Consultation Regulation Impact Statement:

Regulating the advertising of therapeutic goods to the general public

19 July 2013

Medical Technology ASSOCIATION OF AUSTRALIA

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Executive Summary

MTAA welcomes the opportunity to comment on the Therapeutic Goods Administration's (TGA) Consultation Regulation Impact Statement (CRIS): Regulating the advertising of therapeutic goods to the general public.

MTAA supports the objectives of the CRIS which seek to improve efficiency in the system.

MTAA acknowledges that consumers of therapeutic goods are becoming more proactive with respect to making informed decisions about treatment options and will seek to obtain accurate and balanced information from all sources of media including the internet.

MTAA recommends that the current regulatory framework is reformed to allow sponsors to provide accurate and balanced information to the general public, and to facilitate this, the current prohibited and restricted representations should be reviewed to allow the provision of reliable, good quality information provided that the information given is within the scope of the intended purpose of the device.

MTAA's examination of the complaints considered by the Complaints Resolution Panel (CRP) showed that only approximately 3% of complaints were determined to be related to medical devices included on the Australian Register of Therapeutic Goods (ARTG). Hence, MTAA questions if there is a demonstrated need to support broad-based prepublication approval for medical devices (Proposal 1).

MTAA is supportive of Proposal 1, Option 3 with changes to the Therapeutic Goods Advertising Code (TGAC) to allow sponsors to provide information to the general public that is within the intended use of a device without preapproval. MTAA recommends that the determination of risk categorization criteria should be linked to advertisement risk categorization and not to device risk classification. This will require further consultation with the criteria well understood and transparent prior to any changes to the current scheme. .

MTAA agrees that the current complaint handling process is cumbersome and slow and does not allow for immediate action to be taken when an advertisement is clearly in breach of the TGAC or poses a risk to public health and safety. For this reason MTAA supports reforms which allow quick action to be taken by TGA to require the removal of offending advertisements.

MTAA agrees with Option 2a for Proposal 2, that a dedicated office within TGA should receive the complaints. The delegates within the TGA's dedicated complaints resolution office should have powers to action immediate bans on advertisements making therapeutic claims which could be a serious risk to the general public. There should also be distinct pathways which deal with ARTG included and non ARTG included device complaints separately.

With respect to Proposal 3 on the provision of advice, Option 2 to establish a statutory advisory committee would be preferable as long as the function of the committee does not mimic the current functions of the CRP and the Therapeutic Goods Advertising Code Council (TGACC). The advisory body should comprise expert representatives of the advertising industry, media, consumers and industry.

With respect to Proposal 4, MTAA is supportive of enhancing investigation and enforcement powers. However, MTAA believes that these powers already exist for products that are entered on to the ARTG as medical devices.

MTAA strongly opposes Proposal 5, Option 2 to prohibit the advertising of higher risk medical devices as consumers may seek out information from less reliable sources.

MTAA supports Proposal 6, Option 2 to update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the Health Practitioner Regulation National Law.

MTAA makes no comment on proposal 7 and 8 as they do not affect the medical device industry.

MTAA believes that any proposed changes to the regulation of advertisements should include regulation of the use of the internet, acknowledging the challenges in limiting regulation to the Australian site.

MTAA is of the opinion that medical devices should not be bolted on to advertising schemes that are applicable for medicines. MTAA believes that as separate regulations for medical devices have been in force since 2002 a similar approach should be adopted for advertising regulations.

About the Medical Technology Association of Australia

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. MTAA represents companies which account for the majority of products included on the ARTG and approximately 75% of the higher risk implantable medical devices products listed on the Prostheses List and used in the Australian marketplace. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small to medium sized Australian innovator companies.

General Comments

MTAA acknowledges the objectives of the CRIS and supports those objectives which seek to improve efficiency in the system. MTAA notes that the CRIS states "*The regulation of advertising should contribute to the quality and safe use of therapeutic goods by ensuring that the general public receives accurate and balanced information about the quality, safety and efficacy (performance) of those goods*"[1].

MTAA submits that consumers of therapeutic goods are becoming more proactive with respect to making informed decisions about treatment options and frequently seek to obtain accurate and balanced information about therapeutic goods from all sources of media including the internet. They also make direct approaches to sponsors seeking more detailed and accurate information than can currently be provided.

MTAA believes that the current regulatory system for advertising of therapeutic goods on many occasions does not allow medical device sponsors to relay accurate and balanced information to the general public because of the limitations of prohibited and restricted representations. Medical device sponsors have reported that they have been contacted by patients seeking information about a medical device. However the sponsors have been unable to supply the information directly to the patient because it could be deemed as an advertisement containing prohibited or restricted representations. For example, information stating that a medical device is intended for the treatment of a cancer, if provided to the general public under the current regulations, would be in breach of the TGAC.

There have also been instances where the patient has already been prescribed a particular category of device but the physician has invited the patient to make their choice of preferred brand. This may happen with devices such as cochlear implants or insulin pumps where different product features may suit the lifestyle of some patients but not others. However prohibited/restricted representations have again made it difficult for sponsors to provide the information to a patient. Under the current system a sponsor would have to gain preapproval to supply this information due to restricted representations. Given that the treatment pathway to be prescribed these products requires robust assessment from the relevant medical specialists, it is unlikely advertisements such as these would result in unsuitable patients being prescribed these products.

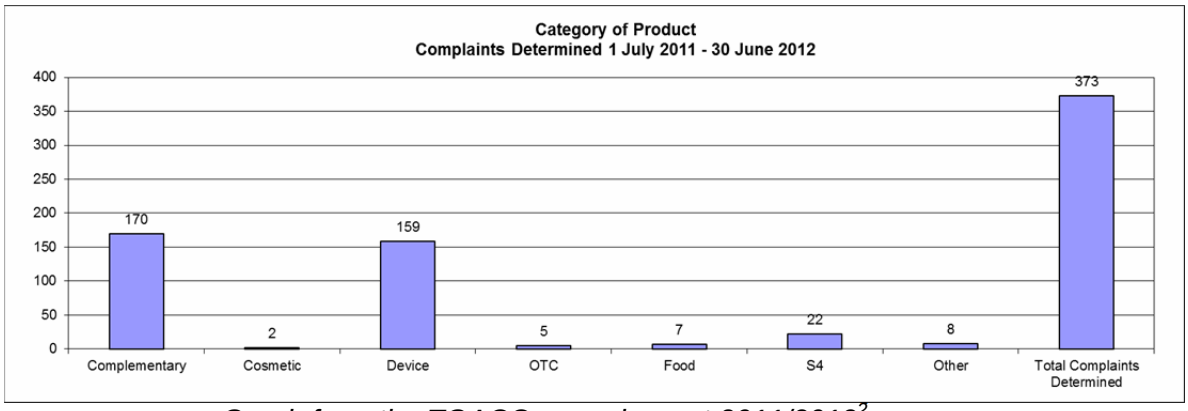
MTAA notes that there are many sources from which the general public may obtain negative information about medical devices such as TGA's System for Australian Recall Actions (SARA) and Device Adverse Event Notification (DAEN) databases. However, due to prohibited representations it is often difficult for patients to obtain positive balanced information about medical devices.

MTAA recommends that the current regulatory framework is reformed to allow sponsors to provide accurate and balanced information to the general public,

[1] CRIS - Principles to guide objectives for reform

provided that the information provided is within the scope of the intended purpose of the device as specified by the manufacturer.

MTAA asserts that there is no clear and demonstrated need for prepublication approvals. MTAA conducted a review of the complaints determined by the CRP from 1 July 2011 to 30 June 2012. The graph below is taken from the TGACC annual report of 2011/2012 and shows 159 (42.6%) complaints determined relating to devices.



Graph from the TGACC annual report 2011/2012[2]

MTAA's examination of CRP complaints showed that approximately 3%[3] of complaints related to medical devices included on the ARTG.

It was also noted that none of the complaint records reviewed from 1 July 2011 to 30 June 2012 were for high risk class medical devices.

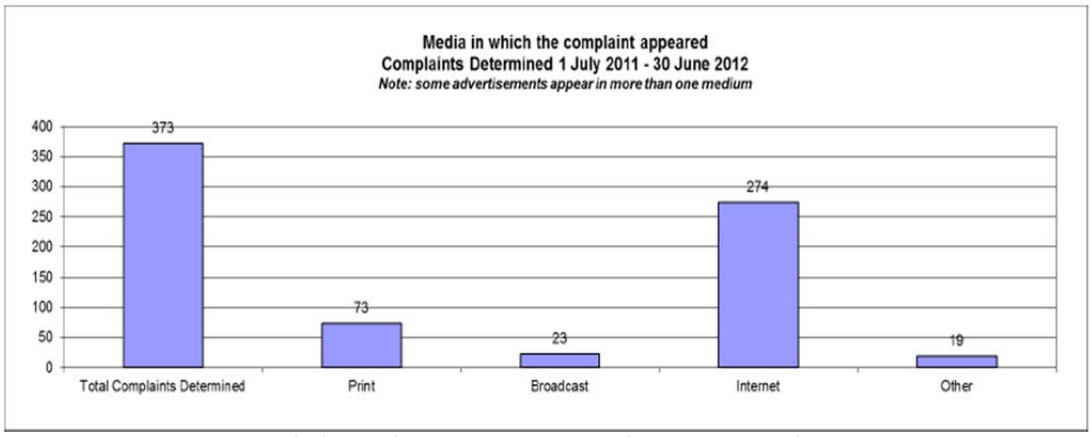
Of the complaints determinations reviewed, 46% were for non-ARTG registered products which could be described as medical devices. Medical devices are defined by the *Therapeutic Goods Act 1989*. MTAA asserts that if the advertisements for products about which a complaint is made are differentiated between those on the ARTG and those which are not on the ARTG, it would become clear that the bulk of complaints about products currently described as "devices" in the TGACC annual report are not about medical devices registered on the ARTG. Instead, the bulk of complaints are about non-ARTG registered products being promoted for therapeutic use. These products should be treated as unapproved therapeutic goods and the suppliers of these products should be required to cease supply until the product is entered on the ARTG or the therapeutic claim is retracted. This would address the key source of complaints currently considered "device" complaints without unnecessarily imposing increased regulatory requirements on the medical technology industry.

MTAA supports proposals to strengthen enforcement powers so that immediate action can be taken if an advertisement for a product makes unsubstantiated

[2] http://www.tgacc.com.au/download/TGACC_Annual_Report_2011-12_final_report_27_Sep_2012.pdf
[3] ARTG status was deduced from the TGACC complaint record.

therapeutic claims. However, the Secretary already has the power to take immediate action in the case of advertisements for ARTG included medical devices which make unsubstantiated claims.

MTAA questions why alternatives to the pre-approval scheme do not cover advertising via the internet given that the majority of the complaints determined by CRP were from this medium.



Graph from the TGACC annual report 2011/2012

Any proposed changes to the regulation of advertisements should include advertisements via the internet, noting that TGA has the jurisdiction only to regulate material which appears on the Australian site.

MTAA is of the opinion that medical devices should not be bolted on to schemes that are applicable for medicines. MTAA believes that as separate regulations for medical devices have been in force since 2002 a similar approach should be adopted for advertising regulations.

Proposal 1: Alternatives to the pre-approval scheme

MTAA believes that there is no evidence to support the need for prepublication approval for medical devices advertisements. MTAA recommends that a change to the TGAC is required to allow devices to be represented to the general public according to their intended purpose. This recommendation is in keeping with the need for transparency and the guiding principles of the objective of the CRIS "…..*to ensure the general public receives accurate and balanced information*".

MTAA recommends that the current prohibited representations be removed from the TGAC for medical devices and recategorised as restricted representations. ARTG included medical devices should be permitted to be advertised to the general public provided the claims are within the intended purpose. Only "higher risk" advertisements should undergo prepublication approval.

MTAA recommends that the determination of risk categorization criteria should be linked to advertisement risk categorization and not to device risk classification. This

will require further consultation with the criteria well understood and transparent prior to any changes to the current scheme. The type of criterion which might be considered could include an advertisement which induces a patient to rely on utilisation of the device to his/her detriment, in the absence of healthcare professional advice.

MTAA is therefore supportive of option 3: Limit the current pre-approvals scheme to cover only "higher risk" categories of advertisement, with changes to the TGAC which allow sponsors to provide the general public with information within the intended use of a device without preapproval.

MTAA disagrees with the statement when applied to medical devices that option 3 would "*expose the public to some advertisements that breach the advertising requirements to which they are exposed now because under this approach compliance would always be by means of post-broadcast/publication review*"[4]. MTAA's review of CRP's complaints shows that the majority of "device" breaches are not with ARTG-included medical devices. The majority of "device" type complaints relate to products making therapeutic claims such as amber teething necklaces and foot massagers - products which are not included on the ARTG.

MTAA also disagrees with the statement that option 3 "*could decrease levels of certainty for businesses….*". Many medical device companies have more stringent policies with respect to the creation and pre-approval of marketing materials than the requirements of the TGAC or industry codes. Most medical device companies have a marketing material approval process to ensure that the materials comply with the law in order to mitigate risk of legal actions or complaints from competitor companies.

Proposal 2: The complaints handling process

MTAA agrees that the current complaint handling process is cumbersome and slow and does not allow for immediate action to be taken when an advertisement is clearly in breach of the TGAC or poses a risk to public health and safety.

It is noted that the CRP's current function is to consider complaints about the advertising of medical devices and medicines through specified media, including the internet. It is interesting that internet advertisements are considered in the complaint handling process, but are not subject to current regulations.

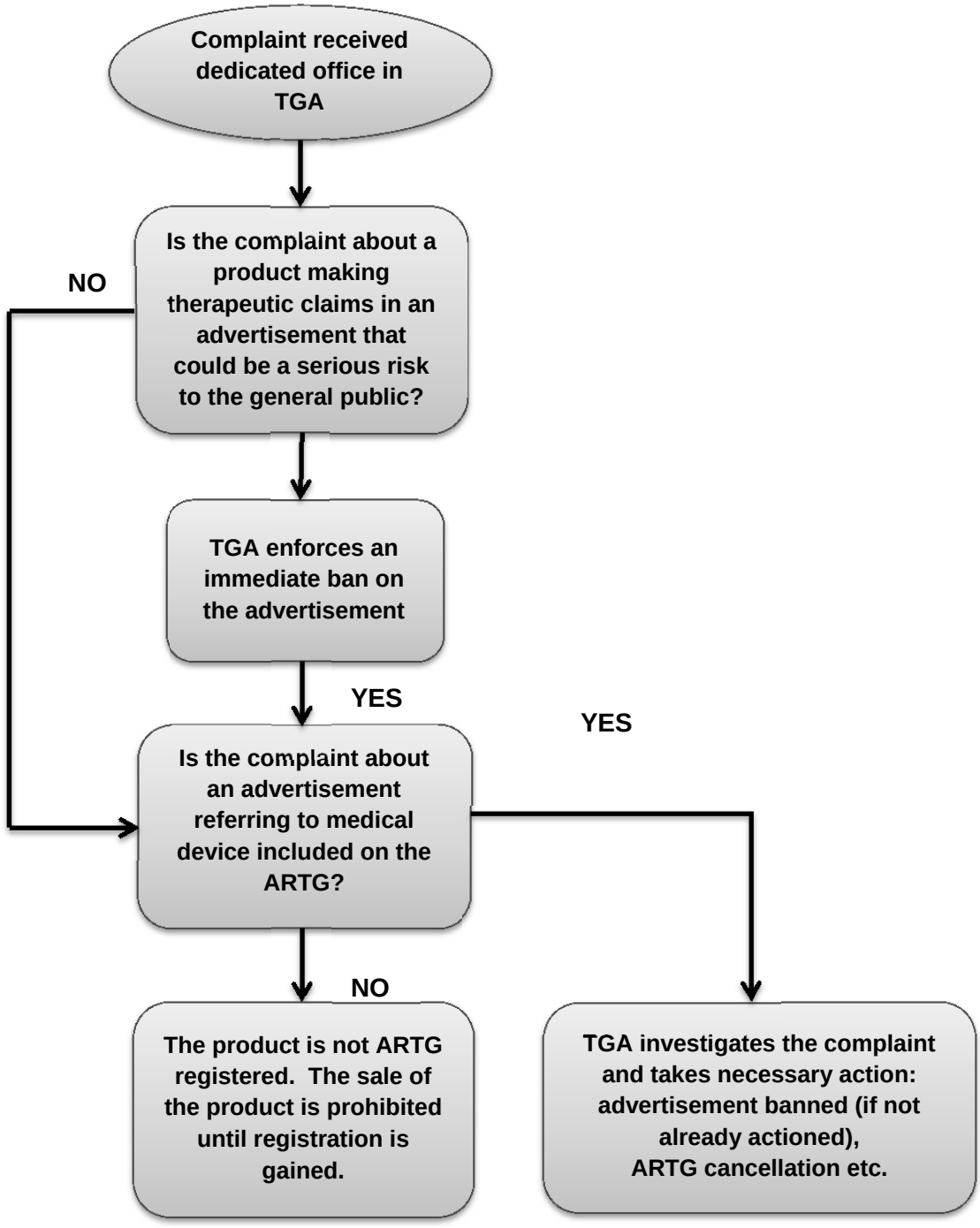
MTAA believes that in order to improve the efficiency of the process, Proposal 2 needs to go further than suggesting that all complaints about the advertising of therapeutic goods to the general public should be handled by either the TGA or an independent statutory body. The proposal needs to explore the pros and cons of using either TGA or a statutory body to handle complaints and provide possible process paths for each situation.

[4] CRIS page 33

MTAA agrees with option 2a, that a dedicated office within TGA should receive the complaints.

The delegates within the TGA's dedicated advertising complaints office should have powers to action immediate bans on advertisements making therapeutic claims which could be a serious risk to the general public. For example if an advertisement for a home use product is making claims that the product can cure cancer, it may prevent a symptomatic patient seeking medical attention. There should also be distinct pathways which deal with ARTG-included and non ARTG-included device complaints separately.

A suggested decision tree for advertisements making therapeutic claims could be as follows:



The suggested decision tree would ensure that immediate action could be taken with respect to high risk advertisements and TGA only investigates complaints relating to ARTG included devices. All other products should be treated as unregistered therapeutic goods with TGA acting to remove the product from the market until ARTG approval has been gained.

Proposal 3: Provision of advice in relation to advertising matters.

MTAA supports Option 2, to establish an expert advertising advisory committee. MTAA recommends that the advisory body should comprise expert representatives of the advertising industry, media, consumers and industry. MTAA's Code Complaints Committee chair is required to be a person experienced in the regulation of advertising, marketing and dispute resolution. They are also required to be familiar with competition, consumer and fair trading legislation. A similar skill set would be recommended for an expert on the advertising advisory committee.

Proposal 4: Investigation and enforcement powers

MTAA is supportive of enhancing investigation and enforcement powers. However, MTAA believes that these powers already exist for products that are entered on to the ARTG as medical devices.

The *Therapeutic Goods Act 1989* clearly stipulates that a product which is a medical device should be included on the ARTG. In the case of medical devices, advertising material constitutes part of the intended purpose of the device, which is a certified matter under 41FD of the Act. There are existing powers that allow the Secretary to take action against false statements.

MTAA believes that enhanced enforcement powers are required to allow a dedicated office within the TGA to take immediate action with respect to advertisements that pose serious risks to the general public and products making therapeutic claims that are not entered on the ARTG.

Proposal 5: Advertising of higher risk medical devices.

MTAA strongly opposes Option 2 to prohibit the advertising of higher risk medical devices. As previously discussed, MTAA does not believe it is appropriate to align the regulation of medical devices with medicines. MTAA strongly disagrees with the advantage and disadvantage statements in the CRIS:

"Advantages: The advertising of higher risk medical devices would be on the same basis as the prohibition on advertising of higher risk medicines given the similar risk

profiles and that there is a need for the involvement of a healthcare practitioner to ensure safe use of the product".

MTAA disagrees that the risk profile of higher risk medical devices is similar to those of higher risk medicines. MTAA agrees that health practitioner involvement is required for both high risk medical devices and medicines, however all implantable high risk medical devices cannot be used/implanted without physician involvement. This is contrary to prescription medicines that could be obtained illegally and taken without further healthcare professional involvement.

As discussed in the general comments the prohibition of advertisements of higher risk medical devices to consumers may prevent them from making an informed choice whether based on aesthetics or some other criterion, once an implant has been prescribed by a healthcare professional.

"*Disadvantage: Sponsors would not be allowed to advertise higher risk medical devices to the public which could have an impact on their business*".

The decision to recommend a high risk medical device is made by a healthcare professional, hence there are rarely high risk medical device advertisements directed at patients. The prohibition on advertisements for high risk medical devices would have limited impact on a sponsor's business. MTAA contends the true disadvantage of Option 2 is to the consumer. As discussed in the general comments and the response to Proposal 1, the current system of prohibited and restricted representations limits the beneficial information on medical devices that can be provided direct to consumers and makes it difficult for sponsors to provide good quality, clear and balanced information to consumers. Consumers will continue to seek information from less reliable sources if the prohibition continues on provision of information direct to consumers about high risk class medical devices.

Furthermore, the information gained from examining the complaints to CRP shows no complaints for high risk classification medical devices, indicating that the current process is working well and that there is no obvious need for additional scrutiny or restrictions.

Proposal 6: Advertising direct to health professionals

MTAA agrees with Option 2: Update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the Health Practitioner Regulation National Law.

Proposals 7 and 8

MTAA makes no comment on proposals 7 and 8 as they do not apply to the medical device industry.