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Medicines regulation in Australia and New Zealand – Unique and changing. An industry perspective

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Abstract

Since 1991 dietary supplements/traditional medicines have been regulated in Australia as medicines – complementary medicines. Consumer surveys have consistently shown that 75% of Australiansuse complementary medicines.Itseems that Australian consumers have a high level of confidence in the supplements they are taking - but has Australia got the right balance in its Regulations?

Complementary medicines are governed by the same Australian legislation as orthodox medicines, with the same objective of controlling the supply of quality, safe and efficacious products.

The regulatory framework for complementary medicines is based on a risk management approach, designed to ensure public health and safety, while at the same time freeing industry fromunnecessary regulatory burdens. All therapeutic goods must be entered on a Register before they can be supplied in Australia. The Register is a database of information about therapeutic goods for human use approved for supply within, or exported from, Australia.

In June 2011, the Prime Ministers of Australia and New Zealand reaffirmed their commitment to the establishment of the Australia New Zealand Therapeutic Products Agency (ANZTPA) to administer a joint regulatory scheme for therapeutic products. This reaffirmation acknowledged that the New Zealand Government will introduce a separate scheme to regulate certain natural health products in the New Zealand market.

ANZTPA will establish a single entry point for industry and a common trans-Tasman regulatory framework. In the first stageeach country will retain its own regulator and continue to make its own regulatory decisions, however the industrywill benefit from having only one set of requirements to operate in two countries. The creation of the new regulatory framework will further increase the public health benefit for consumers and reduce the regulatory burden for industry.

Biography

John has over 35 years' experience in the Complementary/ Pharmaceutical medicines industry. He has wide experience in the regulation, advertising, formulation and manufacture of medicines and foods, within Australia, New Zealand and internationally. He is a longstanding member of the Therapeutic Goods Administration / Industry interface committee which considers technical and regulatory issues influencing the regulation of complementary medicines in Australia. He also chairs various Industry Association committees dealing with GMP, advertising and technical standards. Additionally, John is the founding Chair of MediQ - an initiative of the Queensland medicines industry which is supported by the Queensland Government. This forum drives strategic development and research opportunities building networks between researchers, academics, industry and Government.