DSAA
DIRECT SELLING
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Dear Dr Skerritt

The Direct Selling Association of Australia (DSAA) writes in regard to the proposed changes to the 'evidence required to support indications for listed medicines'.

The DSAA's comments are substantively similar to the submission made earlier this year when this matter was first released for comment. While it is appreciated the TGA has accepted that some of the proposals put forward in its original paper would have been overly burdensome on complementary healthcare businesses, many of the proposals in this subsequent paper will again burden businesses with unnecessary regulation.

The DSAA supports the approach that the Complementary Healthcare Council (CHC) has taken as a responsible and functional methodology for achieving the TGA's public safety, quality and efficacy objectives as well as enabling business to operate within an appropriate regulatory system.

From a policy standpoint, the level of regulation, the compliance regime and cost of compliance for the listing of complementary healthcare products must be commensurate with the risk profile of the products. While the requirement to hold forms of evidence in regard to claims made about listed medicines is supported, the risk profile of the product must dictate the form and substance of the evidence required to be held.

Even though the draft guideline states (on page 8) that "listed medicines are low risk medicines", in practical terms the complex and detailed evidentiary requirements as proposed will continue to ensure high regulatory cost to business, and thus ultimately higher costs to the consumer, that does not correspond to risk or the nature of claims being made.

The DSAA considers that the proposed regime of evidentiary requirements is not supported by a substantive need for change and therefore does not support the changes sought. Indeed these proposals should be reviewed so as to reduce the regulatory burden on business and should more fully explore other less onerous methods for achieving the TGA's objectives.

In addition, in order to properly assess the merits of any proposed changes, it is imperative that evidence is provided of the cost benefit analysis that must be undertaken to determine the impact of these proposals. Without such an assessment's findings being provided as part of the consultation process, it is difficult to provide adequate advice to the TGA on the merits of the proposed regime.

The DSAA is available for further discussions on these matters and would direct the TGA to the detailed comments on this matter made by the CHC.

John Holloway
Executive Director