is excessive given the length of time that they have been on the market.

He said that a consultation paper on the planned OTC reforms would be released early in 2012.

Dr Hammett was speaking at the ASMI conference, titled *Promoting Self Care Literacy*, at Sydney Olympic Park.

Further information on the 2011 ASMI Conference is available at www.asmiconference.com

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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