ATMS submission to the Department of Health on the review of medicines and medical devices regulation

On behalf of members and the industry, the Australian Traditional-Medicine Society (ATMS) submitted a response to the Department of Health on the review of medicines and medical devices regulation. Following is an abridged version of the response submitted in April 2015.

Theme 1: Duplication of regulatory processes

Issue 1 – Requirement of TGA assessment of ingredients approved overseas

In the respect of the duplication of regulatory processes of an ingredient (e.g. Methylcobalamin and other activated B vitamins), it should be considered that if an ingredient has been 'approved' by a trusted overseas regulator it has been subjected to some form of assessment. ATMS have considered that this should include some form of assessment of quality and safety and that the evidence standards be comparable with, or superior to, those currently applying in Australia. ATMS suggests that ingredients should be assessed on the basis of quality as per the current Australian GMP requirements. Australia is a signatory to PIC/S (Pharmaceutical Inspection Convention Scheme). Any other signatory country should have the same GMP requirements as Australia and therefore any therapeutic good exported by them should be produced to the same quality and manufacturing standard as those produced here.

Issue 2 – Interface between advertising and listing evidence requirements

ATMS supports an enhancement of the existing process where product sponsors must be made to submit evidence to substantiate therapeutic claims (and this evidence must be assessed by suitably qualified personnel) prior to listing approval. ATMS considers that the TGA introduce a modified registration pathway for complementary medicines seeking to make higher level health claims. If there is evidence of higher level health claims and that these claims can be supported (such as with clinical trials), ATMS support the view that the sponsor should be able to submit these claims to the TGA for assessment for potential use of marketing complementary medicine products.

Theme 2: Regulatory requirements are not commensurate with risk

Issue 2 – Threshold for Therapeutic Goods

ATMS believes that all therapeutic goods should be required to be listed on the ARTG, regardless of their risk. Any product making a therapeutic claim is deemed to be a therapeutic good and should conform to the therapeutic goods regulations. ATMS suggests that any complementary medicines withdrawn from the ARTG should be assessed as a completely new entity and receive approval on this basis before being re-listed. ATMS supports the continuation of post-market surveillance and roles including the monitoring of adverse reactions/events to ensure the ongoing safety of therapeutic products and the regulation of advertising for therapeutic products.

Issue 5 – Compliance with GMP

ATMS would support the continuation for the requirement for manufacturers of low risk products or ingredients to comply with medicinal Good Manufacturing Practice (GMP) standards. Good Manufacturing Practice (GMP) maintains the standards of manufacturing complementary medicines that could potentially lead to adverse effects if the product was not produced by a company not adhering to Good Manufacturing Practice guidelines.

ATMS suggest that the current system of advertising clearance should remain and suggest that investigations be conducted into the feasibility of extending the clearance via social media.

Theme 3: Complex Regulatory framework

Issue 1– Lack of understanding of requirements for listing

ATMS support the TGA's suggestion that all sponsors of therapeutic goods should undergo training in regulatory compliance.

Issue 2– Poor Consumer Understanding

ATMS will call for the development of consumer friendly resources to inform and explain the regulatory environment, including the difference between AUST R and AUST L, to consumers.

ATMS will also call for a statement on the benefits of consulting a qualified health care professional in making choices on using complementary medicines. These qualified health care professionals include, but are not limited to, naturopaths, herbalists, nutritionists, general practitioners and other health care professionals with training in naturopathy, herbal medicine and nutritional medicine.