Australian Government

Department of Health
Therapeutic Goods Administration

Executive Officer – Medical
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TGA Reference: R15/481515

Dear Sir/Madam

Submission – Public Consultation Paper and Regulation Impact Statement – Registered medical practitioners who provide cosmetic medical and surgical procedures

The Therapeutic Goods Administration (TGA) welcomes the Medical Board of Australia's Public Consultation Paper and Regulation Impact Statement (RIS) on *Registered medical practitioners who provide cosmetic medical and surgical procedures*.

The TGA is primarily involved with the cosmetic medical profession through the regulation of the various medicines and medical devices that are commonly used in cosmetic procedures, such as prescription-only (Schedule 4) cosmetic injectables (muscle relaxants, dermal fillers) and laser devices for therapeutic use. The regulatory framework administered by the TGA also encompasses the advertising of therapeutic goods to consumers.

The TGA notes that the Board is seeking feedback on the extent and nature of problems that have been identified in the consultation paper. The attached submission discusses advertising non-compliance issues that the TGA handles in relation to cosmetic medical and surgical services that incorporate prescription-only cosmetic injectables.

As identified in the consultation paper, non-compliant advertising is likely to influence consumers to consider prescription-only cosmetic injectables to be simple consumer goods without realising that they have inherent risks and their use could result in adverse health consequences. This 'information asymmetry' may lead to consumers giving less scrutiny to the decisions they make when seeking such treatments.

The commoditisation of prescription-only cosmetic injectables appears to have led to a large commercial interest by healthcare professionals and non-healthcare professionals and this is likely to be one of the drivers of some of the non-compliant advertising behaviours the TGA is seeing within the industry.

The TGA would welcome the opportunity to work with AHPRA and the Medical Board of Australia to improve compliance outcomes in this sector.

Yours faithfully

Dr Larry Kelly

First Assistant Secretary

Monitoring and Compliance Division

16 June 2015

Encl. Submission – Public Consultation Paper and Regulation Impact Statement – Registered medical practitioners who provide cosmetic medical and surgical procedures

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TGA Submission on the Public Consultation Paper and Regulation Impact Statement – Registered medical practitioners who provide cosmetic medical and surgical procedures

1. About the TGA

The TGA administers the *Therapeutic Goods Act 1989* (the Act) and subordinate legislation to regulate the import, export, supply, manufacturing and advertising of therapeutic goods in Australia including medicines, medical devices and biologicals. In doing so, the TGA ensures that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. Additionally, the TGA monitors signals from information reports provided post-market in relation to these products, such as adverse drug reactions and medical device incidents.

2. The TGA's jurisdiction in relation to prescription-only cosmetic injectables

Under the Act, consumer advertising of therapeutic goods that contain prescription-only substances is prohibited (refer to Attachment A for a description of the legislative basis). The majority of cosmetic injections contain prescription-only (Schedule 4[1]) substances and therefore, advertising such products to consumers is prohibited. It is also prohibited to advertise a therapeutic good for purposes other than those accepted by the TGA for entry in the Australian Register of Therapeutic Goods (ARTG).

The TGA does not regulate the medical practice of healthcare professionals or procedures/services/treatments provided by healthcare professionals. However, practice issues (including advertising) can intersect with therapeutic goods regulatory issues and this is commonly seen in the cosmetic procedures sector. When the advertising of medical services crosses into promoting the use and/or supply of prescription-only substances, the TGA has the authority to take regulatory action against those responsible.

3. Compliance of prescription-only cosmetic injectables advertisers

Over the past 5 years, the TGA has observed a significant growth in the advertising of prescription-only cosmetic injectables to consumers - mainly via the internet, including individual websites, "group buying" websites, directories and social media. In our experience, most of the material is published by businesses registered to healthcare professionals. Beauty clinics are the second most represented advertiser in this field.

In addition to the offence for advertising prescription-only substances to consumers, a small proportion of advertisers also commit additional offences by advertising cosmetic

[1] As specified in the Poisons Standard known as the *Standard for the Uniform Scheduling of Medicines and Poisons*

injections that are not entered on the ARTG or advertising injections for purposes other than those accepted by the TGA (generally the purposes as stated on the relevant ARTG entries).

The TGA has also observed numerous advertisers publishing price information about cosmetic injections to consumers. While the therapeutic goods legislative framework provides for the publication of price information to consumers for prescription-only substances, such information is required to comply with the Price Information Code of Practice (the Price Code)[2]. However, the requirements set out in the Price Code do not support the publication of prices for cosmetic injections. Therefore the publication of price information for prescription-only cosmetic injectables is also prohibited.

4. The TGA's approach to non-compliance

The TGA manages all advertising complaints in accordance with the TGA's Regulatory Compliance Framework[3]. Under this framework, complaints are prioritised based on risk to public health and safety. The framework also provides an escalating range of actions, from education to prosecution, that the TGA may use in relation to non-compliant entities.

While the TGA is yet to prosecute an individual or corporation in this specific field of practice, persistent non-compliant advertisers generally become compliant when they realise they have received the natural justice and procedural fairness available to them and that it is not in the best interests of their/their businesses reputation and/or status as a registered healthcare professional to continue on the path of non-compliance.

The TGA is also achieving a much improved rate of compliance from these advertisers through:

- the education of non-compliant advertisers, including the production of a pamphlet on Advertising Cosmetic Injections, which is available on the TGA website[4] and at selected conferences and exhibitions, and
- collaboration with motivated professional colleges and individuals who are dedicated to raising the bar in this progressively commercial area of medical practice.

However, the rate of emergence of new businesses and the use of Search Engine Optimisation (SEO) companies to promote such businesses, both of which usually are not familiar with the therapeutic goods advertising legislation, impacts on the TGA's ability to achieve complete compliance across the sector.

5. Matters that fall outside of the TGA's legal authority

While most of the complaints the TGA receives relating to cosmetic procedures are about references to prescription-only substances in consumer advertising, the TGA also receives complaints about matters which the TGA does not have the legal authority to pursue. Most commonly:

- Offers of inducements e.g. time limited specials;
- Injecting by an unqualified person;
- Injecting without supervision, when supervision is required;
- Lack of initial consultation with the appropriate healthcare professional
- Other complaints about services or treatments.

[2] http://www.tga.gov.au/publication/price-information-code-practice

[3] http://www.tga.gov.au/regulatory-compliance-framework

[4] http://www.tga.gov.au/advertising-cosmetic-injections

In such cases, the TGA will either request the complainant to forward the matter to the relevant state/territory authority or AHPRA for investigation or, in some cases, the TGA will refer the matter directly. The TGA is likely to refer the matter directly where there is a need for the TGA to proceed with the advertising aspects of the complaint. These decisions are made on a case by case basis.

6. Collaborative approach

The TGA has collaborated with professional colleges and individuals where there is motivation toward improving advertising standards in the field of cosmetic medicine.

The TGA believes that continued collaboration with professional colleges and individuals is important to ensure that advertising and other behaviours relating to the promotion of cosmetic medical procedures is of the same standard that applies to therapeutic medical procedures.

7. Comment on proposal for providing consumer education and addressing 'information asymmetry'

The TGA notes one of the options under consideration in this consultation is "Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners".

The TGA considers that the provision of non-promotional and balanced educational material to consumers to assist them in understanding the nature of the medicines/devices used in cosmetic medical procedures may be appropriate. The TGA also notes that the Consumer Medicines Information (CMI) leaflets for botulinum toxin products are available on the websites of both the TGA[5] and National Prescribing Service[6].

However, CMIs are generally not available for the cosmetic injections regulated as medical devices (e.g. hyaluronic acid).

The TGA considers that where individual practitioners or clinics attempt to provide such material on their website or via other means outside of a patient consultation, the information is invariably promotional and therefore is subject to the advertising requirements in the Act.

The TGA considers that the publication of consumer educational material about prescription-only cosmetic injectables may be facilitated on an independent website, such as www.healthdirect.gov.au (formerly HealthInsite) or NPS.

8. Comment on proposal to strengthen current guidance for medical practitioners providing cosmetic and surgical procedures

The TGA supports the strengthening of such guidelines. In particular, these guidelines should clarify that prescription-only cosmetic injectables cannot be advertised directly to consumers, including their prices.

[5] www.tga.gov.au

[6] www.nps.org.au

9. Closing remarks

To ensure that the use, supply and promotion of prescription-only substances used in cosmetic medical procedures is appropriately managed according to the level of control for which they have been scheduled, and that the regulatory requirements around the level of scheduling are understood and adhered to, further education of healthcare professionals appears to be required.

Additionally, education of non-healthcare professionals involved in the business of cosmetic medicines, for example beauty clinics should also be targeted with this type of education.

Attachment A - Legislative basis for advertising requirements

The TGA administers the *Therapeutic Goods Act 1989* (the Act) and subordinate legislation.

Under the Act, therapeutic goods made available for commercial supply in Australia are required to be entered in the Australian Register of Therapeutic Goods (ARTG). Products are entered in the ARTG as either medicines or medical devices, according to their physical properties and the way they work in or on the body. It is an offence to supply or advertise a therapeutic good that has not been entered in the ARTG (refer to sections 19B and 42DL(1)(g) of the Act respectively).

In Australia it is also illegal to advertise Schedule 3 (some exceptions), 4 and 8 medicines/substances to consumers. This prohibition is written into legislation by state/territory and federal governments and is reflected in the Code of Conduct Guidelines set out by AHPRA which applies to all registered healthcare professionals.

The advertising offence under section 42DL(1)(f) of the Act provides:

A person must not publish or broadcast an advertisement about therapeutic goods: that contains a statement referring to goods, or substances or preparations containing goods, included in Schedule 3, 4 or 8 to the current Poisons Standard, other than a statement authorised or required by a government or government authority (including a foreign government or foreign government authority)

The Act applies to all Australian corporations as well as individuals in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the states, between a state and a territory or between two territories.

However, the TGA considers that sole traders who advertise on the internet (including social media) are captured by the Commonwealth legislation because of the cross-border reach of their advertising.

The above offence provision is one of strict liability and allows for a financial penalties for each offence. Currently, this translates into fines of up to $10, 200 for individuals and $51,000 for corporations.

The Act also prohibits the advertising of a therapeutic good (to any entity) for purposes other than those accepted in relation to the good (subsection 22(5) and section 41ML of the Act for medicines and medical devices respectively). The purposes accepted in relation to a therapeutic good are specified on the good's ARTG entry. These offences also attract fines of up to $10, 200 for individuals and $51,000 for corporations.