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Direct Selling Association of Australia Inc

Rcvd RMC 27/8/10

The Project Officer
Advertising Consultation
Regulatory Reform
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir / Madam

Re: Advertising Therapeutic Goods in Australia Consultation Paper

The Direct Selling Association is the relevant Industry Association for direct selling in Australia. The annual sales of our Members, at retail, is approximately $1.6 billion and our Members represent a substantial segment of the complementary healthcare market in Australia.

A list of members is attached.

For ease of dealing with the issues raised in the Consultation Paper, our comments will be noted in the same order.

1. Under the heading "**Objectives**" the Paper states that:

   "**The Government's objectives are to achieve a regulatory framework for advertising therapeutic goods . . . . . that adopts a risk management approach complementary to that used for regulating therapeutic goods**".

   The risk management approach adopted for regulating therapeutic goods is based on the level of claim/indication for the product, i.e. general level, medium level or high level.

   To obtain that "complementary level" referred to above, consideration should be given to restricting pre-clearance of advertisements to those products which are registered (AUSTR) which are the only products permitted to make high level claims, or products which are listed (AUSTL) making medium level claims.

(It should be noted that listed products (AUSTL) are not permitted to make high level claims).

2. In commentary on the "**current model**" the Paper states that:

   "**Concerns have been raised by some opponents of the current advertising framework that the system is not working to protect consumers as well as it might**".

   These concerns would, we believe, arise principally from efficacy issues. Efficacy is not evaluated by the TGA for listable products and many of the complaints received by Complaints Resolution Panel and other complaints bodies relate to efficacy issues. In the present system, the ASM's are expected to establish and verify efficacy issues as part of the pre approval process. We strongly disagree with this position as we state when dealing with "efficacy" hereunder.

   The Therapeutic Goods Advertising Code is a very detailed and proscriptive document which provides consumers with a high level of protection arising from the advertising of non-prescription medicines. The Code is developed and administered by the Therapeutic Goods Advertising Code Council which comprises experts from Industry and Government as well as Consumer Representatives. The Code Council closely monitors the operation of the Code and recommends changes to the Minister. The existence of the Code and the operations of the Code Council provide a high level of consumer protection and this is surely evident from the lack of empirical evidence to the contrary.

3. Commentary on the "**current model**" also states that:

   "**There have been claims that the current arrangements impose unnecessary regulatory burdens on some industry sectors**".

   We agree, to some extent, with this comment in as much as the system applies to all therapeutic products, and makes no allowance for the risk management issues raised above.

4. Under the heading "**Optimising Current Arrangements**", the Paper states that:

   ". . . . **there is perceived inconsistency in the approach to handling of advertisements in different media**".

   There is an inconsistency in the approach to the handling of advertisements in different media but this is, we believe, a sensible and practical approach. To include all advertisements in the pre clearance system, particularly with the current definition of advertisement, would

produce a situation which would be totally unworkable and unmanageable. Under the existing definition, even the routine correspondence of Sponsors could be an advertisement. We believe the present approach is a reasonable and acceptable compromise between the need to protect consumers and to establish a system which recognises the levels of risk and the costs to manage the system.

5. The Paper states that:

"..... **the complaints mechanism ..... and spends much of its time dealing with efficacy issues**."

We agree with that comment.

The question of efficacy is not a matter which should be examined or determined as part of the advertising pre-approval process. We do not believe that the Advertising Service Managers have the training or expertise to determine efficacy matters and these should properly be the responsibility of the TGA.

The ASM's should be permitted to refer efficacy matters arising during the pre approval process to the TGA. The TGA should establish procedures to deal with any such referred efficacy matters expeditiously and instruct the ASM's accordingly. Such a procedure should be built into the pre approval process so that advertisers / sponsors receive decisions on their proposed advertisements in a timely manner and not too far outside existing time parameters.

6. The Paper states that:

"..... **the sanctions available to CRP and the TGA do not provide sufficient deterrence**."

We believe that the present sanctions are adequate to provide the required level of deterrence. Publication of offences is a strong measure and the TGA has the power to enforce the decisions of the CRP where required. Additionally, the TGA has the power to impose the ultimate sanction, viz: cancellation of the product license. We believe that the TGA should be encouraged to use its existing powers on a more regular basis than it has been prepared to in the past.

7. Under the heading "**Some Options**" the Paper lists a number of potential options, viz:

a. The TGA could publish on its website the information related to products removed from the ARTG for advertising offences.
b. The Complaints Resolution Panel could refer directly to TGA all matters related to efficacy of products.

c. The Government could move to increase and broaden the level of penalties and sanctions associated with breaches of the advertising arrangements.
d. The Government could reconstitute the membership of the Complaints Resolution Panel to ensure greater independence.

We agree that the proposals in (a) and (b) should be adopted.

For reasons stated in 6 above, we do not see any need to increase or broaden the level of penalties and sanctions for breaches of the Advertising Code. We support greater use of TGA's existing powers.

We do not agree that the Complaints Resolution Panel requires any greater independence. It is certainly true that the Panel is made up of nominees from industry associations, professional organisations, consumer organisations and an independent Chair but we do not believe that this composition has compromised the independence of the Panel. The presence of representatives from a number of business and professional organisations and consumer organisations together with observers from the TGA, provides a good level of independence and this is supported by the complaint statistics for 2009, viz:

Number of complaints determined	173
Number of complaints justified	167
	96.5%

We believe that the deliberations of the Panel require a high level of technical and professional knowledge and experience and we believe the Panel's work would be compromised if its members were independent of the therapeutic goods and advertising industries. If the members of the Panel were "independent" as proposed, they would need a great deal of technical assistance to properly deal with issues. The Panel Secretariat would be required to assemble this information prior to the panel hearing or alternatively, the Panel would be required to obtain the information from witnesses called for the purpose. We believe that the time involved in such a process would exacerbate one of the complaints about the current system, viz, the time taken to deal with and dispose of complaints. In addition, we believe the proposal would add greatly to the costs of the system and therefore, a further burden on industry.

8. "**Should the current pre-approval process for advertising be retained**"

We refer to our comments in 1 above that consideration should be given to restricting the pre-clearance of advertisements to registered (AUSTR) products. This would, we believe, greatly reduce the workloads of the Advertising Services Managers of the various Industry Bodies, and substantially reduce the costs to Industry. Such a change would, as mentioned earlier, achieve the level of risk management complementary to that used for regulating therapeutic goods.

"**Should all forms of advertising be considered for this process**"

We do not believe that all forms of advertising should be included in the pre-approval process. The definition of advertising in the Code is:

"**. . . . . includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods**"

This definition is so broad that if the pre-approval system was extended to include all forms of advertising, it could extend to the routine correspondence of a Sponsor. As we mentioned in 4 above, such a system would be unworkable and unmanageable. Our proposal to restrict pre clearance to those products making higher level claims (AUSTR) is, we believe, a reasonable compromise between the need to protect consumers and the need for a system which recognises the levels of risk and costs.

9. "**Should the TGA publish on its website information related to products removed from the ARTG**".

We agree with this proposal to enhance the transparency of the regulatory processes.

10. "**Should the CRP be reconstituted as an independent body**"

We do not agree with such a proposal for the reasons set out in 7 above.

11. **"Should the CRP consider complaints about all forms of advertising**".

We strongly oppose this proposal. The "below the line" advertising currently dealt with by the relevant Industry Bodies' complaints handling mechanisms is in general at the lower end of the claims table and can be appropriately and economically dealt with through Industry Codes and the TGAC. Advertising in specified media reaches a much larger audience and in general promotes products with higher level claims.

Handling complaints for "below the line" advertising is more cost effective since the relevant Industry Bodies bear most of the costs of the system. The CRP on the other hand operates as a function of the TGACC and requires a separate and more costly level of expenditure.

We agree that some of the complaints handled by the CRP are essentially trivial. However, we cannot understand why trivial complaints are regarded as such a problem. Surely it can be quickly seen by expert and experienced members that a complaint is trivial and therefore disposed of quickly if not summarily. We are not aware of any regulation which requires such complaints to take up the time of the Panel.

We note the suggestion that complaints which are essentially trivial and straightforward may be better dealt with in another way. In principle we could agree with such a proposal but that would surely involve somebody making such a judgement. We don't know who, or in what circumstances, such a decision would be made and in view of our earlier comments, we believe that it should be left to the CRP to determine. The Panel could be encouraged to categorise all complaints and those considered to be trivial and/or straightforward could be referred to a smaller group, say a Committee of the Panel, or in some

circumstances the Secretariat. It should be noted however, that advertisers generating trivial and/or straightforward complaints retain the same rights of appeal as other advertisers.

12. In paragraph 7 above we commented on the need for additional penalties and sanctions for advertising breaches. We do not support the need for additional penalties and sanctions, but we do support greater use of the TGA's existing powers. Industry Codes, in the main, already contain or will contain substantial monetary penalties for breaches of the Code, including advertising breaches. We believe that the existing powers of the TGA and the sanctions contained in the Industry Codes provide a sufficient deterrent. We understand that it is proposed that Sponsors will, at the time of application for listing or registration, be required to nominate the Industry Code to which they will be committed and we would strongly support such a proposal.

    We would support the proposal that the TGA be given the power to refuse to list a product that was substantially similar to one that had been cancelled, unless and until the relevant remedial action had been taken.

    We assume that this would only apply to products presented for listing by the offending Sponsor. If that was not the case, there would need to be safeguards for Sponsors of substantially similar products who were totally independent of the offending Sponsor.

For any further information or discussion of matters included in our response please call John Holloway or Les Dell on 02 9567 8566.

Sincerely,

John Holloway
Executive Director
25 August 2010