

RMI SUBMISSION ON THE AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS REGULATORY SCHEME (ADVERTISING) RULE 2006

1. PREAMBLE

- 1.1 The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.
- 1.2 The RMI supports the development of a co-regulatory system under the auspices of ANZTPA for the advertising of therapeutic products in Australia and New Zealand.

2. KEY ISSUES

2.1 Central Complaints Panels

- 2.1.1 We acknowledge that the proposed model has been based on the existing New Zealand model and we endorse this approach. The Rule however embodies a major change for the prescription medicines industry and that is the requirement that all complaints regarding advertising directed to consumers must be referred to, and adjudicated by, the Central Complaints Panel. In New Zealand the Central Complaints Panel will be the Advertising Standards Complaints Board (ASCB).
- 2.1.2 Currently in New Zealand complainants, whether they are competitors, consumers or health professionals, can choose to have their complaints regarding advertisements of prescription medicines heard by the RMI Code of Practice Standing Committee or the ASCB. Direct-to-consumer advertising of prescription medicines is legal in New Zealand and the issues and technical complexities relating to these advertisements can bring in many factors that are normally outside the realm of the ASCB.
- 2.1.3 It should also be noted that the draft Australia New Zealand Therapeutic Products Advertising Code states in Part B1 that "Where the Researched Medicines Industry Association of New Zealand (RMI) Code of Practice contains additional requirements or limitations for the advertising of prescription medicines,

advertisers must comply with these provisions.” This means that the Central Complaints Panel (ASCB) will have the authority to consider complaints about advertisements that may meet the generic requirements of the Australia New Zealand Therapeutic Products Advertising Code that applies to all therapeutic products, but fail to meet the more stringent industry standards for the advertising of prescription medicines in New Zealand.

- 2.1.4 As such, the industry and consumers need to have confidence that the Central Complaints Panel (ASCB) has the technical competency and experience to deal with such complaints and that it can appropriately interpret and apply the standards set out in the RMI Code of Practice.
- 2.1.5 It is noted that Division 5.2 in the draft Rule sets out different expertise criteria for the complaints panels in Australia and New Zealand. The Australian Central Complaints panel must, as its principle member, have a person with expertise in the field of public health who is experienced in community practice in a healthcare profession or, a person with expertise in consumer issues. Whereas the principle member of the New Zealand Central Complaints Panel must be someone who has expertise in the field of corporate or public sector governance or someone with expertise in consumer issues.
- 2.1.6 A difference in expertise requirements between Australia and New Zealand also exists in the Complaints Panel membership outlined in section 5.06.

In Australia each member must have experience or expertise in at least one of the following:

- Public health, with experience in community practice in a healthcare profession
- Consumer issues
- Advertising sector issues
- The regulation of advertising of therapeutic products
- The over-the-counter medicines industry
- The complementary medicines industry
- The medical devices industry

- 2.1.7 Division 5.10 also provides for the inclusion of a person with expertise in the prescription medicines industry should the subject of a complaint be about a prescription medicine. Furthermore, division 5.14 requires that a quorum for the Australian Central Complaints Panel must include a member with expertise in the therapeutic products industry that is relevant to the product concerned.
- 2.1.8 The New Zealand Central Complaints Panel on the other hand only requires that of a panel of 7 persons that at least 4 members have appropriate expertise or experience in advertising or the media. Section 5.06 also stipulates that the remaining 3 members must not be associated with any sector of the therapeutic products industry.

Therefore, while the Australian panel requires public health expertise, regulatory expertise and relevant therapeutic product industry expertise, the provisions for the

New Zealand panel not only omit these requirements, they go one step further and specifically prohibit industry expertise on the panel.

- 2.1.9 No rationale has been offered to explain these differences in expertise requirement and it is the RMI's view that the expertise requirements should be equivalent in both countries.
- 2.1.10 We strongly endorse the Australian requirement that a person with expertise in the prescription medicines industry should be appointed to the New Zealand Central Complaints Panel when the subject of a complaint is about an advertisement for a prescription medicine and the requirement that the Complaint Panel Quorum must include a member with expertise in the sector of the industry that is relevant to the product concerned.
- 2.1.11 The industry will only have confidence in the New Zealand Central Complaint Panel if amendments are made to bring New Zealand's expertise requirements into line with those that are proposed for Australia. As the ANZTPA regulatory system, including the regulation of advertising, is to be fully cost recovered from the industry any associated costs with achieving this standard of expertise should not be an issue for the Government or the ASCB.

2.2 Relationship with Industry Codes

- 2.2.1 It is understood that compliance with the relevant industry codes of practice and conduct will be a condition of product licence as is currently the case in Australia. To date however this has not been formally expressed within the draft legislation or rules.
- 2.2.2 Part 2 section 2.03 of the draft Rule does allow industry bodies to apply to have their industry codes of conduct accepted by the Authority which will therefore mean that compliance with the relevant industry code will also be a condition of product licence. The RMI supports this approach, as far as it goes, as it helps reinforce the provision in Part B1 of the Advertising Code that requires all advertising of prescription medicines to consumers in New Zealand be compliant with the stringent standards set down in the RMI Code of Practice.
- 2.2.3 It is however the RMI's view that using the Advertising Rule as the vehicle to require compliance with the relevant industry code will necessarily limit the compliance with industry codes to matters relating to advertising only whereas industry codes in fact work to promote and enforce standards of practice across all areas of promotional activity. Observance of industry standards by all therapeutic product manufacturers and suppliers, regardless of whether they belong to the industry body or not, will be more effectively guaranteed if a mechanism can be established that explicitly makes compliance with an industry code (approved by the Authority) a condition of product licence.

3. OTHER MATTERS

3.1 Advertisements directed to consumers – particular requirements

3.1.1 Division 3.2 section 3.05

There appears to be a formatting error in the draft Rule. It is assumed that subsections (3) (4) and (5) apply equally to medicines and devices as opposed to devices alone.

3.1.2 Division 3.2 section 3.06

The RMI supports that the concept that if the advertiser has not heard from the Authority within a certain period of time from the application for approval, it can be taken that the Authority has approved the advertisement. We are however of the view that 60 days is too long and that this should be reduced to a maximum of 30 calendar days.

3.1.3 Division 3.2 section 3.16

The ANZTPA Managing Director can delegate authority for the approval of advertisements to external delegates in much the same way as delegated authorities currently operate in New Zealand. This provision however allows the Managing Director to revoke the delegation should the delegate fail to comply on more than one occasion.

Given the volume of advertisements that some delegated authorities might deal with and the need to interpret the code and make judgements a ‘two-strikes-and-you’re-out’ approach may not be reasonable, particularly if they are not serious breaches. The RMI also notes that there is no provision to allow a revocation of delegation to be appealed.

3.2 General restrictions on advertising

3.2.1 Division 4.2

The proposed limitations regarding restricted representations would appear to be a double up of approval requirements. All mainstream media advertisements already require prior approval from the Authority under division 3.2. If the intent of these restrictions is to require prior approval for those advertisement that are not in mainstream media (otherwise known as below the line) then this should be made clear.

3.2.2 It is also understood that restricted representation rules in the current legislation apply to consumer advertising only and do not apply to advertising to healthcare professionals. Again this needs to be made clear in the draft Rule.

3.3 Complaints about advertisements

Please also refer to the key issues noted above concerning the expertise of the Central Complaints Panels.

3.3.1 Division 5.3 section 5.23

The RMI is of the view that notice of acceptance of a complaint should be given to the media (e.g. the publication) as well as the complainant and advertiser particularly as the media is able to be fined in relation to a breach of the Code.

3.3.2 Division 5.3 section 5.29

The draft Rule allows complaints to be transferred between the New Zealand and Australian Central Complaints Panels. It is understood that this is to allow the panels to deal with issues of forum shopping however it would be helpful to have some clear guidelines or criteria for transfer developed.

3.4 Advertising Council

3.4.1 Division 6.2 section 6.04

The RMI supports the structure of the proposed Advertising Council as set out in this division. We are however of the view that all of the nominating bodies have the right to be represented. As such the Rules should state that the Council will consist of 20 members appointed from the categories mentioned, as opposed to the statement that the Council will consist of “not more than 20” members.

3.4.2 Division 6.2 section 6.05

The RMI notes that appointments to the Advertising Council are made by the Ministerial Council on the recommendation of the Authority. It would be our preference that the Ministerial Council receives notification of all nominees, rather than only those recommended by the Authority.

3.4.3 Division 6.4 section 6.20

While the RMI is relaxed about having a signal nomination from Medicines Australia and the RMI to represent the prescription medicines industry on the Management Subcommittee, we note that there is no provision to ensure trans-Tasman balance on this committee. It is possible that this constitution could result in the entire committee being populated with Australians or New Zealanders or heavily represented by one side of the Tasman or the other. The RMI therefore suggest that the Advertising Council be required to take into account trans-Tasman balance when appointing members to this committee.