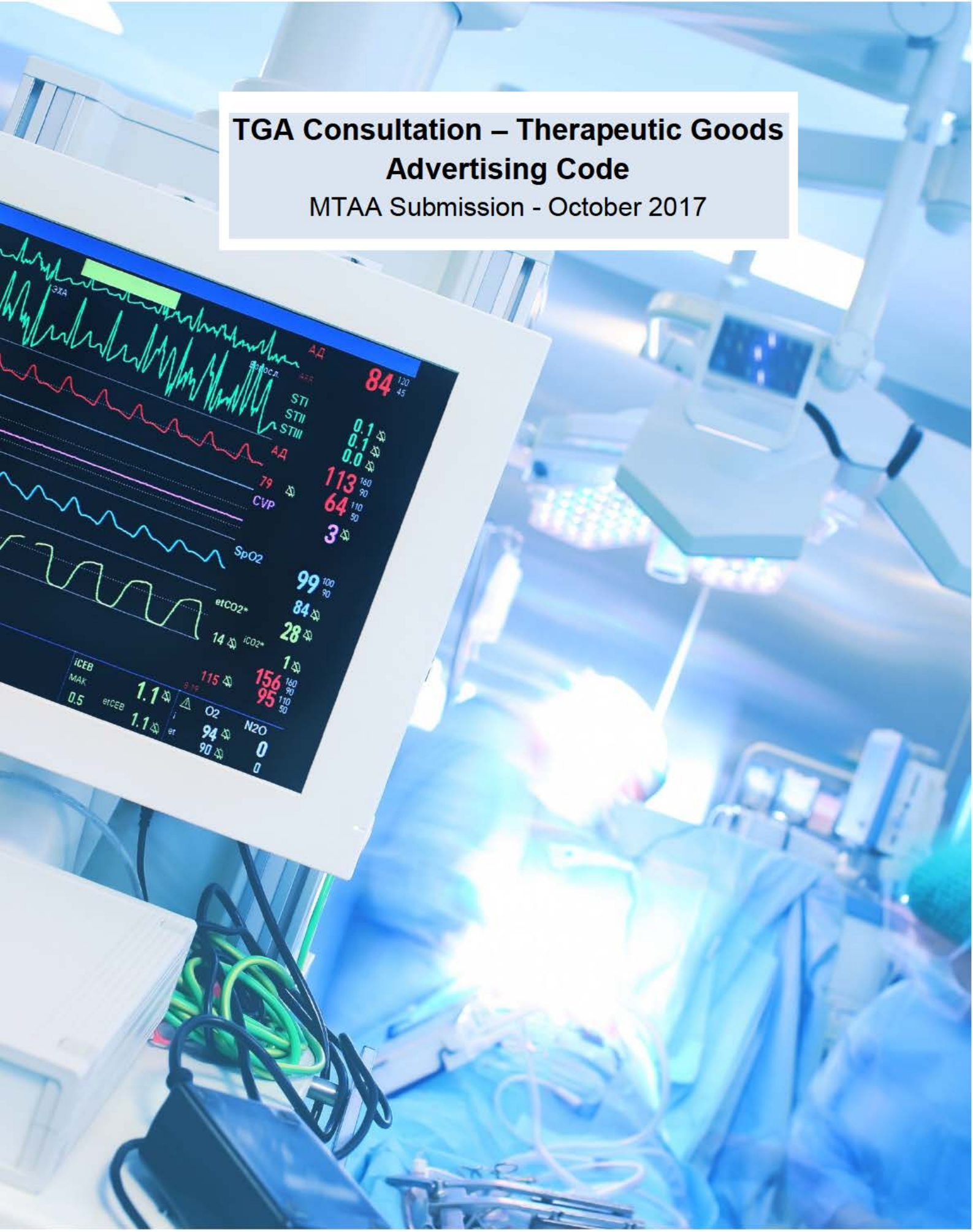
TGA Consultation – Therapeutic Goods Advertising Code

MTAA Submission - October 2017



MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Medical Technology
ASSOCIATION OF AUSTRALIA

Level 12, 54 Miller St,
North Sydney
NSW 2060 Australia
P (+612) 9900 0600
F (+612) 9900 0655

Contents

1 Executive Summary

On 31st August 2017, the TGA opened the consultation: *Therapeutic Goods Advertising Code* which proposes improvements to the advertising of therapeutic goods framework.

MTAA appreciates the opportunity to comment on this consultation. MTAA supports updating the regulatory requirements for the advertising of therapeutic goods to the public, to address latest developments in advertising of therapeutic goods, such as a broadening of the types of therapeutic goods being promoted and sold directly to the public and the methods and media used for promotion. MTAA has been supportive of recommendations 52, 54, 55, 56, 57 and 58 of the 2015 Medicines and Medical Devices Review (MMDR) by the independent expert panel lead by Emeritus Professor Lloyd Sansom AO.

In our December 2016 submission to the TGA consultation: *The regulatory framework for advertising therapeutic goods* we supported the proposed changes to the advertising of medical devices to the public, including the re-drafting of the TG Advertising Code. We did however propose that sponsors of products falling under the "prohibited" or "restricted" representations should be allowed to post information about their products that is consistent with the indications approved in the ARTG. This would be consistent with the current practice for prescription medicines that makes Consumer Medicine Information (CMI) available to patients, and with the TGA proposal to make product information available to implant patients, in alignment with Article 18 of the European Medical Device Directive (MDR). The latter was included in the TGA consultation: *Alignment with European medical device regulatory framework – Up-classification of surgical mesh & Patient implant cards* (closed on 25 August 2017).

In our May 2017 submission to the TGA consultation: *Enhancing sanctions and penalties in the TG Act 1989* we also stated our support for the introduction of a three tiered offences regime with corresponding civil penalty provisions to address non-compliance with advertising rules for therapeutic goods.

In the next sections we provide detailed feedback to the proposed Code changes.

2 Proposed Code changes

2.1 Changes to support effective sanctions and enforcement of advertising requirements

MTAA supports the introduction of clearer and more detailed objective requirements applying to direct-to-consumers (DTC) advertisements about therapeutic goods, to remove or minimise subjectivity in the interpretation and implementation of the specific advertising provisions set out in the Code. There should be a balance between defining general principles for compliance with the Code and specific details of what is and is not permitted with regards to therapeutic goods advertisements.

2.2 Core objectives for the new Code

MTAA agrees with the proposed four core objectives (reproduced below) and the requirements under the new Code as described in the consultation paper.

1. Advertisements must comply with the TG Act 1989, regulations made under this Act, and the TG Advertising Code
2. Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG
3. All claims used in advertisements for therapeutic goods must be substantiated
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

MTAA strongly supports the development of guidelines for the new Code, as these will provide the necessary clarity and ensure consistent implementation with requirements. We recommend that these guidelines be available on the TGA website and be the subject of dedicated training for relevant stakeholder groups, i.e. sponsors, medical colleges and healthcare professionals, consumer and patient advocacy groups and media organisations.

2.3 The Council recommendations

MTAA supports the proposed changes to the definitions of prohibited and restricted representations, in line with the recommendations of Therapeutic Goods Advertising Code Council (the Council).

Along with the changes to definitions, MTAA recommends that the Code be revised to allow sponsors of products falling under the prohibited and restricted representations to post information about their products that is consistent with the indications approved in the ARTG. This practice has been successfully implemented for prescription medicines, enabling public access to information in the form of Consumer Medicine Information (CMI).

We believe that a similar practice should be implemented for products falling under prohibited and restricted representations, to allow patients to directly access information about the product, that is correct and consistent with the indications approved in the ARTG. This would address the ongoing situation where patients go outside Australia to get information about products available in Australia, including from unauthorised sources, because they cannot get it locally.

2.4 Consultation comments

MTAA supports the three recommendations mentioned in the consultation paper that were made in response to the 2016 TGA consultation: *The regulatory framework for advertising therapeutic goods* (reproduced below).

1. Support for the **development of a new Code** to remove subjectivity by revising the interpretative provisions, particularly in light of the proposed enhanced sanctions and penalties, and consideration that it is important that any 'simplification' of the process for advertising regulation is not compromised by increased uncertainty around the implementation of the Code itself;
2. The Code should **clearly and unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising**, and that the requirements should be consistently interpreted and applied, as well as being updated on a regular basis; and
3. There should be accompanying **guidelines** to assist with understanding of the requirements to enable compliance with the Code.

However, MTAA would like to reiterate our recommendation to allow sponsors of products falling under the "prohibited" or "restricted" representations to be allowed to make publicly available information about their products that is consistent with the indications approved in the ARTG. The new Code should include relevant text to this effect.

3 Price Information Code of Practice (PICOP)

MTAA supports introduction of a mechanism to permit the price of therapeutic goods to be communicated to consumers even where the goods themselves cannot lawfully be promoted directly to consumers. We acknowledge the need for better underpinning of the *Price Information Code of Practice – September 2006* (PICOP).

Of the three options put forward in the consultation paper:

- PICOP should remain in the new Code, or
- PICOP should be established as a separate legislative instrument under the the TG Act 1989, or
- Adopting other mechanisms for managing compliance with the PICOP

MTAA recommends adopting the first one, i.e., incorporating the PICOP in the new Code.