accord
hygiene, cosmetic & specialty products industry

Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Therapeutic Goods Administration
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Email: advertising.consultation@health.gov.au

Dear Madam/Sir

Accord is pleased to provide this submission to the TGA's consultation *Therapeutic Goods Advertising Code: Proposed improvements including proposed framework for Schedule 3 medicines advertising* (new Advertising Code).

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, household pesticides, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses with 57 percent of members operating as SME (<200 employees). A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

Accord supports a stronger role for self-regulation of therapeutic goods advertising. Accord member products are mostly considered as consumer goods rather than medicines given their risk profile and market positioning. We have always supported a self-regulatory model over any other form of regulatory intervention. We continue to support this approach. The development of the new Advertising Code provides an opportunity for a more balanced approach for increased industry control in advertising given that pre-clearance will no longer be a mandatory requirement. The new Advertising Code will need to clearly outline industry requirements for compliance.

Accord's comments will be limited to the new Advertising Code and will not address the Price Information Code of Practice or proposals for Schedule 3 medicines advertising as this is not currently within Accord's scope of activities. Comments to the specific questions/issues raised in the new Advertising Code are at Attachment 1.

I trust our comments are of assistance. The contact person for this matter is [redacted]

Yours sincerely

[redacted]

Bronwyn Capanna
Executive Director
10 October 2017

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ATTACHMENT 1

Specific comments raised in the Advertising Code consultation

4.1 Changes to support effective sanctions and enforcement of advertising requirements

Accord supports the proposal for minimising subjectivity in the interpretation of the provisions of the new Advertising Code given that strict liability provisions will apply. However, the new Advertising Code should be drafted in such a way that it does not limit evolutions or future innovations in advertising media, especially developments in the digital space. Industry training and information including case studies will be required to assist with compliance.

4.2 Core objectives for the new Code

4.2.1 Advertisements must comply with the Therapeutic Goods Act 1989, regulations made under this Act, and Therapeutic Goods Advertising Code.

Supported.

4.2.2 *Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of goods in the ARTG.*

The statement that advertisements must not contain ... *any matter that is likely to lead a person to believe that they are suffering from a serious ailment* (p10) should be amended to be consistent with the terminology on page 12 of the current Code which refers to *probable impact upon a reasonable person*. The term reasonable person should be defined in the new Advertising Code.

4.2.3 All claims used in advertisements for therapeutic goods must be substantiated

Supported but substantiation requirements should be consistent with requirements under Australian Consumer Law (ACL). The TGA will need to provide information to industry regarding its requirements for validation of scientific information. In addition, it should be made clear that ACL requirements apply for non-therapeutic claims such as cosmetic claims on secondary therapeutic sunscreens. Similarly, the threshold for testimonials for non-therapeutic claims related to a therapeutic good should be consistent with ACL requirements for consumer goods as it would be unreasonable to expect these to have the same requirements as for therapeutic goods.

4.2.4 Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help.

Supported – consistent with current requirements.

4.2.4 *Advertisements must not offer any personal incentives including product based contests, to pharmacy assistants, or other sales personnel employed by healthcare practitioners to recommend or supply therapeutic goods.*

Accord suggests that there should be some liberalisation in this area. Consideration could be given to exempting certain product categories from this requirement to include low risk everyday products.

4.3 The Council Recommendations

Accord does not support the recommendations in section 4.3 for incorporation in the new Advertising Code. The issues raised by the Council have been adequately addressed throughout the new Advertising Code in Sections 4.1 and 4.2.

Accord does not support the prohibition of free samples of therapeutic goods as part of advertising. The current exceptions for sunscreens and medical devices should be expanded to include a broader range of low risk products. The TGA's concept of low risk is discussed in its Consultation Paper: *Options for the future regulation of "low risk" products* (March 2017).

The low risk consultation paper found that in addition to the 'physical and use' criteria, a criterion that takes into account the 'degree of regulatory familiarity' also needs to be considered when identifying product types for consideration. That is, product types that pose well known risks. Examples of this concept applied to therapeutic goods are tampons and hard surface disinfectants, which could both be considered moderate to high risk product types, however the 'everyday' use of both of these products by consumers and well known regulatory risks, lowers their risk when used correctly (p9).

The low risk consultation paper provided a broad range of products which consumers identified as low risk such as: sunscreens, registered desensitising toothpastes; rubefacient preparations for minor aches and pains of muscles (e.g. methyl salicylate, menthol, capsicum, etc.); antidandruff antifungal shampoos, lozenges – for relief of sore throats, contain anti-microbial active ingredients, antiseptic mouth washes, anti-acne products (p13). All of which would be suitable for free samples. Alternatively, the product categories listed in Appendix 5 of the current Therapeutic Goods Advertising Code 2015 could be considered as a suitable starting point with the possible exception of devices for the management of chronic conditions under medical supervision.

4.4 Consultation Comments

Accord supports the changes proposed in section 4.4 (1 and 2) in the 2016 advertising consultation comments. Concern has been expressed regarding the development of prescriptive Guidelines which can take on a quasi-regulatory role. Guidelines are meant to provide examples to assist with industry compliance. However, in many cases, Guidelines become the standard by which regulators assess industry compliance and hence have become avenues for regulatory creep. Accord supports industry information and education but not prescribed rules on how to achieve regulatory compliance.